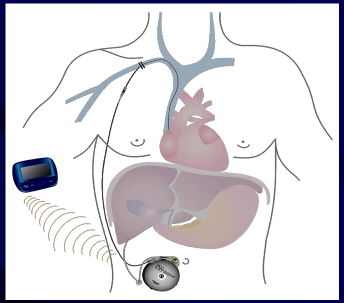
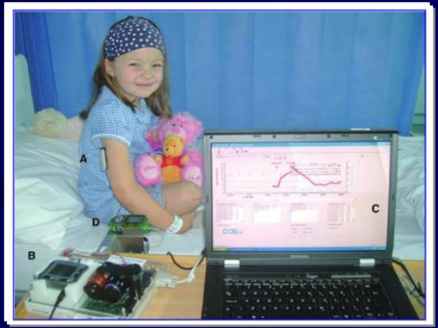
Rationnel, Concept et Historique du Développement de l'Insulinothérapie Automatisée





Professeur Eric RENARD

Service d'Endocrinologie – Diabétologie & Centre d'Investigation Clinique INSERM 1411, CHU de Montpellier; Institut de Génomique Fonctionnelle, CNRS, INSERM, Université de Montpellier; Montpellier, France

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Liens d'Intérêt

Eric Renard

Consultant/Orateur: A. Menarini Diagnostics, Abbott, Adelia Medical, Air Liquide SI, Astra-Zeneca, Asten, Bastide Médical, Becton-Dickinson, Boehringer-Ingelheim, Cellnovo, Dexcom Inc., Dinno-Santé, Eli-Lilly, Elivie, Hillo, Insulet Inc., Johnson & Johnson (Animas, LifeScan), Medtronic, Medirio, Nestlé Home Care, Novo-Nordisk, Orkyn, Roche, Sanofi-Aventis, VitalAire.

Soutiens pour la Recherche: Abbott, Dexcom Inc., Insulet Inc., Roche, Tandem.

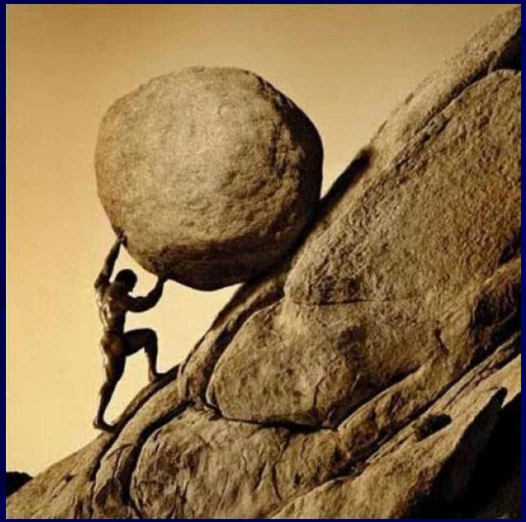
CIC 1411

IGF

Le Diabète Insulinoprive

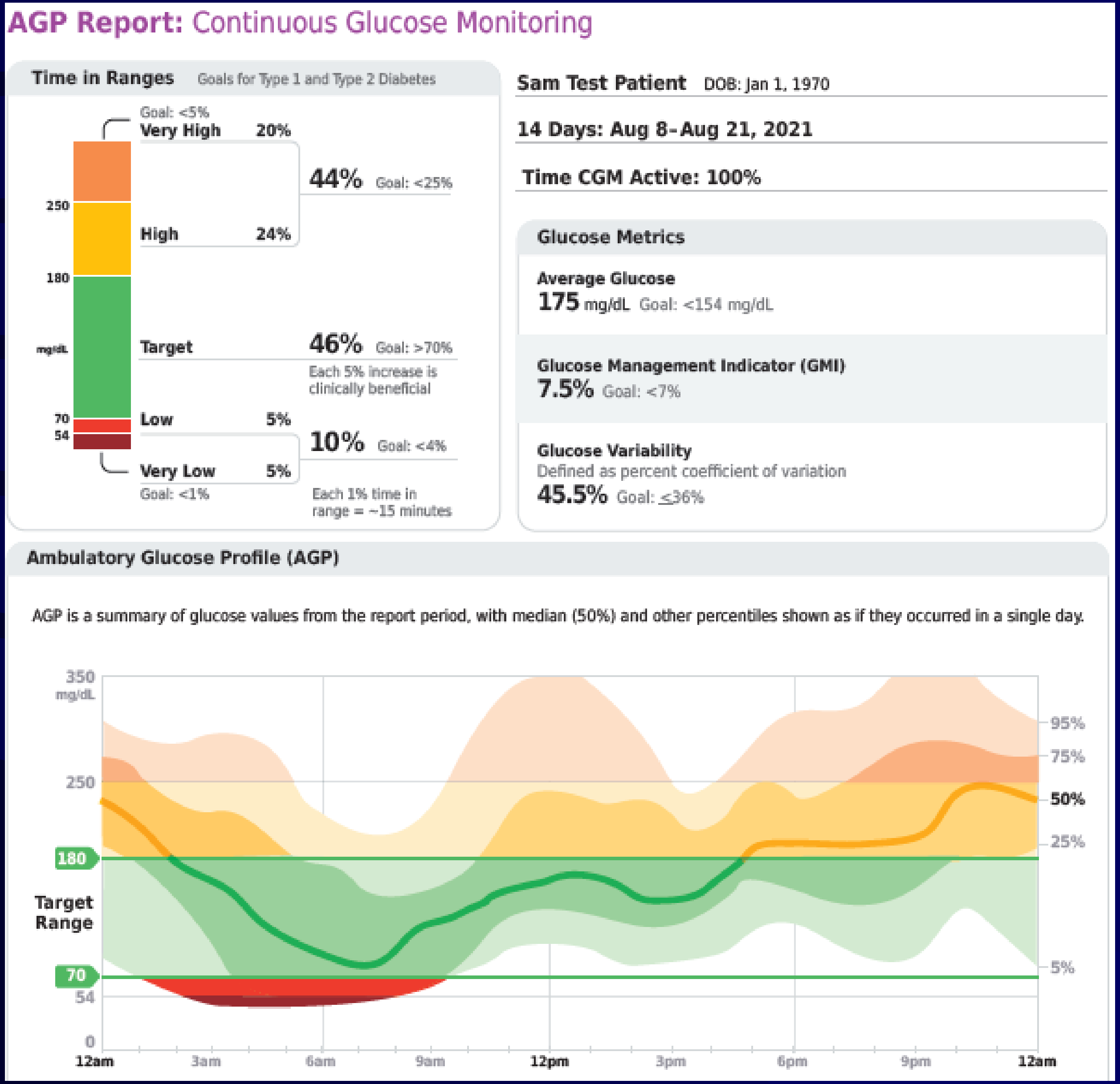
Un Problème Thérapeutique Non Résolu

- Une hyperglycémie chronique à risque de complications sévères
- Des épisodes hypoglycémiques iatrogènes récurrents invalidants
- Une variabilité glycémique non contrôlée
- Une qualité de vie altérée

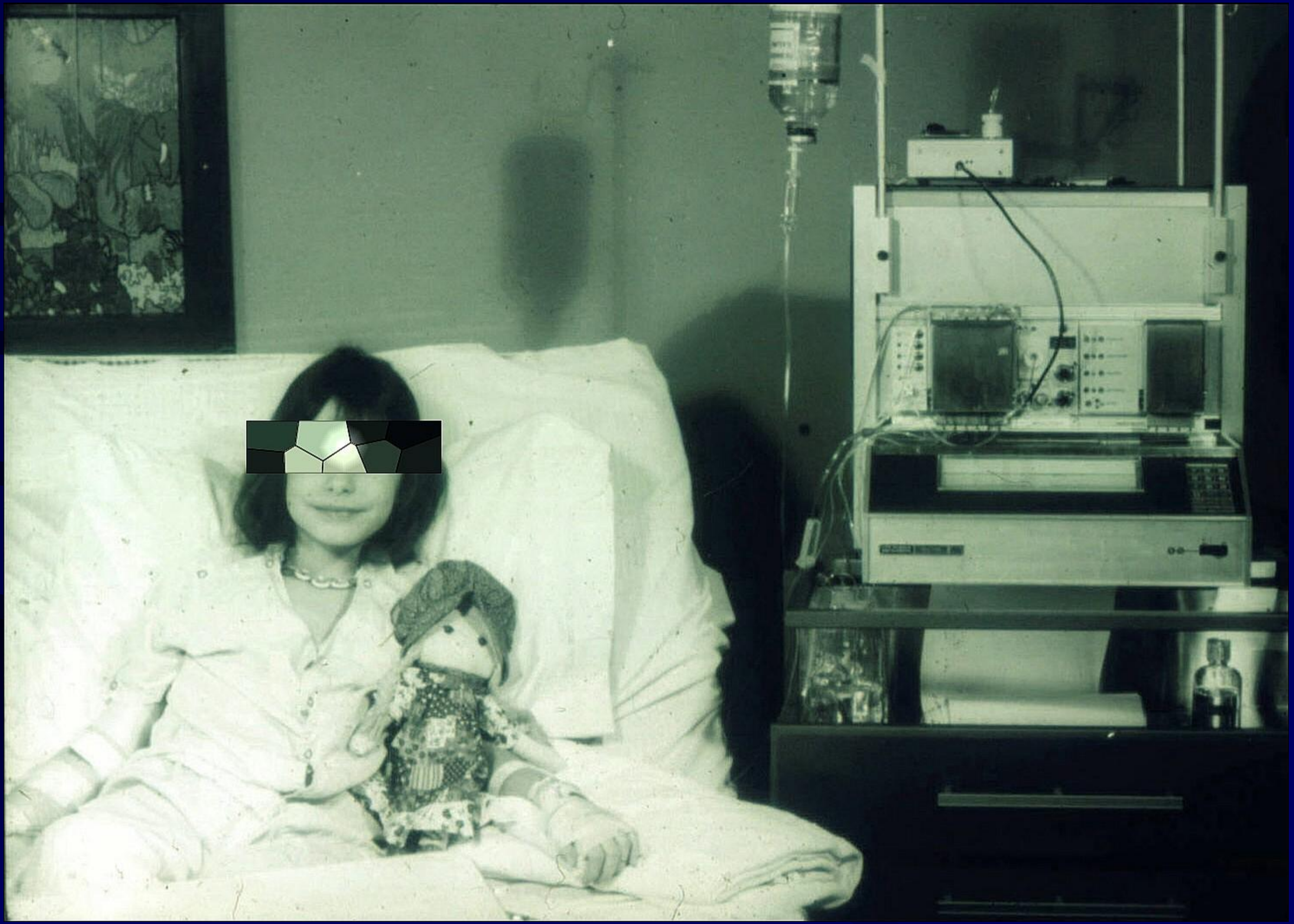


- Une insulinothérapie peu flexible et exigeante
- Un monitoring glycémique obsédant
- Des besoins insuliniques toujours changeants
- Une vigilance de tous les instants

La Photographie du Diabète de Type 1 Aujourd'hui

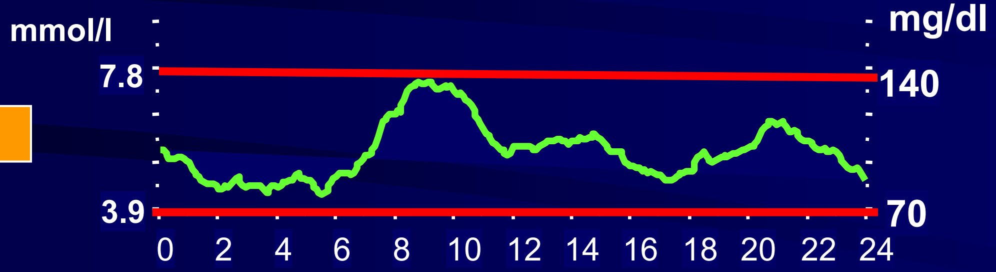


Il était une fois, le pancréas artificiel au lit du malade



1974

The Quest for the Artificial Pancreas



IV Glucose

IV

Continuous Glucose Monitoring → Control Algorithm → Insulin Delivery

IV

Closed-Loop

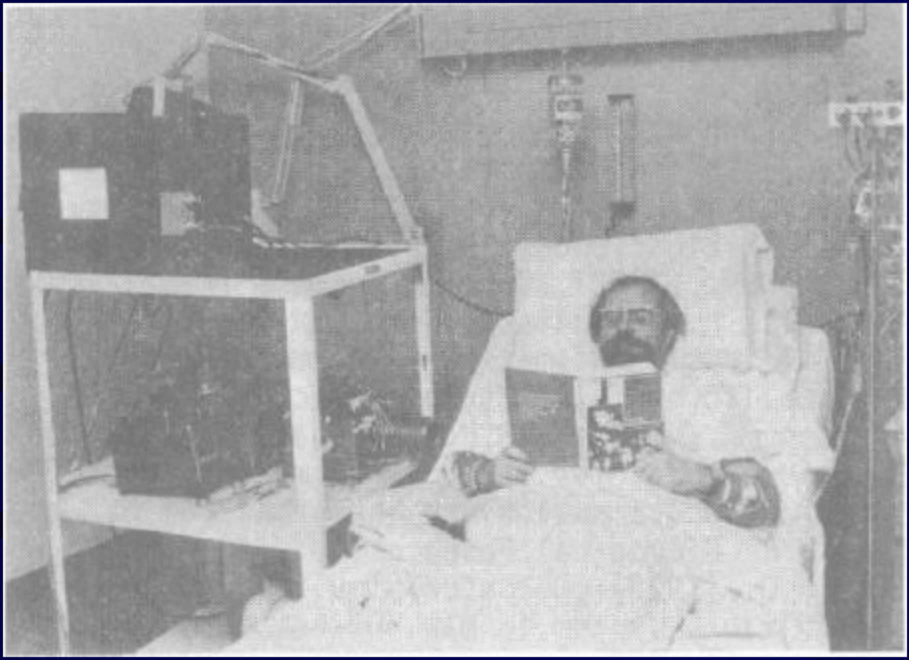


Figure 3. Photograph of the glucose analyser apparatus at the bed-side. The glucose analyser is composed of an AutoAnalyser (pump, dialyser, colorimeter, and chart recorder) from Technicon Instruments. Now shown in the photograph is the pump control unit from Life Science Instruments.

Static control law

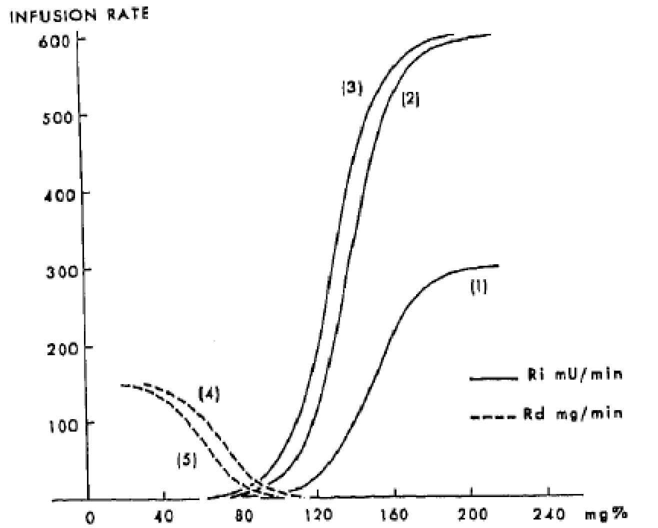
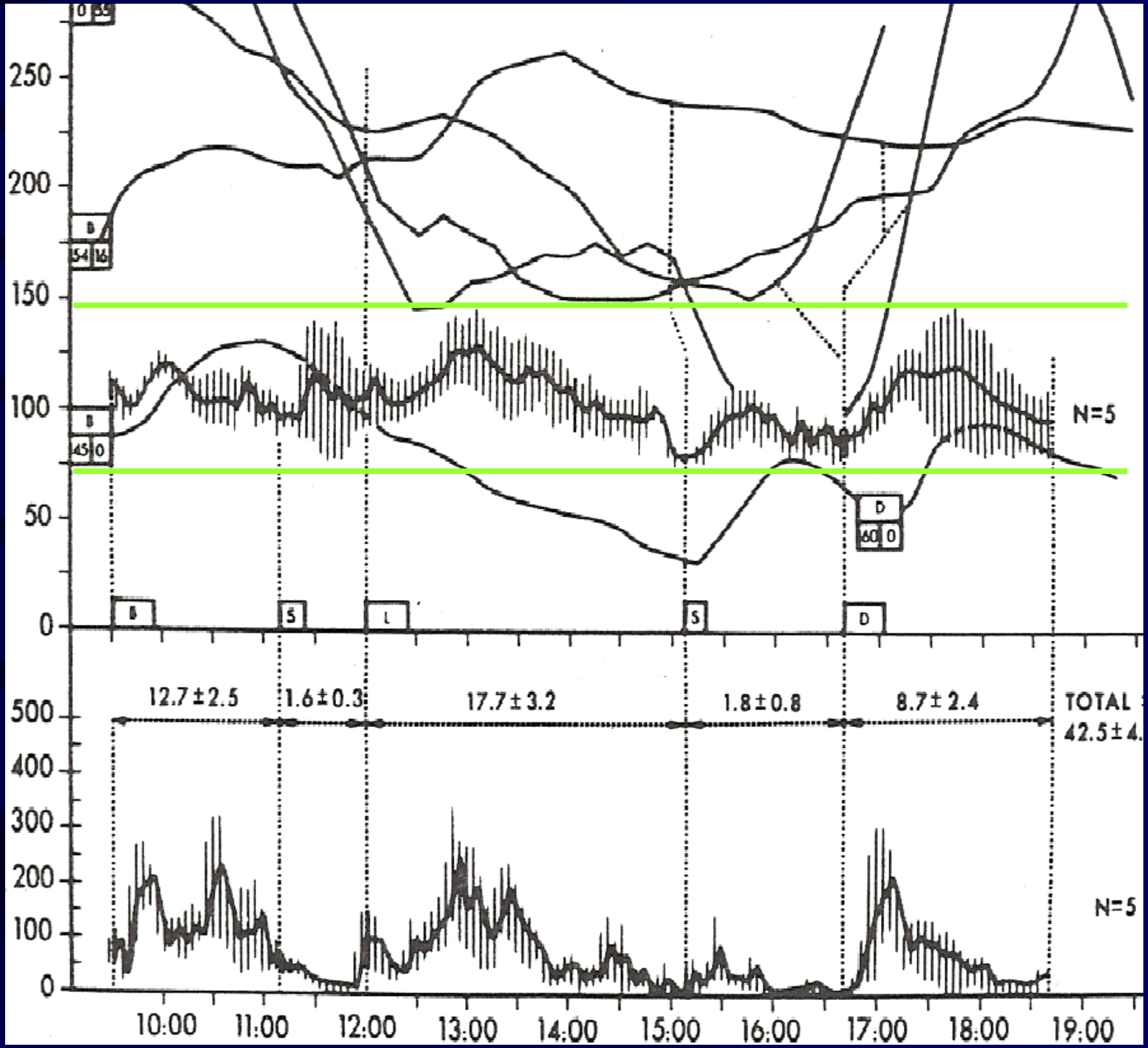
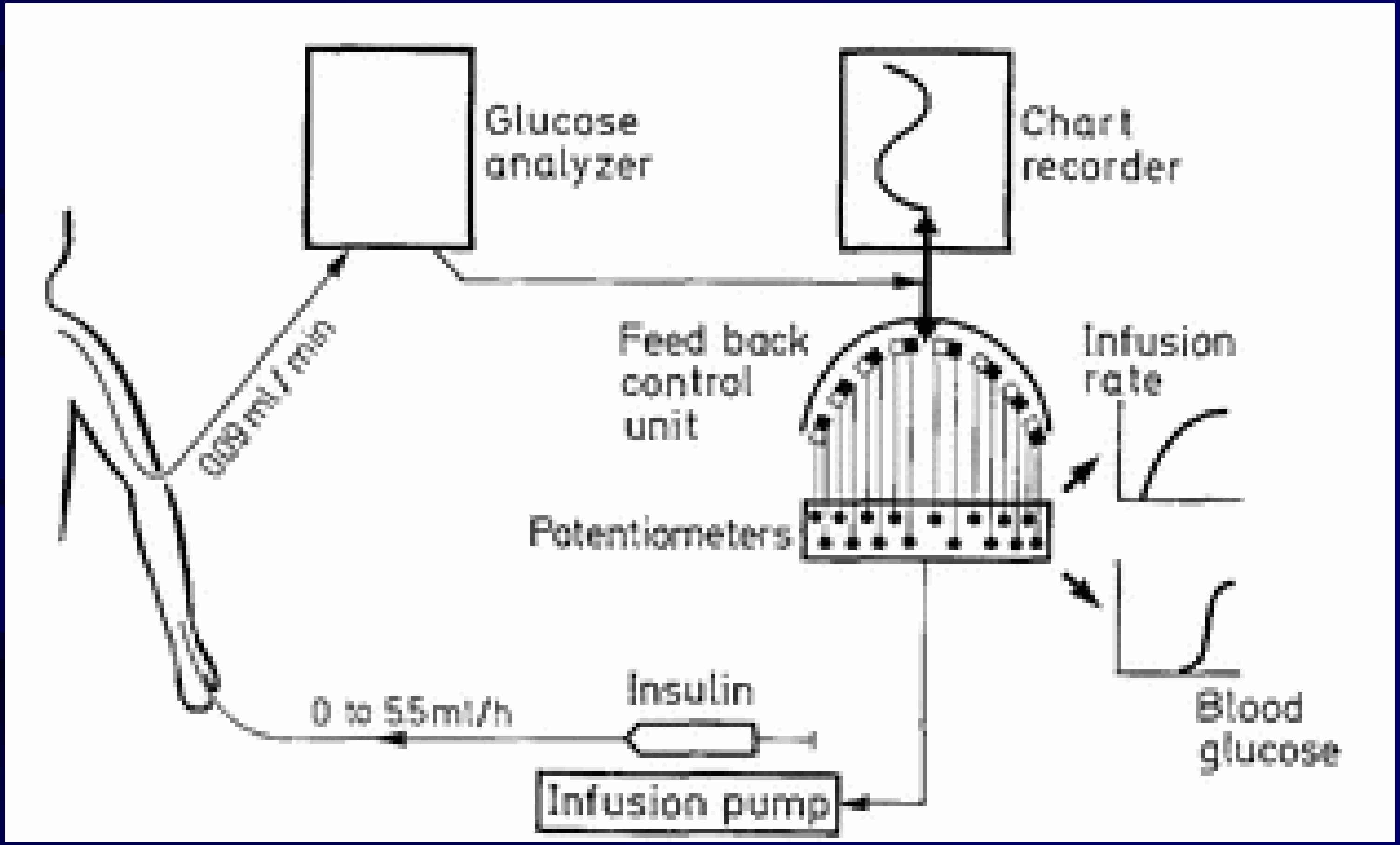


FIG. 2. Control algorithms relating insulin and dextrose infusion rates to projected blood glucose concentration. Curve parameters M, S, B are as follows: (1) 300, 0.04, 150; (2) 600, 0.04, 140; (3) 600, 0.04, 130; (4) 150, 0.05, 70; (5) 150, 0.05, 60.

[Albisser et al., 1974]



Albisser AM *et al*, Diabetes; 23: 389-396,1974



Mirouze J *et al*, Diabetologia; 13: 273-278, 1977

Diabetologia. 1977 May;13(3):273-8. doi: 10.1007/BF01219712.

Evaluation of exogenous insulin homoeostasis by the artificial pancreas in insulin-dependent diabetes

J Mirouze, J L Selam, T C Pham, D Cavadore

PMID: 873095 DOI: 10.1007/BF01219712

Abstract

With the artificial pancreas used by the authors, insulin was delivered through a venous infusion and the rate of delivery was adjusted according to data provided by a continuous blood glucose monitor. After different trials we selected control algorithms integrating two parameters: instantaneous blood glucose concentration and increasing or decreasing patterns of blood glucose. A constant basal insulin infusion rate was added and improved the control of glycaemic excursions. Different parameters concerning exogenous insulin homoeostasis were determined. The delay to reach an insulin effect was 18+/-2 min and was shortened by a priming-dose at the beginning of the infusion. The insulin effect remained for 28+/-2 min after the infusion had been stopped, but differences were noted in the morning (21+/-2 min), in the afternoon (32+/-2 min) and during the night (25+/-3 min). Insulin needs were evaluated during meals. Related to the amount of carbohydrates, the doses fell from 0.53 units/hr/g of carbohydrate for breakfast to 0.15 for dinner. From these data, it appears that the efficiency of exogenous insulin exhibits a circadian rhythm.

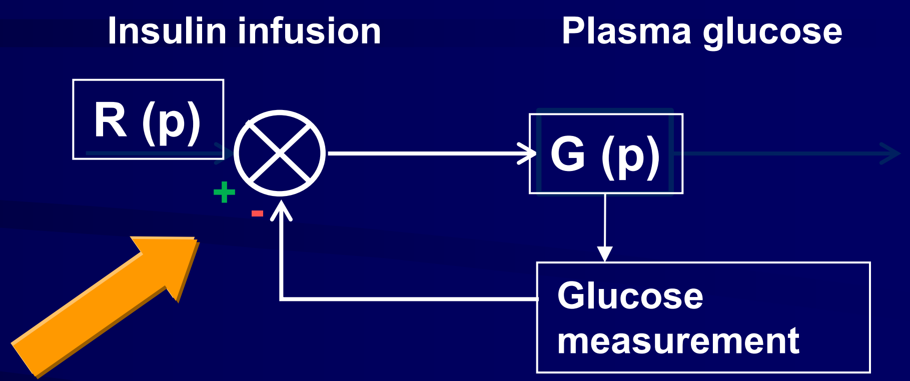
ALGORITHME PID

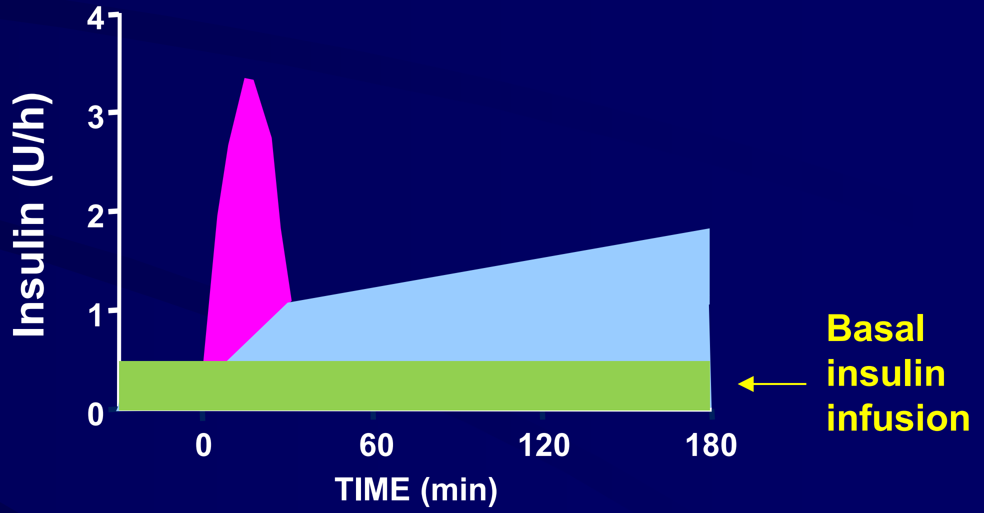
DUREE D'INSULINE ACTIVE = SENSIBILITE A L'INSULINE VARIABLE SUR 24H

RATIOS INSULINE/GLUCIDES VARIABLE

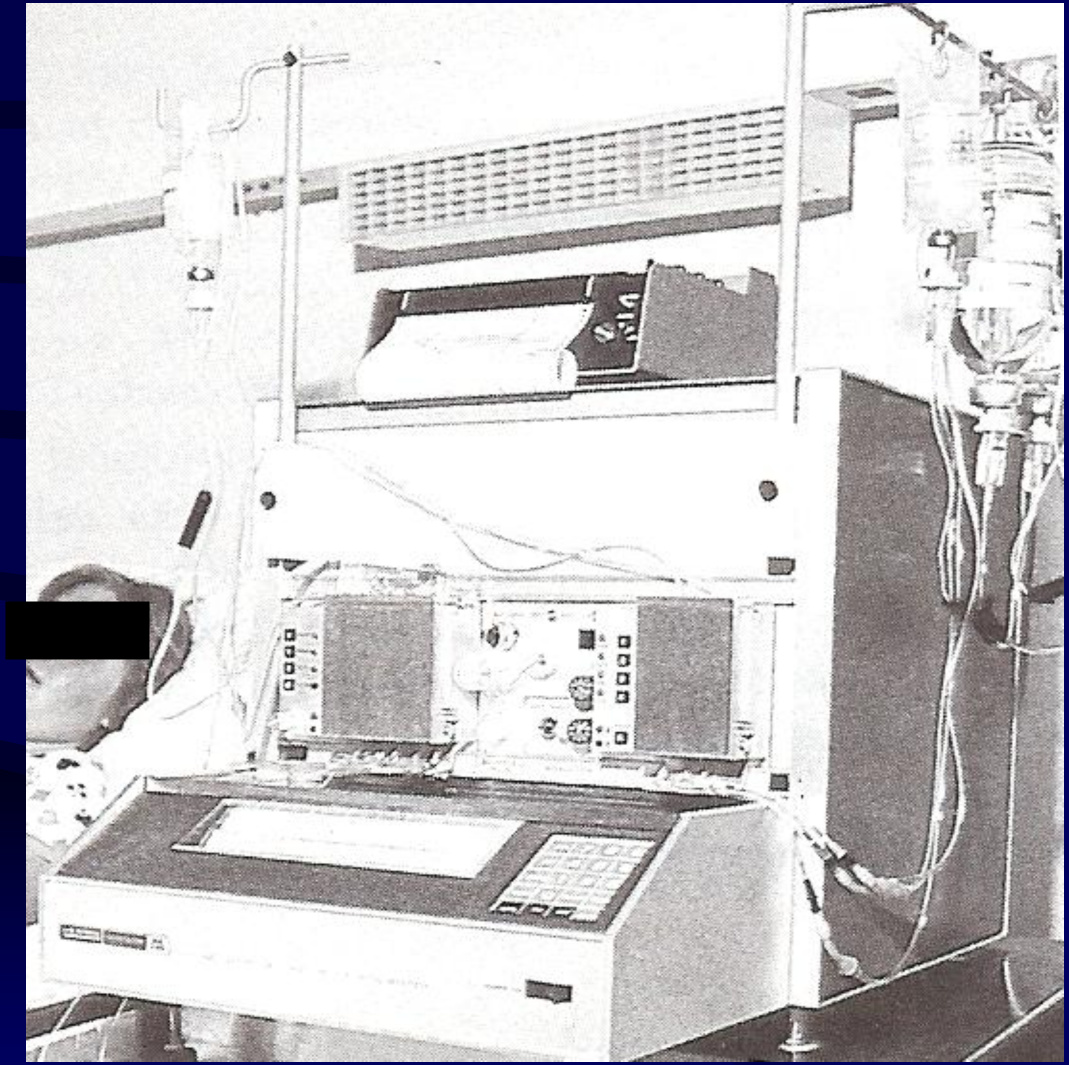
Feedback Control (PID) in order to Mimic Physiology

- Well adapted for closed-loop control using **reactive systems**
- Insulin delivery is modulated according to:
  - Difference between **current glucose level** and target glucose level (proportional component)
  - Time during which current glucose level is different from target glucose level (integral component)
  - Variation of blood glucose on short-term (derivative component)





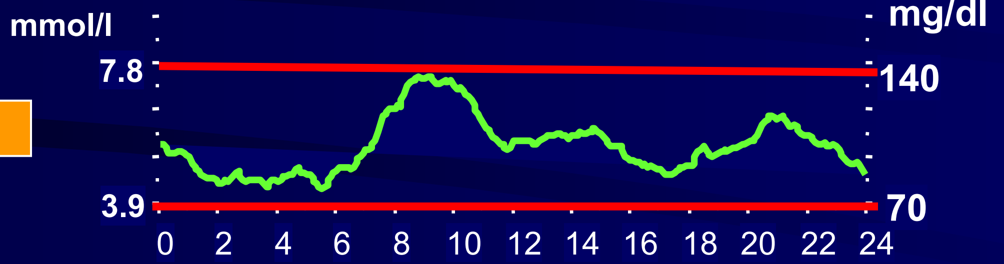
Le BIOSTATOR: Premier Modèle de Pancréas Artificiel Commercialisé



Pfeiffer EF *et al*, Horm Metab Res; 6: 339-342,1974

“Can we get it smaller, please ?”

The Quest for the Artificial Pancreas



IV

Continuous Glucose Monitoring → Control Algorithm → Insulin Delivery

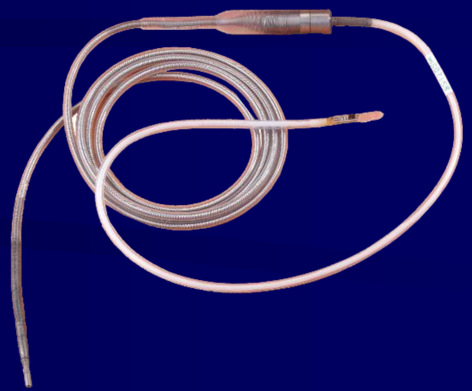
IP

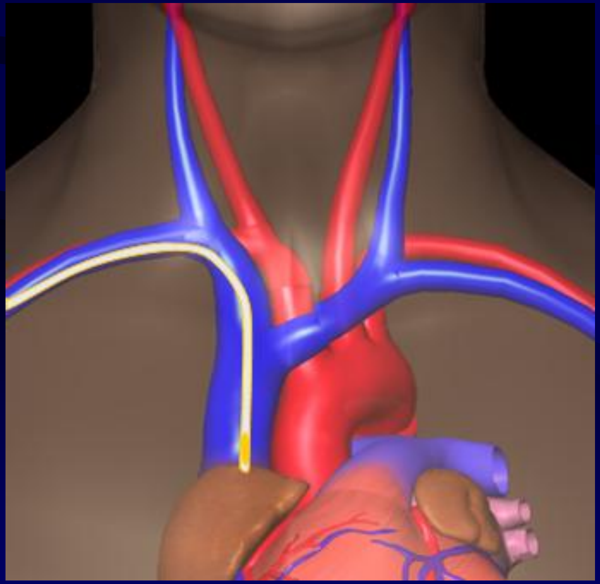
Closed-Loop

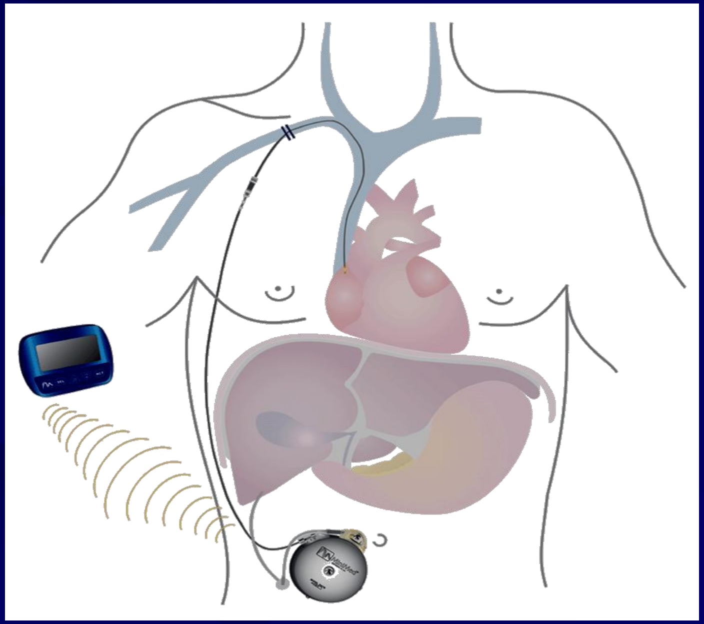
The Long-Term Sensor System (LTSS): A Fully Implantable Automated Insulin Delivery System

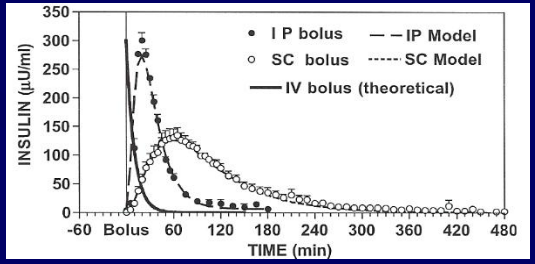
Renard E. Implantable closed loop glucose-sensing and insulin delivery: the future for insulin pump therapy. Curr Opin Pharmacol, 2: 708-716, 2002

Fully Implantable Glucose Sensor (LTSS): an Option for IV Sensing



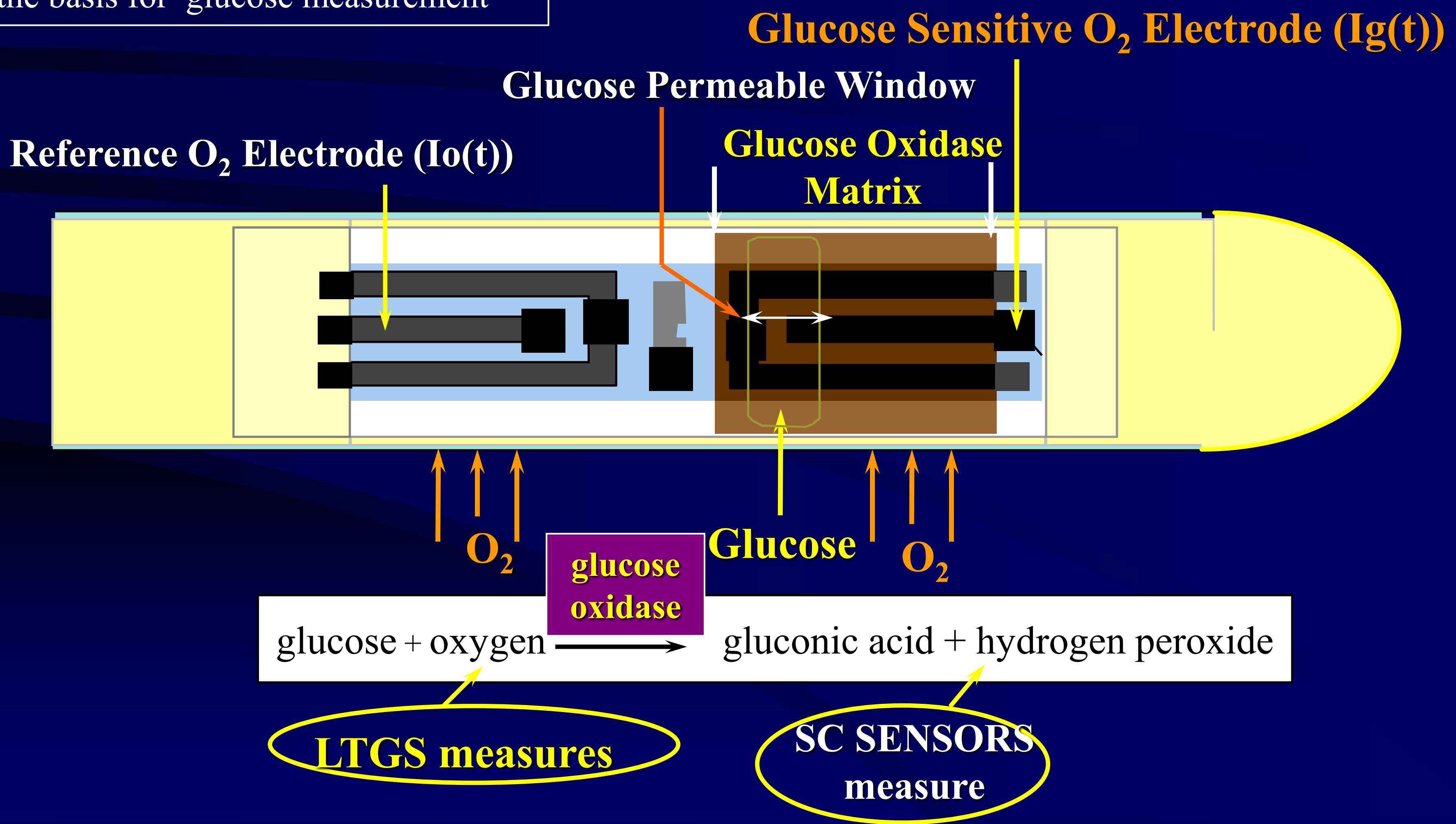




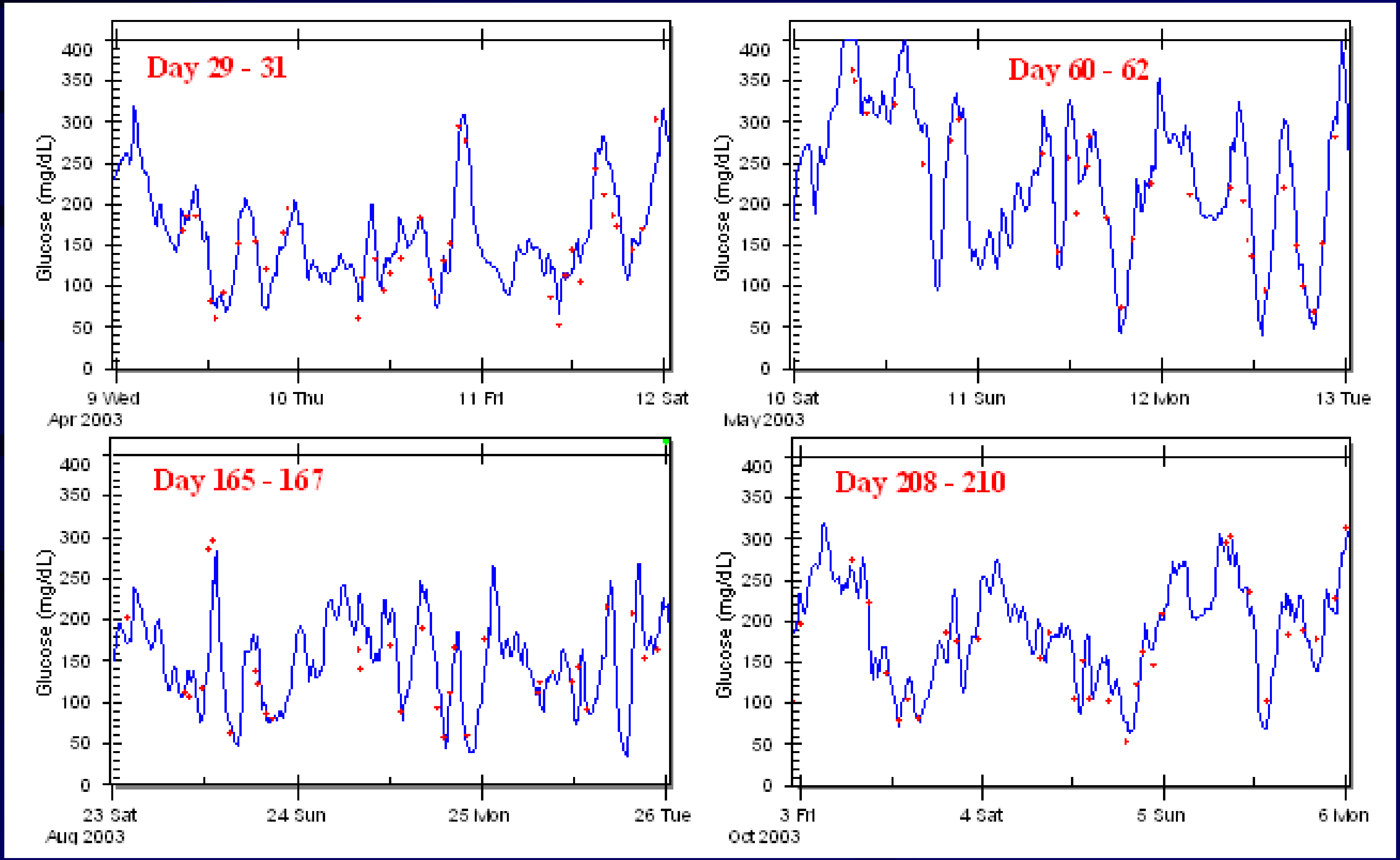


LONG-TERM IV GLUCOSE SENSOR (LTGS)
(Medtronic-MiniMed)

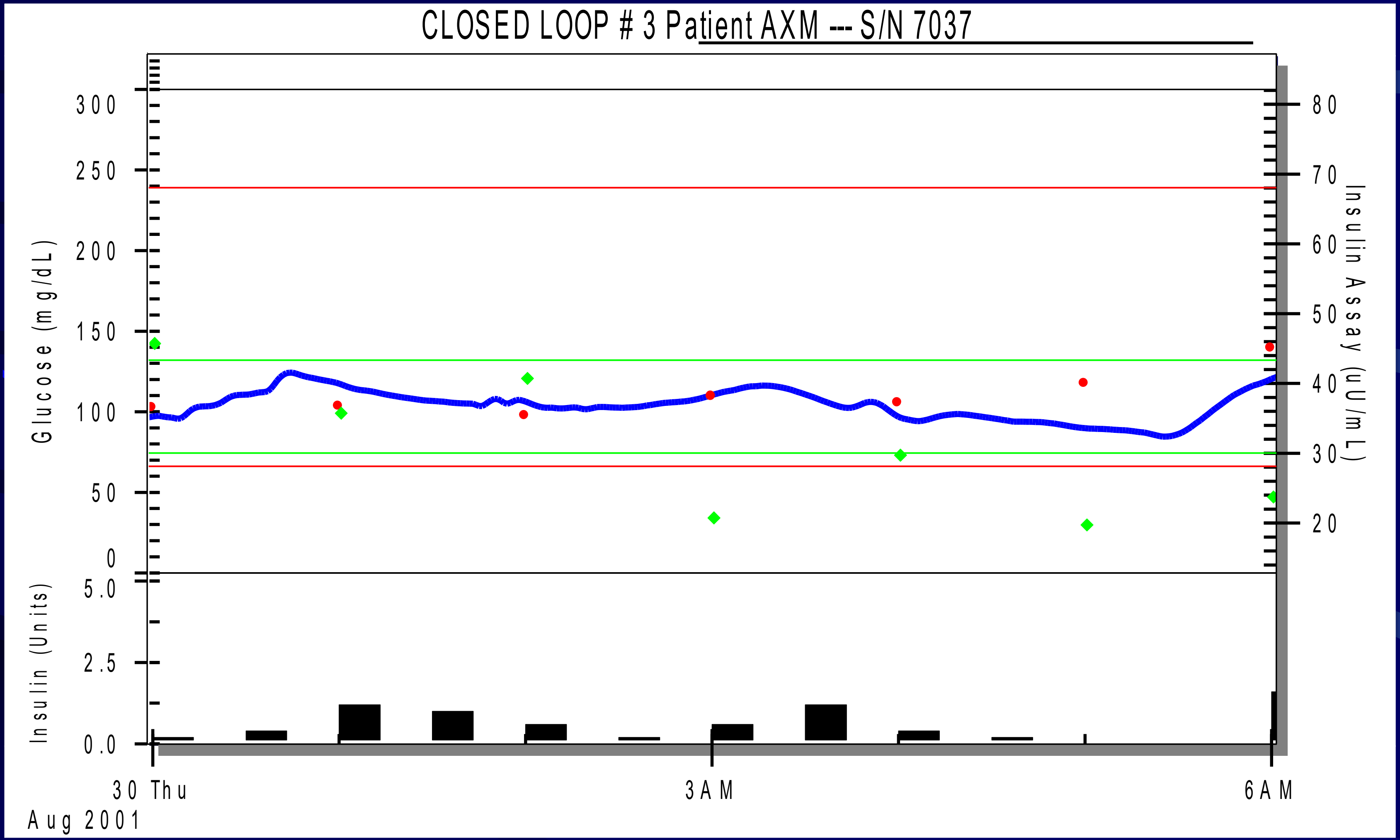
The current ratio Iglu/Ioxy provides the basis for glucose measurement



Long-term Accuracy of Glucose Sensing With LTSS



CLOSED-LOOP GLUCOSE CONTROL USING LTSS AT NIGHT-TIME (12 AM - 6 AM)



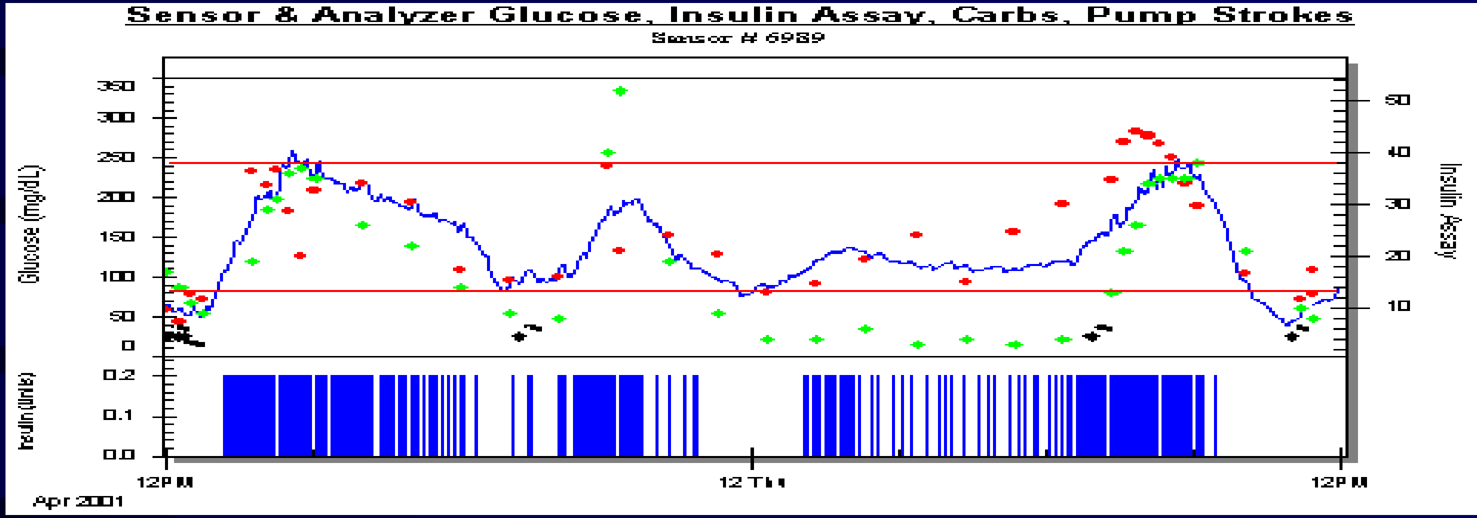
TIGHT BASAL GLUCOSE CONTROL

Instituts thématiques Inserm

Institut national de la santé et de la recherche médicale

CIC 1411

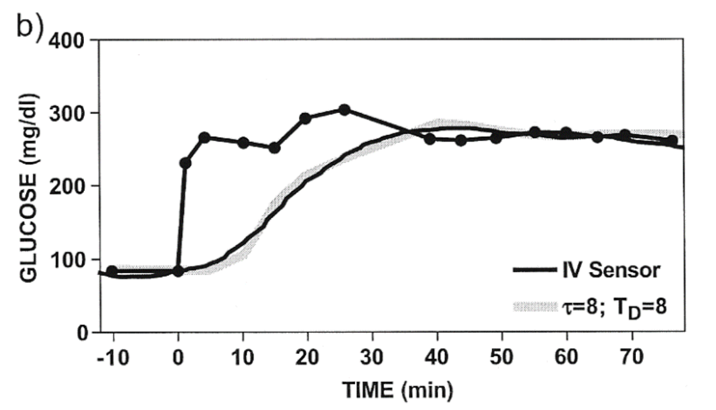
LTSS Study (2000-2007)

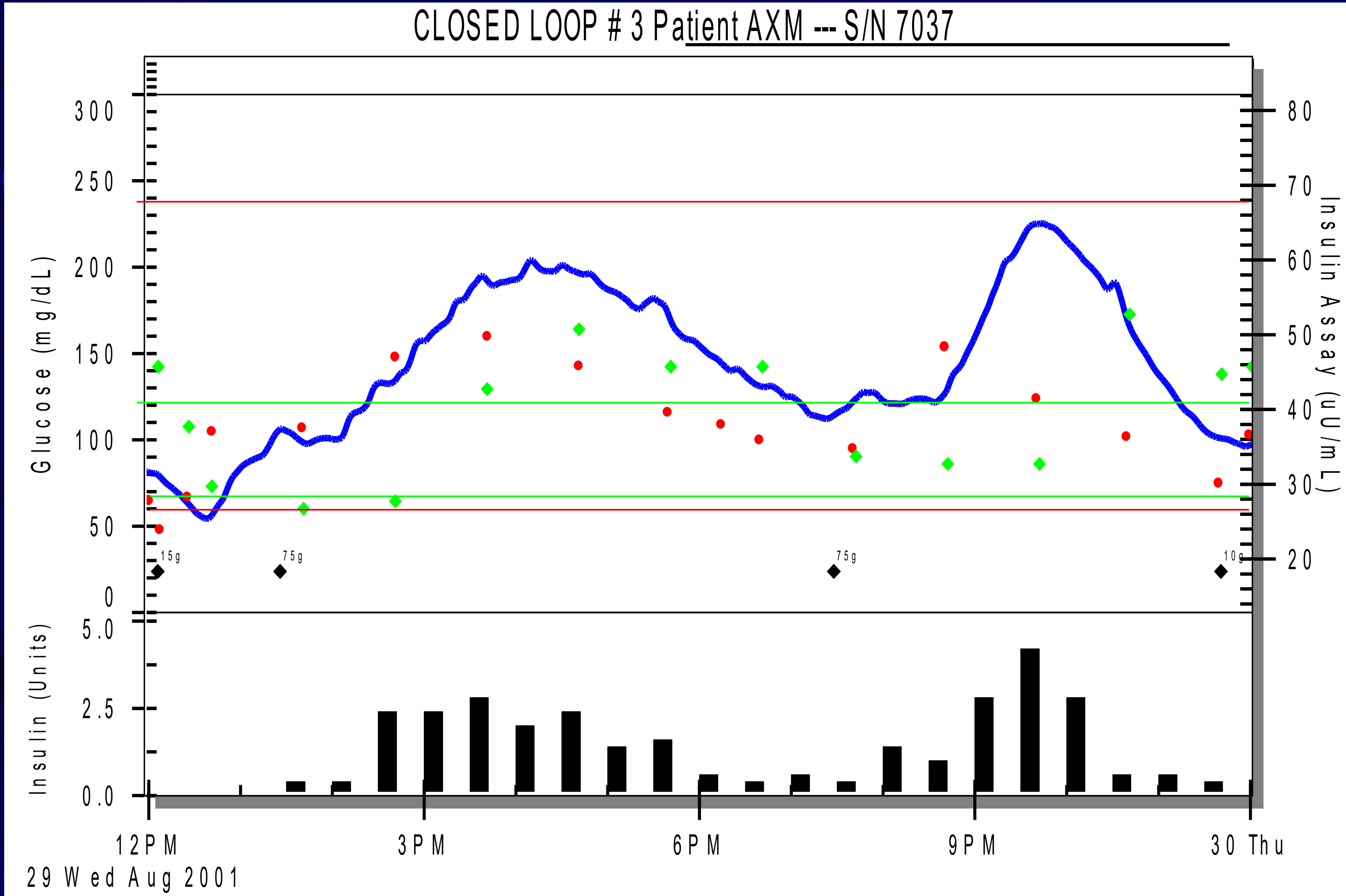


	During Closed Loop
Less Than 70 mg/dl	5.9 %
Between 70 and 120 mg/dl	42.0 %
Between 120 and 240 mg/dl	50.1 %
Above 240 mg/dl	2.0 %
Average Glucose	131 mg/dl
Insulin Use	51 U/day

Renard E, Curr Opin Pharmacol, 2002

CLOSED-LOOP GLUCOSE CONTROL USING LTSS BETWEEN NOON AND MIDNIGHT (12 PM - 12AM)

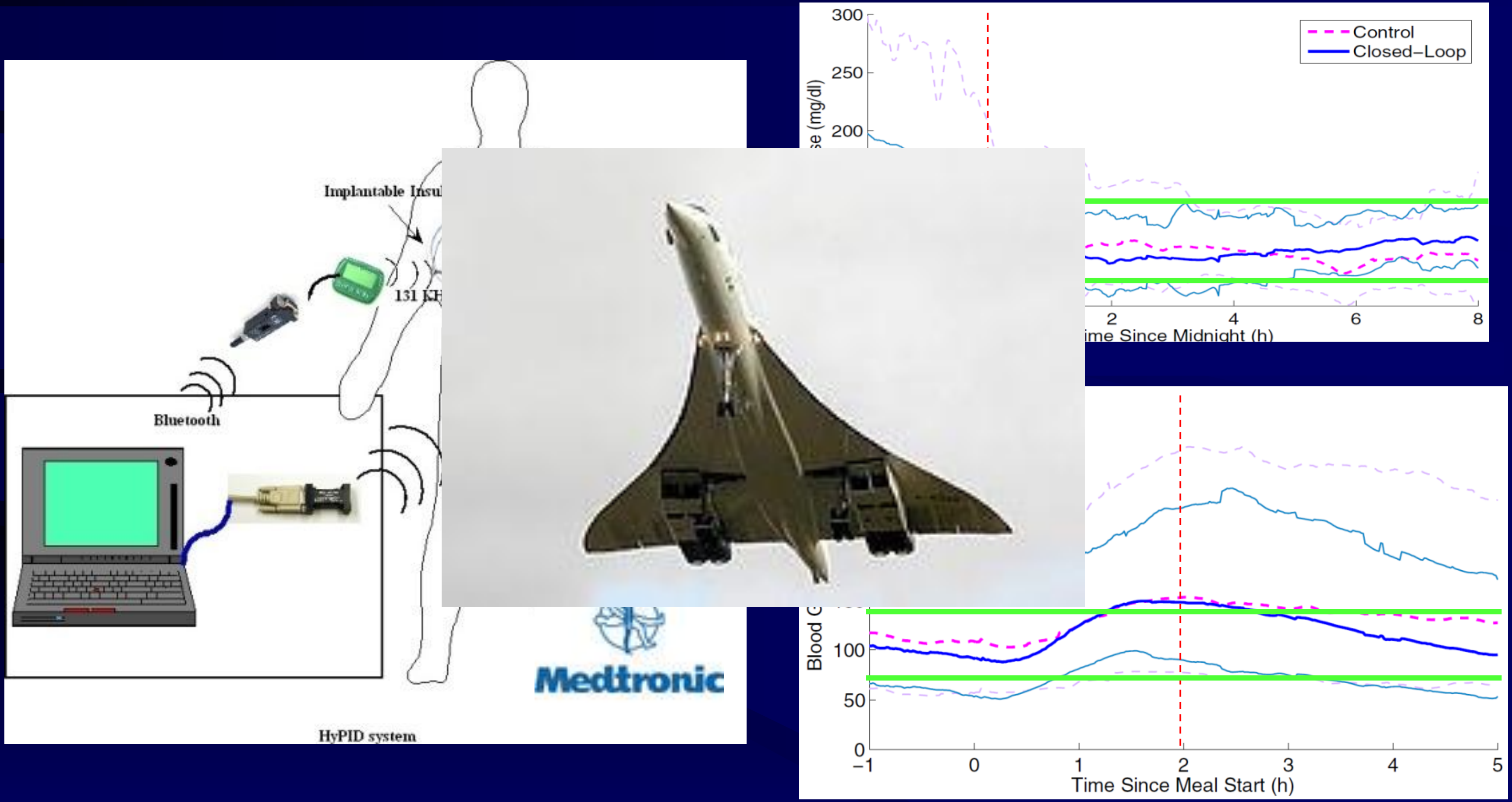




DELAYED SENSING AND INSULIN DELIVERY EXPLAIN POST-MEAL HYPERS

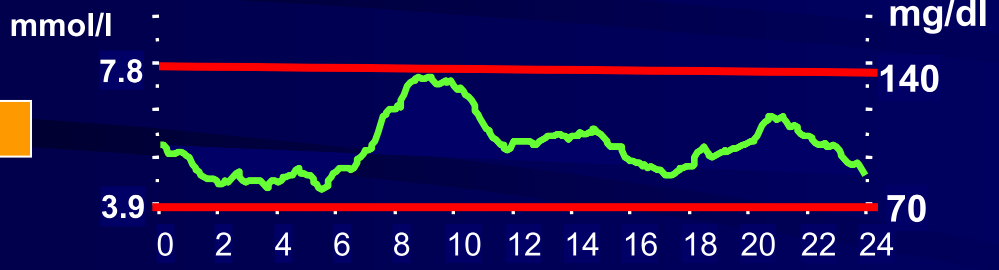
Hybrid PID Closed-Loop System, 2008-2010

SC Glucose Sensor + IP Insulin Infusion



Renard E, *et al. Diabetes Care* 2010;33:121–7.

The Quest for the Artificial Pancreas



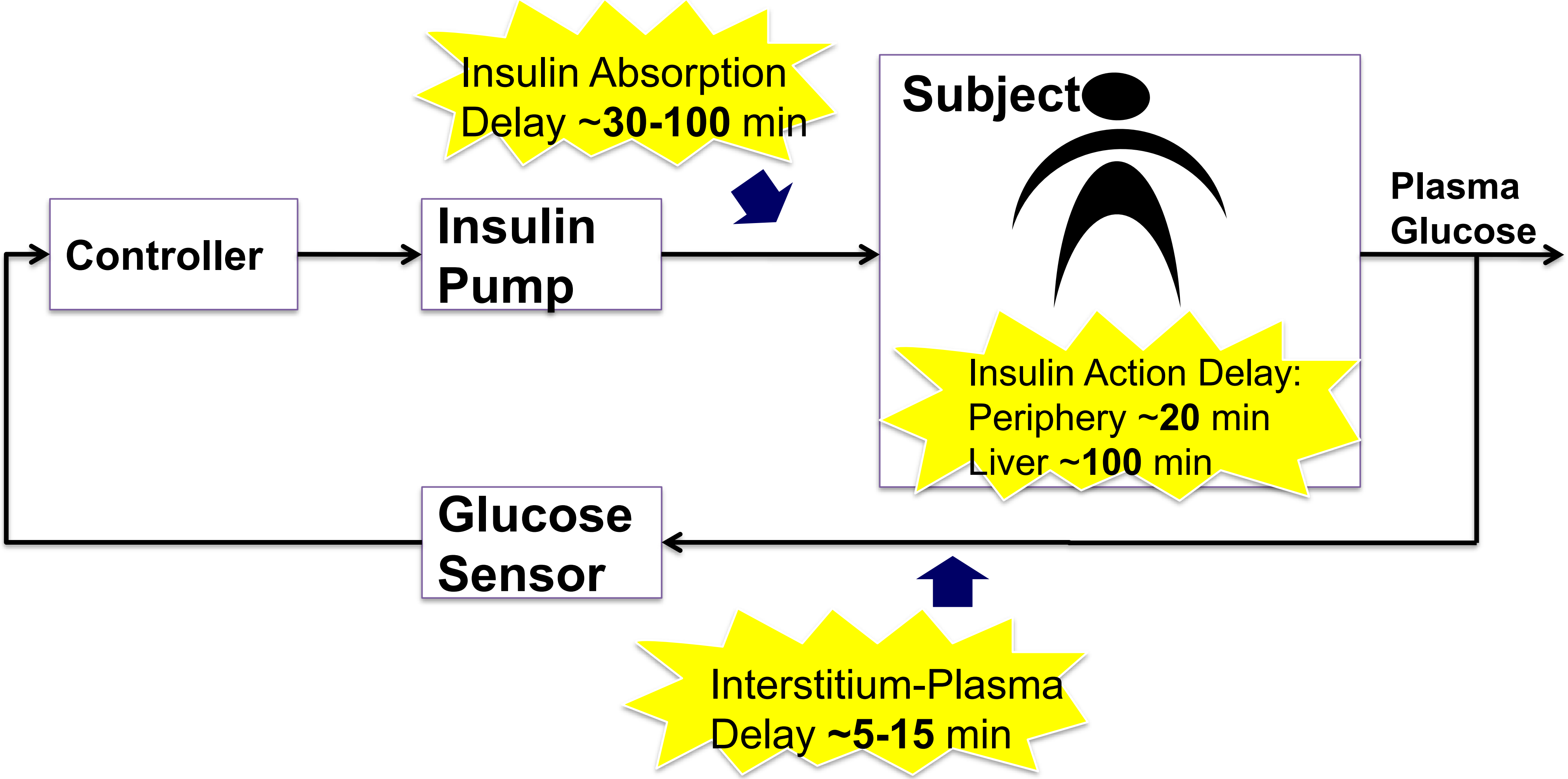
SC

Continuous Glucose Monitoring → Control Algorithm → Insulin Delivery

SC

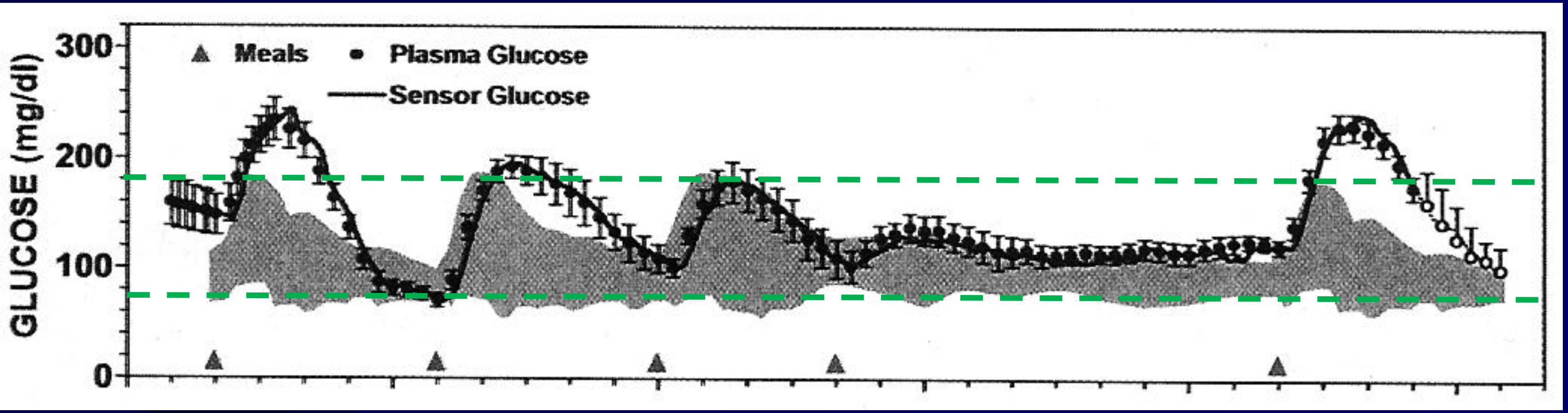
Closed-Loop

Le problème de la boucle fermée en SC: Les délais !



Cobelli C, Renard E, Kovatchev B. Artificial pancreas: past, present, future. **Diabetes 60: 2672-82, 2011**

Full Closed-Loop Using SC Glucose Sensing and Insulin Infusion with a PID Algorithm



- 10 type 1 diabetic patients, closed-loop for 30 hours vs. open-loop for 3 days
- Blood glucose: 133 ± 63 vs. 133 ± 52 mg/dl
- Time spent b/w 70 and 180 mg/dl: 75 vs. 63%
- Blood glucose < 60 mg/dl: similar

Steil GM et al. *Diabetes* 2006; 55:3344-50.

Fully Automated Closed-Loop Insulin Delivery Versus Semiautomated Hybrid Control in Pediatric Patients With Type 1 Diabetes Using an Artificial Pancreas

Diabetes Care 31:934–939, 2008

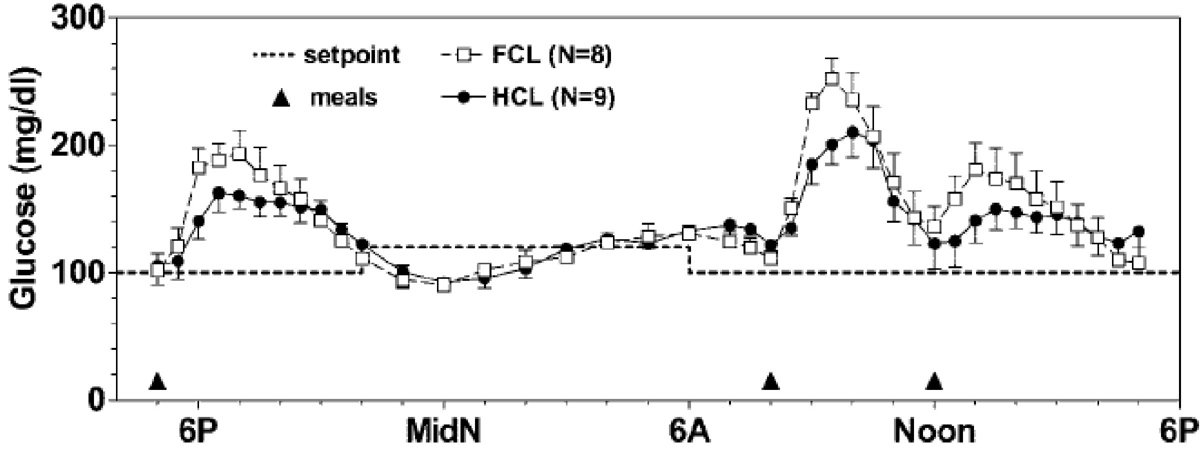


Figure 2—*Glucose control in FCL control versus HCL control. Glycemic excursions under FCL (□– – –□) versus HCL(●——●). Horizontal dashed line, target glucose level (100 mg/dl from 6 A.M. to 10 P.M. and 120 mg/dl from 10 P.M. to 6 A.M.); ▲, meal markers.*

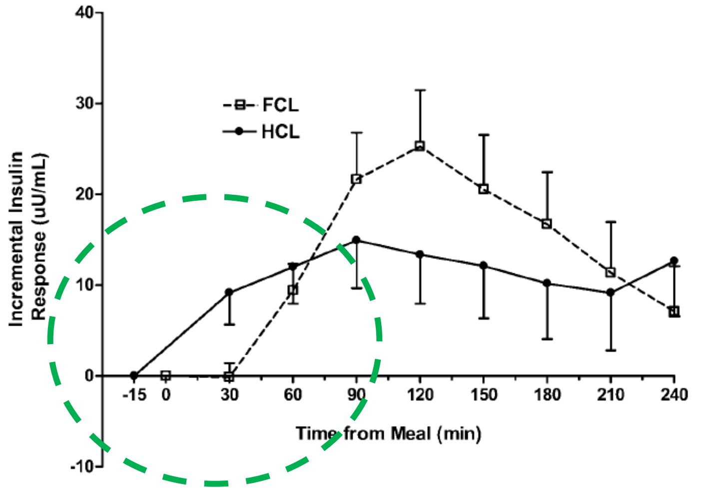
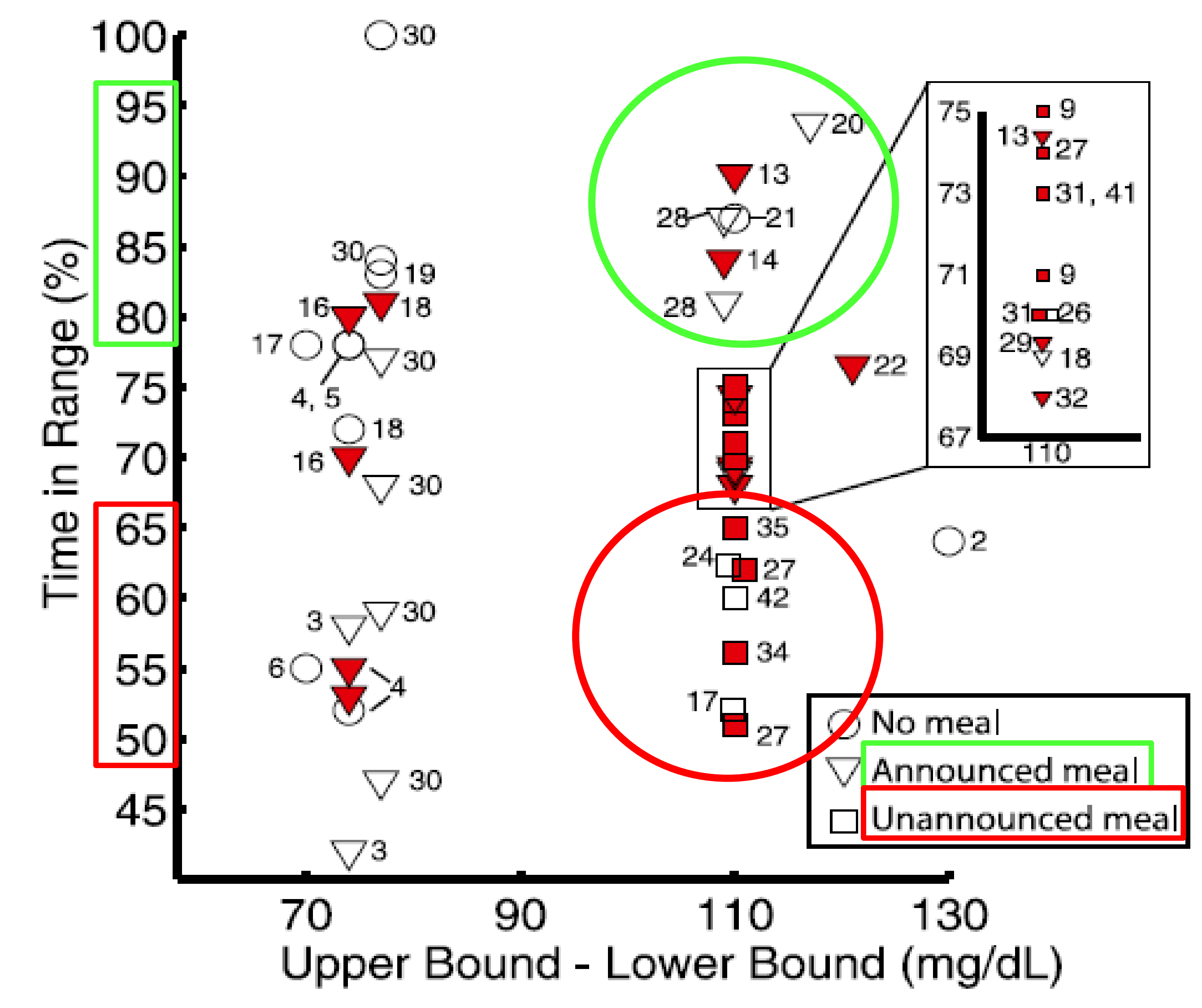


Figure 3—*Early insulin response in FCL versus HCL control. Incremental increase in plasma insulin concentrations from baseline after meals in FCL (□– – –□) and HCL (●——●) groups. Baseline insulin level was calculated from the 0-min point (time of meal) for the FCL group and from the −15 min point for the HCL group.*

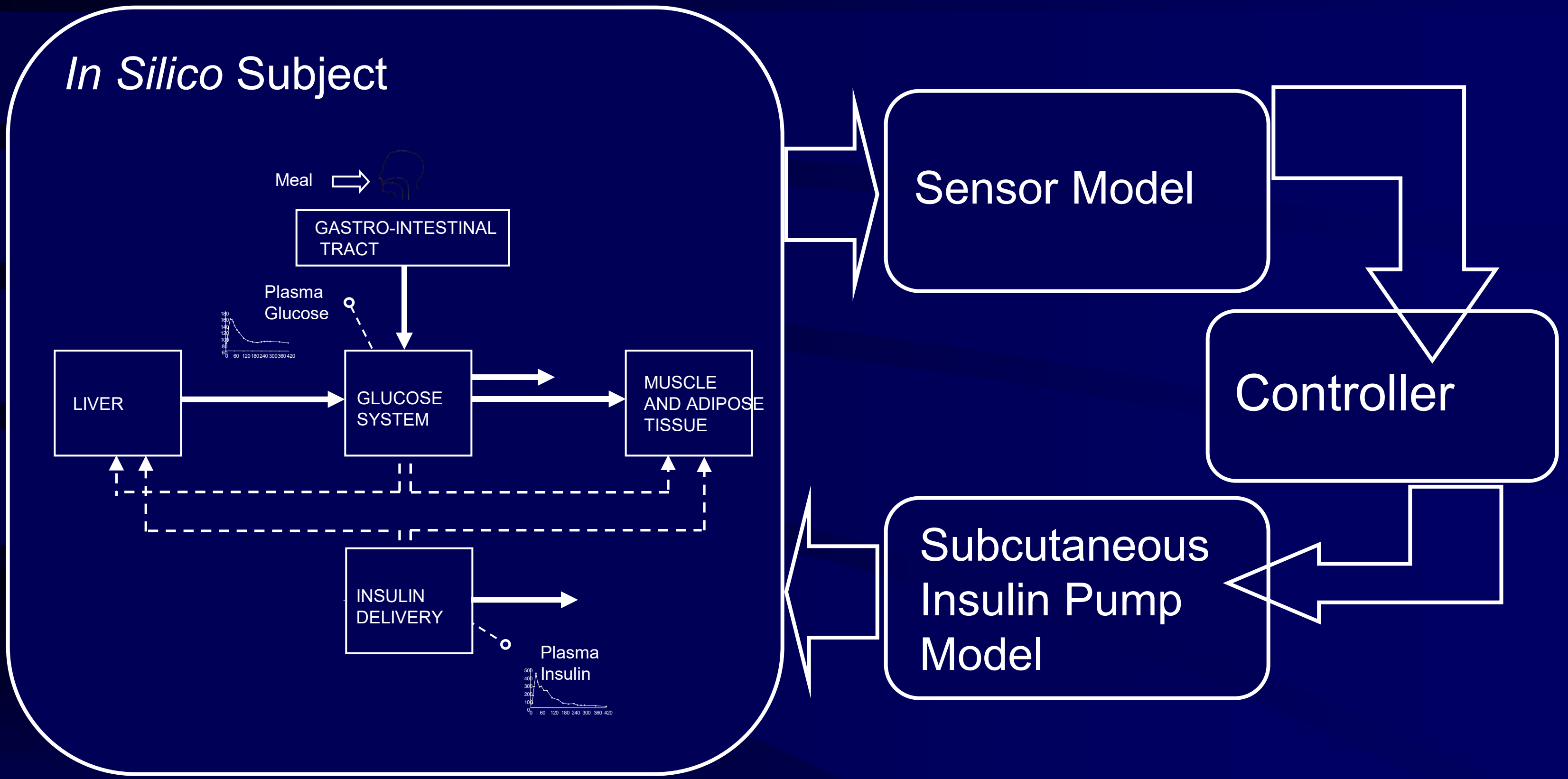
→ **Systèmes de Boucle Fermée HYBRIDES**

Meal Announcement Improves Percent Time in Target Range



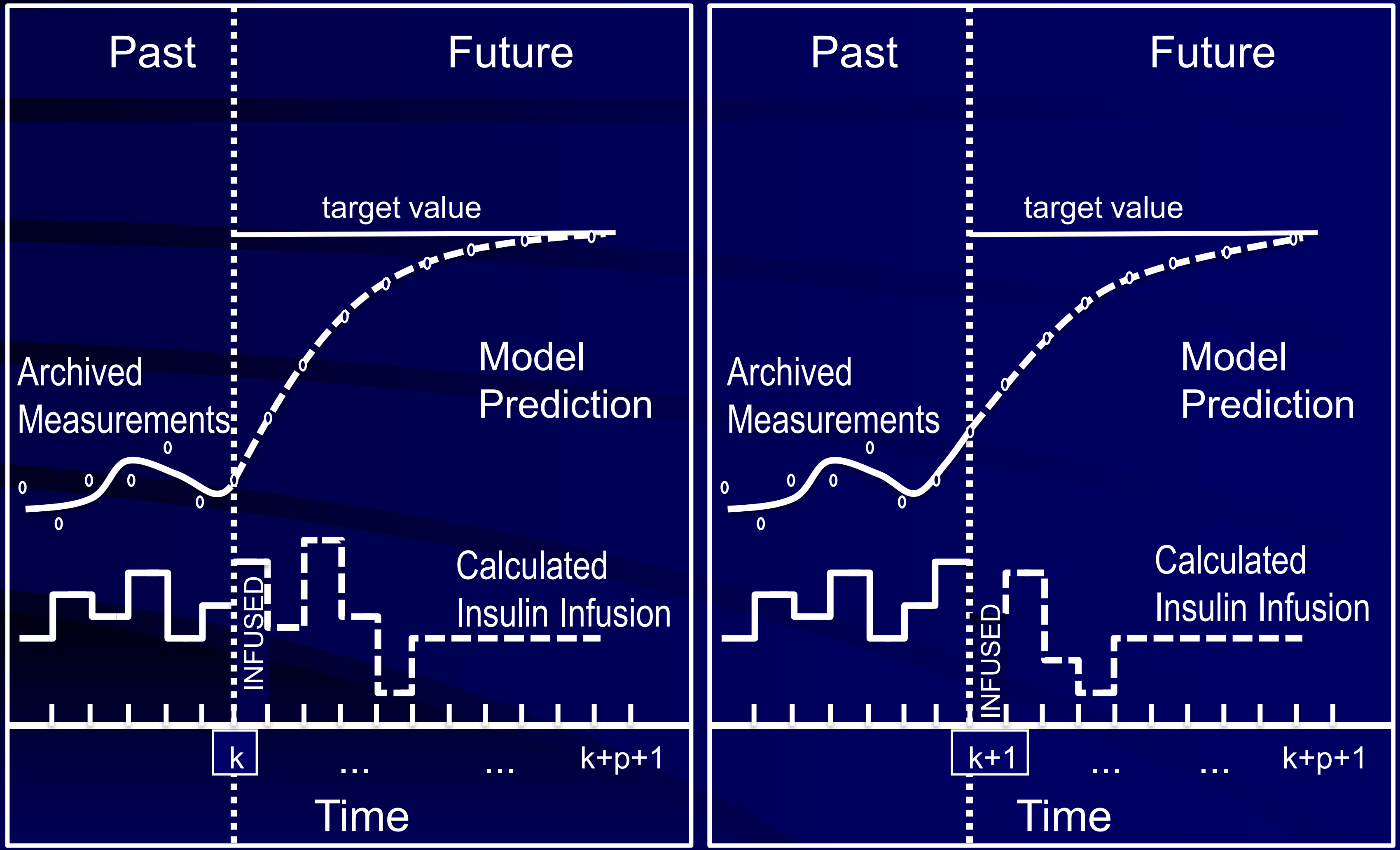
Doyle FJ III et al, Diabetes Care 2014

La Solution: Modéliser l'action de l'insuline et créer un modèle prédictif



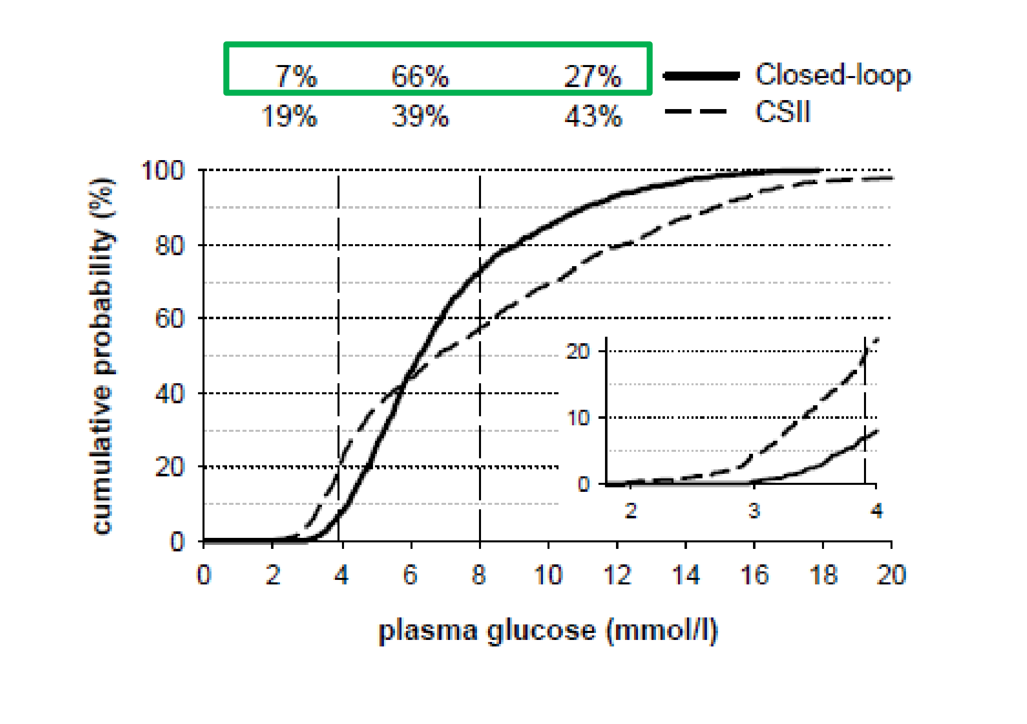
Cobelli C, Renard E**,** Kovatchev B. Artificial pancreas: past, present, future. **Diabetes 60: 2672-82, 2011**

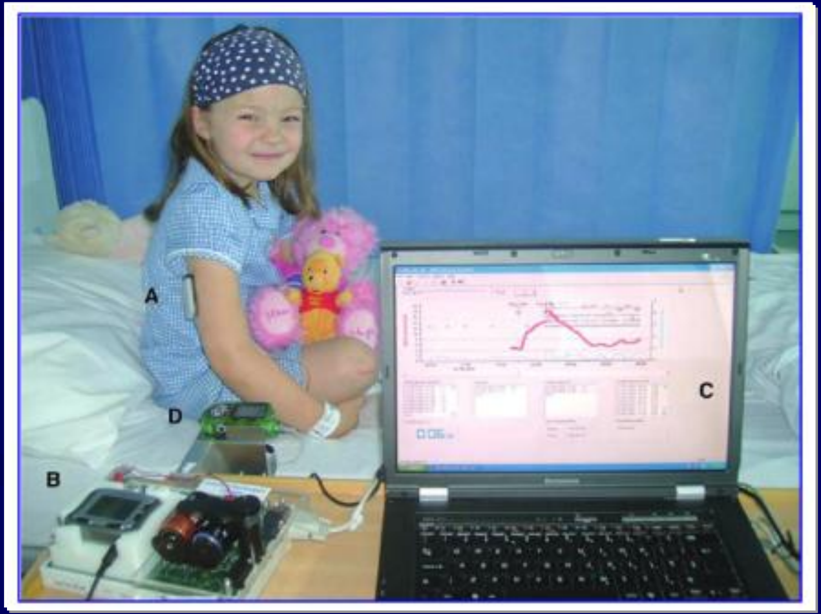
L'Algorithme Model Predictive Control



Cobelli C, Renard E, Kovatchev B. Artificial pancreas: past, present, future. **Diabetes 60: 2672-82, 2011**

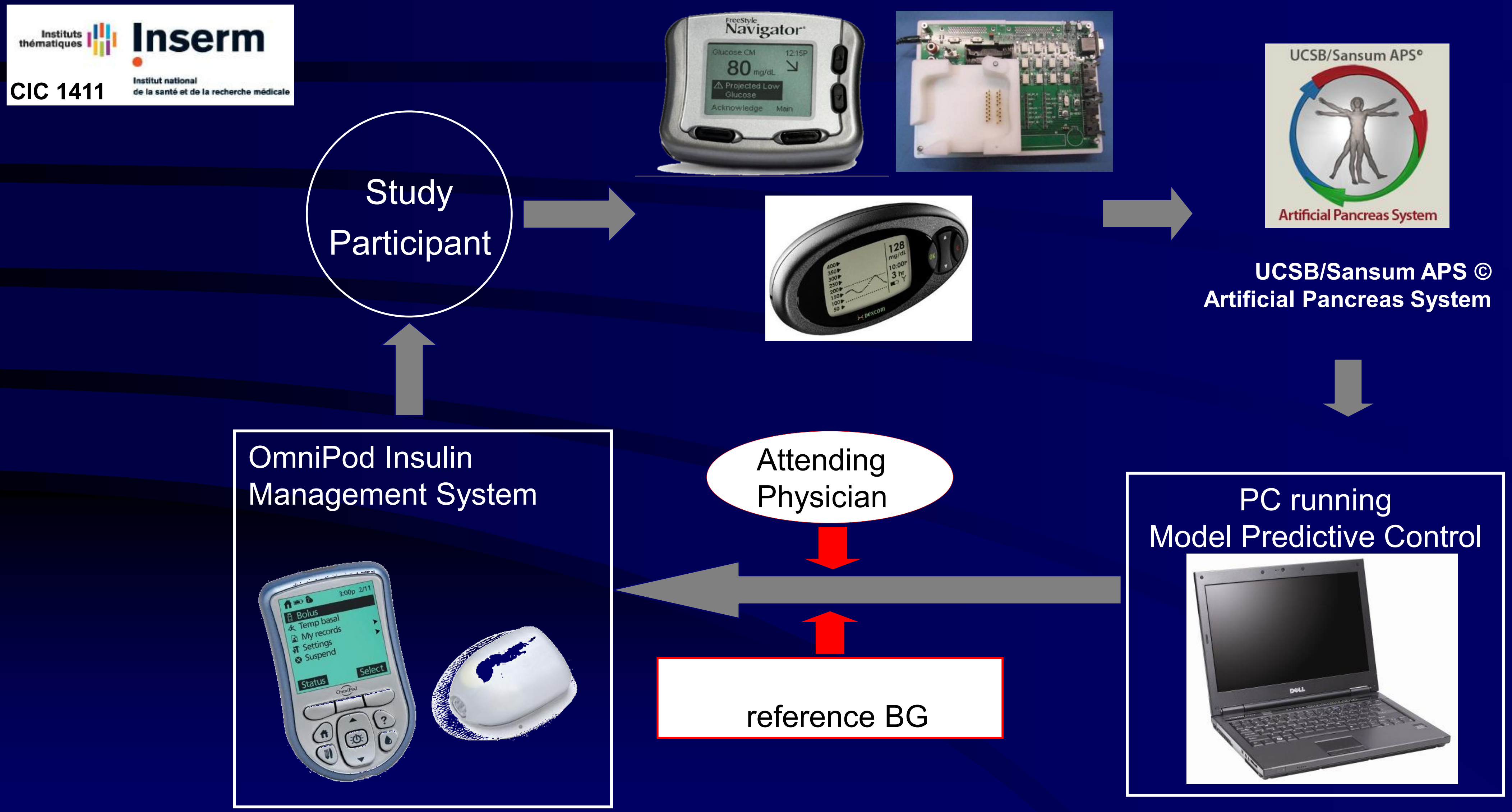
The Cambridge Experience of MPC Closed-Loop at Night-Time in Type 1 Diabetic Children and Adolescents: Minimized Time Spent in Hypoglycaemia





Hovorka R. *et al*, Lancet 2010

Subcutaneous Glucose Sensing, Algorithm Management, and Subcutaneous Insulin Delivery: UVA, UCSB, Padova & Montpellier System

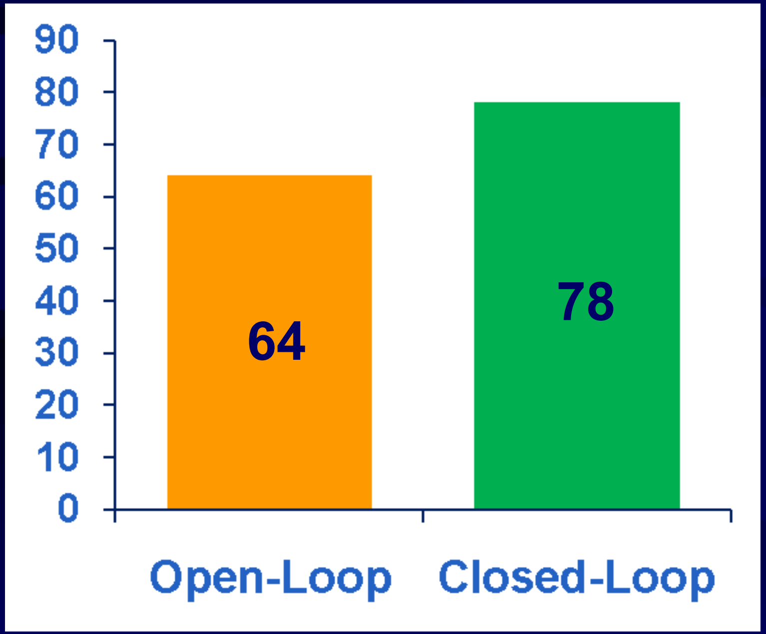


Multi-national study of subcutaneous MPC closed-loop control in Adults with T1DM

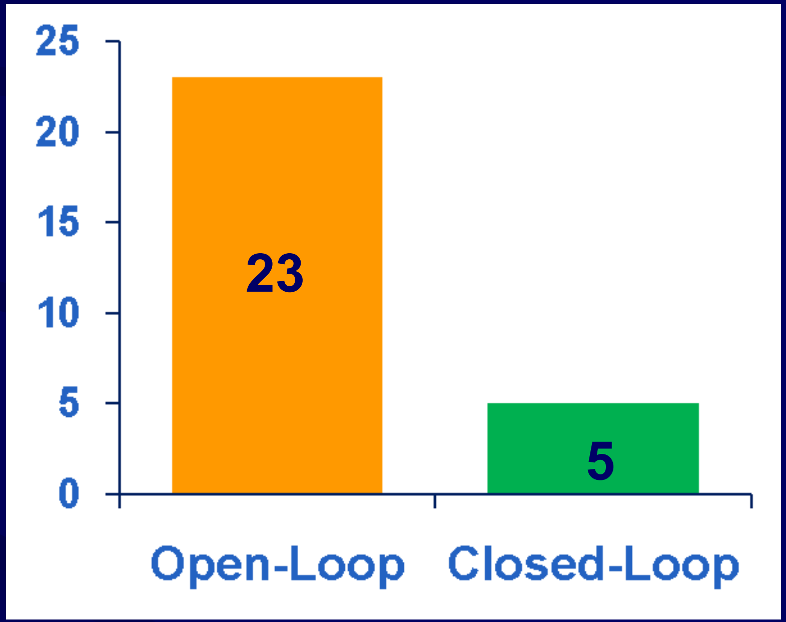
CIC 1411

5-fold reduction in nocturnal hypoglycaemia
with better overall glucose control within target range

Overnight time (%) within the target range of 70–140 mg/dL



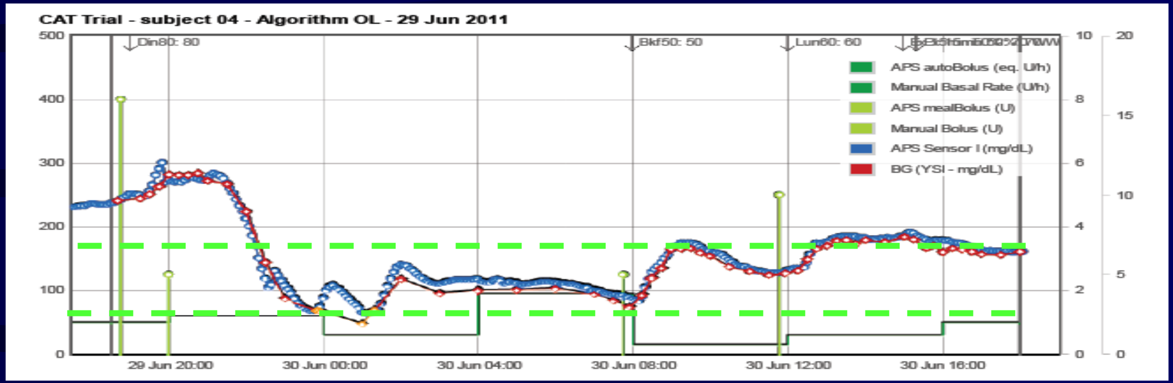
Nocturnal hypoglycaemic episodes (BG <70 mg/dL)

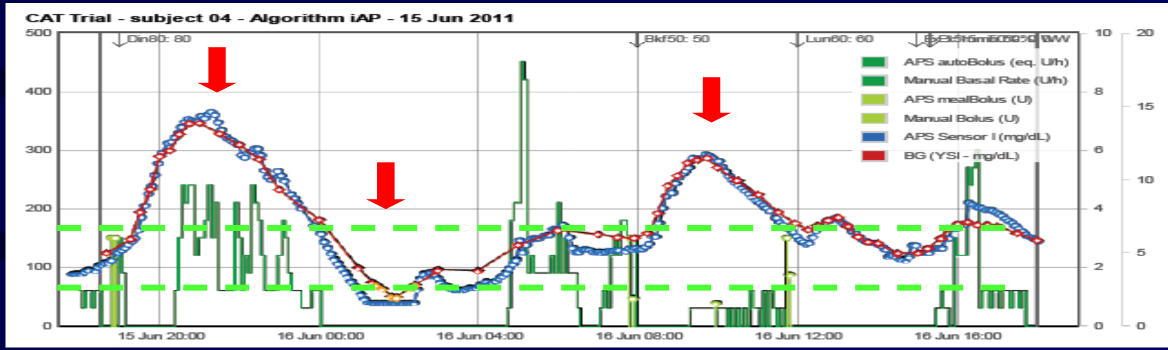


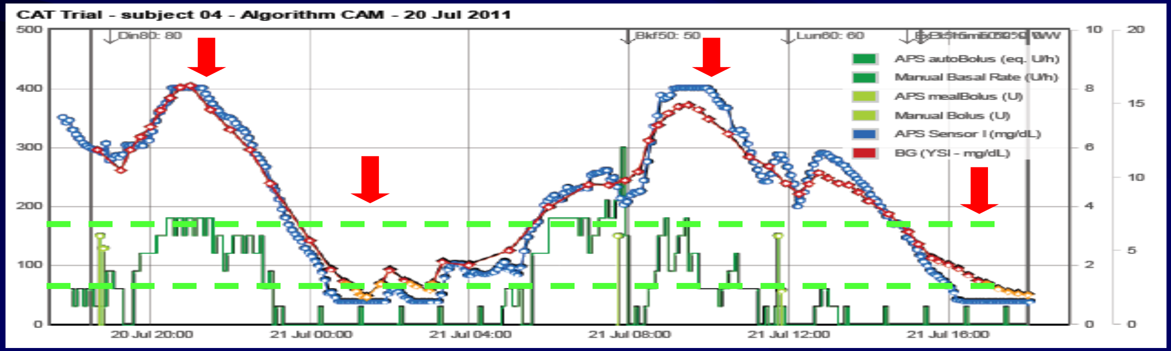
Kovatchev B, Cobelli C, Renard E et al, J Diabetes Sci Technol 2010

MPC Meal Control remains the Weak Point

CIC 1411

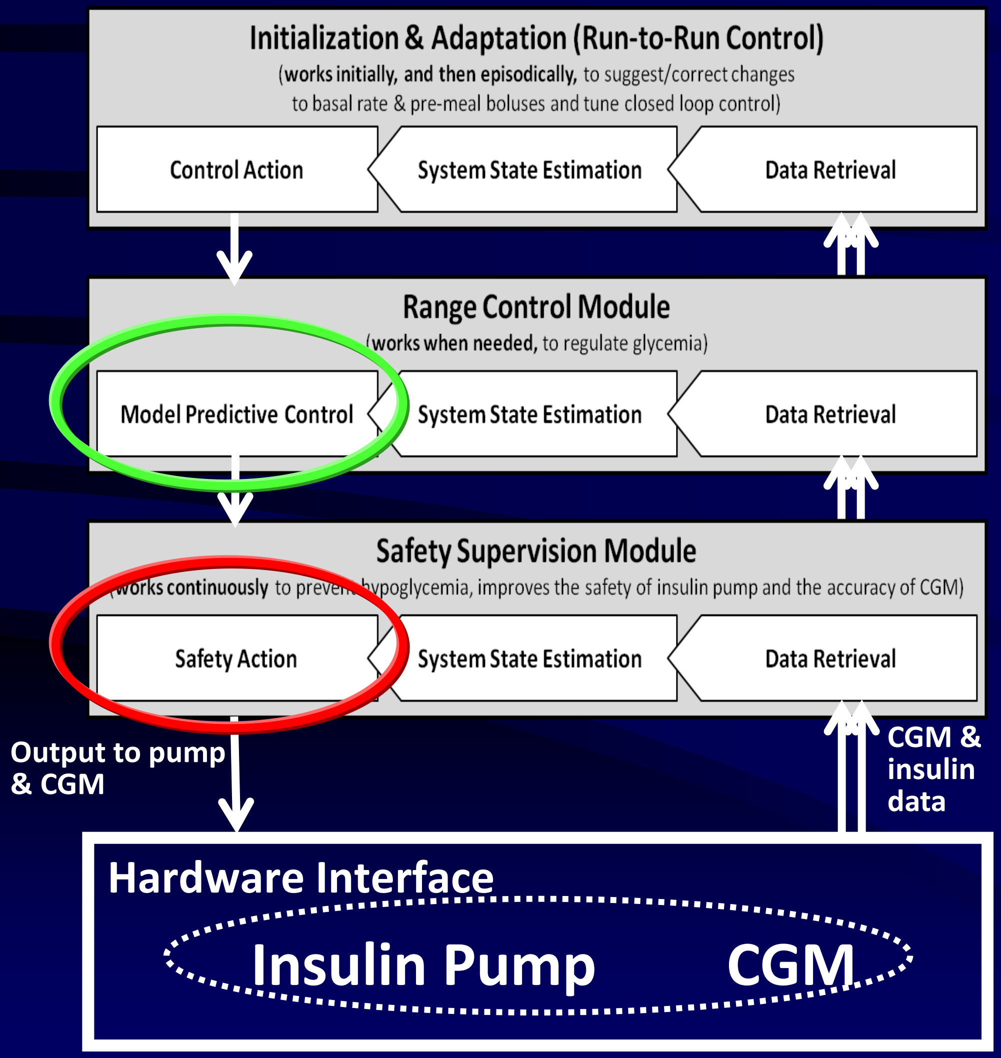






Ljuif YM et al, Diabetes Care; 36: 3882-7, 2013

Modular Algorithms Allow Increased Safety of Glucose Control



SSM

- detects imminent hypoglycemia
- attenuates insulin delivery
- intercepts boluses potentially requiring additional carbohydrate

RCM

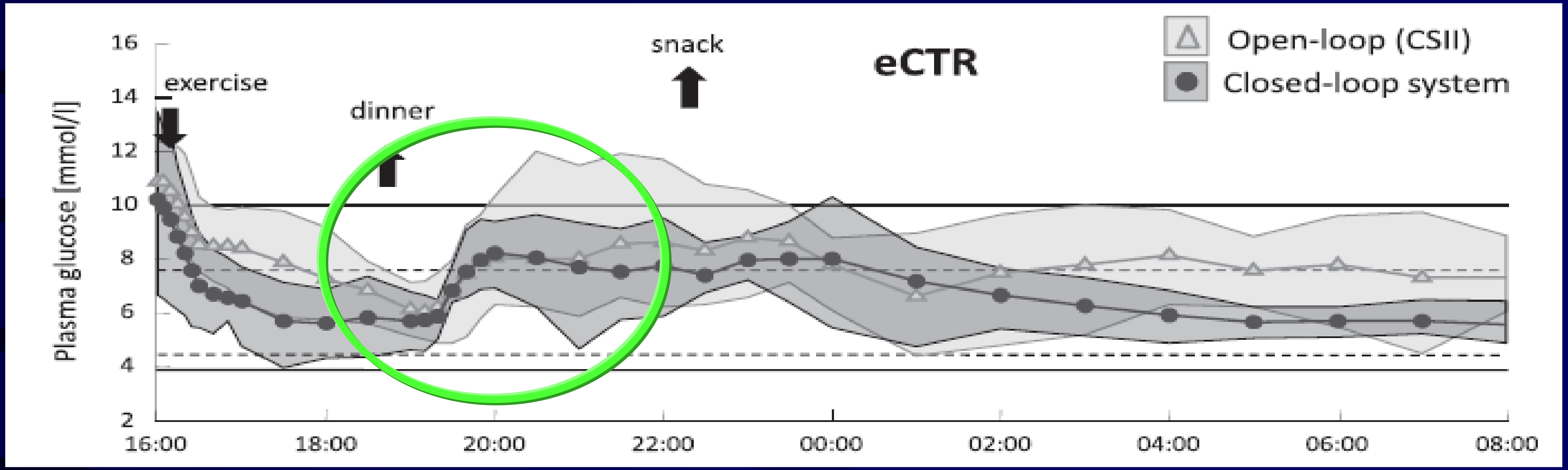
- computes the optimal insulin infusion to control glucose
- works using information of the individual conventional therapy

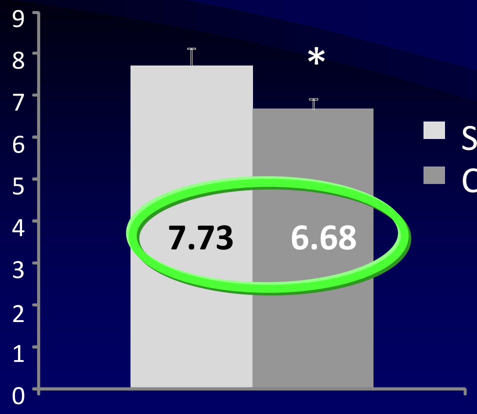
Modular Closed-Loop Control of Diabetes[1]

S. D. Patek*[2], L. Magni†[2], E. Dassau‡§[2], C. S. Hughes*, C. Toffanin†, G. De Nicolao†, S. Del Favero¶, M. Breton*, C. Dalla Man¶, E. Renard‖, H. Zisser‡§, F. J. Doyle III‡§, C. Cobelli¶, B. P. Kovatchev*
*University of Virginia, Center for Diabetes Technology & Department of Systems and Information Engineering
†University of Pavia, Department of Systems and Informatics
‡University of California, Santa Barbara, Department of Chemical Engineering
§Sansum Diabetes Research Institute
¶University of Padova, Department of Information Engineering
‖University Hospital of Montpellier, Department of Endocrinology, Diabetes, Nutrition; INSERM Clinical Investigation Center 1001; Institute of Functional Genomics, University of Montpellier I, Montpellier, France.

IEEE Trans. Biomedical Eng.

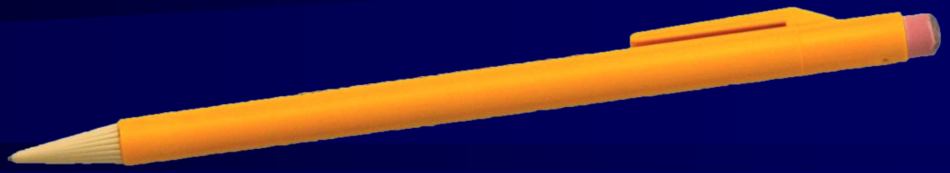
Improved Time in Range and Mean Blood Glucose with MPC Modular Algorithm





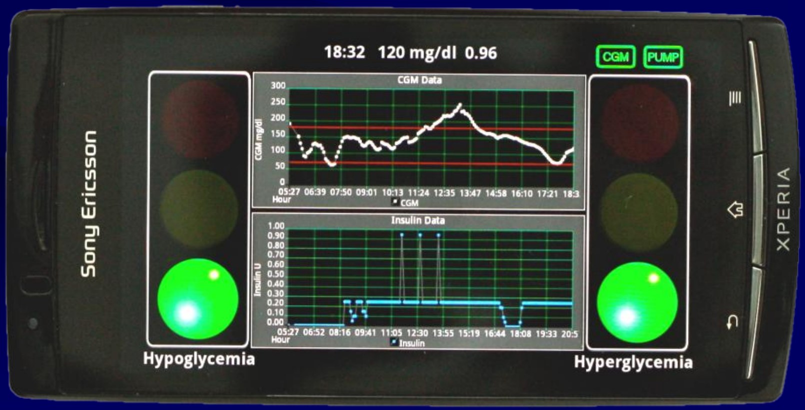
Breton M, Farret A, Bruttomesso D et al, *Diabetes* 2012; 61: 2230-7

The Needed Tool to Go Home with AP



A

B



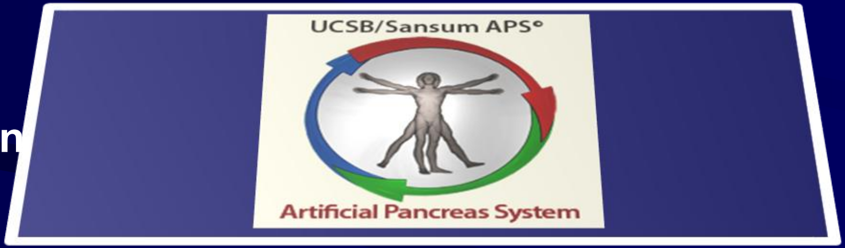
The Home AP System

One-way 3G connection to remote server.

DiAs – the Diabetes Assistant platform running user interface and control algorithms.

Low-power Bluetooth connection.

AP Communication System (APCS) – a portable implementation of the APS®.

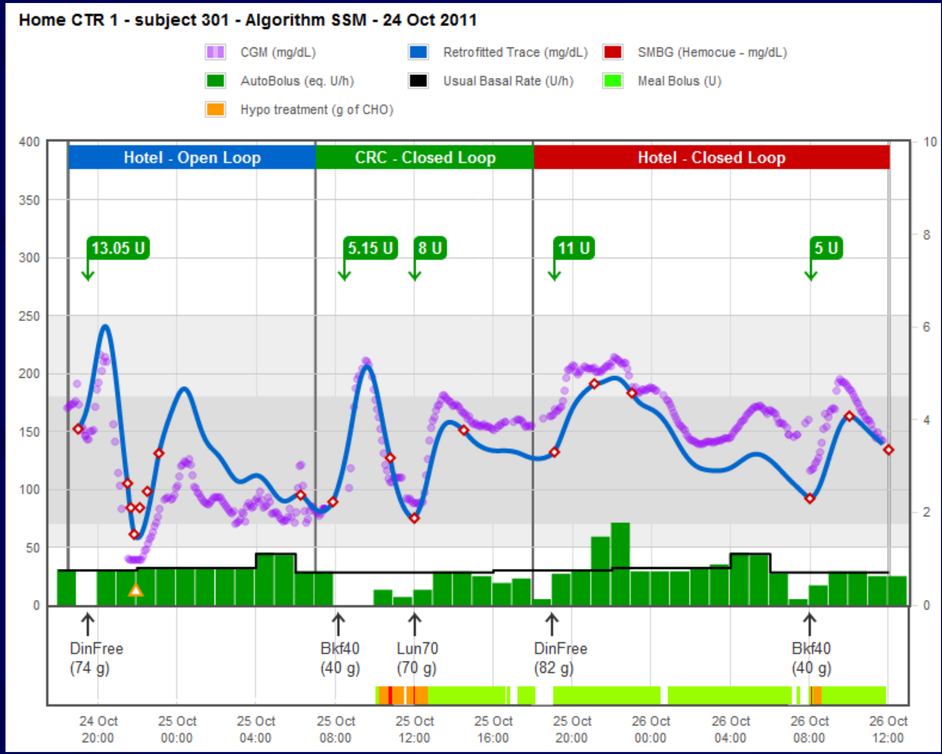


ANT+ and/or Bluetooth connection.

Various CGM and insulin pumps

JDRF Juvenile Diabetes Research Foundation International
dedicated to finding a cure

First Outpatient Experience with Artificial Pancreas, Montpellier & Padova, 25-26/10/2011



Cobelli C, Renard E, Kovatchev BP, et al. *Diabetes Care* 2012; 35: e65-7.

JDRF Juvenile Diabetes Research Foundation International
dedicated to finding a cure

Safety of Outpatient Closed-Loop Control: First Randomized Crossover Trials of a Wearable Artificial Pancreas

Diabetes Care 2014;37:1789–1796

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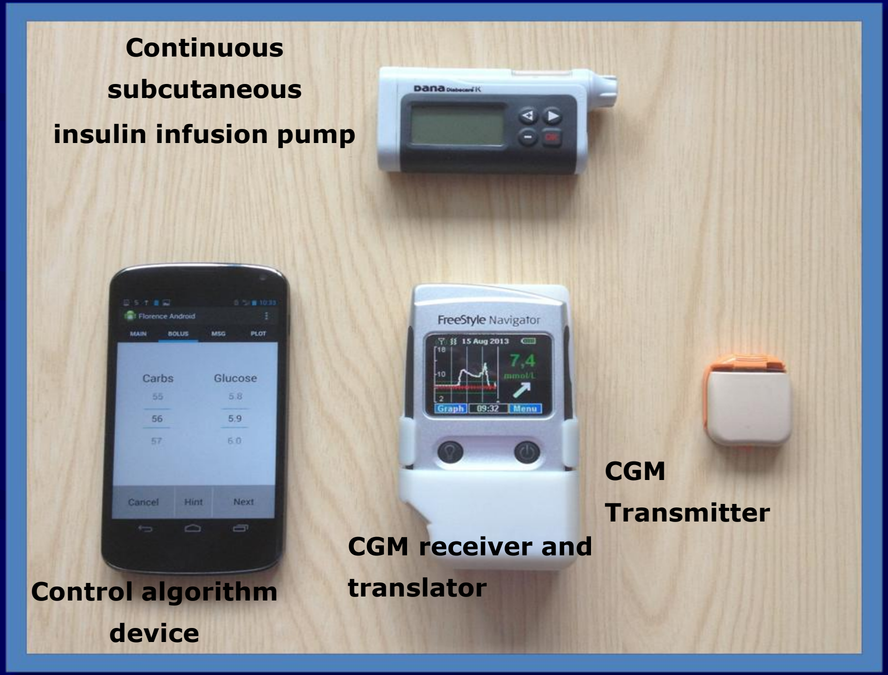
Table 1—Summary of study outcomes

Metric	OL	Closed loop	*P* level
Primary outcomes: reduction in hypoglycemia			
LBGI	1.12	0.64	0.003
Percentage of time below 3.9 mmol/L (70 mg/dL)	1.25	0.70	>0.1
Number of hypoglycemic episodes/person/session requiring carbohydrate treatment	2.39	1.22	0.021
Grams of carbohydrate/person/session used for treatment of hypoglycemia	39.7	17.6	0.022

The Closed-Loop Insulin Delivery Wearable Tools

Diabetes Assistant (DiAs), University of Virginia, VA, USA



Closed-Loop Insulin Delivery System, University of Cambridge, UK

Overnight Closed-Loop Insulin Delivery in Young People With Type 1 Diabetes: A Free-Living, Randomized Clinical Trial

Roman Hovorka,[1,2] Daniela Elleri,[1,2] Hood Thabit,[1] Janet M. Allen,[1,2] Lalantha Leelarathna,[1,3] Ranna El-Khairi,[1,2] Kavita Kumareswaran,[1,3] Karen Caldwell,[1,2] Peter Calhoun,[4] Craig Kollman,[4] Helen R. Murphy,[1] Carlo L. Acerini,[2] Malgorzata E. Wilinska,[1,2] Marianna Nodale,[1] and David B. Dunger[1,2]

Diabetes Care 2014;37:1204–1211

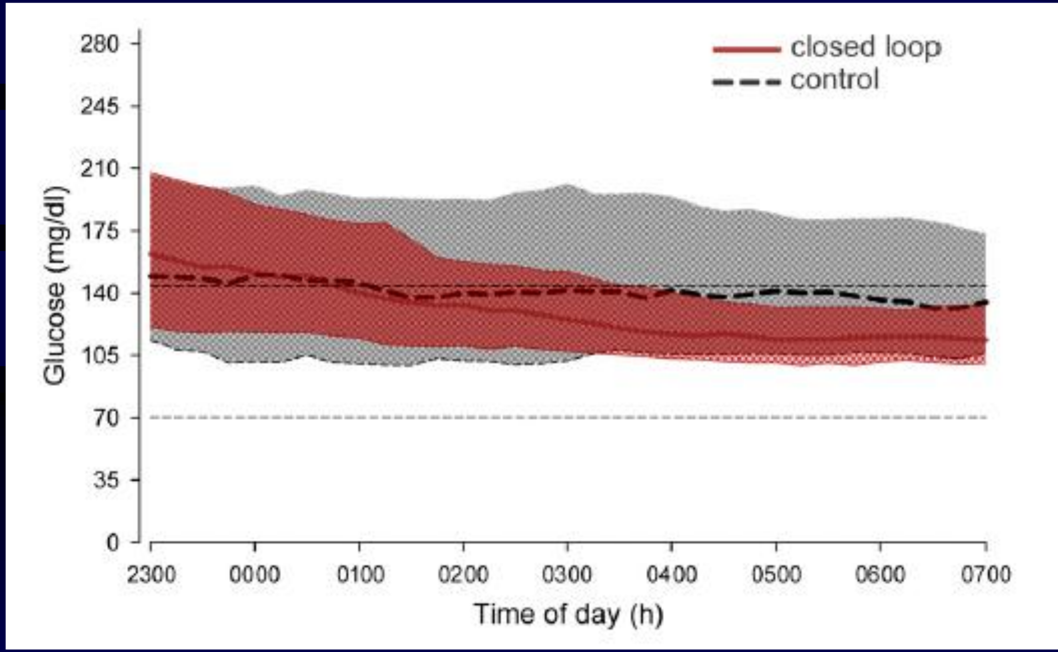


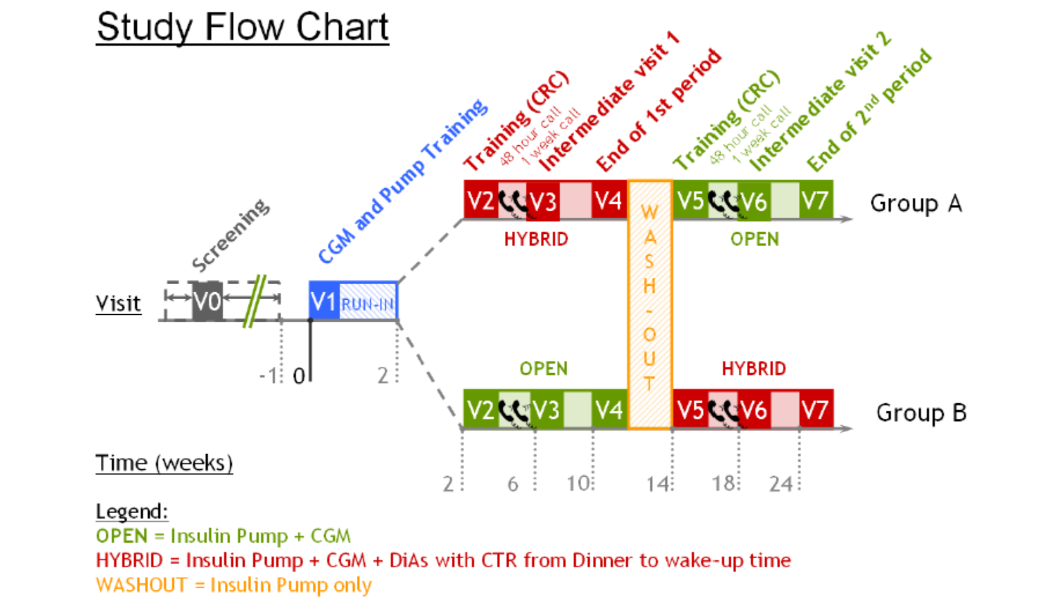
Table 1—Secondary comparisons during evaluable nights and evaluable days

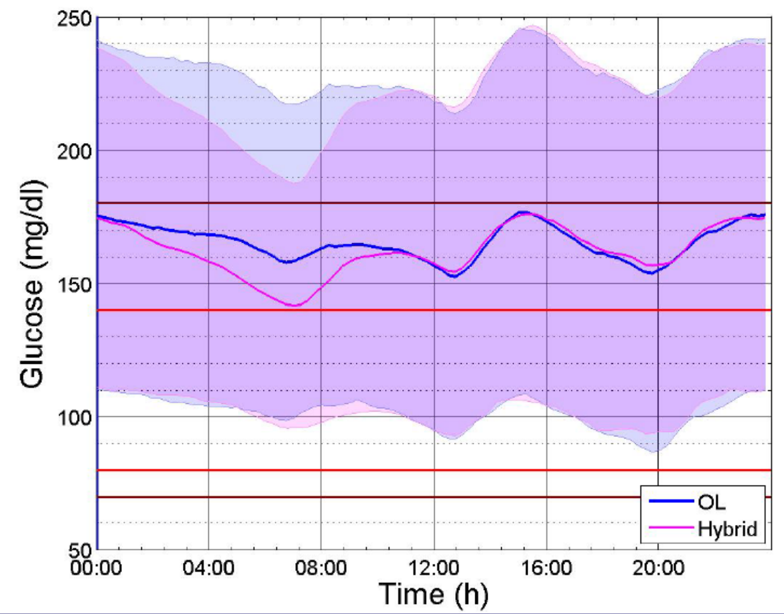
	Overnight closed loop (*N* = 16 subjects)	Control group (*N* = 16 subjects)	Paired difference[a]	*P* value
From 2300 to 0700 h				
Number of evaluable nights	269	282		—
Mean glucose (mg/dL)	137 (32)	151 (52)	−14 (58)	<0.001
Within-night CV of glucose (%)	22 (17–29)	20 (13–28)	3 (−7 to 12)	0.01
Between-night CV of glucose (%)	21 (17–28)	29 (25–33)	—	0.003
Time spent at glucose level (%)[b]				
70–180 mg/dL	85 (68–94)	69 (42–87)	12 (−5 to 39)	<0.001
<54 mg/dL	0.1 (0.0–0.4)	0.0 (0.0–1.1)	0.0 (−0.6 to 0.2)	0.07
<63 mg/dL	0.4 (0.1–1.9)	0.3 (0.0–4.4)	0.1 (−2.6 to 1.0)	0.11
<70 mg/dL	1.4 (0.4–5.0)	0.9 (0.0–9.7)	0.2 (−5.6 to 2.4)	0.13
>144 mg/dL	30.1 (15.6–51.8)	42.6 (15.4–81.8)	−10.6 (−43.8 to 14.6)	<0.001
>180 mg/dL	9.5 (1.9–27.8)	16.2 (2.2–53.2)	−4.7 (−36.3 to 7.5)	<0.001
>300 mg/dL	0.0 (0.0–0.1)	0.0 (0.0–0.9)	0.0 (−0.5 to 0.0)	0.01
Number of nights when glucose <63 mg/dL[c]	27 (10%)	48 (17%)	—	0.01
Low blood glucose index	0.26 (0.05–0.87)	0.17 (0.00–1.67)	0.02 (−1.01 to 0.47)	0.26

Evening and night closed-loop control in patients with type 1 diabetes under free living conditions: a randomised crossover trial

Jort Kropff†, Simone Del Favero†, Jerome Place†, Chiara Toffanin†, Roberto Visentin, Marco Monaro, Mirko Messori, Federico Di Palma, Giordano Lanzola, Anne Farret, Federico Boscari, Silvia Galasso, Paolo Magni, Angelo Avogaro, Patrick Keith-Hynes, Boris Kovatchev, Daniela Bruttomesso, Claudio Cobelli†, J Hans DeVries†, Eric Renard†, Lalo Magni†, AP@home consortium

8 weeks





Lancet Diabetes Endocrinol, 2015

Day and Night Closed-Loop Glucose Control in Patients With Type 1 Diabetes Under Free-Living Conditions: Comparison of a Single-Arm 1-Month Experience to Results of a Previously Reported Feasibility Study of Evening and Night at Home

Eric Renard,[1] Anne Farret,[1] Jort Kropff,[2] Daniela Bruttomesso,[3] Mirko Messori,[4] Jerome Place,[1] Roberto Visentin,[5] Roberta Calore,[5] Chiara Toffanin,[4] Federico Di Palma,[4] Giordano Lanzola,[6] Paolo Magni,[4,6] Federico Boscari,[3] Silvia Galasso,[3] Angelo Avogaro,[3] Patrick Keith-Hynes,[7] Boris Kovatchev,[7] Simone Del Favero,[5] Claudio Cobelli,[5] Lalo Magni,[5] and J. Hans DeVries,[2] AP@home consortium

Diabetes Care 2016

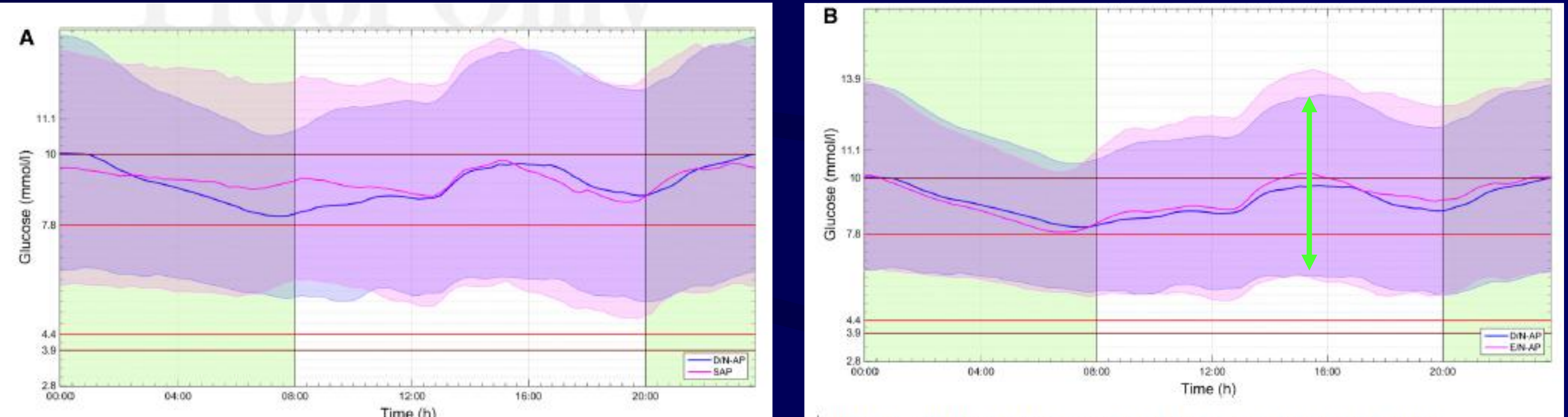


Figure 1—Glucose profile (mean ± SD) over 24 h for SAP and D/N-AP periods (*A*) and for E/N-AP and D/N-AP periods (*B*).

CONCLUSIONS

D/N-AP and E/N-AP both achieved better glucose control than SAP under free-living conditions. Although time in the different glycemic ranges was similar between D/N-AP and E/N-AP, D/N-AP further reduces glucose variability.

Home Use of an Artificial Beta Cell in Type 1 Diabetes

H. Thabit, M. Tauschmann, J.M. Allen, L. Leelarathna, S. Hartnell, M.E. Wilinska, C.L. Acerini, S. Dellweg, C. Benesch, L. Heinemann, J.K. Mader, M. Holzer, H. Kojzar, J. Exall, J. Yong, J. Pichierri, K.D. Barnard, C. Kollman, P. Cheng, P.C. Hindmarsh, F.M. Campbell, S. Arnolds, T.R. Pieber, M.L. Evans, D.B. Dunger, and R. Hovorka, for the APCam Consortium and AP@home Consortium*

12 weeks

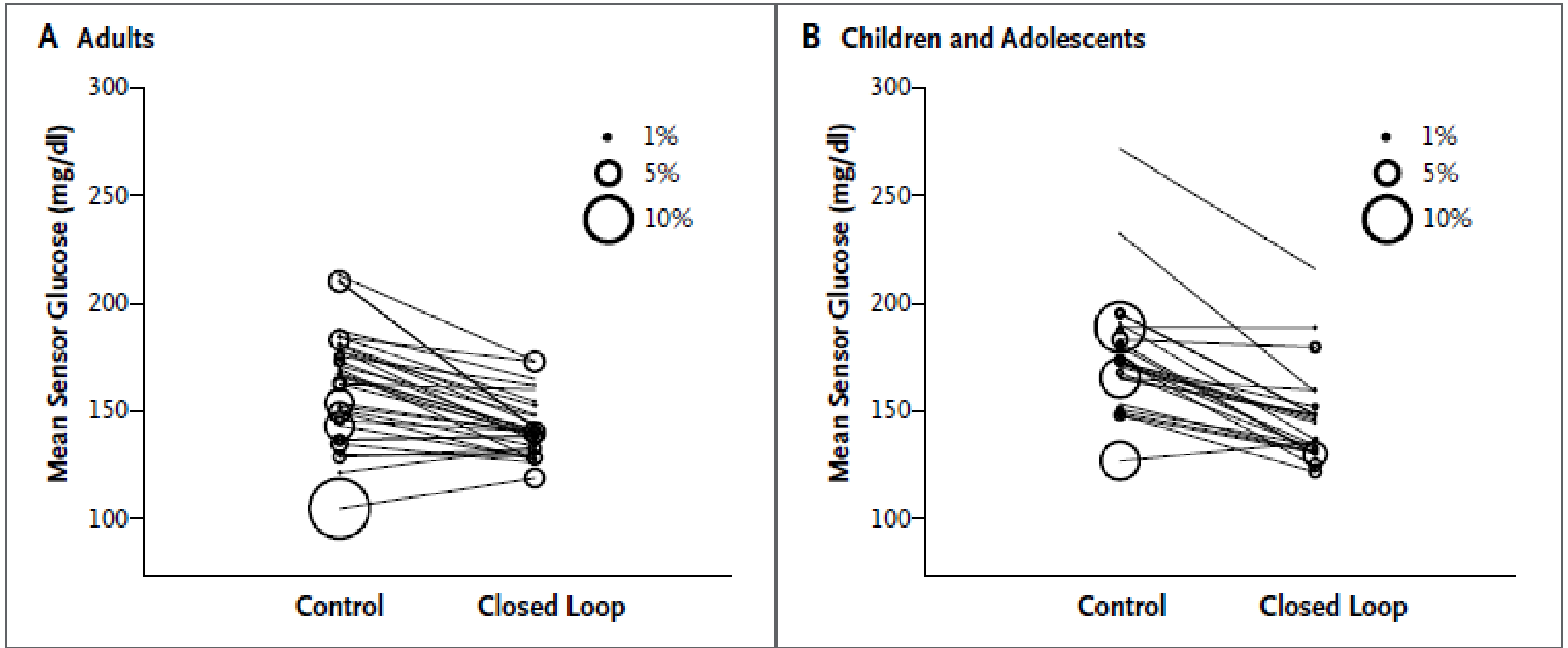


Figure 2. Overnight Glucose Levels.

Shown are the individual overnight mean sensor glucose levels in adults (Panel A) and in children and adolescents (Panel B). Adults used the closed-loop systems day and night and children and adolescents used the closed-loop systems overnight. The size of the bubble indicates the proportion of time overnight during which the glucose level was below 50 mg per deciliter (2.8 mmol per liter).

Shown are the median sensor glucose levels and the median values for insulin delivery during the day-and-night closed-loop study involving adults (Panel A) and the overnight closed-loop study involving children and adolescents (Panel B). The bands indicate interquartile ranges. To convert the values for glucose to millimoles per liter, multiply by 0.05551.

DOI: 10.1056/NEJMoa1509351

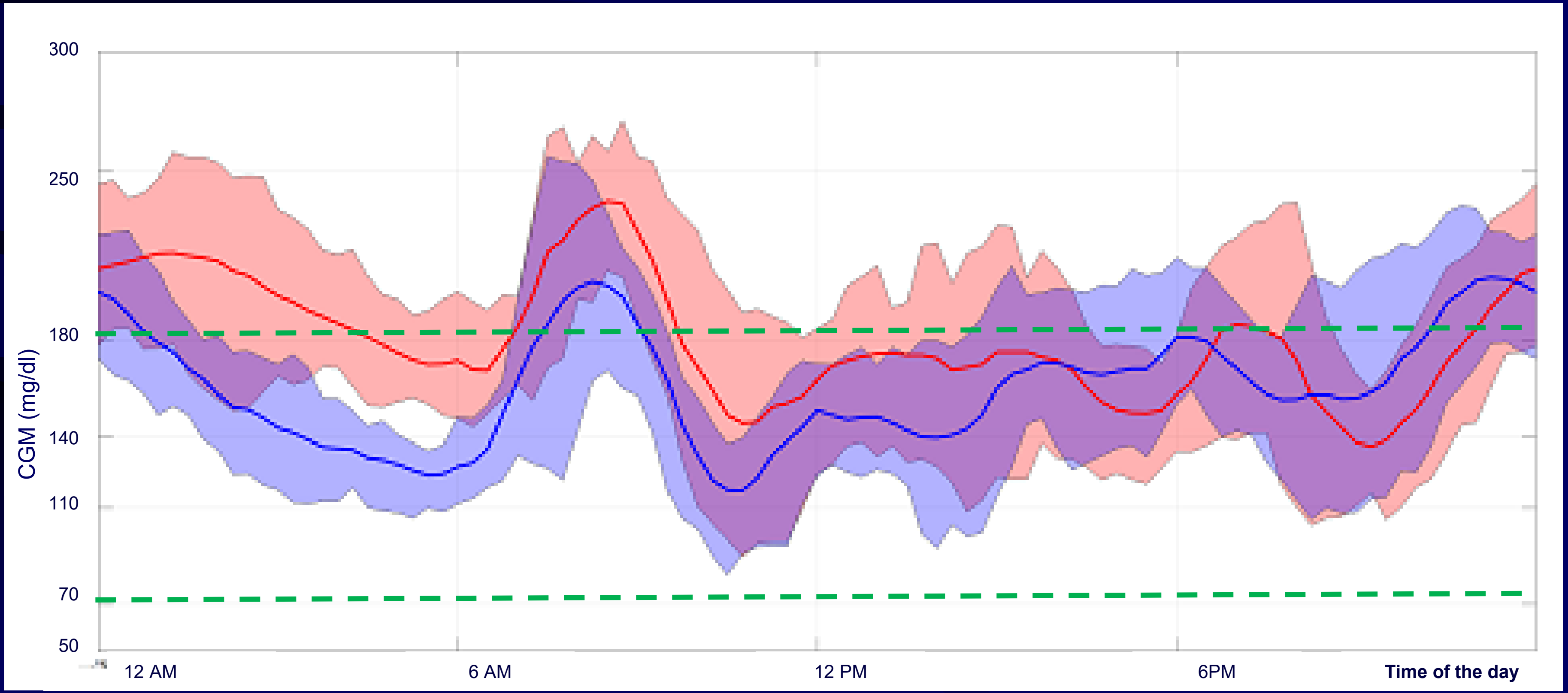
French Study of Closed-Loop vs. Threshold Low Glucose Suspend in Children with Type 1 Diabetes


Montpellier


Tours


Angers


Paris



Renard E et al, Diabetes, Obes Metab 2019

Daily Glucose Profiles with TLGS vs. Modular CTR

Median and IQR

Closed-loop insulin delivery in adults with type 1 diabetes in real-life conditions: a 12-week multicentre, open-label randomised controlled crossover trial

*Pierre-Yves Benhamou, Sylvia Franc, Yves Reznik, Charles Thivolet, Pauline Schaepelynck, Eric Renard, Bruno Guerci, Lucy Chaillous, Celine Lukas-Croisier, Nathalie Jeandidier, Helene Hanaire, Sophie Borot, Maeva Doron, Pierre Jallon, Ilham Xhaard, Vincent Melki, Laurent Meyer, Brigitte Delemer, Marie Guillouche, Laurene Schoumacker-Ley, Anne Farret, Denis Raccah, Sandrine Lablanche, Michael Joubert, Alfred Penfornis, Guillaume Charpentier, on behalf of the DIABELOOP WP7 Trial Investigators**

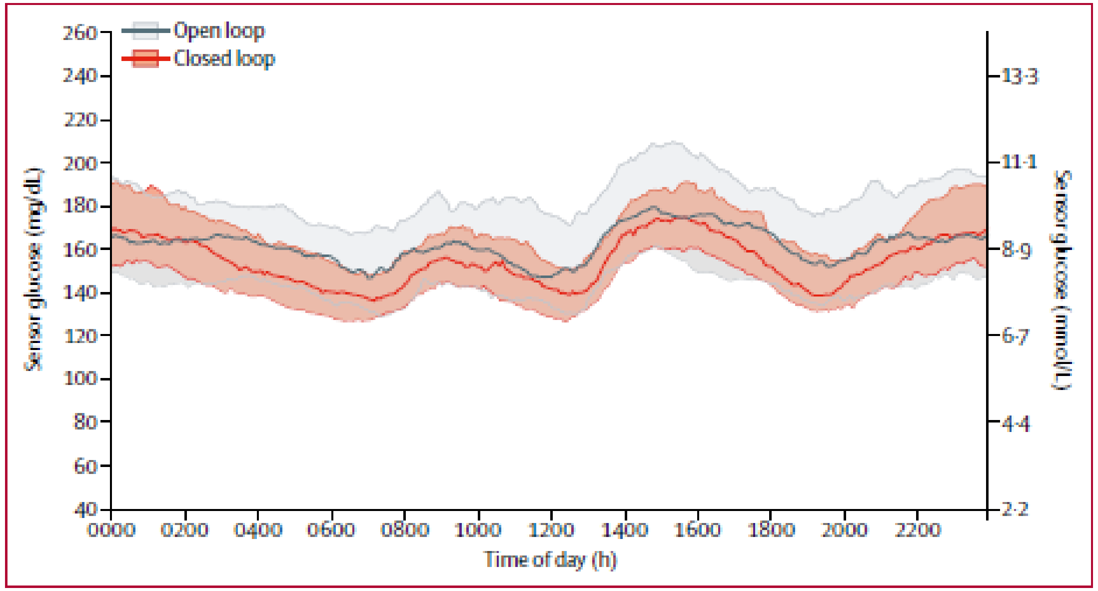


Figure 2: Median (IQR) sensor glucose concentrations during closed-loop and control periods for the 24 h duration over the study period

	DBLG1 (n=63)	SAP (n=63)	Paired difference* (95% CI)	p value
Time spent at glucose concentration				
3·9–10·0 mmol/L†	68·5% (9·4)	59·4% (10·2)	9·2% (6·4 to 11·9)	<0·0001
4·4–7·8 mmol/L	39·3% (7·9)	33·5% (7·9)	5·8% (3·7 to 7·9)	<0·0001
>10·0 mmol/L	29·5% (10·2)	36·3% (10·2)	−6·8% (−9·7 to −3·9)	<0·0001
>13·9 mmol/L	7·4% (6·3)	11·7% (6·3)	−4·3% (−6·2 to −2·4)	<0·0001
>16·7 mmol/L	2·4% (3·1)	4·3% (3·1)	−2·0% (−3·0 to −1·0)	0·0002
<3·9 mmol/L	2·0% (2·4)	4·3% (2·4)	−2·4% (−3·0 to −1·7)	<0·0001
<3·3 mmol/L	0·8% (0·8)	2·0% (1·6)	−1·3% (−1·6 to −0·9)	<0·0001
<2·8 mmol/L	0·2% (0·8)	0·7% (0·8)	−0·5% (−0·7 to −0·3)	<0·0001
HbA_{1c} change from baseline‡	−0·29% (0·6)	−0·14% (0·6)	−0·15 (−0·33 to 0·03)	0·098
HbA_{1c} change from baseline‡ (mmol/mol)	−3·20 (5·7)	−1·57 (5·6)	−1·63 (−3·57 to 0·31)	0·098
Glucose concentration (mmol/L)	8·7 (0·8)	9·1 (0·8)	−0·4 (−0·6 to −0·1)	0·012
Coefficient of variation of sensor glucose (%)	31·0 (3·9)	33·3 (3·9)	−2·3 (−3·1 to −1·5)	<0·0001
LBGI			−0·5 (−0·6 to −0·4)	<0·0001
HBGI			−1·7 (−2·6 to −0·9)	0·0001
BGRI			−2·2 (−3·0 to −1·4)	<0·0001

Data are mean (SD) or … eneration 1. SAP=sensor-assisted pump. HbA_{1c}=glycated haemoglobin. LBGI=lo… *Adjusted for baseline HbA_{1c} and site. Mean difference of closed-loop period mi… t sequence.

Table 2: **24 h glucos… urements (modified intention-to-treat analysis set)**

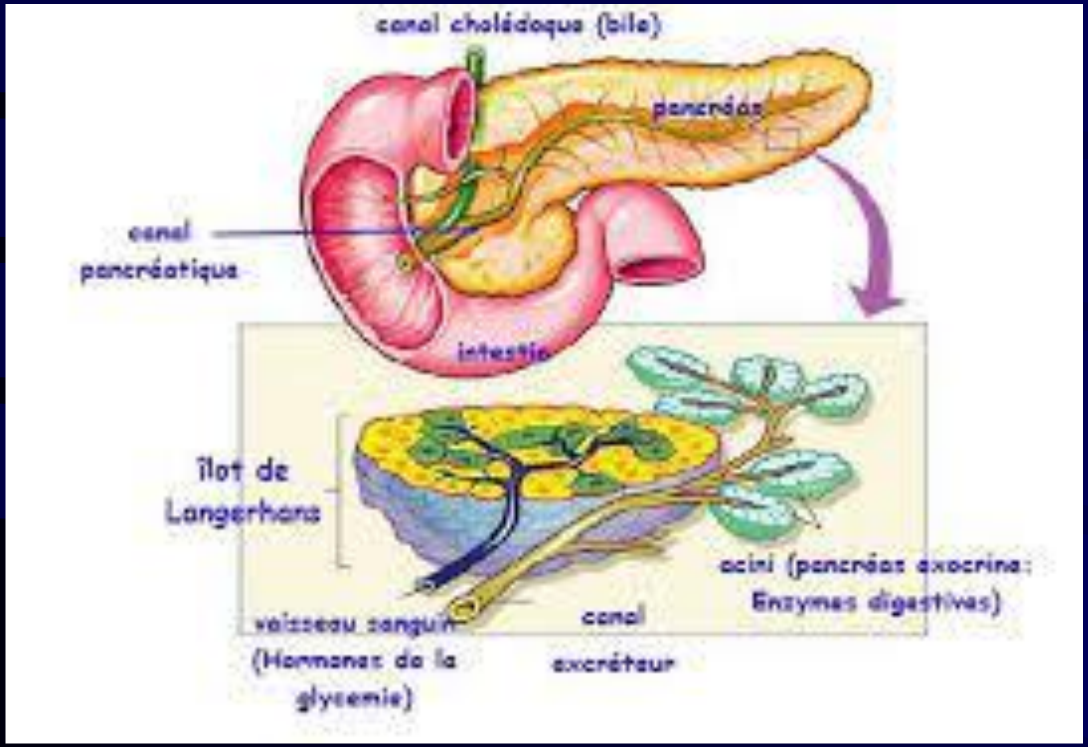
	Closed-loop period (n=68)	Control period (n=68)
Diabetic ketoacidosis	0	0
Severe hyperglycaemia	9*	0
Severe hypoglycaemia	5†	3‡

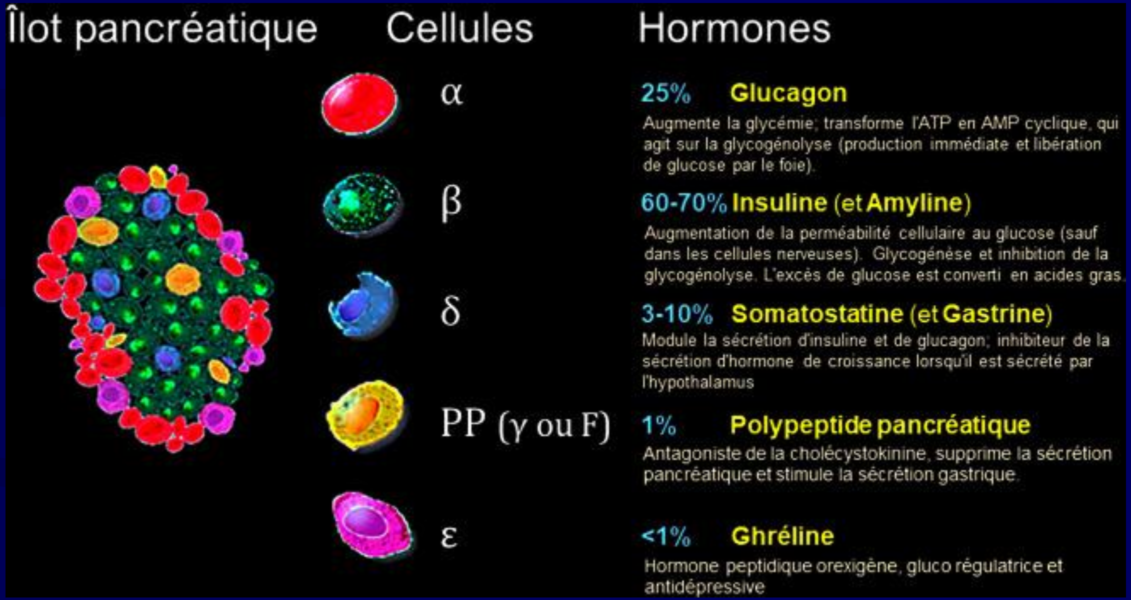
Data are number of events. Severe hyperglycaemia was defined as capillary blood glucose >20 mmol/L. Severe hypoglycaemia was defined as intervention of a third party for correction of hypoglycaemia. *Five severe hyperglycaemic events occurred in one patient, and four severe hyperglycaemic events occurred in three patients. †Three severe hypoglycaemia events (one event in three patients) occurred during the first 12 week treatment period due to hardware dysfunction and two events (one event in two patients) occurred during the second 12 week treatment period due to human error. ‡Two severe hypoglycaemia events (one event in two patients) occurred during the first 12 week treatment period and one severe event occurred in one patient during the second 12 week treatment period.

Table 3: **Serious adverse events in the safety analysis set**

Lancet Digital Health 2019; 1: e17–25

Le Régulateur Endocrinien Essentiel de la Glycémie: L'îlot pancréatique





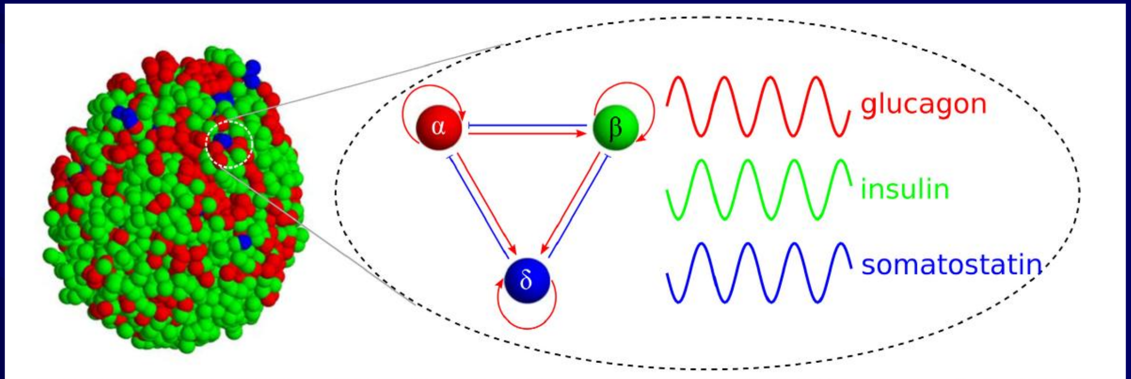
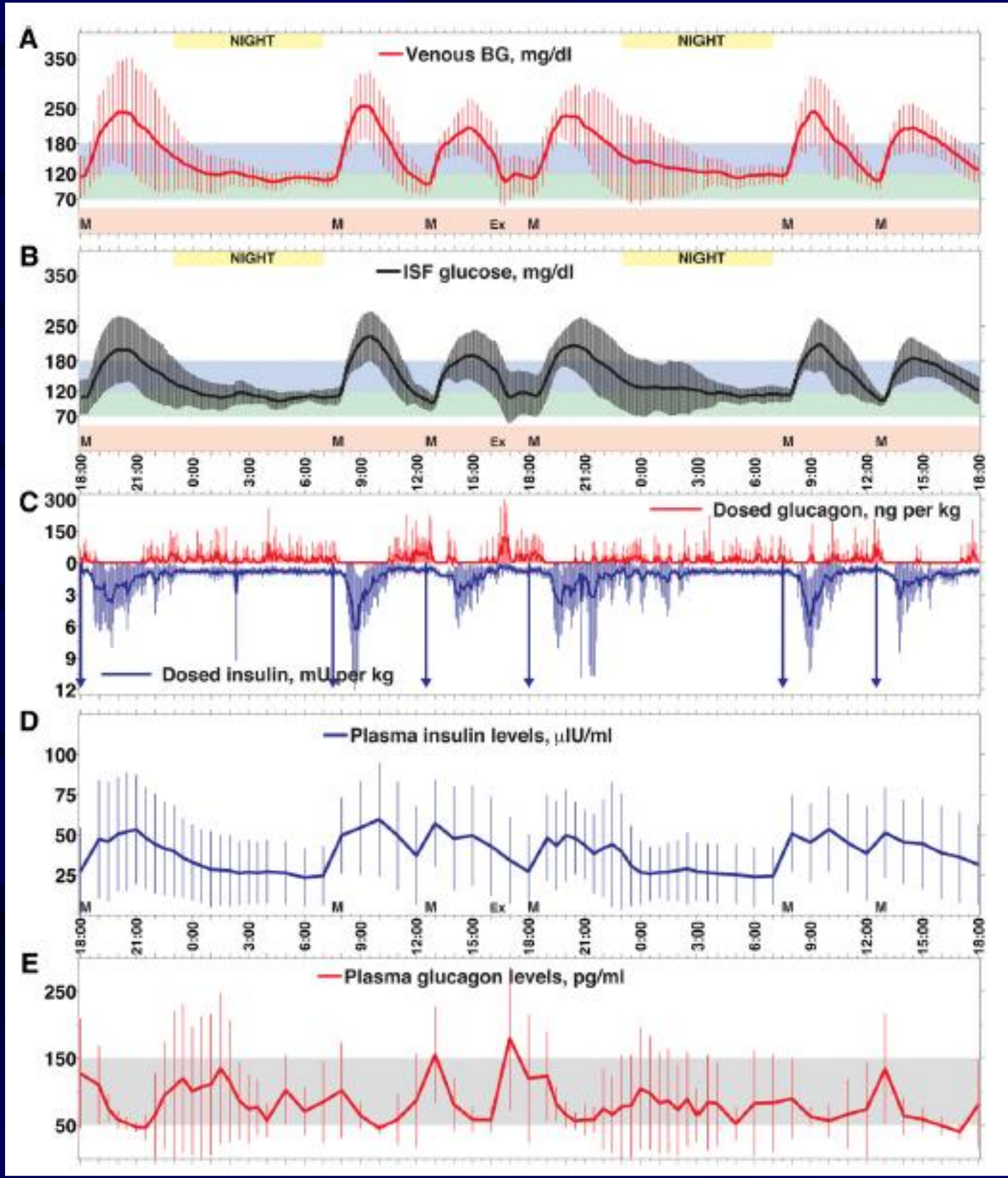


Fig 1. Cellular organization and interaction in pancreatic islets. Endocrine *α* (red), *β* (green), and *δ* cells (blue) generate pulses of glucagon, insulin, and somatostatin, respectively. They positively (red arrows) or negatively affect (blue bar-headed arrows) hormone pulses of neighboring cells.

The BIONIC PANCREAS



Diabetes Care 35:2148–2155, 2012

Day and night glycaemic control with a bionic pancreas versus conventional insulin pump therapy in preadolescent children with type 1 diabetes: a randomised crossover trial

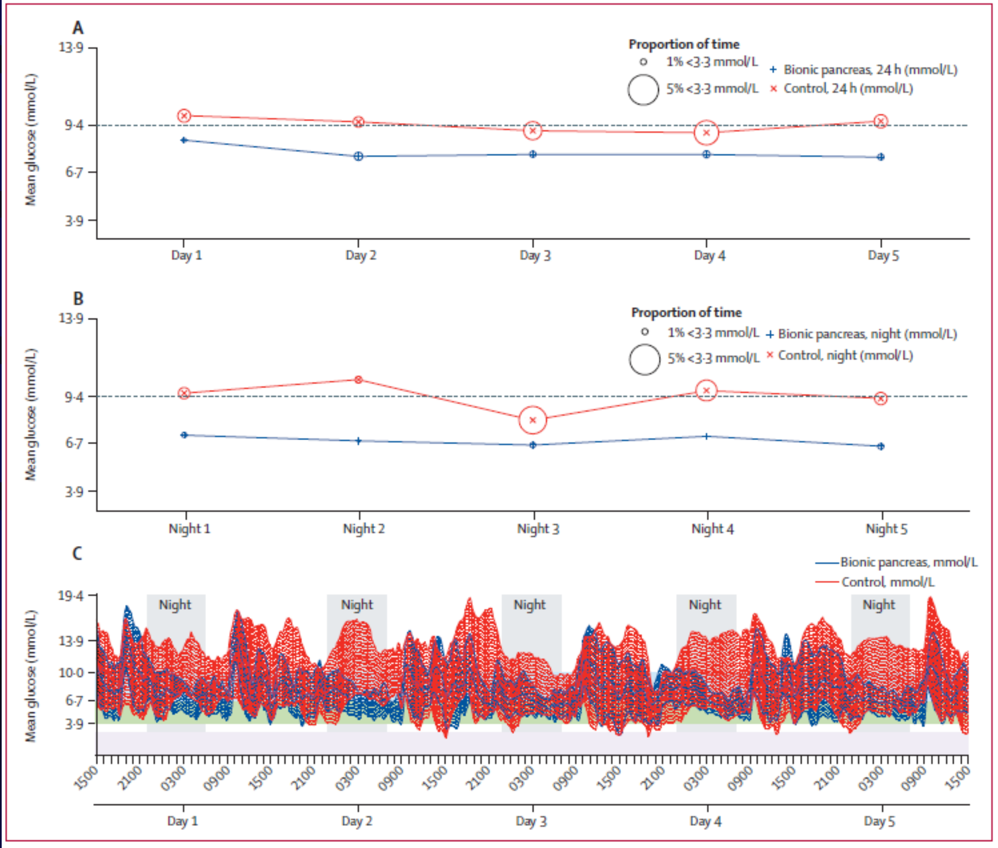


Figure 3: **Variation in the CGM-measured mean glucose concentration during the bionic pancreas and control periods over the course of the study**
Mean daily (A) and night-time (B) CGM-measured glucose concentrations and proportion of time spent with a glucose concentration lower than 3·3 mmol/L on days (or nights) 1–5 during the bionic pancreas period (blue) and the control period (red). (C) Superposition of tracings of mean glucose concentrations at all 5 min intervals during the bionic pancreas (blue) and control (red) periods. Each tracing is surrounded by an area of shading of the same colour that spans 1 SD in both directions from the mean. The horizontal region shaded in purple corresponds to glucose concentrations of less than 2·8 mmol/L, green to 3·9–6·7 mmol/L, and blue to 6·7–10 mmol/dL. To convert the values for glucose to mg/dL, multiply by 18. CGM=continuous glucose monitoring.

	Bionic pancreas (n=19)	Control (n=19)	Unadjusted p value
Day and night			
Glucose concentration measured by CGM device on days 2–5			
Mean, mmol/L*	7·6 (0·6)	9·3 (1·7)	0·00037
<3·3 mmol/L, % of time	1·2% (1·1)	2·8% (1·2)	<0·0001
3·9–10 mmol/L, % of time	80·6% (7·4)	57·6% (14·0)	<0·0001
>10 mmol/L, % of time	16·5% (6·4)	36·3% (15·7)	<0·0001
SD, mmol/L†	2·8 (0·9)	4·2 (1·0)	<0·0001
Coefficient of variation, %	37% (9)	45% (8)	0·0017
Mean of daily differences, mmol/L/day	0·8 (0·5)	2·1 (1·3)	0·00083
Plasma glucose concentration measured by fingerstick testing on days 1–5			
Mean, mmol/L	7·6 (0·4)	9·8 (1·4)	<0·0001
<3·3 mmol/L, % of time	0% (0–6·7)	3·3% (0–6·7)	0·065‡
Number of carbohydrate interventions per participant on days 1–5§	3 (0–8)	5 (0–14)	0·037‡
Night only			
Glucose concentration measured by CGM device on nights 2–5			
Median, mmol/L¶	6·8 (5·7–7·6)	9·4 (6·6–14·6)	<0·0001‡
<3·3 mmol/L , % of time	0·6% (0·8)	2·8% (2·7)	0·0027
3·9–10 mmol/L, % of time	91·9% (7·3)	58·8% (17·4)	<0·0001
>10 mmol/L, % of time	6·4% (6·4)	36·5% (18·3)	<0·0001
SD, mmol/L†	1·7 (0·5)	3·5 (1·3)	<0·0001
Coefficient of variation, %	25% (6)	35% (9)	0·00024
Plasma glucose concentration measured by fingerstick testing on days 1–5			
Mean, mmol/L	7·6 (0·7)	9·8 (1·8)	<0·0001
<3·3 mmol/L, % of time	0% (0–0)	0% (0–10·0)	0·031‡
Number of carbohydrate interventions per participant on days 1–5§	0 (0–1)	1 (0–4)	0·0020‡

Data are mean (SD) for normally distributed date and median (range) for non-normally distributed data, unless otherwise specified. CGM=continuous glucose monitoring. *Mean (SD) of each participant's mean of all their 5 min CGM-measured concentrations during the study period. †Mean (SD) of each participant's SD of all their 5 min CGM-measured concentrations during the study period. ‡Non-normally distributed data; p value from Wilcoxon signed rank test. §Given when glucose concentrations were below 3·9 mmol/L. ¶Median (range) of each participant's mean of all their 5 min CGM-measured concentrations during the study period.

Table 2: **Glucose concentrations measured by CGM and fingerstick testing during 24 h day and night only**

Lancet Diabetes Endocrinol 2016; 4: 233–43
Russell SJ

Bionic Pancreas is Great on Glucose Control…

But Somewhat Cumbersome !

Improvement to come…

Perfusion Automatisée d'Insuline
(« Pancréas Artificiel» ou « Boucle Fermée »)

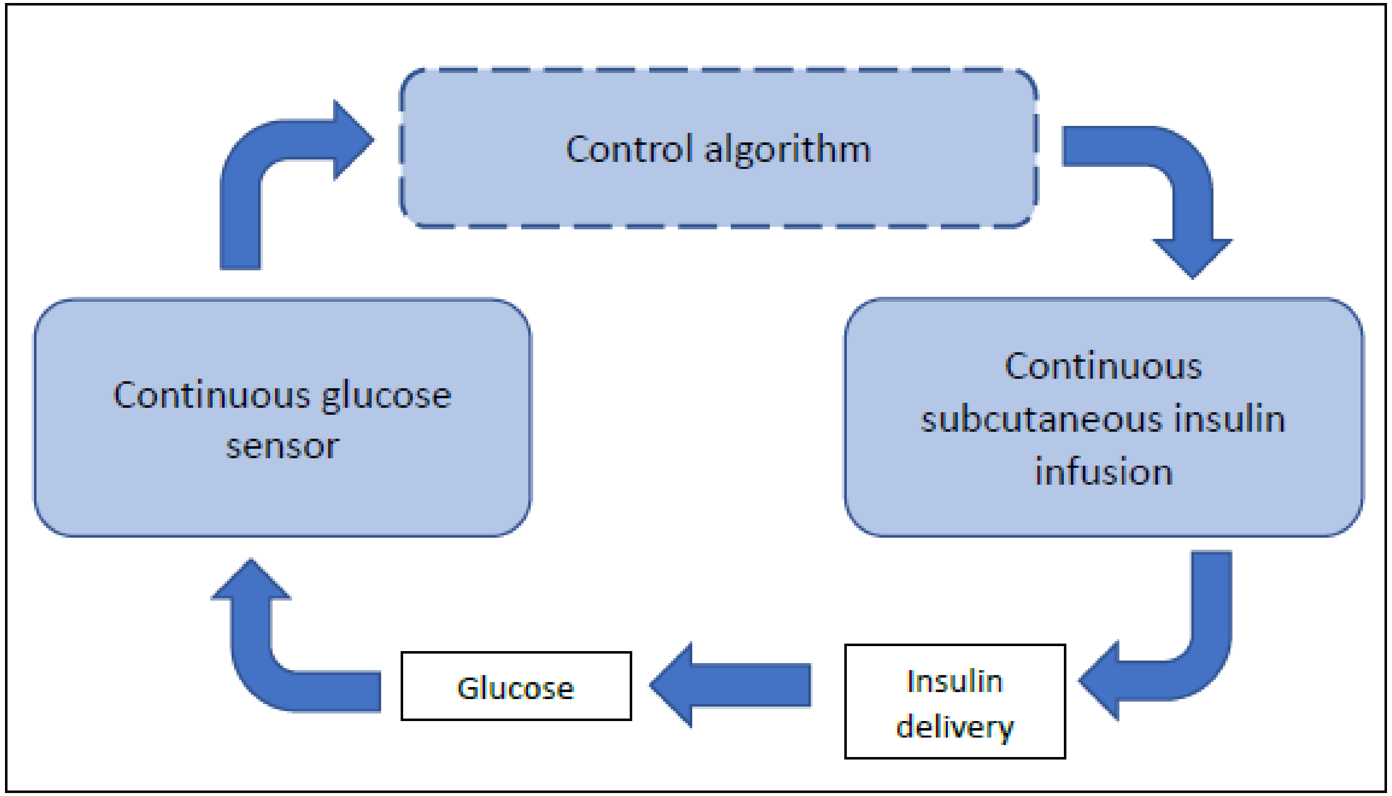


Figure 1. A model of an artificial pancreas, comprising of a continuous glucose sensor and a continuous subcutaneous insulin infusion which are connected by a control algorithm. Insulin delivery is dependent on the glucose level and the algorithm, which in turns affect the final glucose levels.

FIGURE 1 Artificial pancreas (single hormone). A sensor (black rectangle) transmits information about interstitial glucose levels to a mobile-phone-sized controller (red box located in the hand), which runs a control algorithm and interacts with the user. An insulin pump (blue box) delivers a rapid-acting insulin analogue subcutaneously. Insulin delivery is modulated in real-time by the control algorithm. The communication among system components is wireless. Reproduced with permission from Hovorka [5]. The control algorithm can be embedded in the pump (not shown).

Diabet. Med. 36, 279–286 (2019)

Drugs. 2019 Jul;79(10):1089-1101

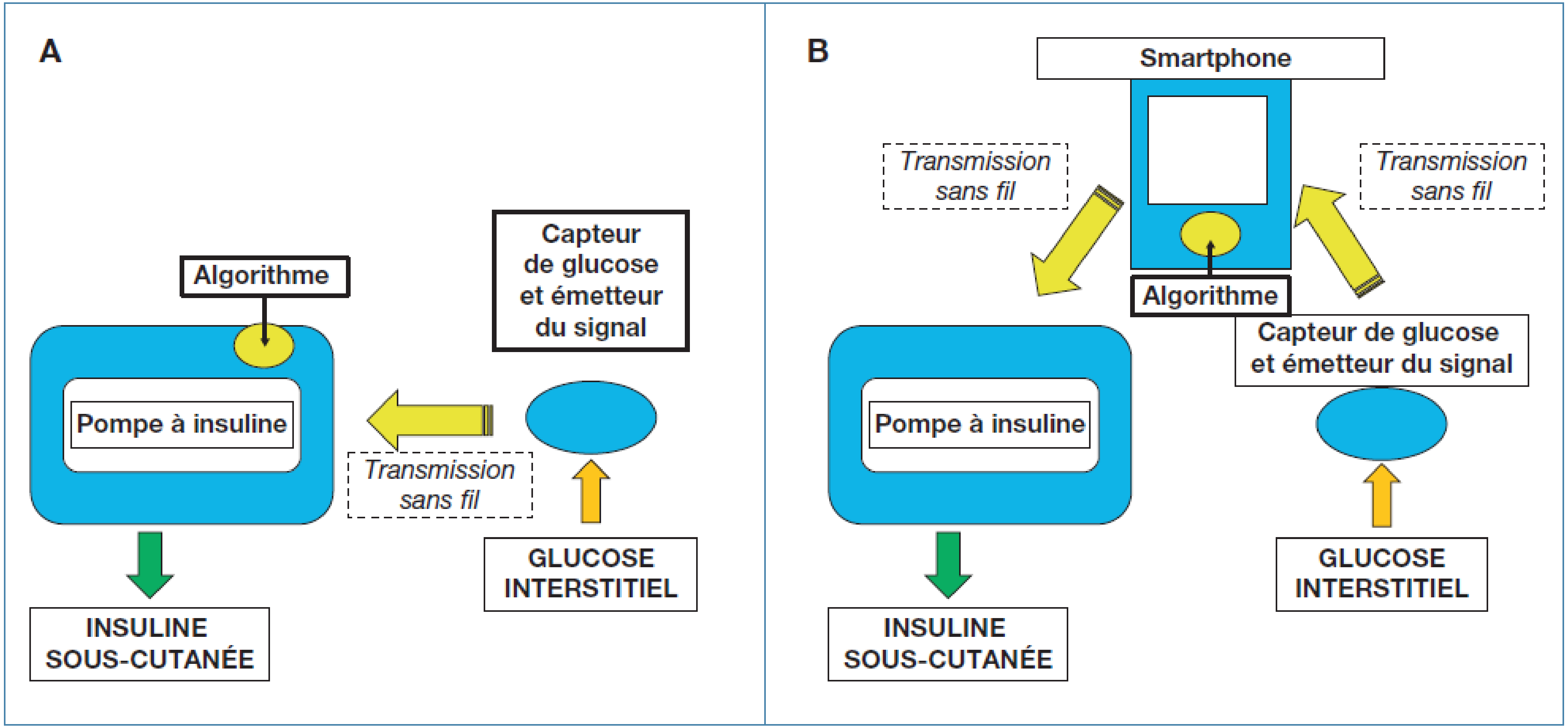


Figure 1. Schéma illustrant les deux types de systèmes disponibles d'insulinothérapie automatisée.
Les systèmes Medtronic MiniMed 670G, Tandem t:slim X2 Control-IQ, Insulet Horizon placent l'algorithme dans la pompe à insuline qui reçoit le signal du capteur de glucose (schéma de gauche A). Le système Diabeloop DBLG1 place l'algorithme dans un boitier informatique (smartphone) qui reçoit le signal du capteur et transmet le signal de commande à la pompe à insuline (schéma de droite B).

Safety of a Hybrid Closed-Loop Insulin Delivery System in Patients With Type 1 Diabetes

JAMA Published online September 15, 2016

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Table 2. Glucose Control, Insulin Usage, and Weight Among Patients Using Hybrid Closed-Loop Systems

Parameter	Run-in Period	Study Period
Sensor glucose, mean (SD) [median], mg/dL	150.2 (22.7) [150.1]	150.8 (13.7) [149.9]
Percentage of time with glucose level in range, mean (SD); median (IQR)		
Sensor glucose values		
>300 mg/dL	2.3 (4.2); 1.3 (0.2-2.6)	1.7 (1.9); 0.9 (0.5-2.1)
>180 mg/dL	27.4 (13.7); 26.7 (16.0-37.2)	24.5 (9.2); 24.1 (17.3-29.[illegible]
71-180 mg/dL	66.7 (12.2); 67.8 (59.0-75.1)	[illegible]
≤70 mg/dL	5.9 [illegible]	[illegible]
≤50 [illegible]	[illegible]	[illegible]
[illegible]	[illegible]; 26.4 (15.3-35.8)	21.6 (9.9); 20.6 (13.6-28.5)
[illegible] mg/dL	66.8 (14.0); 67.0 (57.6-75.2)	75.3 (9.8); 76.4 (69.0-83.1)
≤70 mg/dL	6.4 (5.3); 5.4 (2.3-8.5)	3.1 (2.2); 2.6 (1.7-4.2)
Within-day SD of glucose, mean (SD); median (IQR), mg/dL[b]	50.1 (9.9); 48.9 (43.7-56.2)	46.7 (7.3); 45.6 (41.7-50.4)
Within-day coefficient of variation of glucose, mean (SD); median (IQR), %[b]	33.5 (4.3); 33.1 (30.3-36.4)	30.8 (3.3); 30.7 (28.2-33.0)
Glycated hemoglobin, mean (SD) [median], %	7.4 (0.9) [7.3]	6.9 (0.6) [6.8]
Total daily dose of insulin, mean (SD) [median], U	47.5 (22.7) [43.9]	50.9 (26.7) [44.1]
Weight, mean (SD) [median], kg	76.9 (17.9) [73.5]	77.6 (16.1) [74.7]

HEALTH NEWS | Wed Sep 28, 2016 | 9:41pm EDT

FDA approves Medtronic's 'artificial pancreas' for diabetes

	No. of Events	
	Run-in Period[b]	Study Period[b]
[illegible]	8	20
Skin irritation	3	1
Hyperglycemia	0	6
Rash	0	1
Severe hyperglycemia[c]		
Due to infusion set	5	6
Due to software or hardware issues	0	5
Due to sensor issues	0	1

FDA approves first automated insulin delivery device for type 1 diabetes

Systèmes de Boucle Fermée Hybride Mono-hormonaux

Medtronic 780G

Tandem Control-IQ

Diabeloop DBLG1

CamDia APS

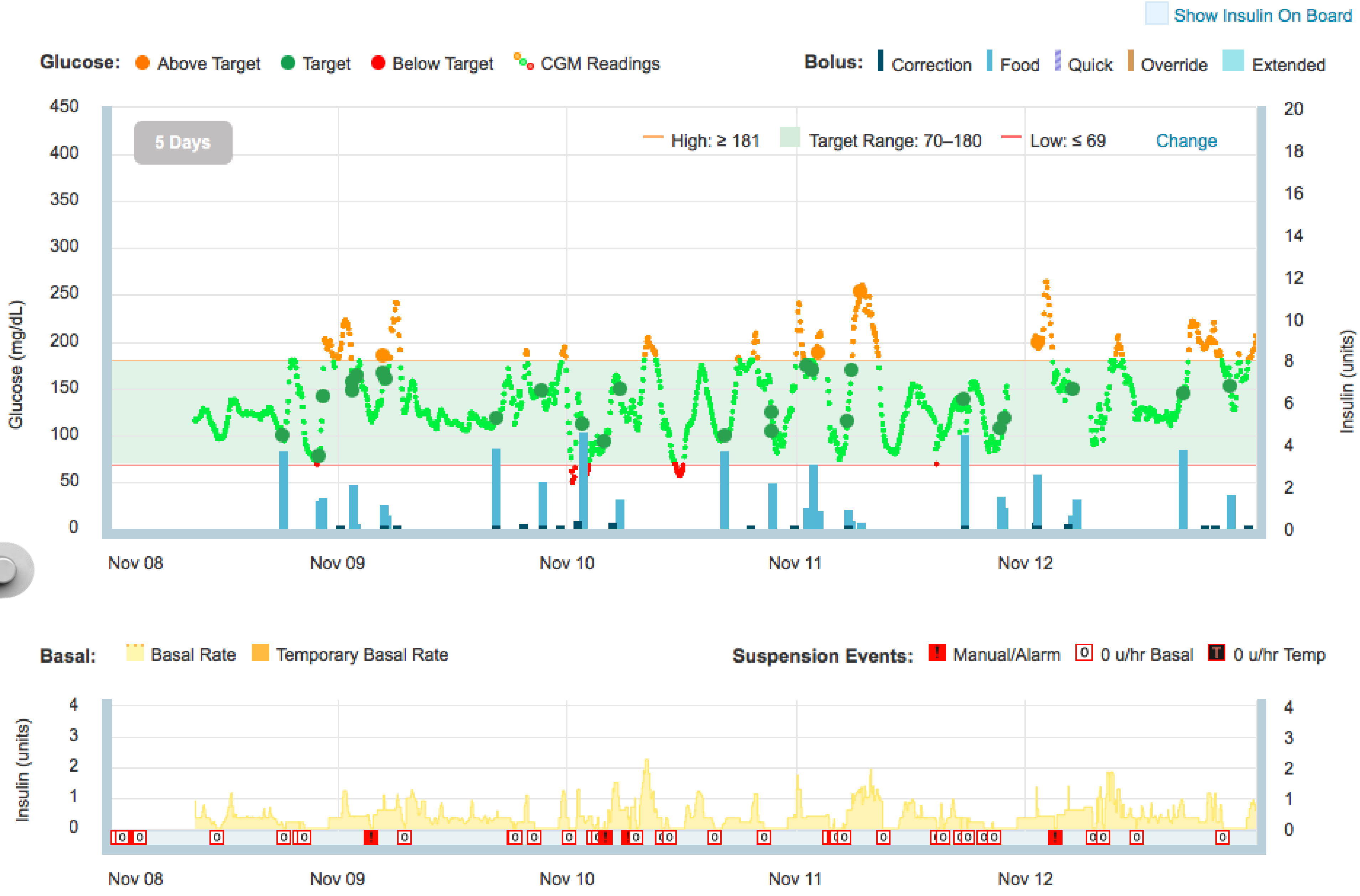
OmniPod 5

Tableau I

Différents systèmes de délivrance automatisée d'insuline approuvés par la HAS en France en 2024

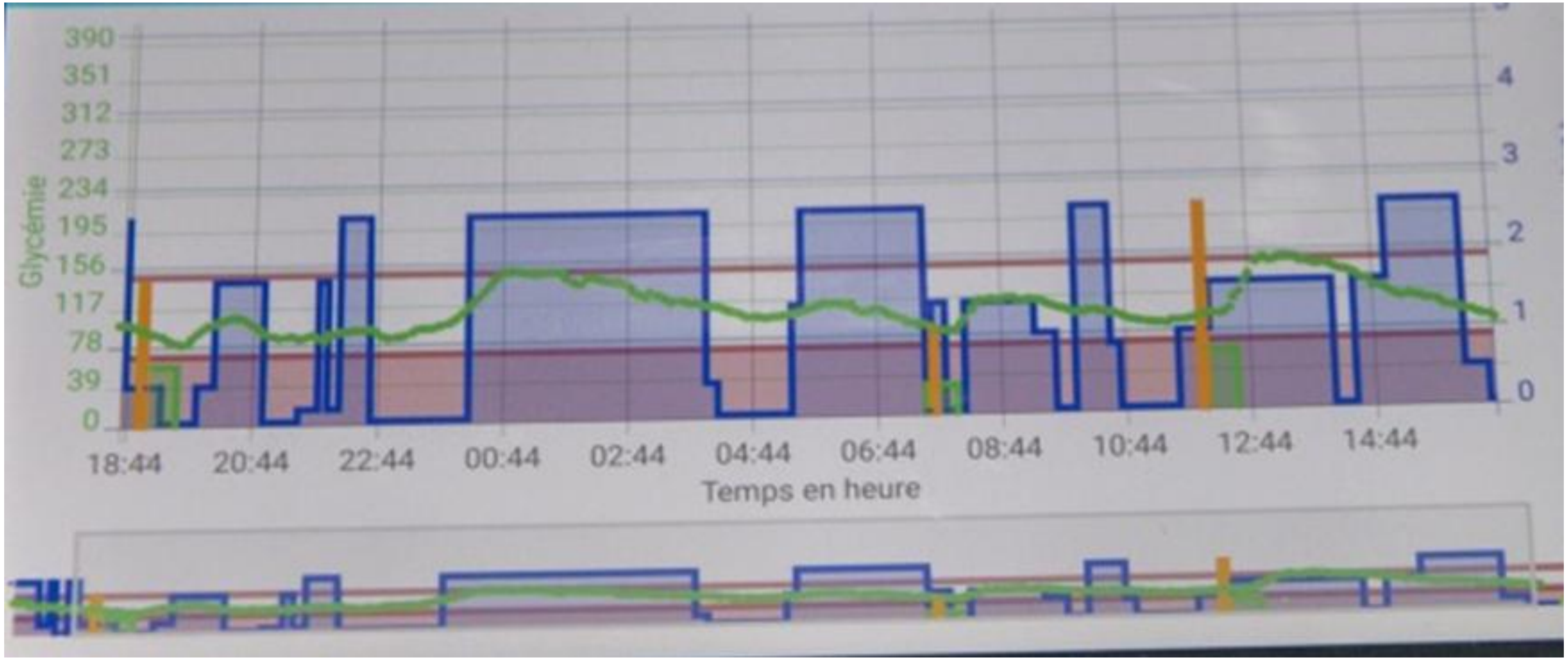
Systèmes	Medtronic 780G	Tandem control-IQ	CamAPS FX	Diabeloop DBLG1	Diabeloop DBLHU	OmniPod 5
Algorithme	SmartGuard Minimed 780G *Advanced Hybrid Closed-loop*	Control-IQ 1.0	CamAPS FX	DBLG1	DBLHU	SmartAdjust
Interface utilisateur	Pompe à insuline	Pompe à insuline	Smartphone Android	Terminal spécifique	Terminal spécifique	Contrôleur spécifique
CGM compatibles	Gardian Link 3 ou 4	Dexcom G6	Dexcom G6 FreeStyle Libre 3	Dexcom G6	Dexcom G6	Dexcom G6
Pompes à insulines compatibles	Medtronic 780G	Tandem t:slim X2	Ypsopump	Kaleido	Kaleido	OmniPod 5
Plateforme téléchargement	CareLink	MyDiabby Glooko-XT	Glooko-XT	YourLoops	YourLoops	GlookoXT
Marquage CE	Âge ≥ 7 ans	Âge ≥ 6 ans	Âge ≥ 1 an	Âge ≥ 18 ans	Âge ≥ 18 ans	Âge ≥ 2 ans
Approbation HAS	Âge ≥ 7 ans	Âge ≥ 6 ans	Âge ≥ 2 ans Âge ≥ 4 ans	Âge ≥ 18 ans	Non	Âge ≥ 2 ans

Tandem Control-IQ



Medtronic 780G

Diabeloop DBLG1



Observatoire de la Boucle Fermée en France (OB2F)

A Nationwide 12-Month observatory of automated insulin delivery shows improved glucose control, sustained adoption, and reduced acute severe events

Diabetes Obes Metab, *in press*, 2025

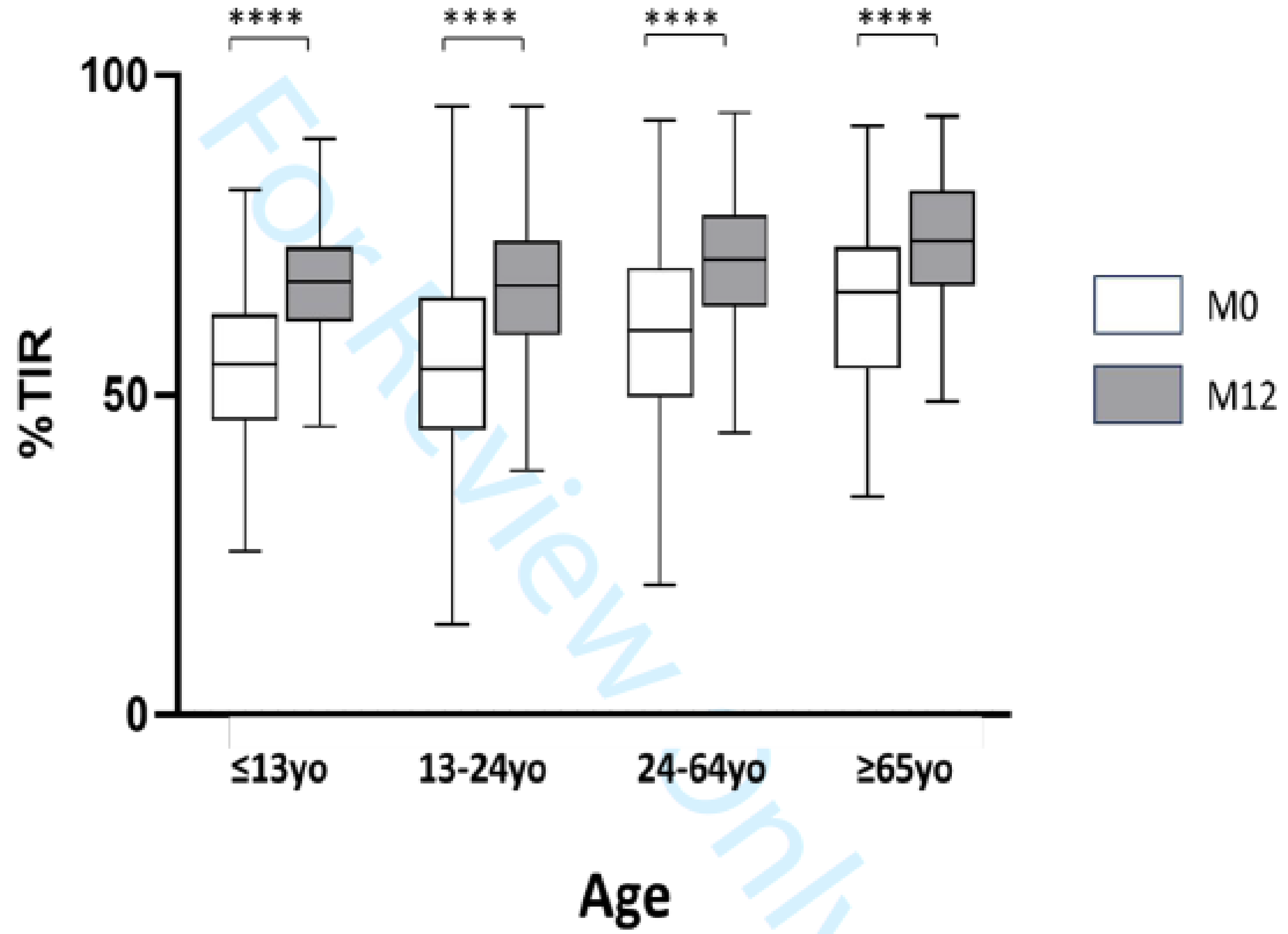
- 79 centres de diabétologie français (56 adultes et 23 pédiatriques); 2741 participants
- 1171 adultes (âge médian 44 ans, durée médiane du diabète 24 ans)
- 450 ados/jeunes adultes (âge médian 18 ans, durée médiane du diabète 10 ans)
- 307 enfants (âge médian 10 ans, durée médiane du diabète 6 ans)
- 99% sous BF Medtronic 780G ou Tandem Control-IQ entre 1/1 et 31/12/2022 en vie courante

Table 2. Evolution of glucose control and percentages of people experiencing severe hypoglycemia or ketoacidosis before and after AID initiation.

	M0	M3	M6	M12	p$	p£	IC¥	IC‡
Number	2741	2461	2235	2215	NA	NA	NA	NA
HbA1c, %	7.6 [1.2]	7.0 [0.8]	7.0 [0.6]	7.0 [0.8]	<2e-16	<2e-16	[-0.01;0.02]	[0.08;0.12]
Number of people with HbA1c < 7% (%)	718 (26)	813 (55)	859 (53)	855 (51)	<2e-16	<2e-16	[-0.17;0.04]	[-0.35;-0.16]
Number of people experiencing at least one SH for the last 12 months (%)	112 (4.1)	-	-	19 (0.86)	2.11e-10	NA	NA	NA
Number of people experiencing at least one DKA for the last 12 months (%)	34 (1.2)	-	-	13 (0.6)	<2e-16	NA	NA	NA
Number of people with available CGM data (%)	1989 (73)	2242 (91)	1995 (89)	1923(87)	NA	NA	NA	NA
TIR, %	58 [21]	72 [13]	71 [14]	70 [14]	<2e-16	<2e-16	[-1.6;-1.16]	[-2.2;-1.75]
TBR, %	2.0 [3.0]	1.9 [2.0]	1.6 [2.1]	1.5 [2.1]	<2e-16	3.73e-10	[-0,3;-0.1]	[-0,3;-0.2]
TAR, %	38.7 [22]	25 [14]	27 [15]	27 [14]	<2e-16	<2e-16	[1.4;1.83]	[1.9;2.4]
GMI, %	7.5 [1.0]	6.9 [0.6]	7.0 [0.7]	7.0 [0.7]	<2e-16	<2e-16	[0.06;0.08]	[0.09;0.11]
CV, %	36 [8]	35 [7]	35 [7]	35 [8]	<2e-16	<2e-16	[-0.11;0.1]	[-0.02;0.2]
Number of people with TIR above 70% (%)	429 (22)	1307 (58)	1035 (52)	963 (50)	<2e-16	<2e-16	[-0.5;-0.33]	[-0.61;-0.44]
Number of people with TBR below 4% (%)	1382 (72)	1838 (82)	1648 (83)	1593 (83)	<2e-16	6.17e-15	[0.04;0.35]	[0.12;0.43]
Number of people with TIR above 70% and TBR below 4% (%)	265 (13)	1065 (48)	846 (42)	776 (40)	<2e-16	<2e-16	[-0.36;-0.2]	[-0.5;-0.35]

Continuous variables are presented as median [IQR], and categorical variables as number (percentage). AID: Automated Insulin Delivery; SH: Severe Hypoglycemia; DKA: Diabetic KetoAcidosis, CGM: Continuous Glucose Monitoring; TIR: Time in Range; TBR: Time Below Range; TAR: Time Above Range; GMI: Glycemic Monitoring Index; CV: Coefficient of variation of glycemia.; NA : Not Applicable.

p$: M0 vs Follow up; p£: Superiority analysis M3 vs M0; IC¥ Non inferiority analysis M3 vs M6;IC‡: Non inferiority analysis M3 vs M12

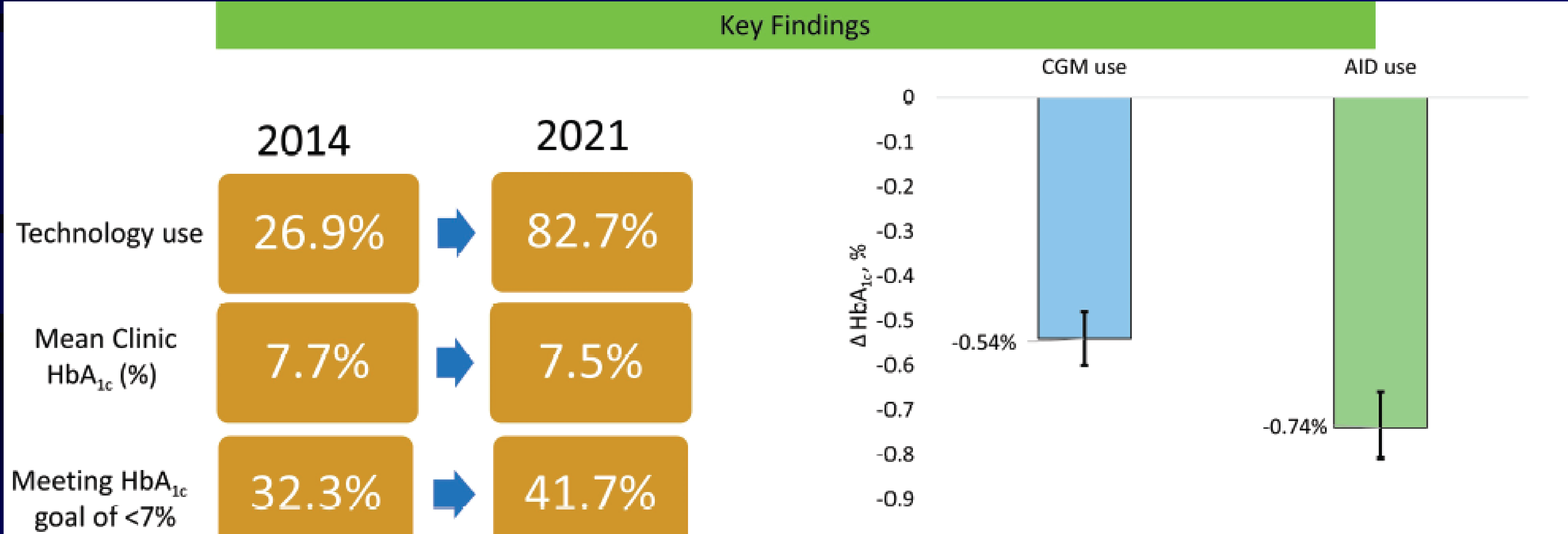


%TIR: percentage of time in target range (3.9-10 mmol/l)

Association Between Diabetes Technology Use and Glycemic Outcomes in Adults With Type 1 Diabetes Over a Decade

Kagan E. Karakus, Halis K. Akturk, G. Todd Alonso, Janet K. Snell-Bergeon, and Viral N. Shah

Diabetes Care 2023;46(9):1646–1651 | https://doi.org/10.2337/dc23-0495



There was a significantly lower HbA1c in adults with type 1 diabetes using continuous glucose monitoring (CGM) or automated insulin delivery (AID) compared to adults not using diabetes technology.

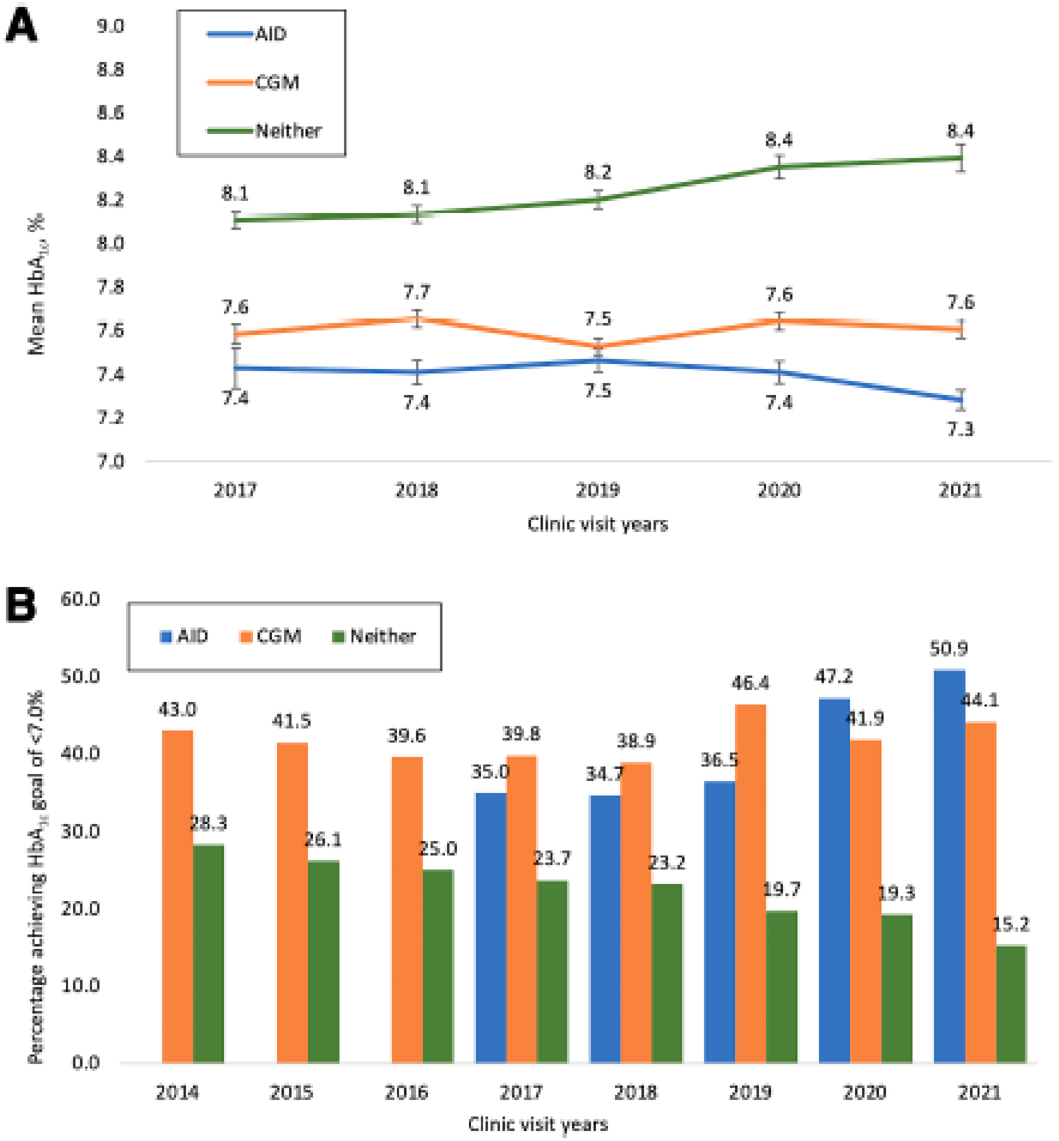


Figure 3—*A*: Least-squares mean and SEs of HbA_{1c} by AID use, CGM use, or no diabetes technology use. The HbA_{1c} of AID users was lower than diabetes technology nonusers in all years ($P < 0.001$ for all time points) and was lower than CGM users in all years ($P < 0.05$ in 2017, $P < 0.001$ in 2018, 2020, and 2021) except 2019. The HbA_{1c} of CGM users was lower than that of diabetes technology nonusers in all years ($P < 0.001$ for all time points). *B*: Percentage meeting the HbA_{1c} goal of <7.0% by AID use, CGM use, or no diabetes technology use. Percentage who achieved the goal differed significantly between groups ($P < 0.001$ for all years). There were no AID users in 2014–2015, and three AID users in 2016 were not included.

Diabetes Care 2023;46:1646–1651

Mise en place de l'insulinothérapie automatisée en boucle fermée : position d'experts français

Practical implementation of closed-loop automated insulin delivery: a French position statement

Sylvia Franc*, Pauline Schaepelynck*, Nadia Tubiana-Rufi*, Lucy Chaillous, Michaël Joubert, Eric Renard, Yves Reznik, Charlotte Abettan, Elise Bismuth, Jacques Beltrand, Élisabeth Bonnemaison, Sophie Borot, Guillaume Charpentier, Brigitte Delemer, Agnès Desserprix, Danielle Durain, Anne Farret, Nathalie Filhol, Bruno Guerci, Isabelle Guilhem, Caroline Guillot, Nathalie Jeandidier, Sandrine Lablanche, Rémy Leroy, Vincent Melki, Marion Munch, Alfred Penfornis, Sylvie Picard, Jérôme Place, Jean-Pierre Riveline, Pierre Serusclat, Agnès Sola-Gazagnes, Charles Thivolet, Hélène Hanaire, Pierre Yves Benhamou

Au nom de : SFD (Groupe de travail Télémédecine et Technologies Innovantes de la SFD), SFD paramédical, SFE, SFEDP, AJD, FFD, FENAREDIAM, CNPEDN
*ont contribué de façon égale à ce travail

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Diabetes & Metabolism

Practical implementation of automated closed-loop insulin delivery: A French position statement

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Actualisation de la prise de position des experts français sur l'insulinothérapie automatisée en boucle fermée☆

Éric Renard, Nadia Tubiana-Rufi, Lucy Chaillous, Élisabeth Bonnemaison, Hélène Hanaire, Élise Bismuth, Michael Joubert, Régis Coutant, Pauline Schaepelynck, Jacques Beltrand, Yves Reznik, Florence Authier, Sophie Borot, Sophie Brunot, Claire Calvez, Guillaume Charpentier, Fabienne Dalla-Vale, Anne Delawoevre, Brigitte Delemer, Agnès Desserprix, Danielle Durain, Salha Fendri, Sylvia Franc, Cécile Godot, Didier Gouet, Agathe Guenego, Bruno Guerci, Isabelle Guilhem, Nathalie Jeandidier, Sandrine Lablanche, Claire Le Tallec, Mathilde Malwe, Laurent Meyer, Carole Morin, Alfred Penfornis, Sylvie Picard, Jen-Pierre Riveline, Valérie Rossignol, Sarra Smati, Agnès Sola-Gazagnes, Charles Thivolet, Orianne Villard, Pierre Yves Benhamou,
Au nom de : SFD (Groupe de travail télémédecine et technologies innovantes de la SFD), SFD paramédical, SFE, SFEDP, AJD, FFD, FENAREDIAM, CNP-EDDM, CODEHG

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Practical implementation of automated insulin delivery systems in 2025: A French position statement update - 19/03/25

Doi : 10.1016/j.diabet.2025.101637

E Bismuth [a], M Joubert [b], E Renard [c], N Tubiana-Rufi [a], L Chaillous [d], E Bonnemaison [e], H Hanaire [f], R Coutant [g], P Schaepelynck [h], J Beltrand [i], Y Reznik [b], F Authier [j], S Borot [k], S Brunot [l], C Calvez [m], G Charpentier [n], F Dalla-Vale [o], A Delawoevre [p], B Delemer [q], A Desserprix [r], D Durain [s], S Fendri [t], S Franc [u], C Godot [v], D Gouet [w], A Guenego [x], B Guerci [y], I Guilhem [z], N Jeandidier [aa], S Lablanche [ab], C Le Tallec [ac], M Malwe [ad], L Meyer [ae], C Morin [af], A Penfornis [ag], S Picard [ah], JP Riveline [ai], V Rossignol [aj], S Smati [ak], A Sola-Gazagnes [al], C Thivolet [am], O Villard [an], PY Benhamou [ab]

on behalf SFD, SFD paramédical, SFE, SFEDP, AJD, FFD, FENAREDIAM, CNP-EDDM and CODEHG

TABLEAU V

Synthèse des préconisations pour l'utilisation de la boucle fermée chez l'adulte et l'enfant en 2024

	Indications en 2020	Indications en 2024
Prérequis		
Type de diabète	Type 1	Autres diabètes insulinoprives : A discuter (voir texte)
Âge	≥ 6 ans	≥ 2 ans
Ancienneté	> 6 mois	Possible dès le diagnostic chez l'adulte (voir texte pour l'enfant)
Traitement préalable	Pompe depuis 6 mois	– Pompe sans nécessité d'une durée préalable de 6 mois – Multi-injections possible
Formation	Comptage des glucides	Comptage préférable mais non indispensable
Engagement	Respect d'un parcours de soin spécifique	idem
HbA1c	Limitations réglementaires	Pas de limites, possible avec prudence et conditions si A1c très élevée (voir texte)
Contexte		Grossesse Diabète instable
Critères		
	Objectifs métaboliques (critères internationaux ADA/ISPAD) et/ou qualité de vie non atteints	Idem

Centres Initiateurs de Boucle Fermée

Ces équipes multiprofessionnelles hospitalières, libérales ou mixtes, sont composées d'au moins deux médecins spécialistes en endocrinologie-diabétologie, d'une infirmière et d'une diététicienne expérimentées en diabétologie, formés à l'éducation thérapeutique :

- ayant suivi et validé la formation du fabricant du dispositif de boucle fermée ;
- ayant suivi et validé la formation au DIU d'insulinothérapie automatisée (au moins 2 membres de l'équipe, dont au moins un médecin) ;
- disposant d'une formation à l'éducation thérapeutique ;
- assurant un suivi minimal de 80 patients sous pompe à insuline ;
- assurant (ou prévoyant pour la première année de fonctionnement) un suivi minimal de 20 patients sous BF par an ;
- justifiant d'une formation continue annuelle au système de BF (congrès, réunions régionales et nationales) ;
- pouvant développer une prise en charge pluriprofessionnelle lors de l'initiation du dispositif de boucle fermée au sein d'une équipe associant 2 médecins spécialistes en endocrinologie-diabétologie, une IDE et une diététicienne formés ;
- pouvant assurer (pour les services hospitaliers) ou participer (pour les diabétologues libéraux) à une astreinte 24 h/24 et 7 j/7 pour les gestions des situations d'urgence métaboliques ;
- organisant ou participant à des RCP ou télé-expertise à la demande des diabétologues de suivi ;
- pouvant initier et assurer une télésurveillance des patients sous boucle fermée pendant la période initiale d'initiation de 3 mois pour tous les patients ou au-delà des 3 mois pour les patients dont l'équilibre glycémique ou l'autonomisation sous boucle fermée le nécessiterait.

Les critères sur la file active restent également inchangés depuis ceux de 2020, fort des travaux initiaux menés sur les centres de ressources et de compétences de diabétologie pédiatriques (CRCDP) dans le cadre du livre blanc adressé au ministère en 2019 :

- centres initiateurs pédiatriques de boucle fermée : file active de patients suivis ≥ 150 dont au moins 75 d'enfants et adolescents sous pompe à insuline et assurant (ou prévoyant pour la première année) l'initiation minimale de 10 boucles fermées ; disposant d'une astreinte de diabétologie pédiatrique 24 h/24 h et 7 j/7 et d'un service d'urgence pédiatrique ;
- centre de suivi pédiatrique de boucle fermée : file active de patients porteurs d'un diabète de type 1 suivis entre 50–150, dont au moins 35 enfants et adolescents sous pompe à insuline et assurant (ou prévoyant d'assurer la première année) le suivi de 5 boucles fermées ; disposant d'une organisation locale ou régionale permettant d'assurer une astreinte de diabétologie pédiatrique 24 h/24 h et 7 j/7 et d'un service d'urgence pédiatrique.

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Instituts thématiques Inserm
CIC 1411
Institut national de la santé et de la recherche médicale

IGF
Institut de Génomique Fonctionnelle

MRG
Medical Research Group

JDRF
Juvenile Diabetes Research Foundation International
dedicated to finding a cure

Seventh Framework Programme

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Merci !