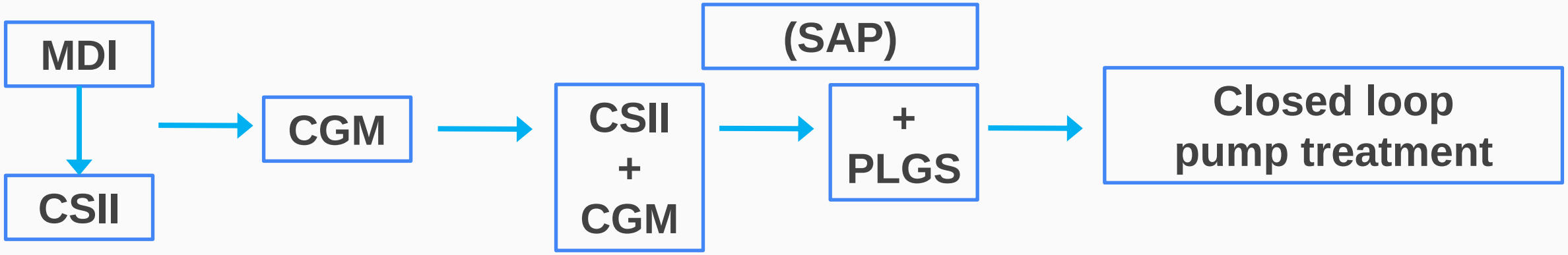
Συστήματα συνεχούς έγχυσης ινσουλίνης κλειστού κυκλώματος (closed-loop insulin delivery systems)

Κωνσταντίνος Μαρκάκης
Παθολόγος με εξειδίκευση στο Σακχαρώδη Διαβήτη
Επίκουρος Καθηγητής Παθολογίας
Τμήμα Ιατρικής, Σχολή Επιστημών Υγείας Πανεπιστημίου Πατρών
Παθολογική Κλινική Πανεπιστημιακό Γενικό Νοσοκομείο Πατρών

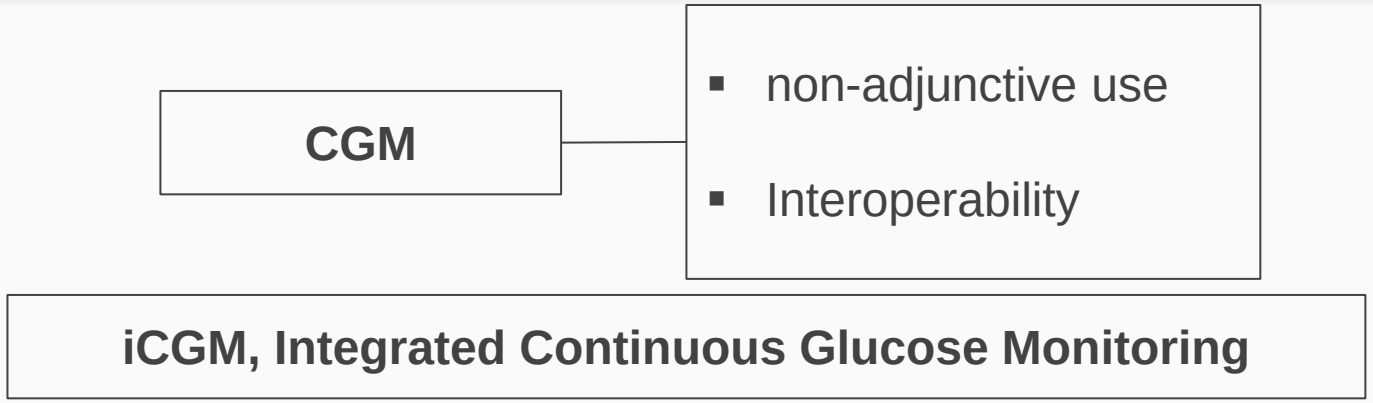
Εξέλιξη στη θεραπεία του ΣΔ1



MDI: multiple daily injection
CSII: continuous subcutaneous insulin infusion
CGM: continuous glucose monitoring
Sensor Augmented Pump (SAP)
PLGS: predictive low glucose suspension

CGM Ακρίβεια - Χαρακτηριστικά		Ακρίβεια (MARD, %)	Διάρκεια αισθητήρα (ημέρες)	Χαρακτηριστικά	Απαιτήσεις
Dexcom	**G7**	**8,1 arm 9,1 abdomen**	**10**	**Βέλη μεταβολής**, Υπερ – Υπο-**alarms** Σύνδεση σε **smartphones, closed loop CSII**	**Δεν απαιτεί βαθμονόμηση (δέχεται βαθμονόμηση)**
Medronic	**Guardian sensor 3**	**9,6 -10,6 (abdomen) 9,1 (arm)**	**7**	**Βέλη μεταβολής**, Υπερ – Υπο-**alarms** Σύνδεση σε **Medronic 780G, iPhones**	**Βαθμονόμηση** τουλάχιστον κάθε 12h
	Guardian sensor 4	**10,6**	**7**	**Βέλη μεταβολής**, Υπερ – Υπο-**alarms** Σύνδεση σε **Medronic 780G, iPhones**	**Δεν απαιτεί βαθμονόμηση (δέχεται βαθμονόμηση)**
Abbott	**Freestyle Libre**	**Freestyle Libre 2 plus → 8,2 Freestyle Libre 3 MARD → 7,9**	**14 2 plus: 15**	**Βέλη μεταβολής,** Υπερ – Υπο-**alarms**, Σύνδεση σε **smartphones/**Υπερ – Υπο-**alarms**	**Δεν απαιτεί βαθμονόμηση (δεν δέχεται βαθμονόμηση)**
Senseonics Eversense E3 εμφυτεύσιμος		**8,5**	**90**	**Βέλη μεταβολής**, Υπερ – Υπο-**alarms** Σύνδεση σε **smartphones**	**Βαθμονόμηση** κάθε 12h πρώτες 21 ημέρες
Menarini GlucoMen Day		**9,9**	**14**	**Βέλη μεταβολής,** Υπερ – Υπο-**alarms** Σύνδεση σε **smartphones**	**Βαθμονόμηση** κάθε 24h

iCGM, Integrated Continuous Glucose Monitoring



An **integrated continuous glucose monitoring system (iCGM)** is intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. Integrated CGM systems are designed to **reliably and securely transmit glucose measurement data to digitally connected devices, including automated insulin dosing systems** and are **intended to be used alone or in conjunction with these digitally connected medical devices** for the purpose of managing a disease or condition related to glycemic control. This category of CGM performance specified by the U.S. FDA is the strictest accuracy standard defined by any regulatory agency in the world

Pemberton et al Diabetes Obes Metab. 2023 Apr;25(4):916-939

CGMs evaluation and approval

≥ 70% T1DM (ενήλικες)
≥ 98% T1DM (παιδιά -έφηβοι)

Αντιπροσωπευτικός πληθυσμός

ζεύγη μετρήσεων
≥ 10.000 (ενήλικες)
≥ 2,500 (παιδιά -έφηβοι)

>8% σε εύρος <80mg/dL
>5% σε εύρος >300mg/dL

- Published in a in peer-reviewed journal?
  - Peer review increases the likelihood of scientific rigour and reduces the risk of bias.
- Is the study population clearly defined by type of diabetes and demographics?
  - CGM studies approved by international regulators for people with type 1 diabetes have ≤2% of subjects with type 2 diabetes using insulin for ages <18yrs and <30% >18yrs.
  - Does the study population fairly represent the intended use population in terms of distribution of HbA1c, gender, body mass index, diabetes duration and therapy type (15)?
- At least three unique sensor lots used in the accuracy study (15)?
- Number of paired reference§ readings tested on each anatomical insertion site?
  - CGM studies approved by international regulators for people with type 1 diabetes have paired reference§ readings >10,000 for ages ≥18yrs and >2,500 for ages <18yrs for each anatomical insertion site.
- Days of sensor use life assessed: Beginning, middle and end of the wear period (15):
  - CGM studies approved by international regulators for people with type 1 diabetes tested on the first and last day and tested on >40% of total days of sensor life.
- Glucose and insulin challenges performed to induce fast rates of change and time spent in extreme glucose ranges?
  - Do the percentage of paired reference§ readings in low and high ranges meet guideline recommendations (15):
    - >8% of readings <4.4mmol/L (<80mg/dL) and >5% of readings >16.7mmol/L (>300mg/dL).

Continue to Reporting if the study design applies to the patient population supported and the protocol will produce results that represent real-world conditions for that population.

Pemberton et al Diabetes Obes Metab. 2023 Apr;25(4):916-939

CGMs evaluation and approval

Τύπος διαβήτη, ηλικία

Aggrement rates

MARD, aggrement rates across sensor use life

Error Grid Analysis

Precision

- Report performance by type of diabetes (type 1 and type 2) and age (<18yrs and ≥18yrs) (15)?
- Report performance by different agreement rates (15/15, 20/20, 30/30, 40/40, ±20%) across full glucose range and in TBR, TIR and TAR with lower one-sided 95% confidence bounds‡ (15)?
- Report performance of sensor stability by detailing accuracy (MARD and agreement rates) across sensor use life (15)?
- Report performance by agreement rates when CGM result is outside display range (15)?
- Report performance on the Continuous Error Grid Analysis (84)?
- Report performance of precision by paired absolute relative difference or co-efficient of variation (15)?
- Report the time between sensor activation the first glucose reading.

Continue to Performance if the reporting provides adequate information to assess point accuracy of the CGM device against iCGM criteria. Specifically, are the lower 95% bound bounds‡ within 15/15, 40/40 and ±20 in TBR, TIR and TAR reported. If not, ask the manufacturer/author for the data.

Pemberton et al Diabetes Obes Metab. 2023 Apr;25(4):916-939

CGMs evaluation and approval

Point Accuracy Performance

- Adult† FDA iCGM point accuracy performance requirement for 15/15 across all days of assessed sensor life
  - Within 15mg/dL (0.8mmol/L) for TBR the lower one-sided 95% confidence bound must exceed 85%‡
  - Within 15% for TIR the lower one-sided 95% confidence bound must exceed 70%‡
  - Within 15% for TAR the lower one-sided 95% confidence bound must exceed 80%‡

- Adult† FDA iCGM point accuracy performance requirement for 40/40 across all days of assessed sensor life
  - Within 40mg/dL (2.2mmol/L) for TBR the lower one-sided 95% confidence bound must exceed 98%‡
  - Within 40% for TIR the lower one-sided 95% confidence bound must exceed 99%‡
  - Within 40% for TAR the lower one-sided 95% confidence bound must exceed 99%‡

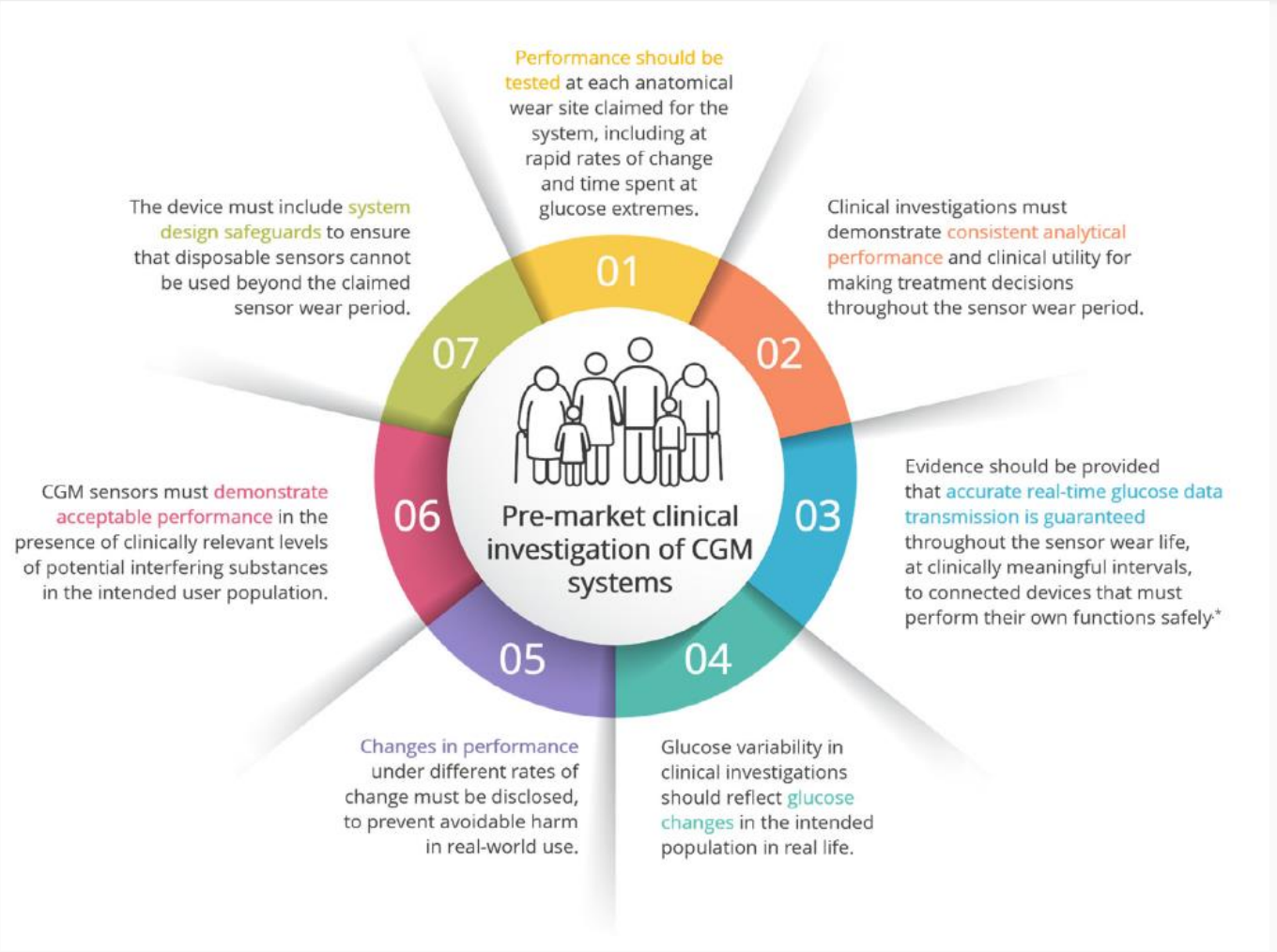
- Adult† FDA iCGM point accuracy performance requirement for ±20% across the full glucose range measured by the device on all days of assessed sensor life states the lower one-sided 95% confidence must exceed 87%‡

The iCGM standards apply for interoperability indications, however, standards for non-interoperability indications may be lower based on user risk. Evaluate point accuracy first, then consider trend and threshold accuracy (15). Once accurate for intended indications, discuss other selection factors such as alerts, integration with insulin therapy, smartphone requirement and psychosocial factors when offering choice.

Pemberton et al Diabetes Obes Metab. 2023 Apr;25(4):916-939

CGMs evaluation and approval

- Performance metrics
  - point accuracy
  - trend accuracy
  - threshold alarm accuracy
- Data security and cybersecurity



Mathieu et al Diabetes Obes Metab. 2025 Mar;27(3):1025-1031

Pemberton et al Diabetes Obes Metab. 2023 Apr;25(4):916-939
Freckmann et al J Diabetes Sci Technol. 2023 Nov;17(6):1506-1526
Klonoff et al J Diabetes Sci Technol. 2024 May 3:19322968241250357

CGMs evaluation and approval

CGM accuracy: Contrasting CE marking with the governmental controls of the USA (FDA) and Australia (TGA): A narrative review

Diabetes Obes Metab. 2023 Apr;25(4):916-939

John S Pemberton BSc[1] | Emma G Wilmot PhD[2,3] | Katharine Barnard-Kelly PhD[4] | Lalantha Leelarathna PhD[5,6] | Nick Oliver FRCP[7] | Tabitha Randell MD[8] | Craig E Taplin FRACP[9,10,11] | Pratik Choudhary FRCP[12] | Peter Adolfsson PhD[13]

Importance of FDA-Integrated Continuous Glucose Monitors to Ensure Accuracy of Continuous Glucose Monitoring

J Diabetes Sci Technol. 2024 May 3:19322968241250357

David C. Klonoff, MD[1], Monica Gabbay, MD, PhD[2], Sun Joon Moon, MD[3], and Emma G. Wilmot, MD, PhD[4]

CGMs evaluation and approval

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Diabetes Obes Metab. 2023 Apr

John S Pemberton BSc[1] | Emma G Wilmot PhD[2,3] |
Katharine Barnard-Kelly PhD[4] | Lalantha Leelarathna PhD[5,6] | N
Tabitha Randell MD[8] | Craig E Taplin FRACP[9,10,11] | Pratik Chou
Peter Adolfsson PhD[13]

Clinical Performance Evaluation of Continuous Glucose Monitoring Systems: A Scoping Review and Recommendations for Reporting

J Diabetes Sci Technol. 2023 Nov;17(6):1506-1526

Guido Freckmann, MD[1,2], Manuel Eichenlaub, PhD[2],
Delia Waldenmaier, PhD[2], Stefan Pleus, PhD[2],
Stephanie Wehrstedt, PhD[2], Cornelia Haug, MD[2],
Lilian Witthauer, PhD[3,4], Johan Jendle, MD, PhD[1,5],
Rolf Hinzmann, MD, PhD[1,6], Andreas Thomas, PhD[1,7],
Elisabet Eriksson Boiia. PhD[1,8]. Konstantinos Makris. PhD[1,9].

Importance of FDA-Integrated Continuous Glucose Monit Accuracy of Continuous Gl Monitoring

J Diabetes Sci Technol. 2024 May 3:1

David C. Klonoff, MD[1], Monica Gabbay
Sun Joon Moon, MD[3], and Emma G. Wil

Minimum expectations for market authorization of continuous glucose monitoring devices in Europe—'eCGM' compliance status

Diabetes Obes Metab. 2025 Mar;27(3):1025-1031

Chantal Mathieu MD[1] | Concetta Irace MD[2] | Emma G. Wilmot MD[3,4] |
Bassil Akra PhD[5] | Stefano Del Prato MD[6] | Martin Cuesta MD[7] |
Peter Adolfsson MD[8,9] | Tomasz Klupa MD[10] | Eric Renard MD[11] |
Tadej Battelino MD[12,13]

CGMs evaluation and approval

TABLE 2 CE marking, FDA approval, TGA approval, and clinical data provided by manufacturers for CGM devices available in the UK in December 2022

Sensor	Device or application (APP)	CE marking class & notified body 4-digits	USA FDA approval class and code	Australian TGA approval for the ARTG class and code	Age range indication	Non-adjunctive therapy decisions indication	Age range of subjects tested in clinical data	Number subjects P: <18 y A: ≥18 y C: all	Subjects with type 1 diabetes P: <18 y A: ≥18 y C: all	Mean absolute relative difference P: <18 y A: ≥18 y C: all	20/20 across full glucose range P: <18 yA: ≥18 y C: all	Prescribed in primary care in the UK
Dexcom ONE™	APP or receiver	IIb[b] CE 2797	×	×	≥2 y	Yes	≥2 y[11,12]	P: 165 A: 159	P: 100% A: 99%	P: 7.7-10.1% A: 9.8-9.9%	P: 92.0-96.2% A: 91.8-92.5%	✓
Dexcom G6™	APP or receiver	IIb[a] CE 2797	II iCGM QBJ[13]	III ID330535	≥2 y	Yes	≥2 y[11,12]	P: 165 A: 159	P: 100% A: 99%	P: 7.7-10.1% A: 9.8-9.9%	P: 92.0-96.2% A: 91.8-92.5%	×
Dexcom G7™	APP or receiver	IIb[b] CE 2797	II iCGM QBJ[14]	×	≥2 y	Yes	≥2 y[15,16]	P: 127 A: 316	P: 100% A: 81%	P: 8.1-9.0% A: 8.2-9.1%	P: 92.9-95.3% A: 93.2-95.3%	×
Guardian™ sensor 3 and Guardian™ connect transmitter	MiniMed Guardian™ connect APP	IIb[a] CE 0459	III MDS[17]	III ID 313741	≥14 y	No	≥2 y[18,19]	P: 124 A: 82	P: 100% A: 70%	P: 10.1% A: 9.4%	P: 90.2% A: 89.5%	×
Guardian™ sensor 3 and Guardian™ link 3 transmitter	MiniMed 670G™	IIb[a] CE 0459	III QZP[20]	III ID 313741	≥7 y	No	≥2 y[18,19]	P: 124 A: 82	P: 100% A: 70%	P: 10.9% A: 8.7%	P: 87.6% A: 92.0%	×
Guardian™ sensor 4 and Guardian™ link 4 transmitter	MiniMed 780G™ InPen™	IIb[a] CE 0459	×	×	≥7 y	Yes	≥2 y[c]	P: 108 A: 153	[f]	P: 11.6-12.3% A: 10.6-10.8%	P: 82.7-85.6% A: 88.3-88.8%	×
FreeStyle libre® 2[e]	APP or reader	IIb[a] CE 2797	II iCGM QLG[21]	III ID 358292	≥4 y	Yes	≥4 y[22]	P: 129 A: 144	C: 98%	P: 9.2% A: 9.7%	P: 92.1% A: 93.2%	✓
FreeStyle libre® 3	APP	IIb[a] CE 2797	II iCGM QLG[23]	×	≥4 y	Yes	≥4 y[c]	C: 100	C: 83%	P: 8.7% A: 7.6%	P: 89.7% A: 94.9%	×
GlucoMen day®	APP	IIb[a] CE 1304	×	×	≥6 y	Yes	≥18 y[24]	A: 57	A: 84%	A: 9.9%	A: 85/0%	✓
GlucoRx Adiex™	APP	IIa[a] CE 0197	×	×	≥14 y	No	≥18 y[25]	A: 114	A: 11%	A: 9.1%	A: 95.8%	✓
Medtrum TouchCare®	APP or receiver	IIa[a] CE 0197	×	×	≥2 y	Yes	≥18 y[26]	A: 63	A: 16%	A: 9.1%	A: 90.5%	×
Medtrum TouchCare® Nano	APP	IIa[a] CE 0197	×	×	≥2 y	Yes	≥14 y[d]	C: 61	C: 57%	A: 9.7%	A: 89.5%	×

Pemberton et al Diabetes Obes Metab. 2023 Apr;25(4):916-939

CGMs evaluation ar approval

CGMs which meet those requirements:

Abbott FreeStyle Libre 2 Abbott FreeStyle Libre 3	≥4 years
Abbott FreeStyle Libre 2 Plus Abbott FreeStyle Libre 3 Plus	≥2 years
Dexcom G6 Dexcom G7	≥2 years
Guardian 4, Simplera sync	σαν τμήμα Medronic Minimed HCL
Eversense 365	≥18 years

Pemberton et al Diabetes Obes Metab. 2023 Apr;25(4):916-939
Klonoff et al J Diabetes Sci Technol. 2024 May 3:19322968241250357
ADCES/Danatech https://www.adces.org/

Pemberton et al Diabetes Obes Metab
2023 Apr;25(4):916-939

CGM – ακρίβεια / το MARD μόνο δεν είναι αρκετό

CGM		Ακρίβεια (MARD, %)
Dexcom	G6, G7	8,1 arm 9,1 abdomen
Medronic	Guardian 4	10,6
Abbott	Freestyle Libre	Freestyle Libre 2 plus → 8,2 Freestyle Libre 3 → 7,9
Senseonics	Eversense E3, E365 εμφυτεύσιμος	8,5

iCGM

CGM		Ακρίβεια (MARD, %)
Medtrum	TouchCare Nano	8,1 arm 9,1 abdomen
Sibionics	SiJoy GS1	9,6 -10,6 (abdomen) 9,1 (arm)
MicroTech Medical (Hangzhou) Co., Ltd	Aidex	9,1
Wellion	based on the technology of the AiDEX CGM	9,1
Menarini	GlucoMen iCan	8,7

MDI vs CSII

Αντλίες συνεχούς υποδόριας έγχυσης ινσουλίνης (Continuous Subcutaneous Insulin Infusion, CSII)

- Προφίλ βασικού ρυθμού

Διαφορετικά επίπεδα βασικού ρυθμού για διαφορετικά διαστήματα της ημέρας

Basal

Maximum Basal Rate	2.00 U/Hr

Basal 1 (active)

24-Hour Total	16.725 U

Time	U/Hr
0:00	0.450
2:00	0.600
5:00	0.750
8:30	0.800
12:00	0.700
14:30	0.500
18:00	0.850

Day Off

24-Hour Total	--

Time	U/Hr
--	--

Workday

24-Hour Total	--

Time	U/Hr
--	--

Bolus

Bolus Wizard	On
Units	g, mmol/L
Active Insulin Time (h:mm)	4:00
Maximum Bolus	12.0 U

Easy Bolus	0.10 U
Bolus Increment	0.1 U
Bolus Speed	Standard
Dual/Square	Off/Off

Carbohydrate Ratio (g/U)

Time	Ratio
0:00	21.0
12:00	18.0
17:30	12.0
20:30	15.0

Insulin Sensitivity (mmol/L per U)

Time	Sensitivity
0:00	4.5
8:00	4.5
12:00	4.5
17:00	4.5

Blood Glucose Target (mmol/L)

Time	Low	High
0:00	6.0	8.0

Preset Bolus

Name	Normal	Square
Bolus 1		
Breakfast		
Dinner		
Lunch		
Snack		
2		

Sensor

Sensor	On

High Alerts — On (Snooze 1:00)

Start Time	High (mmol/L)	Alert On High	Alert Before High	Rise Alert Limit (mmol/L)
0:00	15.0		x	

Low Alerts — On (Snooze 0:20)

Start Time	Low (mmol/L)	Suspend	Alert On Low	Alert Before Low	Resume Basal Alert
0:00	3.8	Before Low	x		
7:00	3.8	Before Low	x		

Auto Calibration	Off
Calibration Reminder	On
Calibration Reminder Time	1:05

- Προσωρινός βασικός ρυθμός

Άσκηση
Ασθένεια

Προσωρινός ρυθμός

Ασθένεια

Stress

Άσκηση - αυξημένη φυσική δραστηριότητα

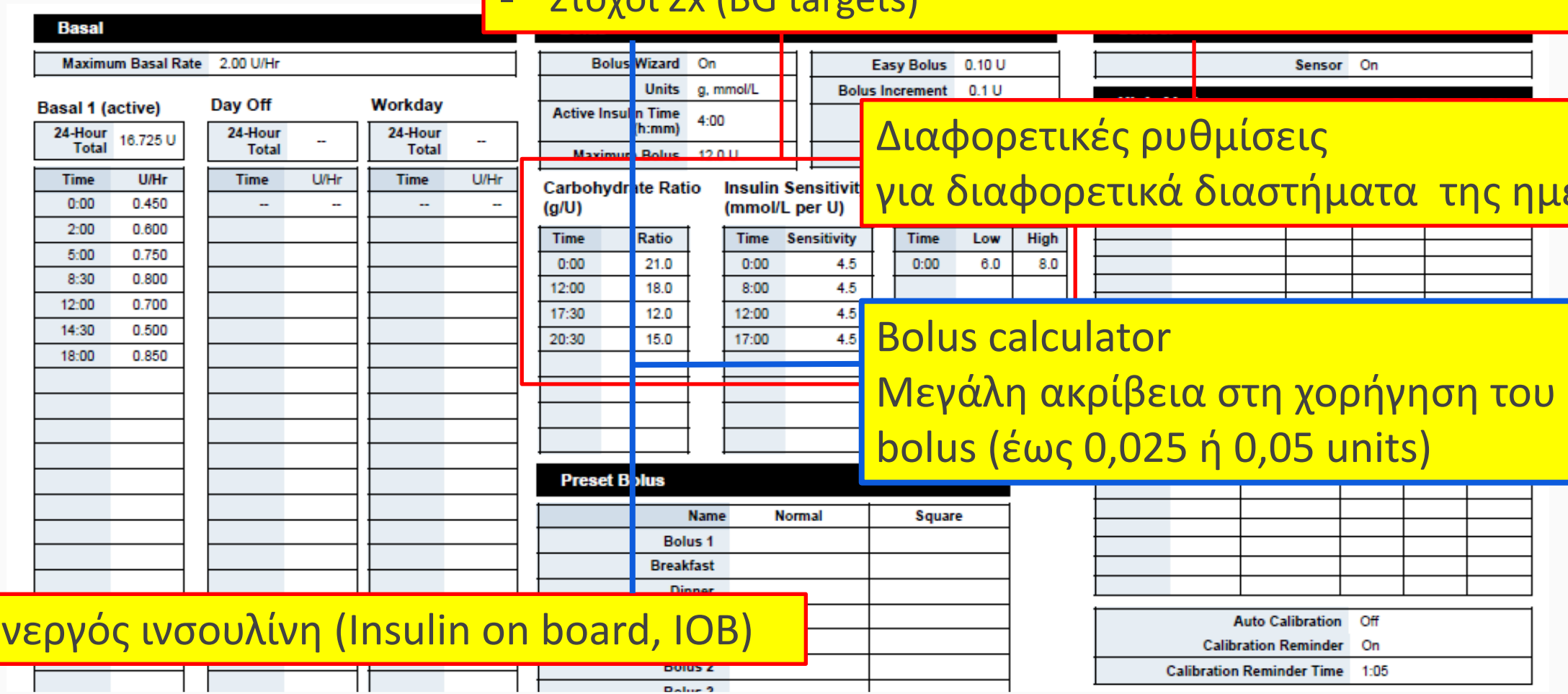
Κατανάλωση αλκοόλ

Προσοχή
Έναρξη προσωρινού ρυθμού 1-2 ώρες πριν

Αντλίες συν… (Continuous…

- Αναλογία ινσουλίνης/ γρ. υδατανθράκων ή ισοδύναμο (Insulin to Carbohydrate Ratio, ICR)
- Παράγοντας ευαισθησίας ινσουλίνης (Insulin Sensitivity Factor, ISF)
- Στόχοι Σχ (BG targets)

➢ Γευματική ινσουλίνη/ Διόρθωση



Basal

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24-Hour Total	16.725 U

Time	U/Hr
0:00	0.450
2:00	0.600
5:00	0.750
8:30	0.800
12:00	0.700
14:30	0.500
18:00	0.850

Day Off

24-Hour Total	--

Time	U/Hr
--	--

Workday

24-Hour Total	--

Time	U/Hr
--	--

Bolus Wizard	On
Units	g, mmol/L
Active Insulin Time (h:mm)	4:00
Maximum Bolus	12.0 U

Easy Bolus	0.10 U
Bolus Increment	0.1 U

Sensor	On

Carbohydrate Ratio (g/U)

Time	Ratio
0:00	21.0
12:00	18.0
17:30	12.0
20:30	15.0

Insulin Sensitivity (mmol/L per U)

Time	Sensitivity
0:00	4.5
8:00	4.5
12:00	4.5
17:00	4.5

Time	Low	High
0:00	6.0	8.0

Preset Bolus

Name	Normal	Square
Bolus 1		
Breakfast		
Dinner		
Bolus 2		
Bolus 3		

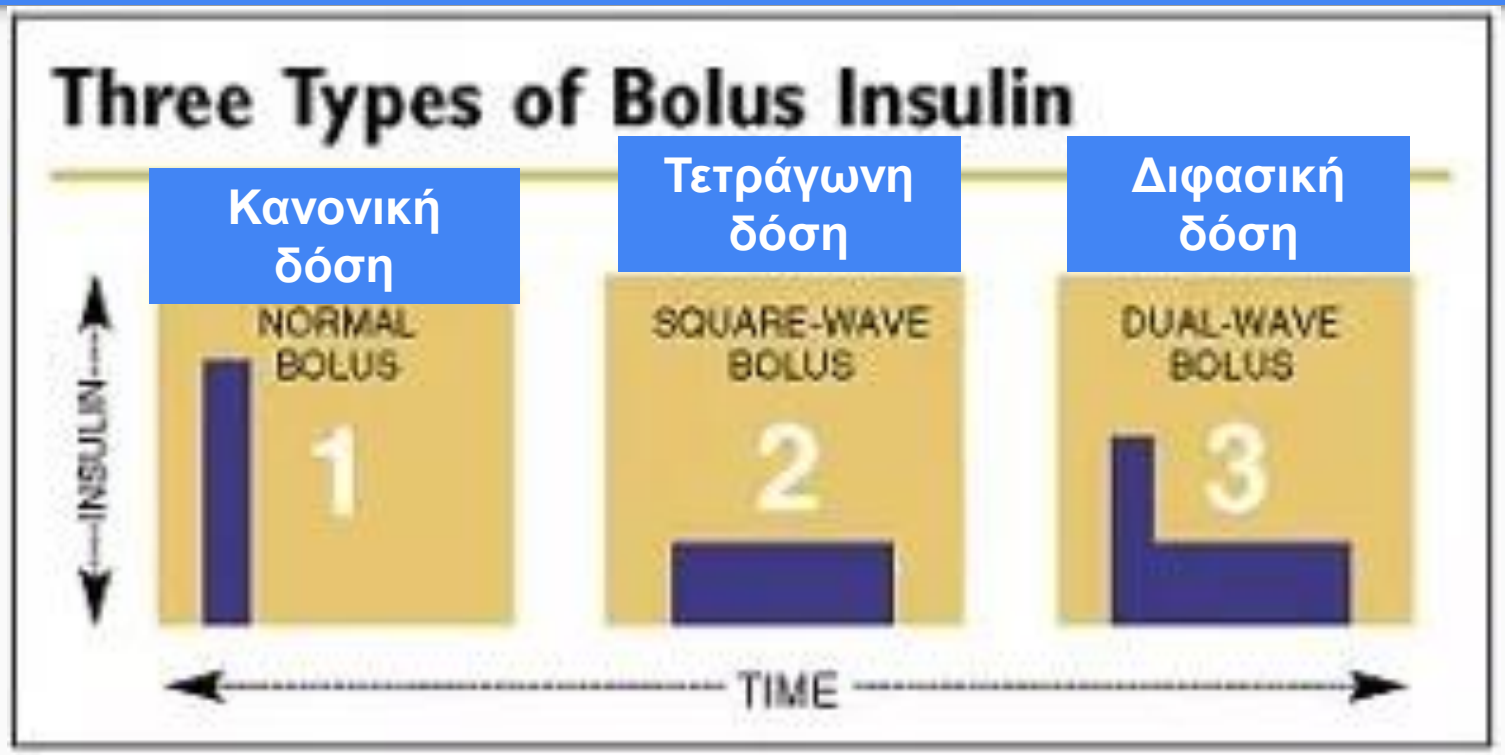
Auto Calibration	Off
Calibration Reminder	On
Calibration Reminder Time	1:05

Διαφορετικές ρυθμίσεις για διαφορετικά διαστήματα της ημέρας

Bolus calculator
Μεγάλη ακρίβεια στη χορήγηση του bolus (έως 0,025 ή 0,05 units)

➢ Ενεργός ινσουλίνη (Insulin on board, IOB)

Χορήγηση γευματικής ινσουλίνης με αντλία



- Υψηλή περιεκτικότητα σε πρωτεΐνη/λίπος
- Μεγάλα γεύματα
- Γαστροπάρεση

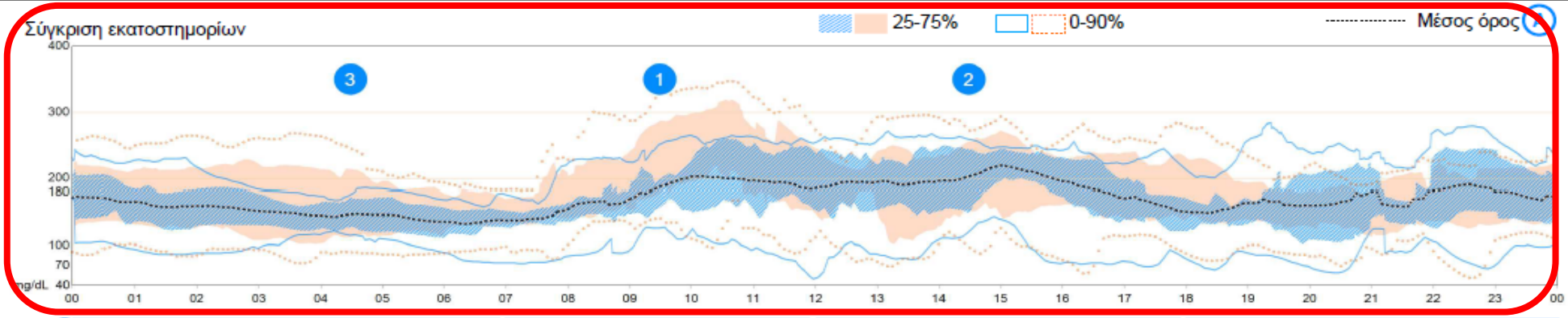
Insulin Pump Report

AGP report

Medtronic

Αξιολόγηση και πρόοδος
Α 18.06.2022 - 01.07.2022 (14 Ημέρες)
Β 04.06.2022 - 17.06.2022 (14 Ημέρες)

Δημιουργήθηκε: 01.07.2022, 09:23 **Σελίδα 1 από 22**
Πηγές δεδομένων: MiniMed 640G, MMT-1512/1712 (NG2225227H)



Αναλ. υδ/κων (g/U) *				
Α	12.0	10.0	9.0	9.0
Β	12.0	10.0	9.0	9.0

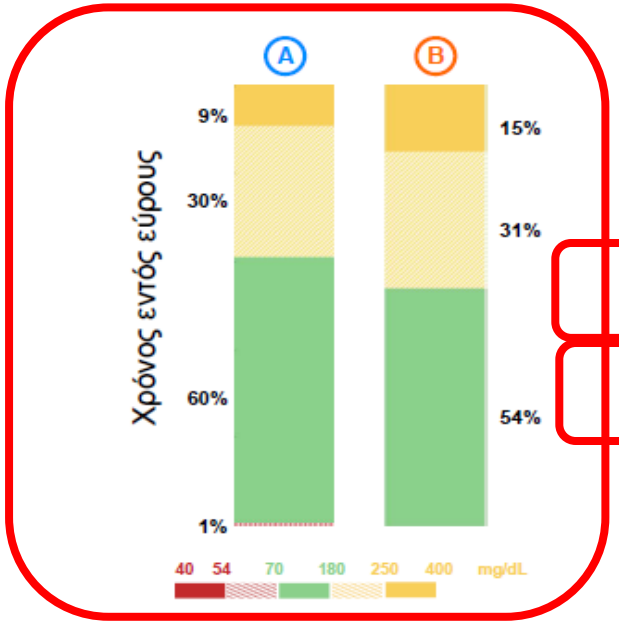
Α

Πρότυπα υπογλυκαιμίας (0) — Αρ. επεισοδίων (ανά ημ.): 0.1

Καμία

Πρότυπα υπεργλυκαιμίας (10)** — Αρ. επεισοδίων (ανά ημ.): 2.7

1 09:00 - 09:59 (6 συμβάντα)
2 14:00 - 14:59 (5 συμβάντα)
3 04:00 - 04:59 (3 συμβάντα)

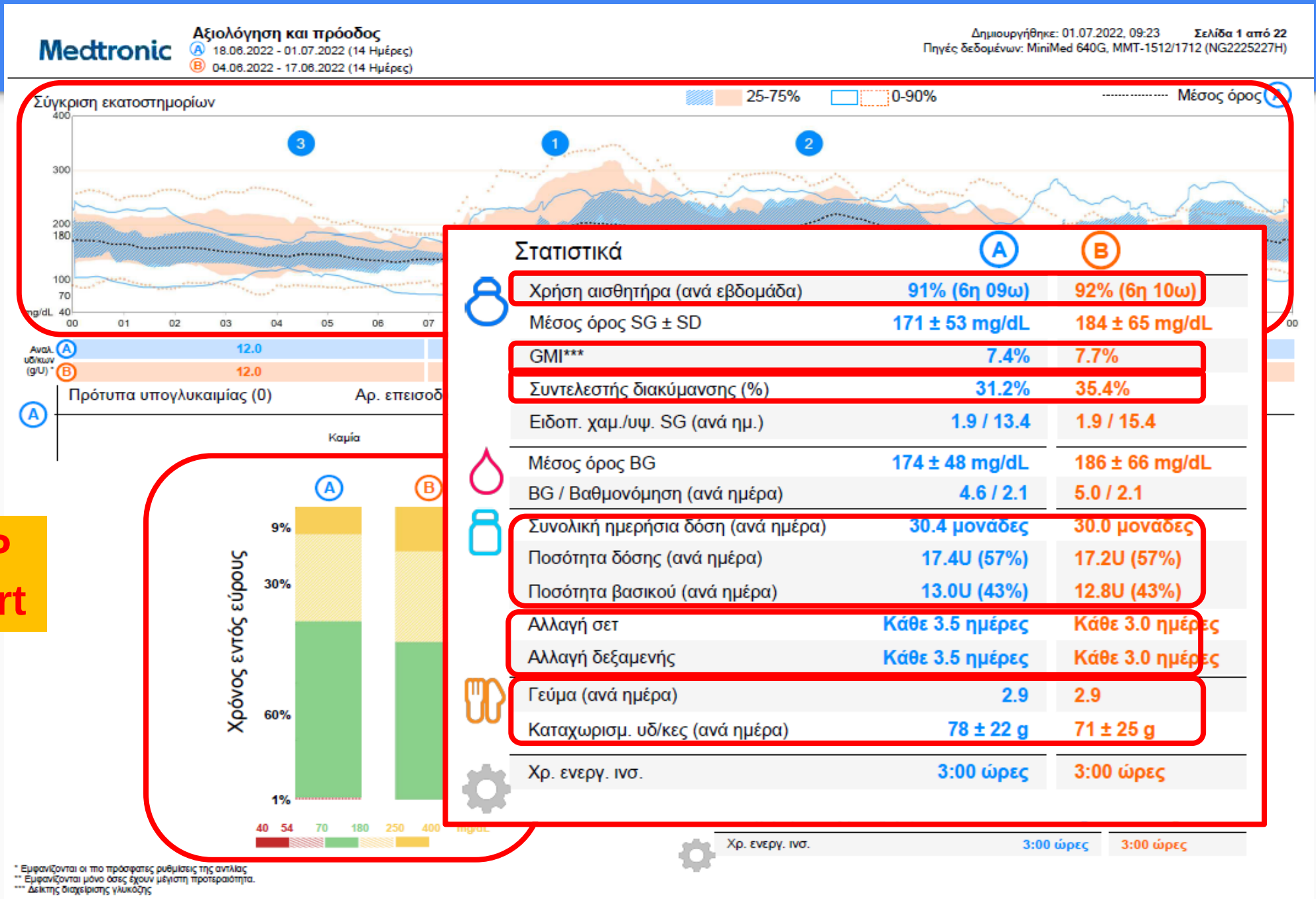


Στατιστικά	Α	Β
Χρήση αισθητήρα (ανά εβδομάδα)	91% (6η 09ω)	92% (6η 10ω)
Μέσος όρος SG ± SD	171 ± 53 mg/dL	184 ± 65 mg/dL
GMI***	7.4%	7.7%
Συντελεστής διακύμανσης (%)	31.2%	35.4%
Ειδοπ. χαμ./υψ. SG (ανά ημ.)	1.9 / 13.4	1.9 / 15.4
Μέσος όρος BG	174 ± 48 mg/dL	186 ± 66 mg/dL
BG / Βαθμονόμηση (ανά ημέρα)	4.6 / 2.1	5.0 / 2.1
Συνολική ημερήσια δόση (ανά ημέρα)	30.4 μονάδες	30.0 μονάδες
Ποσότητα δόσης (ανά ημέρα)	17.4U (57%)	17.2U (57%)
Ποσότητα βασικού (ανά ημέρα)	13.0U (43%)	12.8U (43%)
Αλλαγή σετ	Κάθε 3.5 ημέρες	Κάθε 3.0 ημέρες
Αλλαγή δεξαμενής	Κάθε 3.5 ημέρες	Κάθε 3.0 ημέρες
Γεύμα (ανά ημέρα)	2.9	2.9
Καταχωρισμ. υδ/κες (ανά ημέρα)	78 ± 22 g	71 ± 25 g
Χρ. ενεργ. ινσ.	3:00 ώρες	3:00 ώρες

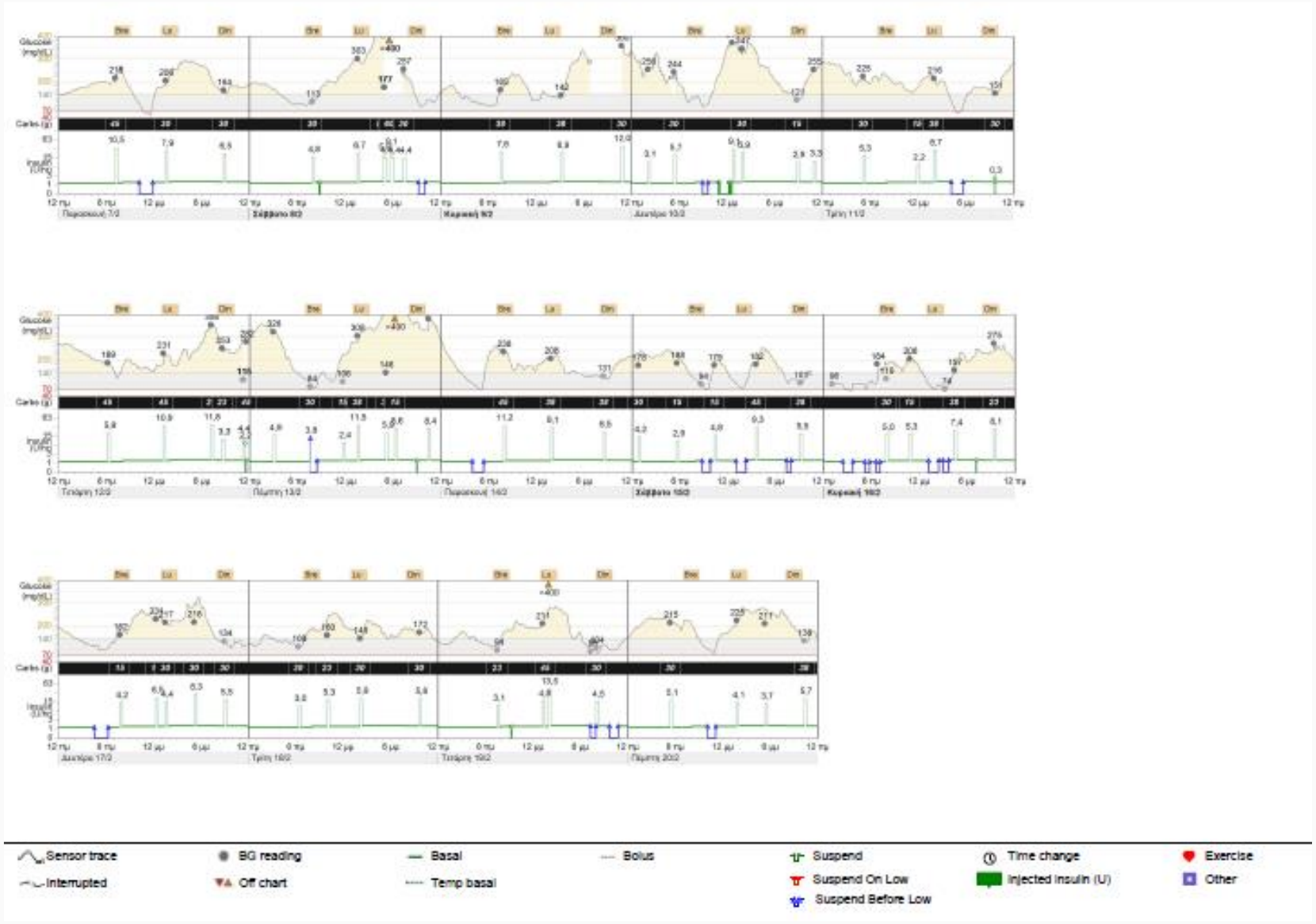
* Εμφανίζονται οι πιο πρόσφατες ρυθμίσεις της αντλίας
** Εμφανίζονται μόνο όσες έχουν μέγιστη προτεραιότητα.
*** Δείκτης διαχείρισης γλυκόζης

Insulin Pump Report

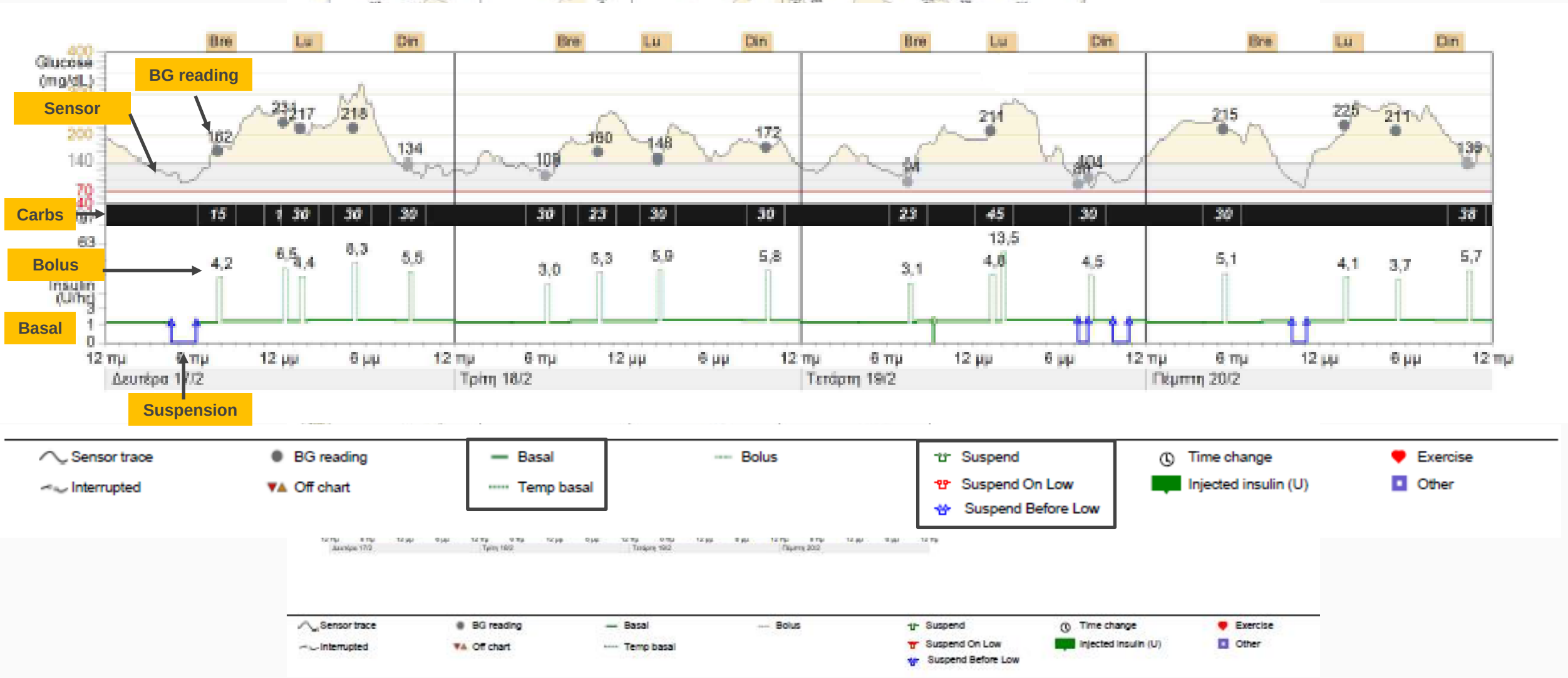
AGP report



Insulin Pump Report
Γλυκαιμική διακύμανση – Ημέρα με ημέρα



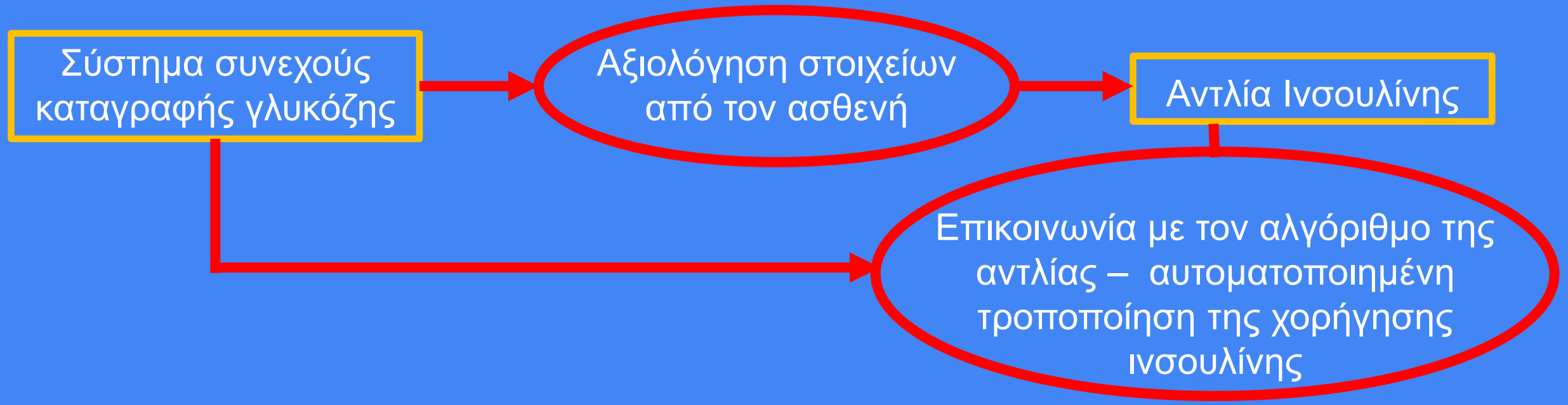
Insulin Pump Report
Γλυκαιμική διακύμανση – Ημέρα με ημέρα



Sensor augmented pump (SAP)

SAP + Predictive Low Glucose Management (PLGM)

Sensor-Augmented Pump (SAP)



Sensor-Augmented Pump (SAP) με Predictive Low Glucose Suspension (PLGS)

Sensor-Augmented Pump (SAP)

CSII → SAP

- > 1 επεισόδια σοβαρής υπογλυκαιμίας το έτος χωρίς εμφανές αντιμετωπίσιμο αίτιο
- Πλήρη απώλεια επίγνωσης της υπογλυκαιμίας
- Συχνή υπογλυκαιμία (≥ 2 επεισόδια την εβδομάδα) που δημιουργεί προβλήματα στην καθημερινή δραστηριότητα
- Εντονος φόβος υπογλυκαιμίας
- Κακή γλυκαιμική ρύθμιση (HbA1c ≥ 9%] παρά τη συχνή μέτρηση τριχοειδικού σαγχάρου

NICE, National Institute for Health and Care Excellence
nice.org.uk/guidance/ng17

Sensor-Augmented Pump (SAP)

Sensor-Augmented Pump (SAP)
Predictive Low Glucose Suspension (PLGS)

Medronic
Minimed 640G
Insulin Pump

INSULIN DELIVERY
Medtronic offers a wide range of infusion sets so that you can choose the right infusion set for your comfort and safety.

actual size

CONTINUOUS GLUCOSE MONITORING
The Enlite™ sensor provides a reliable[2] CGM experience for you.[3]

THERAPY MANAGEMENT TOOLS
CareLink™ Pro software includes insightful trend reports and therapy considerations to help you make informed treatment decisions for you.

BLOOD GLUCOSE TESTING
Contour™Next LINK 2.4 meter links wirelessly to MiniMed 640G and provides proven[4,5] testing accuracy and discreet remote bolusing.

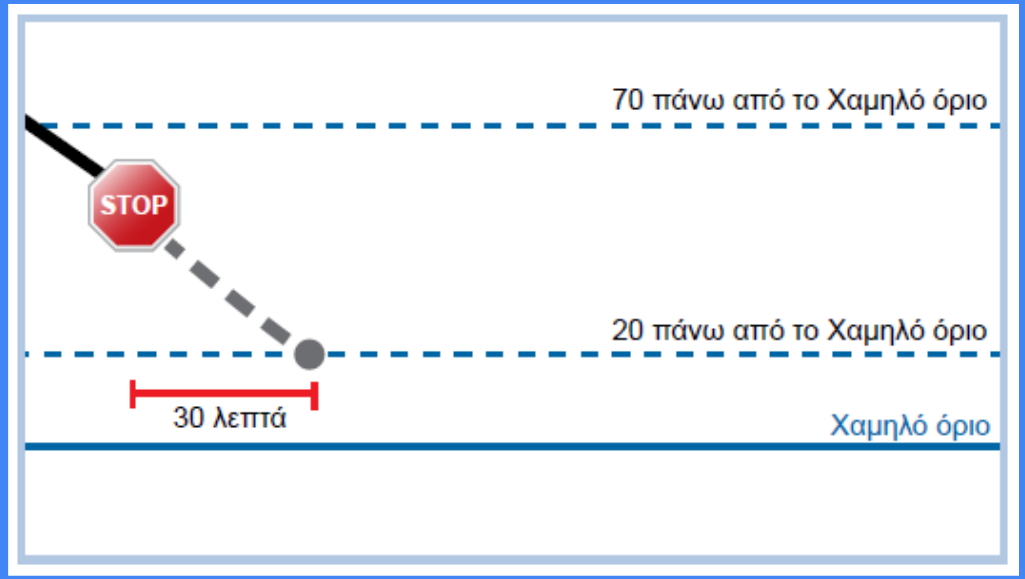
Predictive Low Glucose Suspension (PLGS)

Medronic 640G

Λειτουργία SmartGuard

Ορισμός χαμηλού ορίου (50-90 mg/dL)

Αναστολή χορήγησης ινσουλίνης
- προ χαμηλού ορίου
  Predictive Low Glucose Suspension (PLGS)
- στο χαμηλό όριο



MiniMed™ 640G Οδηγός χρήσης συστήματος

Predictive Low Glucose Suspension (PLGS)

Αναστολή:

τιμή εντός 70mg/dL πάνω από το χαμηλό όριο

προβλεπόμενη τιμή → κάτω από 20mg/dL πάνω από το χαμηλό όριο εντός 30 min ┐ απαιτούνται και τα δύο

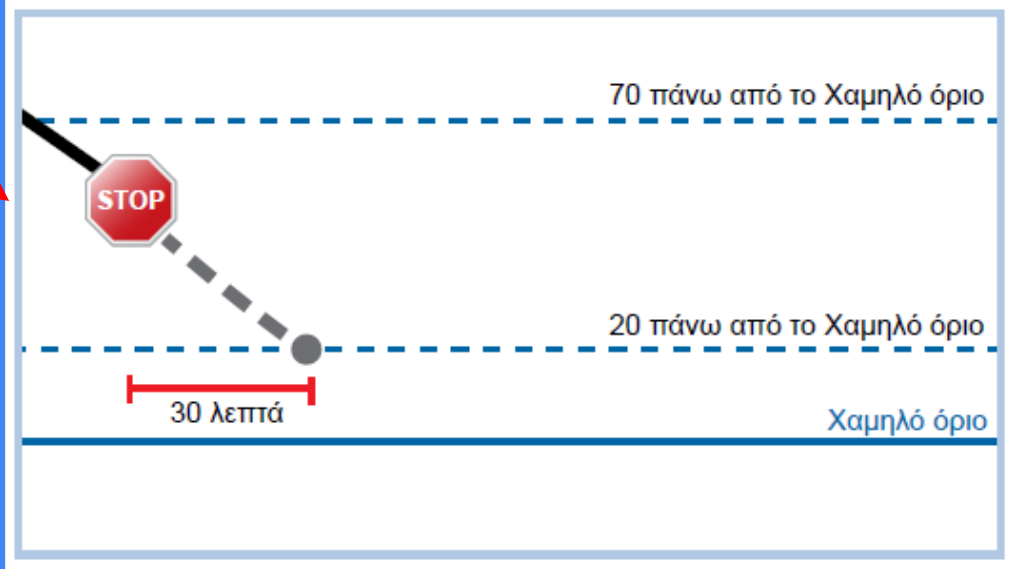
Επανέναρξη:

άνοδος σε τιμή τουλάχιστον 20mg/dL πάνω από το χαμηλό όριο

προβλεπόμενη τιμή → πάνω από 40mg/dL πάνω από το χαμηλό όριο εντός 30 min ┐ απαιτούνται και τα δύο

Μέγιστη διάρκεια αναστολής 2h

nsion (PLGS)



Predictive Low Glucose Suspension (PLGS)

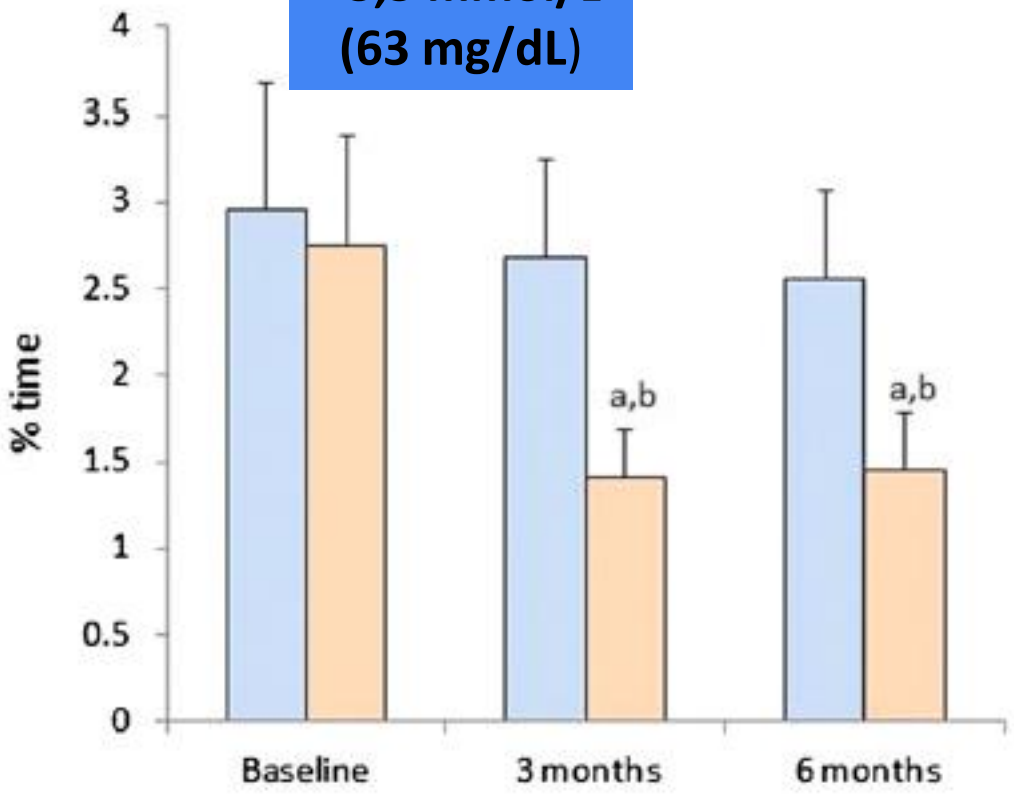
Predictive Low Glucose Suspension (PLGS)

SAP PLGS (+) vs SAP PLGS (-)

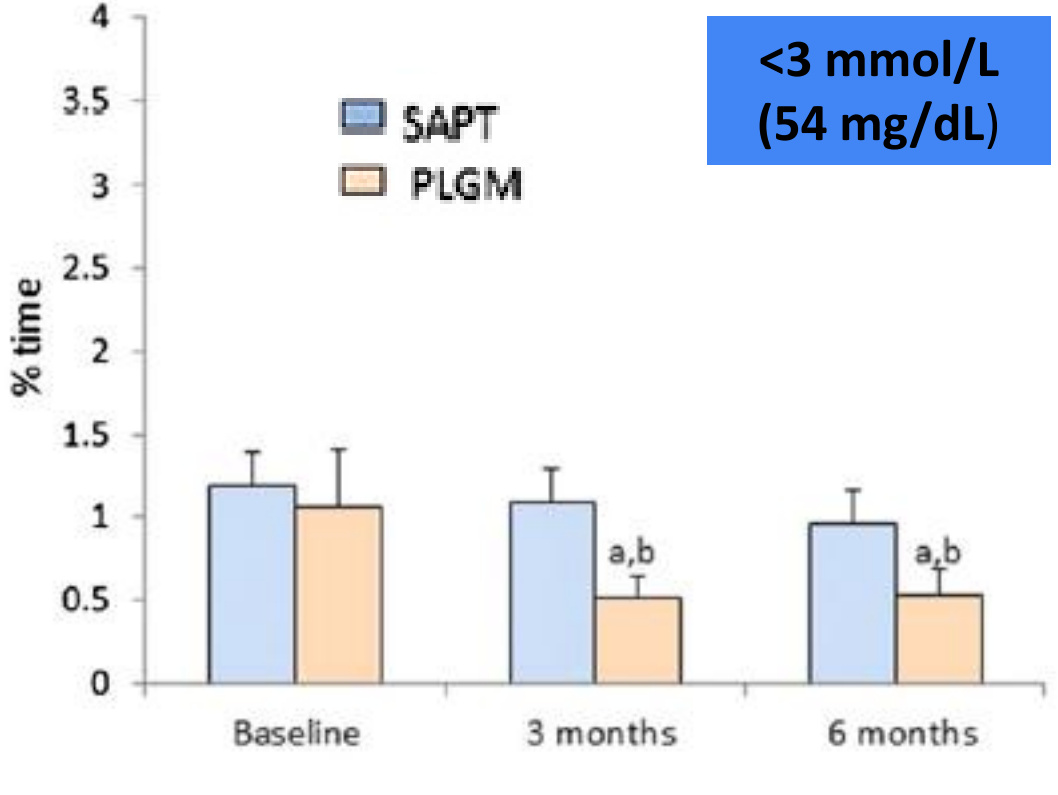
Minimed 640G

PLGS → Μείωση υπογλυκαιμίας κατά ~50%

<3,5 mmol/L (63 mg/dL)



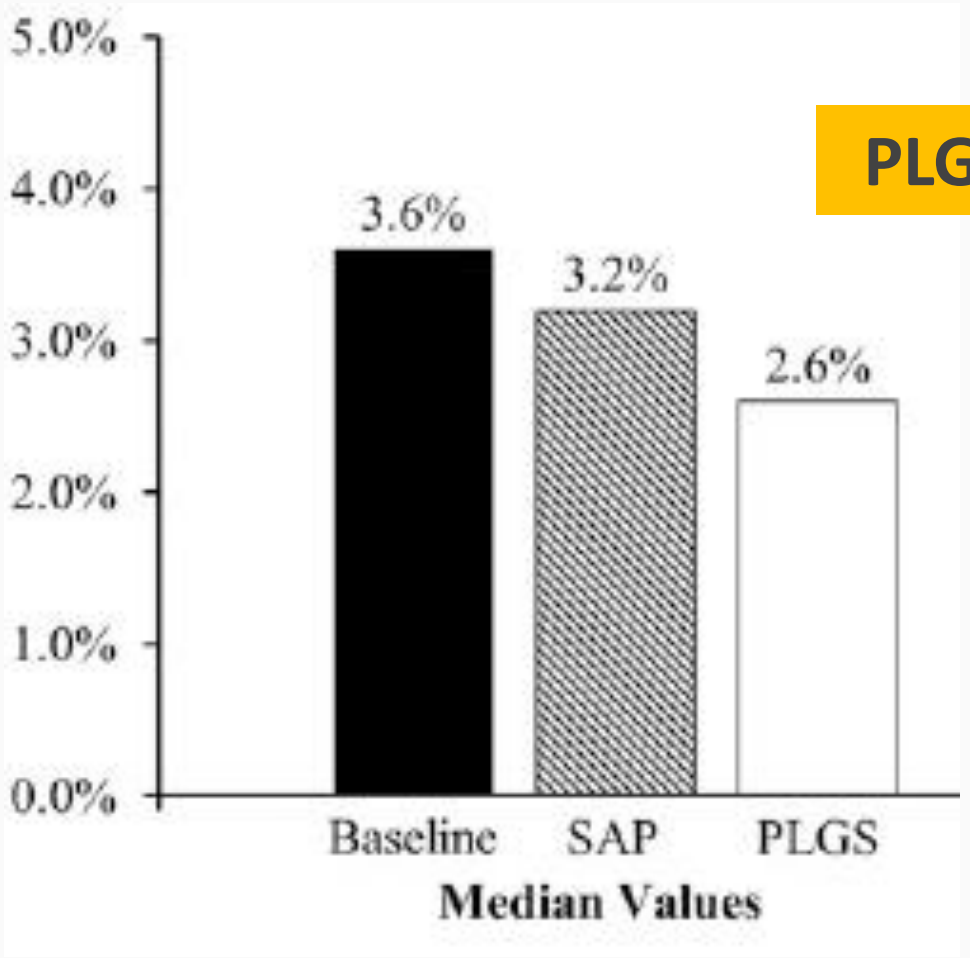
<3 mmol/L (54 mg/dL)



Abraham et al Diabetes Care. 2018 Feb;41(2):303

Predictive Low Glucose Suspension (PLGS)

Tandem Diabetes Care t:slim X2 with Basal-IQ Technology (Tandem Diabetes Care) - Dexcom G5



SAP PLGS (+) vs SAP PLGS (-)

PLGS → Μείωση υπογλυκαιμίας κατά ~30%

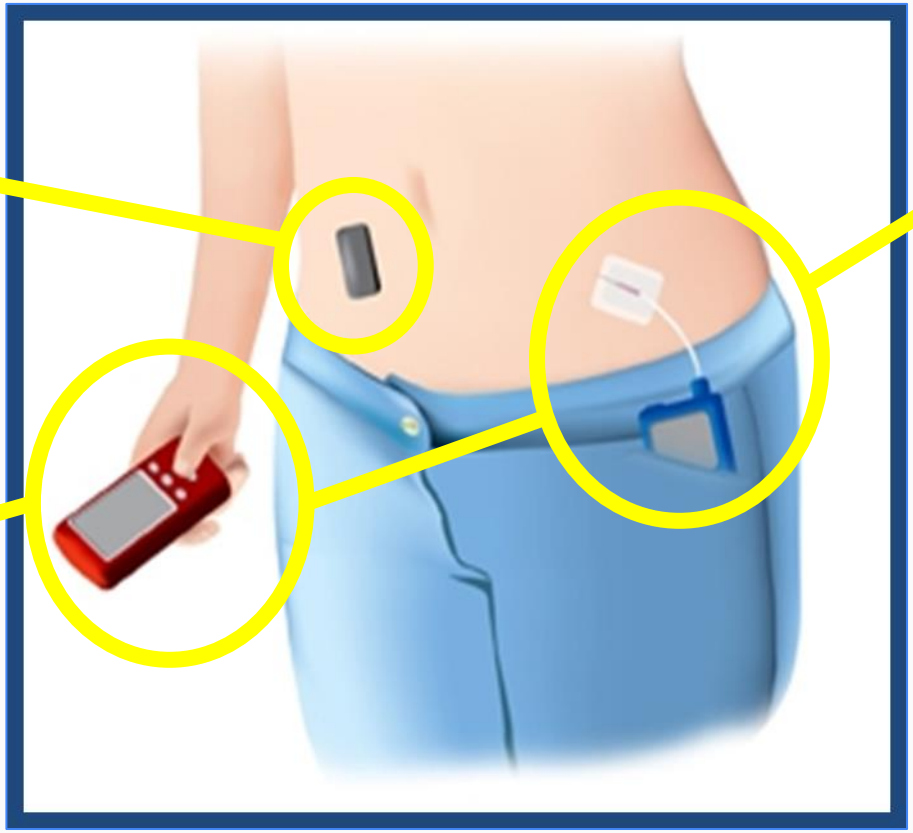
- **Στην ομάδα με αυξημένη baseline συχνότητα υπογλυκαιμίας**

PLGS → Μείωση υπογλυκαιμίας κατά ~50%

Forlenza et al Diabetes Care. 2018 Oct;41(10):2155

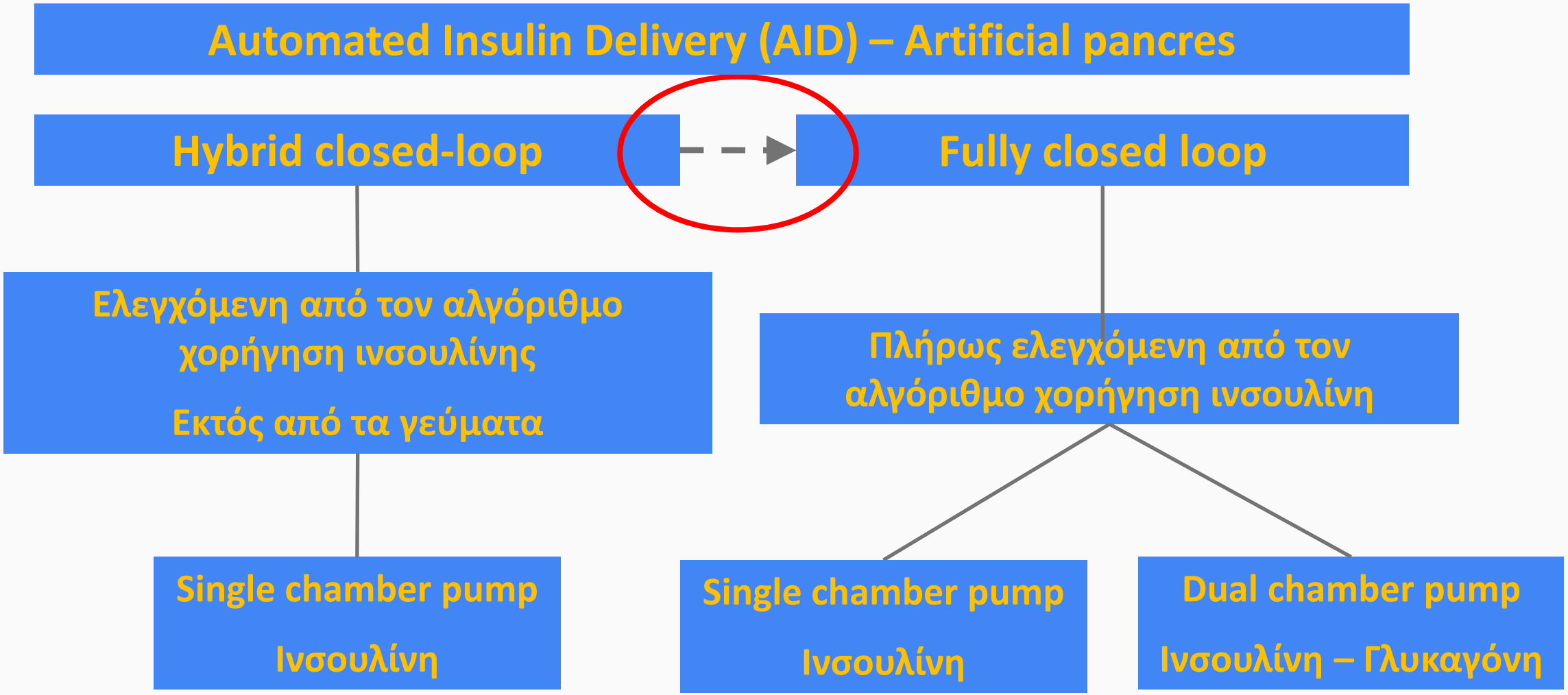
Closed loop CSII

Συστήματα συνεχούς έγχυσης ινσουλίνης κλειστού κυκλώματος (closed-loop insulin delivery systems)



- Παρακολούθηση και πρόβλεψη των μεταβολών των επιπέδων γλυκόζης
- Αυτόνομη σταδιακή προσαρμογή του ρυθμού χορήγησης ινσουλίνης με στόχο τη διατήρηση των επιπέδων γλυκόζης σε προκαθορισμένο στόχο

Συστήματα συνεχούς έγχυσης ινσουλίνης κλειστού κυκλώματος (closed-loop insulin delivery systems)



Hood and Hovorka Diabetologia (2016) 59:1795
Bally et al BMC Medicine (2017) 15

Battelino et al Best Pract Res Clin Endocrinol Metab. 2015 Jun;29(3):315
Castle et al Diabetes Technol Ther. 2017 Jun;19(S3):S67

Συστήματα συνεχούς έγχυσης ινσουλίνης κλειστού κυκλώματος (closed-loop insulin delivery systems)

Τα συστήματα συνεχούς έγχυσης ινσουλίνης κλειστού κυκλώματος καλούνται να απαντήσουν στην ανάγκη διαρκούς προσαρμογής της ινσουλίνης στα διαρκώς μεταβαλλόμενα επίπεδα Σχ
(stress, φυσική δραστηριότητα / άσκηση, διαφορετικό μεταβολικό-ορμονικό περιβάλλον, …… άγνωστοι παράγοντες)

Προσομοίωση λειτουργίας β-κυττάρου

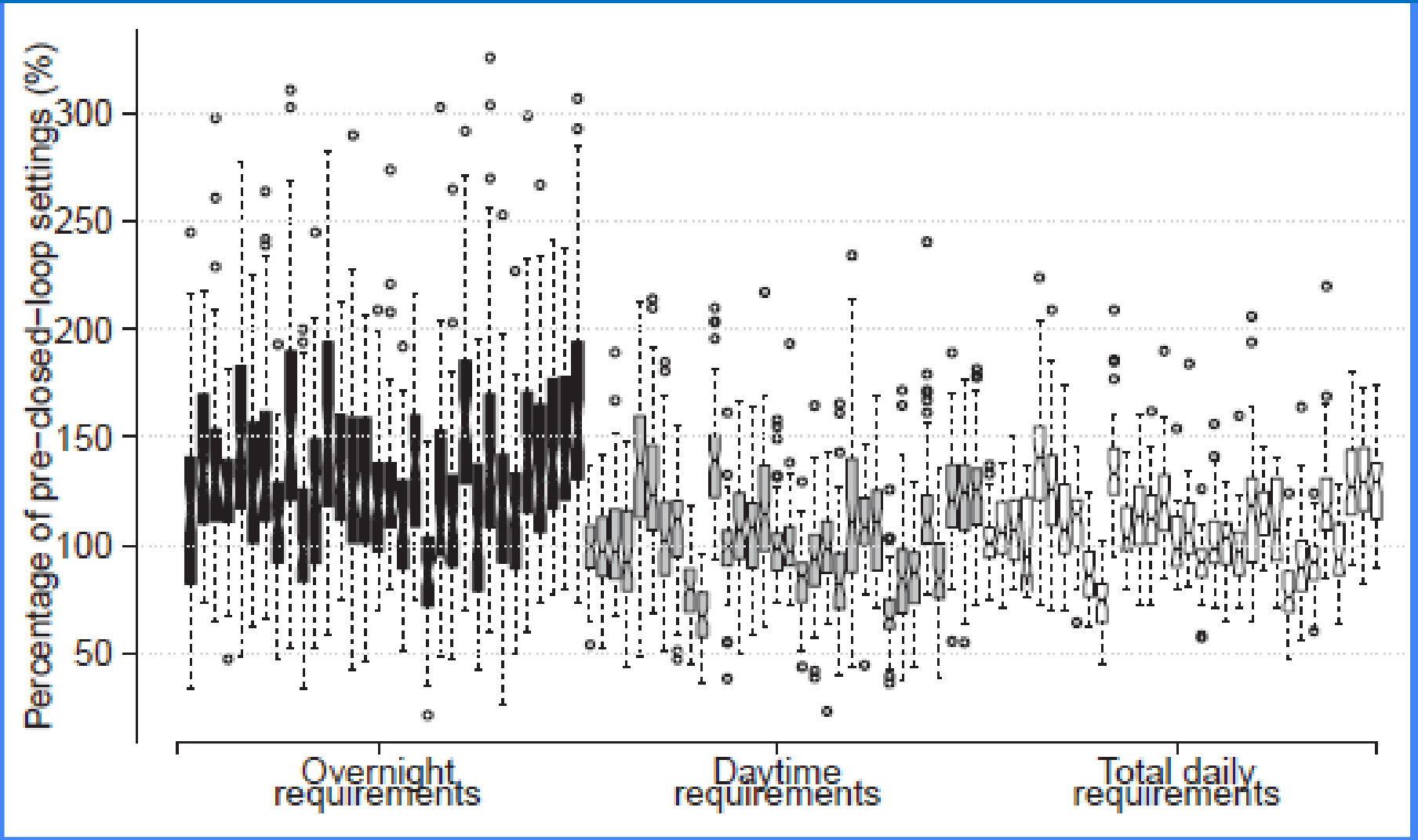
β-κύτταρο

Συνεχής αίσθηση (sensing) επιπέδων γλυκόζης από το β-κύτταρο → **Τροποποίηση έκκρισης ινσουλίνης**

Closed-loop pump

Συνεχής καταγραφή επιπέδων γλυκόζης από τον αισθητήρα (CGM) → **Αλγόριθμος αντλίας ινσουλίνης** → **Αυτόματη τροποποίηση έκκρισης ινσουλίνης**

Μεταβλητότητα αναγκών σε ινσουλίνη



Ανάλυση δεδομένων ασθενών σε closed-loop αντλία
Διπλάσια μεταβλητότητα κατά τη διάρκεια της νύχτας

Ryan et al Diabetes Care. 2016 May;39(5):830

Αντλίες κλειστού κυκλώματος
Εξέλιξη κλινικών μελετών

- Ασφάλεια
- Βελτίωση γλυκαιμικού ελέγχου
  - ↑ χρόνου εντός στόχου
  - ↓ υπογλυκαιμίας
  - ↓ υπεργλυκαιμίας

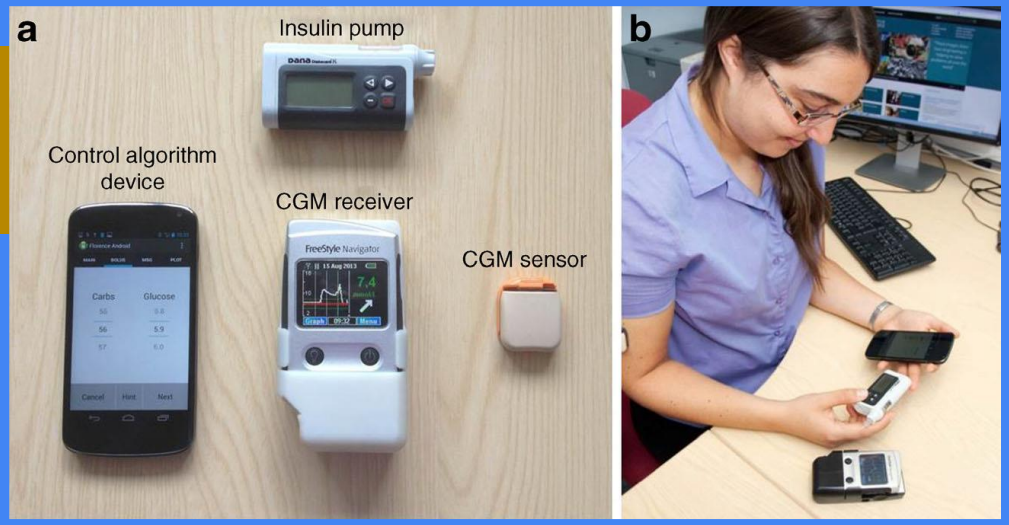
Μικρές μελέτες

Ελεγχόμενο ερευνητικό περιβάλλον

Περιβάλλον υπό επίβλεψη (ξενώνες κα)

Ελεύθερη διαβίωση στο σπίτι

Μεγάλες πολυκεντρικές τυχαιοποιημένες μελέτες



Hovorka et al BMJ. 2011;342:d1855

Del Favero et al Diabetes Obes Metab. 2015;17:468
Battelino et al N Engl J Med. 2013;368:824

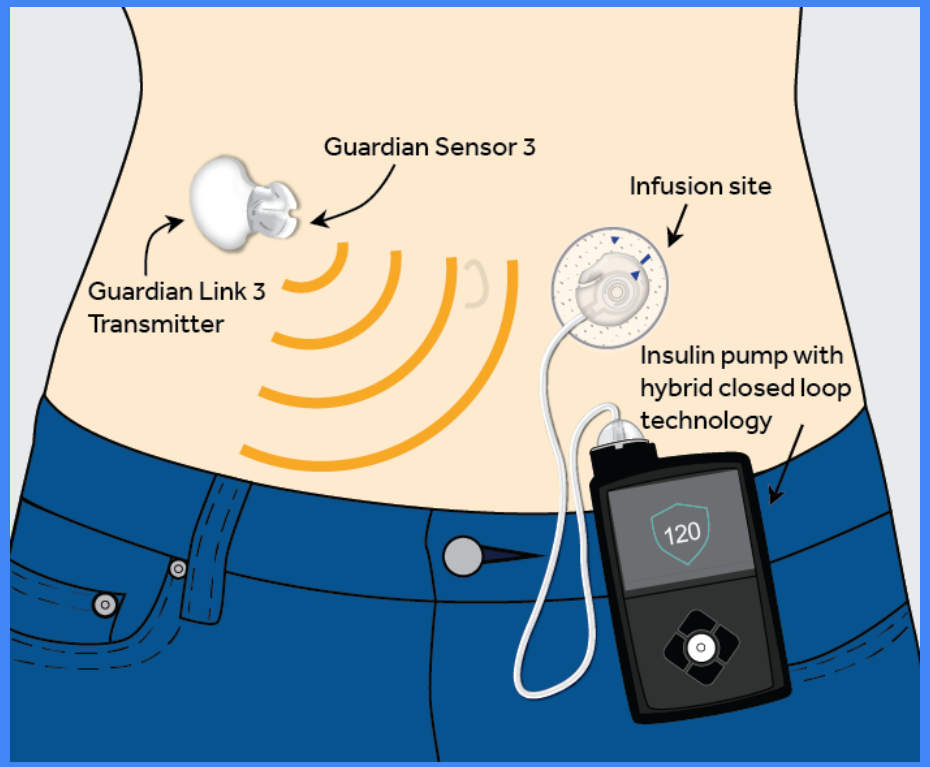
Thabit et al N Engl J Med. 2015;373:2129–40.
Kropff et al Lancet Diabetes Endocrinol. 2015;3:939

Hybrid closed-loop
Minimed 670G

≥14 ετών

FDA News Release September 28, 2016

FDA approves first automated insulin delivery device for type 1 diabetes



7-13 ετών

FDA News Release June 21, 2018

FDA approves automated insulin delivery and monitoring system for use in younger pediatric patients

ΣΥΣΤΗΜΑ MINIMEDTM 780G ΜΕ ΤΕΧΝΟΛΟΓΙΑ SMARTGUARDTM

ΠΡΟΣΑΡΜΟΖΕΙ & ΔΙΟΡΘΩΝΕΙ ΤΑ ΕΠΙΠΕΔΑ ΓΛΥΚΟΖΗΣ, ΚΑΘΕ 5 ΛΕΠΤΑ

Guardian 3 sensor
- requires calibrations (2-4/day)
- adjuncti

Guardian 4 sensor
- ➢ no calibrations

Δυνατότητα αυτόματων διορθωτικών bolus έως και κάθε 5 min

IG/DL

ψηλότερα όρια

Ο χρήστης [illegible] αλλά **όχι correction factor**

ΠΡΟΣΦΕΡΕΙ ΣΥΝΔΕΣΙΜΟΤΗΤΑ & ΑΝΑΒΑΘΜΙΣΕΙΣ

Οι ασθενείς μπορούν να ελέγχουν τα επίπεδα γλυκόζης & να λαμβάνουν ενημερώσεις στο κινητό, να επικοινωνούν τα αποτελέσματά τους με τον φροντιστή υγείας και να έχουν πρόσβαση σε μελλοντικές αναβαθμίσεις του λογισμικού.

Minimed 780G

Ρυθμίσεις	Γιατρός	Αλγόριθμος
Auto Basal		V
Αναλογία Υδατανθράκων	V	
Συντελεστής Ευαισθησίας		V
Χρόνος Ενεργής Ινσουλίνης	2-4h 2-3 hours[1] V	
Στόχος Auto Basal	100-110-120 100 mg/dL[1] Προσωρινός στόχος 150 mg/dL (άσκηση κλπ)	
Auto Correction		V έως και κάθε 5 min

Medronic 780G

Randomized cross-over
n=59 patients
AHCL (Advanced Hybrid Closed-Loop) vs **SAP + PLGM** (predictive low glucose management)
Designed to show 8% TIR increase and less than 2% time in hypoglycemia

30 days AHCL + 30 days PLGM

Improved Glycemic Outcomes With Medtronic MiniMed Advanced Hybrid Closed-Loop Delivery: Results From a Randomized Crossover Trial Comparing Automated Insulin Delivery With Predictive Low Glucose Suspend in People With Type 1 Diabetes

Olivia J. Collyns,[1] Renee A. Meier,[2] Zara L. Betts,[2] Denis S.H. Chan,[3] Chris Frampton,[4] Carla M. Frewen,[5] Niranjala M. Hewapathirana,[1] Shirley D. Jones,[5] Anirban Roy,[6] Benyamin Grosman,[6] Natalie Kurtz,[6] John Shin,[6] Robert A. Vigersky,[6] Benjamin J. Wheeler,[3,5] and Martin I. de Bock[1,4]

Diabetes Care 2021;44:969–975 | https://doi.org/10.2337/dc20-2250

Mean	23 years old
7-13 years	19 pts
14-21 years	14 pts
21+ years	26 pts
Baseline Time in Range	**59%** *Poorly controlled*

Medronic 780G

Table 2—Glycemic outcomes

Category*	Run-in	PLGM	AHCL 5.6 mmol/L	AHCL total	Σύνολο % change AHCL vs. PLGM	Σύνολο *P* value§	7–13 ετών % change AHCL vs. PLGM	7–13 ετών *P* value§	14–21 ετών % change AHCL vs. PLGM	14–21 ετών *P* value§	22–80 ετών % change AHCL vs. PLGM	22–80 ετών *P* value§
Subjects, *n*	59	59	52	59	59		19		14		26	
Average SG mmol/L overall	9.3 ± 0.9 (9.2)	9.5 ± 1.1 (9.4)	8.3 ± 0.7 (8.1)	8.5 ± 0.7 (8.4)	−0.6 ± 0.4 (−0.6)†	<0.001	−0.5 ± 0.4 (−0.6)†	<0.001	−0.7 ± 0.4 (−0.7)†	<0.001	−0.5 ± 0.5 (−0.5)†	<0.001
70-180	59.0 ± 10.4 (60.8)	57.9 ± 11.7 (58.4)	72.0 ± 7.9 (71.9)	70.4 ± 8.1 (70.8)	↑ 12,5%	<0.001	↑ 11,8%	<0.001	↑ 14,4%	<0.001	↑ 11,9%	<0.001
70-180 ημέρα	± 11.0 .9)	56.5 ± 12.2 (56.4)	68.7 ± 10.0 (69.5)	66.8 ± 9.9 (65.7)	↑ 10,4%	<0.001	↑ 7,9%	<0.001	↑ 14,1%	<0.001	↑ 10,1%	<0.001
70-180 νύχτα	± 14.7 3.5)	62.0 ± 15.0 (64.9)	81.9 ± 10.6 (82.3)	80.8 ± 10.4 (81.5)	↑ 18,8%	<0.001	↑ 23,6%	<0.001	↑ 15,1%	<0.001	↑ 17,2%	<0.001
>180	37.9 ± 10.6 (37.7)	39.6 ± 12.1 (39.2)	25.8 ± 8.2 (24.4)	27.5 ± 8.1 (27.7)	↓ 12,1%	<0.001	↓ 11,2%	<0.001	↓ 14%	<0.001	↓ 11,8%	<0.001
<70	0.5 ± 0.6 (0.3)	0.5 ± 0.5 (0.3)	0.4 ± 0.4 (0.3)	0.5 ± 0.5 (0.4)	↓ 0,1%	0.025	↓ 0,2%	0.0676	↓ 0,1%	0.2441	↔	0.5462
<54	3.1 ± 2.1 (2.7)	2.5 ± 1.6 (2.2)	2.2 ± 1.6 (1.9)	2.1 ± 1.4 (1.9)	↓ 0,4%	0.0318	↓ 0,7%	0.1216	↓ 0,4%	0.1804	0,1%	0.5184

*Results presented as mean ± SD (median). †SG % change is expressed as relative % reduction (% − %)/%) comparing overall value in AHCL. ‡TIR differences are expressed as absolute difference (% − %). §Analyses using paired *t* test.

Collyns et al Diabetes Care. 2021 Apr;44(4):969

Medronic 780G

AHCL vs SAP + PLGM

Πρωτεύον καταληκτικό σημείο	**Time in Range**	**↑ 12,5%**	**p<0,001**
Δευτερεύοντα Καταληκτικά σημεία	**Time >180 mg/dL**	**↓ 12,1%**	**p<0,001**
	Time <70 mg/dL	**↓ 0,4%**	**p<0,05**

- TIR 72% χρησιμοποιώντας σαν στόχο τιμή 100 mg/dl
- Auto Mode παρέμεινε ενεργός στο 96,4% του χρόνου

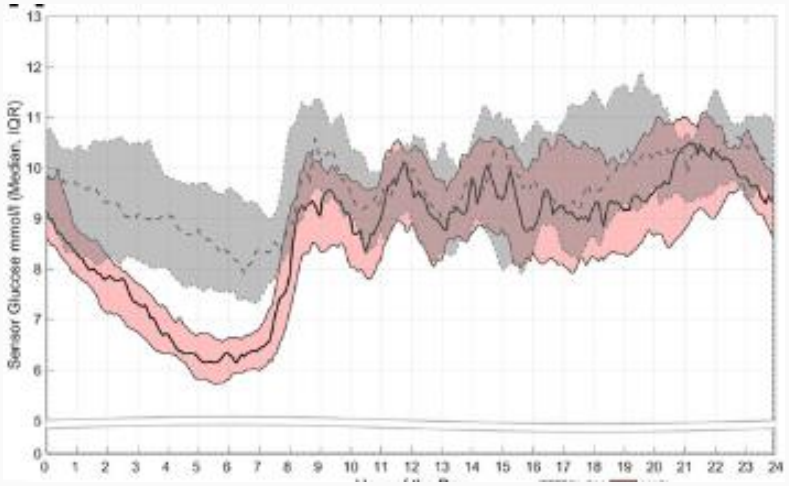
Collyns et al Diabetes Care. 2021 Apr;44(4):969

Medronic 780G

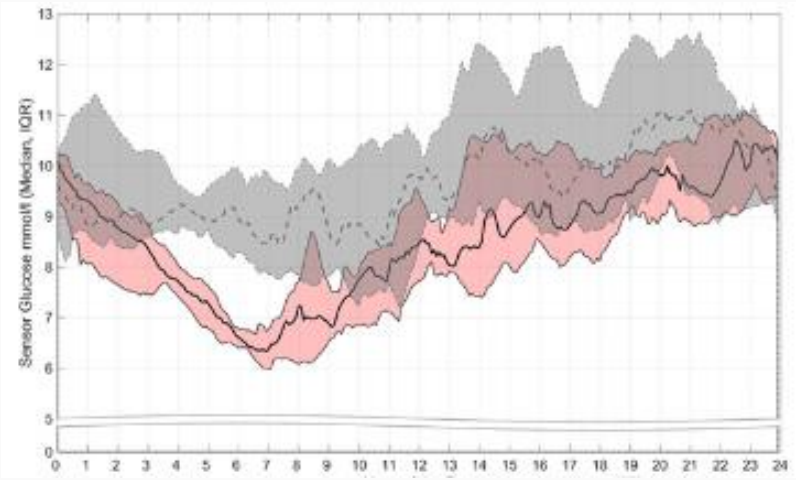
Παρόμοια αποτέλεσματα σε όλες τις ηλικιακές ομάδες

AHCL

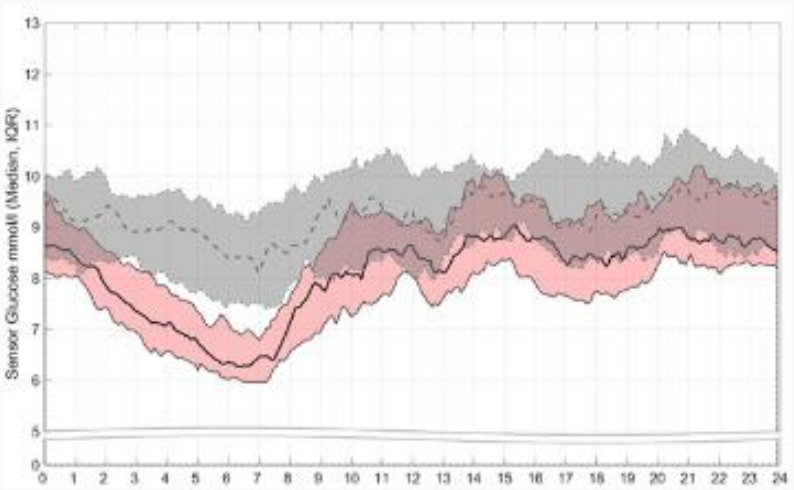
SAP + PLGM



7-13 ετών



14-21 ετών



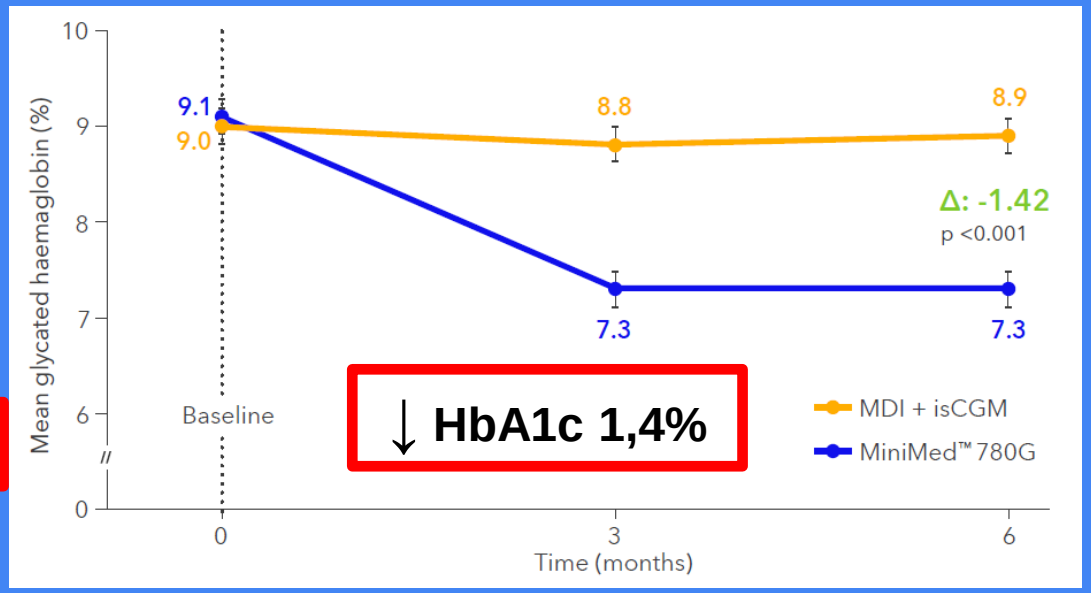
>21 ετών

Collyns et al Diabetes Care. 2021 Apr;44(4):969

Medronic 780G

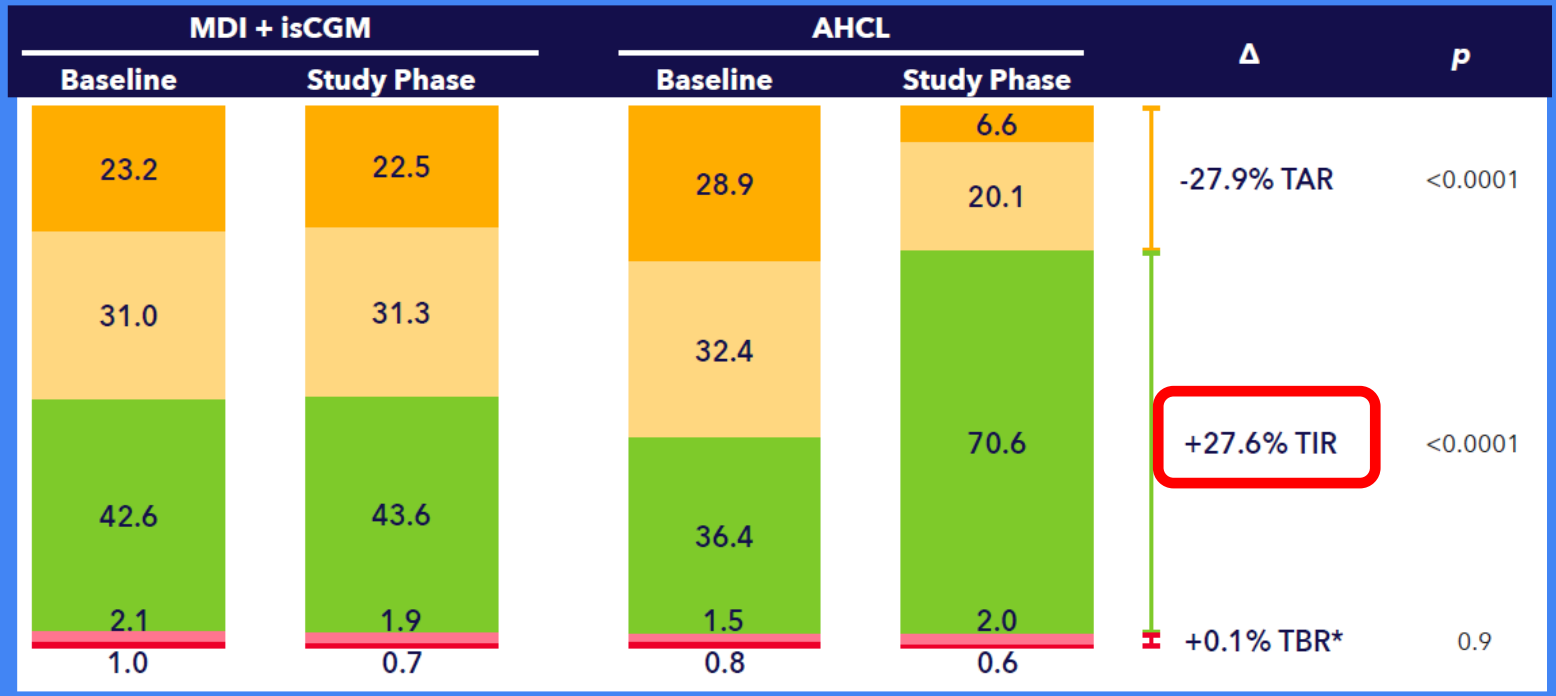
Advanced hybrid closed loop therapy versus conventional treatment in adults with type 1 diabetes (ADAPT): a randomised controlled study

AHCL (Advanced Hybrid Closed-Loop) vs **MDI + iCGM**



6 months
Randomized controlled
n=82 patients
≥18 years, with T1D duration ≥2 years,
HbA1c ≥8.0%
and using MDI+isCGM for ≥3 months

AHCL improved treatment satisfaction
decreased fear of hypoglycemia



Choudhary et al Lancet Diabetes Endocrinol 2022 Sep 1;S2213-8587(22)00212-1969

ACHIEVEMENTS
ACROSS THE DIFFERENT COUNTRIES

EASD 2021

	Overall	IT	NL	BE	SE	GB	CH	FI	CZ	PL	ZA	IE	TR	IS	GR	SK	SI
Number of users, *n*	12,870	3,584	1,830	1,163	1,031	996	745	728	712	418	417	210	194	137	132	102	100
Time in AHCL, %	92.3	91.7	93.5	94.9	93.7	91.4	92.3	93.9	87.6	92.6	89.8	93.4	93.4	92.5	95.1	84.7	93.8
Mean SG, *mg/dL*	145.1	145.2	146.4	142.9	145.9	149	145.8	150.2	139.2	134.5	148.1	147.4	137	155.4	135.1	148.1	143.5
GMI*, %	6.8	6.8	6.8	6.7	6.8	6.9	6.8	6.9	6.6	6.5	6.9	6.8	6.6	7.0	6.5	6.9	6.7
Users with GMI* <7%, %	76.4	77.2	75.2	81.3	75.4	69.1	75.0	65.2	88.3	93.5	68.8	70.5	89.7	56.9	92.4	64.7	81.0
Users with TIR >70%, %	76.0	78.2	73.5	81.3	73.4	68.9	73.8	63.6	88.2	92.3	68.6	68.1	91.2	56.2	91.7	69.6	82.0

Time in Ranges, %

Medtronic data on file: MiniMed ™ 780G data uploaded voluntarily by 12.870 users in EMEA to CareLink™ Personal, from 27 August 2020 to 22 July 2021.
Data is displayed for individual countries having at least 100 users in scope of the analysis
BE= Belgium, CH= Switzerland, CZ= Czech Republic, FI= Finland, GB= Great Britain, GR= Greece, IE= Ireland, IS= Iceland, IT= Italy, NL= Netherlands, PL= Poland, SE= Sweden, SI= Slovenia, SK= Slovakia, TR=Tukey, ZA= South Africa. *Glucose Management Indicator (GMI) based on reported mean glucose values. Calculated using JAEB https://www.jaeb.org/gmi/.

Medtronic

Medronic 780G – EASD 2021 – Real world data in Europe

diaTribe Learn
MAKING SENSE OF DIABETES

Highlights from EASD 2021

MiniMed 780G System Leads to Improvements in Glucose Levels and Time in Range

Cohort 1

Users with more than 10 days of data after initiating the MiniMed 780G (12,870 users)

- 76% of users achieved a GMI less than 7%
- 76% of users achieved a TIR greater than 70%
- 82% of users achieved a Time Below Range (TBR) (less than 70 mg/dL) of less than 4%
- 58% of users achieved all three of these metrics

Medronic 780G – EASD 2021 – Real world data in Europe

diaTribe Learn
MAKING SENSE OF DIABETES

Cohort 2

Users with more than 10 days of data both when they were on the MiniMed 780G in "open-loop" and after using it in advanced hybrid closed-loop (2,977 users)

- 75% of users achieved a GMI less than 7% when in closed loop (only 41% ac… open loop) — **41% → 75%**
- 75% of users achieved a TIR greater than 70% when in closed loop (only 36%… open loop) — **36% → 75%**
- The average sensor glucose readings decreased by 15 m/dL fr… open loop to 146 mg/dL — **161 → 146**
- Averag… GMI …decreased by 0.4 percentage points from 7.2% in op… — **7,2% → 6,8%**
- Averag… TIR …ncreased by 11.4 percentage points from 64… — **64% → 76%** …o 76%
- Averag… TBR …de… …centage points from 3.3… …8% — **3,3% → 2,8%**

TAR — **33% → 22,1%**

Medronic 780G – EASD 2021 – Real world data in Europe

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MAKING SENSE OF DIABETES

Cohort 3

Users with more than 10 days of data in each of the first six months after initiating the MiniMed 780G (2,566 users)

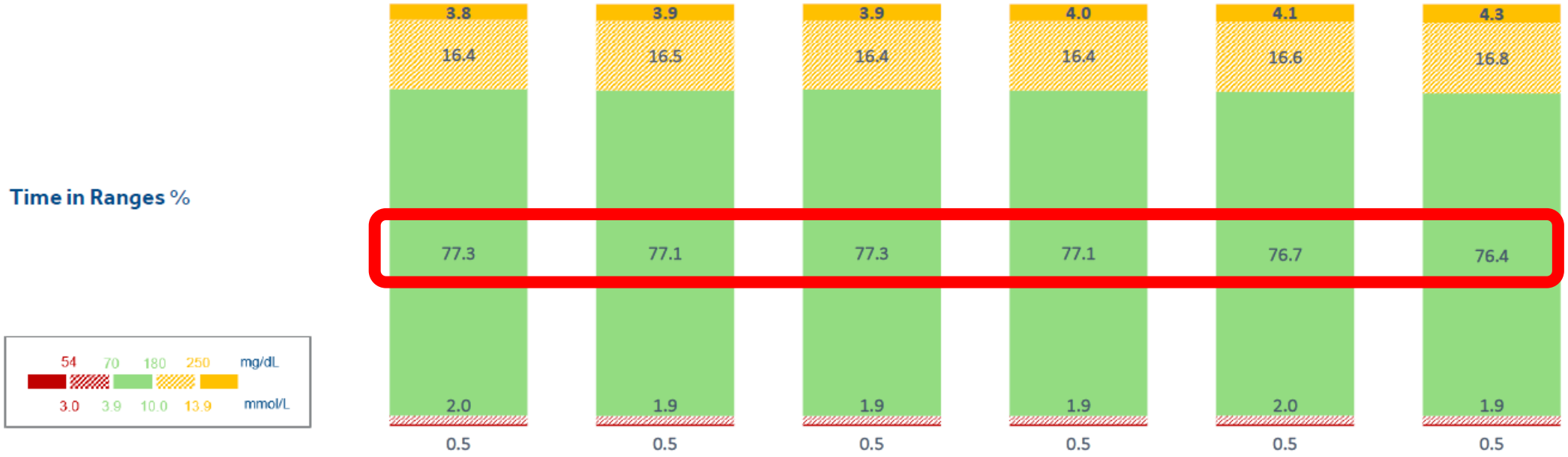
- At one month, users mean sensor glucose was 143 mg/dL, GMI was 6.7%, TIR was 77% and TBR was 3%
- These positive metrics were sustained out to six months – users mean sensor glucose was 144 mg/dL, GMI was 6.8%, TIR was 76% and TBR was 2.9%

➢ Όμοια αποτελέσματα στον 1ο και στον 6ο μήνα

IMPROVEMENTS ARE OBSERVED IN THE FIRST MONTH AFTER INITIATING AHCL AND SUSTAINED OVER 6 MONTHS

	1st Month	2nd Month	3rd Month	4th Month	5th Month	6th Month
Number of users, *n*	2,566	2,566	2,566	2,566	2,566	2,566
Time in AHCL, %	95.0	94.9	95.1	94.6	94.3	94.0
Mean SG, *mg/dL*	142.6	143.2	143.0	143.4	143.7	144.2
GMI*, %	6.7	6.7	6.7	6.7	6.7	6.8
Users with GMI* <7%, %	82.0	80.1	80.9	80.1	78.2	76.5
Users with TIR >70%, %	80.2	78.9	79.6	79.4	77.7	76.3

Time in Ranges %

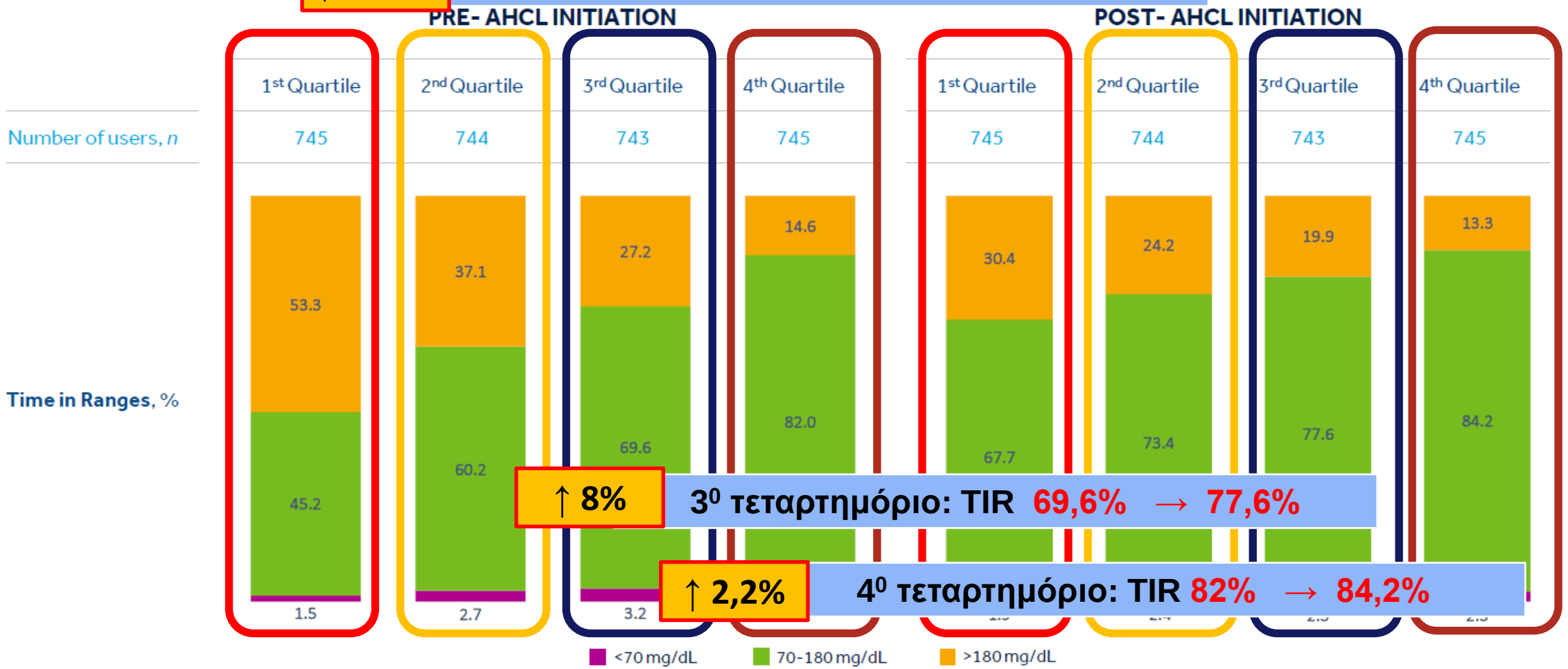


Medtronic data on file: MiniMed ™ 780G data uploaded voluntarily by 12.870 users in EMEA to CareLink™ Personal, from 27 August 2020 to 22 July 2021.
*Glucose Management Indicator (GMI) based on reported mean glucose values. Calculated using JAEB https://www.jaeb.org/gmi/.

USERS W… THE HIGHEST TIR
USERS W… E BEST IMPROVEMENT

↑ 22,5% | 1⁰ τεταρτημόριο: TIR 45,2% → 67,7%

↑ 13,2% | 2⁰ τεταρτημόριο: TIR 60,2% → 73,4%



↑ 8% | 3⁰ τεταρτημόριο: TIR 69,6% → 77,6%

↑ 2,2% | 4⁰ τεταρτημόριο: TIR 82% → 84,2%

Medtronic data on file: MiniMed ™ 780G data uploaded voluntarily by 12.870 users in EMEA to CareLink™ Personal, from 27 August 2020 to 22 July 2021.

EASD 2021

Medtronic

OPTIMAL GLUCOSE TARGET AND ACTIVE INSULIN TIME
ALLOWS FOR TIR >80%

Number of users		Active Insulin Time (≥95% of the time)				
		2 Hours	2-3 Hours	3-4 Hours	>4 Hours	Total
Glucose Target (≥95% of the time)	100 mg/dL	1,482	1,448	177	7	**3,316**
	110 mg/dL	306	707	120	2	**1,183**
	120 mg/dL	289	764	129	3	**1,254**
	Total	**4,507**	**6,172**	**954**	32	**12,870**

TIR (70-180 mg/dL), %		Active Insulin Time (≥95% of the time)				
		2 Hours	2-3 Hours	3-4 Hours	>4 Hours	Total
Glucose Target (≥95% of the time)	100 mg/dL	80.7	78.2	75.0	76.8	**79.3**
	110 mg/dL	77.4	75.3	75.3	64.4	**75.9**
	120 mg/dL	74.6	73.2	69.9	68.7	**73.2**
	Total	**77.8**	**74.8**	**72.4**	70.1	**75.8**

GMI*, %		Active Insulin Time (≥95% of the time)				
		2 Hours	2-3 Hours	3-4 Hours	>4 Hours	Total
Glucose Target (≥95% of the time)	100 mg/dL	6.6	6.7	6.8	6.8	**6.6**
	110 mg/dL	6.8	6.8	6.8	7.2	**6.8**
	120 mg/dL	6.9	7.0	7.1	6.8	**7.0**
	Total	**6.7**	**6.8**	**6.9**	7.0	**6.8**

TBR (<70 mg/dL), %		Active Insulin Time (≥95% of the time)				
		2 Hours	2-3 Hours	3-4 Hours	>4 Hours	Total
Glucose Target (≥95% of the time)	100 mg/dL	2.9	2.6	2.6	1.7	**2.8**
	110 mg/dL	2.2	2.1	2.0	1.4	**2.1**
	120 mg/dL	1.9	1.7	1.5	6.1	**1.8**
	Total	**2.7**	**2.3**	**2.2**	2.5	**2.5**

Medtronic data on file: MiniMed ™ 780G data uploaded voluntarily by 12.870 users in EMEA to CareLink™ Personal, from 27 August 2020 to 22 July 2021.
*Glucose Management Indicator (GMI) based on reported mean glucose values. Calculated using JAEB https://www.jaeb.org/gmi/.

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MiniMed™ 780G AHCL algorithm with and without meal announcement

Unannounced Meal Challenges Using an Advanced Hybrid Closed-Loop System

Shalit al Diabetes Technol Ther . 2023 Sep;25(9):579

14 adults with type 1 diabetes

supervised environment for **5 days of not announcing meals (≤80 g of carbohydrate)**

↓

90-day at-home **"unannounced" phase**

↓

90-day at-home phase in which **all meals were announced**

	"unannounced" phase	all meals announced	P
TIR	67.5%	**77.7%**	< 0.01
180-250 mg/dL	22.7%	**15,7%**	
>250 mg/dL	7.9%	**3.6%**	
54-70 mg/dL	**1.6%**	2.8%	
<54 mg/dL	**0,3%**	0.7%	

MiniMed™ 780G AHCL algorithm with and without meal announcement

Unannounced Meal Challenges Using an Advanced Hybrid Closed-Loop System

Shalit al Diabetes Technol Ther . 2023 Sep;25(9):579

14 adults with type 1 diabetes

supervised environment for **5 days of not announcing meals (≤80 g of carbohydrate)**

90-day

90-day

- Not announcing meals containing **up to 60 g** of carbohydrate **did not lead to increase in postprandial extreme dysglycemia >250 mg/dL**
- Not announcing meals containing **up to 20 g** of unannounced carbohydrates **did not significantly change the TIR 70-180 mg/dL** compared with full announcement

TIR	67.5%	**77.7%**	< 0.01
180-250 mg/dL	22.7%	**15,7%**	
>250 mg/dL	7.9%	**3.6%**	
54-70 mg/dL	**1.6%**	2.8%	
<54 mg/dL	**0,3%**	0.7%	

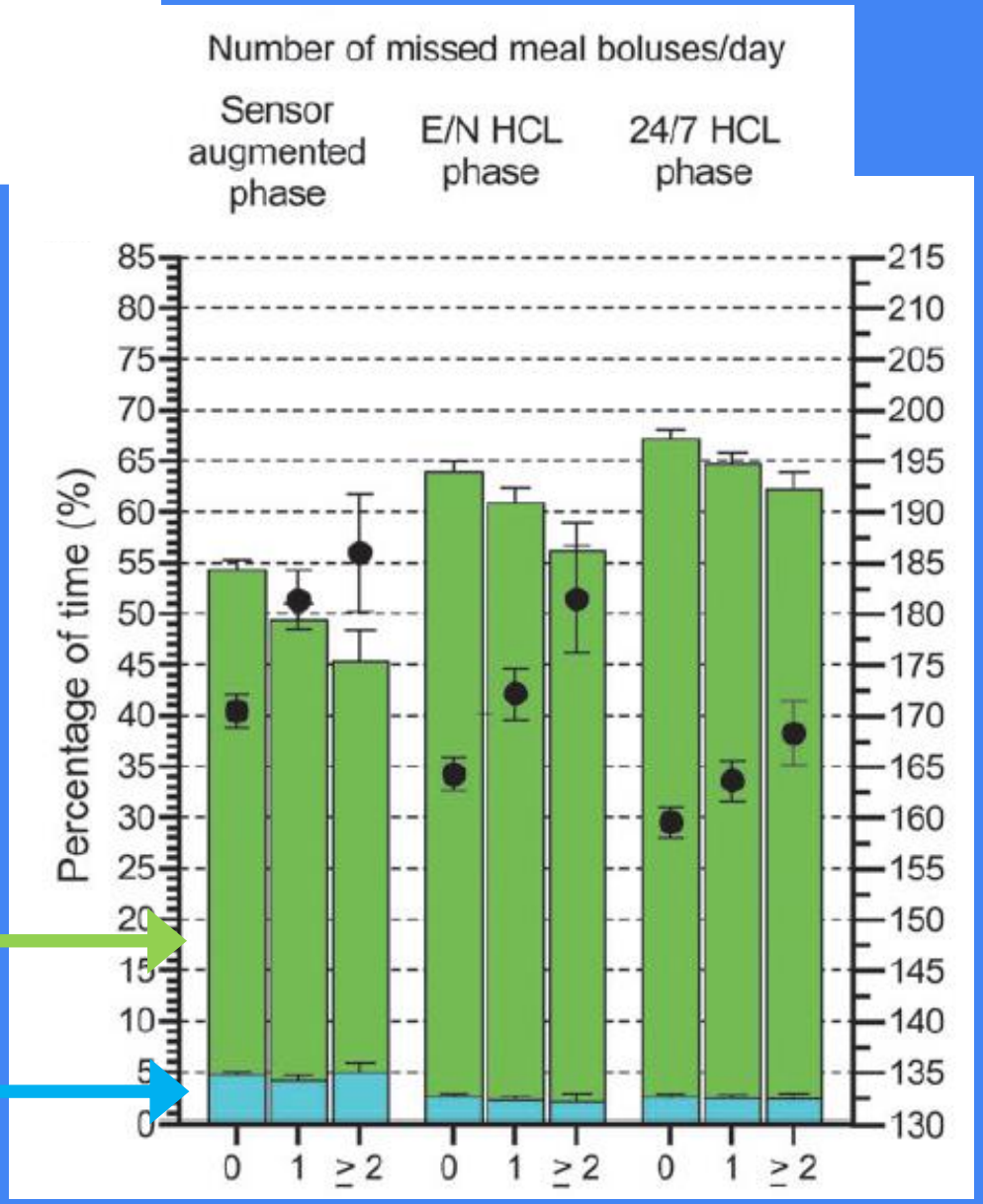
Hybrid Closed Loop Overcomes the Impact of Missed or Suboptimal Meal Boluses on Glucose Control in Children with Type 1 Diabetes Compared to Sensor-Augmented Pump Therapy

Coutant et al Diabetes Technol Ther. 2023 Jun;25(6):395

children (n=60) between 6 and 12 years old
36 weeks

TIR

TBR



Insulin Pump Report - Settings

Βασικός

Max βασ. ρυθμ.	2.50 U/Hr		Ενημερ.

Βασικός 1 (ενεργό)

Σύν. 24ώρ.	29.700 U

Ώρα	U/Hr
00:00	1.10
04:00	1.40
07:00	1.25
23:00	1.10

Βασικός 2

Σύν. 24ώρ.	--

Ώρα	U/Hr
--	--

Βασικός 3

Σύν. 24ώρ.	--

Ώρα	U/Hr
--	--

Δόση

Bolus Wizard	On
Μονάδες	g, mg/dL
Χρ. ενεργ. ινσ. (ω:ΛΛ)	2:30
Max δόση	15.0 U

Εύκολη δόση	Off
Προσαύξ. δόσ.	0.1 U
Ταχύτητα δόσης	Συνήθης
Διφασ./Τετρ.	On/On

Αναλογία υδ/κων (g/U)

Ώρα	Αναλογία
0:00	8.0
6:00	7.0
23:00	8.0

Ευαισθ. ινσ. (mg/dL ανά U)

Ώρα	Ευαισθ.
0:00	40
6:00	30
23:00	40

Στόχος γλυκόζης αίματος (mg/dL)

Ώρα	Χαμηλ	Υψηλή
0:00	100	120

Insulin Pump Report - Settings

Βασικός

Max βασ. ρυθμ.	2.50 U/Hr		Ενημερ.

Βασικός 1 (ενεργό)

Σύν. 24ώρ.	29.700 U

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00:00	1.10
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23:00	1.10

Βασικός 2

Σύν. 24ώρ.	--

Ώρα	U/Hr
--	--

Βασικός 3

Σύν. 24ώρ.	--

Ώρα	U/Hr
--	--

SmartGuard

SmartGuard	On
Στόχος	100 mg/dL
Αυτόμ. διόρθωση	On

Υψηλές ειδοποιήσεις — On (Αναβολή 1:00)

Ώρα εκκίν.	Υψηλός (mg/dL)	Υψηλή ειδ.	Ειδ. προ υψηλ.	Όριο ειδ. ανόδ. (mg/dL)
0:00	200	x		

Χαμηλές ειδοποιήσεις — On (Αναβολή 0:30)

Ώρα εκκίν.	Χαμηλός (mg/dL)	Αναστ.	Χαμηλ. ειδ.	Ειδ. προ χαμ.	Ειδοπ. επαν. βασικ.
0:00	65	Προ χαμ.	x	x	

Αισθητήρας

Αισθητήρας	On
Υπενθύμιση βαθμονόμησης	Off
Χρόνος υπενθύμισης βαθμονόμησης	Off

η	Off
σ.	0.1 U
ης	Συνήθης
ρ.	On/On

(ος γλυκόζης
ιτος (mg/dL)

	Χαμηλ	Υψηλή
0	100	120

Minimed 780G Report

Medtronic

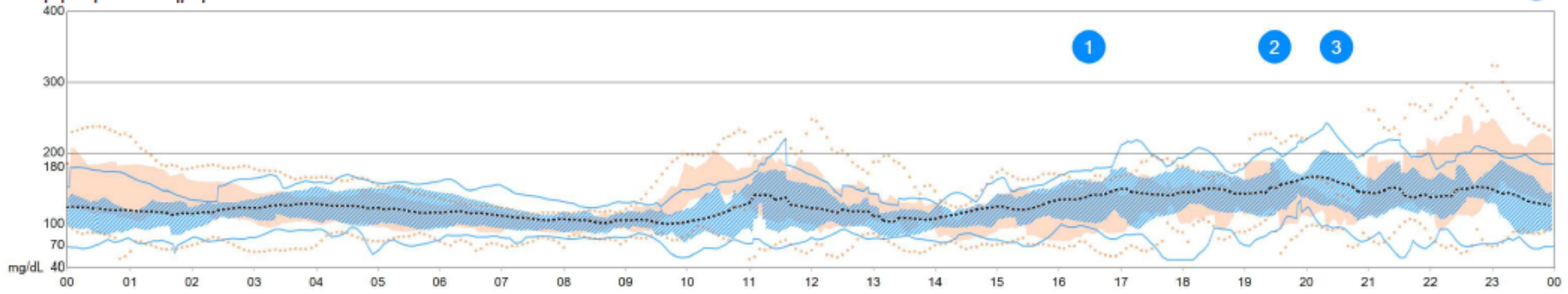
Αξιολόγηση και πρόοδος
Α 01.09.2021 - 14.09.2021 (14 Ημέρες)
Β 02.08.2021 - 15.08.2021 (14 Ημέρες)

[redacted]

PID: 02062021

Δημιουργήθηκε: 14.09.2021, 14:10 **Σελίδα 1 από 15**
Πηγές δεδομένων: MiniMed 780G, MMT-1886 (NG2606309H)

Σύγκριση εκατοστημορίων — 25-75% — 0-90% — Μέσος όρος Α



Αναλ. υδ/κων (g/U) * Α	15.0	4.5	5.0	8.0	8.0	10.0	8.0
Β	15.0	4.5	5.0	8.0	8.0	10.0	8.0

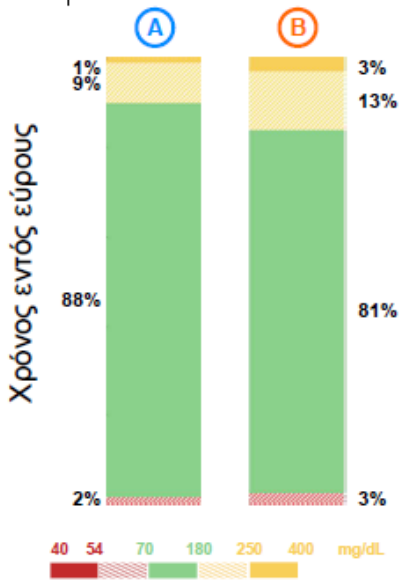
Α

Πρότυπα υπογλυκαιμίας (0) — Αρ. επεισοδίων (ανά ημ.): 0.3

Καμία

Πρότυπα υπεργλυκαιμίας (5)** — Αρ. επεισοδίων (ανά ημ.): 1.4

1 16:00 - 16:59 (3 συμβάντα)
2 19:00 - 19:59 (3 συμβάντα)
3 20:00 - 20:59 (2 συμβάντα)

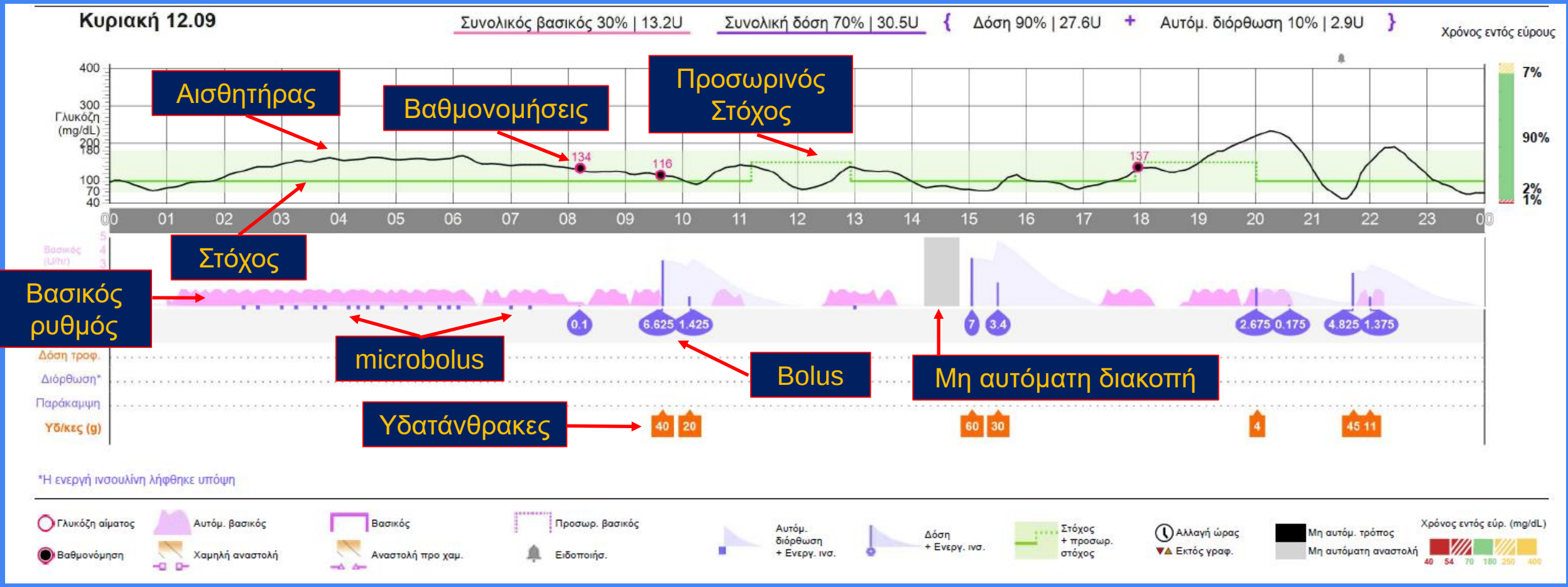


Έξοδοι SmartGuard	Α	Β
Χωρίς βαθμονόμηση	0	0
Μέγ. χορήγηση SmartGuard	0	0
Ελάχ. χορήγηση SmartGuard	0	0
Απαιτείται BG για SmartGuard	0	0
Μειωμένη ένδειξη αλγόριθμου αισθητήρα	0	0
Ενημέρωση αισθητήρα	0	0
Καμία τιμή SG	• 1	0
Ο αισθητήρας έληξε	0	0
Απενεργοποίηση SmartGuard από τον χρήστη	•• 2	14 •••••+
Παρατεταμένη αναστολή	0	0
Προθέρμανση SmartGuard	0	0
Αγνώστου ταυτότητας	0	0

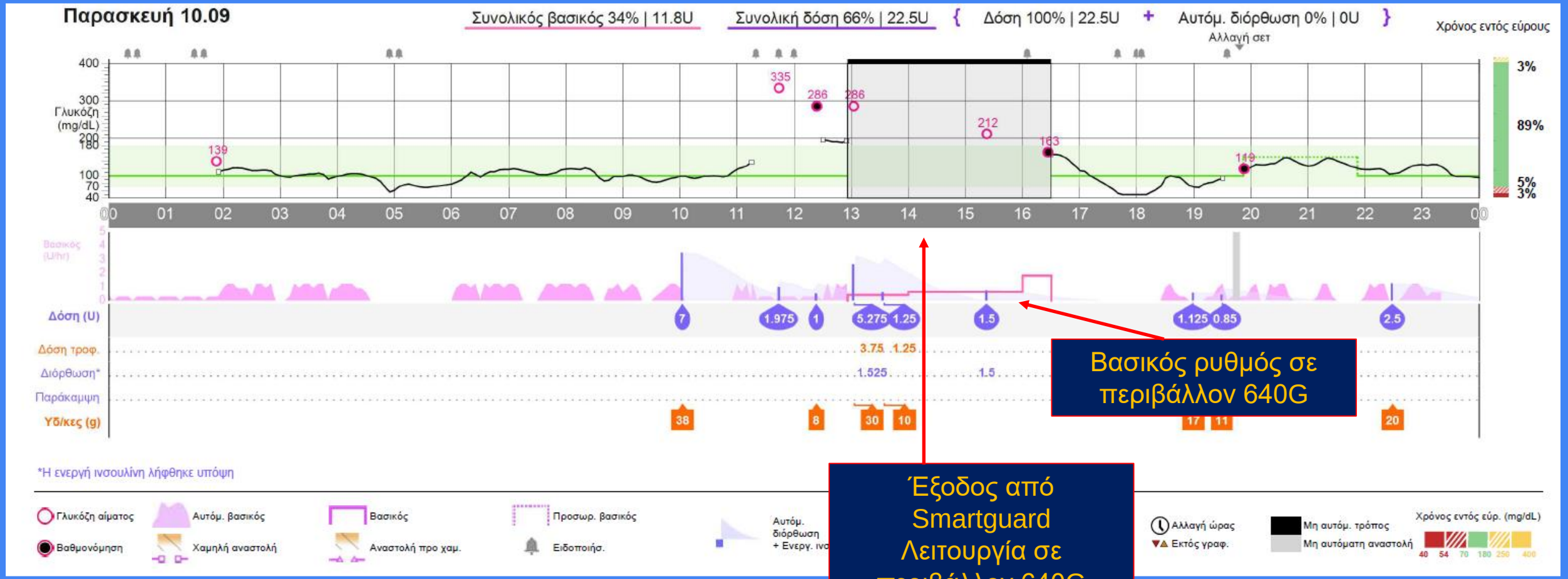
Στατιστικά	Α	Β
SmartGuard (ανά εβδομ.)	98% (6η 21ω)	86% (6η 00ω)
Μη αυτόματος τρόπος (ανά εβδομάδα)	2% (03ω)	14% (1η 00ω)
Χρήση αισθητήρα (ανά εβδομάδα)	87% (6η 02ω)	87% (6η 02ω)
Μέσος όρος SG ± SD	126 ± 39 mg/dL	134 ± 49 mg/dL
GMI***	6.3%	6.5%
Συντελεστής διακύμανσης (%)	31.1%	36.8%
Ειδοπ. χαμ./υψ. SG (ανά ημ.)	1.0 / 0.0	1.1 / 0.0
Μέσος όρος BG	157 ± 64 mg/dL	166 ± 83 mg/dL
BG / Βαθμονόμηση (ανά ημέρα)	2.7 / 2.4	3.5 / 2.9
Συνολική ημερήσια δόση (ανά ημέρα)	39.2 μονάδες	40.3 μονάδες
Ποσότητα δόσης (ανά ημέρα)	25.1U (64%)	28.5U (71%)
Ποσότ. αυτ. διόρθωσης (ανά ημ.)	3.6U (14%)	4.2U (15%)
Αυτόμ. βασ. / Ποσότ. βασ. (ανά ημέρα)	14.1U (36%)	11.8U (29%)
Αλλαγή σετ	Κάθε 1.8 ημέρες	Κάθε 4.3 ημέρες
Αλλαγή δεξαμενής	Κάθε 1.1 ημέρες	Κάθε 2.0 ημέρες
Γεύμα (ανά ημέρα)	6.4	9.0
Καταχωρισμ. υδ/κες (ανά ημέρα)	148 ± 53 g	174 ± 27 g
Χρ. ενεργ. ινσ.	2:00 ώρες	2:00 ώρες

* Εμφανίζονται οι πιο πρόσφατες ρυθμίσεις της αντλίας
** Εμφανίζονται μόνο όσες έχουν μέγιστη προτεραιότητα.
*** Δείκτης διαχείρισης γλυκόζης

Minimed 780G Report



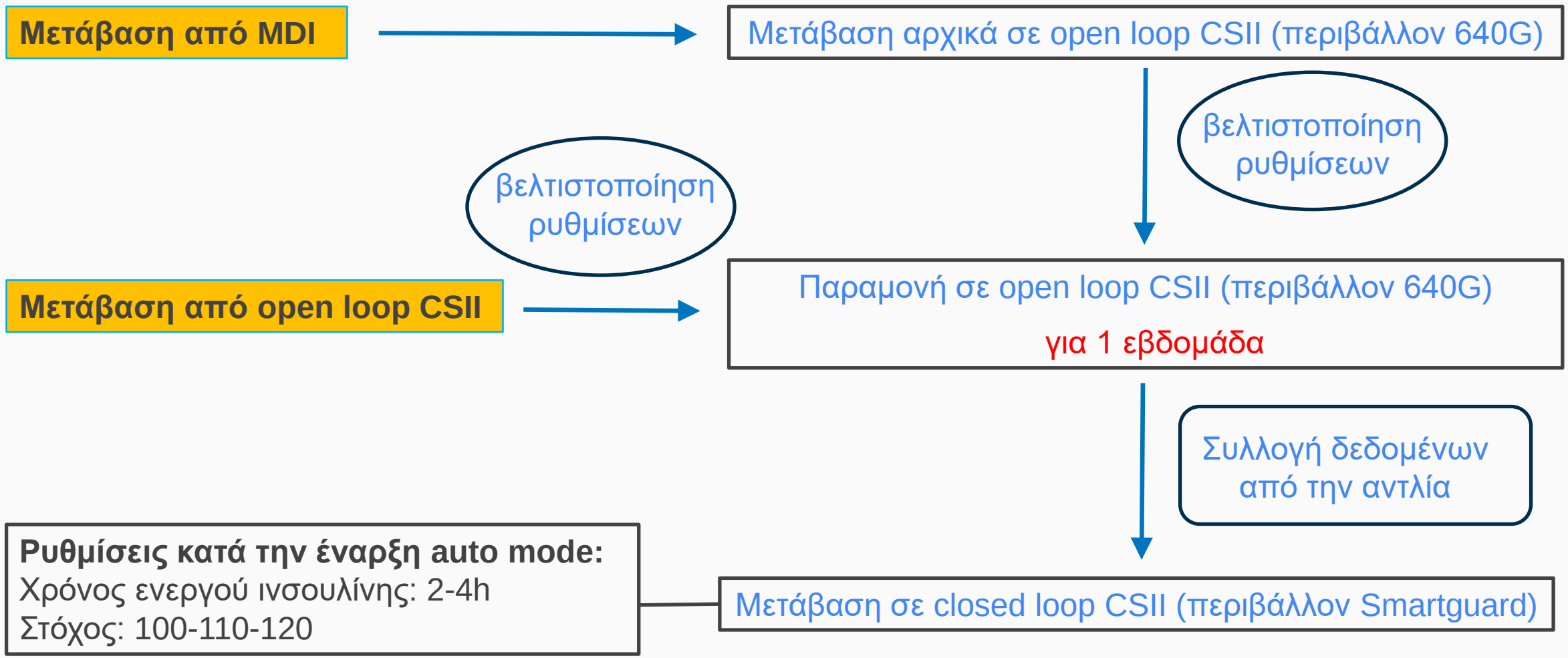
Minimed 780G Report



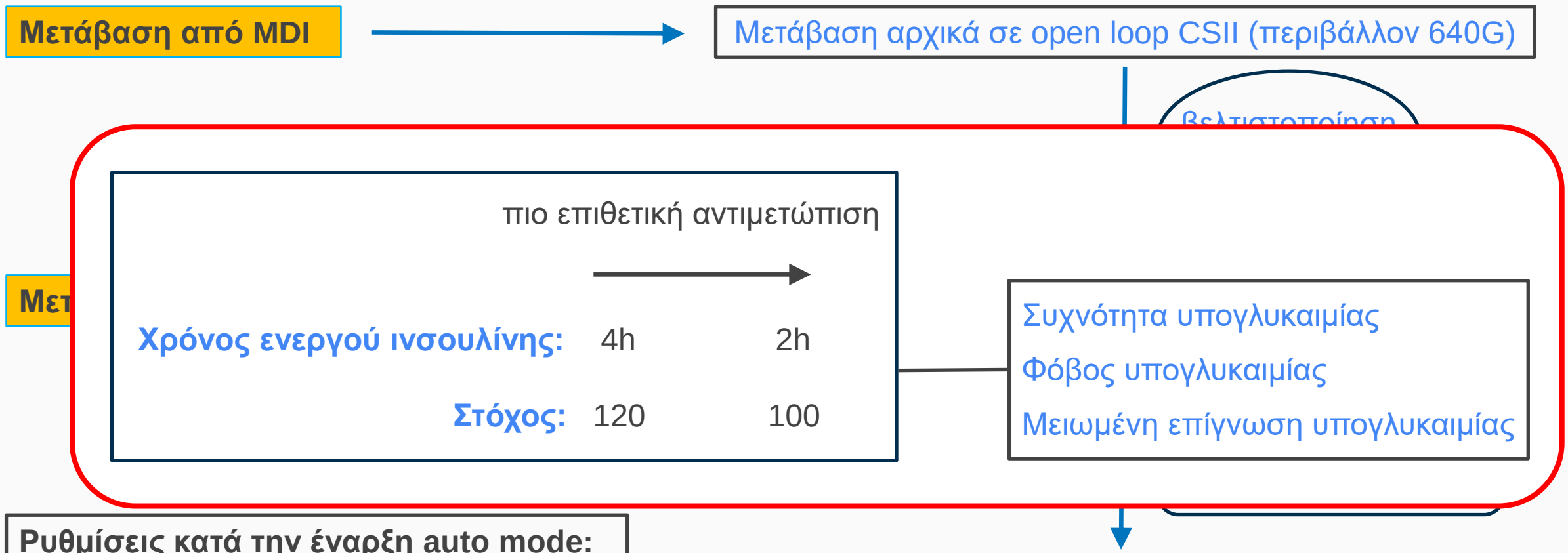
Βασικός ρυθμός σε περιβάλλον 640G

Έξοδος από Smartguard Λειτουργία σε περιβάλλον 640G

Minimed 780G: Έναρξη - Μετάβαση από MDI ή open loop CSII



Minimed 780G: Έναρξη - Μετάβαση από MDI ή open loop CSII



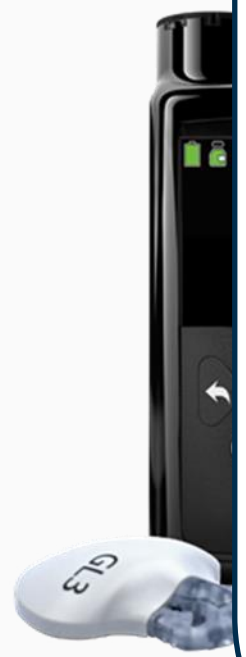
Hybrid closed-loop insulin pumps

Minimed 780G

Guardian 4

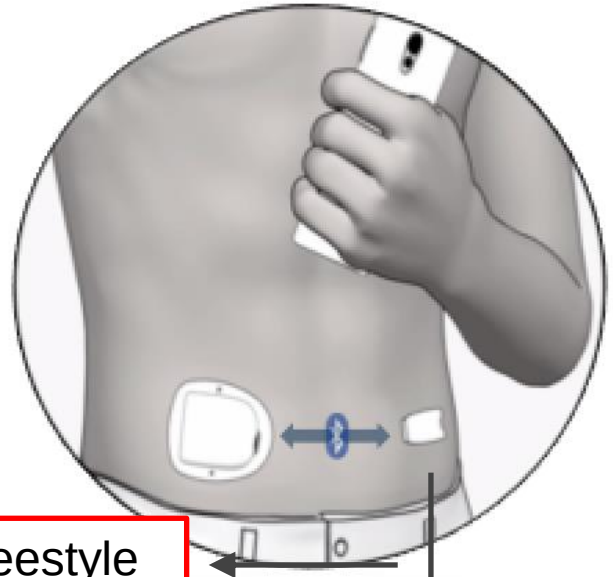
Hybrid closed-loop insulin pumps

Minimed 780G



Guardian 4

Omnipod 5



Freestyle Libre 2 plus

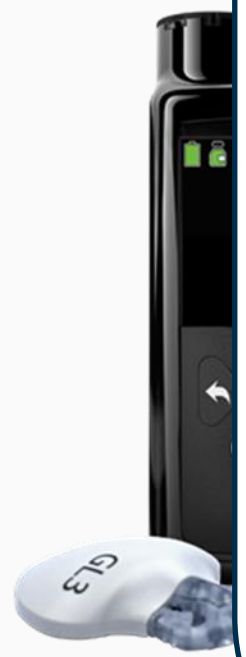
Dexcom 7

Mobile app (Omnipod 5 app)

POD
with an embedded automated insulin delivery algorithm (Omnipod 5),

Hybrid closed-loop insulin pumps

Minimed 780G



Guardian 4

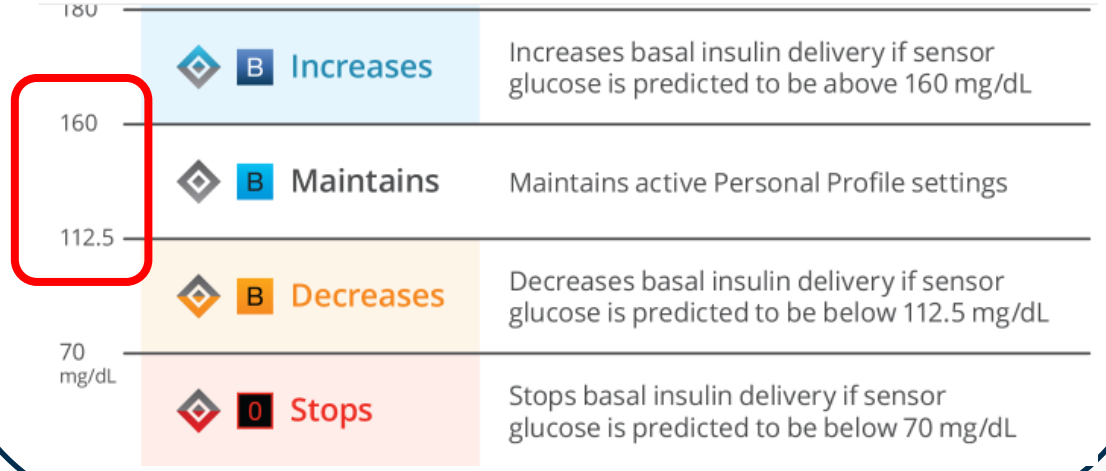
Omnipod 5

Freestyle Libre 2 plus

with an embe
algor

Tandem Diabetes Care t:slim X2 with Control-IQ Technology

Dexcom 6



Hybrid closed-loop insulin pumps

Minimed 780G

Omnipod 5

Tandem Diabetes Care t:slim X2 with Control-IQ Technology

Guardian 4

with an embe
algor

70 mg/dL

0 Stops

Stops basal insulin delivery if sensor glucose is predicted to be below 70 mg/dL

Hybrid closed-loop insuli

Minimed 780G

Omnipod 5

Tandem Diabet with Control

CamAPS FX
Hybrid closed - loop

Dexcom 6
Pump: Dana ή mylife YpsoPump

Guardian 4

with an embe
algori

70
mg/dL

0 Stops

Stops basa
glucose is predicted to be below 70 mg/dL

Hybrid closed-loop insuli

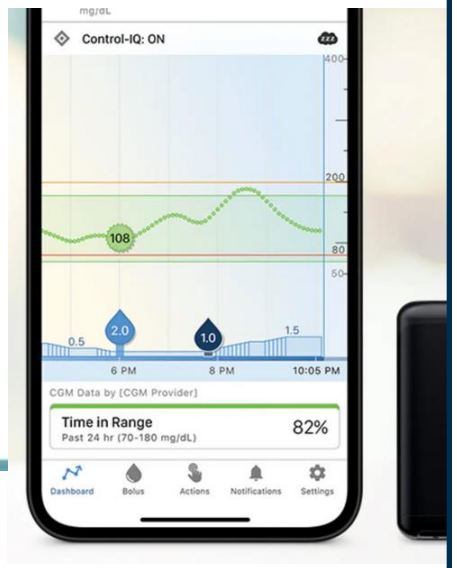
Minimed 780G

Omnipod 5

Tandem Diabet with Contro

CamAPS FX Hybrid closed - loop

iLET bionic pancreas BetaBionics



Guardian 4

with an embe
algori

70
mg/dL

Stops

Hybrid closed-loop insuli

Minimed 780G

Omnipod 5

Tandem Diabet with Contro

CamAPS FX Hybrid closed - loop

iLET bionic pancreas etaBionics

DBLG1 Diabeloop

Hybrid closed-loop insuli

Minimed 780G

Omnipod 5

Tandem Diabet with Contro

CamAPS FX Hybrid closed - loop

iLET bionic pancreas
BetaBionics

TouchCare Nano system Medtrum

Diabeloop

Hybrid closed-loop insuli

Minimed 780G

Omnipod 5

Tandem Diabet with Contro

CamAPS FX Hybrid closed - loop

iLET bionic pancreas
BetaBionics

Tou Na

Twiist AID system

Diabe

Automated Insulin delivery

Consensus Recommendations for the Use of Automated Insulin Delivery Technologies in Clinical Practice

Phillip et al Endocrine Reviews, 2023, 44, 254–280

Automated insulin delivery: benefits, challenges, and recommendations. A Consensus Report of the Joint Diabetes Technology Working Group of the European Association for the Study of Diabetes and the American Diabetes Association

Sherr et al Diabetologia (2023) 66:3–22

Closed-loop therapy: recent advancements and potential predictors of glycemic outcomes

Expert Opin Drug Deliv. 2025 Jun;22(6):875

Chloë Royston, Roman Hovorka & Charlotte K. Boughton

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Characteristics of the most common commercially available hybrid closed loop systems

Hybrid closed loop system	Cam APS FX CamDiab	Control-IQ Tandem	DBLG1 Diabeloop	iLet Bionics BetaBionics	MiniMed 780G Medtronic	Omnipod 5 Insulet
Pumps	 DANA RS pump  DANA-i pump  YpsoPump	 Tandem t:slimx2 pump  Tandem Mobi pump	 Kaleido pump	 iLet ACE pump	 MiniMed pump	 Omnipod 5 pump
Sensors	 Libre 3  Dexcom G6	 Libre 2 Plus  Dexcom G6  Dexcom G6  Dexcom G7  Dexcom G7	 Dexcom G6  Libre 2 plus	 Dexcom G6  Dexcom G7  Libre 3 plus	 Guardian 4  Simplera sync	 Dexcom G6  DexcomG7  Libre 2 plus

Markakis and Vazeou. Insulin Pumps and Artificial Pancreas. Encyclopedia of Endocrine Diseases 3rd edition, in press

www.diabetotech.com

Available AID systems	Diabeloop	TouchCare Nano System	AndroidAPS	(Tidepool) Loop	iAPS / Trio
Photo					
Firm	Diabeloop (France)	Medtrum (China)	Open-source		Open-source
Indications	≥ 18 years and 8-90 U insulin per day	≥ 6 year, ≥ 22 kg and ≥ 10 U insulin/day	On your own risk		On your own risk
Availability	CE-label, FDA pending	CE-label	/	FDA-label for earlier version (Tidepool Loop)	/
CGM	Dexcom G6	TouchCare Nano CGM	Dexcom, FreeStyle Libre, Eversense, PocTech, Glunovo, Enlite, Syai Tag, Ottai, Sibionics	Dexcom ONE/ONE+/G5/G6/G7, FreeStyle Libre 1/2, MiniMed Enlite CGM	Dexcom ONE/ONE+/G5/G6/G7, FreeStyle Libre 1/2, MiniMed Enlite CGM
Pump	Accu-Chek Insight, Kaleido, Dana-i	TouchCare Nano Pump 200 U or 300 U	Accu-Chek Combo/Insight, DanaR, Dana-i/RS, some old Medtronic pumps, Omnipod Eros/DASH, DiaconnG8, EoPatch2, Medtrum Nano/300U, Equil	Omnipod Eros; Omnipod DASH, some old Medtronic pumps	Omnipod Eros; Omnipod DASH, some old Medtronic pumps, Dana-i, Dana-RS
Mobile Control	/	Full phone control (Android & iOS)	Full phone control (only Android)	Full phone control (only iOS)	Full phone control (only iOS)
Target	100-130 mg/dl (5,5-7,2 mmol/l)	100, 110 or 120 mg/dl (5.5, 6.1 or 6,6 mmol/l)	80-200 mg/dl (4,4-11 mmol/l) (value or range, adjustable per time block)	87-180 mg/dl (4,8-10 mmol/l) (value or range, adjustable per time block)	72-180 mg/dl (4-10 mmol/l) (adjustable per time block)
Other Targets	Exercise activity & Zen mode	Exercise mode (less insulin delivery)	Customizable target and % of insulin delivery	Customizable "Overrides" of target and % of insulin delivery	Customizable target and % of insulin delivery
Algorithm	Loopmode: MPC algorithm based on total daily insulin dose, weight and average amount of carbs in a typical meal + autocorrection boluses. Self-learning algorithm based on previous patterns.	APGO: hybrid MPC/PID algorithm based on previous insulin needs and post-meal glucose, and glucose prediction. Self-learning algorithm based on previous patterns.	APS mode: MPC algorithm that modulates basal insulin based on insulin on board and carbs on board. Advanced Meal Assist or Super Micro Bolus. Extra: Autosens, Autotune, Dynamic insulin sensitivity factor	Loop: MPC algorithm that modulates basal insulin based on insulin on board and carbs on board. Temp Basal only or Automatic Bolus.	Closed Loop mode: MPC algorithm that modulates basal insulin based on insulin on board and carbs on board. Uses supermicroboluses and Autosens. Extra: Autotune, Dynamic ISF, Dynamic Carbs
Adjustable Factors	Hypo- and hyperglycemia limit; agressivity of the algorithm at meals, normoglycemia and hyperglycemia (%), total daily insulin dose	Carb ratio	Basal insulin rate (different profiles possible), carb ratio, insulin sensitivity, duration of insulin action, insulin type, advanced algorithm features and limits	Basal insulin rate (different profiles possible), carb ratio, insulin sensitivity, insulin model, glucose safety limit, premeal range, advanced algorithm features and limits	Basal insulin rate (different profiles possible), carb ratio, insulin sensitivity, duration of insulin action, insulin model, advanced algorithm features and limits
Educate	Take rescue carbs as recommended, change total daily insuline dose if needed (higher if to much hyperglycemia; lower if to much proposed rescue carbs)	Consider additional finger stick controls because lack of safety studies	Ask someone who is using this system to help you, have a backup plan, start with time of active insuline of 5h	Ask someone who is using this system to help you, have a backup plan, use different food type icons according to absorption time (lollipop: 2h, taco 3h, pizza: 4h)	Ask someone who is using this system to help you, have a backup plan, utilize advanced settings only if you have a good understanding and have achieved stable glucose control
Unique Features	Self-learning based on previous months. Privacy mode and Zen mode. Suggests amount of rescue carbs to eat.	Optional Auto Meal Handling for meal announcements instead of carb counting	Extra RileyLink device needed if pump has no Bluetooth, you need to build the app yourself (PC needed) and complete 10 objectives (takes 2 months)	Extra RileyLink device needed if pump has no Bluetooth, you need to build the app yourself	Extra RileyLink device needed if pump has no Bluetooth, you need to build the app yourself

Twiist by Sequel

Freestyle 3 plus (planned Eversense 365)

Characteristics of the most common commercially available hybrid closed loop systems (in alphabetical order)

Hybrid closed loop system	Cam APS FX CamDiab	Control-IQ Tandem	DBLG1 Diabeloop	iLet Bionics BetaBionics	MiniMed 780G Medtronic	Omnipod 5 Insulet
Glucose Target (mg/dl)	104.4 (Default) 80-200	Treat to range 112.5-160	100-130	Usual 120 (default) Lower 110 Higher130	100,110,120	110,120,130, 140,150
Initiation	TDD (from last 5 days), Weight	TDD, weight, ICR, ICF, basal rate	TDD, weight, basal rate, average number of carbs per meal type (breakfast, lunch, dinner)	Weight	TDD, ICR, ICF, basal rate	TDD, ICR, ICF, basal rate

Markakis and Vazeou. Insulin Pumps and Artificial Pancreas. Encyclopedia of Endocrine Diseases 3rd edition, in press

	Minimed 780G	Tandem Control IQ	Omnipod 5	CamAPS FX	iLet Bionics	DBLG1 Diabeloop	TouchCare Nano System
Glucose Target (mg/dl)	100,110,120	Treat to range 112.5-160	110,120,130, 140,150	104.4 (Default) 80-200	Usual 120 (default) Lower 110 Higher130	100-130	100,110,120
Additional target personalization during the day	–	–	different values for different times of day	specific glucose target for every 30-minute time block	two different targets per 24-hour period: a "CGM Target" and a "CGM Sleep Target."	–	–
Multiple settings profiles during the day	ICR	ICR Correction factor Basal rate	ICR Correction factor	ICR	–	–	ICR
Exercise	Temporary target - 150 mg/dL	Exercise activity mode- 140-160 mg/dL	HypoProtect: 150 mg/dL	Ease off: + 45 mg/dL	- (no specific feature, manual target change)	Physical activity mode + 70 mg/dL	Exercise activity mode 150 mg/dL
Optional modes		Sleep mode 112.5-120 mg/dL	–	Boost mode +35%	Sleep CGM target	▪ Zen mode +10-40 mg/dL ▪ Aggressiveness	–

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	Minimed 780G	Tandem Control IQ	Omnipod 5	CamAPS FX	iLet Bionics	DBLG1 Diabeloop	TouchCare Nano
ICR	V	V	V	V	_	_	V
Correction factor	_	V	V	_	_	_	_
Επιλογή Correction target	- (fixed 120)	- (fixed 110)	Personal glucose target (100- 150)	Personal glucose target (80-200)	Personal glucose target (100- 150)	Personal glucose target (100- 130)	Personal glucose target (100- 120)
Δυνατότητα τροποποίησης προτεινόμενου bolus	_	_	V	_	_	_	V
Τύποι bolus	Normal	Normal ή Dual wave (extended up to 2h)	Normal	▪ Normal ▪ "slowly absorbed meal" ▪ 3-4 ώρες ▪ Preset bolus Small – Medium – Large	Type of meal Breakfast, lunch, dinner «Usual for me» «more» «less»	Meal announcements and then select portion size (small, medium, large)	▪ Normal or Extended ▪ Auto Meal Handling
Αυτόματα διορθωτικά boluses	V (έως κάθε 5min)	V (έως κάθε 1h)	_	_	V	V	V

Τροποποιημένο από Markakis and Vazeou. Insulin Pumps and Artificial Pancreas. Encyclopedia of Endocrine Diseases 3rd edition, in press

Hybrid closed loop system	Cam APS FX CamDiab	Control-IQ Tandem	DBLG1 Diabeloop	iLet Bionics BetaBionics	MiniMed 780G Medtronic	Omnipod 5 Insulet
Adaptable pump settings	Select target, exercise target, boost mode ICR	ICR ICF Basal rates Select exercise and sleep activities	Select Target, Exercise, Zen mode, Hypo/hyper thresholds	Select targets	Select target Select temporary target ICR, Active insulin time	Select targets, HypoProtect mode, ICR, ICF, Active insulin time for corrections
Meal announcement	Carb counts Under «Add meal» carbs for hypo correction can be added For high fat meals can activate «slowly absorbed meal»	Carb counts Normal or extended bolus for high fat meals	Meal announcements and then select portion size (small, medium, large)	Type of meal Breakfast, lunch, dinner «Usual for me» «more» «less»	Carb counts Normal bolus	Carb counts Normal bolus
Algorithm location	App on phone	On pump	On smartphone	On pump	On pump	On pump
Bolusing from cell phone	Yes	Yes (Mobi)	Yes	No	No	Yes
Remote monitoring	Yes, CamAPS FX Companion feature	Yes, CGM only	Yes, CGM only	Yes, CGM only	Yes, Carelink app	Yes, CGM only

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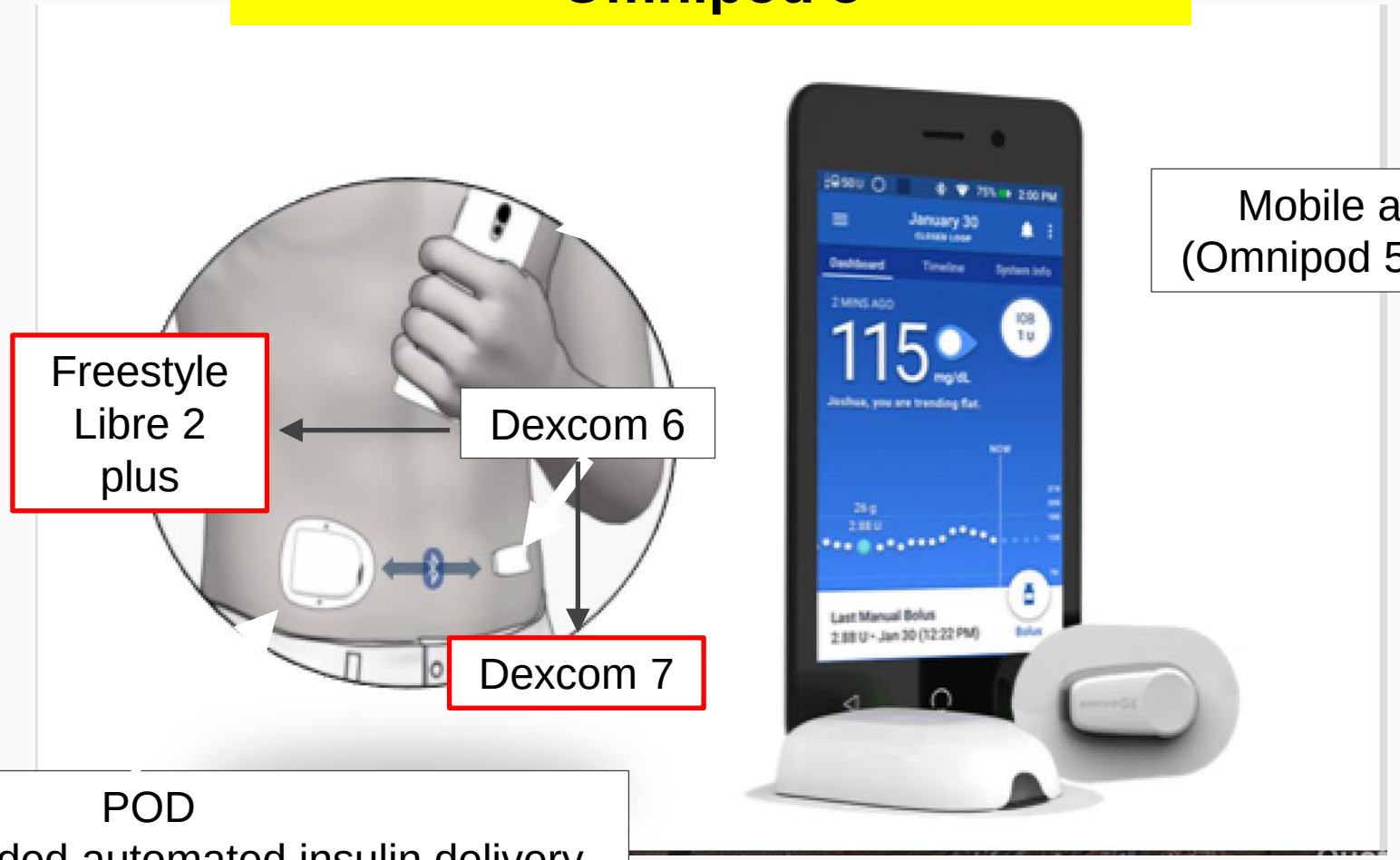
Hybrid closed-loop Omnipod 5

Omnipod 5



POD
with an embedded automated insulin delivery algorithm (Omnipod 5),

Omnipod 5

Table 2—Primary and secondary effectiveness outcomes

automated mode (mean±SD)

6-13,9 ετών: 95.2 ± 4.0%

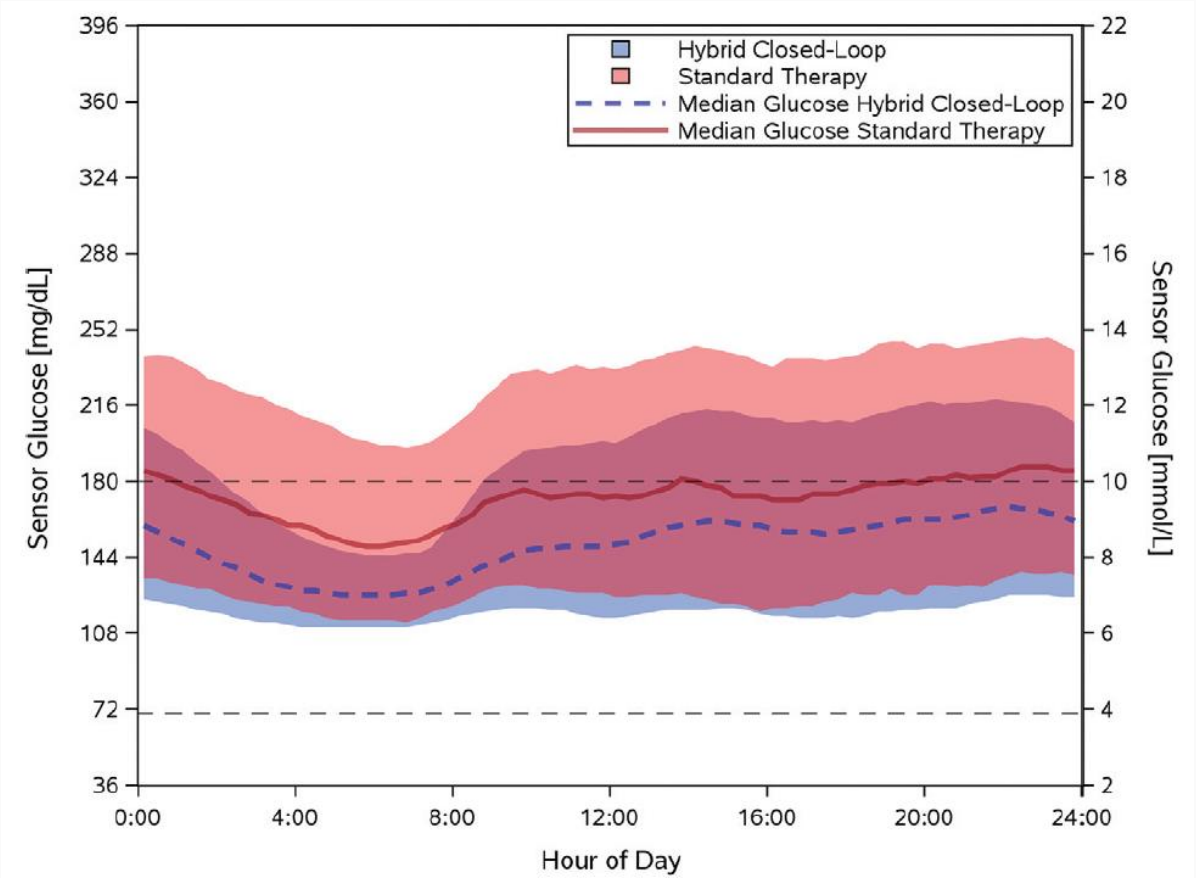
14-70 ετών: 94.8 ± 6.0%

Parameter	Cohort (6-13,9 ετών, n=112) Baseline§ or standard therapy phase	Follow-up§ or automated insulin delivery phase	Change	*P* value‖	Cohort (14-70 ετών, n=128) Baseline§ or standard therapy phase	Follow-up§ or automated insulin delivery phase	Change	*P* value‖
Overall (24 h)								
Primary effectiveness outcome, HbA1c	7.67 ± 0.95, 7.50 (7.00, 8.30)	6.99 ± 0.63, 6.90 (6.50, 7.40)	−0.71 ± 0.63, −0.65 (−1.10, −0.30)	<0.0001	7.16 ± 0.86, 7.10 (6.60, 7.60)	6.78 ± 0.68, 6.70 (6.40, 7.15)	−0.38 ± 0.54, −0.30 (−0.70, −0.00)	<0.0001
mmol/mol	60 ± 10.4, 58 (53, 67)	53 ± 6.9, 52 (48, 57)	−7.8 ± 6.9, −7.1 (−12, 3.3)	—	55 ± 9.4, 54 (49, 60)	51 ± 7.4, 50 (46, 55)	−4.2 ± 5.9, −3.3 (−7.7, 0.0)	—
Primary effectiveness outcome, time 70–180 mg/dL, % TIR	52.5 ± 15.6, 52.8 (39.3, 63.2)	68.0 ± 8.1, 68.2 (63.3, 73.5)	15.6 ± 11.5, 15.0 (7.8, 24.6)	<0.0001	64.7 ± 16.6, 67.1 (51.3, 77.6)	73.9 ± 11.0, 75.8 (68.0, 81.1)	9.3 ± 11.8, 7.9 (0.9, 15.5)	<0.0001
Mean sensor glucose, mg/dL	183 ± 32, 181 (163, 205)	160 ± 15, 159 (150, 171)	−23 ± 23, −21 (−37, −7)	<0.0001	161 ± 28, 156 (138, 178)	154 ± 17, 151 (143, 163)	−8 ± 20, −6 (−16, 7)	0.0002
SD of sensor glucose, mg/dL	68 ± 13, 68 (59, 77)	60 ± 10, 59 (52, 65)	−9 ± 8, −8 (−14, −3)	<0.0001	57 ± 14, 55 (46, 67)	49 ± 11, 48 (42, 55)	−8 ± 9, −7 (−13, −1)	<0.0001
CV of sensor glucose, %‡	37.5 ± 5.1, 37.1 (33.8, 41.0)	37.0 ± 3.9, 37.6 (34.3, 39.8)	−0.4 ± 4.2, −0.6 (−3.5, 2.5)	0.2893	35.2 ± 5.7, 34.6 (31.2, 37.9)	31.7 ± 4.7, 32.1 (28.5, 34.6)	−3.5 ± 4.3, −3.7 (−6.0, −0.3)	<0.0001
Time in glucose range, %								
<54 mg/dL	0.41 ± 0.83, 0.10 (0.00, 0.41)	0.32 ± 0.33, 0.23 (0.08, 0.42)	−0.08 ± 0.66, 0.04 (−0.12, 0.20)	0.1132	0.62 ± 1.24, 0.22 (0.00, 0.77)	0.23 ± 0.27, 0.17 (0.06, 0.28)	−0.39 ± 1.16, −0.08 (−0.46, 0.04)	<0.0001
<70 mg/dL <70	2.21 ± 2.66, 1.38 (0.42, 2.67)	1.78 ± 1.37, 1.48 (0.65, 2.23)	−0.43 ± 2.01, 0.06 (−0.66, 0.68)	0.8153	2.89 ± 3.07, 2.00 (0.63, 4.06)	1.32 ± 1.10, 1.09 (0.46, 1.75)	−1.57 ± 2.55, −0.89 (−2.23, −0.01)	<0.0001
>180 mg/dL >180	45.3 ± 16.7, 44.8 (35.2, 58.9)	30.2 ± 8.7, 29.7 (24.1, 35.5)	−15.1 ± 12.2, −14.3 (−24.5, −6.8)	<0.0001	32.4 ± 17.3, 28.9 (17.6, 46.6)	24.7 ± 11.2, 22.8 (17.0, 31.4)	−7.7 ± 12.1, −6.2 (−13.9, 1.6)	<0.0001
≥250 mg/dL >250	19.1 ± 13.1, 15.9 (9.7, 26.3)	9.6 ± 5.4, 8.9 (5.7, 12.4)	−9.4 ± 9.8, −6.1 (−14.4, −2.1)	<0.0001	10.1 ± 10.5, 6.6 (2.3, 15.4)	5.8 ± 5.5, 3.9 (2.2, 7.7)	−4.3 ± 7.7, −2.3 (−6.9, 0.3)	<0.0001
≥300 mg/dL	8.5 ± 8.9, 5.8 (2.5, 11.5)	3.5 ± 2.9, 2.7 (1.4, 4.8)	−5.1 ± 7.1, −2.6 (−7.5, −0.5)	<0.0001	3.7 ± 5.5, 1.5 (0.2, 5.0)	1.7 ± 2.5, 0.8 (0.3, 2.2)	−2.0 ± 4.3, −0.4 (−2.8, 0.1)	<0.0001

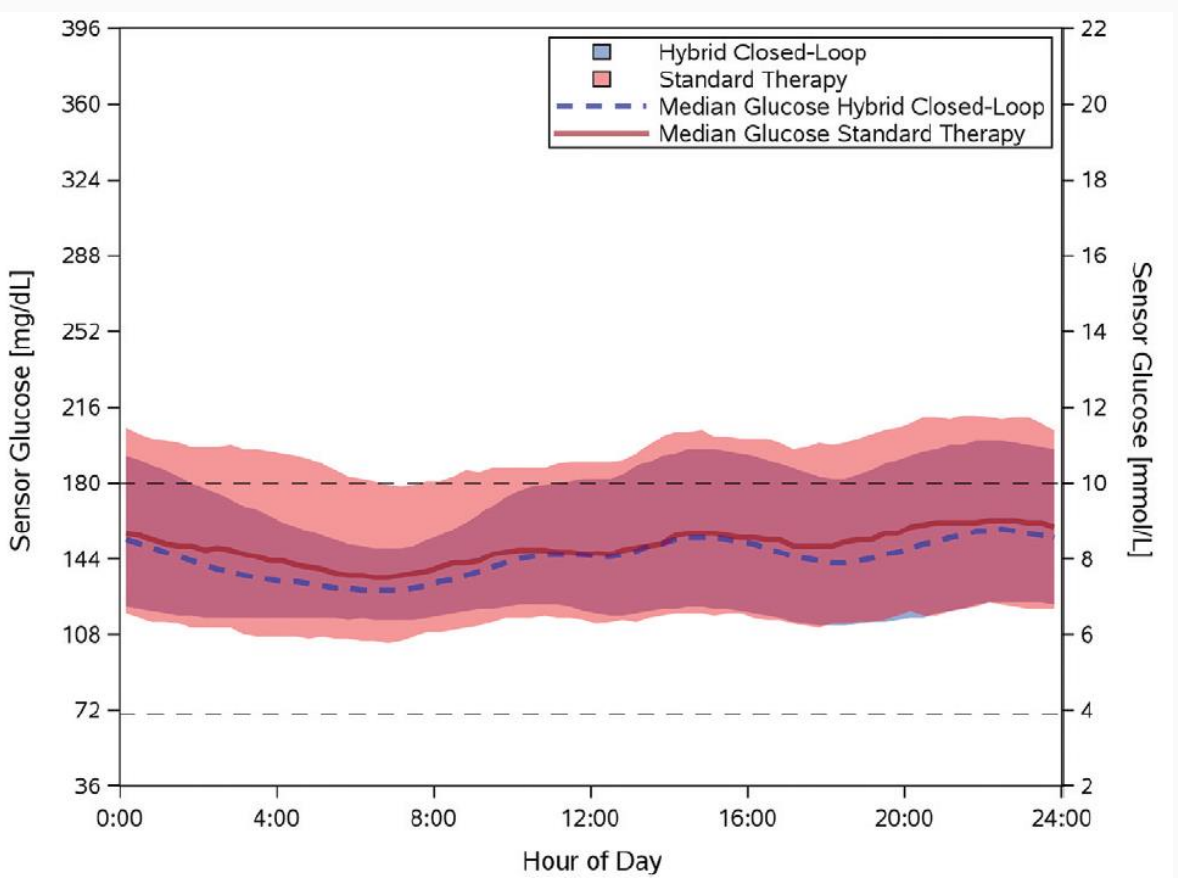
Brown et al Diabetes Care 2021 Jun 7;44(7):1630

Omnipod 5

6-13,9 ετών



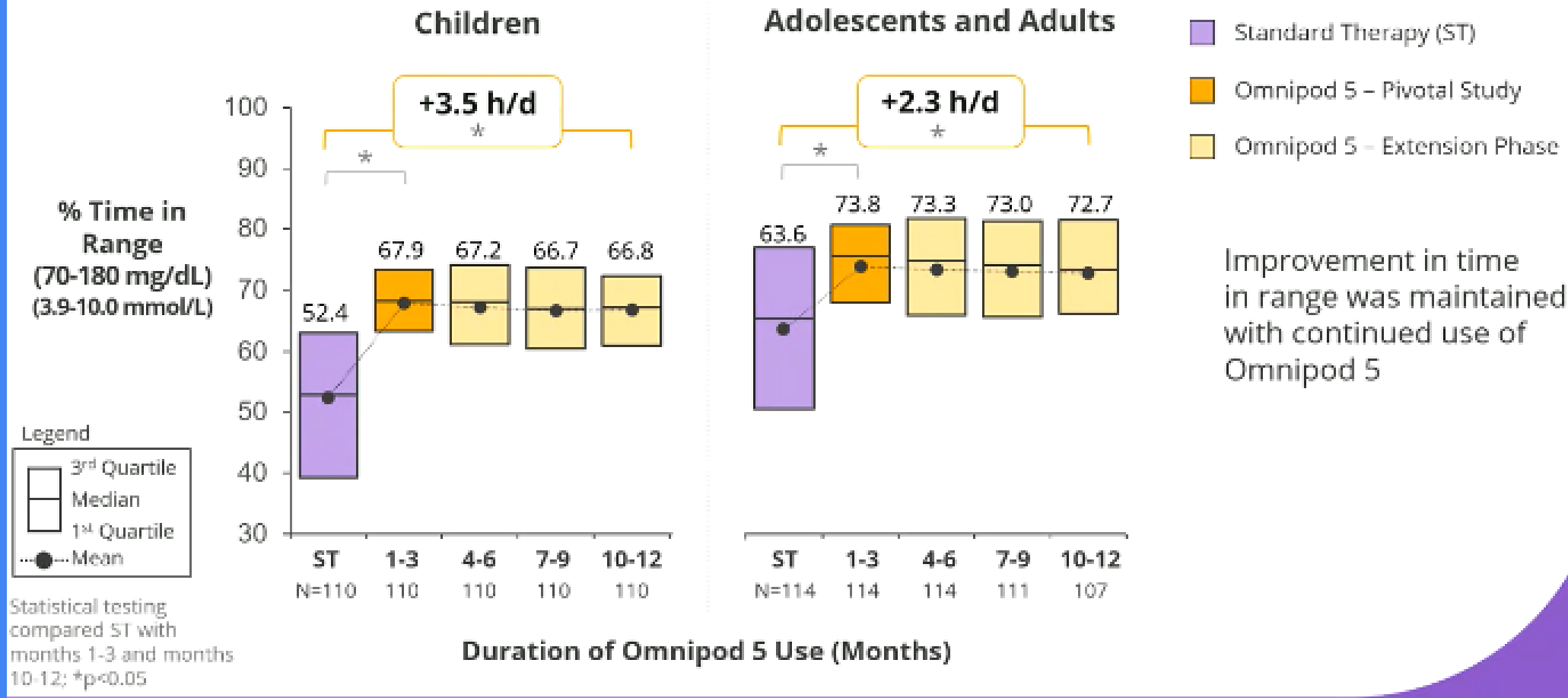
14-70 ετών



μεγαλύτερη βελτίωση τη νύχτα

Brown et al Diabetes Care 2021 Jun 7;44(7):1630

Sustained Improvement in Time in Range Over 12 Months of AID



Improvement in time in range was maintained with continued use of Omnipod 5

[7] The numerical values shown on the graph above each box correspond to the **mean** time in range

Carlson EASD 2021 Insulin pumps SO 43

Hybrid closed-loop

Tandem Diabetes Care t:slim X2 with Control-IQ Technology - Dexcom G6

180

160

112.5

70
mg/dL

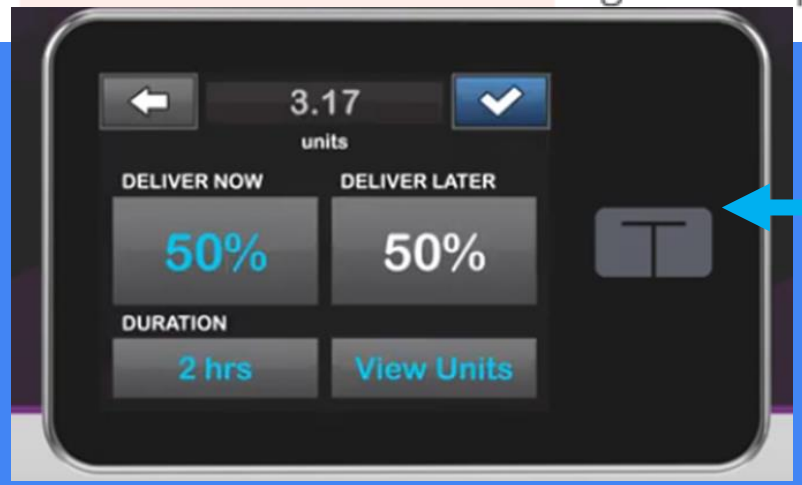
B Increases	Increases basal insulin delivery if sensor glucose is predicted to be above 160 mg/dL
B Maintains	Maintains active Personal Profile settings
B Decreases	Decreases basal insulin delivery if sensor glucose is predicted to be below 112.5 mg/dL
0 Stops	Stops basal insulin delivery if sensor glucose is predicted to be below 70 mg/dL

Automatic Correction Boluses

Control-IQ technology gradually increases basal

Όταν προβλέπεται τιμή >180mg/dL τα επόμενα 30 min με στόχο 110mg/dL

hour as needed to help prevent hyperglycemia.

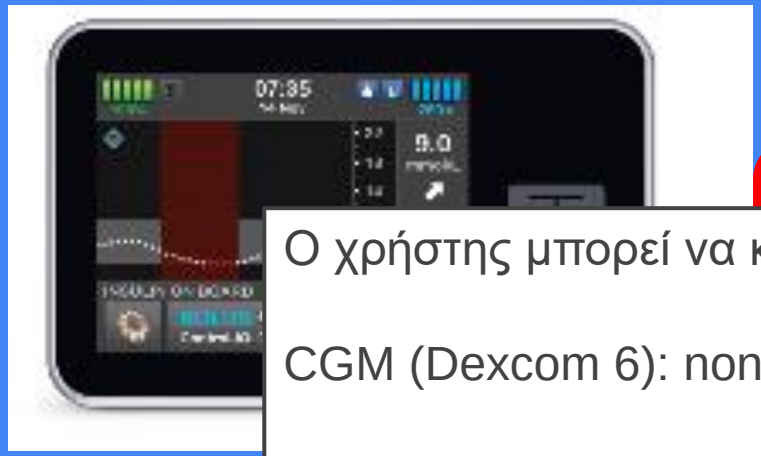


Δυνατότητα extended bolus
Καθορισμός αναλογίας
και διάρκειας

TANDEM DIABETES CARE

Hybrid closed-loop

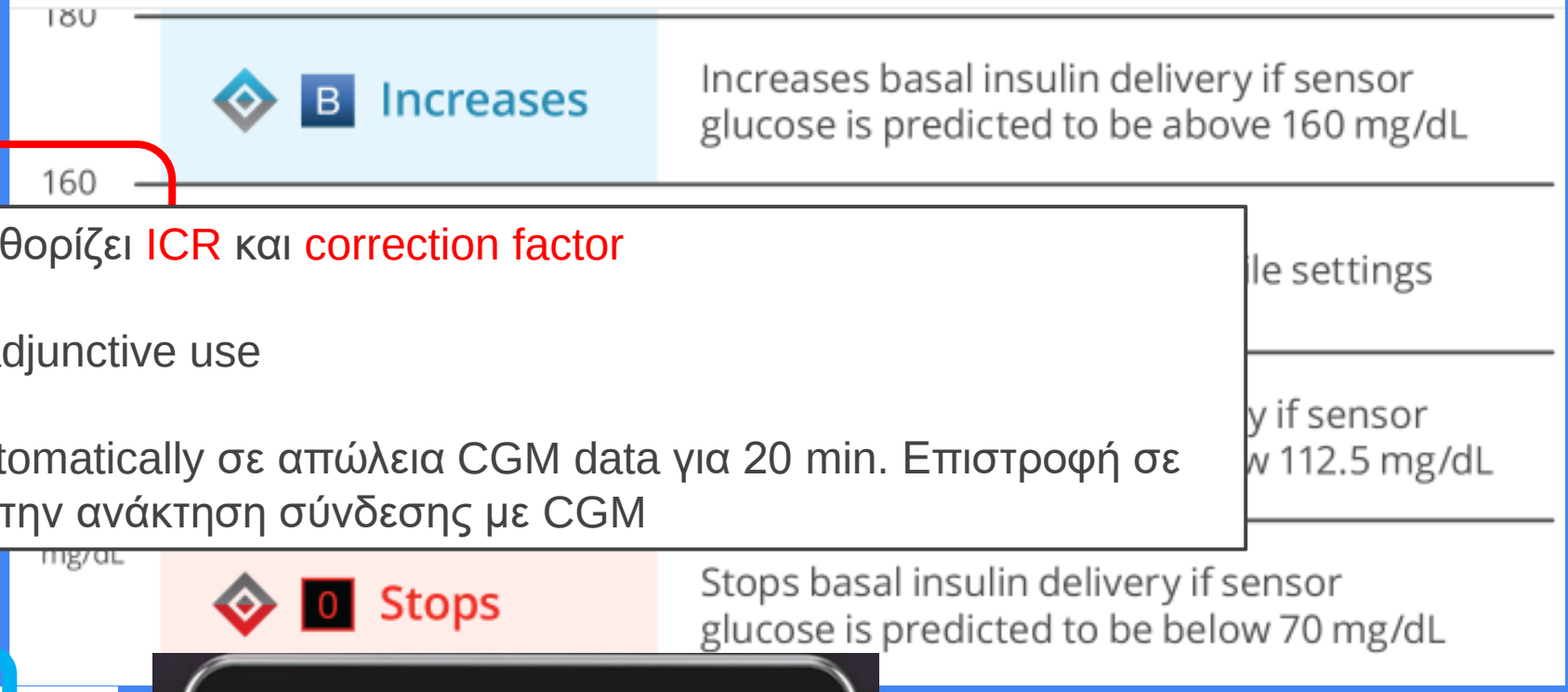
Tandem Diabetes Care t:slim X2 with Control-IQ Technology - Dexcom G6



Ο χρήστης μπορεί να καθορίζει ICR και correction factor

CGM (Dexcom 6): non adjunctive use

Αλλαγή σε open loop automatically σε απώλεια CGM data για 20 min. Επιστροφή σε HCL mode αυτόματα με την ανάκτηση σύνδεσης με CGM



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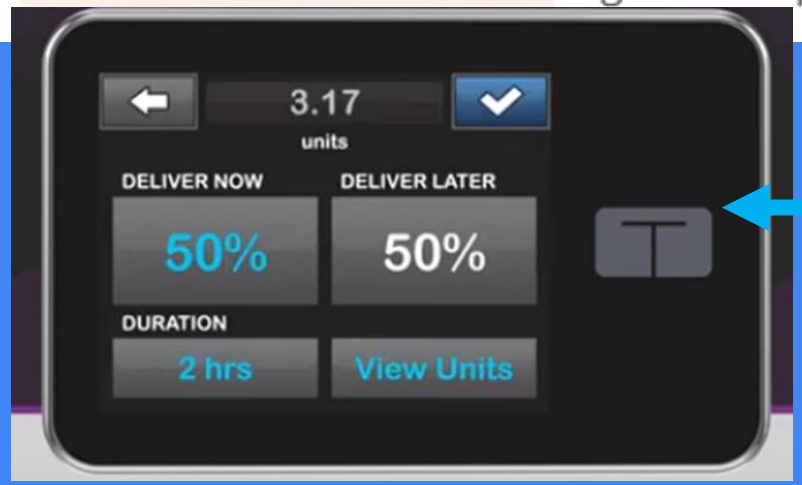


Δυνατότητα extended bolus
Καθορισμός αναλογίας
και διάρκειας

TANDEM DIABETES CARE

Hybrid closed-loop

Tandem Diabetes Care t:slim X2 with Control-IQ Technology - Dexcom G6

TANDEM DIABETES CARE

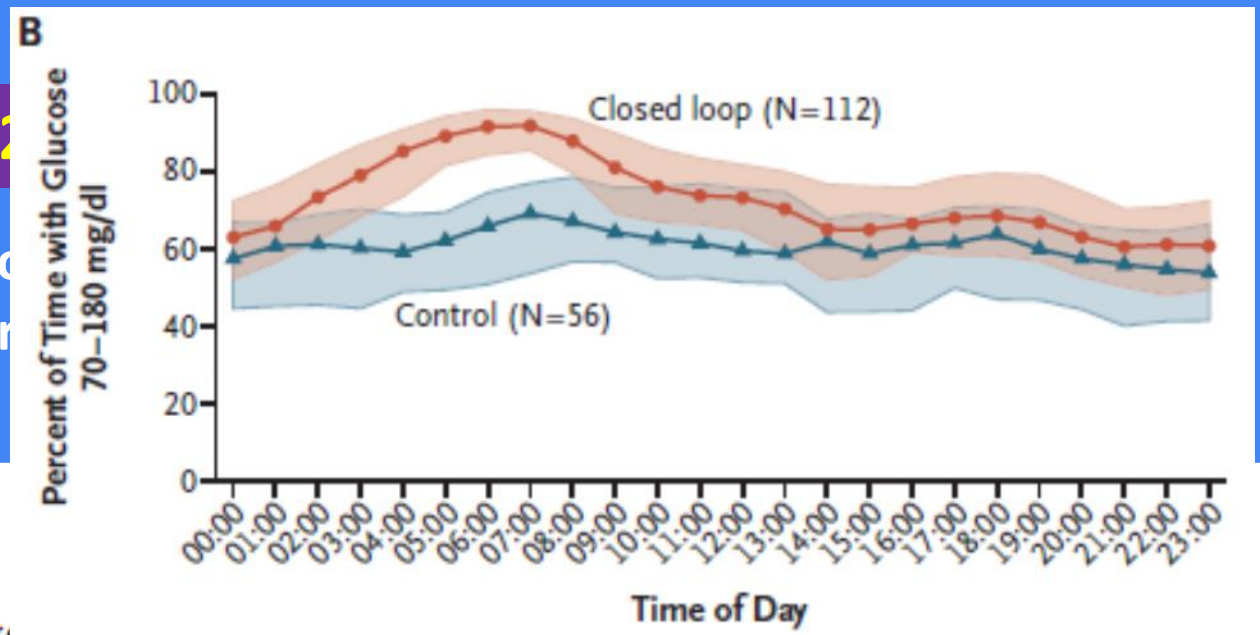
Hybrid closed-loop

Tandem Diabetes Care t:slim X2

n=168, 14-71 ετών
baseline HbA1c 7,4%

τυχαιοποίηση →

Closed loo
Control gr



Outcome	2-Wk Baseline Period			26-Wk Study Period			
	Closed Loop (N=112)	Control (N=56)		Closed Loop (N=112)	Control (N=56)	Closed Loop − Control (95% CI)‡	P Value‡
Median hours of sensor data (IQR)	307 (285–327)	306 (283–330)		4267 (4133–4348)	4141 (3922–4280)		
Primary outcome: percentage of time level in target range of 70 to 180 mg/dl	61±17	59±14	↑ 11%	71±12	59±14	11 (9 to 14)	<0.001
Secondary hierarchical outcomes							
Percentage of time with glucose le…	36±19	38±15	↓10%	27±12	38±15	−10 (−13 to −8)	<0.001
Glucose level — mg/dl	166±32	169±25	↓13mg/dL	156±19	170±25	−13 (−17 to −8)	<0.001
Glycated hemoglobin — %§	7.40±0.96	7.40±0.76	↓0,33%	7.06±0.79	7.39±0.92	−0.33 (−0.53 to −0.13)	0.001
Percentage of time with glucose le…	3.58±3.39	2.84±2.54	↓0,88%	1.58±1.15	2.25±1.46	−0.88 (−1.19 to −0.57)	<0.001
Percentage of time with glucose le…	0.90±1.36	0.56±0.79	↓0,1%	0.29±0.29	0.35±0.32	−0.10 (−0.19 to −0.02)	0.02

70-180

>180

glucose level

HbA1c

<70

<54

Brown et al N Engl J Med. 2019 Oct 31;381(18):1707

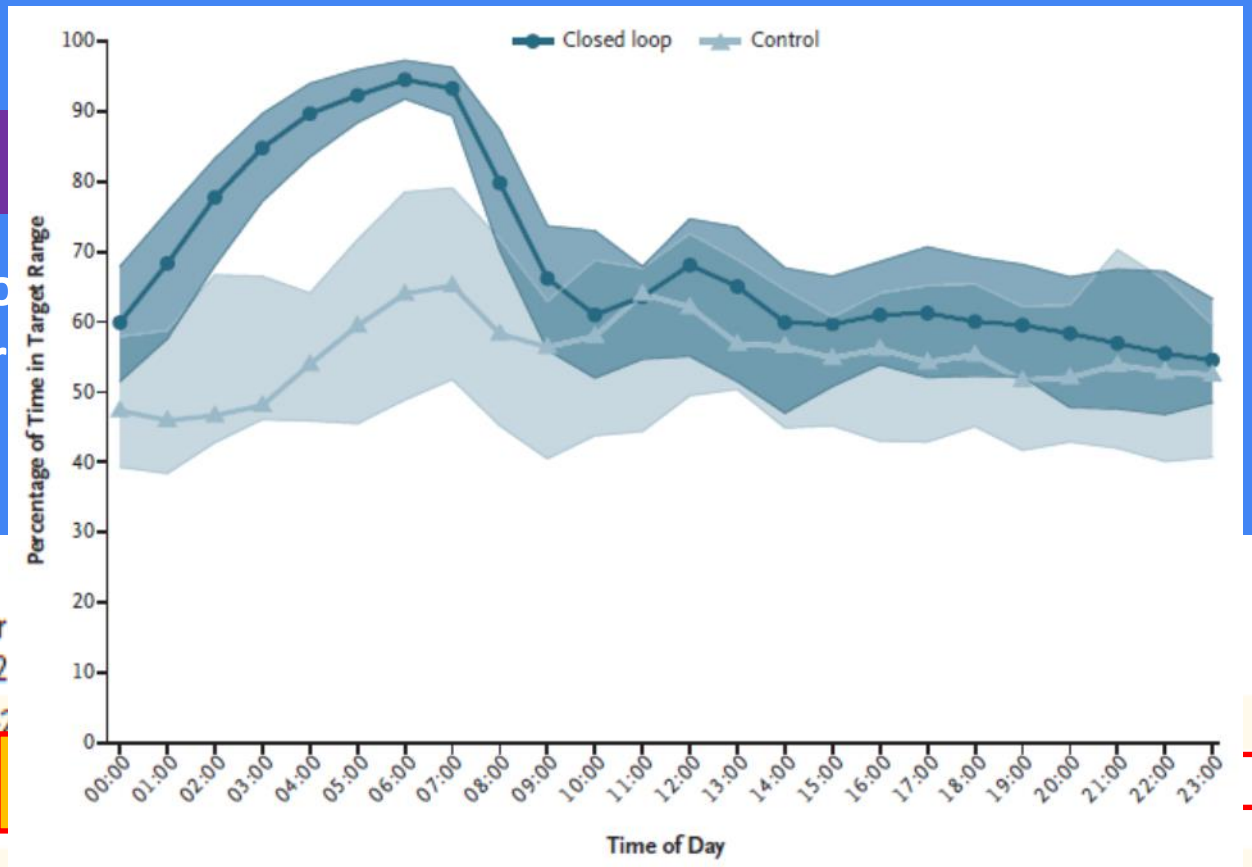
Hybrid closed-loop

Tandem Diabetes Care t:slim X2

n=101, 6-13 ετών
mean HbA1c 7,4%

τυχαιοποίηση →

Closed loo
Control gr



Outcome	Baseline†				
	Closed Loop (N=77)	Contr (N=2			
Hours of sensor data	306±33	311±			
Primary outcome: glucose level in ran 180 mg/dl — % of time	53±17	51±			
Secondary hierarchical outcomes in					
Glucose level >180 mg/dl — %	45±18	47±	↓10%	31±10	43±14	−10 (−14 to −6)	<0.001
Glucose level — mg/d	183±34	189±34		162±18	179±26	−13 (−20 to −7)	<0.001
Glycated hemoglobin level — %	7.6±1.0	7.9±(	↓0,4%	7.0±0.8	7.6±0.9	−0.4 (−0.9 to 0.1)	0.08
Glucose level <70 mg/dl — med)R)**	1.2 (0.5 to 2.4)	1.0 (0.2 to 2.1)		1.6 (0.8 to 2.4)	1.8 (1.1 to 3.0)	−0.40 (−0.83 to −0.02)	NA
Glucose level <54 mg/dl — med)R)**	0.1 (0.0 to 0.4)	0.1 (0.0 to 0.3)		0.2 (0.1 to 0.4)	0.3 (0.1 to 0.6)	−0.07 (−0.19 to 0.02)	NA
Glucose level >250 mg/dl — med QR)**	17.2 (8.6 to 27.6)	20.7 (12.4 to 32.6)		7.8 (5.1 to 14.3)	18.4 (9.4 to 24.6)	−5.8 (−8.7 to −3.0)	NA
Coefficient of variation in the sensor glucose measurement — %	38±5	38±4		38±4	39±4	−1.6 (−2.8 to −0.4)	NA

70-180
>180
glucose level
HbA1c
<70
<54
>250

Breton et al N Engl J Med. 2020 Aug 27;383(9):836

Tandem Mobi Automated Insulin Delivery System – Control-IQ Technology - Dexcom G7

- **Mobile app:** Compatible with an iPhone, the Tandem Mobi can automatically administer insulin via a mobile app. This enables users full control from a smartphone, with the option to manually bolus insulin if needed.
- **Control-IQ technology:** This algorithm interprets CGM data to predict glucose levels. Designed to be used with an AID system, Control-IQ adjusts insulin delivery every five minutes to prevent highs and lows and spend more time in range.
- **Shorter tubing option:** In addition to more than 30 existing infusion sites and tubing length combinations to choose from, users of the new Tandem Mobi insulin pump will also have a shorter 5-inch tubing option.

FlorenceM closed-loop system (University of Cambridge)

CamAPS FX Hybrid closed - loop

CGM (Dexcom 6): non adjunctive use – δυνατότητα calibration ή calibration όταν ζητείται από το σύστημα

Pump: Dana ή mylife YpsoPump

FlorenceM closed-loop system

multicentre, multinational, randomised controlled trial
n=86
12 εβδομάδες

Age subgroup, years	Closed-loop (n=46)	Control (n=40)
6–12	11 (24%)	12 (30%)
13–21	11 (24%)	8 (20%)
22–39	18 (39%)	14 (35%)
≥40	6 (13%)	6 (15%)

closed-loop vs SAP → **Μέση συγκέντρωση γλυκόζης ↓ 15mg/dL**

HbA1c ↓ 0,36%

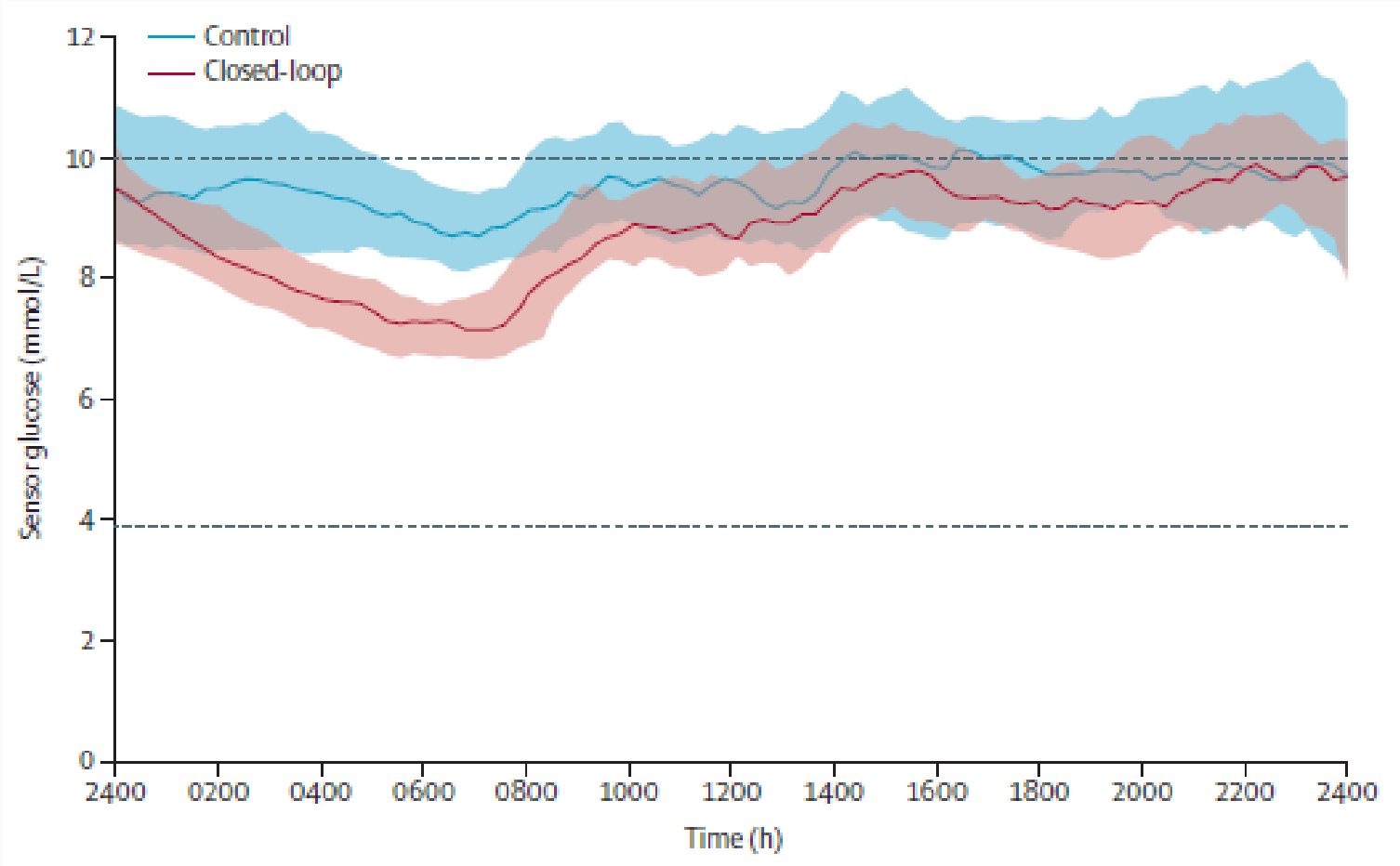
	mg/dL	Baseline		12 weeks		Difference (95% CI)*	p value*
		Closed-loop (n=46)	Control (n=40)	Closed-loop (n=46)	Control (n=40)		
Percentage of time with sensor glucose concentration in range							
↑ 10,8%	70-180						
3·9 to 10·0 mmol/L†		52% (10)	52% (9)	65% (8)	54% (9)	10·8 (8·2 to 13·5)	<0·0001
↓ 0,83%	<70						
Less than 3·9 mmol/L		3·5% (2·0 to 5·4)	3·3% (1·2 to 5·5)	2·6% (1·9 to 3·6)	3·9% (1·7 to 5·3)	−0·83 (−1·40 to −0·16)‡	0·0130
Less than 3·5 mmol/L		1·8% (0·8 to 3·2)	1·9% (0·6 to 3·3)	1·4% (0·9 to 1·9)	2·0% (0·9 to 3·0)	−0·33 (−0·81 to 0·04)‡	0·08
Less than 2·8 mmol/L		0·4% (0·1 to 1·0)	0·5% (0·1 to 1·0)	0·3% (0·2 to 0·6)	0·5% (0·2 to 0·9)	−0·09 (−0·24 to 0·01)‡	0·11
↓ 10,3%	>180						
More than 10·0 mmol/L		44% (11)	44% (11)	32% (8)	42% (10)	−10·3 (−13·2 to −7·5)	<0·0001
More than 16·7 mmol/L		5·5% (3·3 to 8·3)	4·9% (2·7 to 7·3)	3·5% (1·9 to 4·6)	4·4% (2·9 to 6·5)	−1·42 (−2·20 to −0·69)‡	<0·0001

Tauschmann et al Lancet. 2018 Oct 13;392(10155):1321

Hybrid closed-loop

FlorenceM closed-loop system (University of Cambridge) vs SAP

Βελτίωση περισσότερο έκδηλη την νύχτα



Tauschmann et al Lancet. 2018 Oct 13;392(10155):1321

CamAPS FX

Παιδιά με διαβήτη τύπου 1 ηλικίας 1-7 ετών, n=74
multicenter, randomized, crossover trial
hybrid closed-loop vs SAP
Κάθε φάση 16 εβδομάδες

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JANUARY 20, 2022 VOL. 386 NO. 3

Randomized Trial of Closed-Loop Control in Very Young Children with Type 1 Diabetes

End Point	Closed-Loop Period (N=73)	Sensor-Augmented Pump Period (N=74)	Mean Adjusted Difference (95% CI)	P Value
Primary end point				
Percent of time spent at glucose level 70–180 mg/dl	71.6±5.9	62.9±9.0	8.7 (7.4 to 9.9)	<0.001
Key end points				
Median percent of time spent at glucose level >180 mg/dl (IQR)	22.9 (19.3 to 27.3)	31.7 (23.4 to 40.1)	−8.5 (−9.9 to −7.1)	<0.001
Glycated hemoglobin				
Percent	6.6±0.6	7.0±0.7	−0.4 (−0.5 to −0.3)	<0.001
Median glucose AUC (IQR)†				
<63 mg/dl	0.1 (0.0 to 0.1)	0.1 (0.0 to 0.1)	0.002 (−0.006 to 0.009)	—
<54 mg/dl	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.001 (−0.001 to 0.003)	—

baseline 7,3%

Χωρίς διαφορά στην υπογλυκαιμία

Ware et al N Engl J Med. 2022 Jan 20;386(3):209

ADA's 82nd Scientific Sessions

Impressive Results From the iLet Bionic Pancreas Pivotal Trial

Dexcom 7

when someone starts on the device, all that is needed is their weight (no insulin dosing information)

After that, the system constantly adjusts to the user's need, only requiring input when setting the glucose target (Usual, Lower, Higher) and when eating (meal type and meal size, but does not require any carb counting).

All correction doses are automated.

- Target 110 -130mg/dL

4/6/2022

diaTribe Learn
MAKING SENSE OF DIABETES

iLet bionic pancreas (Beta Bionics)

13-week, multicenter, randomized trial
n = 326
6 to 79 years of age with type 1 diabetes

randomization 2:1 ratio: Bionic pancreas or standard care (defined as any insulin-delivery method with unblinded, real-time continuous glucose monitoring)

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 29, 2022 VOL. 387 NO. 13

Multicenter, Randomized Trial of a Bionic Pancreas in Type 1 Diabetes

Bionic Pancreas Research Group*

N Engl J Med 2022;387:1161

Table 1. Characteristics of the Participants at Baseline.*

Characteristic	Bionic Pancreas (N=219)	Standard Care (N=107)
Age — yr		
Mean	28±19	28±20
Glycated hemoglobin — %†		
Mean	7.9±1.2	7.7±1.1

MiniMed 670G or 770G system (Medtronic)
Control-IQ system (Tandem Diabetes Care)

Table 1. Characteristics of the Participants at Baseline.*

Characteristic	Bionic Pancreas (N=219)	Standard Care (N=107)
Insulin-delivery method — no. (%)		
Multiple daily injections	71 (32)	39 (36)
Pump without automation	71 (32)	31 (29)
Pump with predictive low-glucose suspension	9 (4)	5 (5)
Hybrid closed-loop system¶	68 (31)	32 (30)
Use of continuous glucose-monitoring system — no. (%)	194 (89)	97 (91)

iLet bionic pancreas (Beta Bionics)

Table 2. Primary and Secondary Hierarchical Efficacy Outcomes.*

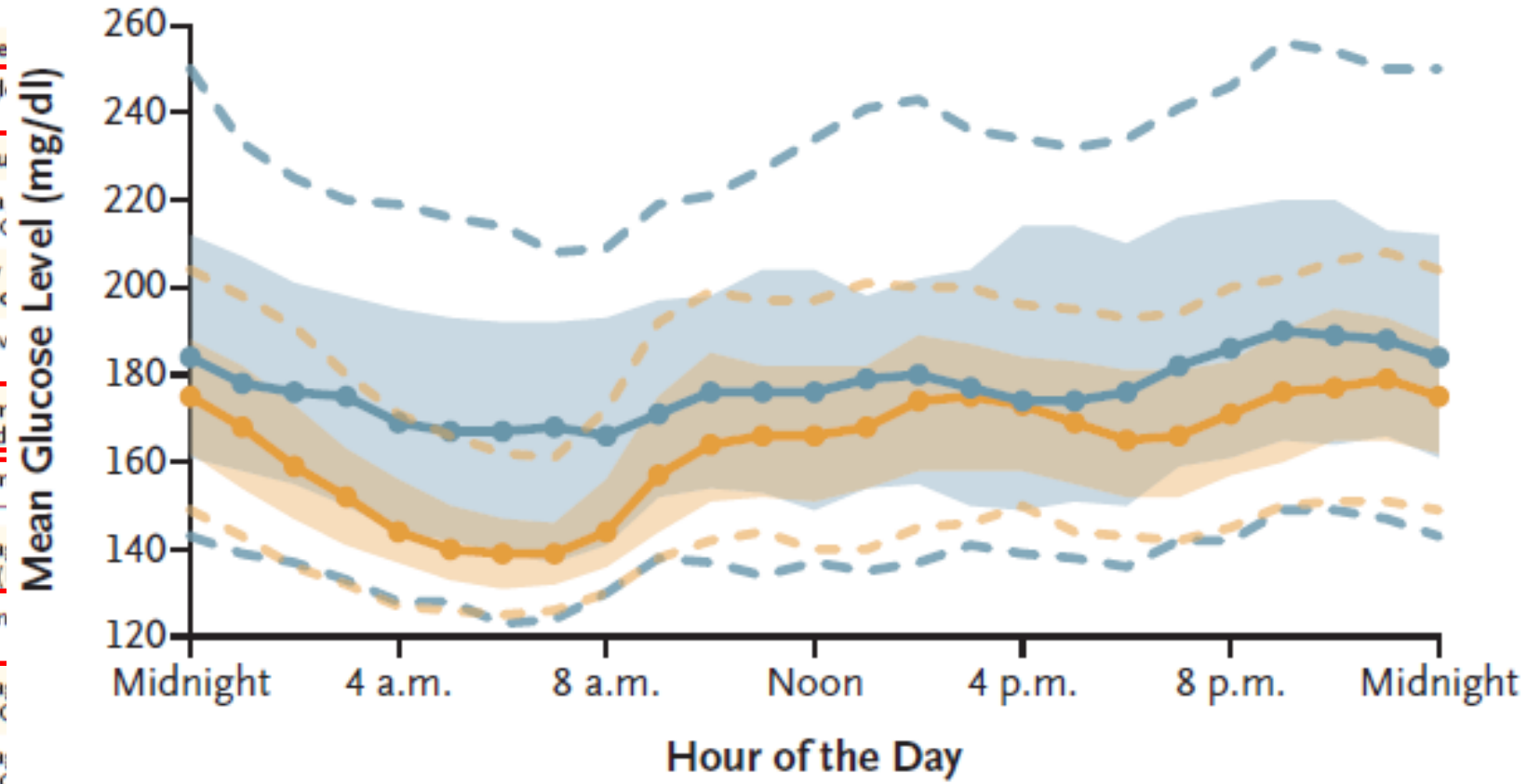
Outcome	Baseline		Follow-up over 13 Wk or at 13 Wk		Adjusted Difference (95% CI)†	P Value
	Bionic Pancreas (N = 219)	Standard Care (N = 107)	Bionic Pancreas (N = 219)	Standard Care (N = 107)		
Primary outcome						
Glycated hemoglobin — %	7.9±1.2	7.7±1.1	7.3±0.7	7.7±1.0	−0.5 (−0.6 to −0.3)	<0.001
Key secondary outcome						
Median percentage of time with glucose level <54 mg/dl (IQR) — %	0.2 (0.02 to 0.6)	0.2 (0.0 to 0.4)	0.3 (0.2 to 0.6)	0.2 (0.1 to 0.6)	0.0 (−0.1 to 0.04)	<0.001‡
Other secondary hierarchical outcomes in prespecified order						
Mean glucose level — mg/dl§	187±40	190±42	164±15	181±32	−16 (−19 to −12)	<0.001
Percentage of time with glucose level in range 70–180 mg/dl — %	51±19	51±20	65±9	54±17	11 (9 to 13)	<0.001
Percentage of time with glucose level >180 mg/dl — %	46±20	47±21	33±9	44±18	−10 (−12 to −8)	<0.001
Median percentage of time with glucose level >250 mg/dl (IQR) — %	16.0 (7.0 to 27.3)	17.8 (6.0 to 33.5)	8.5 (5.3 to 13.2)	14.9 (6.3 to 25.3)	−5.0 (−6.6 to −3.6)	<0.001
Glucose SD — mg/dl¶	67±16	68±18	60±11	67±16	−7 (−8 to −5)	<0.001
Median percentage of time with glucose level <70 mg/dl (IQR) — %	1.5 (0.5 to 2.8)	1.4 (0.4 to 2.9)	1.8 (1.1 to 2.9)	1.8 (0.8 to 3.1)	−0.1 (−0.3 to 0.2)	0.51
Median percentage of time with glucose level <54 mg/dl (IQR) — %‖	0.2 (0.02 to 0.6)	0.2 (0.0 to 0.4)	0.3 (0.2 to 0.6)	0.2 (0.1 to 0.6)	0.0 (−0.1 to 0.04)	—
Glucose coefficient of variation — %¶	36±6	36±6	36±5	37±5	−0.8 (−1.6 to 0.0)	—

N Engl J Med 2022;387:1161

iLet bionic pancreas (Beta Bionics)

Table 2. Primary and Secondary Hierarchical Efficacy Outcomes.*

Outcome	Baseline	Follow-up over 13 Wk or at 13 Wk	Adjusted Difference (95% CI)†	P Value
	Standard care	Bionic pancreas		
Primary outcome				
Glycated hemogl			.5 –0.3)	<0.001
Key secondary ou				
Median percenta <54 mg/dl (I			0 0.04)	<0.001‡
Other secondary prespecified				
Mean glucose lev			6 –12)	<0.001
Percentage of tim 70–180 mg/d			1 13)	<0.001
Percentage of tim >180 mg/dl–			0 –8)	<0.001
Median percenta >250 mg/dl (			.0 –3.6)	<0.001
Glucose SD — m			7 –5)	<0.001
Median percenta <70 mg/dl (I			.1 0.2)	0.51
Median percenta <54 mg/dl (I			0 0.04)	—
Glucose coefficient of variation — %¶	36±6	36±6	36±5	37±5	–0.8 (–1.6 to 0.0)	—



N Engl J Med 2022;387:1161

Hybrid closed-loop insulin pumps vs SAP Trials

	TIR (%) <14 ετών	TIR% >14 ετών
Minimed 780G	+11.8	+11.9 – 14.4
Omnipod 5	+15.6	+9.3
t:slim X2 with Control-IQ	+11	+12%

Collyns et al Diabetes Care. 2021 Apr;44(4):969
Brown et al Diabetes Care 2021 Jun 7;44(7):1630

Breton et al N Engl J Med. 2020 Aug 27;383(9):836
Brown et al N Engl J Med. 2019 Oct 31;381(18):1707

	TIR (%) παιδιά > 6 ετών και ενήλικες	TIR% 1-7 ετών
CamAPS FX	+10.8	+8.7

Tauschmann et al Lancet. 2018 Oct 13;392(10155):1321

Ware et al N Engl J Med. 2022 Jan 20;386(3):209

Hybrid closed-loop insulin pumps – Real world data

Minimed 780G (n=101,629)	TIR: 72.3%, GMI: 7%, TBR: 2% TIR 78.8% (optimal settings)	*Choudhary et al Diabetes Technol Ther. 2024 Mar;26(S3):32*
Omnipod 5 (n=69,902)	TIR: 68.8% (target 110), GMI: 7.2%, TBR: 1.13%	*Forlenza et al Diabetes Technol Ther. 2024 Aug;26(8):514*
CamAPS FX(n=1805)	TIR: 72.6%, GMI: 6.9%, TBR: 2.3%	*Alwan et al J Diabetes Sci Technol. 2025 Mar;19(2):385*
Tandem Control IQ (n=9451)	TIR: 72.6%, GMI: 6.9%, TBR: 1%	*Breton et al J Diabetes Technol Ther. 2021 Sep;23(9):601*
DBLG1 (n=9036)	TIR: 68.1%, TBR: 1%	*Lebbad et al J Diabetes Sci Technol. 2025 Sep;19(5):1257*

Hybrid closed-loop insulin pumps – Diabetes distress

Adults (n=120, RCT, MiniMed™ 670G, Australia)

reduced anxiety, improved sleep, reduced mental and self-management burden, greater flexibility with daily life and improvement in the quality of life

Halliday et al BMJ Open Diabetes Res Care. 2024 Dec 22;12(6):e004428

Adults and adolescents (n=257 - longitudinal real-life study - Tandem Control IQ, CamAPS FX - France)

↓ diabetes distress (concerns regarding serious diabetes complications, feelings of guilt, and anxiety regarding diabetes management, worry about hypoglycaemia, and mental and physical exhaustion caused by diabetes)

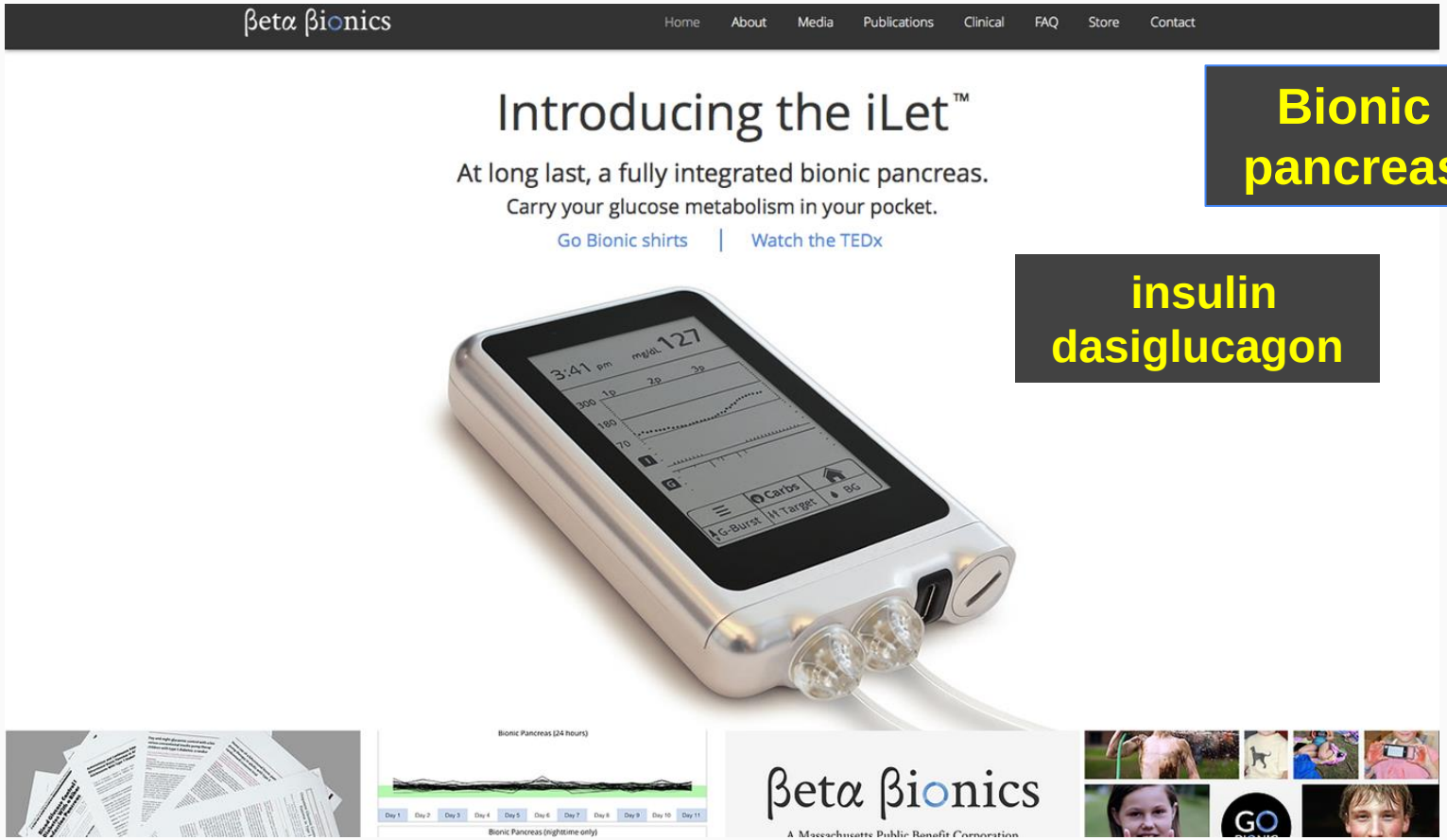
Reznic et al Diabetes Obes Metab. 2024 May;26(5):1962

Parents (n=33, crossover randomized, CamAPS FX, Austria, Germany, Luxembourg and UK)

Children engaged in play, sleep, and social events independently from their parents without interruptions

Hart et al Diabet Med. 2022 Jul;39(7):e14828

Dual hormone closed-loop: Insulin - glucagon



Bionic pancreas

insulin dasiglucagon

βeta βionics

A Massachusetts Public Benefit Corporation

Προαιρετική αναγγελία: γεύματος “breakfast”, “lunch”, “dinner”

μεγέθους “typical”, “more than typical”, “less than typical”, “a small bite”

Dual hormone closed-loop
Insulin - glucagon

Ενήλικοι με διαβήτη τύπου 1,
n=43
Randomized, crossover
Κάθε φάση 11 ημέρες

dual hormone closed-loop vs CSII/SAP

Μέση συγκέντρωση γλυκόζης ↓ 22mg/dL

Μεγαλύτερη βελτίωση τη νύχτα ↓ 31 mg/dL

(% of time)	Bionic pancreas	CSII CSII+SAP	P value
<50	0.4	0.6	<0.0001
<70	2.7	4.5	<0.0001
70 – 180 mg/dL	78.4	61.9	<0.0001
>180 mg/dL	19.8	33.6	<0.0001

El-Khatib et al Lancet. 2017 Jan 28;389(10067):369

Dual hormone closed-loop: Insulin - glucagon

Παιδιά με διαβήτη τύπου 1, n=19
randomized, crossover: Bionic pancreas vs CSII
Κάθε φάση 5 ημέρες

	Bionic Pancreas	Control	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

mg/dL
< 60
70 -180
>180

↓ γλυκαιμικής μεταβλητότητας

➢ Ακόμα καλύτερα αποτελέσματα τη νύχτα

Russell et al Lancet Diabetes Endocrinol. 2016 March ; 4(3): 233

Dual hormone closed-loop: Insulin - glucagon

FCL system (Inreda AP; Inreda Diabetic, Goor, Netherlands

T1DM
n=78
age 18-75 years

Bihormonal fully closed-loop system for the treatment of type 1 diabetes: a real-world multicentre, prospective, single-arm trial in the Netherlands

Lancet Digit Health. 2024 Apr;6(4):e272

A C van Bon*, H Blauw*, T J P Jansen, G D Laverman, T Urgert, J Geessink-Mennink, A H Mulder, M Out, R Groote Veldman, A J Onvlee, B J J W Schouwenberg, M A R Vermeulen, M J M Diekman, M N Gerding, J P H van Wijk, M Klaassen, M Witkop, J H DeVries

- no meal or exercise announcement

Europe: CE certificate

Dual hormone closed-loop: Insulin - glucagon

FCL system (Inreda AP; Inreda Diabetic, Goor, Netherlands

T1DM
n=78
age 18-75 years

- no meal or exercise a

Europe: CE certificate

	Participants (n=78)
Age, years	47·7 (12·4)
BMI, kg/m²	26·7 (4·4)
Diabetes duration, years	26·0 (15·0–39·0)
HbA_{1c}, mmol/mol; %	61·4 (10·7); 7·8% (3·1)
Daily insulin dose, unit	44·0 (33·0–60·8)
Sex	
Female	38 (49%)
Male	40 (51%)
Treatment at preintervention	
Multiple daily injections with FGM	12 (15%)
Multiple daily injections with CGM	2 (3%)
Insulin pump with FGM	36 (46%)
Insulin pump with CGM	23 (29%)
Hybrid closed-loop system	5 (6%)

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Digit Health. 2024 Apr;6(4):e272

R Groote Veldman, A J Onvlee,
Vitkop, J H DeVries

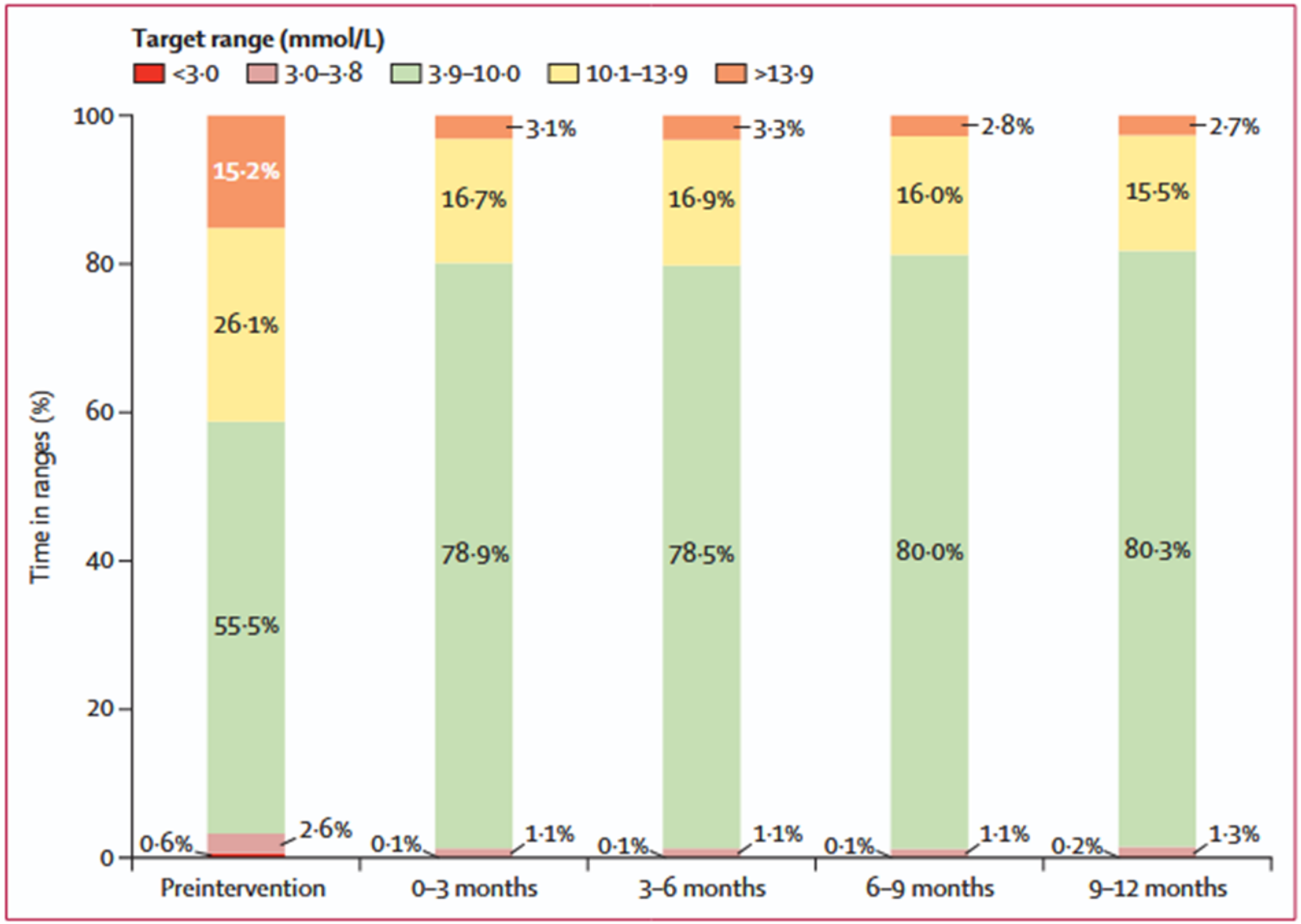
Dual hormone closed-loop: Insulin - glucagon

FCL system (Inreda AP; Inreda Diabetic, Goor, Netherlands

T1DM
n=78
age 18-75 years

➢ no meal or exercise

Europe: CE certificate



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Άσκηση και closed loop CSII

Άσκηση στον Διαβήτη Τύπου 1

Exercise management in type 1 diabetes: a consensus statement

Michael C Riddell, Ian W Gallen, Carmel E Smart, Craig E Taplin, Peter Adolfsson, Alistair N Lumb, Aaron Kowalski, Remi Rabasa-Lhoret, Rory J McCrimmon, Carin Hume, Francesca Annan, Paul A Fournier, Claudia Graham, Bruce Bode, Pietro Galassetti, Timothy W Jones, Iñigo San Millán, Tim Heise, Anne L Peters, Andreas Petz, Lori M Laffel

Lancet Diabetes Endocrinol 2017

Glucose management for exercise using continuous glucose monitoring (CGM) and intermittently scanned CGM (isCGM) systems in type 1 diabetes: position statement of the European Association for the Study of Diabetes (EASD) and of the International Society for Pediatric and Adolescent Diabetes (ISPAD) endorsed by JDRF and supported by the American Diabetes Association (ADA)

Moser et al Diabetologia. 2020 Dec;63(12):2501

ISPAD Clinical Practice Consensus Guidelines 2022: Exercise in children and adolescents with diabetes

Adolfsson et al Pediatr Diabetes. 2022 Dec;23(8):1341

UK

DAFNE

Type 1 Diabetes: Less guesswork. More freedom. Better health.

Άσκηση στον Διαβήτη Τύπου 1

Exercise management in type 1 diabetes: a consensus statement

Michael C Riddell, Ian W Gallen, Carmel E Smart, Craig E Taplin, Peter Adolfsson, Alistair N Lumb, Aaron Kowalski, Remi Rabasa-Rory J McCrimmon, Carin Hume, Francesca Annan, Paul A Fournier, Claudia Graham, Bruce Bode, Pietro Galassetti, Timothy W Jones, Iñigo San Millán, Tim Heise, Anne L Peters, Andreas Petz, Lori M Laffel

Lancet Diabetes Endocrinol 2017

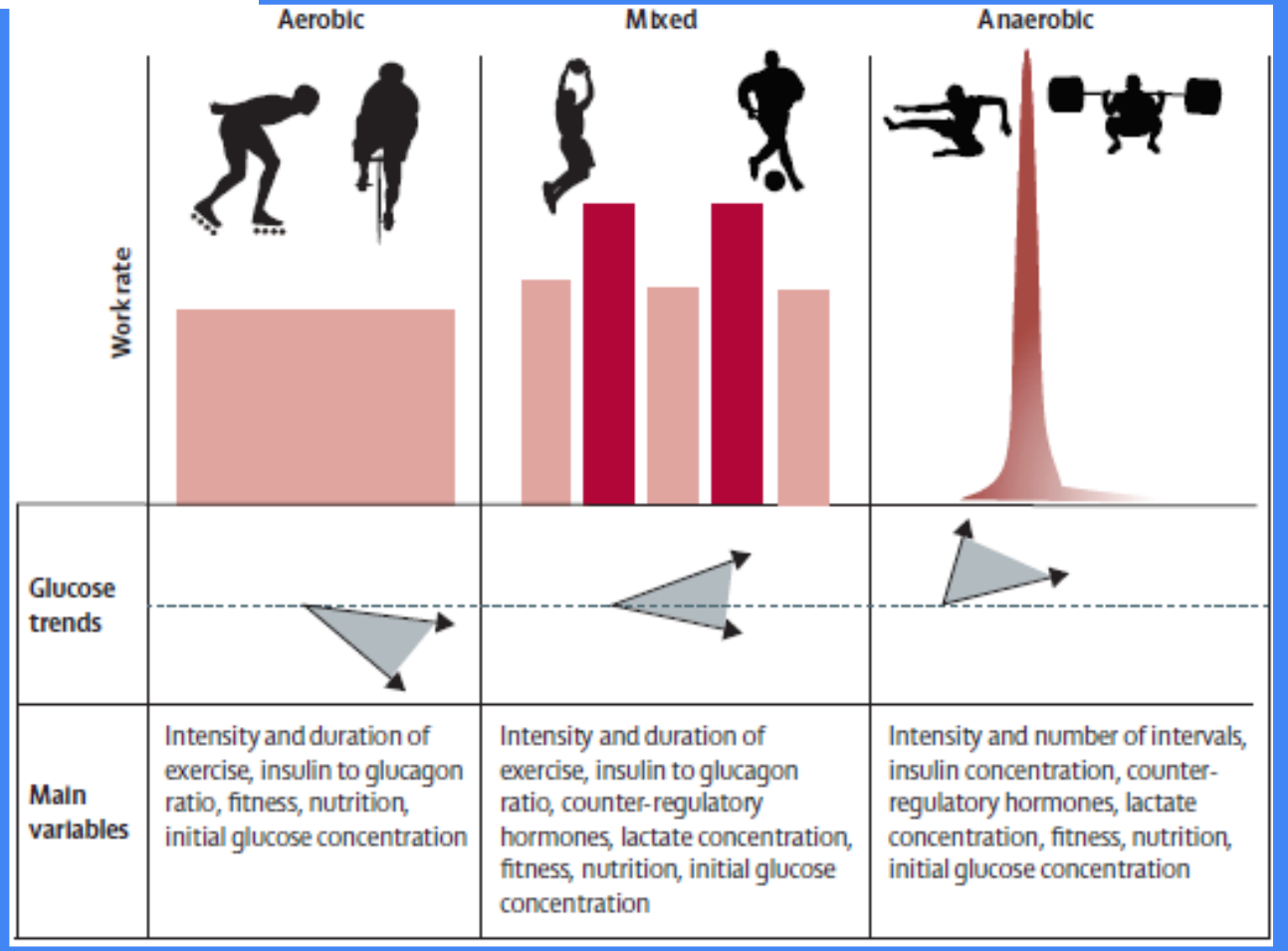
Αερόβια **Μεικτή** **Αναερόβια**

Σημαντικός παράγοντας μεταβλητότητας

Επίδραση στα επίπεδα Σχ κατά τη διάρκεια της άσκησης: Αερόβια → Σχ ↓
Αναερόβια → Σχ ↑

Επίδραση στα επίπεδα και αργότερα μετά το πέρας της άσκησης
→ αύξηση ευαισθησίας στην ινσουλίνη
τάση νυκτερινής υπογλυκαιμίας

Σημαντικό κομμάτι της εκπαίδευσης του ασθενούς



Welcome to Runsweet.com

Helping people with Type 1 Diabetes to be winners!

http://www.runsweet.com

Προβλήματα της άσκησης σε άτομα με σακχαρώδη διαβήτη τύπου 1

Υπογλυκαιμία (σχετική υπερινσουλιναιμία, υπολειπόμενη νευροενδοκρινική απάντηση του οργανισμού στην υπογλυκαιμία)

Υπεργλυκαιμία (αύξηση των αντιρροπιστικών προς την ινσουλίνη ορμονών κατά τη διάρκεια της άσκησης)

Απορρύθμιση ΣΔ ή/και Διαβητική Κετοξέωση

- **Ο κυριότερος αποτρεπτικός παράγοντας για άσκηση είναι ο φόβος της υπογλυκαιμίας**
- **Ιδιαίτερα προβληματική είναι η ομάδα ασθενών με επηρεασμένη επίγνωση υπογλυκαιμίας**

	Minimed 780G	Tandem Control IQ	Omnipod 5	CamAPS FX	iLet Bionics	DBLG1 Diabeloop	TouchCare Nano System
Glucose Target (mg/dl)	100,110,120	Treat to range 112.5-160	110,120,130, 140,150	104.4 (Default) 80-200	Usual 120 (default) Lower 110 Higher130	100-130	100,110,120
Additional target personalization during the day	–	–	different values for different times of day	specific glucose target for every 30-minute time block	two different targets per 24-hour period: a "CGM Target" and a "CGM Sleep Target."	–	–
Multiple settings profiles during the day	ICR	ICR Correction factor Basal rate	ICR Correction factor	ICR	–	–	ICR
Exercise	Temporary target - 150 mg/dL	Exercise activity mode-140-160 mg/dL	HypoProtect: 150 mg/dL	Ease off: + 45 mg/dL	- (no specific feature, manual target change)	Physical activity mode + 70 mg/dL	Exercise activity mode 150 mg/dL
Optional modes		Sleep mode 112.5-120	–	Boost mode +35%	Sleep CGM target	▪ Zen mode ▪ +10-40 mg/dL ▪ Aggressive	–

Τροποποιημένο από Markakis and Vazeou. Insulin Pumps and Artificial Pancreas. Encyclopedia of Endocrine Diseases 3rd edition, in press

Exercise – CL strategies

Planned exercise

ISPAD 2022

Adolfsson et al Pediatr Diabetes. 2022 Dec;23(8):1341

Zaharieva et al Diabetes Spectr. 2023 May;36(2):127

Ιδανικά γεύμα >3h πρό της άσκησης → ↓ IOB

Εάν γεύμα 1-3h προ της άσκησης → ↓ bolus 25-75%

CamAPS FX: επιτρέπει μείωση του bolus

Control-IQ, MiniMed 780G, Omnipod 5: δεν επιτρέπουν μείωση του bolus → εισαγωγή μικρότερης ποσότητας CHO

Προσοχή: σε ACL η αυτόματη χορήγηση ινσουλίνης θα αρχίσει να αυξάνει με την αύξηση του Σχ

Bolus reduction before exercise	• Consider a 25% bolus reduction with meal before exercise (otherwise glucose will rise and automated insulin delivery will increase before exercise, therefore insulin on board [IOB] will be higher) • Bolus reduction will also decrease total IOB at exercise onset
Exercise target before exercise	• Set 1–2 h before exercise • Resume at end of exercise • If increased risk of hypoglycemia, maintain higher exercise/activity target for 1–2 h in recovery
Bolus reduction and exercise target before exercise	• May consider 25% bolus reduction with meal before exercise and set exercise target 1–2 h before exercise
Lower IOB before exercise onset	• Consume main meal at least 3 h before exercise
Pump suspension or disconnect	• Avoid prolonged (>120 min) pump suspension – risk of hyperglycemia or increased ketones

Exercise – CL strategies

Planned exercise

ISPAD 2022

Adolfsson et al Pediatr Diabetes. 2022 Dec;23(8):1341

Zaharieva et al Diabetes Spectr. 2023 May;36(2):127

Uncovered CHO before exercise

HCL technology:

consuming uncovered snacks 30 min before exercise → rise in sensor glucose levels associated with the uncovered snack which will likely lead to a subsequent rise in automated insulin delivery and therefore increase the risk of hypoglycemia during the activity.

The current consensus is that pre-exercise carbohydrate intake should be limited to within 5–10 min before the onset of exercise or if the individual develops hypoglycemia prior to the exercise session.

In situations when carbohydrate intake is necessary in the 1–2 h before exercise, an insulin bolus reduced by approximately 25% should be given and then the HCL system should be placed into “activity mode”.

Exercise – CL strategies

Planned exercise

A single-blind, randomised, crossover study to reduce hypoglycaemia risk during postprandial exercise with closed-loop insulin delivery in adults with type 1 diabetes: announced (with or without bolus reduction) vs unannounced exercise strategies

Tagougui et al Diabetologia. 2020 Nov;63(11):2282

Adults type 1 diabetes N=37, cross-over trial
Closed loop – Dexcom 4 Target 6.0 mmol/l (108mg/dL)
Exercise announcement 90 min before exercise → Target 9.0 mmol/l (162mg/dL)
Moderate intensity exercise 60min
Meal 65gr CHO 90 min before exercise

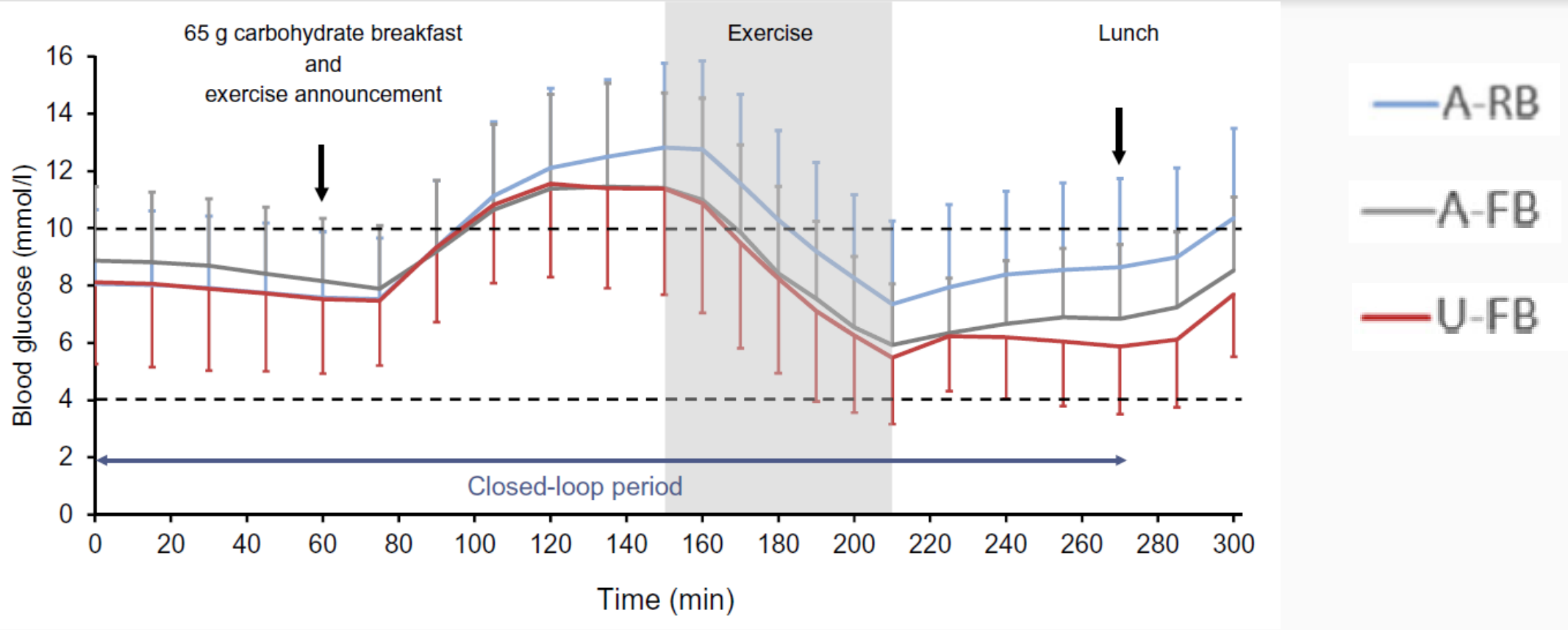
A-RB announced exercise + 33% reduction in meal bolus

A-FB announced exercise and a full meal bolus

U-FB unannounced exercise and a full meal bolus

Exercise – CL strategies

Planned exercise



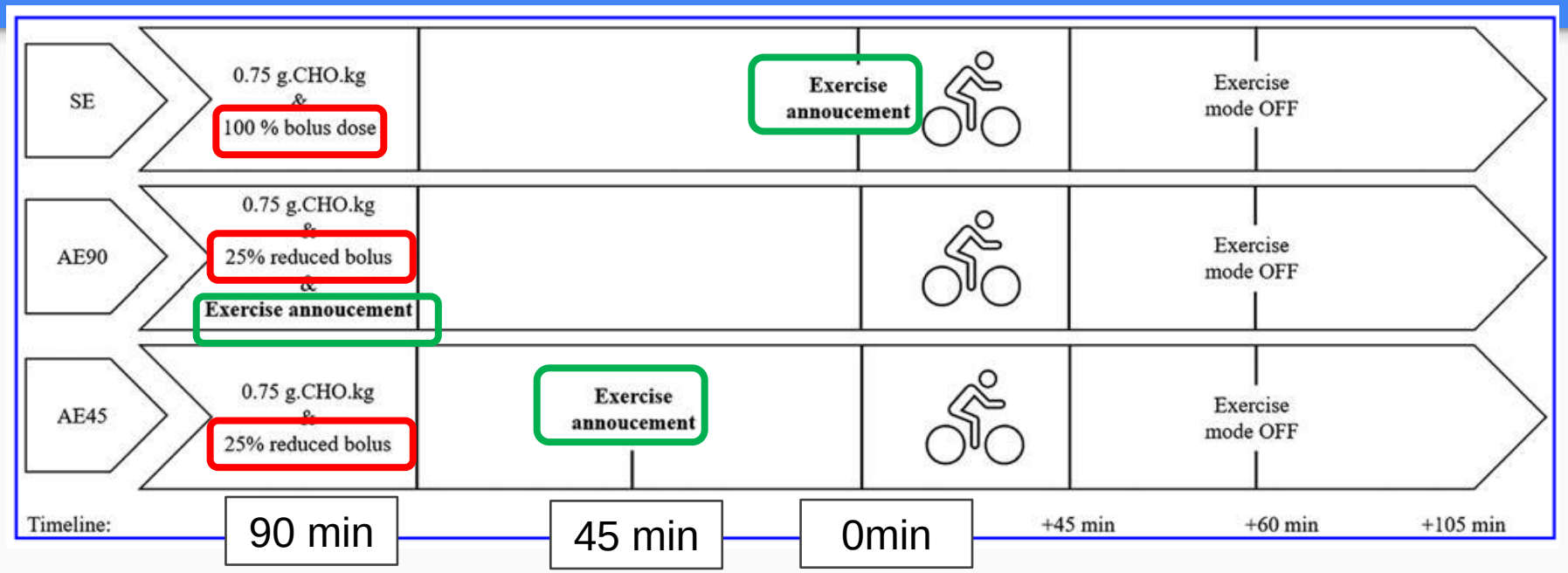
During exercise and the following 1 h recovery period
time spent in hypoglycaemia (<3.9 mmol/l; primary outcome) was reduced with A-RB (mean ± SD; 2.0 ± 6.2%) and A-FB (7.0 ± 12.6%) vs U-FB (13.0 ±19.0%; p< 0.0001 and p = 0.005, respectively)

Tagougui et al Diabetologia. 2020 Nov;63(11):2282

Exercise – CL strategies

Planned exercise

N=10, cross-over,
Medronic 780G,
Moderate intensity exercise

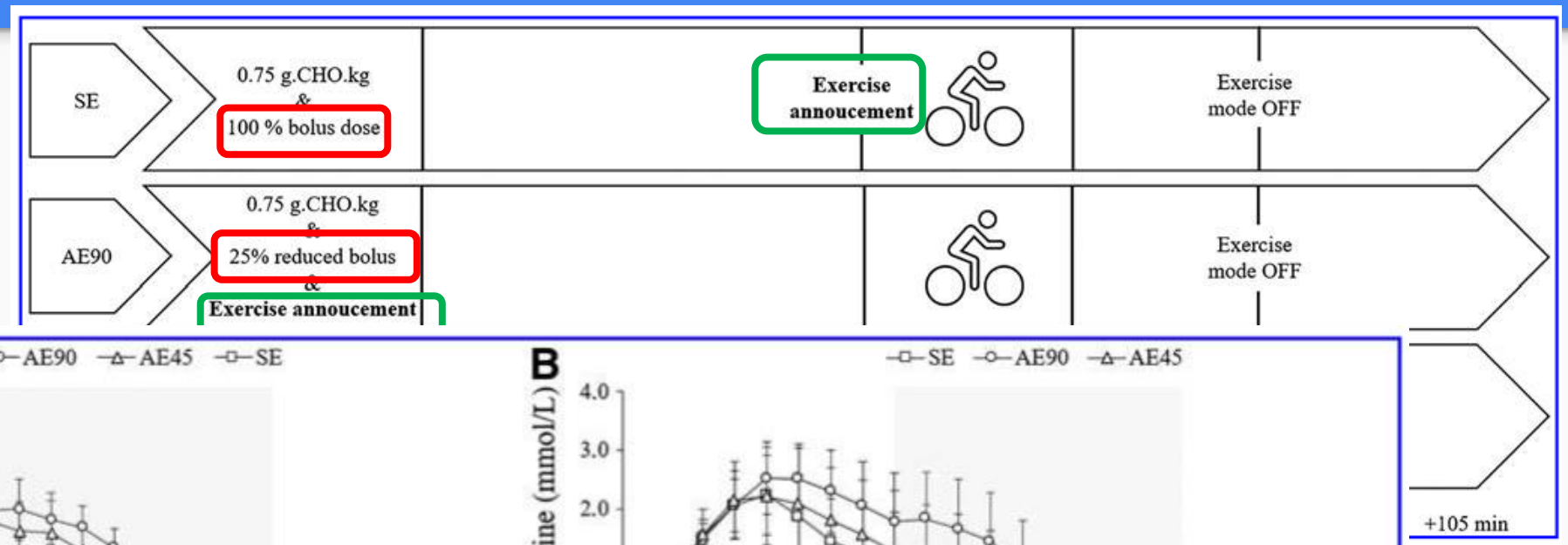


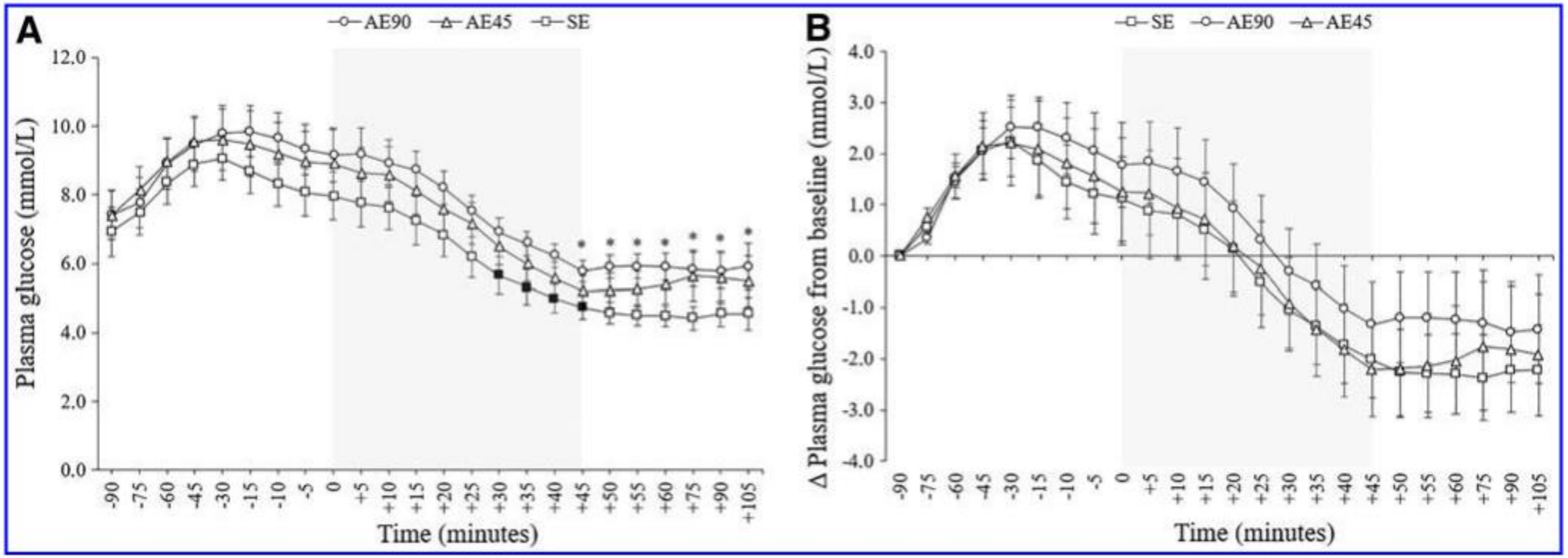
McCarthy et al Diabetes Technol Ther. 2023 Jul;25(7):476

Exercise – CL strategies

Planned exercise

N=10, cross-over,
Medronic 780G,
Moderate intensity exercise





McCarthy et al Diabetes Technol Ther. 2023 Jul;25(7):476

Strengths and Challenges of Closed-Loop Insulin Delivery During Exercise in People With Type 1 Diabetes: Potential Future Directions

Barbora Paldus, MBBS[1,2], Dale Morrison, PhD[1], Melissa Lee, MBBS[1,2], Dessi P. Zaharieva, PhD[3], Michael C. Riddell, PhD[4], and David N. O'Neal, MD[1,2]

J Diabetes Sci Technol. 2023 Jul;17(4):1077

Current CL Systems and Exercise: Limitations

A) The **slower pharmacokinetics of subcutaneous insulin delivery**

B) An absent **glucagon response during exercise** to address falling glucose levels

C) These systems **lack the ability to automatically detect the onset, intensity, and duration of exercise**

J Diabetes Sci Technol. 2023 Jul;17(4):1077

Άσκηση – Dual Hormone Closed-loop

Dual Hormone Closed-loop (DH) → μεγάλες μειώσεις στην επίπτωση υπογλυκαιμίας σε άσκηση

Υπεροχή έναντι SAP – SAP+PLGS και Single Hormone Closed-loop (SH)

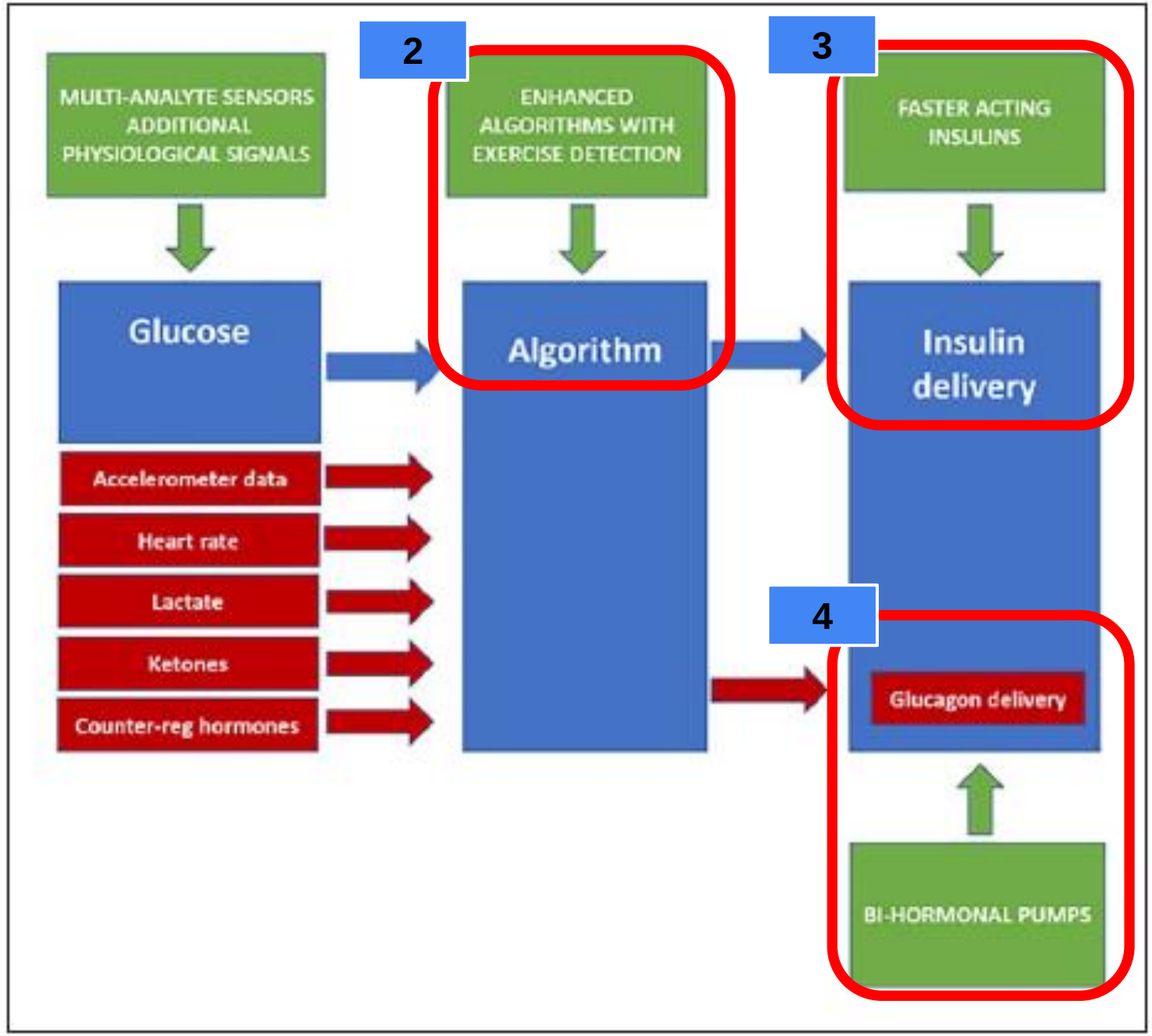
DH closed-loop vs SAP	*Taleb et al Diabetologia (2016) 59:2561*
DH closed-loop vs SH closed-loop	*Jacobs et al Diabetes Obes Metab. 2016 November ; 18(11): 1110*
DH closed-loop vs SH closed-loop vs SAP+PLGS	*Castle et al Diabetes Care. 2018 Jul;41(7):1471*
DH closed-loop vs SH closed-loop vs usual care (post exercise nocturnal TIR and hypoglycaemia)	*Wu et al Diabetes Technol Ther. 2022 Oct;24(10):754*

Potential Strategies to Address HCL Limitations When Challenged by Exercise

1

SENSORS
Physiological signals

Ανίχνευση άσκησης και έντασης άσκησης



J Diabetes Sci Technol. 2023 Jul;17(4):1077

Συστήματα συνεχούς έγχυσης ινσουλίνης κλειστού κυκλώματος
Άσκηση

Ποδήλατο
Κυλιόμενος τάπητας
Σκι

SH-AP vs CSII
SH-AP vs SAP

Χωρίς αναγγελία άσκησης

Μικρές διαφοροποιήσεις υπερ SH-AP

Dovc et al Diabetologia (2017) 60:2157
Breton et al Diabetes Care (2017) 40:1644

SH-AP με ανίχνευση άσκησης vs SH-AP

Με ανίχνευση άσκησης άσκησης

Heart rate monitor
Accelerometer

Καλύτερα αποτελέσματα με ανίχνευση άσκησης

Breton, et al. Diabetes Technol Ther. (2014) 16:506
Jacobs et al. J Diabetes Sci Technol. (2015) 9:1175

SH-AP vs DH-AP
SH-AP vs DH-AP vs PLGS

Υπεροχή DH-AP

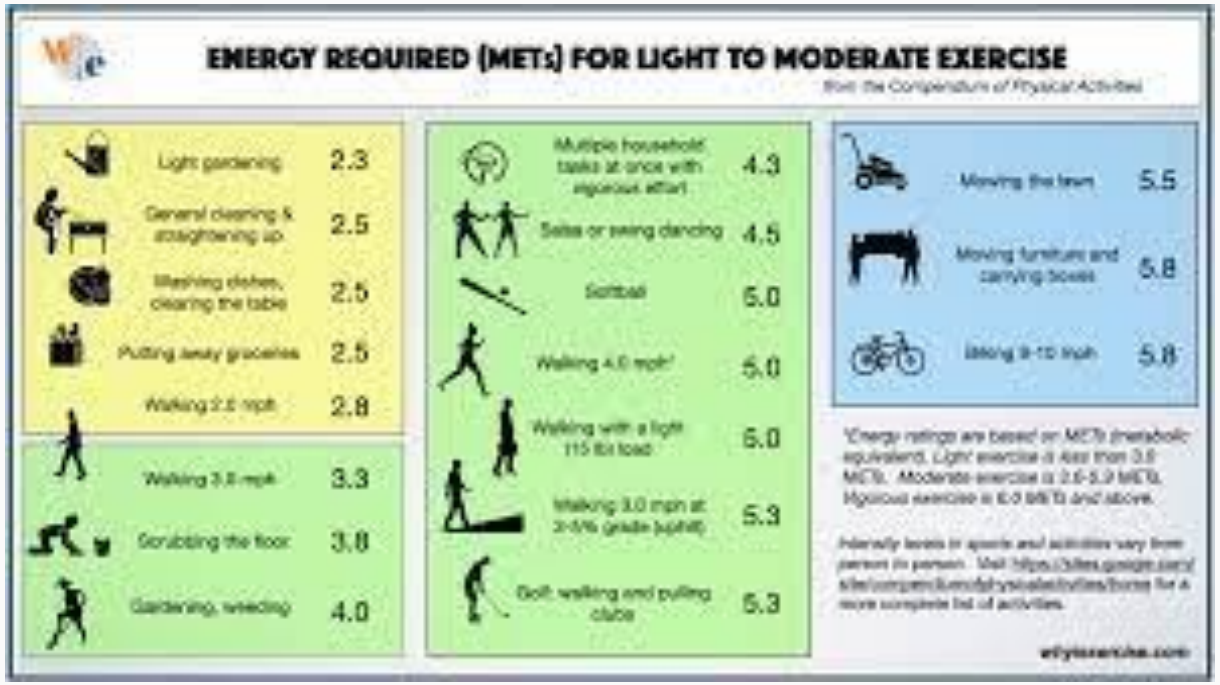
Jacobs et al Diabetes Obes Metab. (2016) 18:1110
Taleb et al Diabetologia (2016) 59:2561
Castle et al Diabetes Care (2018) 41:1471

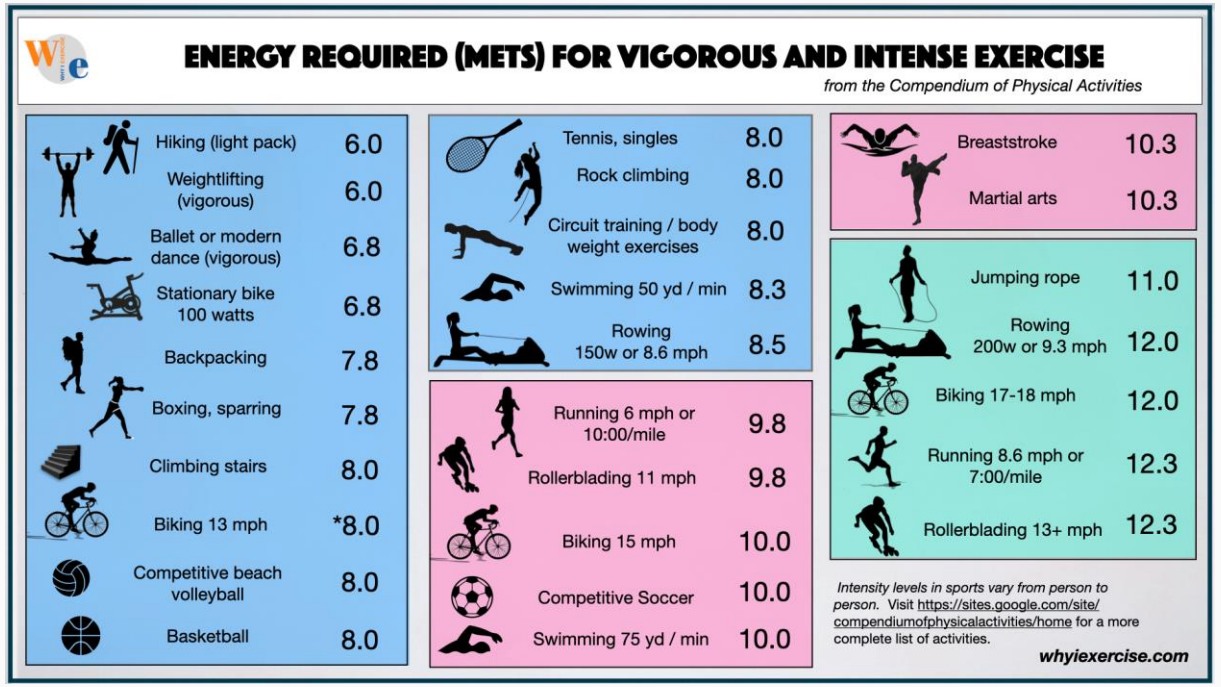
SH-AP: single hormone artificial pancreas, DH-AP: dual hormone artificial pancreas,
SAP: sensor augmented pump, PLGS: presictive low glucose suspension

Metabolic equivalent of task (MET)

The metabolic equivalent of task (MET) is the objective measure of the ratio of the rate at which a person expends energy

One metabolic equivalent (MET) is defined as the amount of oxygen consumed while sitting at rest and is equal to 3.5 ml O2 per kg body weight x min





2011 Compendium of Physical Activities Med Sci Sports Exerc. 2011 Aug;43(8):1575

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One metabolic equivalent (MET) is defined as the amount of oxygen consumed while sitting at rest and is equal to 3.5 ml O2 per kg body weight x min

Estimating metabolic equivalents for activities in daily life using acceleration and heart rate in wearable devices

Nakanishi et al. BioMed Eng OnLine (2018) 17:100

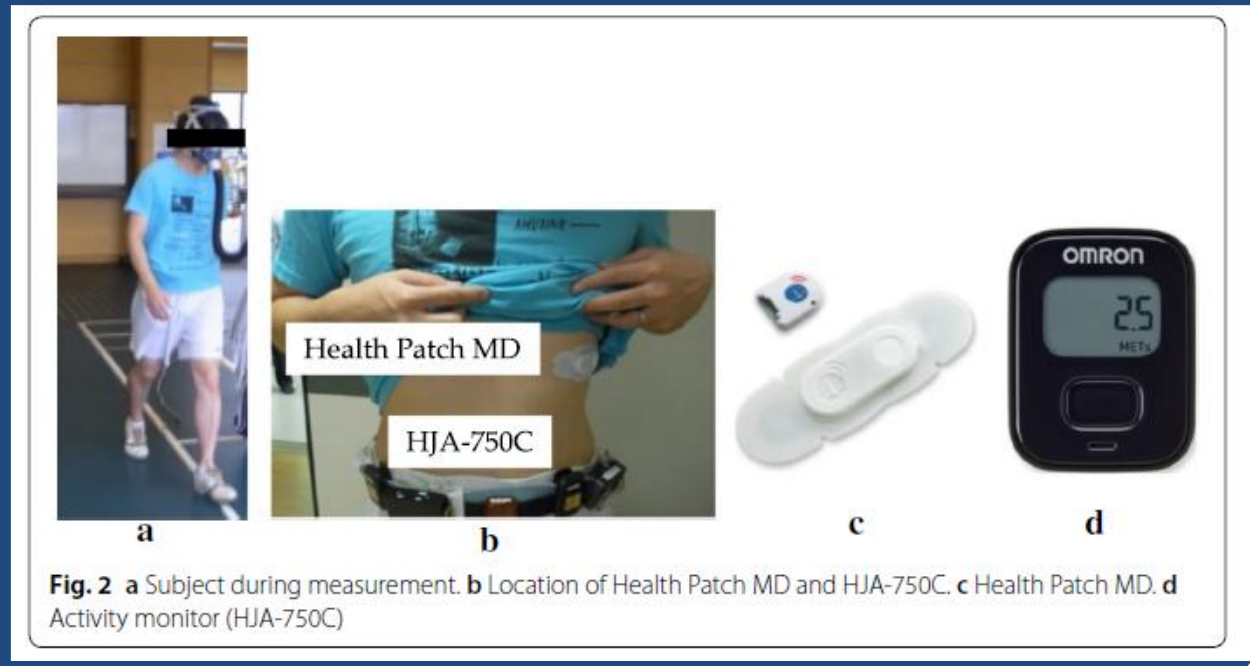


Fig. 2 **a** Subject during measurement. **b** Location of Health Patch MD and HJA-750C. **c** Health Patch MD. **d** Activity monitor (HJA-750C)

2011 Compendium of Physical Activities Med Sci Sports Exerc. 2011 Aug;43(8):1575

Άσκηση – Single Hormone Closed-loop vs Dual hormone closed-loop vs SAP+PLGS

Ανίχνευση άσκησης

Επιβεβαίωση άσκησης από τον ασθενή

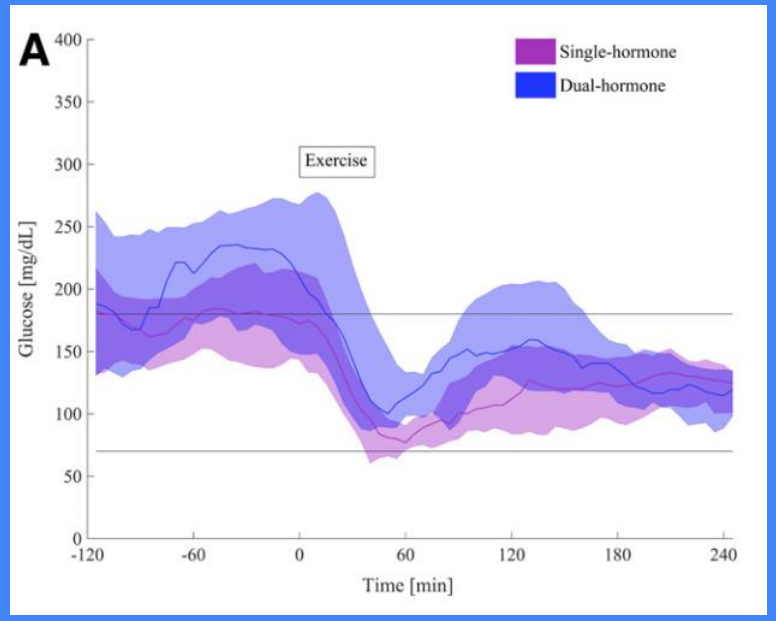
Ενήλικες ασθενείς με διαβήτη τύπου 1, n=23
(αποκλείστηκαν ασθενείς με σοβαρή υπογλυκαιμία τους τελευταίους 12 μήνες
Άσκηση σε κυλιόμενο τάπητα 45 min – moderate intensity aerobic exercise

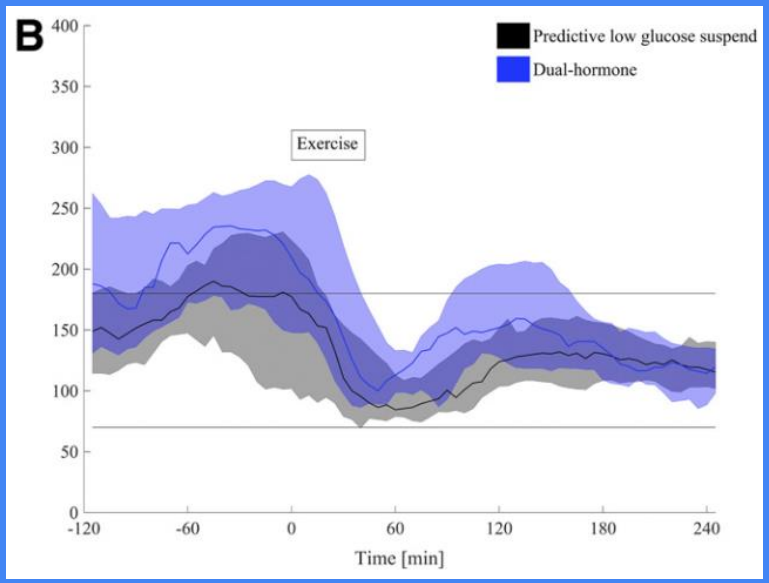
Πειραματικό μοντέλο
Omnipod – Dexcom 6

Χρήση φορητού sensor (Zephyr BioPatch (heart rate and accelerometer) ανίχνευση άσκησης όταν **MET >4 for ≥5 min → επιβεβαίωση άσκησης από ασθενή** → αλγόριθμος άσκησης

MET: metabolic equivalent of task

Crossover design
Dual hormone closed-loop + ανίχνευση άσκησης
Single hormone closed-loop + ανίχνευση άσκησης
SAP+PLGS





Wilson et al Diabetes Care. 2020 Nov;43(11):2721

Άσκηση – Single Hormone Closed-loop

Ανίχνευση άσκησης — **Χωρίς επιβεβαίωση άσκησης από τον ασθενή**

Ενήλικες ασθενείς με διαβήτη τύπου 1, n=27
(αποκλείστηκαν ασθενείς με σοβαρή υπογλυκαιμία τους τελευταίους 12 μήνες)
Αρχικά 12 h σε κλινική επίβλεψη και 2 ημέρες σε ελεύθερη διαβίωση
Crossover study

exMPC (exercise-aware model predictive control)

Ο αλγόριθμος υπολογίζει τα METs → METs > 4 →
Ο ασθενής ειδοποιείται να επιβεβαιώσει την άσκηση →
μετά την επιβεβαίωση η χορήγηση ινσουλίνης διακόπτεται για 30 min και στη συνέχεια μειώνεται κατά 50%

exAPD (exercise-aware adaptive proportional Derivative)

Ο αλγόριθμος δεν απαιτεί επιβεβαίωση από τον ασθενή

iPancreas

Jacobs et al Lancet Digit Health. 2023 Sep;5(9):e607

Άσκηση – Single Hormone Closed-loop

Ανίχνευση άσκησης

Χωρίς επιβεβαίωση άσκησης από τον ασθενή

CGM

Insulin

METs

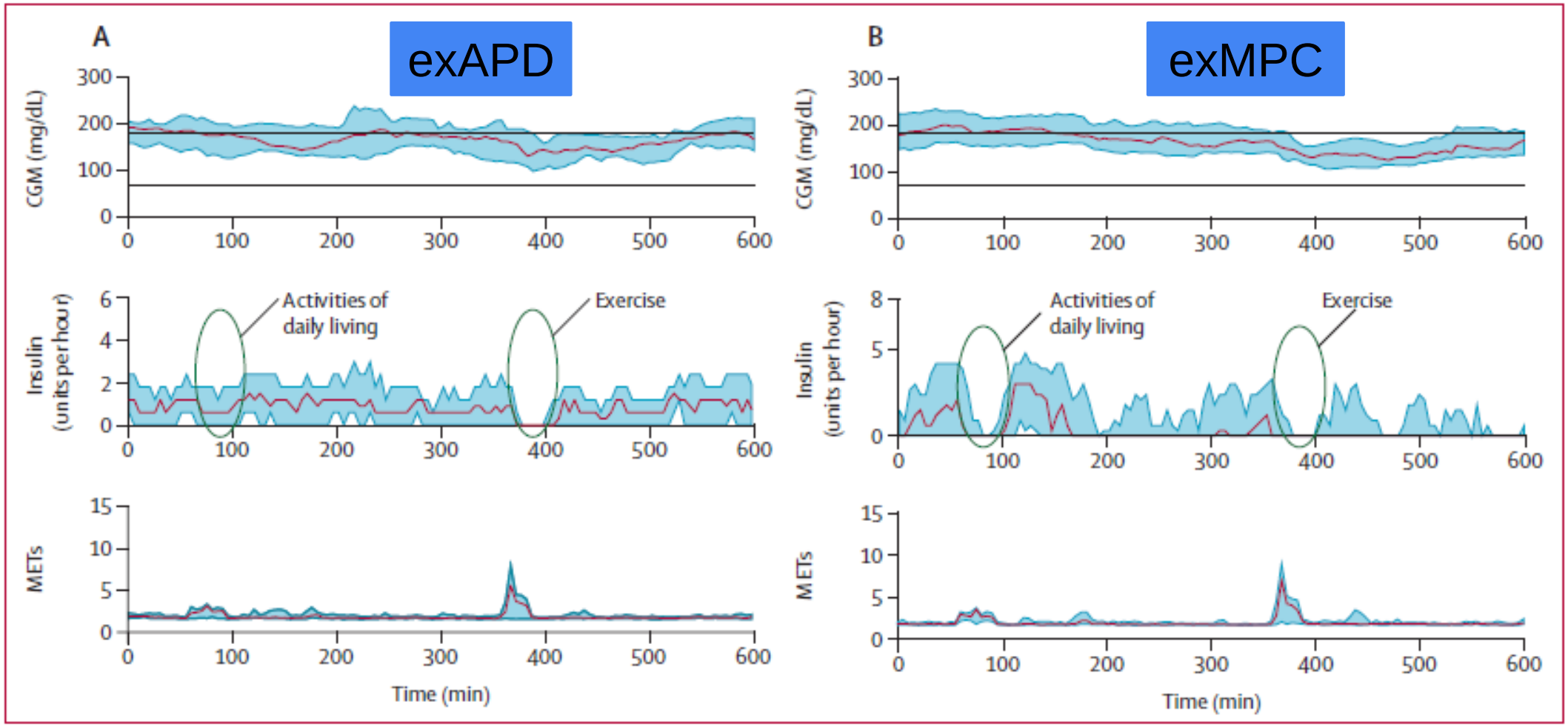


Figure 3: CGM data, insulin, and METs during the primary in-clinic session (0700–1900 h)

Jacobs et al Lancet Digit Health. 2023 Sep;5(9):e607

Άσκηση –Closed-loop systems
ΣΥΝΟΨΗ

Προγραμματισμένη άσκηση → Activity feature (target) 1-2h πριν

Πριν την έναρξη της άσκησης

Γεύμα — Ιδανικά >3h πριν

\+

εάν γεύμα 1-2 πριν → ↓ bolus 25-75%

Σχ ≤126mg/dL → Snack ακριβώς πριν την έναρξη της άσκησης

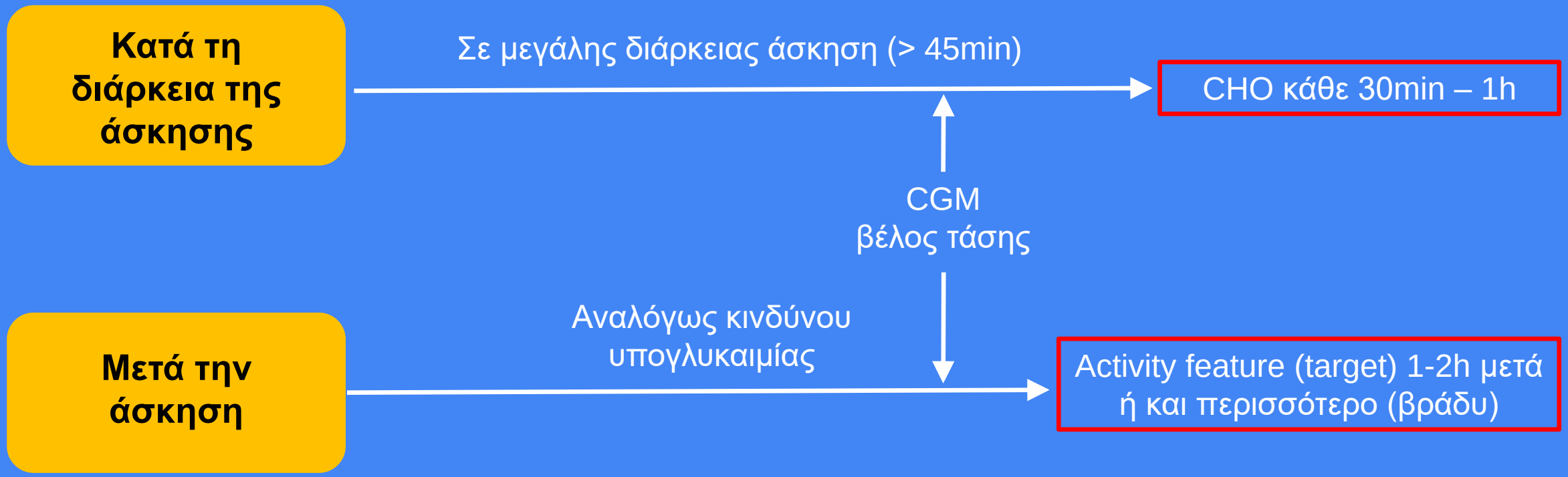
CGM
βέλος τάσης

Μη προγραμματισμένη άσκηση

Τιμή Σχ → CHO ακριβώς πριν την έναρξη της άσκησης

CGM
βέλος τάσης

Άσκηση –Closed-loop systems
ΣΥΝΟΨΗ



Άσκηση –Closed-loop systems
ΣΥΝΟΨΗ

Μελλοντικές προοπτικές

Συστήματα παρακολούθησης βιοπαραμέτρων πέραν του Σχ (κίνηση, καρδιακός ρυθμός, κετόνες κα)

→

Ανίχνευση άσκησης – έντασης άσκησης

→

ενεργοποίηση αλγόριθμου άσκησης

Διορμονικές αντλίες (ινσουλίνη – γλυκαγόνη)

Closed loop CSII – T2DM

T2DM

	type of study	versus	TIR%
Minimed 780G	observational single-arm (n=95)	MDI	+7,8%
Omnipod 5	prospective single-arm (n=305)	most on MDI	+21%
t:slim X2 with Control-IQ	RCT (n=319)	most on MDI	+14%
CamAPS FX	RCT, crossover (n=26)	standard insulin treatment	+35,3%
DBLG1	RCT, crossover (n=17)	CSII plus CGM	+15%

+ real world data

Bhargava et al (2025) Diabetes Technology & Therapeutics [Preprint]. https://doi.org/10.1089/dia.2024.0586
Pasquel, F.J. et al. (2025) JAMA Network Open, 8(2), p. e2459348
Kudva, Y.C. et al. (2025) New England Journal of Medicine, 392(18), pp. 1801
Daly, A.B. et al. (2023) Nature Medicine, 29(1), pp. 203
Borel, A.-L. et al. (2024) Diabetes Care, 47(10), pp. 1778

Closed loop CSII - Inpatients

Closed-loop insulin pump - Inpatients

CamAps fully closed – T2DM, pancreatic, corticosteroid-induced, enteral feeding

	TIR (%) *
T2DM, Non-critically ill (n=136)	**+24**
T2DM – haemodialysis (n=17)	**+37.6**
T2DM/pancreatic/steroid - On enteral or parentereal nutrition (n=43)	**+32**
T2DM – other non type 1 DM – elective surgery (n=45)	**+20**

Bally et al N Engl J Med. 2018 Aug 9;379(6):547
Bally et al Kidney International (2019) 96, 593
Boughton et al Lancet Diabetes Endocrinol. 2019 May;7(5):368
Herzig et al Diabetes Care. 2022 Sep 1;45(9):2076

*TIR: 100-180 mg/dL

Closed loop CSII - Pregnancy

Closed-loop insulin pump σε εγκυμοσύνη
Closed-loop insulin pump vs Standard care

AiDAPT study - CamAPS FX

Multicenter RCT, UK
N=124
CamAPS FX vs Standard Care

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Automated Insulin Delivery in Women with Pregnancy Complicated by Type 1 Diabetes

Lee at al N Engl J Med. 2023 Oct 26;389(17):1566

Closed-loop insulin pump σε εγκυμοσύνη
Closed-loop insulin pump vs Standard care

AiDAPT s

Multicenter
N=124
CamAPS F

with
etes

17):1566

Table 1. Baseline Characteristics of Participants.*

Characteristic	Closed Loop (N=61)	Standard Care (N=63)
Age — yr		
Mean	32.0±5.0	30.2±5.5
Range	19.9–42.7	19.7–44.7
White race — no. (%)†	58 (95)	57 (90)
Duration of diabetes — yr		
Mean	18±8	16±7
Range	2–31	2–33
Body-mass index‡		
Mean	27.9±5.9	26.9±4.8
Range	18.0–48.9	19.9–41.2
Bachelor's degree or equivalent — no. (%)	36 (59)	33 (52)
Week of gestation at recruitment		
Median (IQR)	10.3 (8.0–11.7)	10.0 (8.4–11.3)
Range	6.7–13.7	6.1–14.3

Closed-loop insulin pump σε εγκυμοσύνη
Closed-loop insulin pump vs Standard care

AiDAPT s

Multicenter
N=124
CamAPS F

with
etes

17):1566

Table 1. Baseline Characteristics of Participants.*

Glycated hemoglobin level during early pregnancy**		
6.0 to <7.0% — no. (%)	23 (38)	13 (21)
7.0 to <8.0% — no. (%)	21 (34)	24 (38)
≥8.0% — no. (%)	17 (28)	26 (41)
Mean	7.6±1.1	7.9±1.3
Range	6.0–11.6	6.5–14.0
Continuous glucose monitor — no. (%)	59 (97)	62 (98)
Abbott FreeStyle Libre	43 (73)	47 (76)
Dexcom	12 (20)	14 (23)
Medtronic	4 (7)	1 (2)
Insulin delivery — no. (%)		
Insulin pump	32 (52)	25 (40)
Multiple daily injections	27 (44)	37 (59)
Automated insulin delivery††	2 (3)	1 (2)
Total daily insulin — U/kg/day		
Mean	0.7±0.2	0.7±0.2
Range	0.3–1.3	0.3–1.4

AiDAPT study - CamAPS FX

Lee at al N Engl J Med. 2023 Oct 26;389(17):1566

Closed-loop insulin pump σε εγκυμοσύνη
Closed-loop insulin pump vs Standard care

Table 2. Primary and Secondary Maternal Glucose Outcomes.*

Outcomes	Baseline†		Antenatal Intervention Phase‡		
	Closed Loop (N=59)	Standard Ca (N=59)		Care (N=61)	Adjusted Treatment Difference (95% CI)§
Primary outcome					
Percentage of time with glucose level in range 63–140 mg/dl	47.8±16.4	44.5±14.4	68.2±10.5	55.6±12.5	10.5 (7.0 to 14.0)¶
Key secondary outcomes					
Percentage of time with glucose level >140 mg/dl	48.7±18.0	51.8±16.2		.2	−10.2 (−13.8 to −6.6)
Percentage of overnight time with glucose level in range 63–140 mg/dl (11 p.m. to 7 a.m.)†	47.4±20.8	44.5±16.6	70.8±11.2	56.7±13.6	12.3 (8.3 to 16.2)
Mean glucose level — mg/dl‖	149±28	151±24		6	−9.2 (−13.7 to −4.7)
Glycated hemoglobin level — %	7.6±1.1	7.9±1.3	6.0±0.5	6.4±0.5	−0.3 (−0.5 to −0.1)
Glucose SD — mg/dl**	54±14	55±12	42±11	47±10	−4.5 (−7.3 to −1.6)
Glucose coefficient of variation — %	36±5	37±6	33±5	34±5	−1.1 (−2.5 to 0.3)
Hypoglycemia					
Median percentage of time with glucose level <63 mg/dl (IQR)	2.75 (0.86 to 4.87)	2.22 (0.72 to 6.00)	2.26 (1.54 to 3.31)	2.02 (1.25 to 4.37)	−0.43 (−1.04 to 0.19)
Median percentage of time with glucose level <54 mg/dl (IQR)	1.05 (0.07 to 2.37)	0.79 (0.18 to 2.28)	0.71 (0.49 to 1.19)	0.73 (0.36 to 1.67)	−0.23 (−0.55 to 0.09)
Median no. of mild hypoglycemia events (IQR)††	6.4 (2.2 to 11.5)	5.5 (2.4 to 11.1)	6.7 (4.6 to 9.4)	5.7 (3.1 to 9.4)	0.1 (−1.1 to 1.3)
Median no. of moderate hypoglycemia events (IQR)††	2.2 (0.0 to 5.7)	2.2 (0.0 to 5.9)	2.3 (1.6 to 3.8)	2.1 (1.1 to 4.4)	0.0 (−0.7 to 0.7)

TIR (63-140): ↑10.5%

TAR (>140): ↓10.2%

HbA1c: ↓0.3%

Hypoglycemia (<63): ↔

AiDAPT study - CamAPS FX

Closed-loop insulin pump σε εγκυμοσύνη
Closed-loop insulin pump vs Standard care

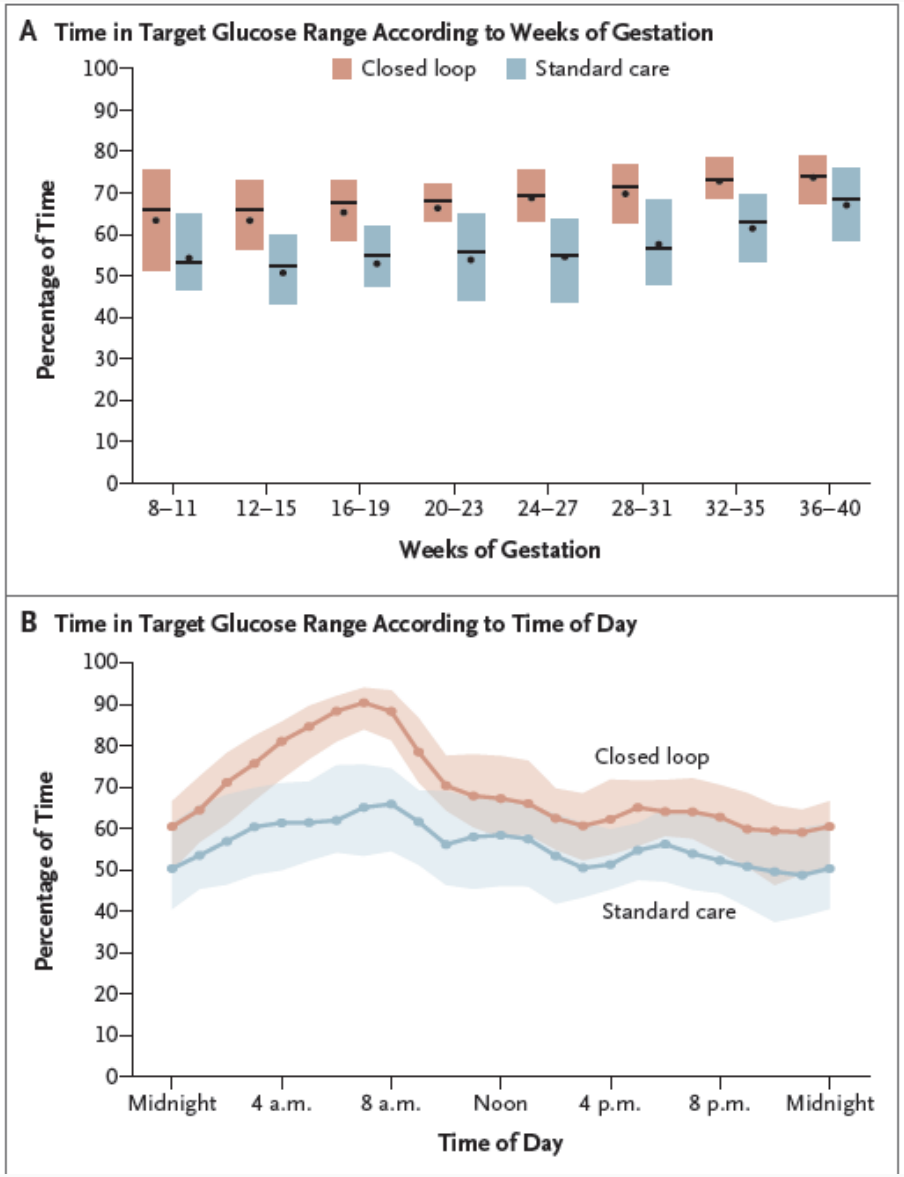


Table 3. Maternal and Neonatal Outcomes.*

Fetal and neonatal outcomes		
Pregnancy loss at <20 wk — no.‡	1	3
Neonatal death — no.§	0	1
Baby alive at discharge — no./total no. (%)¶	59/60 (98)	59/63 (94)
Gestational age at delivery	36 wk 3 days (±2 wk)	37 wk 1 day (±1 wk)
Preterm birth, at <37 wk — no./total no. (%)‖	27/60 (45)	14/63 (22)
Birth weight**		
Mean — kg	3.3±0.6	3.5±0.5
Median customized percentile (IQR)	80.7 (53–97)	90.1 (71–99)
Small for gestational age — no. (%)	3 (5)	1 (2)
Large for gestational age — no. (%)	23 (39)	30 (50)
Extremely large for gestational age — no. (%)	13 (22)	19 (32)
Macrosomia >4.0 kg — no. (%)	4 (7)	9 (15)
Neonatal complications		
Serious birth injury — no. (%)††	1 (2)	4 (7)
Respiratory distress — no. (%)	5 (8)	8 (13)
Hypoglycemia treated with intravenous or oral glucose — no. (%)	26 (44)	25 (42)
Hyperbilirubinemia — no. (%)	40 (68)	37 (62)
Readmission within 7 days — no. (%)	8 (14)	3 (5)
Neonatal intensive care unit stay ≥1 day — no. (%)	13 (22)	15 (25)
Median length of hospital stay (IQR) — days	6 (3–10)	5 (3–7)

Lee at al N Engl J Med. 2023 Oct 26;389(17):1566

Cristal study – Minimed 780G

Closed-loop insulin pump σε εγκυμοσύνη
Closed-loop insulin pump vs Standard care

Multicenter RCT, Belgium, Netherlands
n=95
Minimed 780G vs Standard Care

Comparing advanced hybrid closed loop therapy and standard insulin therapy in pregnant women with type 1 diabetes (CRISTAL): a parallel-group, open-label, randomised controlled trial

Benhalima et al Lancet Diabetes Endocrinol. 2024 Jun;12(6):390

target 100mg/dL, active insulin time 2h

- assisted techniques (fake carbs)

Cristal study – Minimed 78

μοσύνη ard care

Multicenter RCT, Belgium, Netherl
n=95
Minimed 780G vs Standard Care

target 100mg/dL, active insulin tim

- assisted techniques (fake carbs

herapy and
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p, open-label,

2024 Jun;12(6):390

	Advanced hybrid closed loop therapy (n=46)	Standard insulin therapy (n=49)
HbA_{1c} (%)	6·5% (0·6)	6·5% (0·7)
<6·0%	6/46 (13·0%)	9/49 (18·4%)
6·0 to <7·0%	30/46 (65·2%)	29/49 (59·2%)
7·0 to <8·0%	9/46 (19·6%)	9/49 (18·4%)
≥8·0%	1/46 (2·2%)	2/49 (4·1%)
Diabetes therapy		
Continuous glucose monitor	46/46 (100·0%)	49/49 (100·0%)
Medtronic	41/46 (89·1%)	40/49 (81·6%)
Dexcom	4/46 (8·7%)	5/49 (10·2%)
Abbott FreeStyle Libre	1/46 (2·2%)	4/49 (8·2%)
Masked continuous glucose monitor**	3/44 (6·8%)	9/49 (18·4%)
Insulin delivery		
Multiple daily injections††	2/46 (4·3%)	2/49 (4·1%)
Insulin pump‡‡	44/46 (95·7%)	47/49 (95·9%)
Continuous subcutaneous insulin infusion with standalone continuous glucose monitor	3/44 (6·8%)	7/47 (14·9%)
Sensor-augmented pump§§	37/44 (84·1%)	38/47 (80·8%)
Advanced hybrid closed loop therapy	4/44 (9·1%)	2/47 (4·3%)

Cristal study – Minimed 780G

Closed-loop insulin pump σε εγκυμοσύνη
Closed-loop insulin pump vs Standard care

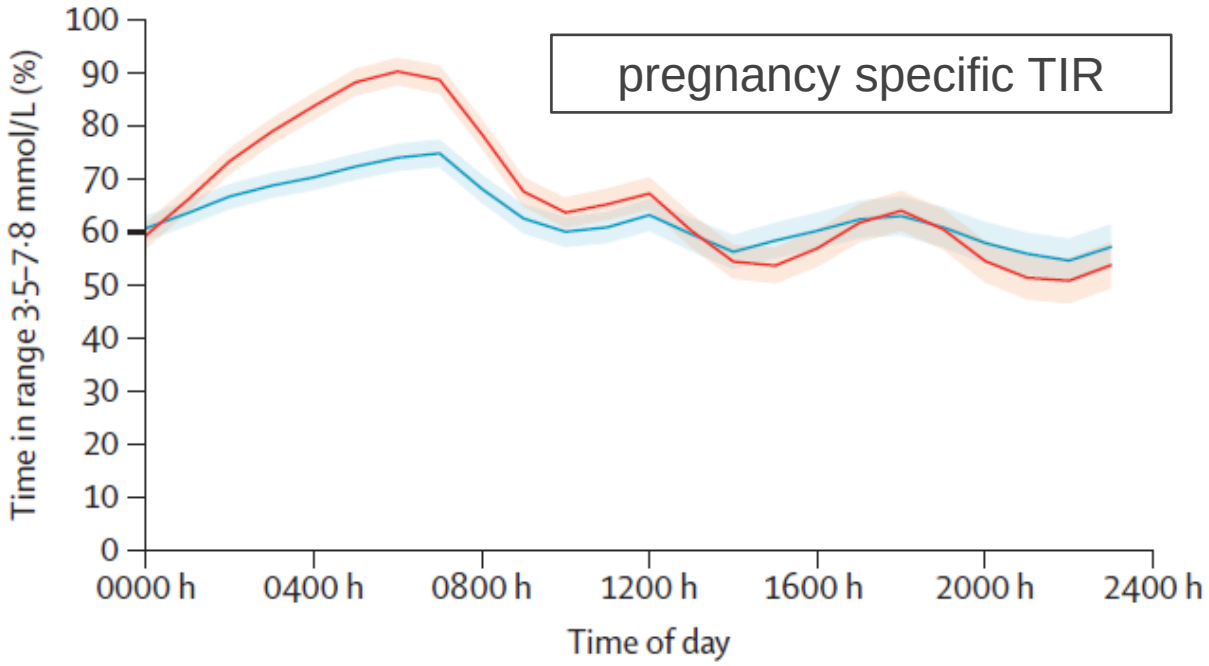
	Baseline		Antenatal period (over four visits)*		Adjusted mean difference (95% CI)†
	Advanced hybrid closed loop therapy (n=46)	Standard insulin therapy (n=49)	Advanced hybrid closed loop therapy (n=46)	Standard insulin therapy (n=49)	
Primary outcome					
Proportion of time with glucose concentration in range 3·5–7·8 mmol/L	60·5% (14·2)	57·6% (13·7)	66·5% (10·0)	63·2% (12·4)	1·88% (–0·82 to 4·58)
Key secondary outcomes					
Proportion of overnight time with glucose concentration in range 3·5–7·8 mmol/L (2400 h to 0600 h)‡	64·8% (17·6)	60·4% (21·9)	75·1% (13·1)	67·2% (14·6)	6·58% (2·31 to 10·85)§
Proportion of time with glucose concentration <3·5 mmol/L	5·3% (4·9)	5·1% (3·2)	2·5% (2·8)	4·1% (3·4)	–1·34% (–2·19 to –0·49)§
Proportion of overnight time with glucose concentration <3·5 mmol/L (2400 h to 0600 h)‡	5·3% (6·8)	4·0% (3·9)	1·9% (3·2)	4·2% (4·7)	–1·86% (–2·90 to –0·81)§

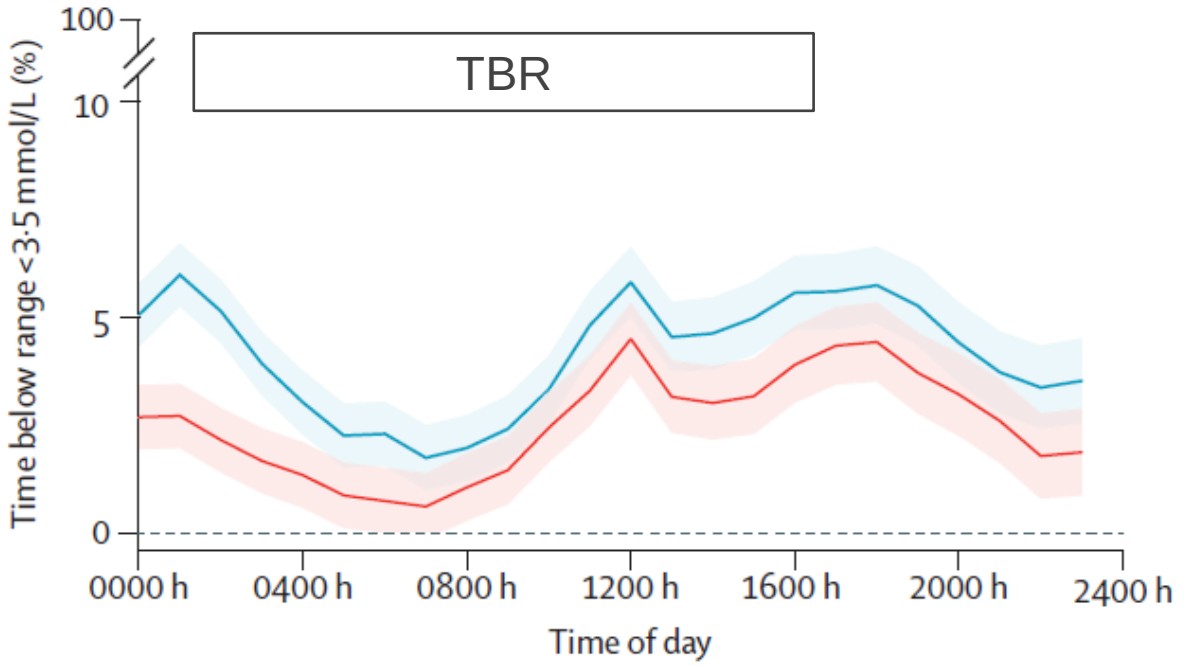
Benhalima et al Lancet Diabetes Endocrinol. 2024 Jun;12(6):390

Cristal study – Minimed 780G

Closed-loop insulin pump σε εγκυμοσύνη
Closed-loop insulin pump vs Standard care

	Baseline		Antenatal period (over four visits)*		Adjusted mean difference (95% CI)†
	Advanced hybrid closed loop therapy	Standard insulin therapy	Advanced hybrid closed loop therapy	Standard insulin therapy	

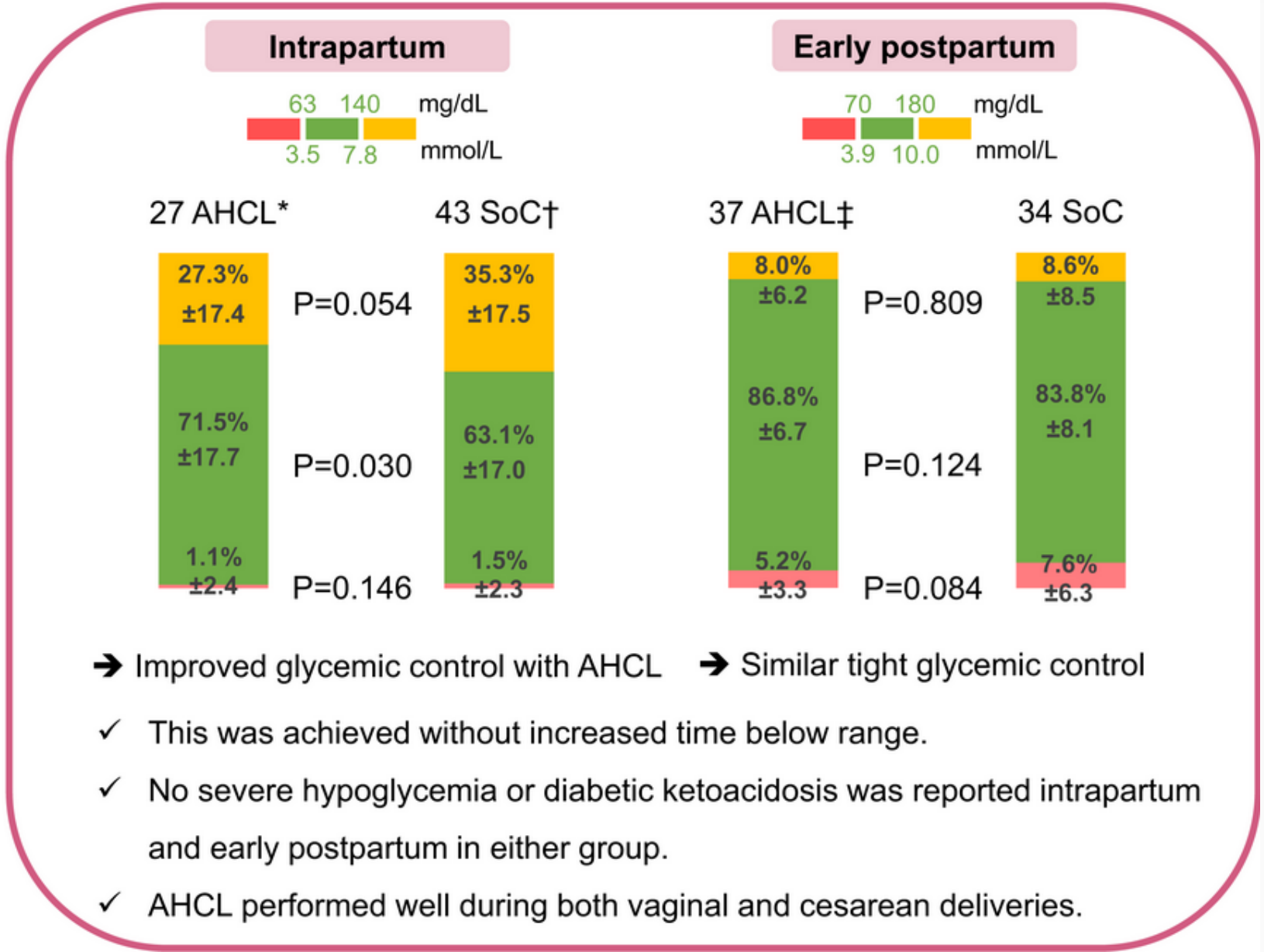




Benhalima et al Lancet Diabetes Endocrinol. 2024 Jun;12(6):390

Cristal study – Minimed 780G

Closed-loop insulin pump σε εγκυμοσύνη
Closed-loop insulin pump vs Standard care



Beunen et al Diabetes Care. 2024 Nov 1;47(11):2002

Closed-loop insulin pump σε εγκυμοσύνη

- Ασφαλής χρήση
- Βελτίωση γλυκαιμικού ελέγχου

➢ Απαιτούνται μεγαλύτερες μελέτες για την εκτίμηση της επίδρασης σε μαιευτικά – νεογνικά συμβάματα

➢ **Μόνο η CamAPS FX έχει δυνατότητα στόχων εγκυμοσύνης**
δυνατότητα στόχου έως 80mg/dL
(όλες οι άλλες δυνατότητα στόχου έως ≥100mg/dL)

➢ **Minimed 780G**: έγκριση στην Ευρώπη – χρήση assisted tecniques (fake carbs)

Murphy et al Diabetes Care. 2011 Dec;34(12):2527
Stewart et al N Engl J Med. 2016 Aug 18;375(7):644
Stewart et al Diabetes Care. 2018 Jul;41(7):1391
Lee at al N Engl J Med. 2023 Oct 26;389(17):1566
Benhalima et al Lancet Diabetes Endocrinol. 2024 Jun;12(6):390

Available CL systems

	FDA - label	CE - label
Cam APS FX (CamDiab, UK)	pending (mylife Loop)	≥1 years Pregnancy
Control-IQ (Tandem, USA)	≥2 years, T2DM	≥2 years
DBLG1 (Diabeloop, France)	pending	≥18 years
iLet Bionics (BetaBionics, USA)	≥6 years	–
MiniMed 780G (Medtronic, USA)	≥7 years T2DM	≥2 years Pregnancy, T2DM
Omnipod 5 (Insulet)	≥2 years T2DM	≥2 years
TouchCare Nano System (Medtrum, China)	–	≥6 years
AndroidAPS (open source)	–	–
(Tidepool) Loop - Twiist (open source)	≥6 years	–
iAPS / Trio (open source)	–	–

Επιλογή συστήματος

Ασφάλεια (iCGM)

Κλινικά δεδομένα

Κλινικές μελέτες
Δεδομένα πραγματικού κόσμου

Ομάδες ασθενών

Παιδιά – Ενήλικες
Πολύ μικρά παιδιά
Εγκυμοσύνη
T2DM

Επιλογή συστήματος

Ηλικία, γνωσιακό επίπεδο, διάθεση δέσμευσης, ιδιαίτερα χαρακτηριστικά

"Hands-off"

- ❑ Χαμηλό επίπεδο ικανότητας χειρισμού και δέσμευσης στην αντλία

Υψηλό επίπεδο αυτοματοποίησης
Απλοποιημένη εισαγωγή/ανακοίνωση γεύματος χωρίς εισαγωγή ποσότητας υδατανθράκων

"Hands-on"

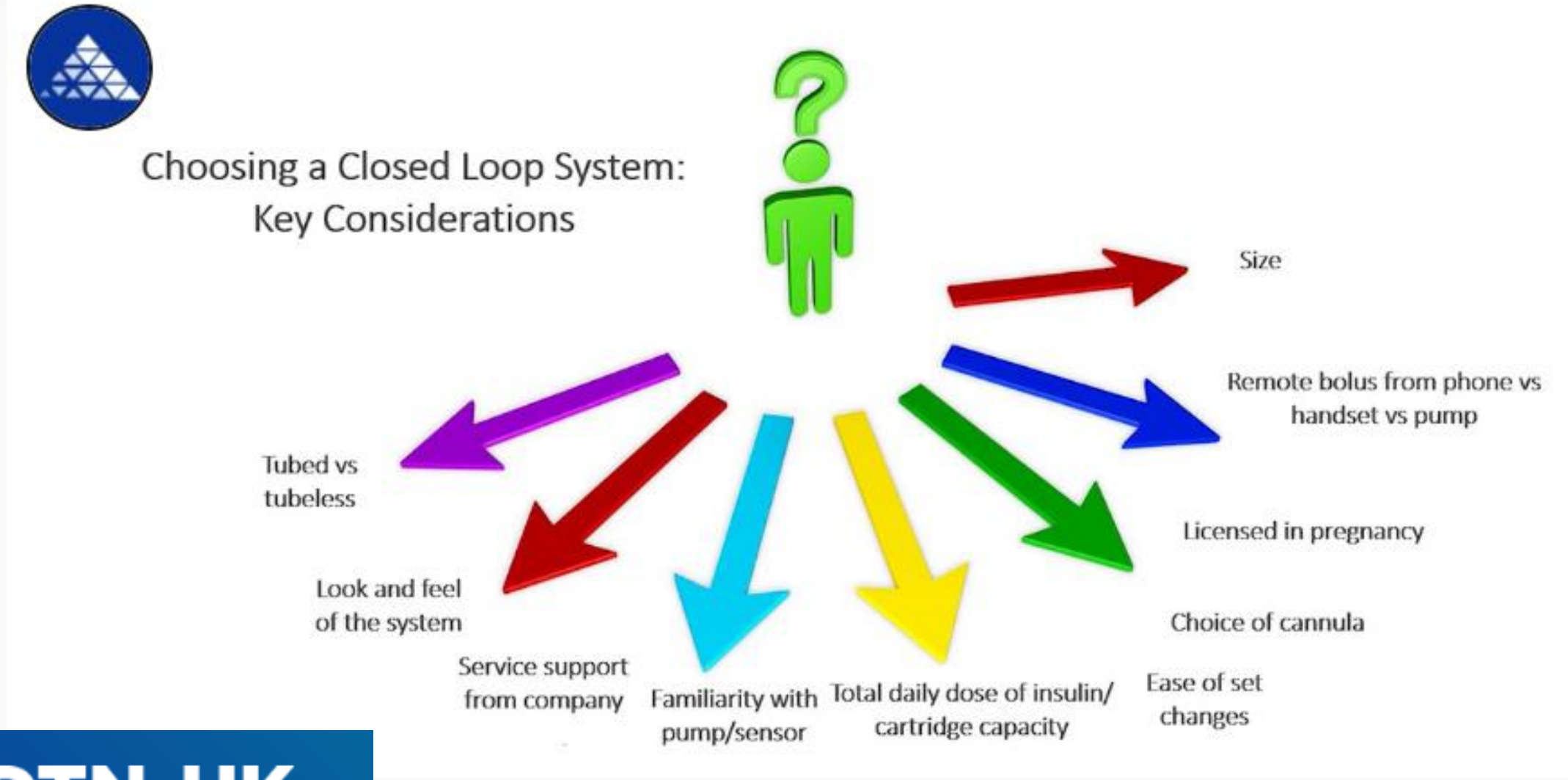
- ❑ Υψηλό επίπεδο ικανότητας χειρισμού και δέσμευσης στην αντλία
- ❑ Άτομα που θέλουν να έχουν τον έλεγχο του fine-tuning

Αντλία που διατηρεί περισσότερες τροποποιήσιμες από το χρήστη παραμέτρους (πολλαπλοί στόχοι για διαφορετικά χρονικά διαστήματα της ημέρας, ISF, τύποι bolus, δυνατότητα τροποποίησης bolus κα)

- ➢ Ιδιαίτεροι παράγοντες που καθιστούν τα ιδιαίτερα προαιρετικά modes.χρήσιμα για τον ασθενή

- ➢ Επίπεδο τεχνικής υποστήριξης από την εταιρεία

Choosing your Hybrid Closed Loop System



DTN-UK
Collaborate • Evolve • Support

Presented by Professor Pratik Choudhary and Dr Emma Wilmot

Παράγοντες προσωπικής προτίμησης

- Tubed vs Patch pump
- Size of the pump - Interface
- Look and feeling of the system - Ease to change set
- Remote monitoring and remote bolus

Σύνοψη

- Συζήτηση για τα οφέλη της μετάβασης σε αντλία
- Ιεράρχηση ασφάλειας – κλινικών δεδομένων → ηλικία, τύπος διαβήτη, εγκυμοσύνη
- Παρουσίαση όλων των διαθέσιμων επιλογών
- Συζητούμε πτυχές της ζωής του ασθενούς που δυνητικά θα επηρεάσουν την απόφασή του
- Κάνουμε τον ασθενή να αισθανθεί ελεύθερος να συζητήσει ότι θέλει σχετικά, και να σκεφτεί πως η αντλία θα ταιριάξει στην καθημερινότητά του
- Ο ασθενής δεν πρέπει να αισθανθεί πίεση ή αίσθημα αποτυχίας πως δεν μπορεί να ανταποκριθεί στις ιατρικές συστάσεις - ότι απογοητεύει τον γιατρό του

➢ **Η μετάβαση σε αντλία και η επιλογή της αντλίας είναι μία προσωπική απόφαση**

Closed-loop insulin pump - Algorithms

Algorithms for Automated Insulin Delivery: An Overview

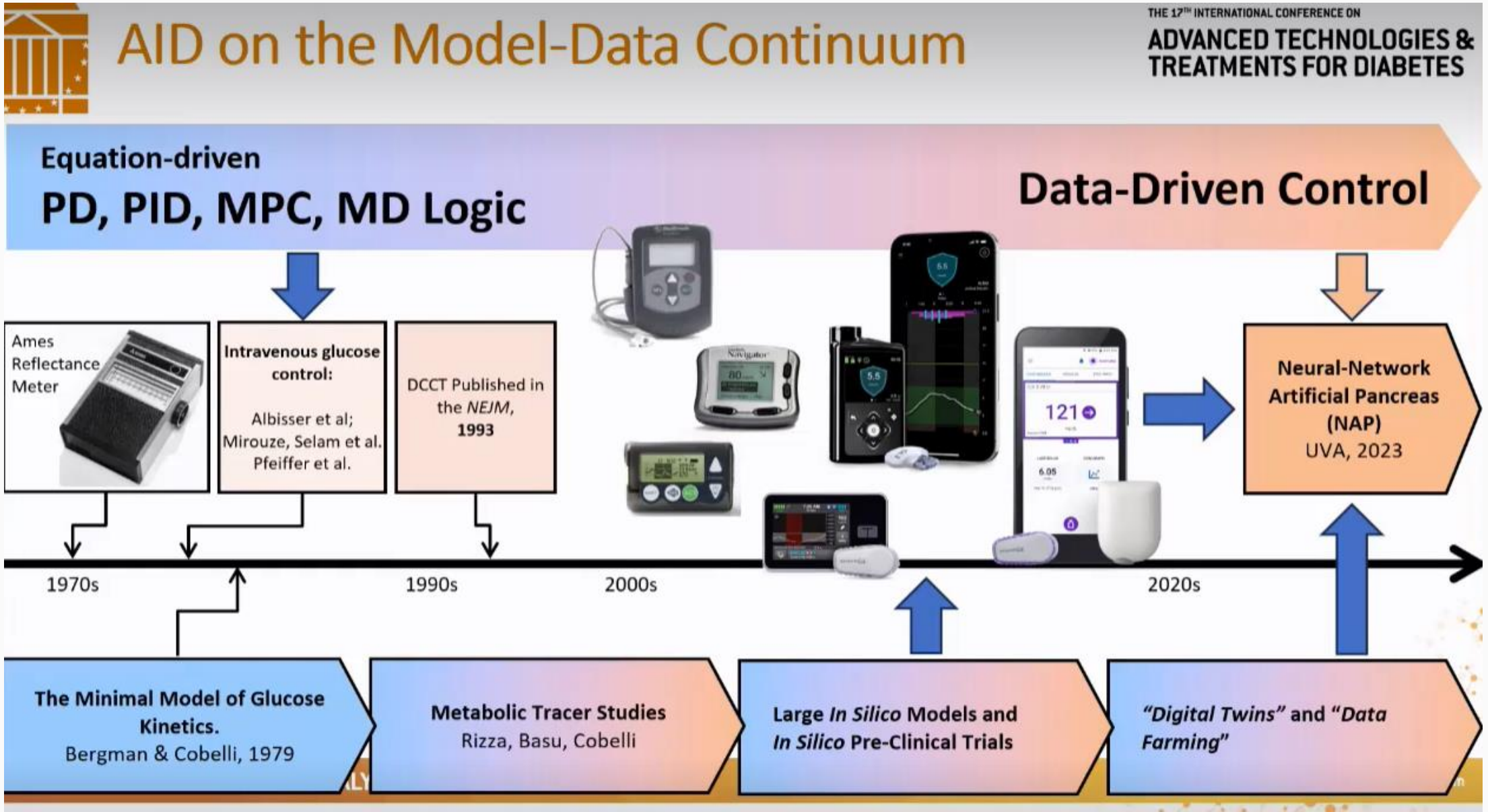
Thomas et al. J Diabetes Sci Technol. 2022. PMID: 33955251

- **PID**: Proportional Integrative Differential
- **MPC**: Model Predictive Control
- **Fuzzy Logic**

Table 1. Main Advantages and Disadvantages of the Currently Most Widely Used Algorithms of Hybrid and Experimental Full AID Systems.

Algorithm	Advantages	Disadvantages	Applied in
PID	- Simple and straightforward, only calculation of the individual components P, I, D - No complex simulation - Initial input of few parameters: Carb/ Insulin factors, insulin action time - Great experience in controlling technical systems (eg, heating systems)	- Only insufficient suited for regulating large glucose rises and falls (eg, after meals, during physical activity) - Only input of static parameters, such as insulin duration of action (information on pharmacokinetics according to insulin manufacturer) - Does not take into account inter- and intra-individual variability of patients - No predictive calculation of the effect of insulin delivery on future glucose levels	- Medtronic MiniMed 670G/770G/ 780G
MPC	- Dynamic model of the control process, does justice to the dynamics of insulin delivery control - Prospective calculation of glucose level based on current insulin dosage (simulation by iteration) - Dynamics of the effect of different insulin doses is taken into account - Takes into account inaccuracies in glucose measurement and delays in insulin absorption	- Only conditionally suitable for regulating of large glucose rises and falls (eg, after meals, physical activity etc.) - The complex model requires initial input of several parameters (eg, basal rate under CSII)	- CamAPS FX (Cambridge App) - iAP (Collaboration Universities Padova, Virginia, Santa Barbara) - Diabeloop DBLG1 (self-learning by applying methods of artificial intelligence) - Tandem CONTOL IQ - Insulet Omnipod 5
Fuzzy-Logic: MD-Logic (DREAMED)	- Simulates glucose regulation, adapted to physiological insulin delivery (combination of "Control to Range" and "Control to Goal") - Fuzzy logic approximates the physiological behavior of an individual patient (adaptation of control parameters) - Algorithm is self-learning - Suitable for regulation of large glucose rises and falls (eg, meals, physical activity) and thus also suitable for delivery of meal boli	- Requires a fuzzy logic controller, in which treatment rules have to be implemented, making the development of the corresponding affiliation function is a challenge	- Cooperation with Medtronic regarding implementation in the future full AID system

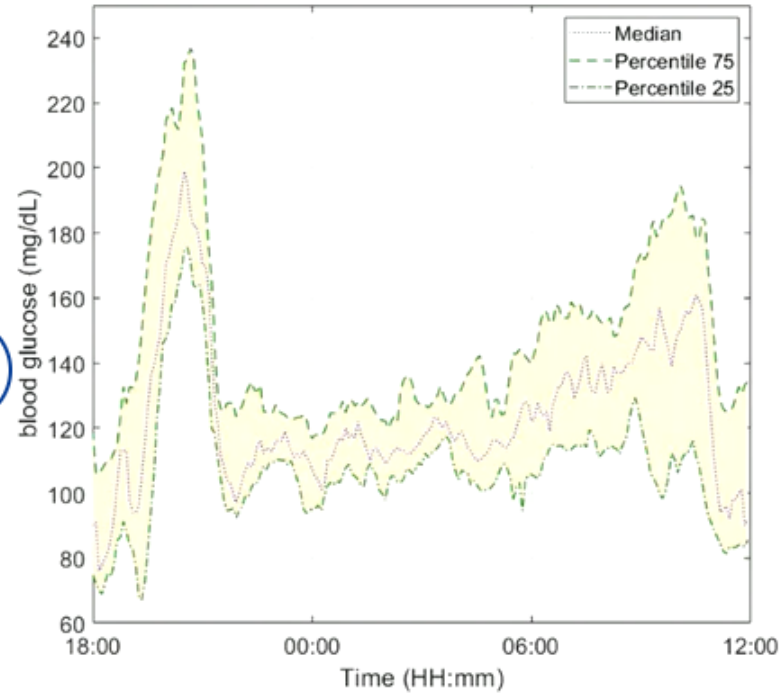
Artificial intelligence
Αλγόριθμοι που βασίζονται στα νευρωνικά δίκτυα



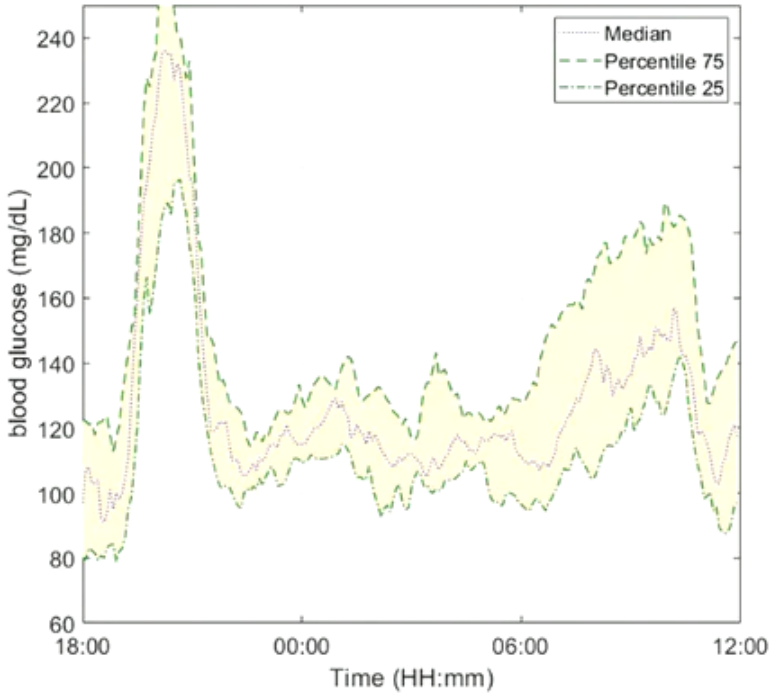
Τεχνητό πάγκρεας βασιζόμενο σε νευρωνικά δίκτυα

Neural-Net Artificial Pancreas: A Randomized Crossover Trial of a First-in-Class Automated Insulin Delivery Algorithm

University of Virginia Model-Predictive Control algorithm



Neural-Net Artificial Pancreas



Conclusion: In a randomized crossover study, a neural-network encoding of a complex model-predictive control algorithm demonstrated similar performance, at **a fraction of the computational demands**. Regulatory and clinical doors are therefore open for contemporary **machine-learning methods to enter the AID field**

Neural-Net Artificial Pancreas: A Randomized Crossover Trial of a First-in-Class Automated Insulin Delivery Algorithm.Kovatchev B, Castillo A, Pryor E, Kollar LL, Barnett CL, DeBoer MD, Brown SA.Diabetes Technol Ther. 2024 Jun;26(6):375-382.

Breakthrough T1D™ Formerly JDRF

Νεώτερες αντλίες ινσουλίνης – Ο δρόμος προς το τεχνητό πάγκρεας

Hybrid closed loop

Medronic 780G
Omnipod 5
Control IQ
CamAPS FX

- ↑ κατά μέσο όρο ~ 10% TIR
- Μεγαλύτερη βελτίωση σε πτωχή γλυκαιμική ρύθμιση
- Εφικτός ο στόχος TIR > 70% στην πλειονότητα των ασθενών
- Εκπαίδευση – στρατηγική αναλόγως με τον τύπο της αντλίας

Diabeloop DBLG1 System

iLet Bionic Pancreas

Fully closed closed loop

Bihormonal Pumps

Σας ευχαριστώ
για την προσοχή σας