



## Καρδιομεταβολική Ιατρική (MSc in Cardiometabolic Medicine)

Εθνικό και Καποδιστριακό Πανεπιστήμιο Αθηνών

*Έξυπνες πένες ινσουλίνης (smart insulin pens)*

*Smart watches*

*Apps*

Κωνσταντίνος Μαρκάκης

Παθολόγος με Εξειδίκευση στο Σακχαρώδη Διαβήτη

Επίκουρος Καθηγητής Παθολογίας

Τμήμα Ιατρικής, Σχολή Επιστημών Υγείας Πανεπιστημίου Πατρών  
Παθολογική Κλινική Πανεπιστημιακό Γενικό Νοσοκομείο Πατρών

# Εκπαίδευση

- Διαβήτης – Επιπλοκές
- Διατροφή
- Μέτρηση υδατανθράκων
- Δυναμική προσαρμογή δόσης ταχείας ινσουλίνης (γεύμα – διόρθωση – στόχοι)
- Εκτίμηση βασικής και γευματικής ινσουλίνης

# Εκπαίδευση

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- Εκτίμηση βασικής και γευματικής ινσουλίνης

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

- Τήρηση ημερολογίου μετρήσεων
- Ερμηνεία μετρήσεων – λήψη θεραπευτικών αποφάσεων
- Τεστ βασικής ινσουλίνης και γευματικής ινσουλίνης

## Σχήμα πολλών βελών (Dental Floss)

- Αντιμετώπιση υπογλυκαιμίας
  - Αναγνώριση υπογλυκαιμίας
  - Αντιμετώπιση υπογλυκαιμίας
  - Πρόληψη
  - Επίγνωση υπογλυκαιμίας
- Προσαρμογή σε αυξημένη φυσική δραστηριότητα – άσκηση (είδη άσκησης)
- Προσαρμογή θεραπείας σε ασθένεια
- Προσαρμογή σε ταξίδια - διακοπές

## Σχήμα πο

- Αντιμετώπιση υπογλυκαιμίας

- Προσαρμογή σε αυξημένη

- Προσαρμογή θεραπείας σε ασθένεια

- Προσαρμογή σε ταξίδια - διακοπές

- Είδη άσκησης (αερόβια – αναερόβια)
- Διάρκεια άσκησης
- Αμεση επίδραση  
Επίδραση αργότερα- κίνδυνος νυκτερινής υπογλυκαιμίας
- Στρατηγικές αποφυγής της επαγόμενης από την άσκηση υπογλυκαιμίας

- Αυξημένες ανάγκες σε ινσουλίνη
- Αποφυγή κετοξέωσης

- Μεταβολή σε διατροφικές συνήθειες – φυσική δραστηριότητα
- Συντήρηση – μεταφορά ινσουλίνης, αναλωσίμων
- Ζώνες ώρας

**Apps**

Δίαιτα  
Μέτρηση υδατανθράκων  
Φυσική δραστηριότητα

Μετρητές  
Σχ

CGM

glooko

TIDEPOOL

Meal photo

Μετρήσεις Σχ, Ινσουλίνη  
Γεύματα, Άσκηση

Carbs & Cals

Fooducate

Gluroo

ελληνική  
εφαρμογή

Euglyka

Carb Manager: Keto Diet App

Calorie Counter & Carb Manager -  
Freshbit

MySugr

Glucose Buddy

Diabetes:M

Diabetes Connect

Sugar Sense Diabetes App

Dexcom CLARITY app

Guardian Connect

Medtronic

Sugar.IQ™ Diabetes Assistant

Medtronic

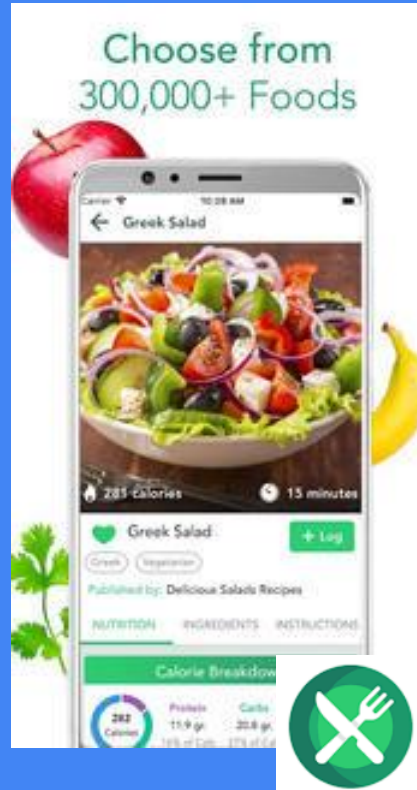
FreeStyle LibreLink

FreeStyle Libre

# Μέτρηση υδατανθράκων

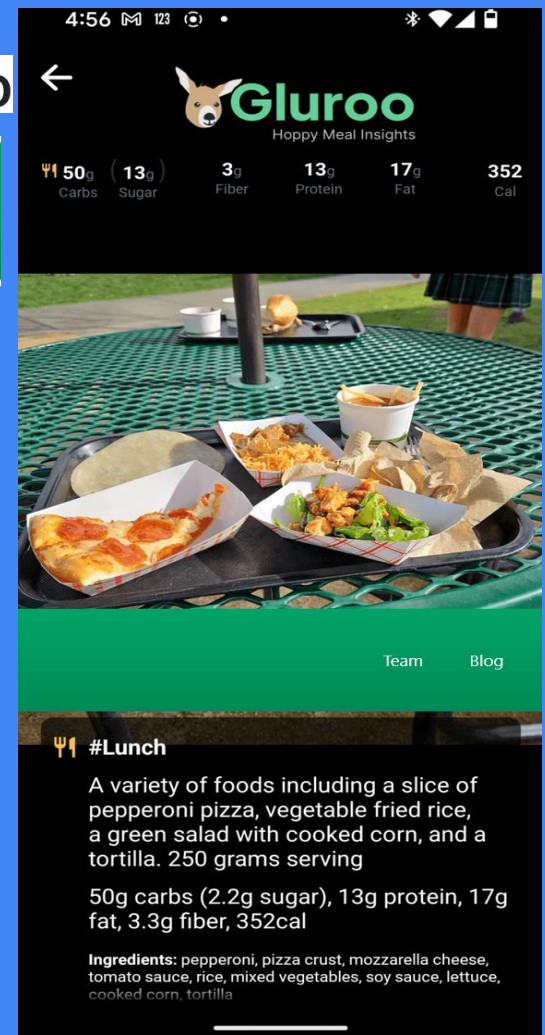
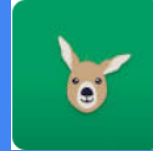


Carbs & Cals



Calorie Counter & Carb Manager -  
Freshbit

Gluroo





# Γευματικό – διορθωτικό bolus

Ρυθμίσεις

Bolus

Βοήθεια στη μέτρηση  
υδατανθράκων

Δυνατότητα διαφορετικών  
ρυθμίσεων (αναλογία  
ινσουλίνης προς υδατάνθρακες,  
συντελεστής ευαισθησίας  
διόρθωση)  
για διαφορετικά διαστήματα της  
ημέρας

CONFIGURATION WIZARD

Δυνατότητα διαφορετικών ρυθμίσεων (αναλογία ινσουλίνης προς υδατάνθρακες, συντελεστής ευαισθησίας διόρθωση) για διαφορετικά διαστήματα της ημέρας

12:00 AM – 2.84;

+ Carbohydrates ratio (hourly) ?

12:00 AM – 14;

BACK NEXT

Diabetes:M

Glucose 137 mg/dL

Carbs 50 grams

Extended Bolus

Proteins 7.1 grams

Fats 15 grams

Calories 350 kcal

Food List

Search food

Long press on items to add/edit food.

Deserts (59)

Fats: 13; Carbs: 37; Prot: 2.4; Cal: 203

Apple Pie - piece (1/8 of ~9", 23cm)

Fats: 19; Carbs: 58; Prot: 3.7; Cal: 411

Apple Strudel - 100g

Fats: 11; Carbs: 41; Prot: 3.3; Cal: 274

Apple Strudel - piece (~2"/2" 5cm/5cm)

➤ Υπολογισμός ενεργού ινσουλίνης (insulin on board)

# Smart watches

# Smart watch - CGM

## Dexcom CGM



Dexcom mobile app is compatible with both Apple and Android watches.

Apple or Android watch syncs with the current CGM data from the app running on your iPhone or Android phone.

It displays your current glucose number and arrow trend, as well as graphs for 1-, 3-, 6-, and 24-hour periods.

High or Low glucose Alerts

# Smart watch - CGM

## Dexcom CGM

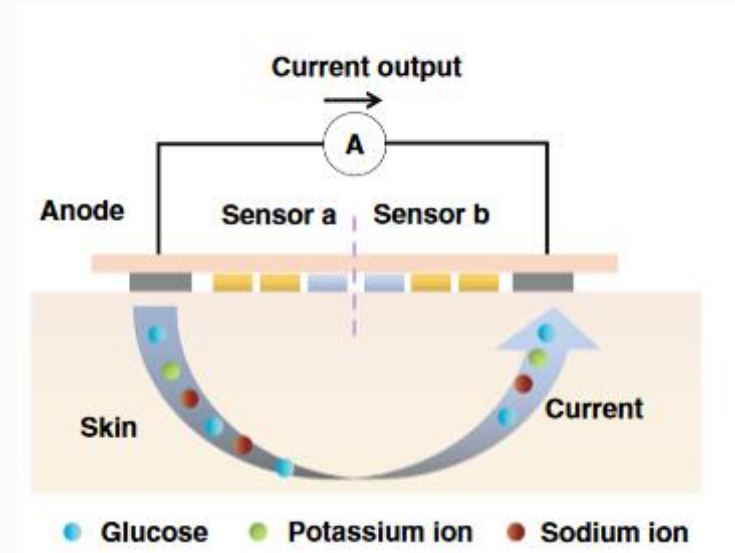
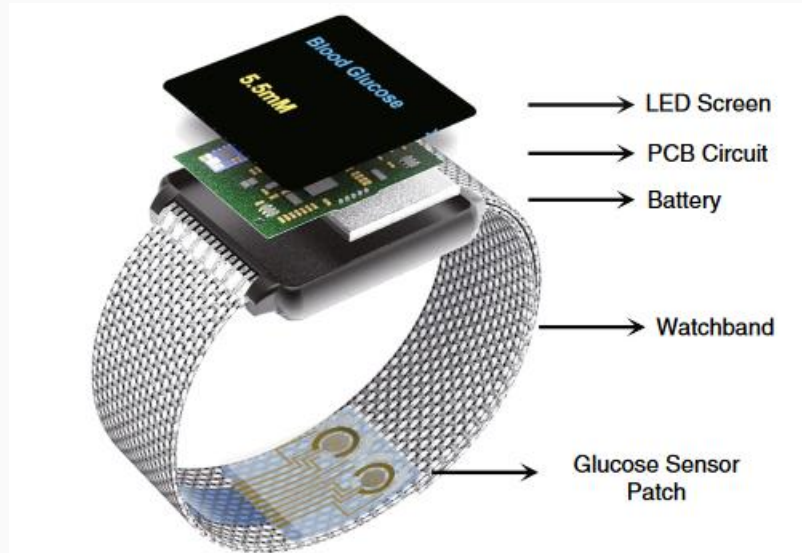
### Garmin watches and diabetes data



Real-time glucose levels as well as a trend arrow and a 3-hour history CGM line.

Alerts

# K'Watch Glucose



84.34% clinical accuracy in the Clarke error grid analysis (zones A + B)

# K'Watch Glucose



**Smart insulin pens /  
Smart caps for insulin pens**

## Smart Insulin Pens



### What makes an insulin pen 'smart'?

- It keeps a record of the time and dose of each injection.
- It can connect to a compatible smartphone app, so you can keep track of your data easily and can choose to share it with your clinic.
- It can enable more accurate dosage calculations through a bolus calculator and so ease the mental burden.
- It can help you avoid missed doses.





Novopen 5

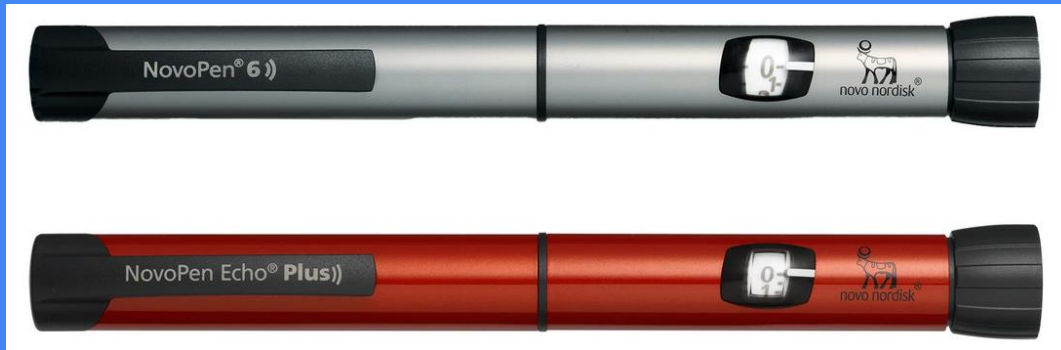


Novopen Echo

## Smart Insulin Pens NovoPen



Novopen 6 / Novopen Echo Plus





Novopen 5



Novopen Echo

## Dose memory



Number of units last injected

Time passed since last injection (hours: minutes: seconds)

## Smart Insulin Pens NovoPen

Novopen 6 / Novopen Echo Plus

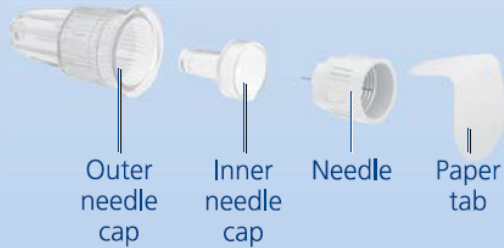


# NovoPen 6

## NovoPen Echo Plus



### Single-use needle (example)



### Insulin cartridge (Penfill® cartridge 3 ml)



#### **NovoPen® 6:**

60-unit maximum dose  
1-unit dose increments

#### **NovoPen Echo® Plus:**

30-unit maximum dose  
0.5-unit dose increments.

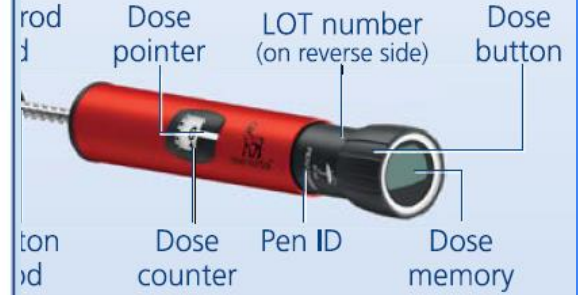
Tresiba, Fiasp

# NovoPen 6

## NovoPen Echo Plus



### Single-use needle (example)



### NovoPen® 6:

60-unit maximum dose  
1-unit dose increments

### NovoPen Echo® Plus:

30-unit maximum dose  
0.5-unit dose increments.

# Smart Insulin Pens NovoPen

NFC



## 4 Transfer your injection history to your device.

- **Hold** the dose memory of the pen straight against the NFC spot on your device.
- **Wait** while the details of your latest injections are automatically transferred to your device.



glooko®

Paired data

Dexcom

FreeStyle  
LibreLink

mySugr®

Bolus calculator

## Smart Insulin Pens NovoPen



- ✓ Insulin doses recorded from the NovoPen® 6 or NovoPen Echo® Plus smart connected insulin pen can be easily transferred to the FreeStyle LibreLink app<sup>2</sup> with a scan.
- ✎ Helps patients see the effect of insulin doses with both glucose and insulin data on the same reports in LibreView<sup>h</sup>
- 💬 Helps you to have more informed patient consultations



# Smart Insulin Pens NovoPen



## WHY FREESTYLE LIBRE SYSTEMS?

## FREESTYLE PORTFOLIO

## SCIENTIFIC RESOURCES & EDUCATION

## FREESTYLE PORTAL

## HELP & SUPPORT



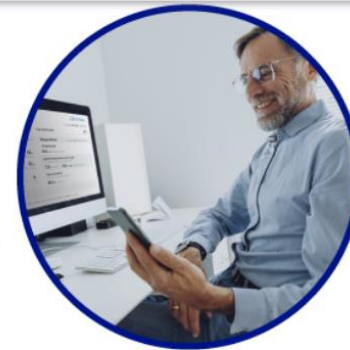
### Connect

Scan and add a compatible smart connected insulin pen<sup>1</sup> to automatically transfer insulin doses to the app<sup>2,0</sup>



### Review

Patients can easily track past insulin doses and their impact. Seeing this information may help your patients avoid missing a dose or taking insulin doses too close together



### Share

Reports showing glucose and insulin data together for more informed patient consultations

# Smart Insulin Pens NovoPen



See insulin and glucose data together to support more efficient patient consultations

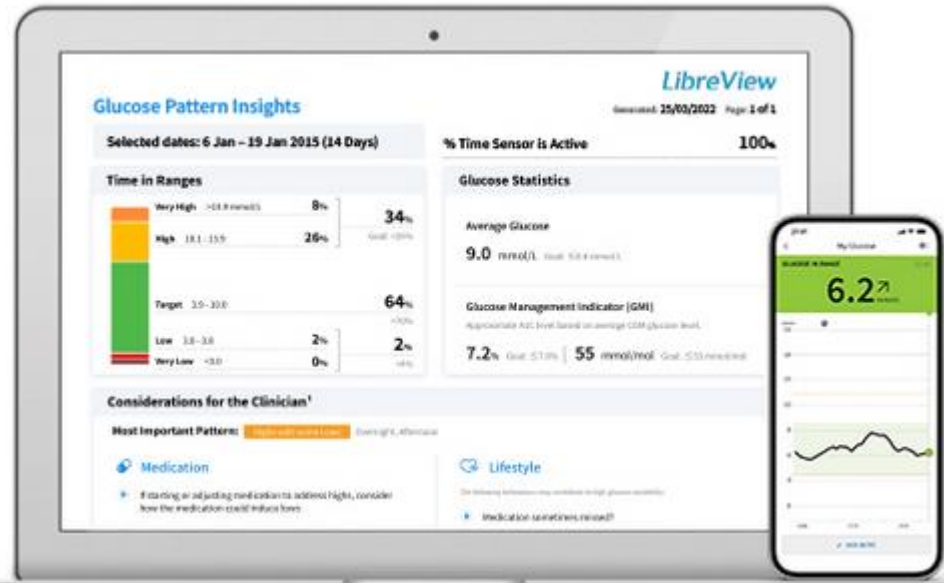
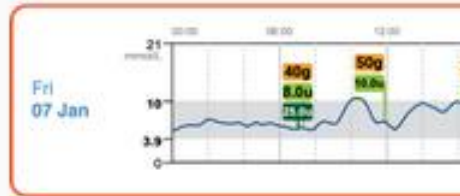




# Smart Insulin Pens NovoPen



See insulin and glucose data together to support more efficient patient consultations

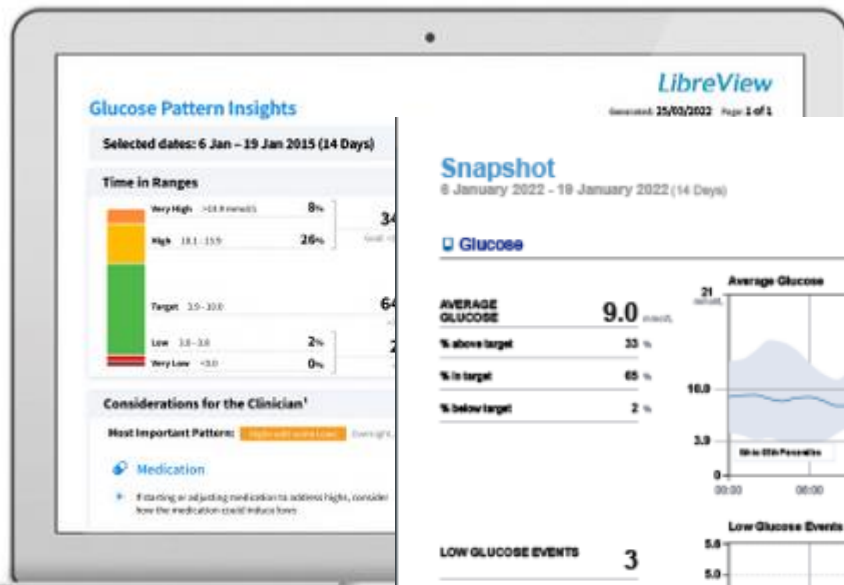
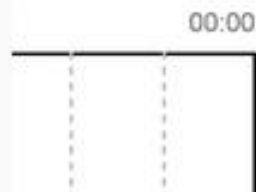


28.0

# Smart Insulin Pens NovoPen



See insulin and glucose data together to support more efficient patient consultations



## Snapshot

6 January 2022 - 19 January 2022 (14 Days)

### Glucose

GMI 7.2% or 66 mmol/mol

**AVERAGE GLUCOSE** 9.0 mmol/L

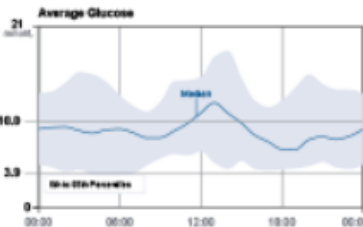
% above target 33 %

% in target 65 %

% below target 2 %

**LOW GLUCOSE EVENTS** 3

Average duration 115 min



## LibreView

### Carbs

**DAILY CARBS** 100g

### INSULIN

**RAPID-ACTING INSULIN** 22.2 units/day

**LONG-ACTING INSULIN** 25.0 units/day

**Total Daily Insulin** 47.2 units/day

### Comments

• Gaps found in food data, 14 days in this reporting period have no recorded food events.

# Smart Insulin Pens- InPen Medronic

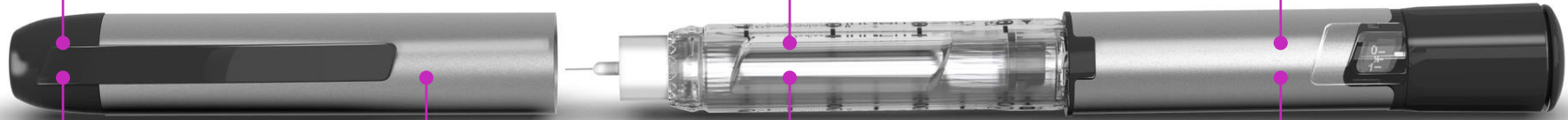
## InPen™ smart pen

Available in two colours

**Blue:** compatible with Novo Nordisk  
**NovoRapid®**, Novo Nordisk **Fiasp®** and Novo  
Nordisk Insulin Aspart Injection, 3 ml cartridges  
(300 units)

**Grey:** compatible with  
Lilly **Humalog®** and Lilly  
**Lyumjev®** cartridges

**Delivers half  
unit doses  
(up to 30 units)**



Share data from multiple  
InPen™ smart pens to the  
same app

Connects to the  
app via Bluetooth®

Monitors insulin  
temperature

**Battery lasts a  
full year with no  
need to charge**

# Smart MDI systemSmart MDI system with Simplera™ & InPen™ 2.0

InPen™ hardware

InPen™ app

Simplera™ sensor

Simplera™ app

Care partner app

Smart watch support



# Simplera™ CGM

## Simplera™ CGM

### Key features



#### Real-time CGM tracing

Records glucose levels every 5 minutes, 24/7 with no fingersticks\*



#### Predictive glucose alerts

Alerts of lows and highs up to 60 minutes ahead of time



#### Discreet design

Simple insertion & wear experience

NEW  
feature

App connectivity to Android and Apple phones, Apple watch & Care Partners app

\* If CGM readings do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions. Refer to System User Guide



NEW  
feature

# InPen™ smart insulin pen



## Tracks dosing data

Active insulin tracking, automatic dose logging and reminders to dose or change cartridges



## Provides real-time dosing guidance

Bolus calculator and Missed dose detection technology recommends a corrective action when a mealtime bolus is missed or not enough to stay in range



## Easy access to reports & insights

Your patients on MDI therapy's glucose and insulin data is available in a single CareLink™ system report



# CGM & insulin dosing in one system

Glucose levels, active insulin, and dose calculations combined to recommend the right mealtime dose\*



## Insulin dosing

InPen™ smart insulin pen tracks dosing data and helps calculate dose



## CGM

Records real-time glucose trends



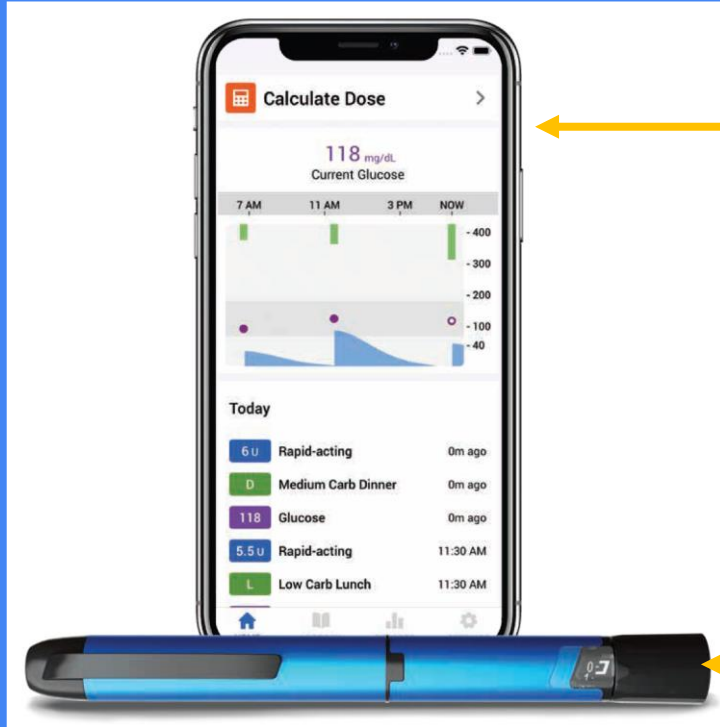
## Smart MDI system

Provides real-time dosing guidance for your patients



# Smart Insulin Pens

## InPen Medtronic



InPen App

ICR, ISF, BG target  
Active insulin time/  
Insulin on board

up to 4  
time intervals

**Bolus calculator**  
Reminders  
Logbook

BG meter  
CGM (Guardian)

**InPen**

30-unit maximum dose  
0.5-unit dose increments

**Cartridges:**

Novorapid  
Fiasp  
Humalog

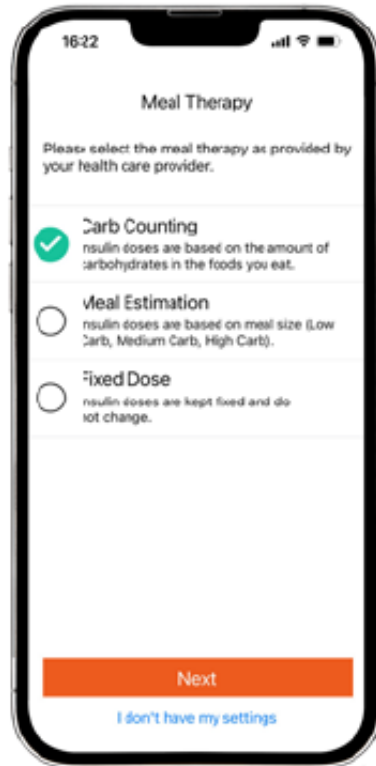
transmits insulin dose data from the smart insulin pen to the user's smartphone app via Bluetooth



# Smart MDI systemSmart MDI system with Simpler<sup>TM</sup> & InPen<sup>TM</sup> 2.0

InPen<sup>TM</sup> app

Dose calculator: meal therapy modes



## Rapid-acting insulin settings

### Dose Calculator settings

Maximum Calculated Dose: \_\_\_\_\_ Units

Duration of Insulin Action: \_\_\_\_\_ hh:mm

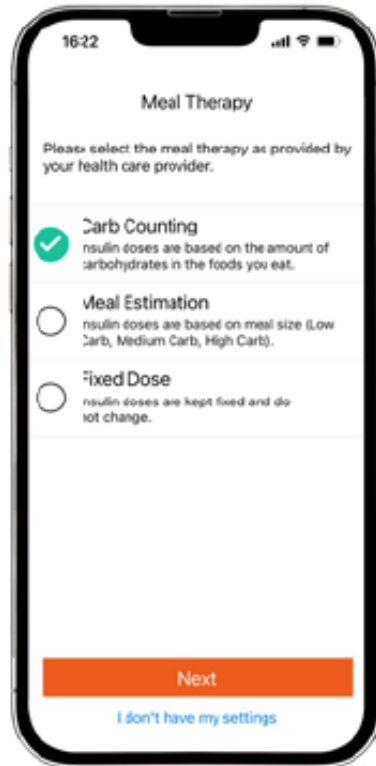
Glucose Target: \_\_\_\_\_ mg/dL

Insulin Sensitivity Factor: \_\_\_\_\_ mg/dL/U

# Smart MDI systemSmart MDI system with Simpler<sup>™</sup> & InPen<sup>™</sup> 2.0

InPen<sup>™</sup> app

Dose calculator: meal therapy modes



Meal therapy mode	Carb Counting	Meal Estimation	Fixed Dose
Dose recommendations description	Insulin doses are based on the amount of carbohydrates in the foods eaten.	Insulin doses are based on carbohydrate content size of the meal ( <i>low, medium, or high carb</i> ).	Insulin doses are kept fixed ( <i>per meal</i> )
Suggested use	People with type 1 diabetes ( <i>T1D</i> ) and those who are experienced with carb counting	People with any diabetes type on MDI who do not count carbs	Newly diagnosed, non-carb-counters, and those with difficulties roughly estimating carbohydrate content
User responsibility	Enter the amount of carbohydrates to be consumed at each meal or snack	Choose the relative carbohydrate content of the meal ( <i>low, medium, high carb meals</i> )	Select the meal type ( <i>breakfast, lunch, dinner, snack</i> ).
Settings for dose calculation	<ul style="list-style-type: none"> <li>• Current glucose</li> <li>• Insulin-to-carb ratio</li> <li>• Insulin sensitivity factor</li> <li>• Glucose Target</li> </ul>	<ul style="list-style-type: none"> <li>• Current glucose</li> <li>• Estimated carbohydrate content of the meal</li> <li>• Insulin sensitivity factor</li> <li>• Glucose Target</li> </ul>	<ul style="list-style-type: none"> <li>• Current glucose</li> <li>• Fixed insulin amount</li> <li>• Insulin sensitivity factor</li> <li>• Glucose Target</li> </ul>

# Smart MDI systemSmart MDI system with Simplera™ & InPen™ 2.0

InPen™ app

Dose calculator: meal therapy modes

## Meal Therapy insulin settings

Select ONE meal therapy below:

☐ Carb Counting:

Insulin to Carb Ratio:

\_\_\_\_\_ g/U

☐ Meal Estimation:

Meal	Low Carb	Med Carb	High Carb
Breakfast	_____ U	_____ U	_____ U
Lunch	_____ U	_____ U	_____ U
Dinner	_____ U	_____ U	_____ U
Snack	_____ U	_____ U	_____ U

☐ Fixed Dose:

Meal	Units per meal
Breakfast	_____ U
Lunch	_____ U
Dinner	_____ U
Snack	_____ U

inpen

# Smart MDI systemSmart MDI system with Simplera™ & InPen™ 2.0

## Alerts & notifications

### Simplera™ CGM alerts



#### Low Limit

Day time: \_\_\_\_\_ mg/dL

Recommended: 70 mg/dL

Night time: \_\_\_\_\_ mg/dL

Recommended: 70 mg/dL

#### Low Alert me

Select: ☐ At Low Limit   ☐ Before Low Limit   ☐ Before and At Low Limit

Recommended: Before and At Low Limit

Time Before Low: 20 minutes

#### High Limit

Day time: \_\_\_\_\_ mg/dL

Recommended: 300 mg/dL

Night time: \_\_\_\_\_ mg/dL

Recommended: 300 mg/dL

#### High Alert me

Select: ☐ At High Limit   ☐ Before High Limit   ☐ Before and At High Limit

Recommended : At High Limit

# Smart MDI systemSmart MDI system with Simplera™ & InPen™ 2.0

## InPen™ app notifications



### Missed Dose alert

Day Time: ☐ ON ☐ OFF (select)

Recommended: ON

Night Time: ☐ ON ☐ OFF (select)

Recommended: OFF

### Correct High Glucose alert

Day Time: ☐ ON ☐ OFF (select)

Recommended: ON

Night Time: ☐ ON ☐ OFF (select)

Recommended: OFF

### Alert Me When I Need:

\_\_\_\_\_ Units

Recommended: Default value

### Long-acting reminder:

☐ ON ☐ OFF (select)

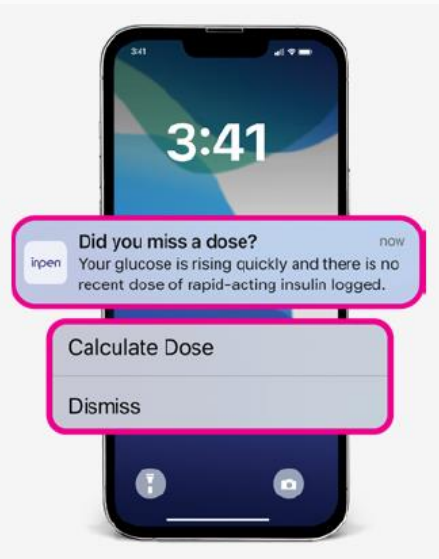
Recommended: ON

- The purpose of the long-acting insulin settings is to remind users to take long-acting insulin doses and log. It is especially recommended for those who often miss their long-acting dose.

## Smart MDI systemSmart MDI system with Simplera™ & InPen™ 2.0

### Missed Dose alert

This alert **detects a missed meal dose and recommends an insulin dose** to the user. When a rate of change detection algorithm detects that SG is rising quickly and there is no recent dose of rapid-acting insulin logged, the Missed Dose Alert will notify the user. **The user can choose to either Calculate Dose or Dismiss the notification.**



When the alert is triggered, **choose Calculate Dose** to open the dose calculator. In the dose calculator, enter **no glucose value** (leave empty) and **enter the full meal carbohydrate value (or the meal type, depending on the meal therapy mode chosen)**; Administer the full suggested dose.

# Smart MDI systemSmart MDI system with Simplera™ & InPen™ 2.0

## Correct High Glucose alert

This alert **notifies a user when more insulin is needed to bring glucose down to target (correction dose)**

### Recommendation for user:

When alert is triggered, choose Calculate Dose to open the dose calculator. The **glucose value will be automatically populated**. Enter **no value for Carbs** (*leave empty*), and **take the dose recommended**.



When this alert is triggered, the user can **choose to Calculate Dose, Snooze 30 mins, or Wait until next meal.**

### Alert Me When I Need

It is the threshold of required insulin units that will trigger the notification. For example, if this value is set to 2 U, the Correct High Glucose alert will only be triggered if the recommended correction does is 2 U or more.

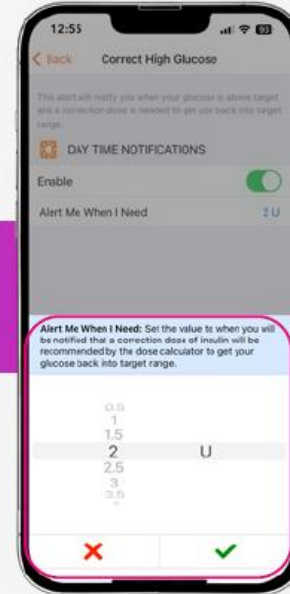
# Smart MDI systemSmart MDI system with Simplera™ & InPen™ 2.0

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# Smart Insulin Pens InPen Medronic

## Meal - Correction

8:38

### Meal Therapy

Please select the meal therapy as provided by your health care provider.

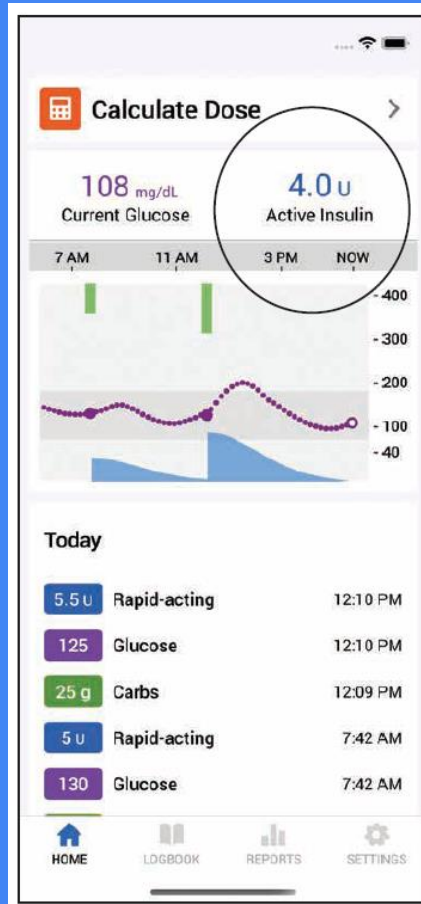
☒ **Carb Counting**  
Insulin doses are based on the amount of carbohydrates in the food you eat.

☐ **Meal Estimation**  
Insulin doses are based on meal size (Low Carb, Medium Carb, High Carb).

☐ **Fixed Dose**  
Insulin doses are kept fixed and do not change.

[Next](#)

[I don't have my settings](#)



8:35

### Calculator

[Cancel](#) [Save](#)

[Recommendation](#)  
5.5 U

210  
Glucose

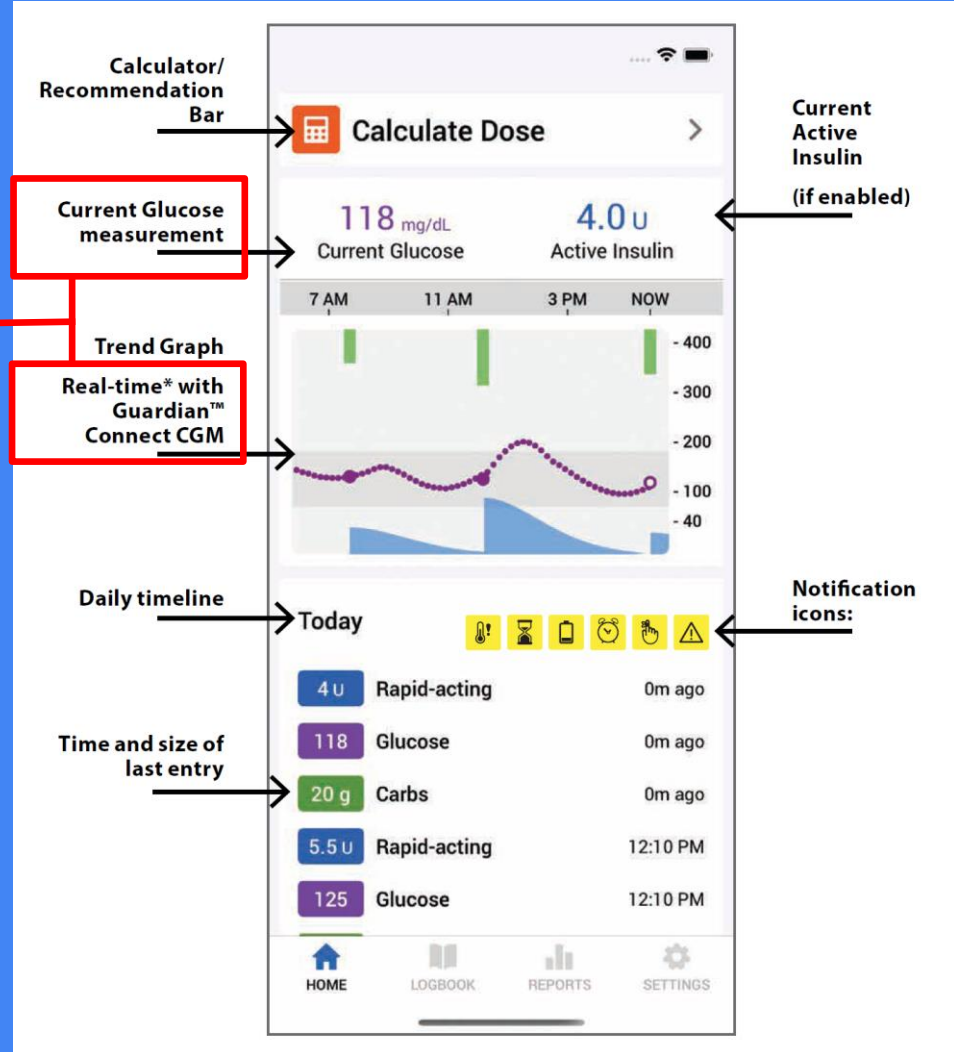
35  
Carbs

1 2 3  
4 5 6  
7 8 9  
0

[X](#)

# Smart Insulin Pens InPen Medtronic

BMG/CGM



# Smart Insulin Pens- InPen Medtronic

## Comprehensive reports

Of a patients' glucose, insulin dosing, and meal data



### Providing healthcare teams

Data and information to facilitate informed discussions with patients



### All in one report

Insights reports integrate insulin, BG, CGM, insulin dose and dose calculator information in an all-in-one report format



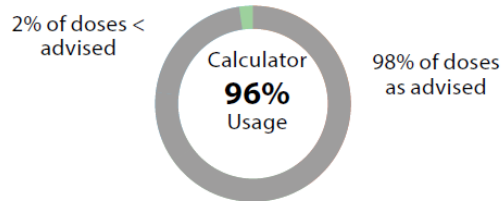
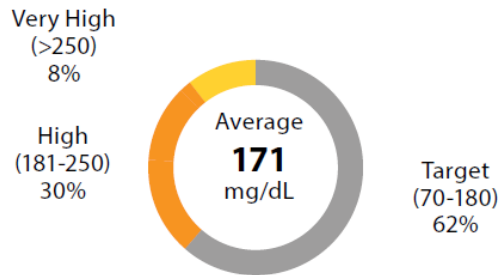
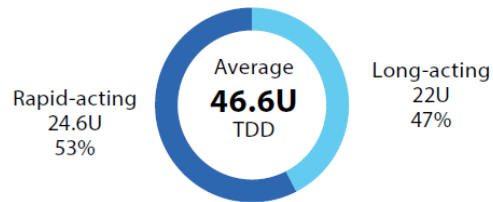
### Fine-tuning based on data

Fine-tune insulin regimen and care plan based on data



# Smart Insulin Pens

## InPen Medronic



### Missed doses:

**Rapid-acting** doses not logged within the time range configured in meal dose reminders are considered missed doses, unless you indicated that you did not eat that meal in the 24 missed dose reminder response.



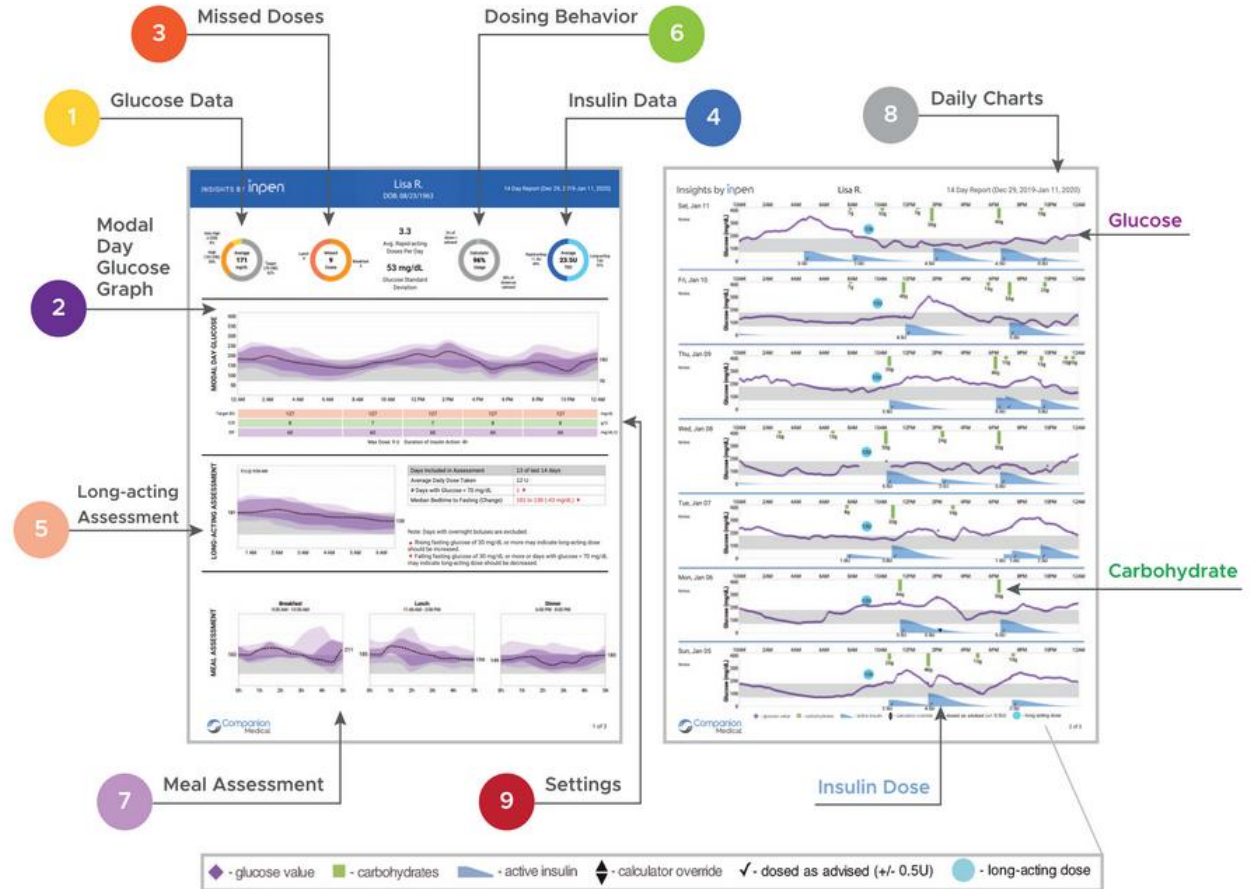
**2.6**  
Avg. Rapid-acting  
Doses Per Day

**Long-acting** doses not logged within three hours before or after the long acting reminder time are considered missed doses.

# Smart Insulin Pens - Roadmap



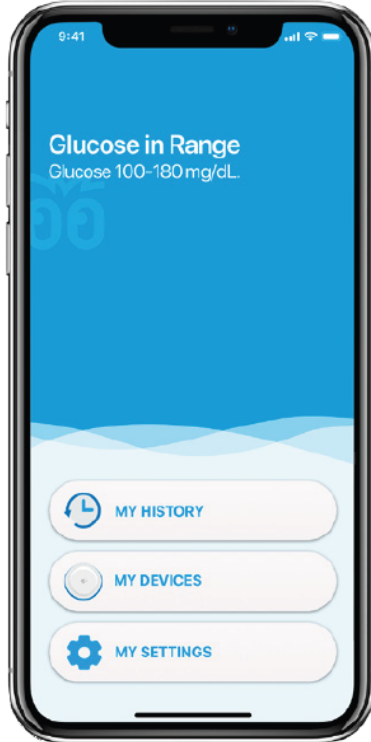
# InPen integrated data report



Warshaw H, Isaacs D, MacLeod J. The Reference Guide to Integrate Smart Insulin Pens Into Data-Driven Diabetes Care and Education Services. *The Diabetes Educator*. 2020;46(4\_suppl):3S-20S.

# Smart cap for insulin pens

## Bigfoot Unity™ Diabetes Management System



Bigfoot Unity App



Black Cap for Long-Acting Insulin

disposable pens



White Cap for Rapid-Acting Insulin



Abbott FreeStyle  
Libre 2 Sensor



Bigfoot Blood  
Glucose Meter



# Smart cap for insulin pens

## Bigfoot Unity™ Diabetes Management System



ulin

disposable pens



g Insulin



Bigfoot Unity App

Abbott FreeStyle  
Libre 2 Sensor

Bigfoot Blood  
Glucose Meter





## Black Cap for Long-Acting Insulin



χρόνος από την τελευταία ένεση

- Δυνατότητα λήψης alert στο κινητό τηλέφωνο ότι ίσως έχει χαθεί δόση

## The White Cap for Rapid-Acting Insulin



**Τιμή Σχ**  
Σύνδεση με BGM ή Freestyle Libre 2

βέλος τάσης

**Δόση** τελευταίας ένεσης  
Γεύμα/διόρθωση

- White Cap → προσλαμβάνει και στέλνει στο App  
τα δεδομένα των τελευταίων 8 ωρών από το Freestyle Libre2

## Bigfoot Unity™ Diabetes Management System

### Meal

9:41 📶 🔋

[Back](#) Insulin Settings

### Choose Meal Dose Label

Choose how to label the meal doses displayed on the White Cap.

Small, Medium, Large  
amount of carbs in my meal

Meal		
- u Small	- u Medium	- u Large

Breakfast, Lunch, Dinner

Meal		
- u Breakfast	- u Lunch	- u Dinner

3 specific carb amounts

Meal		
- u - grams	- u - grams	- u - grams

[Need help?](#)

9:41 📶 🔋

[Back](#) Insulin Settings

Enter the amount of insulin you take for 3 common meal sizes.

Meal		
- u Small	- u Medium	- u Large

*Note: The size refers to the amount of carbs, not necessarily the size of your meal*

MEAL	<INSULIN> (units)
Small	<input type="text"/>
Medium	<input type="text"/>
Large	<input type="text"/>

[Need help?](#)

[Cancel](#) [Done](#)

1

2

3

4 units

5

9:41 📶 🔋

[Back](#) Insulin Settings

Enter 3 different carb amounts and the amount of insulin you take for each.

Meal		
- u - grams	- u - grams	- u - grams

CARB AMOUNT

grams

grams

grams

[Need help?](#)

[Cancel](#) [Done](#)

90

95

100 grams

105

110

## Bigfoot Unity™ Diabetes Management System

### Correction

9:41 📶 🔋

[< Back](#) Insulin Settings [Edit](#)

### Correction Insulin

Enter the units of <Insulin> for each range below.

GLUCOSE RANGE (mg/dL)	<INSULIN> (units)
150 - 200	<input type="text" value="1"/>
201 - 250	<input type="text" value="2"/>
251 - 300	<input type="text" value="3"/>
301 - 350	<input type="text" value="4"/>
351 - 400	<input type="text" value="5"/>
Over 400	<input type="text" value="6"/>

[Need help?](#)

[Next](#)

9:41 📶 🔋

[< Back](#) Insulin Settings

I take <Insulin> to lower glucose to a target of 120 mg/dL .

1 unit of <Insulin> lowers my glucose by  mg/dL

Done

1	2 ABC	3 DEF
4 GHI	5 JKL	6 MNO
7 PQRS	8 TUV	9 WXYZ
0		<a href="#">✕</a>

9:41 📶 🔋

[< Back](#) Insulin Settings

### Notes

Use this space to enter notes about your diabetes care. Notes are displayed only in the App and are not used by Bigfoot Unity Caps.

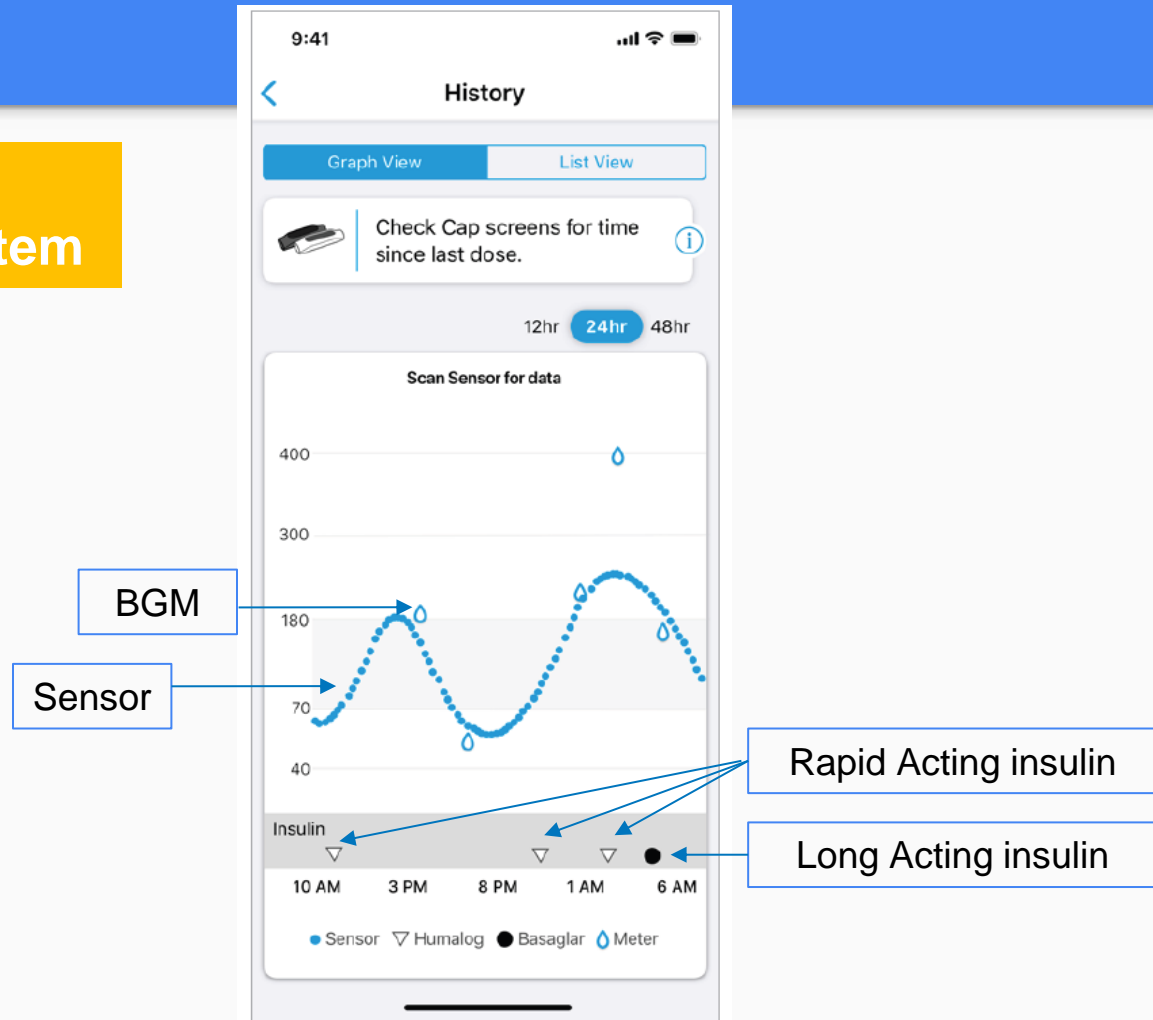
Enter notes here (limit 1000 characters and 3 images)

[Skip](#) [Next](#)

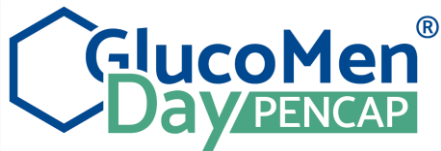
### Notes

# Smart cap for insulin pens

## Bigfoot Unity™ Diabetes Management System



# Smart cap for insulin pens



Smart Insulin  
Pen Cap



disposable pens

## Compatible with insulin pens

Compatible with most common  
insulin pens

## Adherence Check

Check if insulin injections correctly occurred.  
Provides **alarms** in case a due injection is missed.

## **Record** insulin data

Automatically record insulin dosing data and collect them with the other data from the GlucoMen Day line (CGM, SMBGs, Fitbit) in the same organized space (GlucoLog, Diasend (TBC)).

## Check insuling storage

Monitor insulin storage **temperature** in real-time and provide alarms in case of improper conditions.

## Build up a closed loop for MDI patients

The **combination of the CGM, the bolus calculator and this cap** could allow to build up a sort of closed loop system for MDI patients, where the user is assisted in dose calculation, and monitored for the correct insuling injection.



## Injection Reminder

allow to remind insulin  
injection



## Track Insulin Injection

track injection time



## Data sharing via BT

Bluetooth sharing

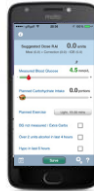
# Smart cap for insulin pens



ICR, ISF,  
BG target, active insulin time  
Insulin on board



Patient Diary App



Insulin Bolus  
Calculator and  
Diary App



Data Management and  
Analysis Software

# Συμμόρφωση στην ινσουλινοθεραπεία Παράλειψη ενέσεων ινσουλίνης (missed insulin injections)



### **Insulin adherence behaviours and barriers in the multinational Global Attitudes of Patients and Physicians in Insulin Therapy study**

*Peyrot et al. Diabet Med. 2012 May;29(5):682*

Internet survey

China, France, Japan, Germany, Spain, Turkey, UK, USA

1530 insulin-treated patients (180 T1DM, 1350 T2DM)

1250 physicians

#### **Patients:**

33.2% reported insulin omission/non-adherence at least 1 day in the last month, with an average of 3.3 days.

#### **Physicians:**

72.5% report that their typical patient does not take their insulin as prescribed, with a mean of 4.3 days per month of basal insulin omission/non-adherence and 5.7 days per month of prandial insulin omission/non-adherence

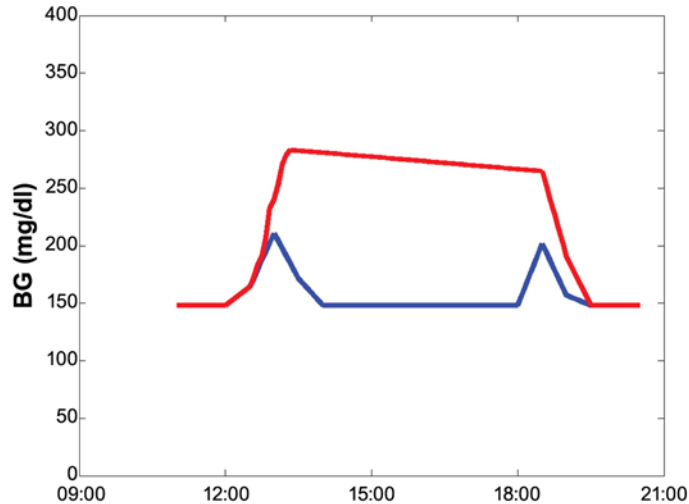
## Insulin adherence behaviours and barriers

Reason	Patients % and rank	Physicians % and rank
Too busy	18.9% 1	41.9% 3
Travelling	16.2% 2	43.6% 2
Skipped meal	15.0% 3	44.8% 1
Stress or emotional problems	11.7% 4	32.2% 5
Embarrassing to inject in public	9.7% 5	36.8% 4
Challenging to take it at the same time everyday	9.4% 6	29.1% 6
Forgot	7.4% 7	2.0% 11
Too many injections	6.0% 8	26.4% 7
Avoid weight gain	4.0% 9	13.4% 9
Regimen is too complicated	3.8% 10	16.8% 8
Injections are painful	2.6% 11	7.8% 10

# Παράλειψη γευματικής ινσουλίνης

## Παράλειψη bolus

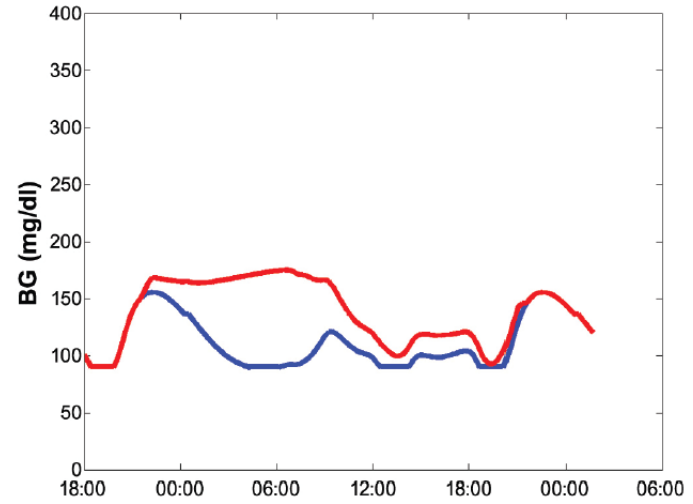
**BG profile with insulin (blue), without (red)**



**Figure 4.** Omitting a meal bolus. The red curve is based on data from the DirecNet study.<sup>6</sup>

## Παράλειψη ινσουλίνης βραδείας δράσης

**BG profile with insulin (blue), without (red)**



**Figure 6.** Forgetting bedtime long-acting insulin. Simulated profiles from AIDA.

# Παράλειψη γευματικής ινσουλίνης

Increased average glycaemia



Increased HbA1c

2.1 omissions per week

2.1 omissions per week

Case— <b>bolus</b>	$\Delta\text{HbA1c}$ using Rohlving's relation	$\Delta\text{HbA1c}$ using Kilpatrick's relation
Forgetting breakfast bolus ( <b>Figure 1</b> )	0.383 ( $\pm 0.014$ )	0.617 ( $\pm 0.022$ )
Omitting a meal bolus ( <b>Figure 4</b> )	0.265 ( $\pm 0.009$ )	0.426 ( $\pm 0.015$ )
Forgetting lunch insulin. AIDA simulation ( <b>Figure 5</b> )	0.278 ( $\pm 0.010$ )	0.448 ( $\pm 0.016$ )

Case— <b>basal</b>	$\Delta\text{HbA1c}$ using Rohlving's relation	$\Delta\text{HbA1c}$ using Kilpatrick's relation
Forgetting long-acting insulin in the early afternoon ( <b>Figure 2</b> )	0.171 ( $\pm 0.006$ )	0.276 ( $\pm 0.010$ )
Forgetting bedtime long-acting insulin. AIDA simulation ( <b>Figure 6</b> )	0.333 ( $\pm 0.012$ )	0.536 ( $\pm 0.019$ )

# Παράλειψη γευματικής ινσουλίνης

Injection remember rate	Injection forget rate	HbA1c deviation from optimum
100%	0%	Optimum treatment
90%	10%	0.3 to 0.4% points
80%	20%	0.6 to 0.8% points
70%	30%	0.9 to 1.2% points
61.5%	38.5%	1.8% points

**Average Insulin remember rate  
(missing about 1 injection every 3!)**

**A Novo Nordisk study (2014) reported 59%**

# Nonadherence to Insulin Therapy – Glycemic control

Nonadherence to Insulin Therapy  
Detected by Bluetooth-Enabled  
Pen Cap Is Associated With Poor  
Glycemic Control

*Munshi et al. Diabetes Care 2019;42:1129*

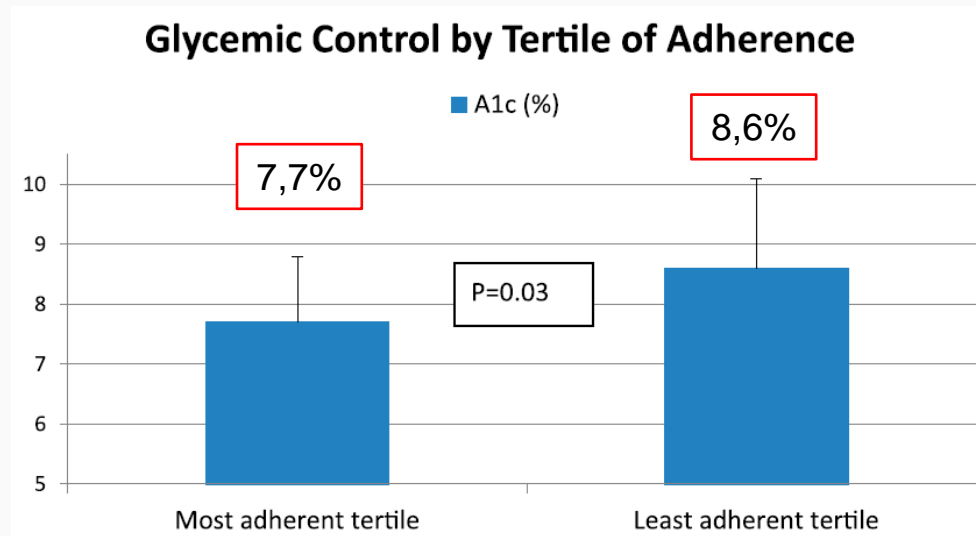
USA

n=75

Young adults T1DM

older adults T1DM or T2DM on two or more insulin injections/day

**Gocap Bluetooth-enabled pen for basal and bolus**



# Missed basal insulin doses – Glycemic control – T1DM

**Sweden**

**T1DM on CGM**

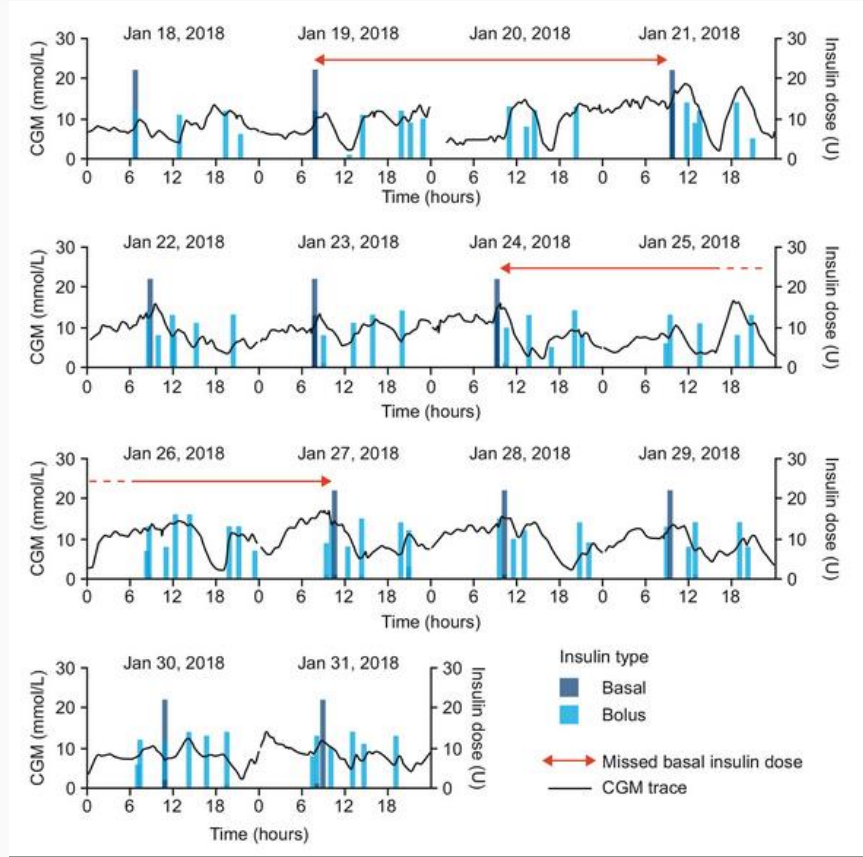
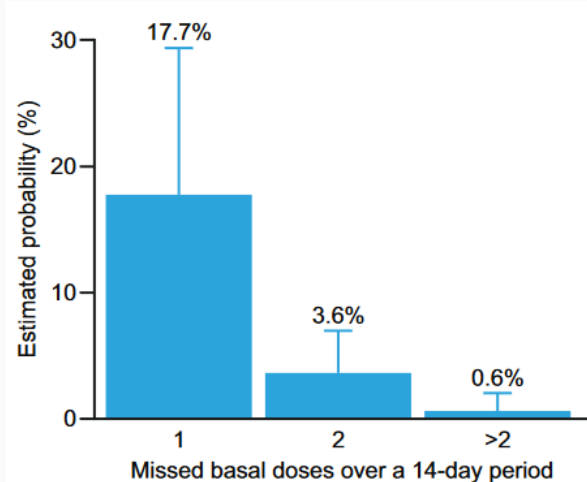
**n=32**

**Novopen 6, basal insulin (n=32)**

**Novopen 6, bolus insulin (n=28)**

**14 days**

**Prospective observational study**



# Missed basal insulin doses – Glycemic control – T1DM

**Sweden  
T1DM on CGM**

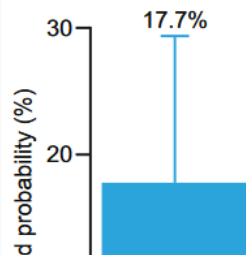
**n=32**

**Novopen 6, basal insulin (n=32)**

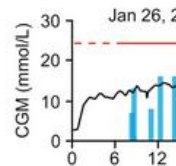
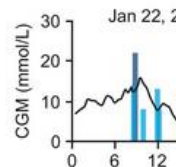
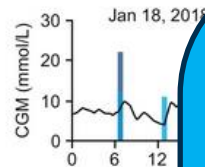
**Novopen 6, bolus insulin (n=28)**

**14 days**

**Prospective observational study**



The estimated probability of **missing at least one basal insulin dose** over a 14-day period was **22%** (95% confidence interval: 10%-40%)



**Meals detection**

**GRID (Glucose Rate Increase Detector) algorithm:**

CGM signal was  $\geq 130$  mg/dL and the rate-of-change was  $\geq 95$  mg/dL/hour) for the last two consecutive readings, or  $\geq 90$  mg/dL/hour for two of the last three readings.

**Missed basal dose (MBD):**

without bolus injection  
+60 minutes from the



## Missed basal insulin doses – Glycemic control – T1DM

Glycemic parameters	Estimated mean change per missed basal insulin injection (95% CI)	P	Estimated mean change per missed bolus insulin injection (95% CI)	P
TIR, %	-2.63 (-4.41, -0.71)	.005	-0.25 (-0.44, -0.07)	.008
TAR L1, %	0.34 (-0.71, 1.34)	.520	-0.03 (-0.14, 0.07)	.525
TAR L2, %	2.91 (0.99, 4.73)	.002	0.26 (0.07, 0.45)	.008
TBR L1, %	-0.28 (-0.65, 0.11)	.154	0.00 (-0.03, 0.04)	.808
TBR L2, %	-0.29 (-0.78, 0.22)	.256	0.02 (-0.04, 0.06)	.556
Mean glucose, mmol/L	0.44 (0.19, 0.69)	<.001	0.02 (-0.00, 0.05)	.085
%CV, %	-0.09 (-1.08, 0.95)	.855	0.19 (0.09, 0.29)	<.001
GMI, %	0.19 (0.08, 0.30)	<.001	0.01 (-0.00, 0.02)	.085

Συμμόρφωση στην ινσουλινοθεραπεία  
Χρόνος bolus για κάλυψη γεύματος  
(bolus timing)

# Time of bolus - Real world data

USA, UK, Germany

n = 906

adults with T1D (39%) and T2D (61%) treated with insulin therapy

Mean age: T1D 37 years, T2D 47 years

## bolus dosing

before meals 57.0%

after meals 18.9%

with meals 12.7%

at varying times (11.5%)

## Bolus dose timing

		before (n=516)	with (n=115)	after (n=171)	
<u>Experienced out-of-range BG in past week<sup>1</sup></u>					
Hypoglycemia <sup>2</sup>	n(%)	56	73	69	**
postprandial hypoglycemia (low BG after eating)	n(%)	28	52	51	**
Hyperglycemia <sup>3</sup>	n(%)	71	84	71	*
postprandial hyperglycemia (high BG after eating)	n(%)	59	74	65	*

\*p<0.05, \*\*p<0.001

# Time of bolus - Real world data

T1D Exchange clinic registry  
(USA)  
n = 4768  
age <26 years

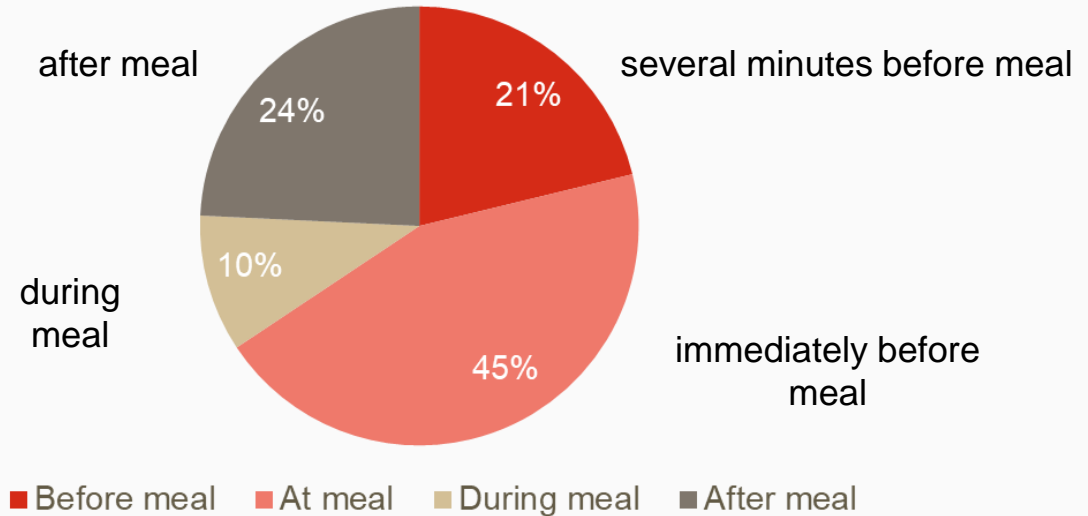
## HbA1c

Bolus before meal: 8,4%

Bolus during or after meal: 8,8%

p<0,001

## Time of Mealtime Insulin Injection<sup>1</sup>



# Σωστός υπολογισμός bolus (bolus calculation)

# Σωστός υπολογισμός bolus (bolus calculation)

Η δυναμική προσαρμογή της ινσουλινοθεραπείας είναι απαραίτητο συστατικό στη θεραπεία του τύπου 1 διαβήτη

*ADA Standards of care 2023*  
*ΕΔΕ Κατευθυντήριες οδηγίες 2023*

Δυναμική προσαρμογή της ινσουλινοθεραπείας → βελτίωση γλυκαιμικού ελέγχου

Αναλογία ινσουλίνης/ γρ. υδατανθράκων ή  
ισοδύναμο (Insulin to Carbohydrate Ratio, ICR)

Παράγοντας ευαισθησίας ινσουλίνης  
(Insulin Sensitivity Factor, ISF)

Στόχοι Σx (BG targets)

↓ μεταγευματικής υπεργλυκαιμίας

↓ μεταγευματικής υπογλυκαιμίας

Δεδομένα από κλινικές μελέτες

**12 Swedish diabetes clinics**  
**T1DM on CGM**  
**n=94**  
**Prospective observational study**

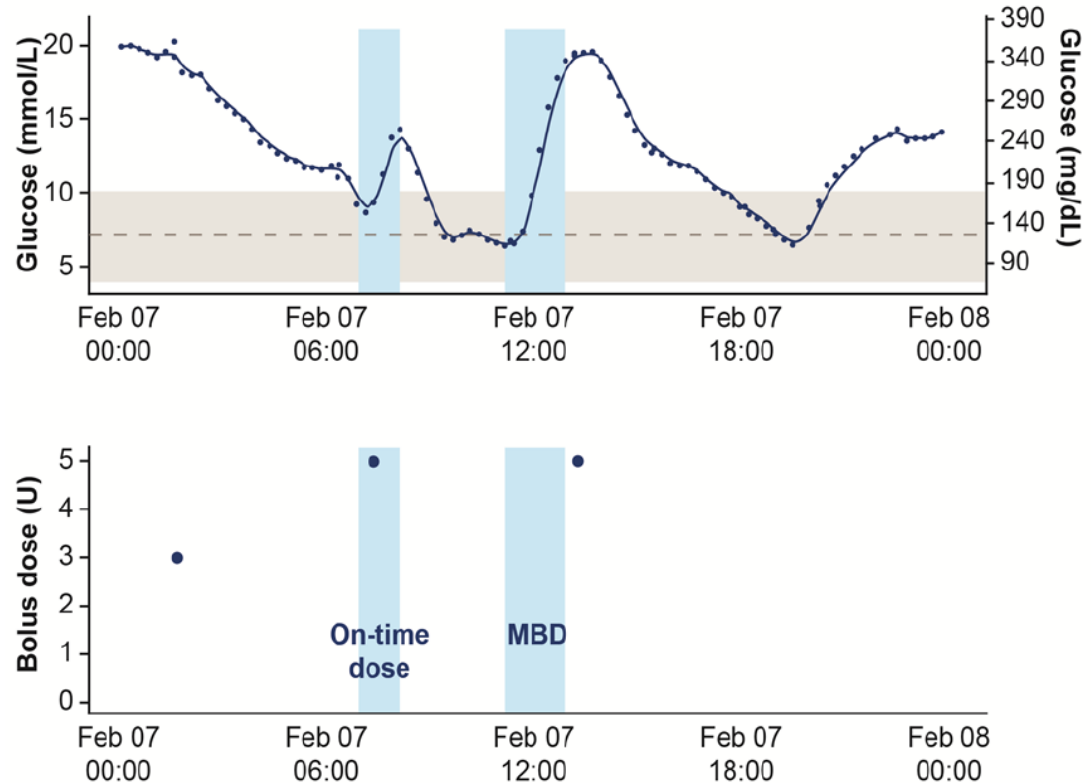
## Meals detection

### **GRID (Glucose Rate Increase Detector) algorithm:**

CGM signal was  $\geq 130$  mg/dL and the rate-of-change was  $\geq 95$  mg/dL/hour) for the last two consecutive readings, or  $\geq 90$  mg/dL/hour for two of the last three readings.

### **Missed bolus dose (MBD):**

were meals without bolus injection within -15 and +60 minutes from the start of a meal





baseline to follow-up period

**TIR**      ↑ 1.9 hours/day;  $p < 0.001$

**TAR**      ↓ 1.8 hours/day;  $p < 0.003$

**L1 hypo**    ↔

**L2 hypo**    ↓ 0.3 hours/day;  $p < 0.005$

use of a connected pen might help to facilitate more **informed dialogs between HCPs and people with T1D**

**Missed bolus dose (MBD):** ↓ 43% ( $p = 0.002$ )

decrease from 25% to 14% based on the assumption that participants had three main meals/day.

P: CLINICAL THERAPEUTICS/NEW TECHNOLOGY—INSULIN DELIVERY SYSTEMS | JUNE 01 2020

## 975-P: Effect of Late Bolus Injections on Glycemic Variability Studied by Connected Pens

*Jendle et al Diabetes 2020;69(Supplement\_1):975-P*

**12 Swedish diabetes clinics**  
**T1DM on CGM**  
**n=96**

**late-bolus dose:**  
bolus dose given **60-120 minutes**  
**after the estimated start of the meal**

mean number of late-bolus doses

Baseline:	0.32 per day
Smart pen follow up:	0.18 per day

↓ 42% (p = 0.005).

A significant correlation between the **timing of the bolus** dose and the **coefficient of variation (CV)** of the CGM signal was found

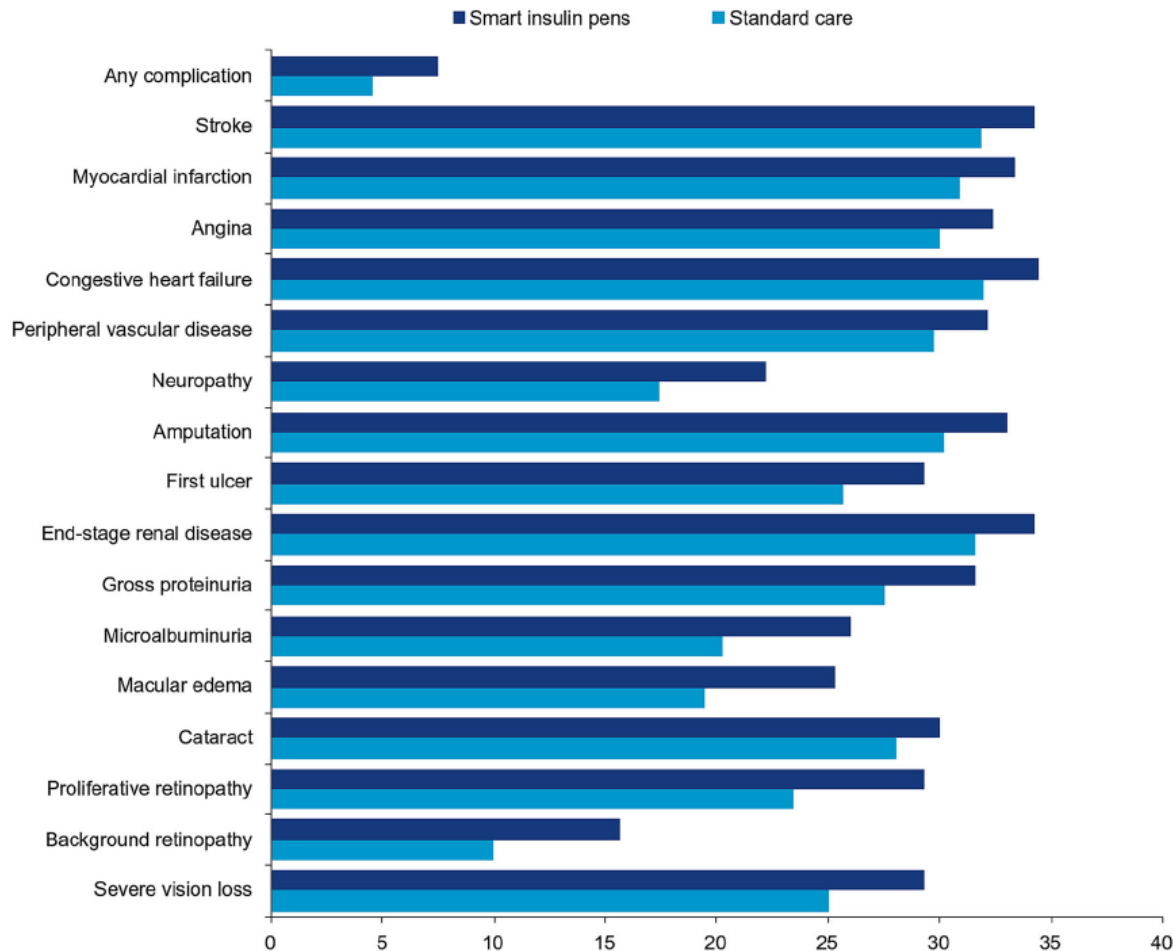
**each 10-minute delay of the bolus dose was associated with an increase of 0.5% CV** (p < 0.0001) on average.

# Cost-Effectiveness Analysis – T1DM - Sweden

Adolfsson et al, Sweden, T1DM → TIR ↑ 1.9 hours/day;  $p < 0.001$



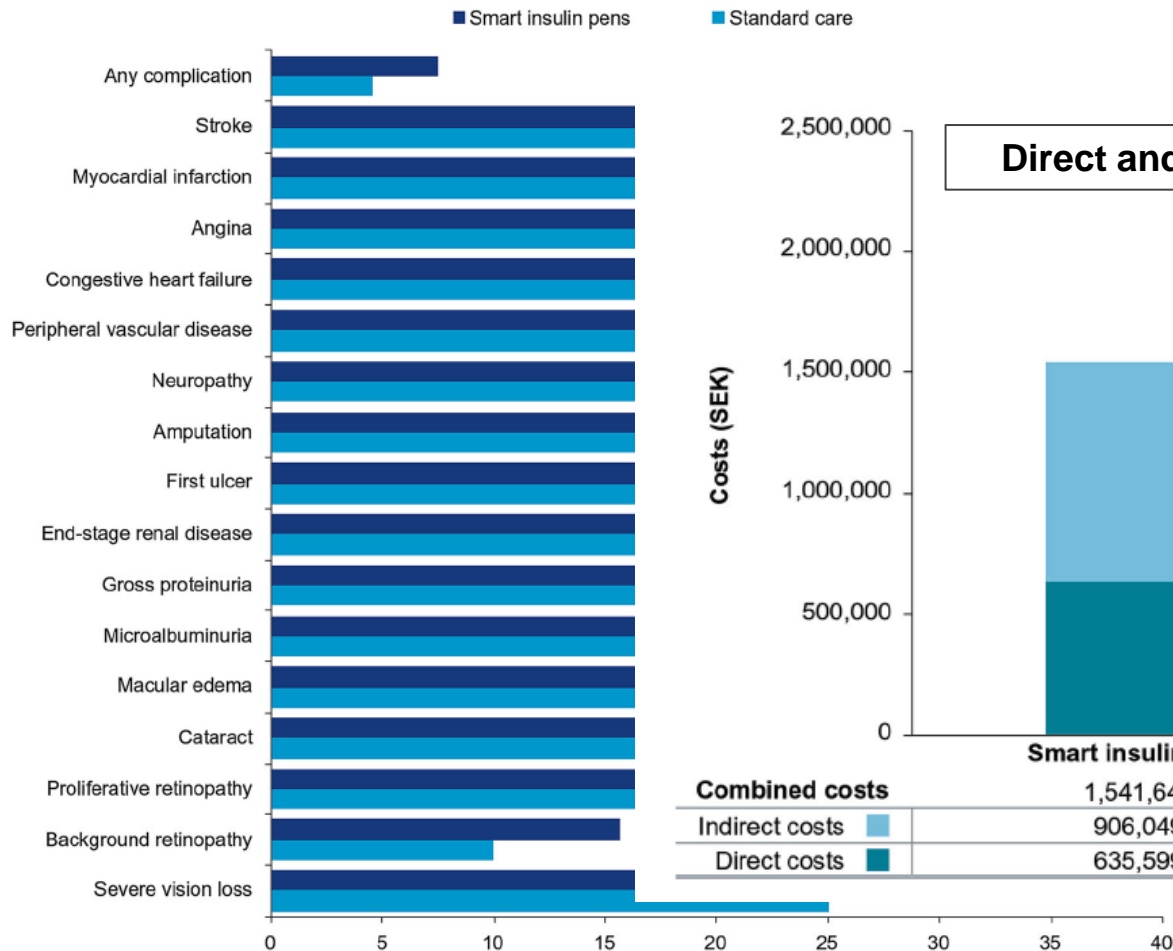
T1DM: Smart pen vs Standard care,  
simulated cohort based on Swedish National Diabetes Register



Mean time to onset of complications (years)

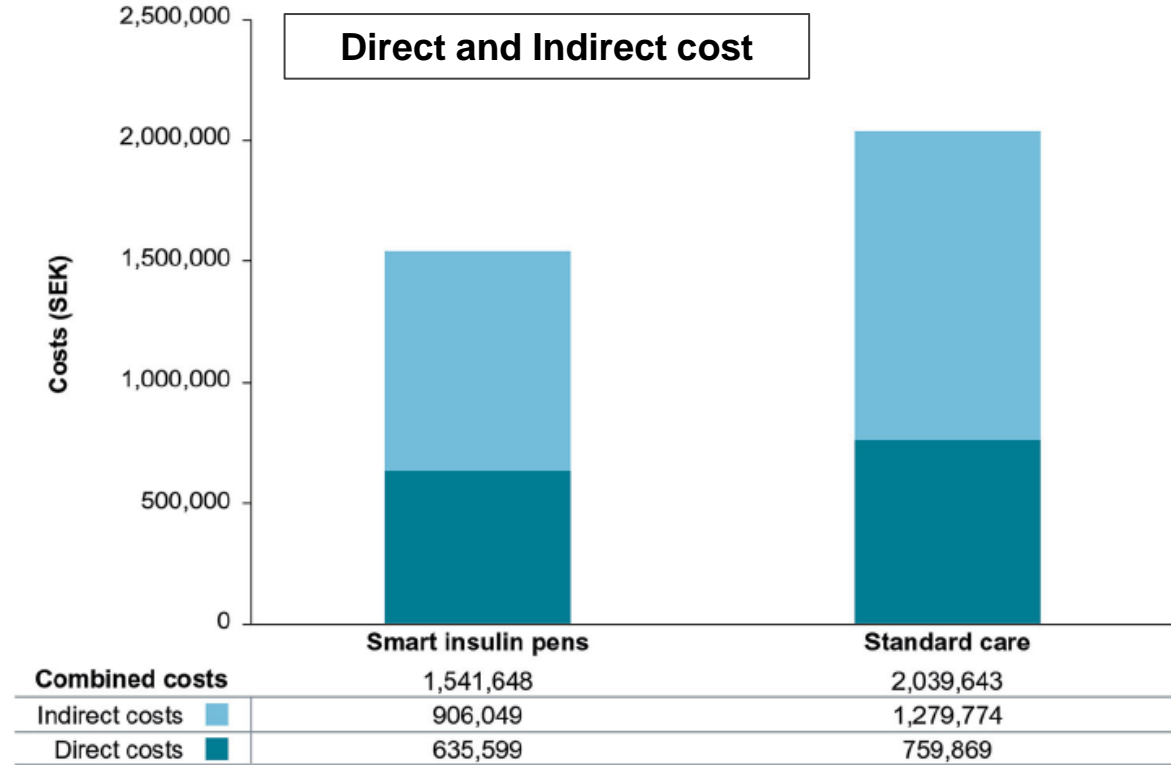
s/day;  $p < 0.001$

etes Register



**Mean time to onset of complications (years)**

### Direct and Indirect cost



# Smart insulin pen cap (Insulclock) – T1DM

**Smart insulin pen cap (Insulclock)**  
**Spain**  
**T1DM uncontrolled**  
**n=16**  
**Randomized Trial: active vs masked**  
**4weeks**

**masked FreeStyle Libre Pro CGM device (professional use)**

**Meals detection**

**GRID** (Glucose Rate Increase Detector) algorithm

**Late meal bolus (mistimed):** insulin  $\geq 30$  min after a glucose rise

**Missed dose:** no insulin  $\geq 2$  h after a glucose rise

## Insulclock (vs masked)

mean daily blood glucose: -27 mg/dL P < 0.013

SD: -14,4 mg/dL P = 0.003

TIR: +7% P = 0.038

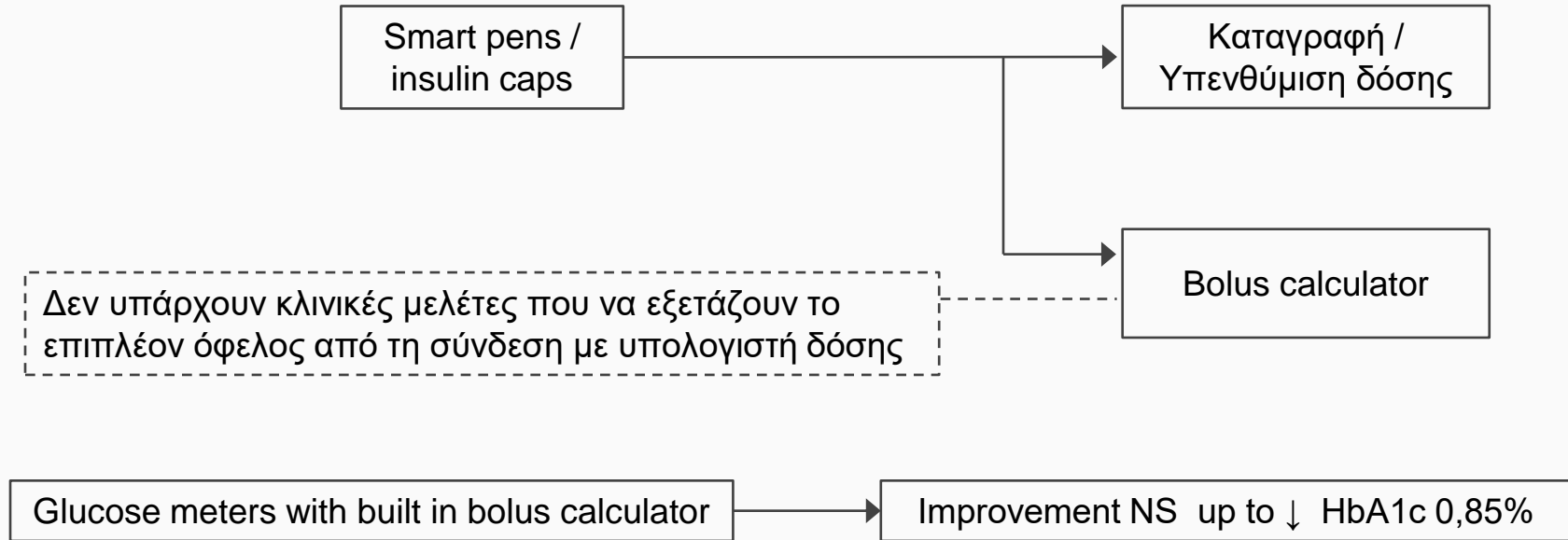
TAR: -12,5% P = 0.0026

number of missed insulin doses / month: -3,9 P = 0.14

number of mistimed insulin doses / month: -5,4 P = 0.032

Insulin Treatment Satisfaction Questionnaire (ITSQ) ↑

# Bolus calculator



*Colin et al Diabetes Ther. 2013 Jun;4(1):1*

*Gonzalez et al Diabetes Technol Ther. 2016 May;18(5):282*

# Smart Meters

	Study design	Results
Maurizi et al.	3- to 6-month randomized trial comparing patients using an ABC to a control group 40 consecutive adult type 1 diabetes patients	At 3 months: nonsignificant improvement in HbA1c levels (-0.61%) At 6 months: significant improvement in HbA1c levels (-0.85%; $P < 0.05$ )
Garg et al.	1-year open-label, randomized, controlled trial 123 adult type 1 diabetes patients randomized on a 1:1 basis to either an ABC or control group	HbA1c improvement by 0.6% at 12 months ( $P < 0.02$ ) Higher proportion of ABC users achieving HbA1c $< 7.5\%$ ( $P < 0.01$ )
Gonzalez et al.	36 weeks, crossover, prospective, randomized, controlled, multicenter study T1DM under MDI treatment (n=51)	Control HbA1c -0.39%; ABC HbA1c -0.52% [ $P = 0.8$ ]

ABC: automated bolus calculator

*Colin et al Diabetes Ther. 2013 Jun;4(1):1*

*Maurizi et al Diabetes Technol Ther. 2011;13:425*

*Garg et al Diabetes Technol Ther. 2008;10:369*

*Gonzalez et al Diabetes Technol Ther. 2016 May;18(5):282*



*Diabet Med.* 2025 Oct 13:e70161



## RESEARCH ARTICLE

### Treatment

# Insights into the effective use of the Smart MDI system: Data from the first 1852 type 1 diabetes users

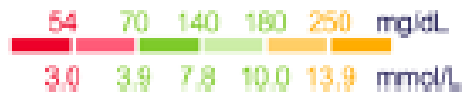
Andrea Laurenzi<sup>1</sup> | Shannon N Edd<sup>2</sup>  | Peter Adolfsson<sup>3,4</sup> | Fabio Di Piazza<sup>2</sup> |  
Benedikt Voelker<sup>2</sup> | Glen Im<sup>5</sup> | Tim van den Heuvel<sup>2</sup>  | Ohad Cohen<sup>2</sup>

Smart MDI users from 21 countries across Europe, the Middle East, and Africa with at least 10 days of InPen use and 10 days of CGM data during the observation period

# Smart MDI – Real world data

## Missed dose alert (MDA)

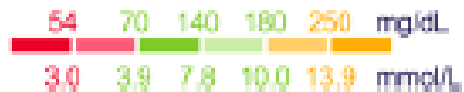
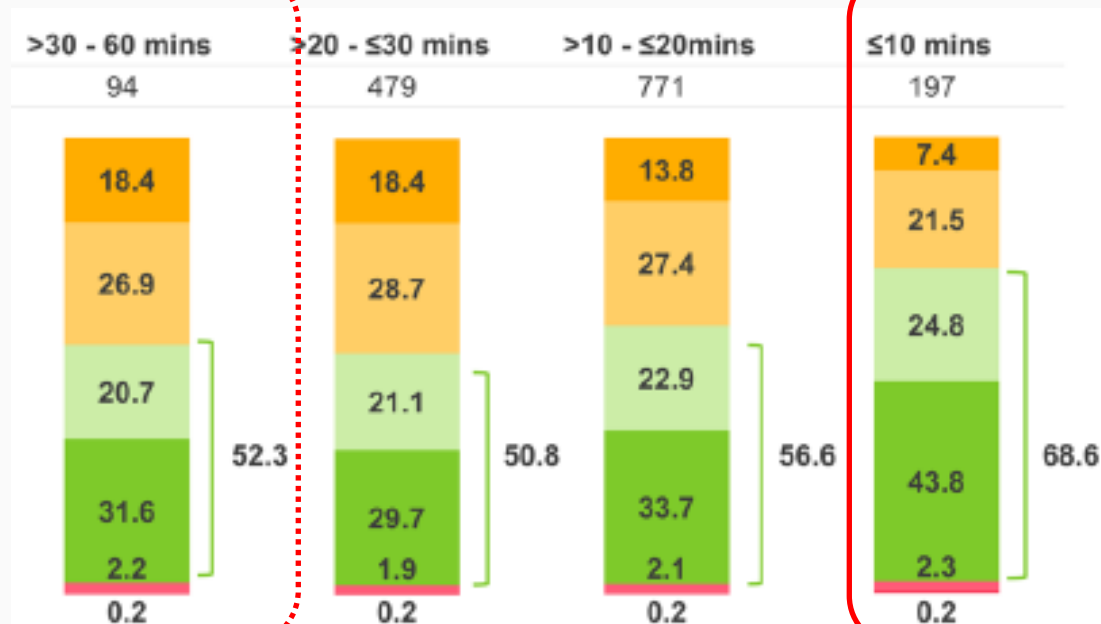
## Bolus response rate



# Smart MDI – Real world data

## Missed dose alert (MDA)

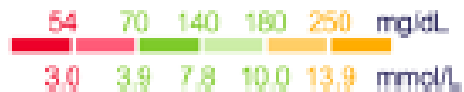
## Bolus response timing



# Smart MDI – Real world data

## Correct high glucose alert (CHGA)

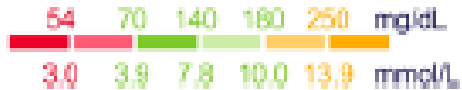
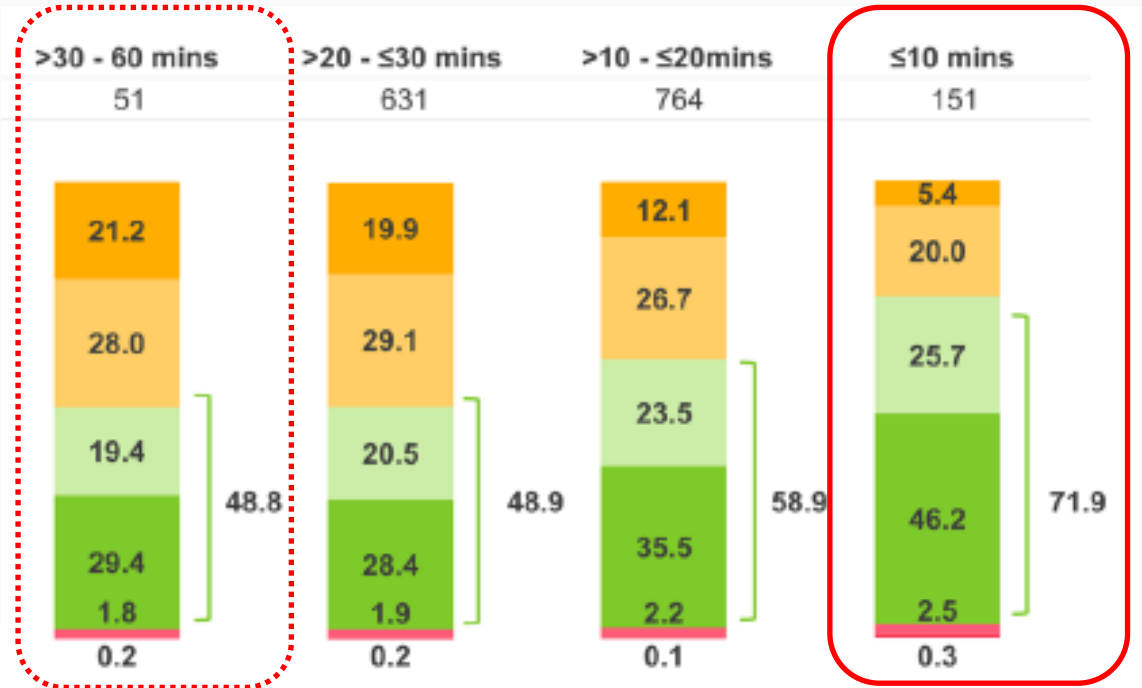
## Bolus response rate



# Smart MDI – Real world data

Correct high glucose alert (CHGA)

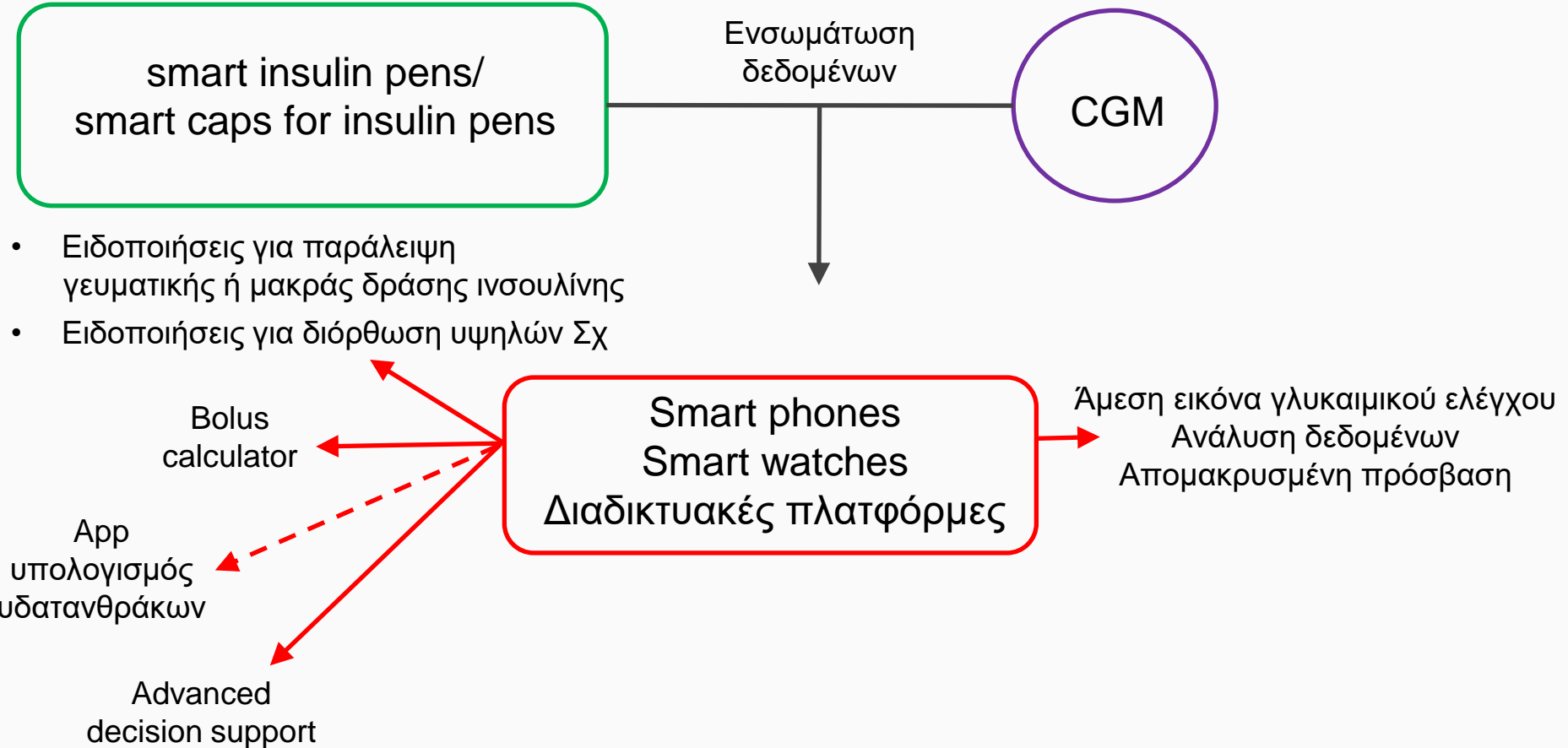
Bolus response timing



# ΣΥΝΟΨΗ

- Οι έξυπνες πένες ινσουλίνης (smart insulin pens) και τα έξυπνα καλύμματα για πένες ινσουλίνης (smart caps for insulin pens) αποτελούν ένα δυναμικά αναπτυσσόμενο πεδίο
- Λίγες κλινικές μελέτες με υποσχόμενα αποτελέσματα όσον αφορά στο όφελος από την καλύτερη συμμόρφωση
- Δεν υπάρχουν ακόμη κλινικά στοιχεία για το πιθανό όφελος από τη βοήθεια που μπορούν να προσφέρουν στη δυναμική προσαρμογή της ινσουλinoθεραπείας (bolus calculator)
- Στην πλήρη ανάπτυξη τους τα συστήματα αυτά θα μπορούσαν να προσφέρουν ένα περιβάλλον με πολλά κοινά στοιχεία με αντλία ινσουλίνης

# ΣΥΝΟΨΗ





*Ευχαριστώ  
για την προσοχή σας*

