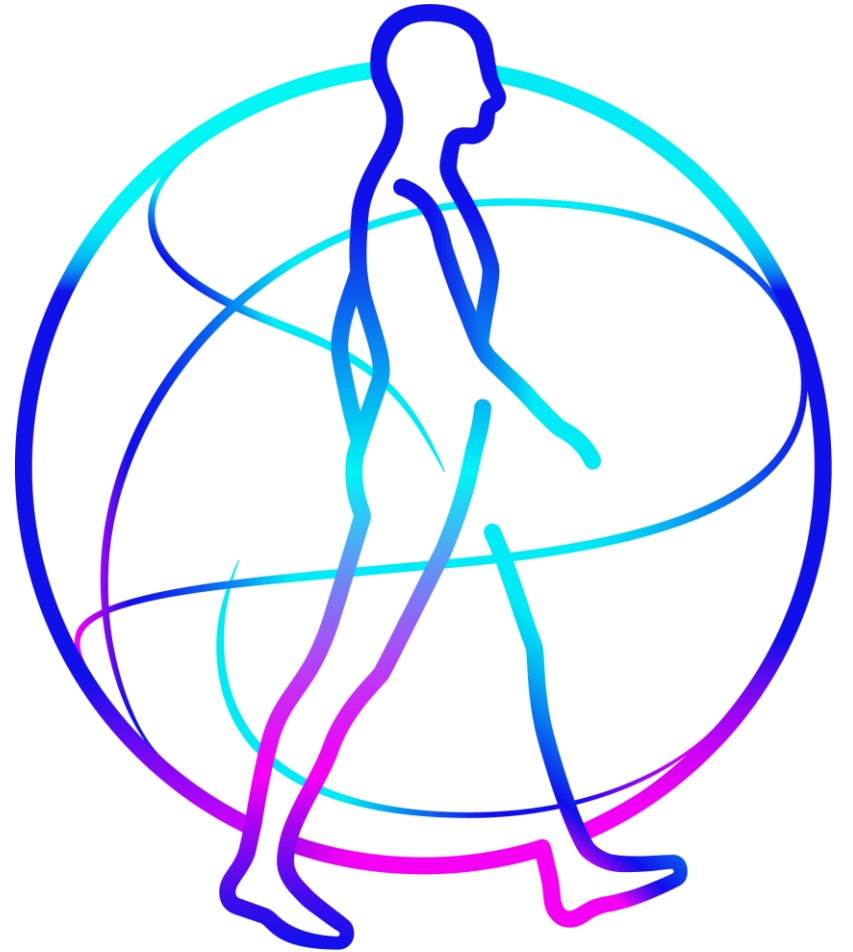


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Engineering the extraordinary

Insulin Pump Therapy & CGM

By: Mehrdad Eskandari, BioMed



Insulin Pumps



Pump Therapy versus Multiple Daily Injections (MDI)

Which Offers Better Control?

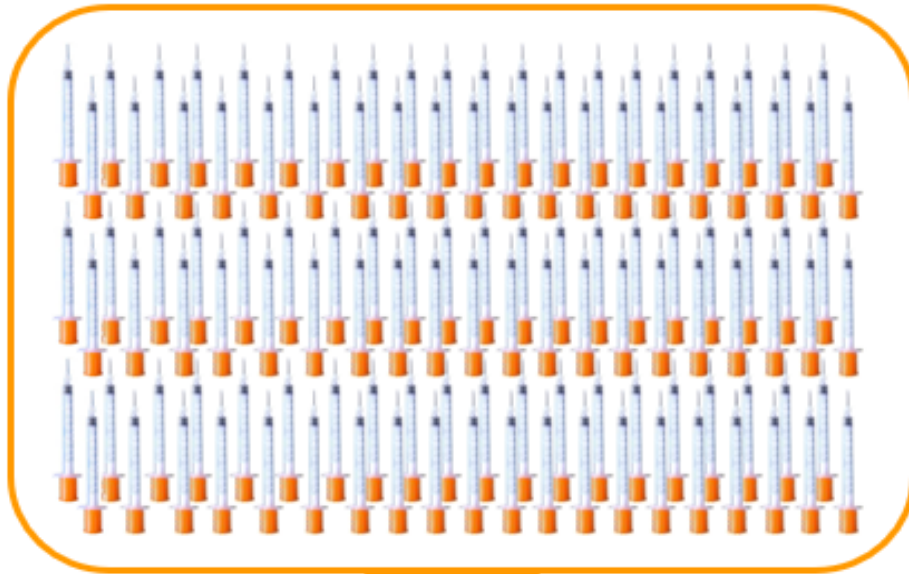


VS.



MDI with Glargine

*Assuming 4 injections per day
120 injections per month*



1,440 injections per year

Insulin Pump Therapy using Veo™

*Assuming set infusion change
every 2-3 days*



10 x less injections

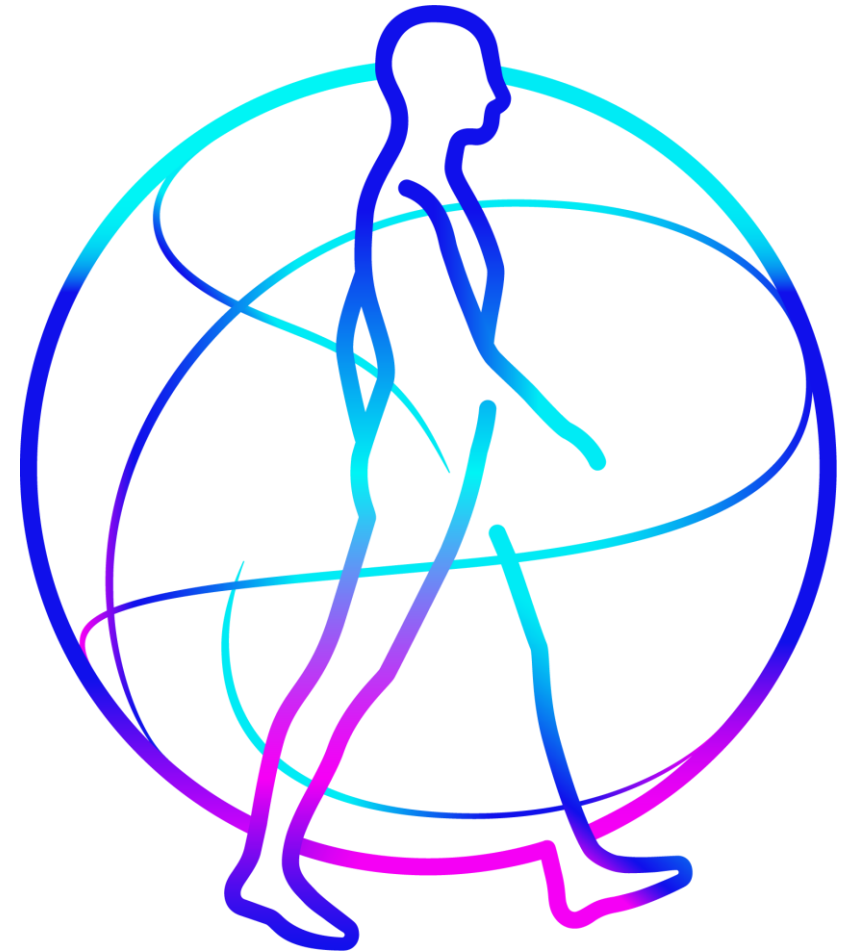
144 site changes per year

MDI = Multiple Daily Injection

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WHAT IS INSULIN PUMP THERAPY?

An insulin pump is a small device that mimics some of the ways a healthy pancreas works.

It delivers continuous and customized doses of rapid-acting insulin 24 hours a day to match your body's needs.

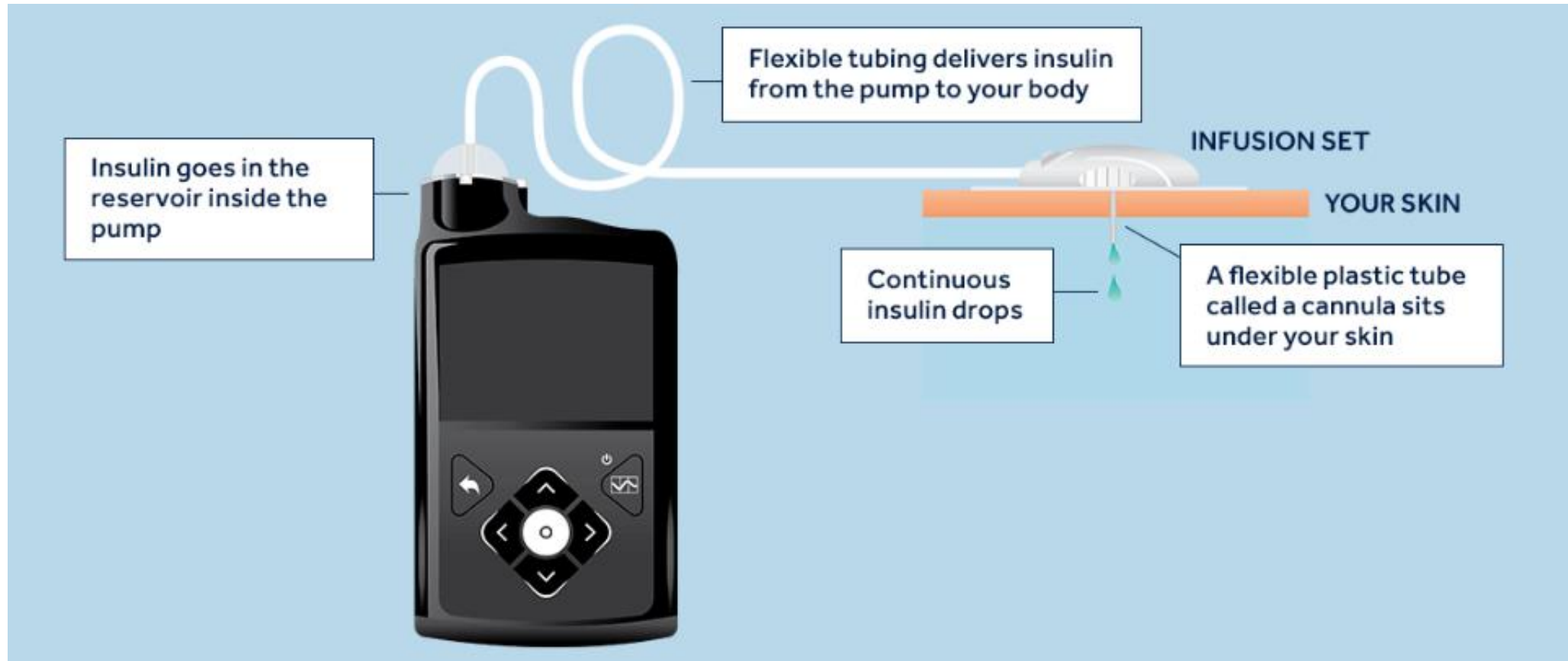
In addition, there is an automatic adjustments and corrections that help diabetes patients gain more control with less effort.

Advanced Hybrid Closed-Loop system (AHCL) insulin pump system has been continuously estimating insulin needs, adjusting insulin delivery and automatically correcting high values, while also helping to protect the diabetic patient from low levels.



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HOW DOES AN INSULIN PUMP WORK?



COMPONENTS OF INSULIN PUMP TECHNOLOGY

1. Insulin Pump

An [insulin pump](#) is a small, durable electronic device used to program your insulin and display how you are tracking. The device also includes a reservoir compartment.

2. Infusion Set

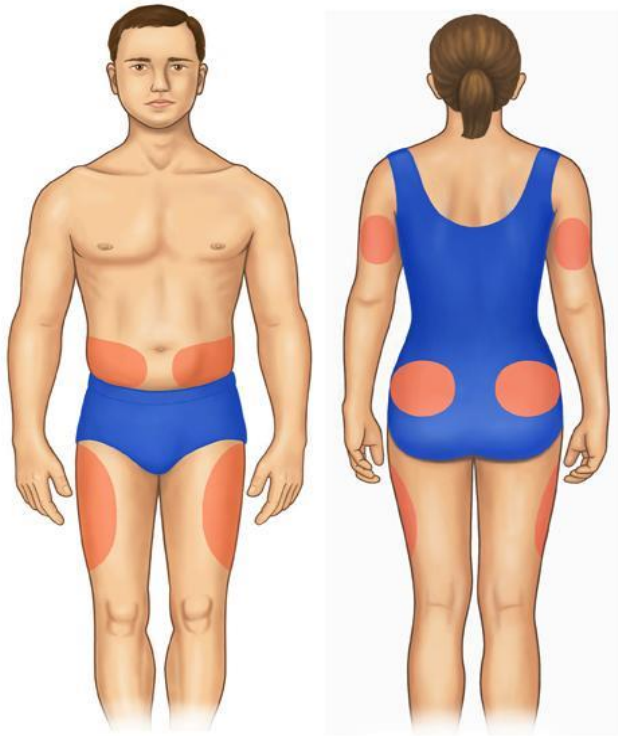
An [infusion set](#) includes a thin cannula that goes from the reservoir to the infusion site on your body. The cannula is inserted into the site, similar to where you would give insulin injections. The infusion set should be changed every two to three days.

3. Reservoir

A [reservoir](#) is a plastic cartridge that holds the insulin and is locked into the insulin pump. A reservoir can hold up to 300 units of insulin and should be changed every two to three days.



INFUSION SET SITE



Adults

Kids

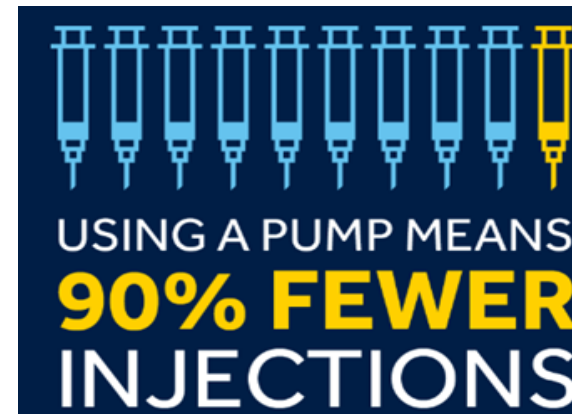


Pregnant

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WHAT ARE THE BENEFITS INSULIN PUMP THERAPY?

- Helps manage overnight and early morning blood sugar variation
- Decreased severity and frequency of hypoglycemia
- Increased flexibility, normalization of lifestyle and sense of well-being
- Precise insulin delivery in smaller amounts (0.025 units minimum)
- More options for exercise management
- Fewer injections
- Handle sick days



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Benefits of Insulin Pump Therapy

- **Improved Control**

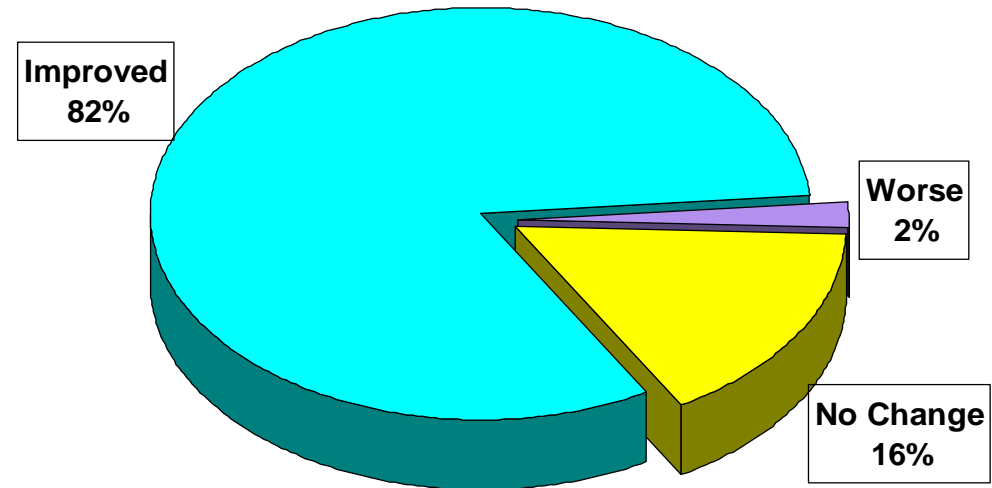
↓ HbA1c

↓ Hypoglycemia

- **Improved Quality of Life**

- **Decreased Cost of Care**

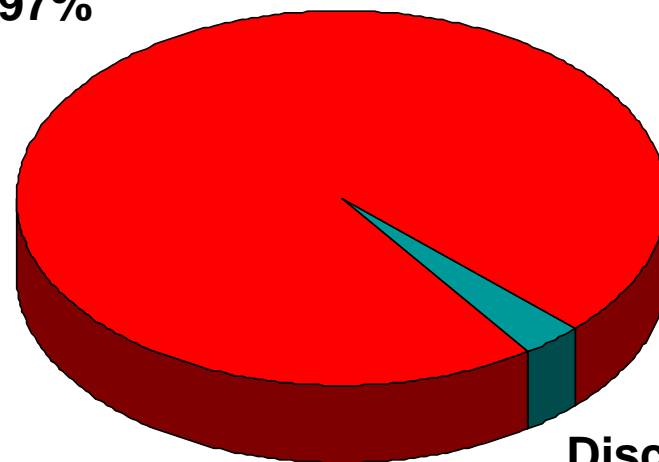
Improved Health Status with Insulin Pump Therapy



N=886
Self-Reported Data

Current Continuation Rate Continuous Subcutaneous Insulin Infusion (CSII)

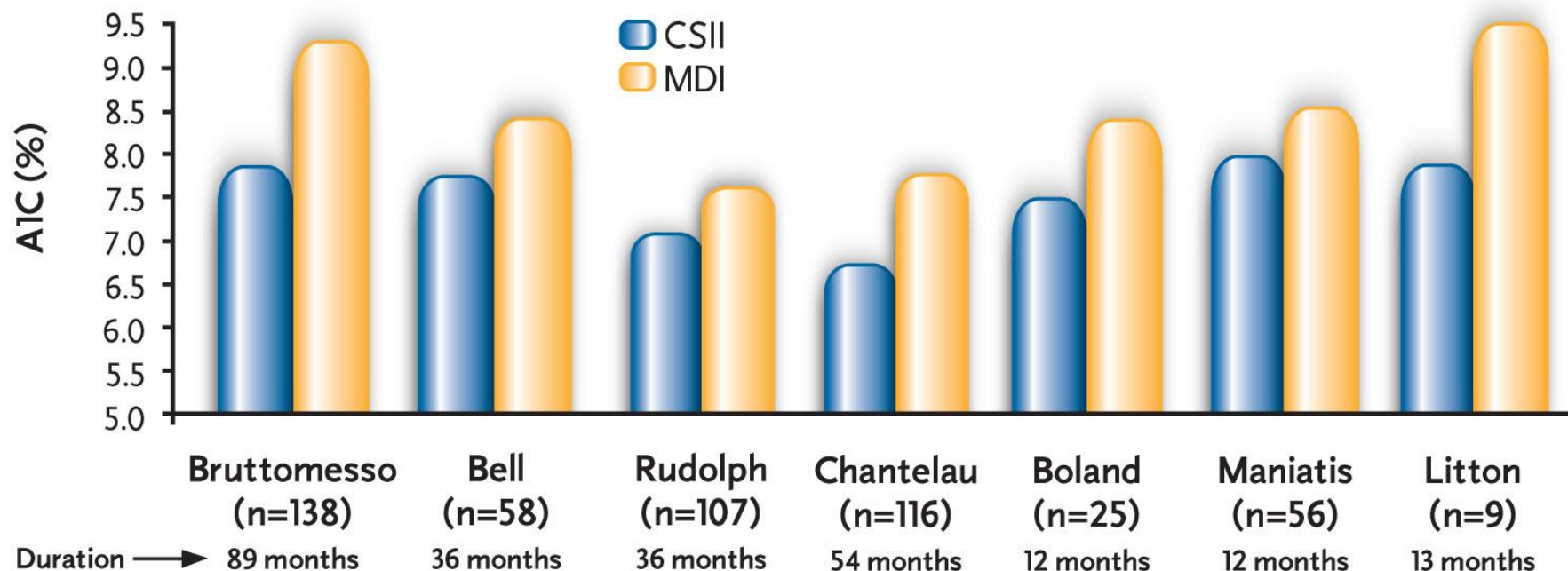
Continued
97%



Discontinued
3%

N = 165
Average Duration = 3.6 years
Average Discontinuation <1%/yr

CSII Improves A1C Compared with MDI

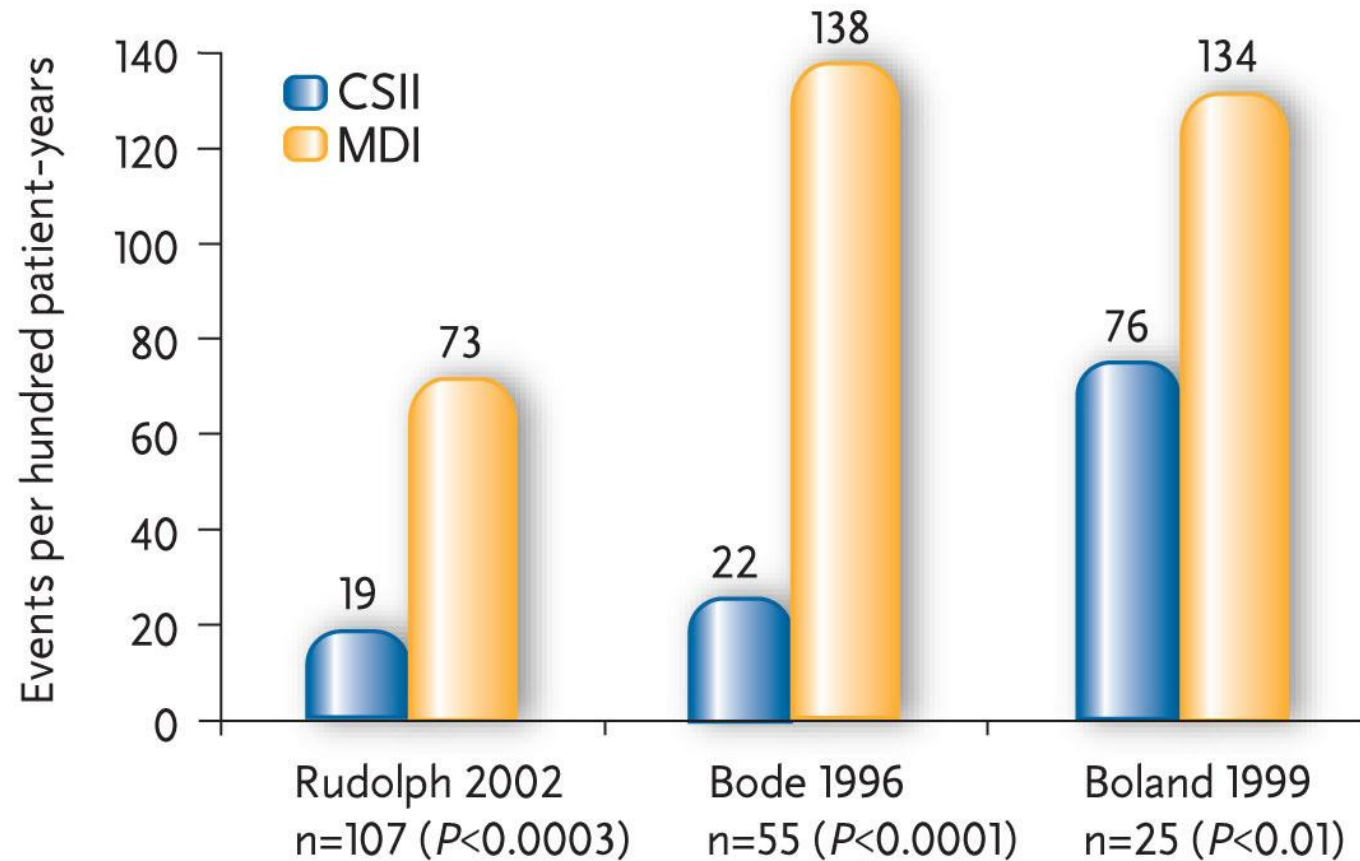


A meta-analysis of 52 studies (1, 547 patients) shows that CSII is significantly more effective in lowering A1C compared to MDI and conventional insulin therapy (MD 0.95)

Bruttomesso D, et al. *Diabet Med*. 2002;19(8):628-634. Bell DSH, et al. *Endocr Pract*. 2000;6(5):357-360. Rudolph DS, et al. *Endocr Pract*. 2002;8(6):401-405. Chantelau E, et al. *Diabetologia*. 1989;32(7):421-426. Boland EA, et al. *Diabetes Care*. 1999;22(11):1779-1784. Maniatis AK, et al. *Pediatrics*. 2001;107(2):351-356. Litton J, et al. *J Pediatr*. 2002;141(4):490-495. Weissberg—Benchell J et al. *Diabetes Care*. 2003

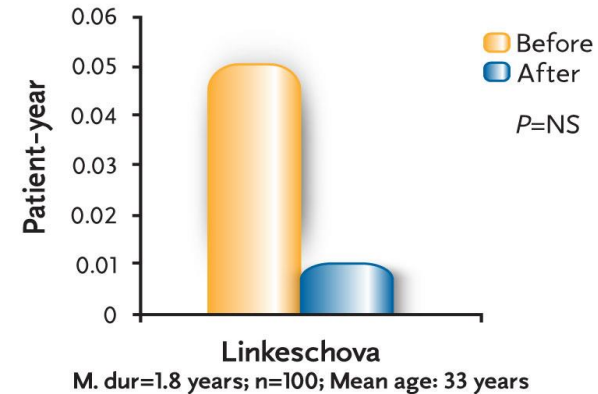
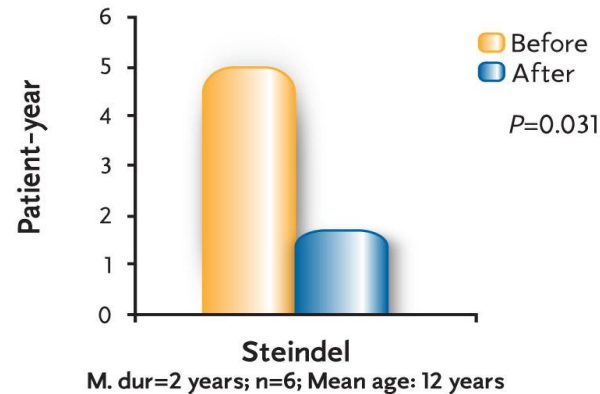
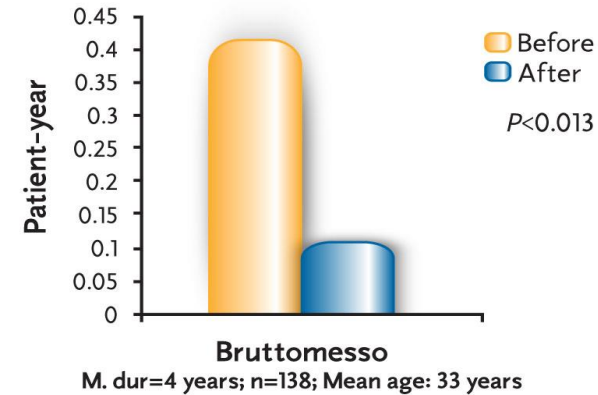
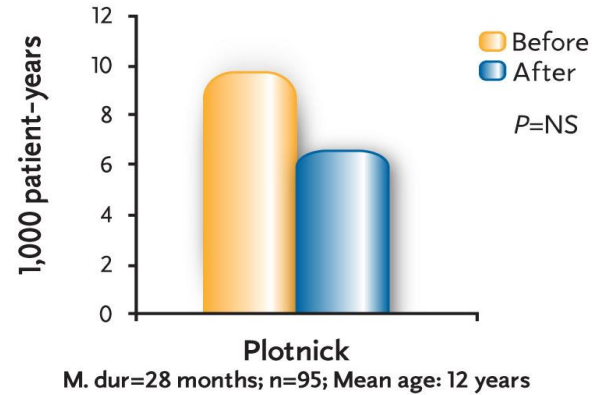
CSII Reduces Incidents of Severe Hypoglycemia

Severe hypoglycemic episodes: CSII vs MDI



Rudolph JW, Hirsch IB. *Endocrine Practice*. 2002; 8:401 – 405.
Bode,BW, Steed RD, Davidson PC. *Diabetes Care*. 1996;19:324-7;
Boland EA, Grey M, Oesterle A, et al. *Diabetes Care*. 1999; 22:1779 – 84;

CSII Use Does Not Increase Risk of DKA



–DeVries JH et al; *Diabetes Care* 2002; 25 (11):2073-2079 M. Dur = 32 weeks, n = 79, Mean Age = 36.5

- No change compared to MDI: 1 episode during study

WHO CAN USE AN INSULIN PUMP?

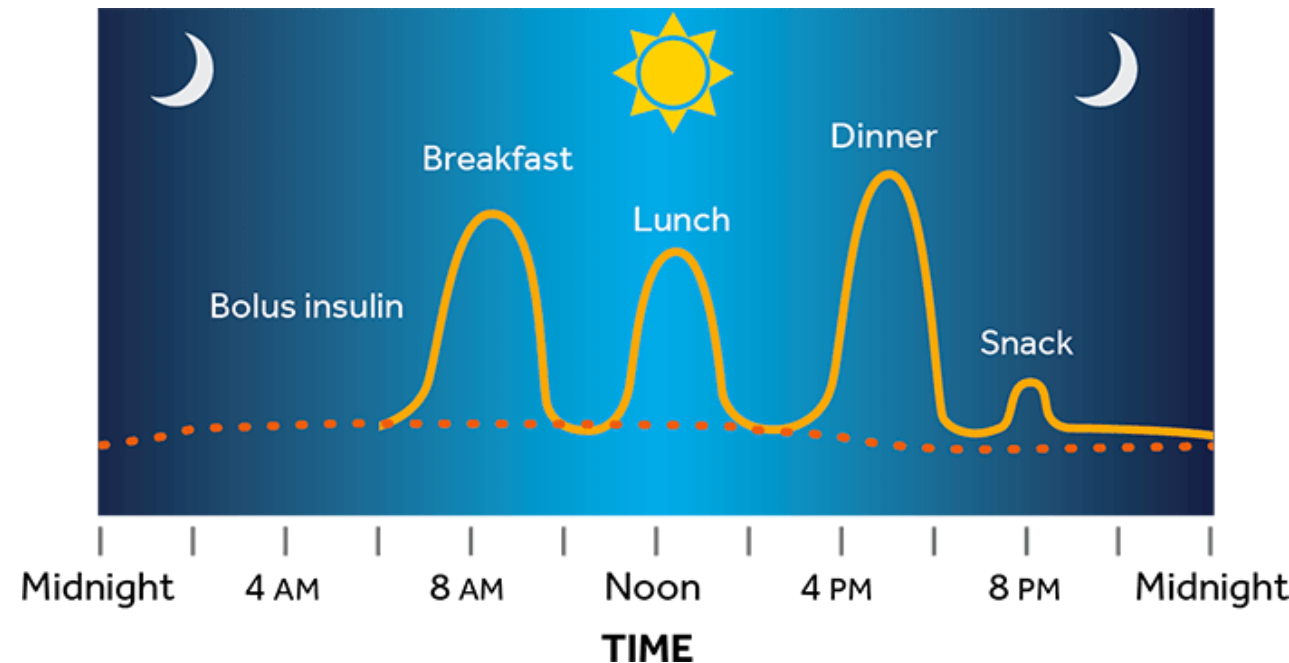
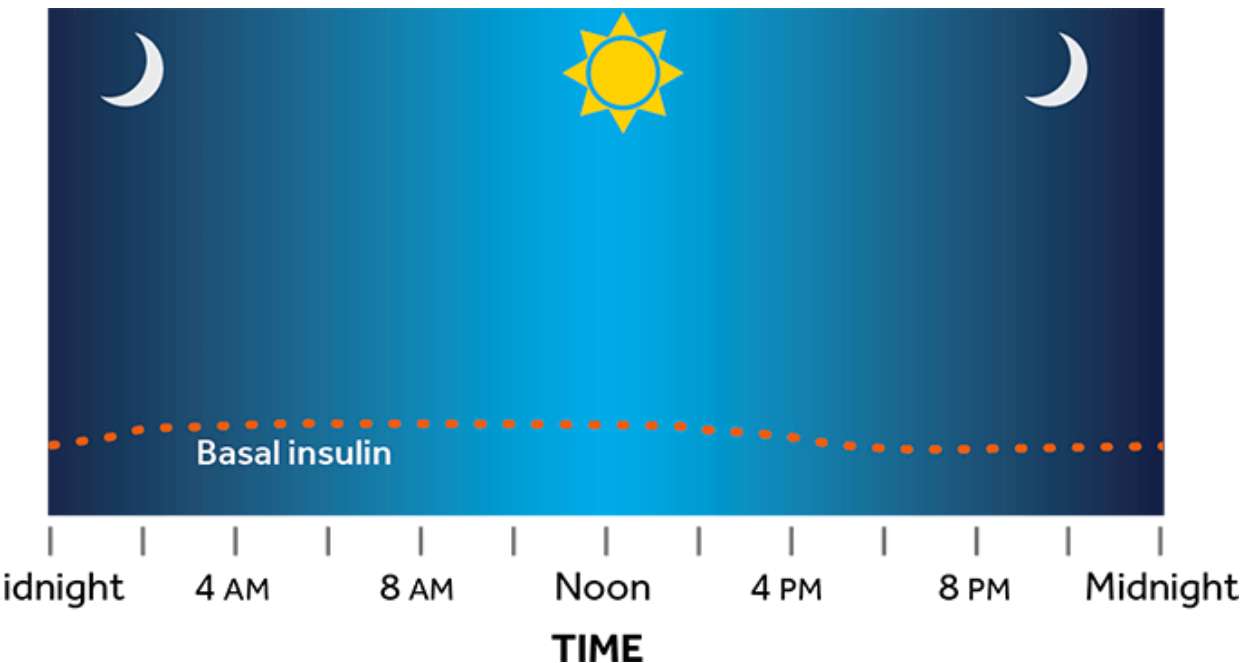


- Have Type 1 or 2 and gestational diabetes
- Take 3 or more insulin injections per day
- Take other medications in addition to insulin to manage your diabetes
- Better management of your diabetes

HOW DOES AN INSULIN PUMP WORK?

Pumps deliver insulin in two ways, basal and bolus: An insulin pump is a small device that mimics some of the ways a healthy pancreas works. It delivers continuous and customized doses of rapid-acting insulin 24 hours a day to match your body's needs. The pump provides insulin to your body in two ways:

- **Basal Insulin** Small amounts of insulin released continuously throughout the day
- **Bolus Insulin** Additional insulin can be delivered on demand to match food intake or to correct high blood sugar.



Pump Therapy Basics

Basal Rate

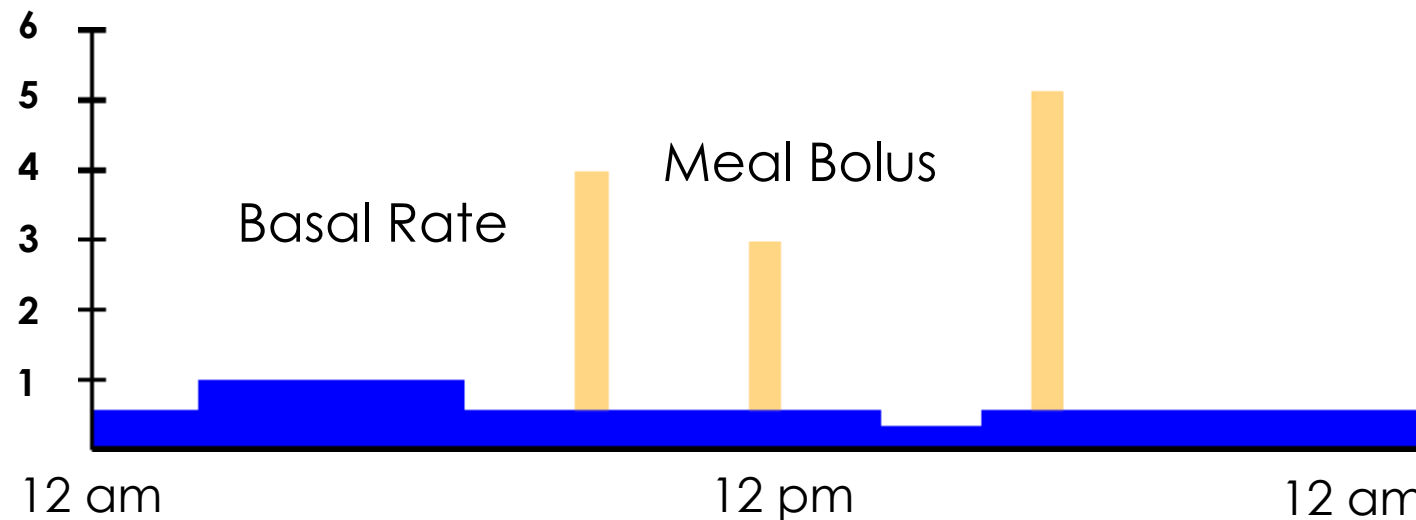
- Preprogrammed
- Continuous subcutaneous flow of fast-acting insulin
- Matching variable metabolic needs

Meal Bolus

- Matching insulin to carbohydrates in meal

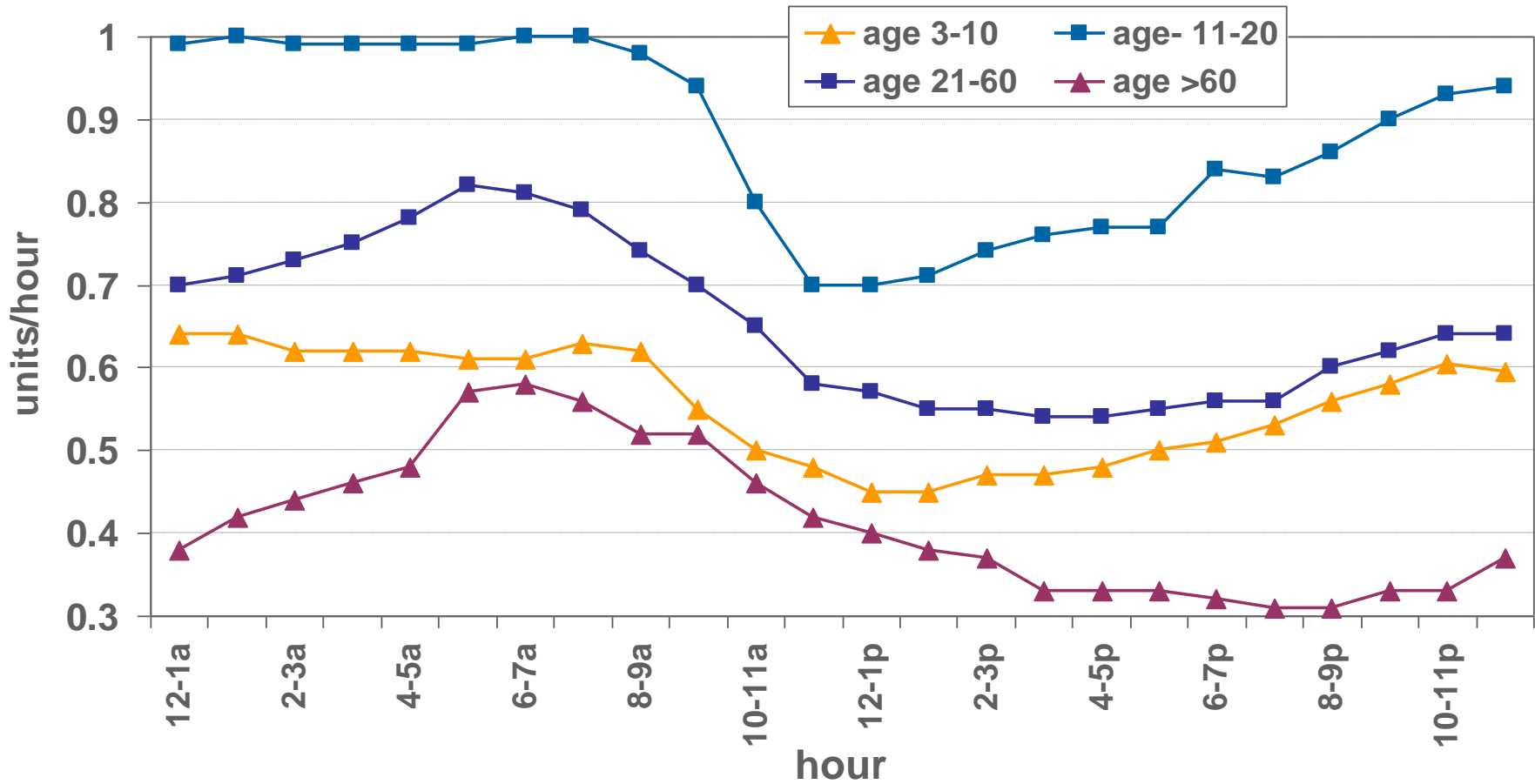
Correction bolus

- For high BG



Basal Insulin Needs Vary Throughout the Day

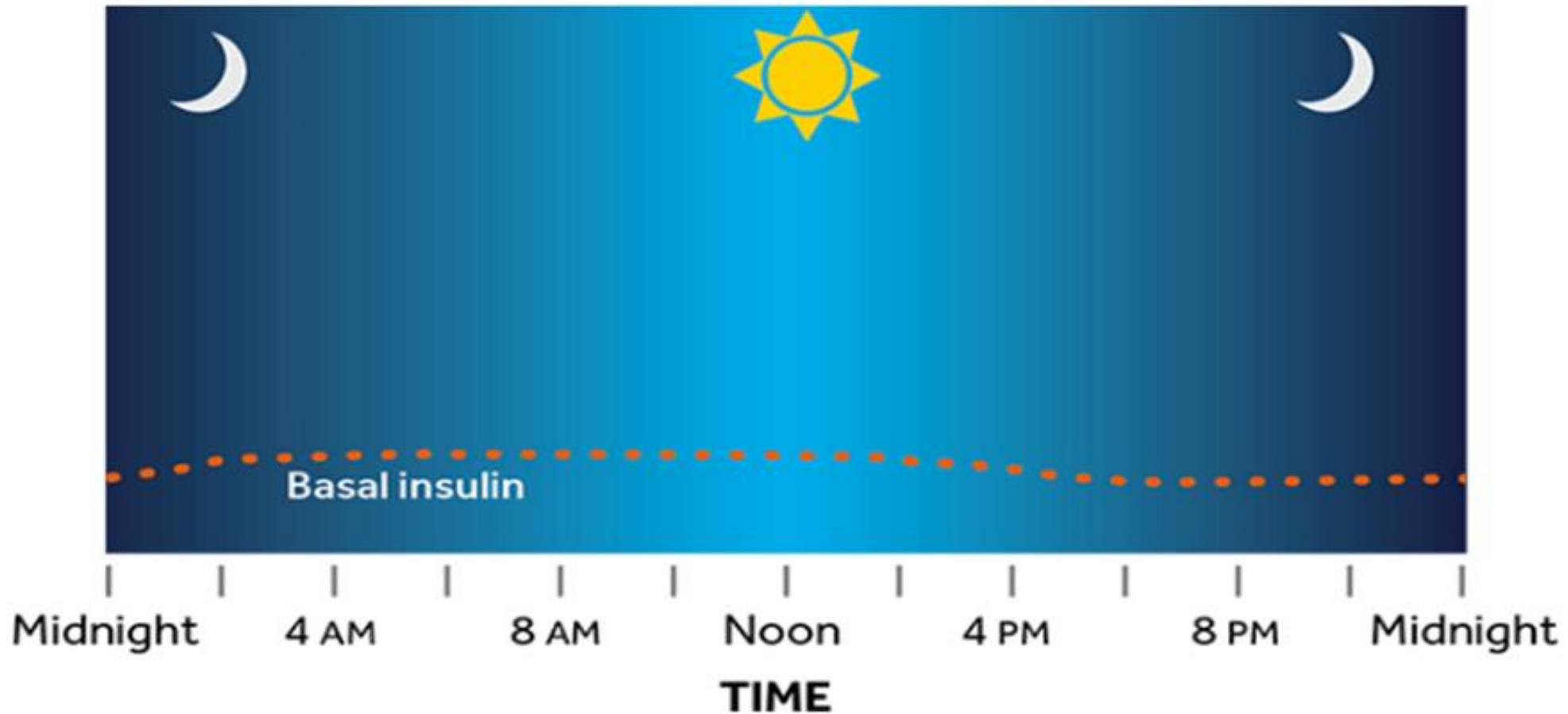
Results indicate it is not reasonable to expect basal insulin needs to be met by a flat rate of insulin delivery for 24 hours.



n=322

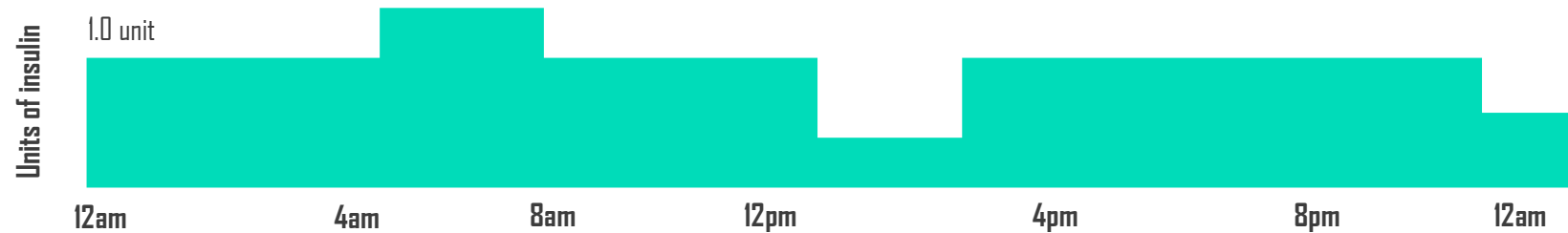
BACKGROUND (BASAL) INSULIN

- ✓ Small amounts of insulin released continuously throughout the day.
- ✓ Keeps blood sugar in target between meals
- ✓ Pump can be programmed with different rates within 24 hrs
- ✓ Temporary rates can be set for various needs
- ✓ The number of units programmed to automatically deliver each hour



PRECISE AND PREDICTABLE DELIVERY – BASAL INSULIN

- Delivers continuously/automatically
- Adjusted to match patient's hepatic glucose production
 - between meals and during the night (nocturnal)
- Similar to a normal functioning pancreas
 - maintains BG stability



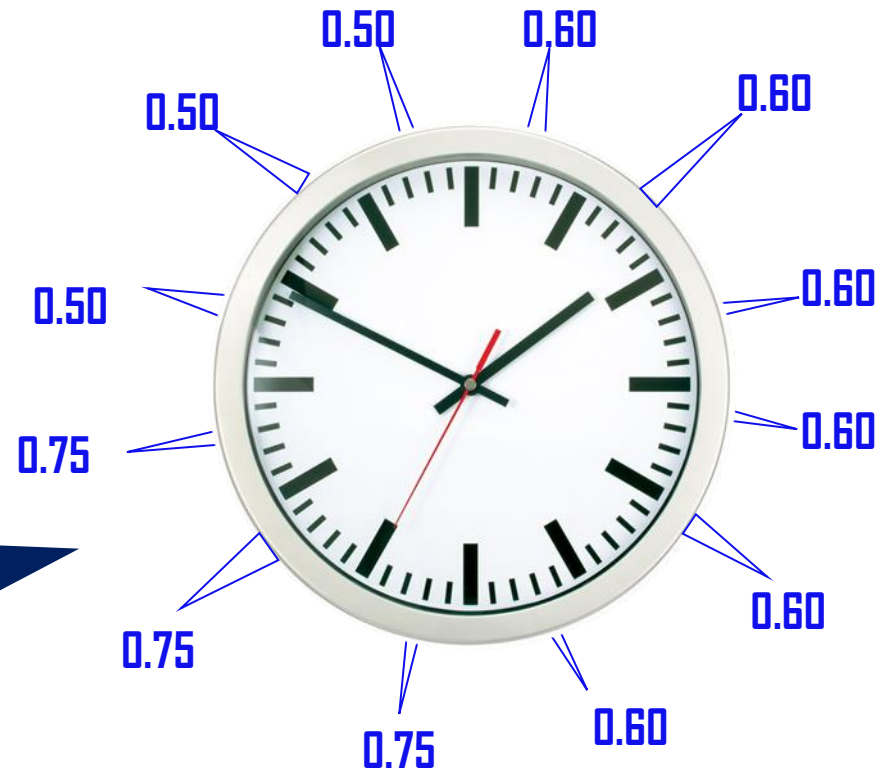
Basal Rate – continuous delivery

Basal Rate

1. 00:00 – 06:00 = 0.60 u/hr
2. 06:00 – 21:00 = 0.75 u/hr
3. 21:00 – 24:00 = 0.50 u/hr

Advantages:

1. Very precise exact delivery.
2. Eliminates large depots.
3. Greatly reduces risk of lows.



Advanced Basal Rate Features on Medtronic Pumps

- Temporary Basal Rates
 - Used to increase or decrease basal insulin during physical activity or during illness
- Basal Rate Patterns
 - The Patterns feature allows customized basal rates to be programmed in order to meet the patient's daily, weekly or monthly needs. This feature is useful in the following circumstances:
 - Changes in sleep times (weekends, shift work)
 - Different schedule during the week vs. weekends
 - High-activity or low-activity days vs. typical day
 - Monthly hormonal shifts

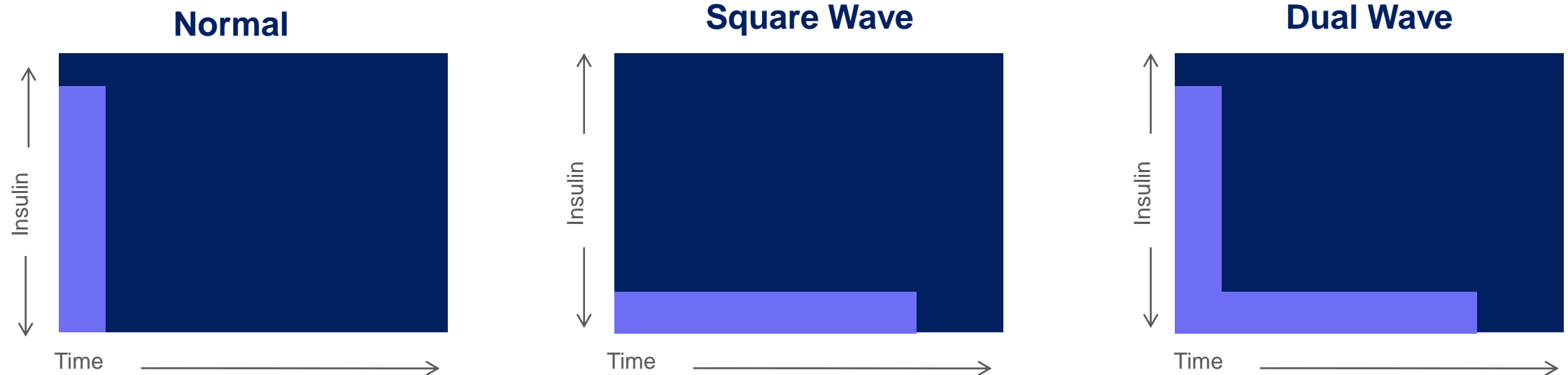
Different Bolus Options

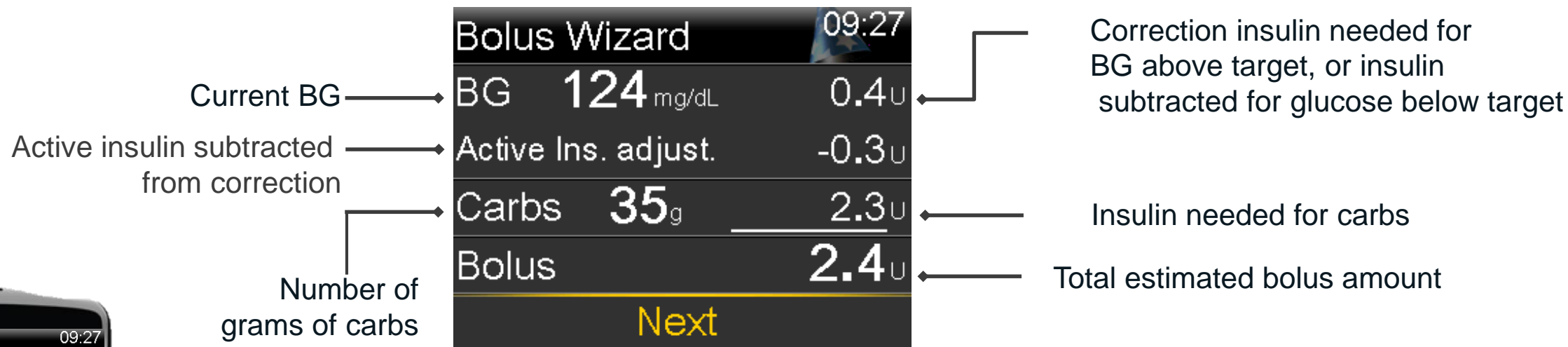
Bolus Insulin is delivered “on-demand,” by the patient, for food intake and/or to correct glucose levels that are above the patient’s target range, delivered separately or together.

Normal Bolus (Rapid Bolus) to cover food intake or to correct a high BG meter reading.

Square Wave Bolus delivers a single bolus evenly over an extended period of time, from 30 minutes to 8 hours.

Dual Wave Bolus (Regular Bolus & Square Wave Bolus) delivers a combination of an immediate Normal bolus followed by a Square Wave bolus.





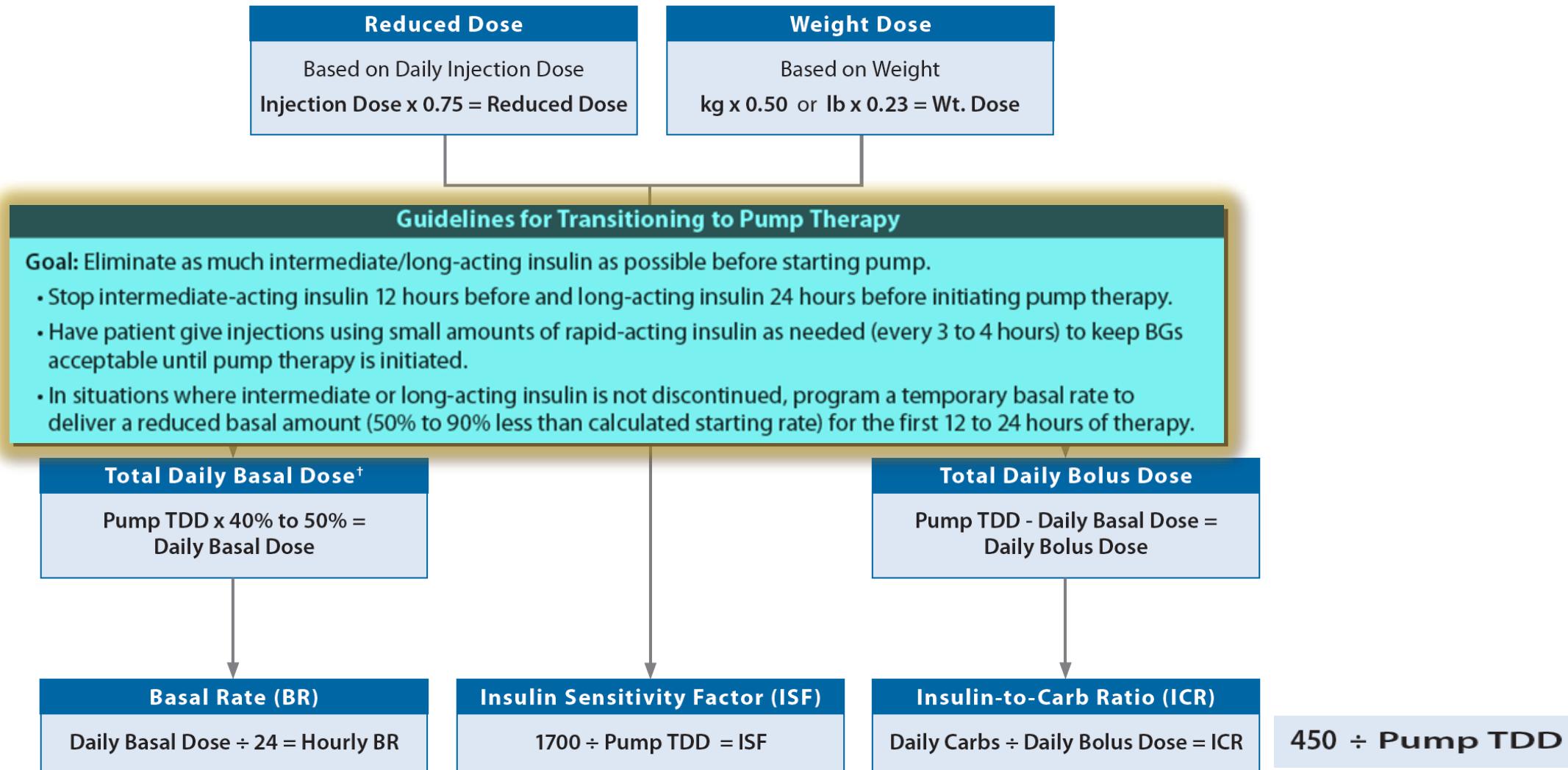
Bolus	09:27
BG	--- mg/dL
Active Insulin	0.3 U
Bolus Wizard	
Manual Bolus	
Insulin Settings	

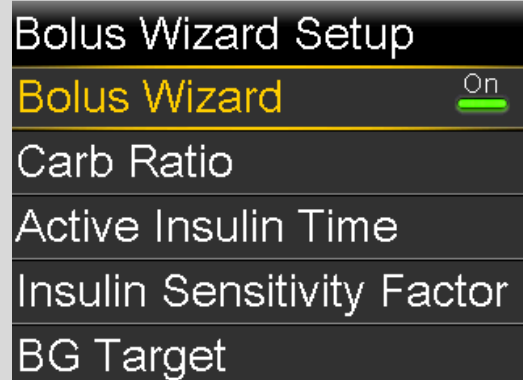
Bolus Wizard	09:27
BG	124 mg/dL
Active Ins. adjust.	-0.3 U
Carbs	35 g
Bolus	2.4 U
Next	

Bolus Wizard	09:27
Bolus	2.4 U
Deliver Bolus	

Guidelines for Initial Pump Settings

Insulin pump therapy uses rapid-acting insulin for both basal and bolus insulin requirements





Bolus Wizard™

On or Off

Carb Ratio

Amount of carbs covered by 1 unit of insulin

Active Insulin Time

Duration of time bolus insulin lowers glucose levels.

Insulin Sensitivity Factor

BG amount reduced by 1 unit of insulin

BG Target

The value blood glucose level will be corrected to

Insulin Settings

Bolus Wizard Setup

Basal Pattern Setup

Preset Temp Setup

Preset Bolus Setup

Dual/Square Wave

Bolus Increment

Max Basal/Bolus

Easy Bolus

Auto Suspend

Bolus Speed

First basal rate start
time always 00:00

Basal rate end time
is changeable



Rate increases by:
0.025 units < 1.00 U/H
0.050 units ≥ 1.00 U/H

WHAT IS Continuous Glucose Monitoring Systems



Technologies for blood glucose monitoring

SMBG

Self-Monitoring Blood Glucose (SMBG)

SMBG methods use finger pricking to obtain a blood sample, which is then analyzed by a BGM.



CGM

Continuous Glucose Monitoring (CGM)

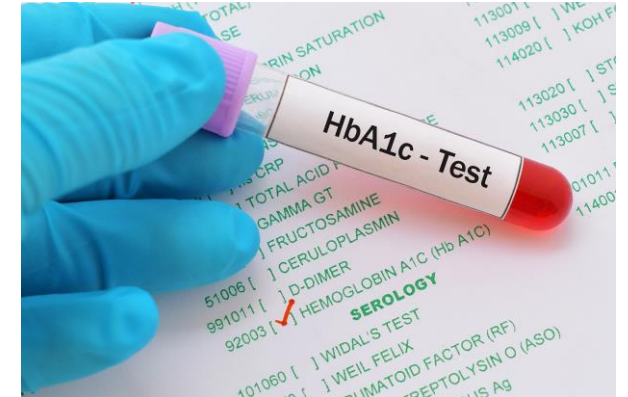
CGM uses a sensor inserted under the skin to take readings from the interstitial fluid (the fluid between blood vessels and cells, IF) rather than from blood.



HbA1c

Glycated haemoglobin

HbA1c is a blood test that is used to diagnose type 2 diabetes. It is also used to monitor blood glucose control in people with diabetes.

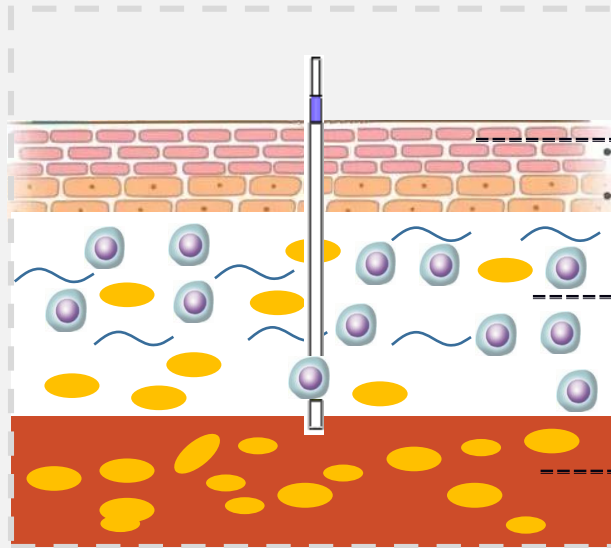


The **detection object** of CGM and BGM

BGM

Blood Glucose Monitoring

Capillary Blood

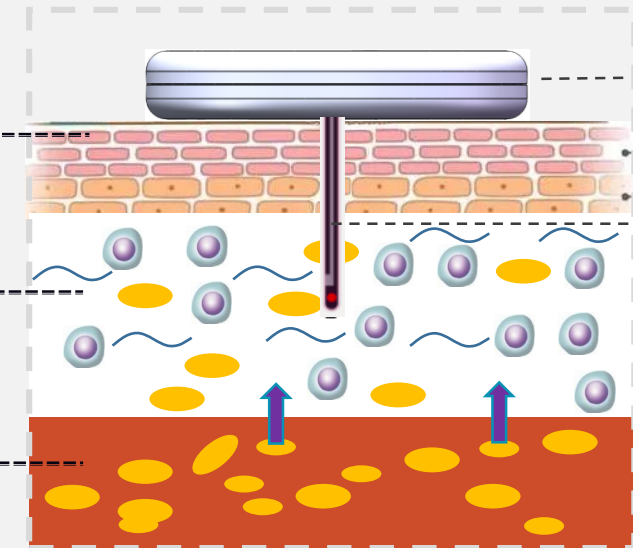


Blood glucose levels are easily **mixed with interstitial fluid** and cells materials when measured

CGM

Continuous Glucose Monitoring

Interstitial Fluid



Transmitter

Sensor

Cell  Glucose 

Skin

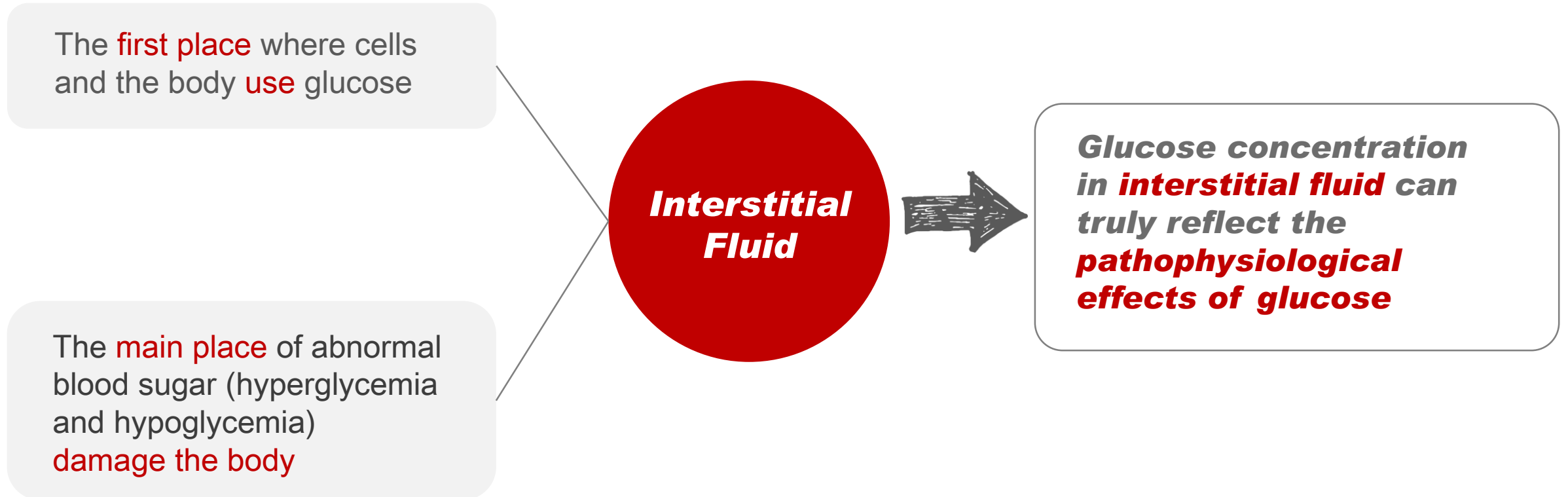
Interstitial fluid

Blood Vessel

Influence factor

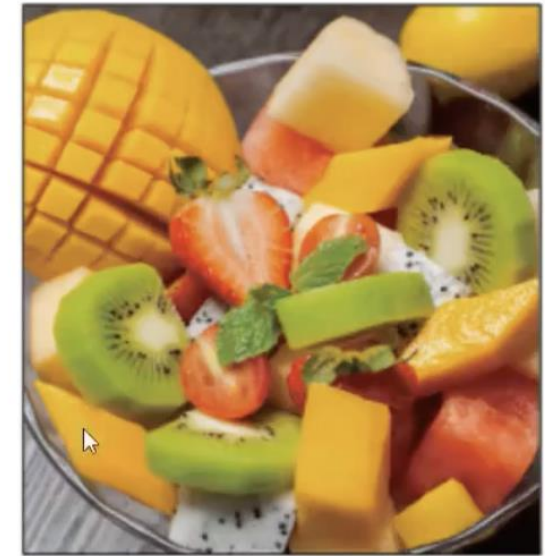
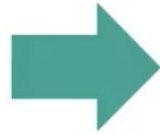
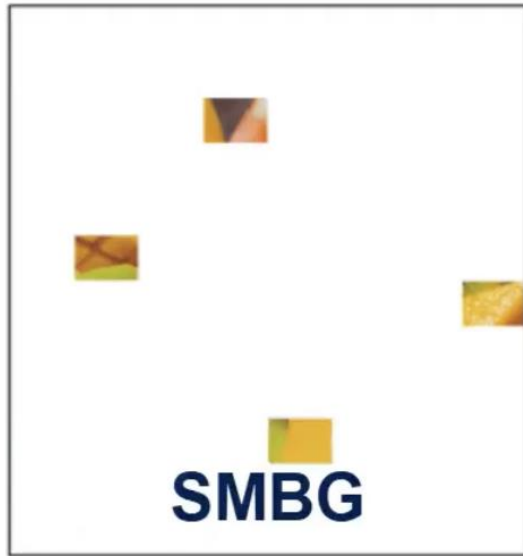
There is a **time delay** of approximately **4-15**[1] minutes in the diffusion of glucose from capillaries to interstitial fluid

The clinical significance of interstitial fluid



Technologies difference

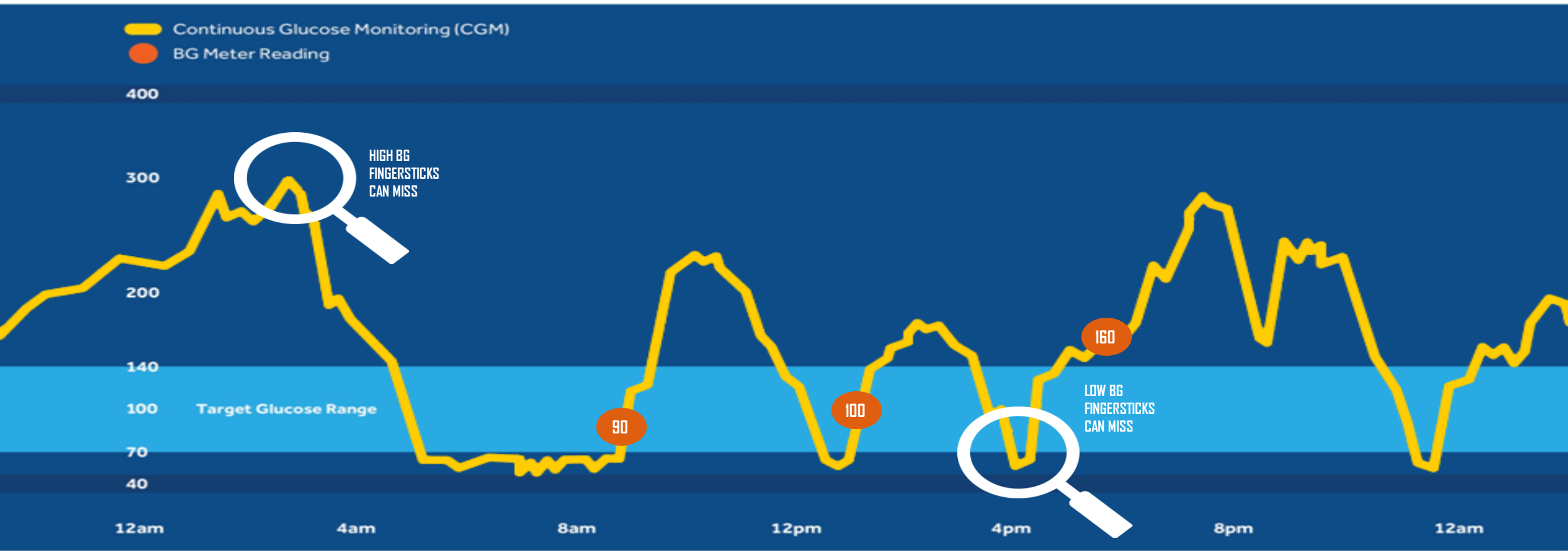
CGM can display blood glucose information **more clearly** and **completely** than BGM and HbA1c



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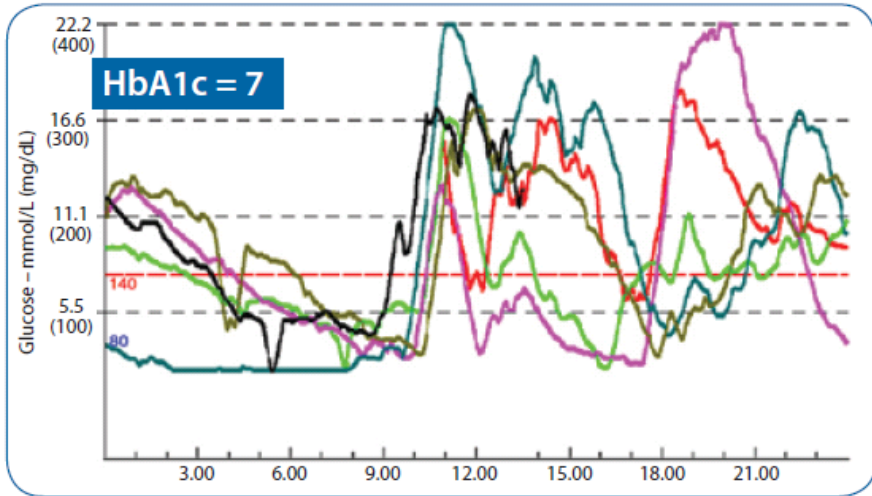
WHAT IS CGM ?

EXAMPLE OF PATIENT WITH HBA1C OF 8%

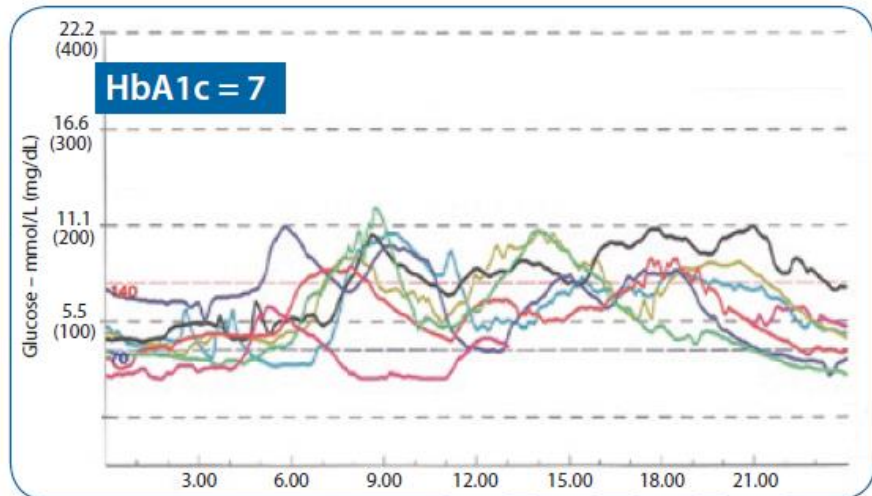


DO HBA1C AND SMBG ALWAYS SHOW THE WHOLE PICTURE?

EVEN PATIENTS WITH ACCEPTABLE HBA1C LEVELS CAN EXPERIENCE GLYCEMIC VARIABILITY^{1,2}



- Give the complete picture by revealing glycaemic excursions that may be missed by HbA1c and finger sticks.
- Understand how behavior and medication affect glucose levels
- Enable effective therapy adjustments



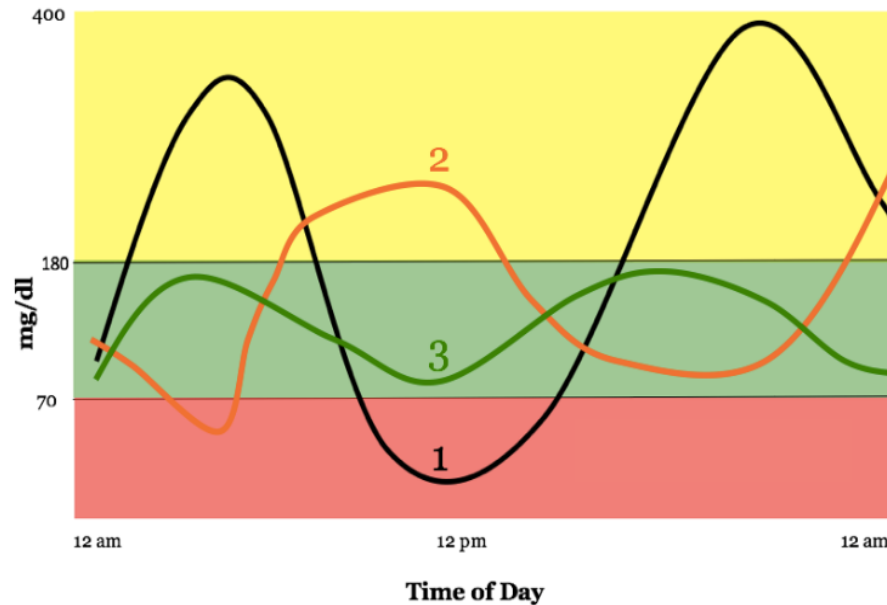
1 Pitzer KR *et al.* Detection of hypoglycemia with the GlucoWatch biographer. Diabetes Care. 2001;24(5):881-885

2 Kaufman FR *et al.* Diabetes Care. 2001;24(12):2030-2034

THE LIMITATIONS OF HBA1C

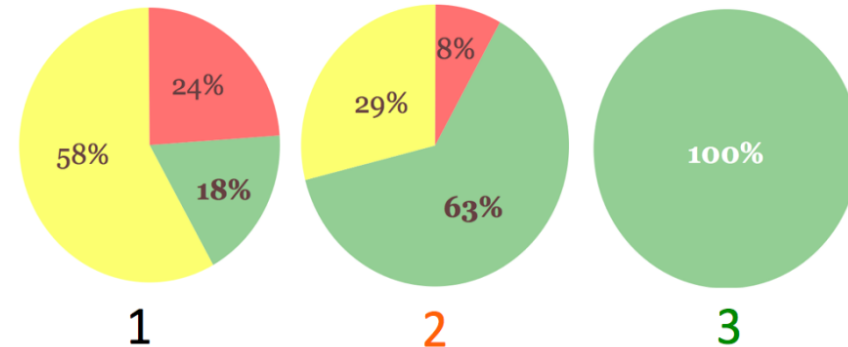
RELATIONSHIP WITH TIME IN RANGE

There are many face of an HBA1C of 7%



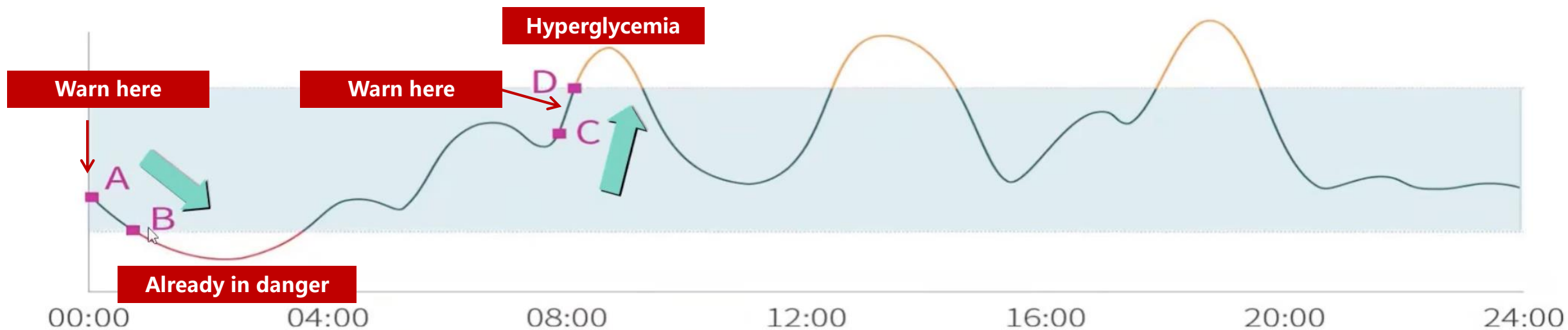
The Many Faces of a 7% A1c

Time spent **HIGH** **IN RANGE** **LOW**



📌 It is early warning, not just warning

Sinocare



📌 What can CGM give to doctors?

Sinocare

Real-time glucose concentration chart

Today

Multiple Days

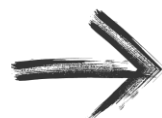
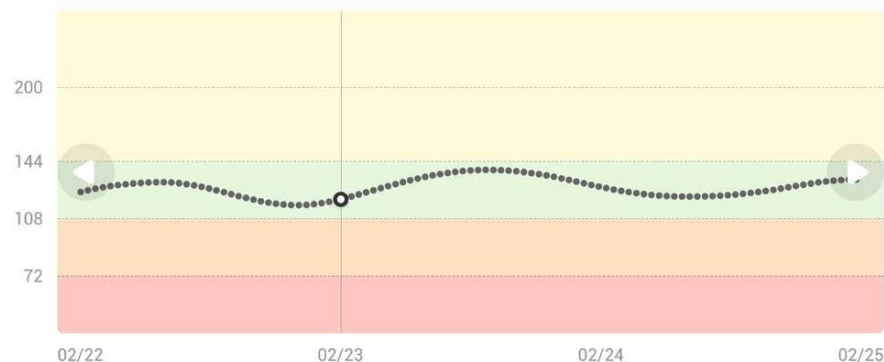
Daily Average

Comparison



110 mg/dL

02/23/2021 6:57 PM



AGP

Ambulatory glucose profile
Report



TIR

Time in range
Parameter

ADA(2021) published standard for CGM

Sinocare

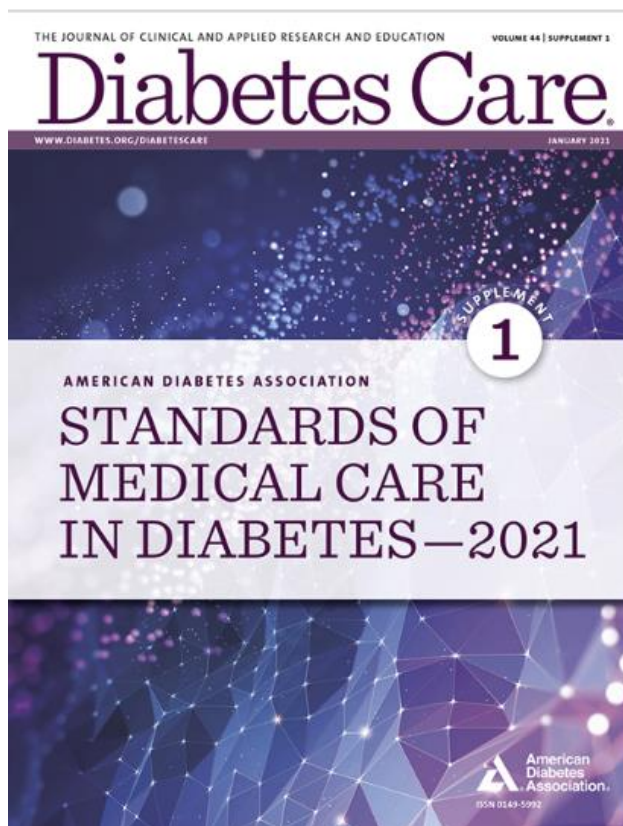


Publications

STANDARDS OF CARE | DECEMBER 04 2020

6. Glycemic Targets: *Standards of Medical Care in Diabetes—2021* **FREE**

American Diabetes Association



Glucose Assessment by Continuous Glucose Monitoring

Recommendations

6.3 Standardized, single-page glucose reports from continuous glucose monitoring (CGM) devices with visual cues, such as the ambulatory glucose profile (AGP), should be considered as a standard printout for all CGM devices. **E** **AGP**

6.4 Time in range (TIR) is associated with the risk of microvascular complications, should be an acceptable end point for clinical trials moving forward, and can be used for assessment of glycemic control. Additionally, time below target (<70 and <54 mg/dL [3.9 and 3.0 mmol/L]) and time above target (>180 mg/dL [10.0 mmol/L]) are useful parameters for reevaluation of the treatment regimen. **C**



Useful tool from CGM-Ambulatory Glucose Profile(AGP)

Sinocare

The AGP report accurately and intuitively reflects

the fluctuations
stability
high blood glucose
low blood glucose

at different time periods.

Note:
Not only reflect the information about the past 14-15 days glucose level, but also estimated the situation of the past 3 months

AGP Report

GLUCOSE STATISTICS AND TARGETS

14 days
% Sensor Time

Glucose Ranges	Targets [% of Readings (Time/Day)]
Target Range 70–180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70–180 mg/dL) is clinically beneficial.

Average Glucose Glucose Management Indicator (GMI) Glucose Variability

Defined as percent coefficient of variation (%CV); target ≤36%

Name

MRN

TIME IN RANGES

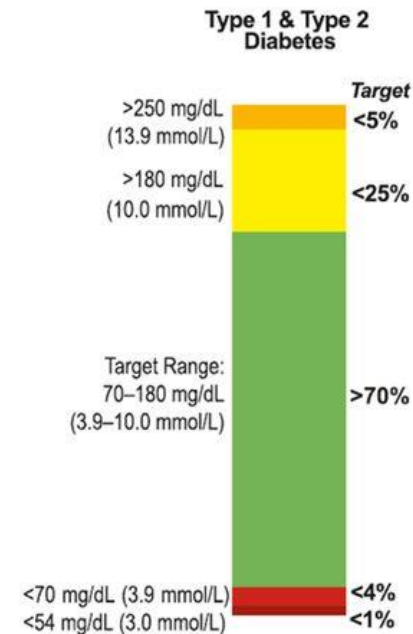


Figure Legend:

Key points included in standard ambulatory glucose profile (AGP) report. Adapted from Battelino et al. (26).

🔴 Useful tool from CGM-AGP report

➤ **GMI**

14-15 days
average glucose level



➤ **Estimated HbA1c**
(eHbA1c)

3-month
average glucose level

Table 6.1—Estimated average glucose (eAG)

A1C (%)	mg/dL*	mmol/L
5	97 (76–120)	5.4 (4.2–6.7)
6	126 (100–152)	7.0 (5.5–8.5)
7	154 (123–185)	8.6 (6.8–10.3)
8	183 (147–217)	10.2 (8.1–12.1)
9	212 (170–249)	11.8 (9.4–13.9)
10	240 (193–282)	13.4 (10.7–15.7)
11	269 (217–314)	14.9 (12.0–17.5)
12	298 (240–347)	16.5 (13.3–19.3)

Data in parentheses are 95% CI. A calculator for converting A1C results into eAG, in either mg/dL or mmol/L, is available at professional.diabetes.org/eAG. *These estimates are based on ADAG data of ~2,700 glucose measurements over 3 months per A1C measurement in 507 adults with type 1, type 2, or no diabetes. The correlation between A1C and average glucose was 0.92 (6,7). Adapted from Nathan et al. (6).

Figure Legend:

Key points included in standard ambulatory glucose profile (AGP) report. Adapted from Battelino et al..

Clinical guidelines are increasingly recommending the use of CGM and related metrics across all diabetes populations

1

ADA Standards of Care in Diabetes¹

"Initiation of CGM should be offered to people with T1D early in the disease, even at time of diagnosis"

"CGM should be considered from the outset of the diagnosis of diabetes that requires insulin management"

2

ADA / EASD consensus reports (T1D² and T2D³)

"CGM is the standard for glucose monitoring for most adults with T1D"

"Consider CGM in people with T2D on insulin"

3

AACE CGM position statement⁴

"CGM is strongly recommended for all persons with diabetes treated with intensive insulin therapy"

"CGM may be recommended for individuals with T2D who are treated with less intensive insulin therapy"

AACE, American Association of Clinical Endocrinology; ADA, American Diabetes Association; EASD, European Association for the Study of Diabetes; T2D, Type 2 diabetes.

1. American Diabetes Association Professional Practice Committee. Diabetes Care 2024;47:S126-44; 2. Holt RIG, et al. Diabetes Care 2021;44:2589-625; 3. Davies MJ, et al. Diabetes Care 2022;45:2752-86; 4. Grunberger G, et al. Endocr Pract 2021;27:505-37.

Authoritative guideline for TIR

Sinocare

Multiple **international guidelines** and **expert consensus** recommend **TIR** (Time in Range) as a **core metric** for blood glucose control in patients with diabetes.

2019
International consensus

2021
Chinese guidelines for blood glucose monitoring

2022
AACE guideline

2022
ADA/EASD expert consensus

2023
ADA guideline





CGM metrics for clinical care

Table 6.2—Standardized CGM metrics for clinical care

1. Number of days CGM device is worn (recommend 14 days)	
2. Percentage of time CGM device is active (recommend 70% of data from 14 days)	
3. Mean glucose	
4. Glucose management indicator	
5. Glycemic variability (%CV) target $\leq 36\%$ *	
6. TAR: % of readings and time >250 mg/dL (>13.9 mmol/L)	Level 2 hyperglycemia
7. TAR: % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	Level 1 hyperglycemia
8. TIR: % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	In range
9. TBR: % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	Level 1 hypoglycemia
10. TBR: % of readings and time <54 mg/dL (<3.0 mmol/L)	Level 2 hypoglycemia

➤ **TIR**

CGM, continuous glucose monitoring; CV, coefficient of variation; TAR, time above range; TBR, time below range; TIR, time in range. *Some studies suggest that lower %CV targets ($<33\%$) provide additional protection against hypoglycemia for those receiving insulin or sulfonylureas. Adapted from Battelino et al. (26).

The role of TIR and HbA1c in diabetes management

TIR

Detailed Glycemic Profile

This metric helps identify patterns of hyperglycemia and hypoglycemia that HbA1c might miss.

Real-time Monitoring

TIR offers real-time insights into glucose levels, enabling immediate adjustments to diet, activity, and insulin dosing.

Improve the quality of Life

TIR is providing immediate feedback and motivation for patients to adhere to their management plans.

HbA1c

Long-term Glycemic Control

It helps in assessing the overall effectiveness of diabetes management strategies over an extended period

Treatment Adjustments

Based on HbA1c levels, healthcare providers can adjust medications, recommend lifestyle changes, and tailor treatment plans to achieve target glycemic control.

Standardized Measurement

A reliable tool for comparing glycemic control across different populations and studies.

Differences vary

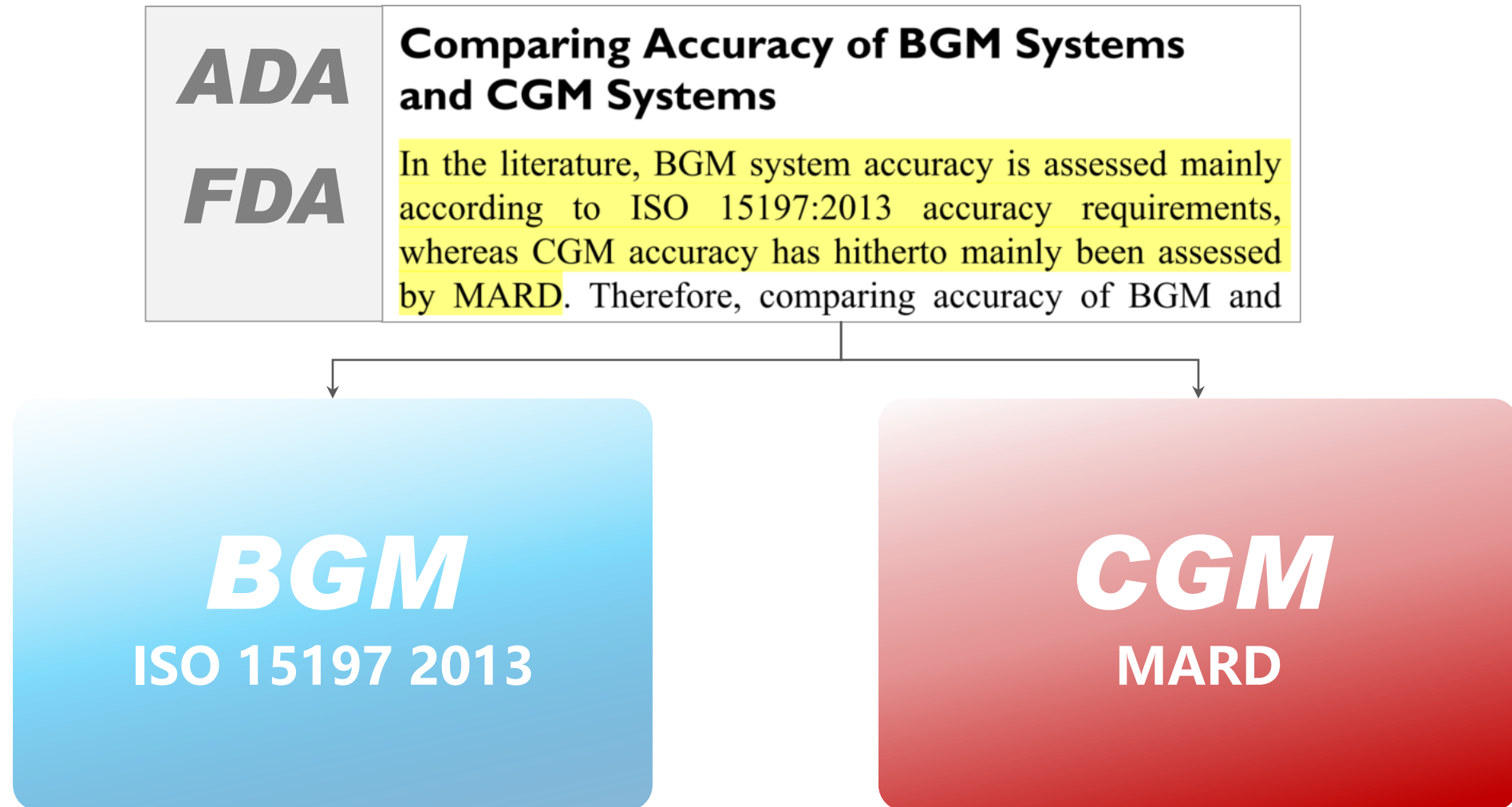
When glucose levels are rising or falling quickly, expect larger differences between BGs and SGs.



Examples:

- after meals or taking a bolus of insulin
- during exercise
- when arrows appear on the pump screen

Accuracy measurement of BGM and CGM



ISO 15197:2013 Standard require tighter BGMS accuracy



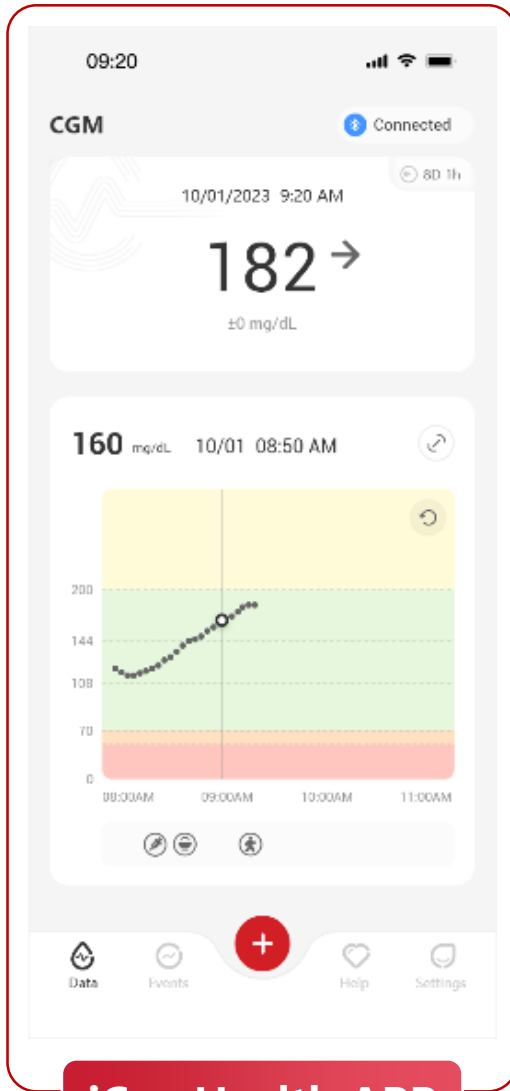
Numerical metric indicator that describes that accuracy of a glucose sensor at a single point in time. Affected by:

- Medication contain acetaminophen or paracetamol
- Severe glucose trend

MARD

Mean Absolute
Relative
Difference

CGM components



iCan Health APP



Sensor Pack



Transmitter Pack



COMPONENTS OF CGM THERAPY with Insulin Pump

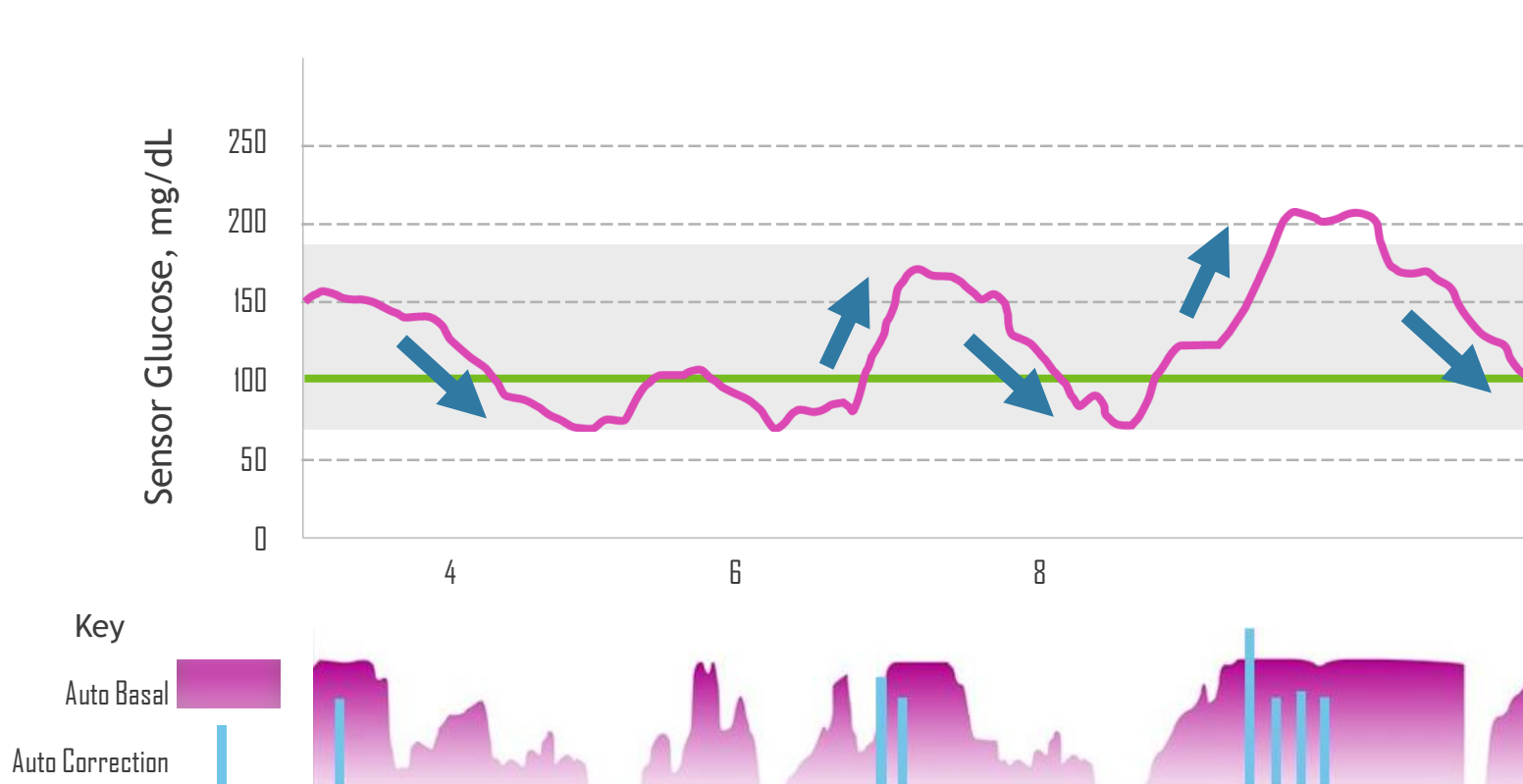


Hybrid closed loop technology

- ❑ Auto Basal Delivery
- ❑ Auto-Correction Bolus Delivery
- ❑ Auto-Change Active Insulin Time

These features work together to reduce the **burden of diabetes management** on the patient by automating insulin delivery adjustments. The system uses an algorithm to integrate the CGM data and insulin pump, making real-time decisions to keep blood glucose in a healthy range.

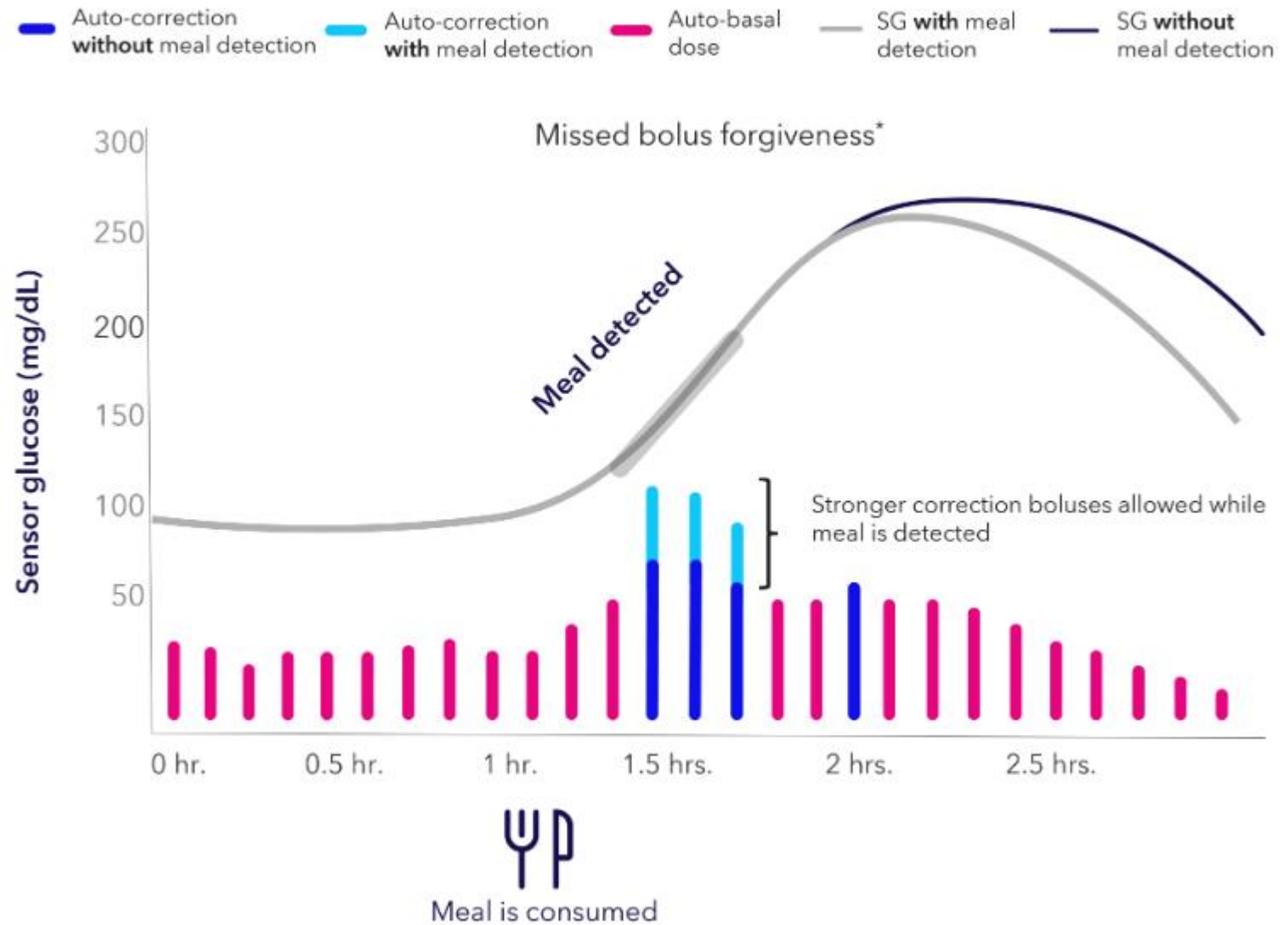
MiniMed™ 780G system with Guardian™ 4 sensor **how it works**



- Selection between the default setting of 100 mg/dL, and 110 mg/dL or 120 mg/dL
- Basal insulin adjusts every 5 mins based on SG values
- The auto correction target is set at 120 mg/dL
- Auto corrections delivered every 5 minutes if max basal reached and SG is above 120 mg/dL, as determined by the algorithm. No automatic corrections if Temp Target is set.

MiniMed™ 780G system with Guardian™ 4 sensor

If the system detects a meal based on the sensor glucose rising rate of change, it can automatically deliver stronger correction doses while sensor glucose values are rising, up to every 5 minutes.

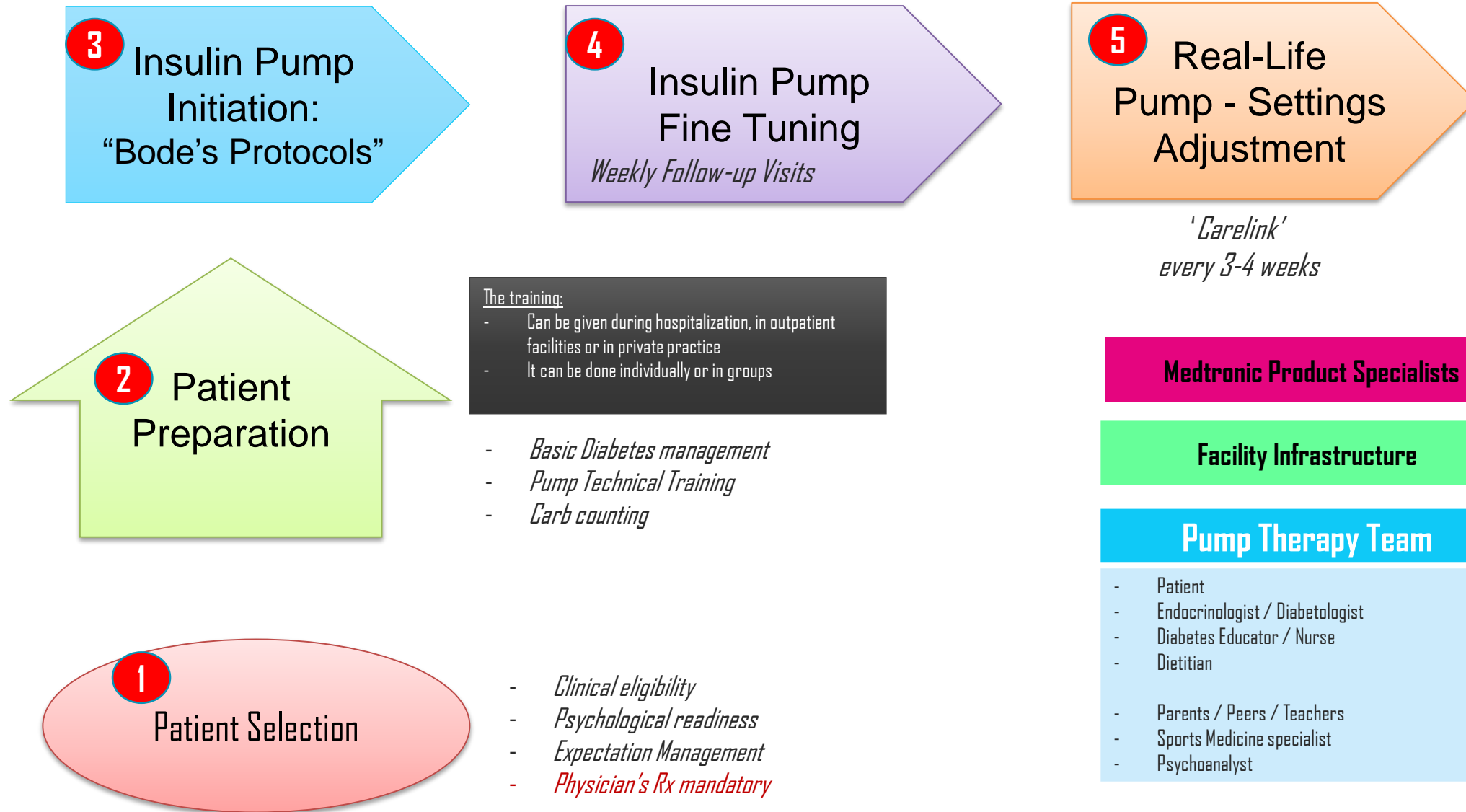


SmartGuard™ feature Settings

Set by Clinician or Algorithm

Setting	Clinician	Algorithm
Auto Basal		✓
Carb Ratio	✓	
Insulin Sensitivity Factor		✓
Active Insulin Time	✓	
Auto Basal Targets	✓	
Auto correction		✓

The Journey of the patient on Insulin Pump Therapy



Medtronic Product Specialists

Facility Infrastructure

Pump Therapy Team

- Patient
- Endocrinologist / Diabetologist
- Diabetes Educator / Nurse
- Dietitian
- Parents / Peers / Teachers
- Sports Medicine specialist
- Psychoanalyst

Medtronic

QUESTIONS?
THANK YOU