Understanding CGM & Flash

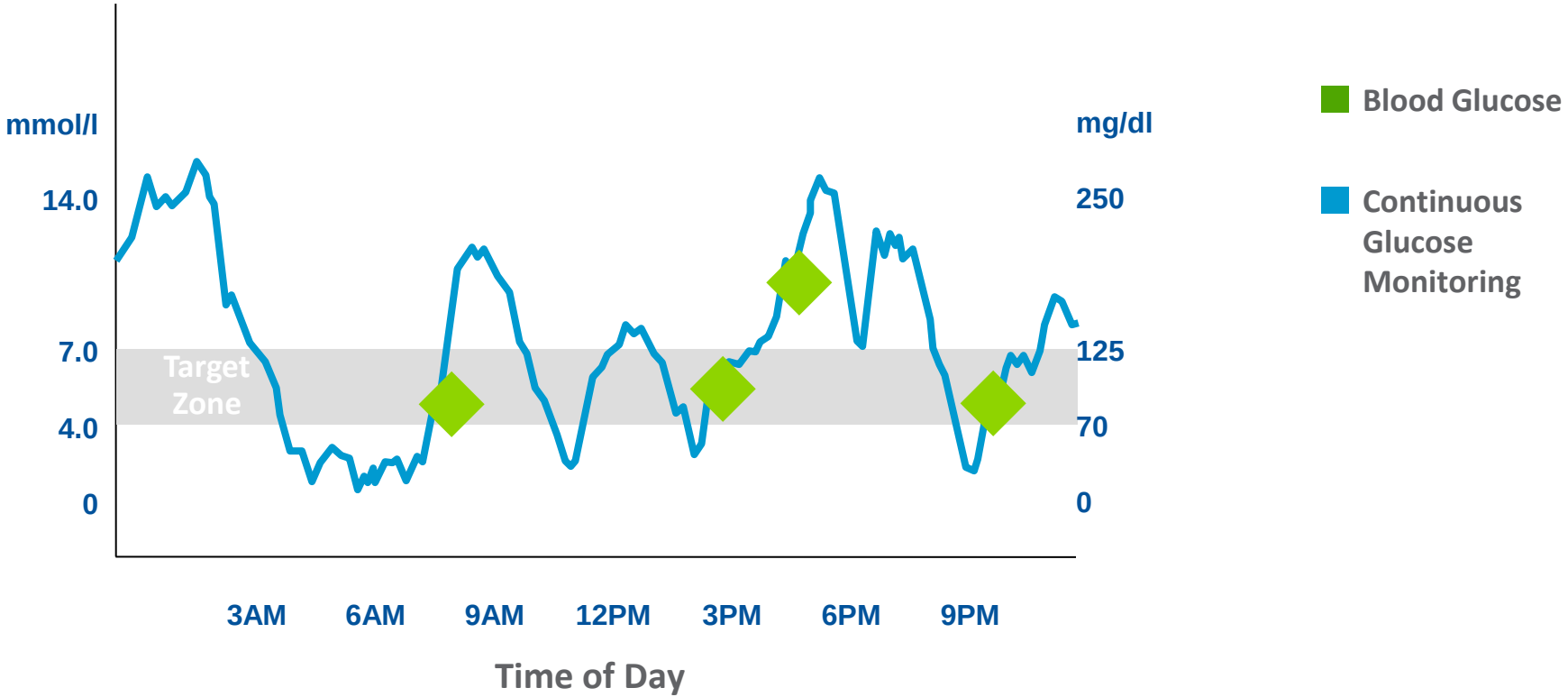
What’s here and what is coming?

John Pemberton
Diabetes Specialist Dietitian
Birmingham Women's and Childrens Hospital

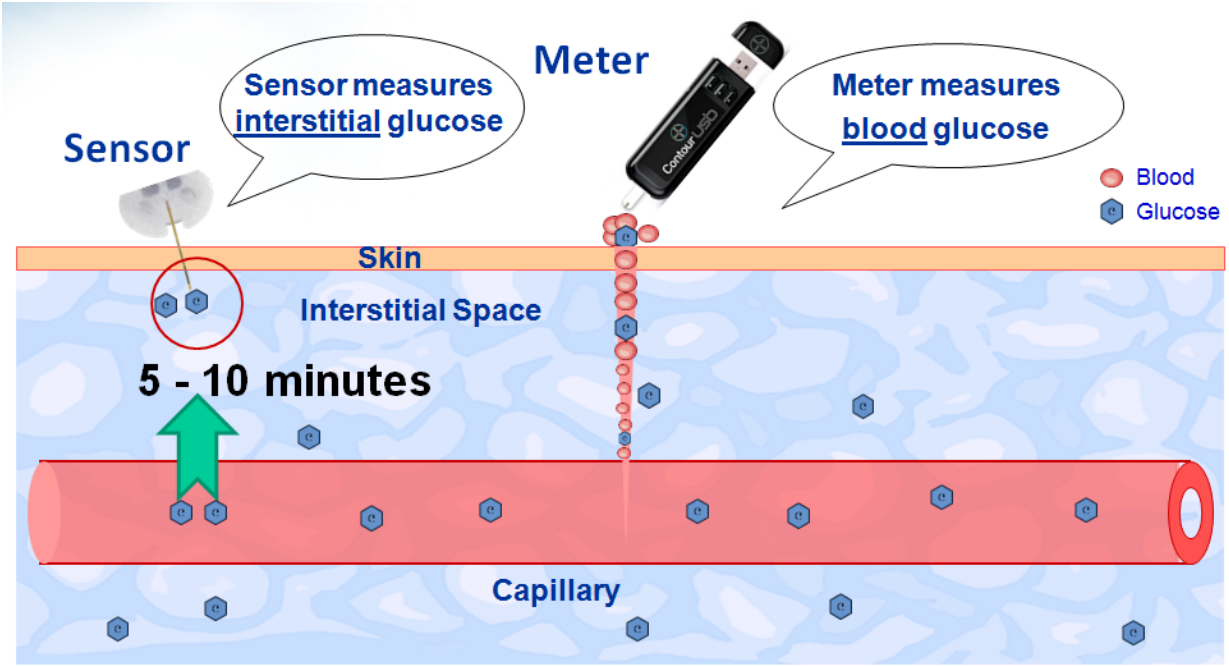
In 30 minutes time you should be able to

- Know what accuracy standards to hold CGM products to, and what questions to ask the companies!
- Explain to patients the benefits of each system.
- Give practical advice that helps your patients be successful with Flash GM / CGM.

What is the difference between blood glucose and CGM?



What is the difference between finger prick and CGM?



Electrical signals generated from the oxidation of glucose are recorded by the sensor, the signals are “calibrated” with meter readings to calculate CGM values

Evidence: ACDC Consensus Guideline 2017

http://www.a-c-d-c.org/

- If used >70% of the time:
  - Improved Hba1c 0.5 – 2.0% (6 – 24mmol/mol)
  - Alarmed CGM = Reduction in hypoglycaemia 20—40%
  - Improved quality of life
  - The more you use proactively the greater the benefit
    - Corrections between meals, temp basals,
    - Preventing hypos

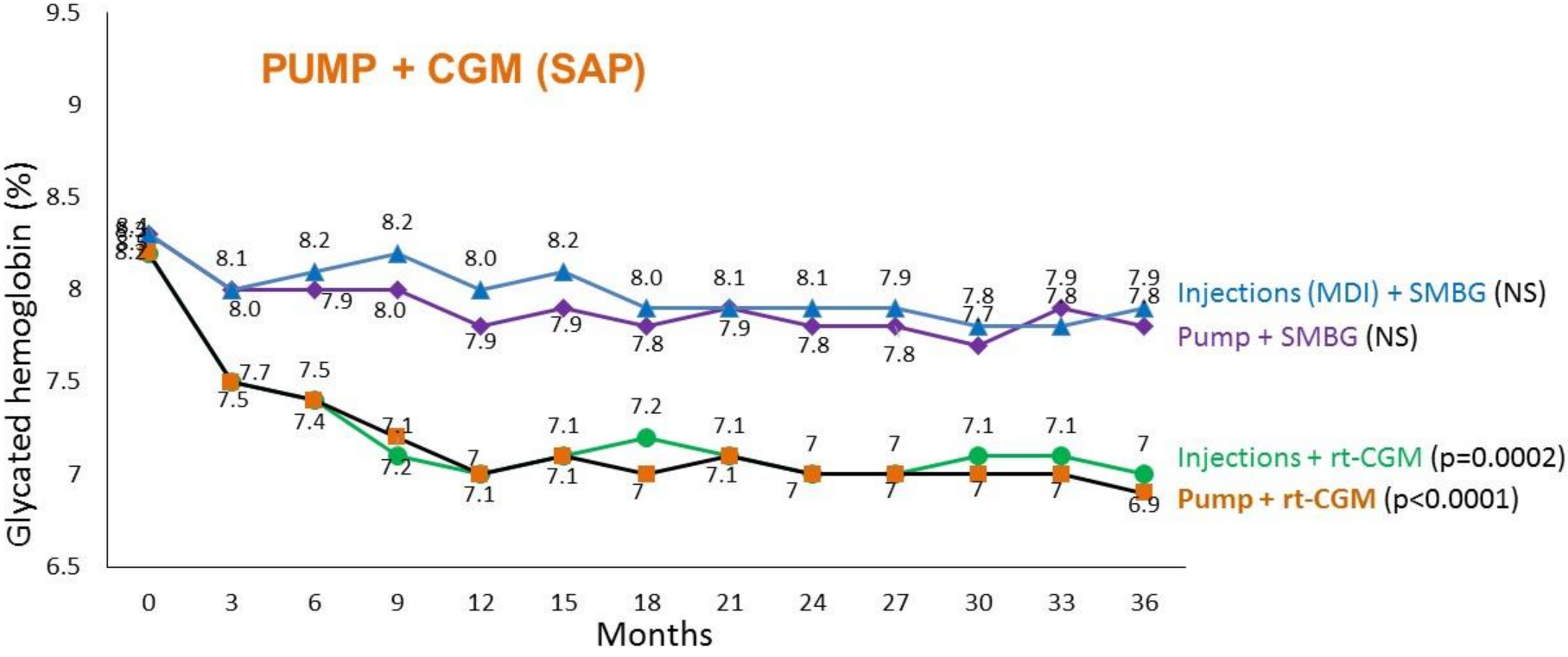
CGM is more important than insulin delivery method for glycemic outcomes of type 1 diabetes: 3 years of follow-up of the COMISAIR study

Comparison of different treatment modalities for Type 1 diabetes Including Sensor-Augmented Insulin Regimens in 3 years of follow-up: the COMISAIR study

Jan Šoupal, MD, PhD

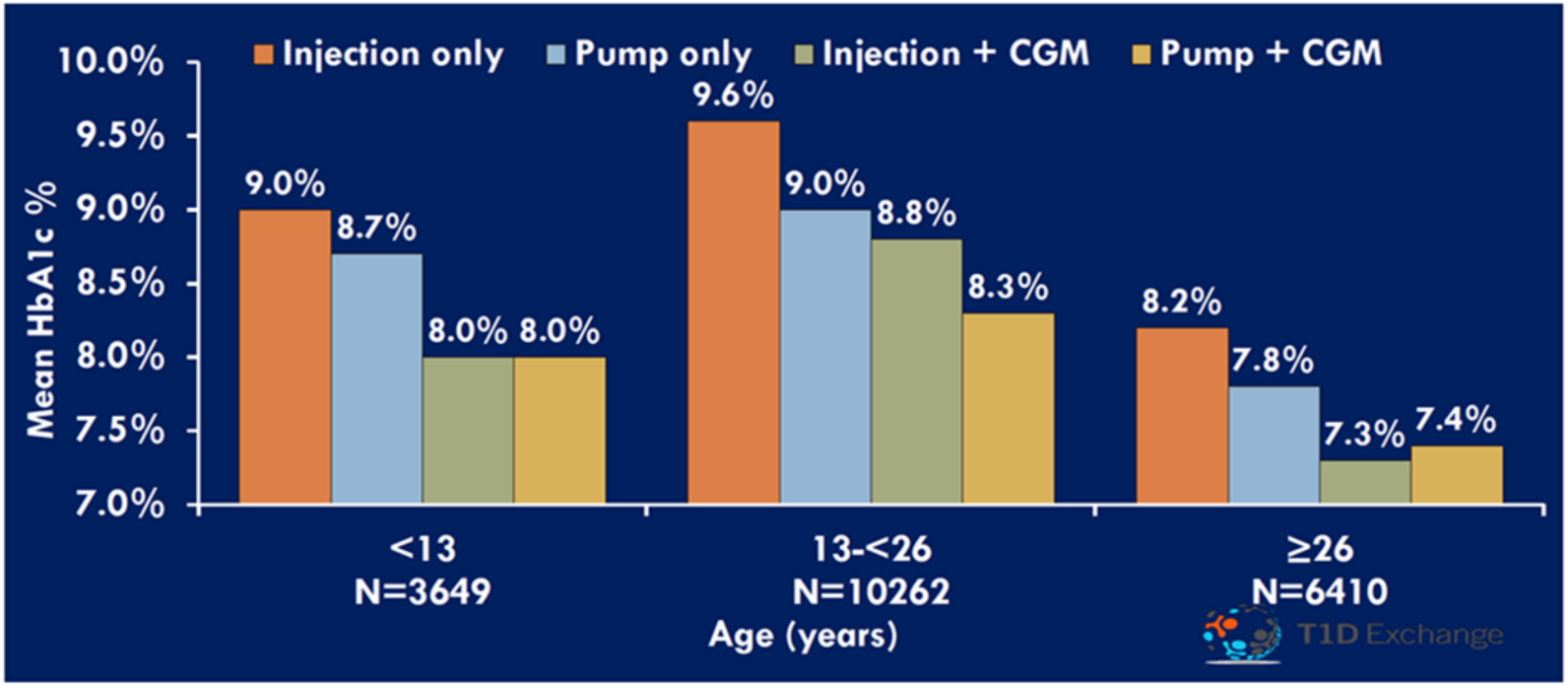
3rd Department of Internal Medicine, 1st Faculty of Medicine, Charles University in Prague, Czech Republic.

HbA_{1c} RESULTS



T1D Exchange Shows Improved A1C with CGM

A1C level similar in CGM users regardless of insulin delivery method



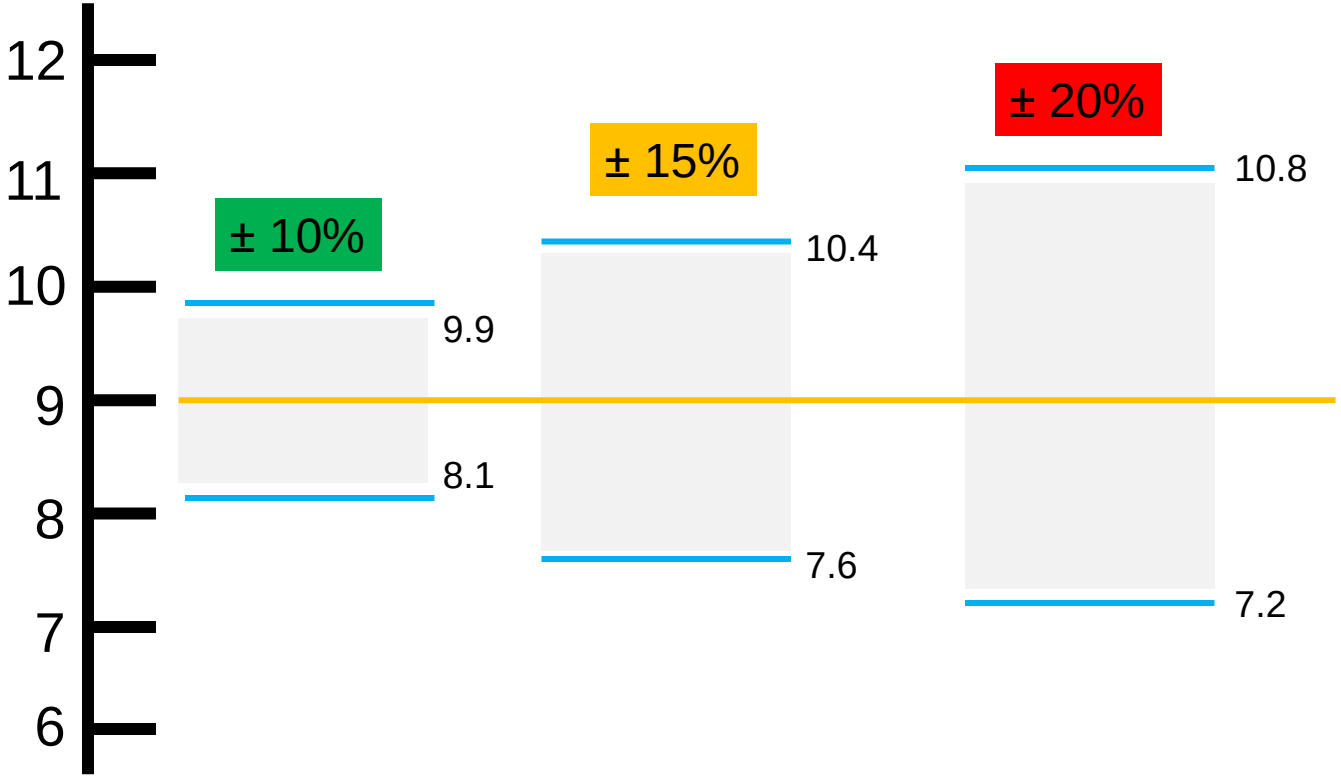
cgm EDUCATION.net
Consortium for Glucose Monitoring Education

T1D Exchange Clinic Registry data through March 31, 2018

How to measure accuracy?

- MARD % – Mean Average Relative Difference %
- Consensus Error Grid – Zone A
  - Number of readings within 20% accuracy
- FDA iCGM Criteria – 15%/15mg/dl or 15%/0.8mmol/l
  - <4.0mmol/l - >85% of the time
  - 4.0 -10.0 mmol/l - >70% of the time
  - >10.0mmol/l > 80% of the time

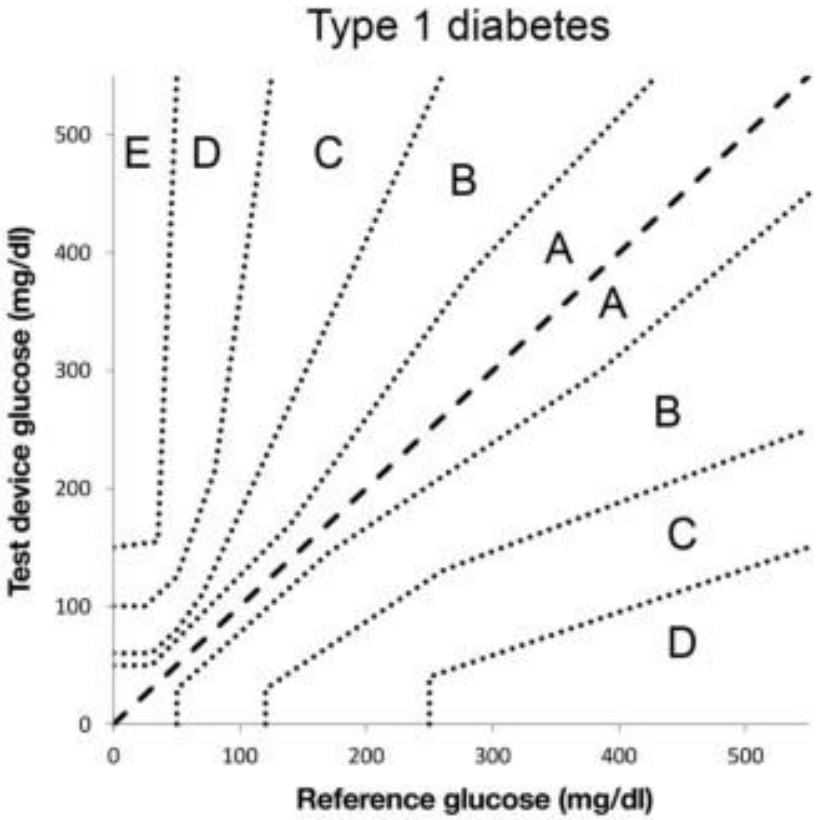
What is MARD – Mean Average Relative difference?



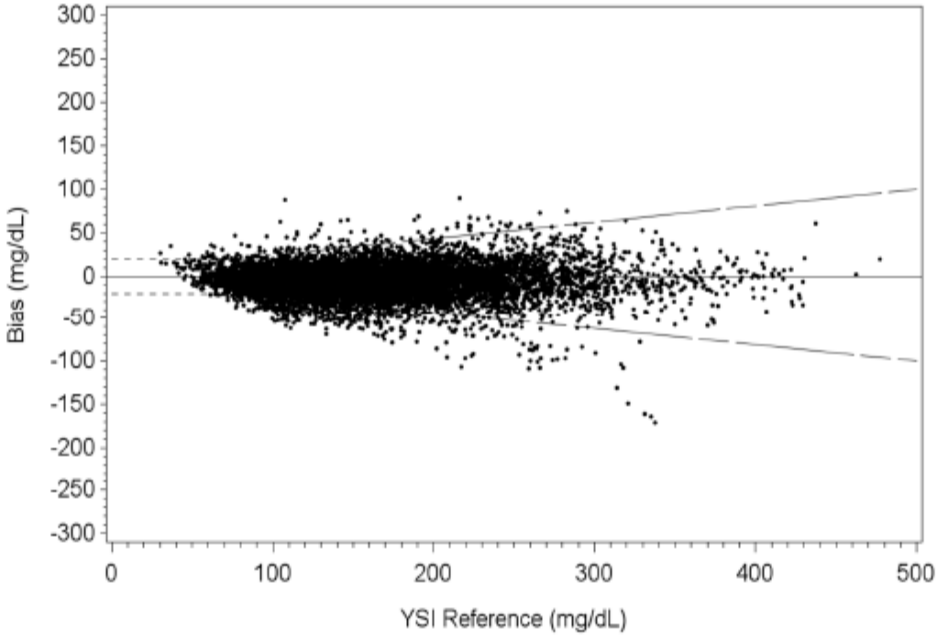
CGM Devices MARD %

Device	MARD %
Dexcom G6 –10 days Zero calibrations - **(Garg 2018)** Dexcom G5 - 7 days 2 Calibrations	**9.8% Adults,** **7.7% Children** **9.0%Adults** **10% Children**
Freestyle Libre – 14 days Zero calibrations Adults **(Bailey 2015),** Children **(Edge 2016)** New Algorithm 2019 – awaiting peer review and new CE mark indication and submission to FDA - **(2019 DDG poster)**	**Adults 11.4%** **Children 13.9%** **Adults 9.5%,** **Children 9.4%**
640G / Guardian Mobile - 6 days- 2-4 Calibrations **Christiansen et al (2017)** 670G – 6 days 2-4 Calibrations **Garg et al (2017); Florenza et al (2019)**	**>14yrs 9.5%** **<14yrs 13-14.0%** **9% - 4 calibrations** **10% - 2 calibrations**

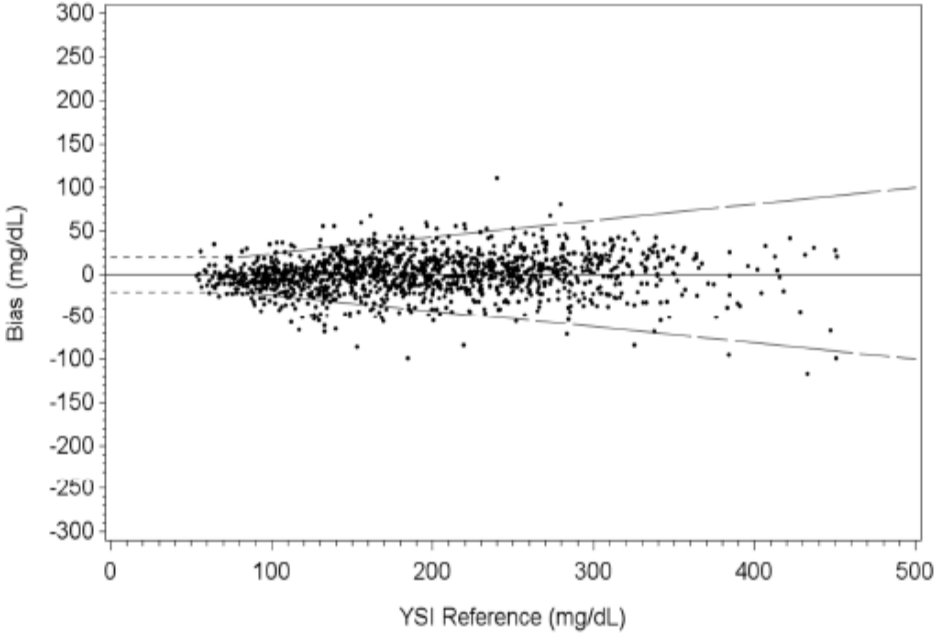
Consensus Error Grid – Zone A = +/-20%



Adult

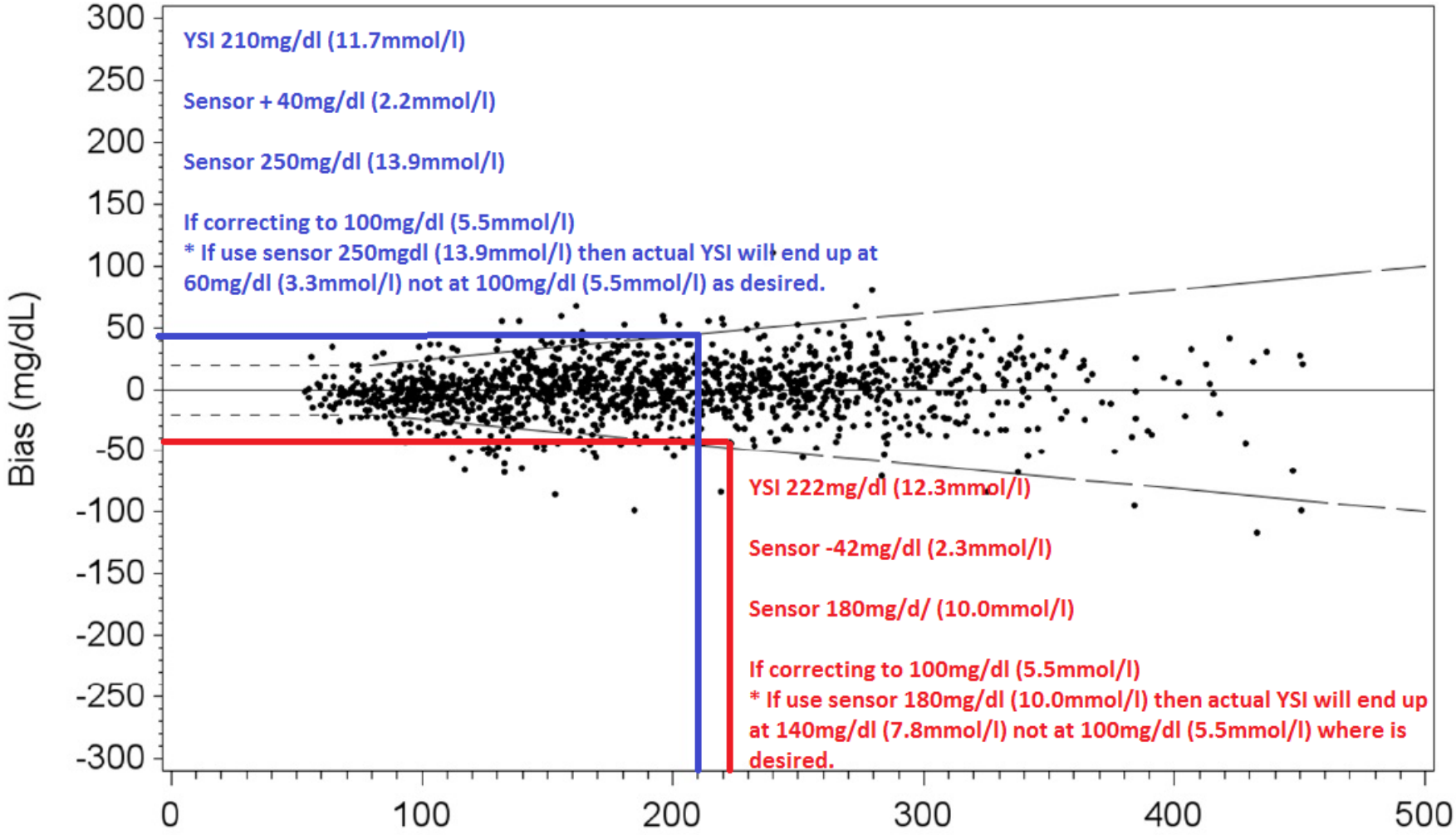


Pediatric



Consensus Error Grid – Zone A = +/-20%

Device	% Zone A
Dexcom G6 –10 days Zero calibrations - **(Garg 2018)**	**Adults – 93%** **Children – 96%**
Freestyle Libre – 14 days Zero calibrations Adults **(Bailey 2015),** Children **(Edge 2016)** New Algorithm 2019 – awaiting peer review and new CE mark indication and submission to FDA - **(2019 DDG poster)**	**Adults – 83%** **Children – 82%** **Adults – 90%** **Children – 90%**
640G / Guardian Mobile - 6 days- 2-4 Calibrations **Christiansen et al (2017)** 670G – 6 days 2-4 Calibrations **Garg et al (2017); Florenza et al (2019)**	**>14yrs– 93%** **<14yrs – 80%** **Adults – 85%** **Children – 85%**


YSI 210mg/dl (11.7mmol/l)
Sensor + 40mg/dl (2.2mmol/l)
Sensor 250mg/dl (13.9mmol/l)
If correcting to 100mg/dl (5.5mmol/l)
* If use sensor 250mgdl (13.9mmol/l) then actual YSI will end up at 60mg/dl (3.3mmol/l) not at 100mg/dl (5.5mmol/l) as desired.
YSI 222mg/dl (12.3mmol/l)
Sensor -42mg/dl (2.3mmol/l)
Sensor 180mg/d/ (10.0mmol/l)
If correcting to 100mg/dl (5.5mmol/l)
* If use sensor 180mg/dl (10.0mmol/l) then actual YSI will end up at 140mg/dl (7.8mmol/l) not at 100mg/dl (5.5mmol/l) where is desired.
Bias (mg/dL)
300
250
200
150
100
50
0
-50
-100
-150
-200
-250
-300
0
100
200
300
400
500

New FDA iCGM standards
Class II medical devices

Sensor Glucose Range	Percentage of sensor glucose readings within 15% (above 4.0mmol/L) or within 0.8mmol/L (below 4.0mmol/L) of reference glucose for readings	Percentage of sensor glucose readings within 40% (above 4.0mmol/L) or within (2.2mmol/L below 4.0mmol/L) of reference glucose for readings	Percentage of sensor glucose readings within 20% reference glucose for readings
<4.0mmol/L	>85%	>98%	>87%
4.0 - 10.0mmol/L	>70%	>99%	>87%

Who meets the FDA iCGM standards?

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 20, Number 6, 2018

DOI: 10.1089/dia.2018.0142

DTT

EDITORIAL

A New Era in Continuous Glucose Monitoring: Food and Drug Administration Creates a New Category of Factory-Calibrated Nonadjunctive, Interoperable Class II Medical Devices

Satish K. Garg, MD, and H. Kaan Akturk, MD

- Dexcom G6 meets the iCGM requirement
- Abbott Libre and Medtronic Guardian CGM systems do not qualify for reclassification.
- Senseonics (Eversense) likely to get approval but waiting.
- Abbott Libre new DDG data is with the FDA for consideration

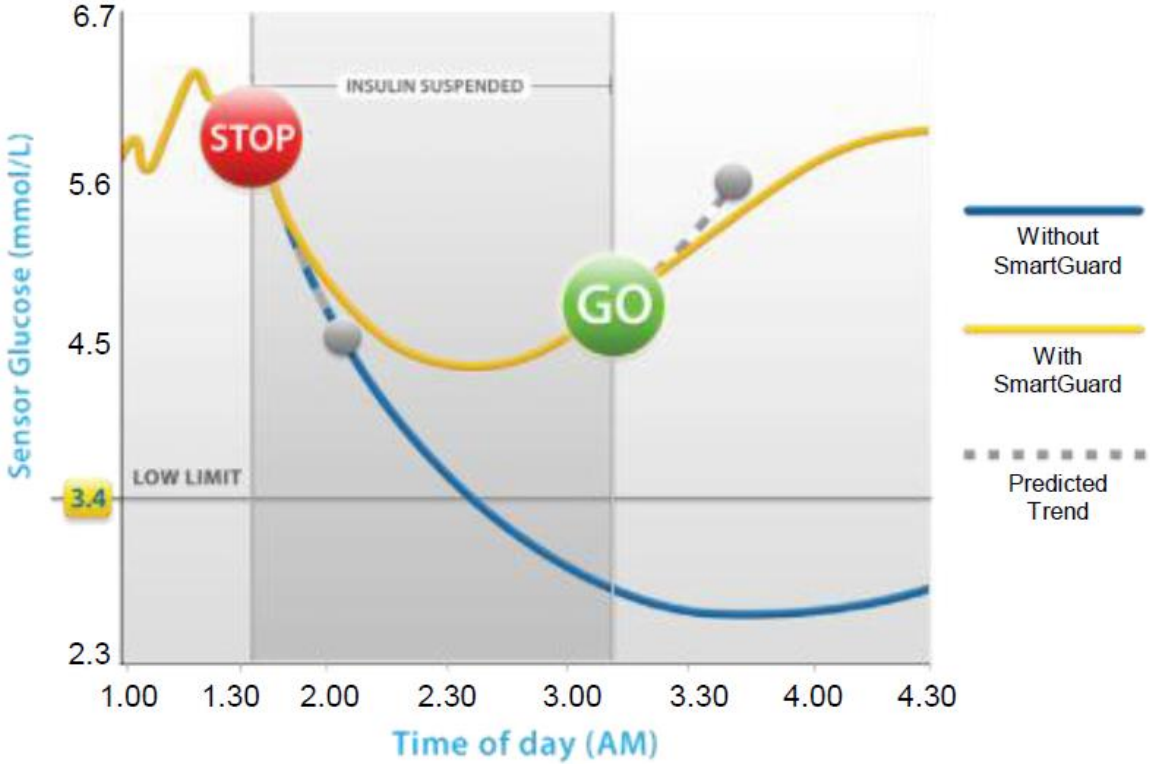
CGM Devices MARD & finger stick replacement?

Device	Finger stick replacement
Dexcom G6 –10 days Zero calibrations - **(Garg 2018)** Dexcom G5 - 7 days 2 Calibrations	FDA Approval & CE Mark **full replacement** for adults and children G6 = Zero calibration G5 = 2 Calibrations
Freestyle Libre – 14 days Zero calibrations Adults **(Bailey 2015),** Children **(Edge 2016)** New Algorithm 2019 – awaiting peer review and new CE mark indication and submission to FDA - **(2019 DDG poster)**	CE Mark Adults and children – **Partial replacement** FDA Approval on adults 10 days (do not trust on day 1) – **Partial replacement**
640G / Guardian Mobile - 6 days- 2-4 Calibrations **Christiansen et al (2017)** 670G – 6 days 2-4 Calibrations **Garg et al (2017); Florenza et al (2019)**	**No approval** – all treatment decisions to be confirmed with a fingerstick **No approval** – all treatment decisions to be confirmed with a fingerstick

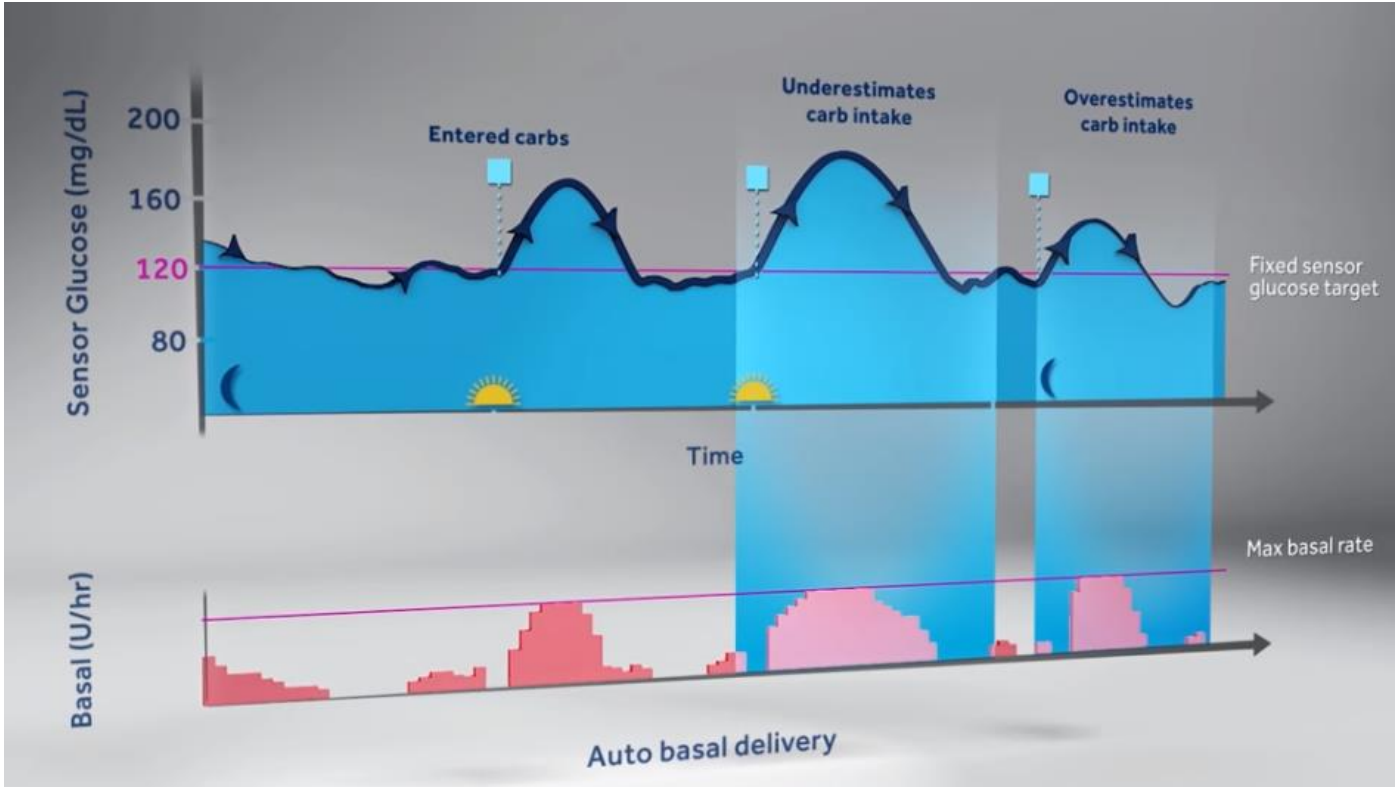
Freestyle Libre

Minimed 640G

MM640G Smart guard



MM670G: AUTO mode



Dexcom G6 Urgent low soon

DEXCOM G6 URGENT LOW SOON 20 MINUTES BEFORE 3.1MMOL/L	DEXCOM G6	DEXCOM G6 URGENT LOW SOON 20 MINUTES BEFORE 55MG/DL
>6.9mmol/l	↓↓	>124mg/dl
5.4 – 6.9mmol/l	↓	97-124mg/dl
4.2 -5.3mmol/l	↘	75 - 96mg/dl

T-slim with Basal IQ – Control IQ to come

It’s a TRIAL: Outcomes

Outcome goals to be achieved at 6 months and on-going:

1.

2.

Process goals to be achieved at 1 month, 6 months and on-going:

1. Attend the three education sessions

2. Have data capture of more than 70% (>5 days a week)

3. Test blood glucose if feel symptomatically different to CGM reading

4. Respond appropriately to high and low glucose alerts

5. Keep a record of insulin doses administered and carbohydrate eaten – Dexcom APP Events or via insulin pump upload.

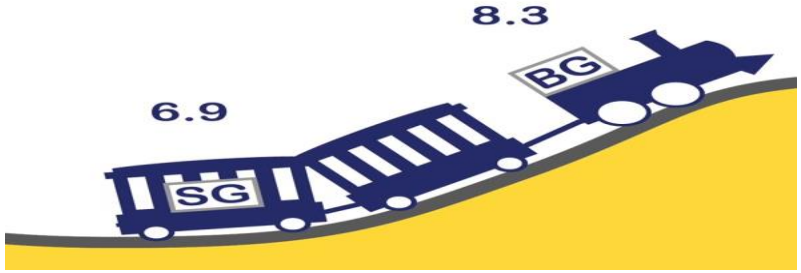
6. Review download information and make proactive adjustments to therapy every two weeks

blood glucose vs sensor glucose

https://youtu.be/P5jRZnF7Mbg

When glucose level is stable

When glucose level is rising after eating



When glucose level is falling after insulin or exercise

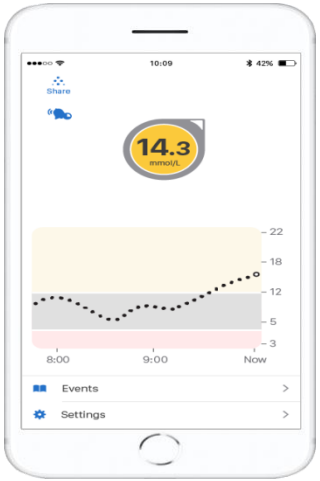
What do the arrows mean?

Trend Arrow	Description	Where the blood glucose is now (10 minutes ahead)
	Rising quickly	2mmol/l higher
	Rising	1mmol/l higher
	Stable	Same
	Falling	1 mmol/l lower
	Falling quickly	2mmol/l lower

Diabetes Team Guidance

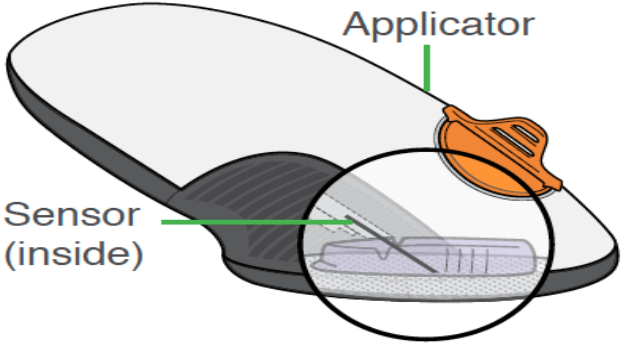
- A BG test is required in the below circumstances due to the **lag time and inaccuracies in low and high glucose ranges**
  - Hyperglycaemia: more than 13.9mmol/l
    - **Libre inaccurate 30-40% of the time leading to over and under corrections**
  - Hypoglycaemia: less than 4.0mmol/l
    - **Libre inaccurate 50-60% of the time leading to treating hypos when not hypo**
  - If arrow straight up or down at a meal time
  - When symptoms do not match the CGM reading

Overview



Dexcom G6 app*
Shows glucose information

*For a list of compatible devices see: dexcom.com/compatibility



Applicator with Sensor
Sensor applicator inserts sensor under your skin
Sensor gets glucose information
Wear for 10 days

Transmitter
Sends glucose information from sensor to Dexcom G6 app
Use for 3 months

Your Settings

· High Alert = 14.0mmol/l
  - If on a insulin pump give a correction dose
  - If on MDI only correct if 3 hours since last insulin

· High Repeat = 90 minutes
  - · **If still above 14.0mmol/l in 90 minutes MUST check ketones**

· Low Alert = 4.0mmol/l
  - · Treat as hypoglycaemia

· Low Repeat = 20 minutes
  - · **If still below 4.0mmol/l in 20 minutes repeat hypo treatment**

· When will the Urgent Low Soon sound?

What do the arrows mean?

Trend Arrow Receiver	Trend Arrow APP	Description	Where the blood glucose is now (10 minutes ahead)
↑↑		Rapidly rising	>2.0mmol/l higher
↑		Rising	1.5mmol/l higher
↗		Slowly rising	1mmol/l higher
→		Stable	Same
↘		Slowly falling	1 mmol/l lower
↓		Falling	1.5mmol/l lower
↓↓		Rapidly Falling	>2.0mmol/l lower

Preventing hypos

Trend Arrow Receiver	Trend Arrow APP	Description	Sensor level and action
		Slowly falling	5.0mmol/l or lower have hypo Treatment
		Falling	5.5mmol/l or lower have hypo Treatment
		Rapidly Falling	6.5mmol/l or lower have hypo Treatment

Adjusting bolus amounts

Insulin sensitivity factor	Direction of trend arrows		
1. Go down to your Insulin sensitivity factor 2. Go across to the arrow displayed on your CGM. 3. This is the amount of insulin to add or take off your total insulin dose	↗ The glucose is rising steadily, **ADD** the amount of units below to the total bolus amount	↑ The glucose is rising moderately, **ADD** the amount of units below to the total bolus amount	↑↑ See note above. The glucose is rising rapidly, **ADD** the amount of units below to the total bolus amount
	↘ The glucose is falling steadily, **TAKE OFF** the amount of units below from the total bolus amount	↓ The glucose is falling moderately **TAKE OFF** the amount of units below to the total bolus amount	↓↓ See note above. The glucose is falling rapidly **TAKE OFF** the amount of units below to the total bolus amount
1.0	1.5	3.0	3.0 - 4.5
1.5	1.0	2.0	2.0 - 3.0
2.0	0.75	1.5	1.5 - 2.25
2.5	0.6	1.2	1.2 - 1.8
3.0	0.5	1.0	1.0 - 1.5
3.5 - 4.0	0.4	0.8	0.8 - 1.2
4.5 - 5.0	0.3	0.6	0.6 - 0.9
5.5 - 6.0	0.25	0.5	0.5 - 0.75
7.0 - 8.0	0.2	0.4	0.4 - 0.6

Write in your bolus adjustments and answer the questions?

Trend Arrow Receiver	Trend Arrow APP	Description	How much insulin to add or take off at meal times
⬆⬆		Rapidly rising	
⬆		Rising	
↗		Slowly rising	
↘		Slowly falling	
⬇		Falling	
⬇⬇		Rapidly Falling	

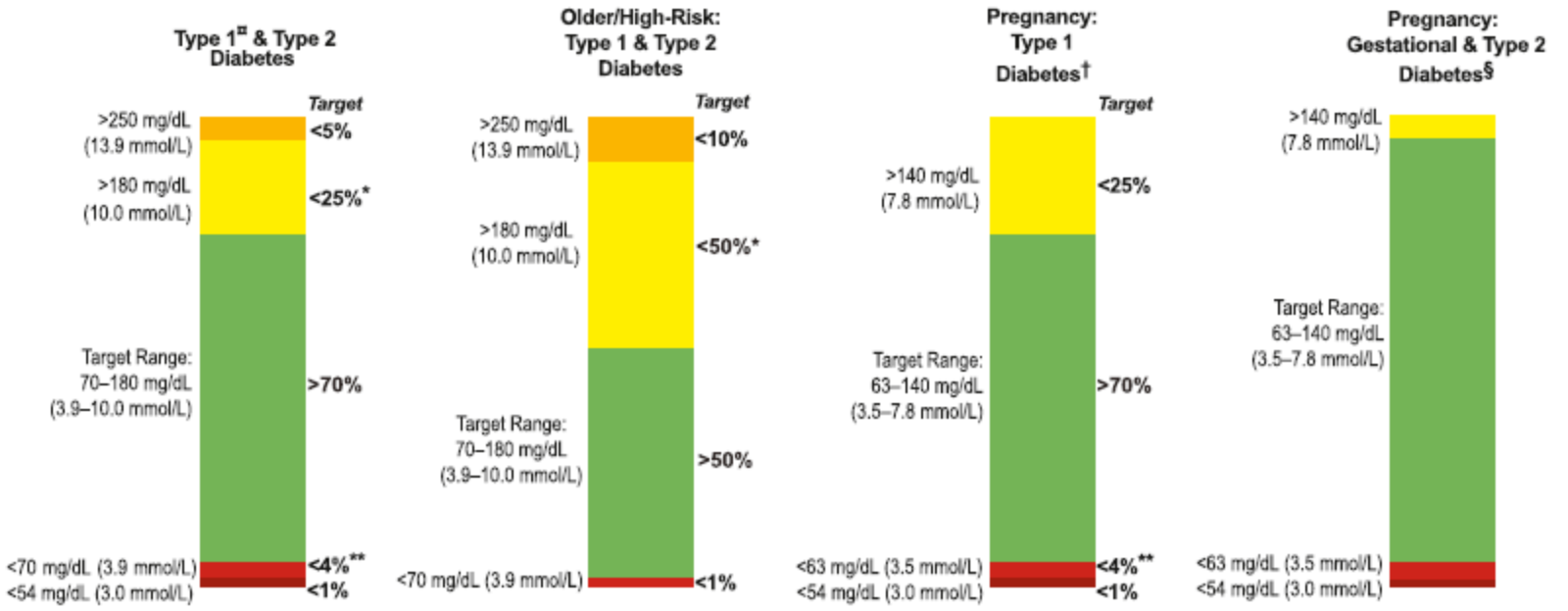
- If your meal time insulin dose came to 5 units:
  - How much would you give if the arrow was straight up “Rising”?
- If your meal time insulin dose came to 7units:
  - How much would you give if the arrow was angled down “Slowly Falling”?

Name & Activity	Joe Bloggs	P.E.	Minutes until next sensor test or time of the total exercise		45
Sensor Glucose level	Rate of glucose change trend arrow & action to take	Carbohydrate grams for designated time	Dextrose (3g each)	Lucozade Original (8.9g/100ml)	Coke or lemonade (11g/100ml)
<4.0 mmol/l	No exercise: Treat hypoglycaemia	15	5	169	136
4.0 - 6.4 mmol/l	↓↓	34	11	387	313
	↓	26	9	290	235
	↘	17	6	193	156
	→	14	5	161	130
	↗	11	4	121	98
	↑	6	2	64	52
	↑↑				
6.5 - 9.9 mmol/l	↓↓	26	9	290	235
	↓	17	6	193	156
	↘	14	5	161	130
	→	11	4	121	98
	↗	6	2	64	52
	↑ OR ↑↑				
10.0 - 13.9 mmol/l	↓↓	11	4	121	98
	↓	6	2	64	52
	↘ OR → OR ↗				
	↑ ↑↑ OR				
>14.0 mmol/l	Check ketones: If less than 0.6mmol.l	Ok to exercise			
	Check ketones: If 0.6mmol/l or above	No exercise and contact parents/guardian or diabetes team			

How to assess CGM downloads?

Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

https://doi.org/10.2337/dci19-0028



¤ For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See *Clinical Applications of Time in Ranges* section in the text for additional information regarding target goal setting in pediatric management.)

† Percentages of time in ranges are based on limited evidence. More research is needed.

§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.

* Includes percentage of values >250 mg/dL (13.9 mmol/L).

** Includes percentage of values <54 mg/dL (3.0 mmol/L).

AGP Report

Data Capture %		
0-70%	70-90%	90-100%

% In target: 4-10mmol/l %		
0-50%	50-70%	70-100%

% High: 10.0mmol/l and Higher		
40-100%	25-40%	0-25%

% Low: less than 4.0mmol/l		
7 - 30%	4-7%	0-4%

% Very Low: less than 3.0mmol/l		
3-10%	1-3%	0-1%

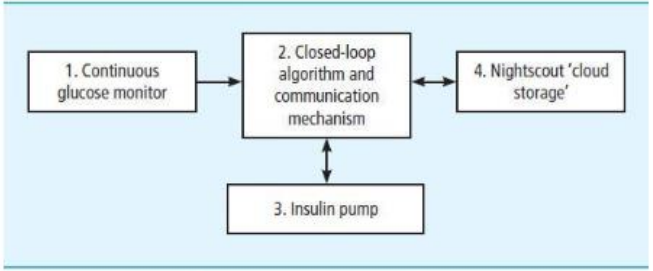


Figure 1. Components of a DIY artificial pancreas system

DIY Loop		
User interface	**Hardware**	**Pump(s)**
iPhone Apple Watch	RileyLink	Medtronic OmniPod (Alpha)
OpenAPS		
User interface	**Hardware**	**Pump(s)**
Pump Pebble watch	Linux microcomputer	Medtronic
Android APS*		
User interface	**Hardware**	**Pump(s)**
Android phone Smart watch	None	Dana R Dana RS Roche Combo Roche Insight Virtual pump

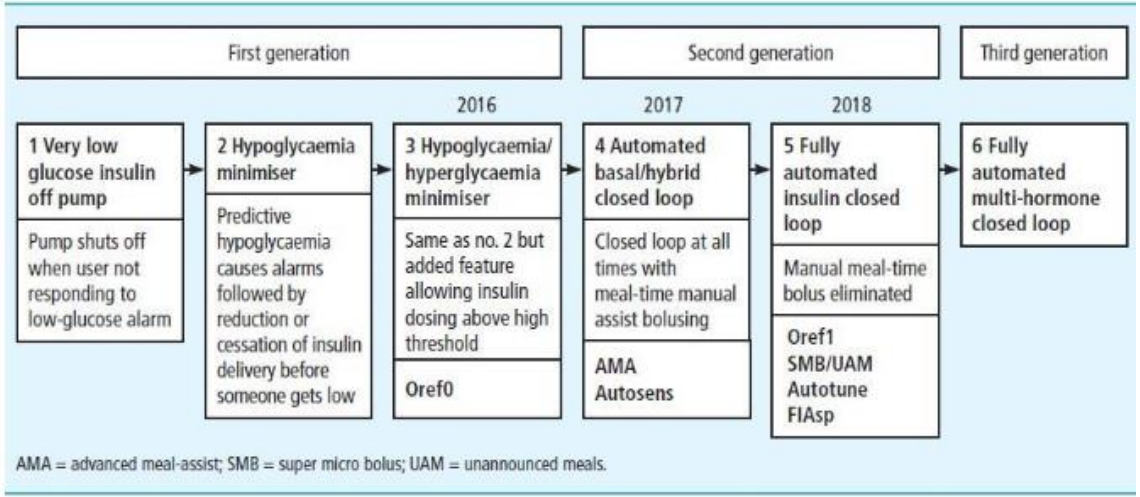
*Work in development with RileyLink to allow Medtronic and OmniPod usage.

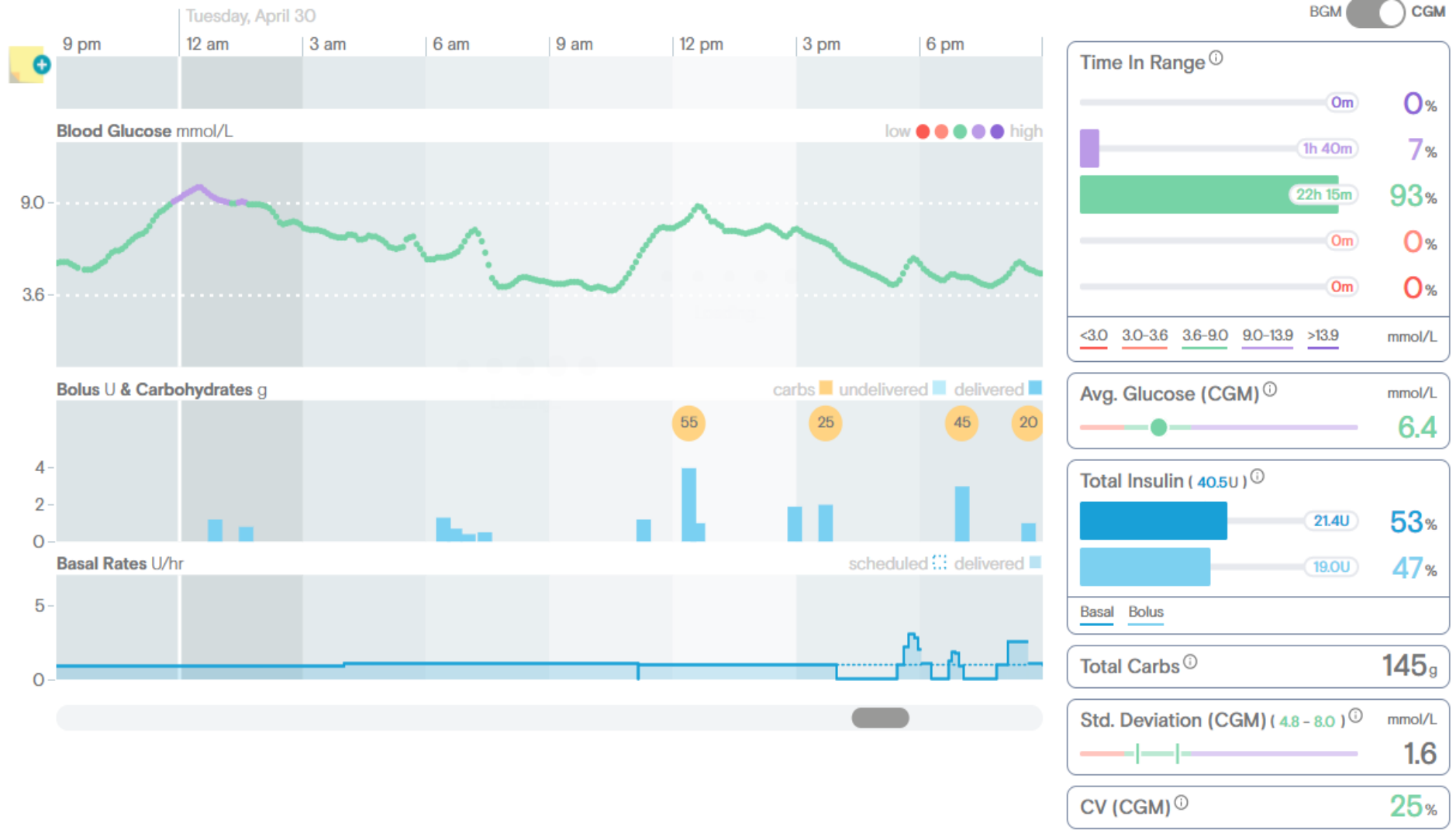
Practical DIABETES

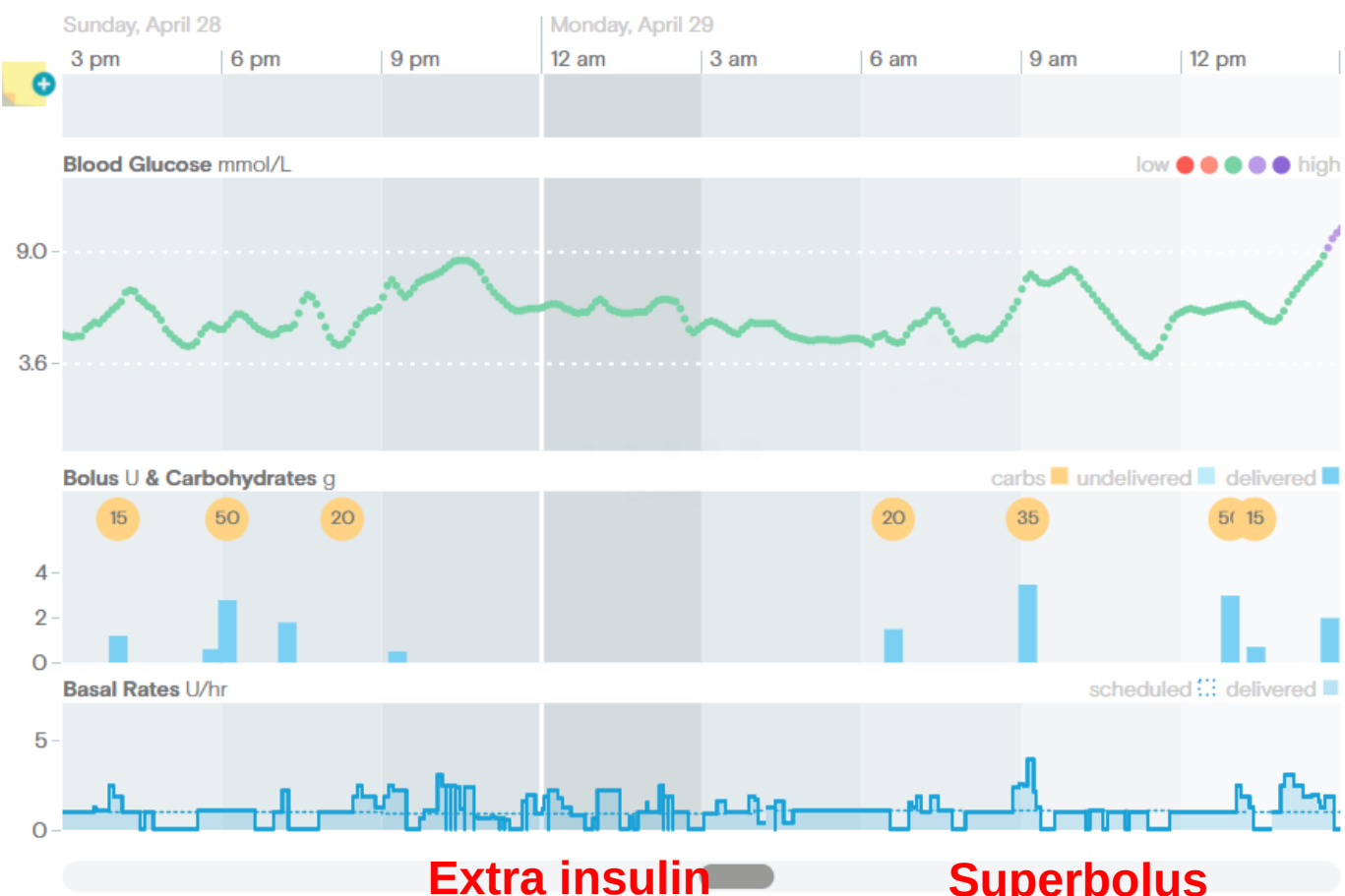
HOME NEWS ISSUES EVENTS NOTABLE LECTURES REVIEWS

DIY artificial pancreas systems: here to stay?

THOMAS SJ CRABTREE, ALASDAIR MCLAY, EMMA G WILMOT MARCH 28, 2019 VOL 36.2 MARCH/APRIL 2019




Tuesday, April 30
9 pm
12 am
3 am
6 am
9 am
12 pm
3 pm
6 pm
BGM
CGM
Blood Glucose mmol/L
low
high
9.0
3.6
Bolus U & Carbohydrates g
carbs
undelivered
delivered
55
25
45
20
4
2
0
Basal Rates U/hr
scheduled
delivered
5
0
Time In Range
0m
0%
1h 40m
7%
22h 15m
93%
0m
0%
0m
0%
<3.0
3.0–3.6
3.6–9.0
9.0–13.9
>13.9
mmol/L
Avg. Glucose (CGM)
mmol/L
6.4
Total Insulin (40.5U)
21.4U
53%
19.0U
47%
Basal
Bolus
Total Carbs
145g
Std. Deviation (CGM) (4.8 - 8.0)
mmol/L
1.6
CV (CGM)
25%



Extra insulin for Pizza

Superbolus for toast

BGM CGM

Time In Range

0m	0%	
15m	1%	
23h 45m	99%	
0m	0%	
0m	0%	

<3.0 | 3.0-3.6 | 3.6-9.0 | 9.0-13.9 | >13.9 mmol/L

Avg. Glucose (CGM) mmol/L

6.0

Total Insulin (41.6U)

24.0U	58%	
17.6U	42%	

Basal Bolus

Total Carbs 205g

Std. Deviation (CGM) (4.9 - 7.2) mmol/L

1.1

CV (CGM) 19%

GCSE

SMBG

A-Level

CGM

Bachelors Degree

APS Basal adjustment

Masters Degree

APS DIY Looping

APS

PhD

APS Dual Hormone CGM

Back to school?

- https://drive.google.com/open?id=1Jz_sjQ9gZG89iH2v43dP29CiOPvHyCaR