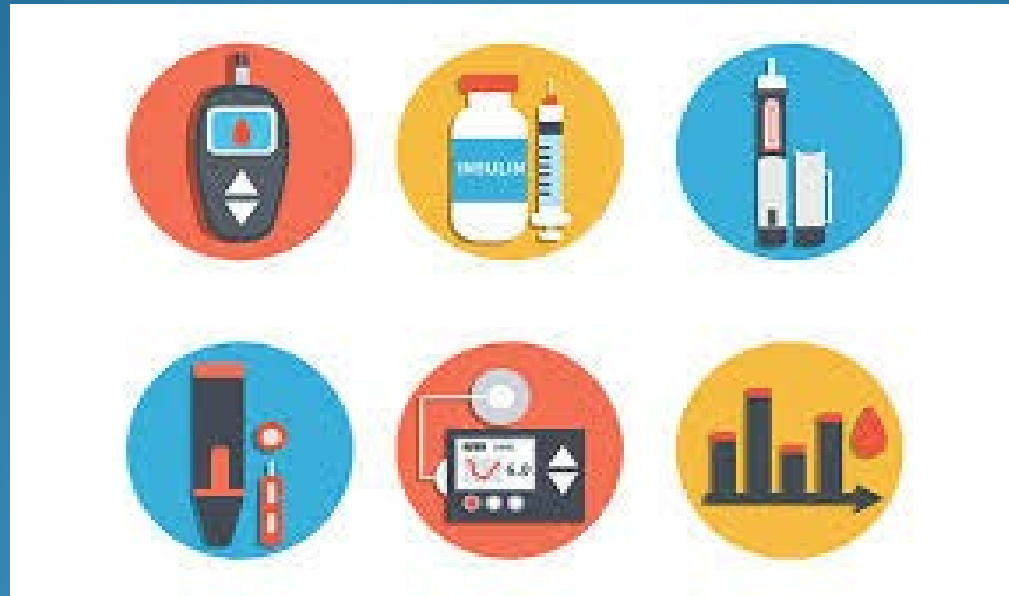


Diabetes Technology Through the Lifespan



Beth Holden, MSN, RN, MLDE, CDE

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Angela Hepner, MEd, RD, LD, MLDE, CDE, CDTC

Objectives

At the conclusion of this activity, participants will be able to:

Insulin Pumps

- Identify 4 major pump options and features of each.
- Describe elements of a basic pump set up as well as special features available for “fine tuning” diabetes pump therapy.
- Define patient teaching opportunities using insulin pump downloads.

CGM

- List the options for professional and personal CGM therapy.
- Review technology used for pump and CGM evaluation.
- Discuss the features of the new Hybrid Closed Loop System.

Adult and Pediatric Applications

- List characteristics of an appropriate adult and pediatric pump candidate.
- Identify when CGM therapy is appropriate for your adult or pediatric patient.
- Discuss specific technology related issues for adult and pediatric populations.

Disclosures

Beth Holden

- *Medtronic, Tandem, Omnipod*

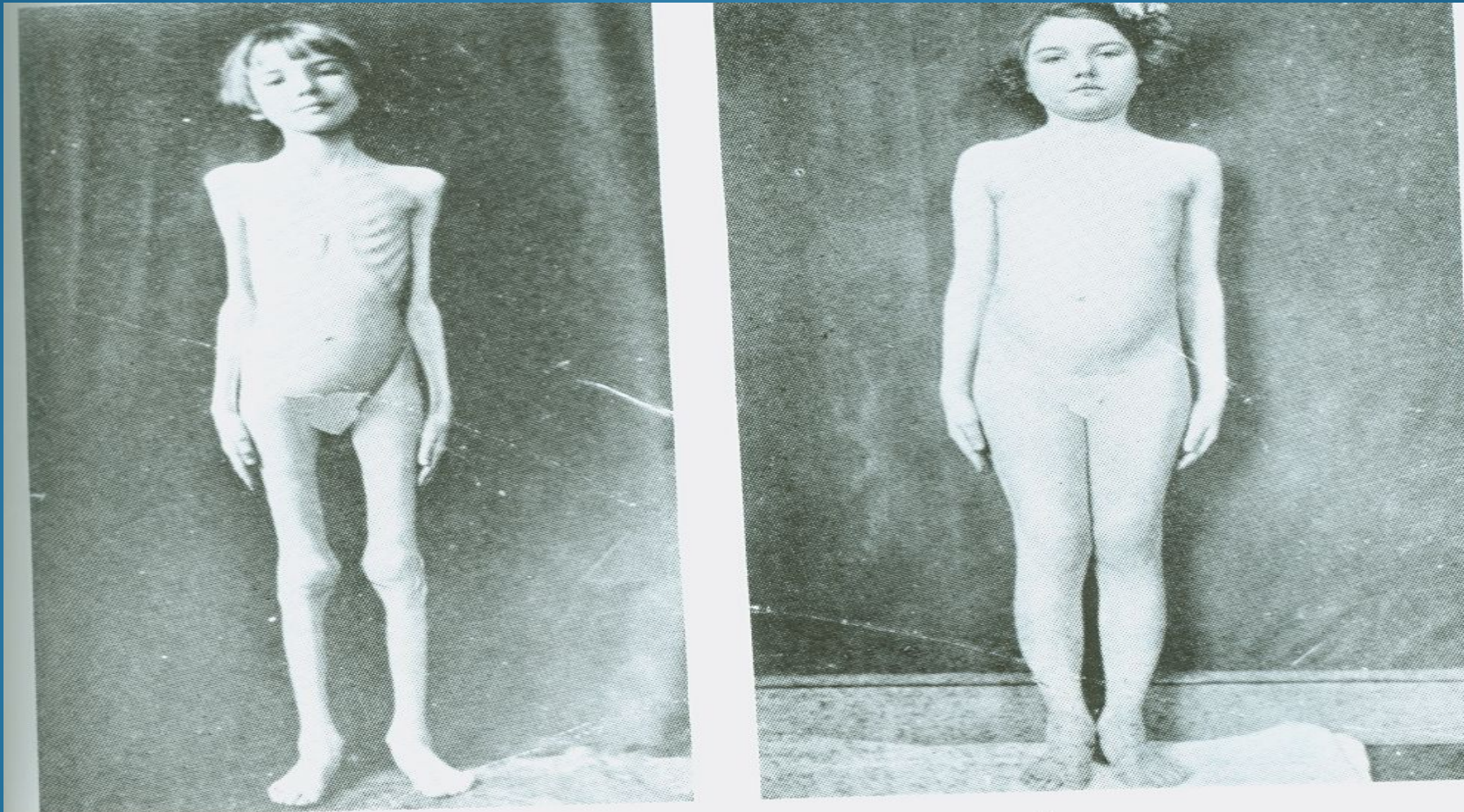
Sheri Setser-Legg

- *Medtronic, Tandem, Omnipod*

Angela Hepner

- *Medtronic, Tandem, Omnipod*

The Miracle of Insulin





First wearable insulin pump

Developed 1963

Dr. Arnold Kadish



First marketable, wearable insulin pump

Brought to market 1976

Dr. Dean Kaneau

Named the “Auto Syringe”



Look how far we have come

September 2016 – FDA approves first hybrid closed loop system

June 2017 – Medtronic Minimed launches the 670G Smart Guard System



What is an insulin pump?

- Theory: microcomputer designed to provide a constant dose of insulin and to make extra insulin available to cover carbs and correct high blood sugar
 - Type of insulin used: fast-acting only (Novolog, Humalog, Apidra)
 - Basal: constant dose
 - Bolus: extra
 - Insulin is infused under the skin through a cannula (tiny tube) or needle that is connected to an insulin reservoir in the pump. This infusion set is changed every 2-3 days.

Identifying the Appropriate Pump Candidate



Clinical Indications for Insulin Pump Use

1. Inadequate glycemic control despite optimized multiple daily injections (MDI)
2. High glucose variability
3. Specific problem issues – nocturnal hypoglycemia, dawn phenomenon, gastroparesis
4. Preconception planning and pregnancy
5. Extreme insulin sensitivity

Lifestyle Indications for Insulin Pump Use

1. Erratic Work Schedule
2. Varied Work Shifts
3. Frequent Travel
4. Inconvenience of Multiple Daily Injections

Behavioral Indications for Pump Use

1. Realistic Expectations of the capabilities of pump therapy
2. Development of a relationship with the care provider
3. Motivation to succeed at pump therapy
 - Demonstration of consistent glucose monitoring
 - Demonstration of appropriate carbohydrate counting
 - Willingness to invest the time for pump training

Behavioral Indications for Pump Use, con't

4. Intellectual capability to problem solve
5. Emotional stability and adequate emotional support.
6. Physical ability
 - to view pump screens
 - to hear pump alarms
 - to manipulate pump equipment
7. Adequate insurance benefits

Pump Selection

- 4 year commitment
- Significant cost
- Some features unique to each pump



Insulet Corporation: Omnipod

2 part delivery system

- Pod
- Personal Diabetes Manager (PDM)



Pod

- Small size 1.6' X2.4"
- Tubeless
- Wear in more places
- Volume 80-200 units
- Pod life – 72 hours
- Automatic cannula insertion
- Waterproof



Personal Diabetes Manager- PDM

- Must be available within 5 feet for bolus
- Does not have to be present for basal flow
- Built in Freestyle Meter
- Contained food log
- Color Screen



Advantages

1. Freedom from tubes
2. Auto insertion
3. Combined meter/pump
4. Auto stop on pods
5. Fewer disconnects
6. Food Library

Disadvantages

1. Volume limitations
2. Cost with more frequent pod changes
3. Inability to disconnect/reconnect
4. Adhesive issues
5. No communication with CGM

Tandem Corporation

T-Slim X2

T-Flex



T-Slim and T-Flex

- Volume 300-450 units
- Size 2.0" X 3.13" X.6"
- Touch Screen
- Rechargeable Battery
- Personal Profile Segments
- Downloadable updates
- Communicates with Dexcom



Advantages

1. Larger reservoirs
2. Touch Screen
3. Small, contemporary profile
4. Rechargeable battery
5. Downloadable updates
6. Communicates with CGM

Disadvantages

1. Slow tubing prime
2. Not approved for Apidra insulin
3. No direct meter communication
4. Does not auto respond to CGM

Medtronic Minimed

Paradigm

630G System



Paradigm

- 2 models 500 series (180 units)
700 series (300 units)
- Size 2"X 3.3" X .82"
- Reservoir /tubing
- Push button
- Has a communicating meter
- Has an integrated CGM
- Has Low Suspend technology



630 G System

- Holds 300 units
- Size – 2.1” x 3.78” x 0.96”
- Improved sensor (Enhanced Enlite)
- Low suspend technology
- Color screen
- Vibrate/Volume alert
- Adjustable volume
- Variable bolus speeds
- Improved screen look



Advantages

530G System

1. Communication CGM
2. Low suspend
3. Meter communication

630G System

1. Communication CGM
2. Low suspend
3. Meter Communication
4. Color Screen
5. Volume control
6. Enhanced Alert Features

Disadvantages

530G System

1. Sensor inaccuracy
2. Black and White screen

630G System

1. Feels bulkier
2. One step away from the hybrid closed loop

Insulin Pump Basics

An Introduction to Important Features of an Insulin Pump

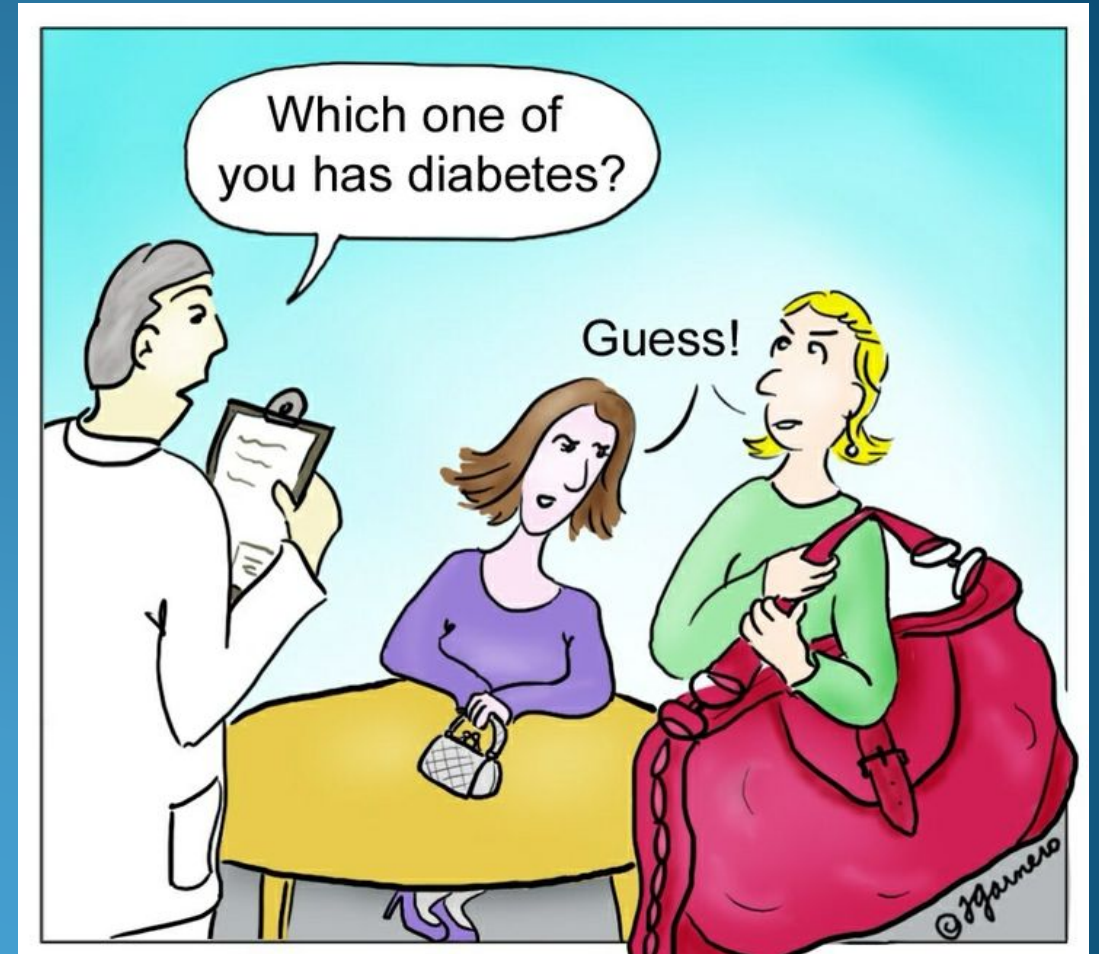
Setting realistic expectations

- Weight gain
- Fancy calculator
- Frequent blood glucose monitoring
- No basal insulin so high risk of DKA with occlusions



What every pump patient should never be without:

- Extra infusion set or pod
- Cartridge/reservoir
- Meter and/or strips
- Insulin vials
- Syringe or pen (backup injection)
- Treatment for hypoglycemia
- Extra batteries or charging cord



Basic Pump Features

- Why is a pump better than injections?
- Important to remember that an insulin pump does not “fix” blood sugars
- Just another method of insulin delivery
- Pump better mimics pancreatic function.

Pump



or

Injections?



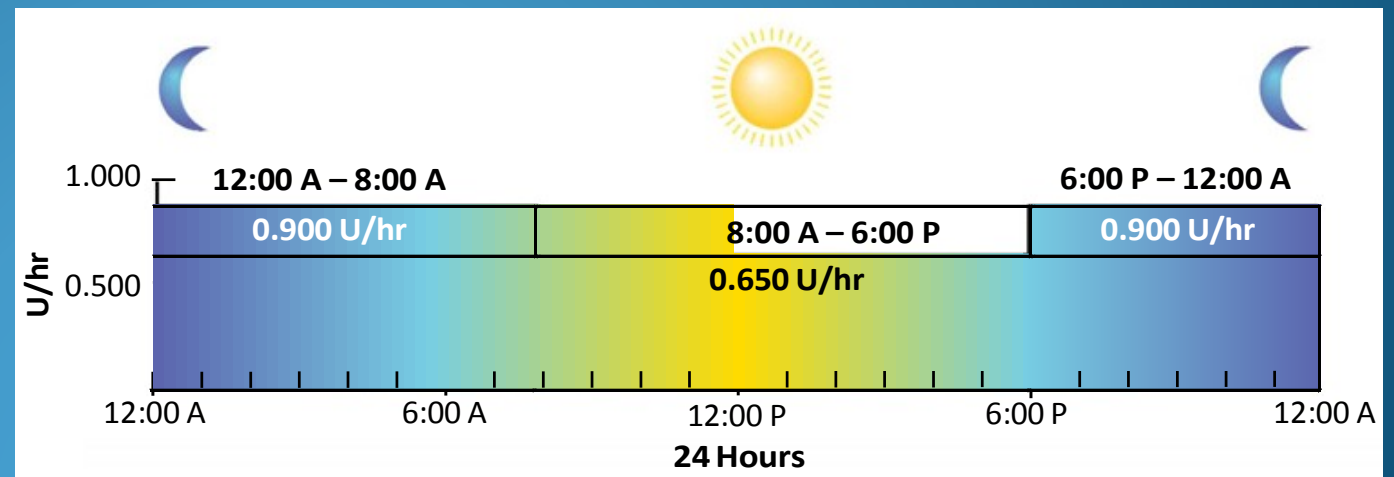
Why choose a pump?

- Multiple basal rates
- Bolus Calculator
 - Multiple Insulin-to-CHO ratios and correction scales
 - Active Insulin or Insulin-On-Board
- Temporary Basal
- Extended bolus features
- Smaller basal and bolus adjustments
- Custom reminders/alerts/alarms



Multiple Basal Rates

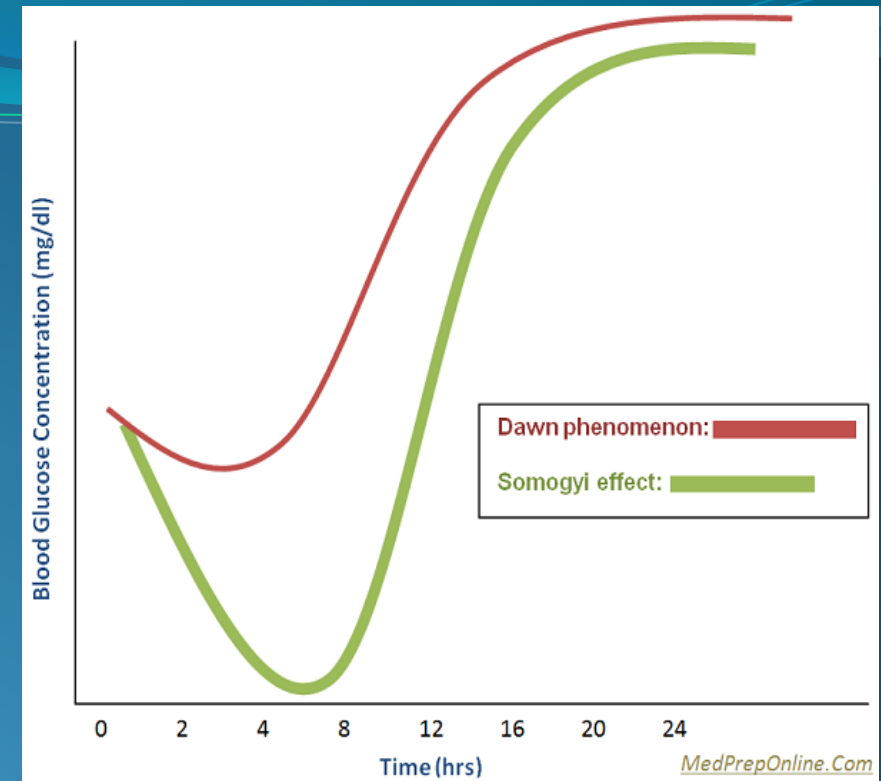
- Insulin pump can adjust basal rate up or down throughout the day.
 - Up to 24 basal rates in a 24 hour period
- Injectable basal insulins cannot be adjusted for varying basal needs.
 - Lantus, Levemir, Basaglar, Tresiba, Toujeo
- Dawn Phenomenon vs. Somogyi Effect
- Changes in daily activity levels
- Pump clock start at midnight



Multiple Basal Rates

- Example: BS at HS 130
BS in AM 240
- Why?
 - Dawn Phenomenon vs. Rebound hyperglycemia

- Rebound hyperglycemia: Can have a lower basal rate when patient first goes to bed (more lows happen from 12-3AM) then increase basal in the hours before waking
- DAWN phenomenon: Do not need lower basal in early nocturnal hours but still need increased basal in hours before waking



Multiple Basal Rates

- Example: Patient continues to have hypoglycemia during the workday d/t a physically active job but then BS spike in PM
- May need a lower basal at work d/t increased activity but a higher basal in the evening when less active “couch potato hours”
- May end up with 3-5 basal rates for the day.

Time Of Day	Basal Rate
Midnight-3 AM	0.70
3 AM – 7 AM	0.95
7 AM – 6PM	0.80
6PM - Midnight	0.90

Think Small (when it comes to basal rates)

- Have to think in much smaller increments in terms of basal.
- For adults, a patient might be on Lantus 30 units so, when an adjustment is made, a 10% change is 33 units and a 20% change is 36 units.
- For a pump patient, you can't make basal adjustments in large increments. For adults, a 1/10 unit increment can be a substantial change. For Pediatrics, it might be an even smaller adjustment.
 - For example, if a patient is on 1.0 unit an hour, a reasonable adjustment would be 0.9 unit/hour for a decrease and 1.1 units/hour for an increase.

Calculating Starting Basal Rate

- Can take the injectable basal (Lantus, Basaglar, Levemir, Toujeo or Tresiba) and divide by 24 (hours in a day)
 - For adults, particularly if the pre-pump A1c is high

Or

- Decrease injectable basal by 20% and then divide by 24 hours.

Time	Basal	Correct	Carb	Target BG
12:00 AM	0.75	1:50	1:15	140
3:00 AM	0.80	1:50	1:15	120
7:00 AM	0.70	1:55	1:12	100

Lower Starting Basal Rate

- Method of insulin delivery with a pump is more “efficient” than an injectable insulin and insulin needs may decrease
 - Would rather patient be slightly high and we increase the basal gradually than to have a dramatic low blood sugar immediately after starting a pump.
- Beginner’s luck: Patients are on their best behaviors immediately after starting a pump therefore the insulin needs might be less.
 - Heavy basal covering prandial needs
 - More attention to eating post pump start

Bolus Calculators

- All pumps are equipped with this feature.
- Ideally, patients should already be on basal/bolus therapy with CHO counting prior to starting pump therapy.
- Insulin-to-CHO ratio
- Correction Factor (CF) or Insulin Sensitivity Factor (ISF)
- Target Blood Glucose
- Insulin-on-Board or Active Insulin



Bolus Calculator: Insulin-to-CHO ratio

- Pump is preprogrammed with the ratio
- Patient only has to enter total carbohydrates
- Easier to have different ratios at different times of the day
 - Ex: More aggressive breakfast ratio
- Boluses can be given in smaller increments.
 - Children/Insulin sensitive
 - More accurate bolusing

Bolus Calculator: CF or ISF

- Pump preprogrammed with the correction or insulin sensitivity scale
- Can have different correction scales for different times of the day
 - Bedtime
 - AM meal
- Can give increments of correction (vs. whole or $\frac{1}{2}$ units)

Bolus Calculator: Target Blood Glucose

- Pre-programmed target glucose (or glucose range)
- Pump will give increments to correct BS down to this target
- Target is individual
 - Tight BS control
 - Fear of hypoglycemia
- Can set multiple targets
 - Ex: Less aggressive target at HS

Bolus Calculator: Insulin-on-Board

- Insulin that remains from previous boluses and has the pharmacodynamics ability to lower blood glucose levels
- Pump subtracts active insulin before calculating bolus
- Takes into account recent correction boluses (and possibly meal boluses)
- Can be set from 2 to 6 hours (Default setting is 4 hours)
 - Shorter duration: Tighter control but higher risk of “stacking”
 - Longer duration: Delayed gastric emptying



Temporary Basal

Feature in the pump that allows pt to temporarily:

- Decrease the basal rate for a period of time (Ex. Physical activity)
- Increase the basal rate for a period of time (Ex. Illness, steroid use)



Extended Bolus Features

- With injections, there is only one way to give a bolus.
- Dual Wave (Combo Bolus): Can give percentage of the bolus immediately (which is just like a normal bolus) but also give the other portion over a period of time (which is the extended portion)
 - High fat and high CHO meals
 - Mixed meals (pizza, Mexican, etc)
- Square Wave Bolus: Can stretch the entire bolus over a period of time. This may match the post-prandial glucose response better depending on the type of meal you have.
 - Snacking or grazing over a period of time

Smaller basal and bolus increments

- The ability to adjust basal rates in very small increments (in some pumps as low as 0.025) can greatly improve glycemic control and reduce hypoglycemia and hyperglycemia.
- Bolus adjustments as low as 0.10 units
- With injections, the options are half or whole unit adjustments.

- Who?
 - Extremely insulin sensitive
 - Pediatric population

Suspend/Disconnecting the Pump

Less is more!

- Shower
 - Forget to resume
- Maximum time: One hour daily
 - Lose basal insulin needed for the day
 - Omnipod: no disconnect
- Swimming or athletics
 - Frequent SBGM
 - Reconnect to bolus periodically
 - Many pumps are waterproof.

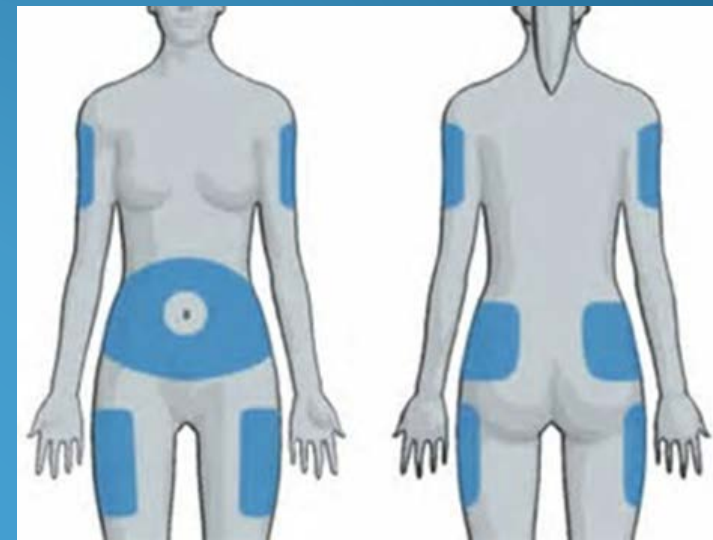


Insulin Pump Sites

- Abdomen: consistent rate of absorption
 - May need to “give it a break”
- Upper hip/buttock
- Thigh
- Arm
 - Popular for Omnipod

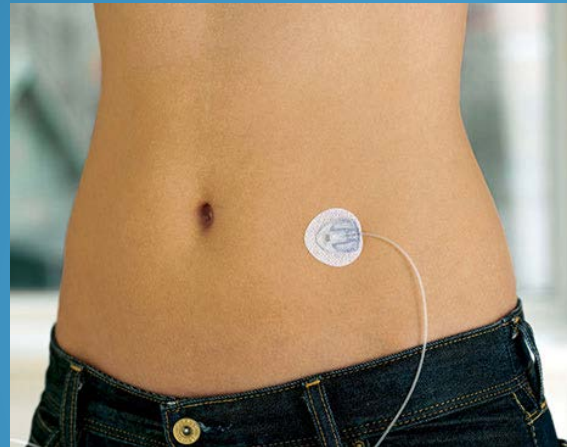
Need to consider

- Ability to disconnect
- Dexterity for insertion



Infusion Sets

- Inserted subcutaneously
- Worn 1-3 days
 - >3 days: Increased risk of infection and/or scarring
- Some sets can be used with multiple pumps and some are brand-specific.



2 basic types:

- Metal/steel needle cannula
 - Less kinking
 - Pediatric population, pregnancy and low BMI
- Teflon cannula
 - May be more comfortable
 - May have more issues with kinking

Pump Downloads

Important Tool for both the patient and provider



Pump settings: Where to find them

1. Basal Rates
2. Carbohydrate Ratios
3. Sensitivity
4. Active insulin time
5. Glucose targets

Medtronic **Device Settings**
9/14/17

Generated: 9/14/17 3:32 PM Page 5 of 6
Data Source: Paradigm Revel - 723 (556642)

Basal			
Basal Rate (U/hr) Updates			
Max Basal Rate	2.00 U/hr		
Temp Basal Type	Percent of Basal		
Standard (active) Updates			
24-Hour Total	20.600 U	24-Hour Total	
Time	U/hr	Time	U/hr
00:00	0.800		
04:00	1.00		
11:00	0.800		
16:00	0.800		

Bolus			
Carb Ratio (g/U) Updates			
Time	Ratio	Time	Ratio
00:00	15.0		

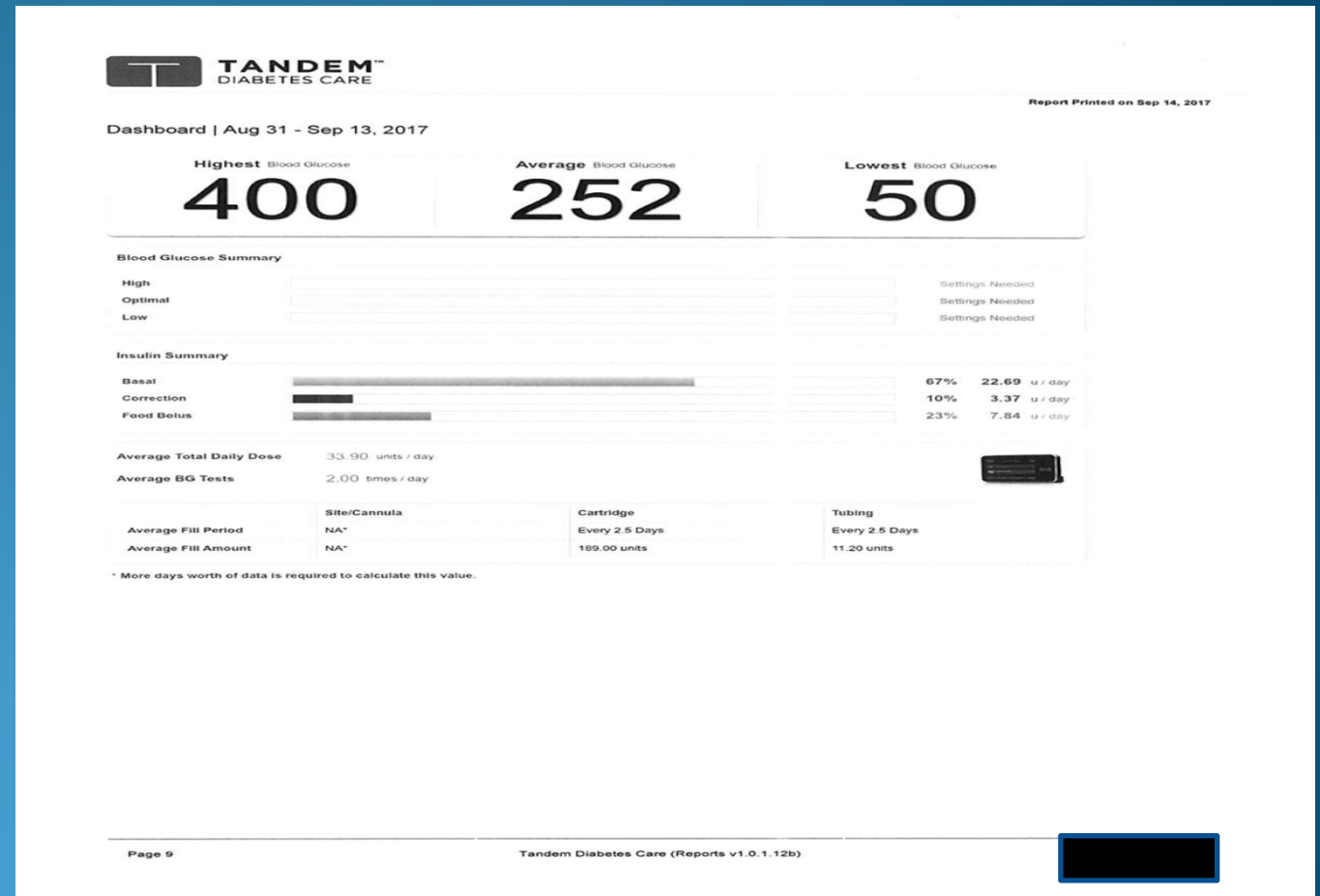
Insulin Sensitivity (mg/dL/U)			
Time	Sensitivity	Time	Sensitivity
00:00	50		

BG Target (mg/dL)					
Time	Low	High	Time	Low	High
00:00	100	150			

Bolus			
Maximum Bolus	25.0 U		
Dual / Square (Variable)	Off		
Blood Glucose Reminder	Off		
Bolus Wizard On			
Active Insulin Time (h:mm)	4:00		
Units	g, mg/dL		
Insulin Concentration	--		
Easy (Audio) Bolus Off			
Entry (Step)	0.10 U		
Missed Bolus Reminder Updates			
Start (h:mm)	End (h:mm)	Start (h:mm)	End (h:mm)
--	--		
Utilities			
Alert Type	Beep Medium		
Low Reservoir Warning	Insulin Units		
Amount	20 U		

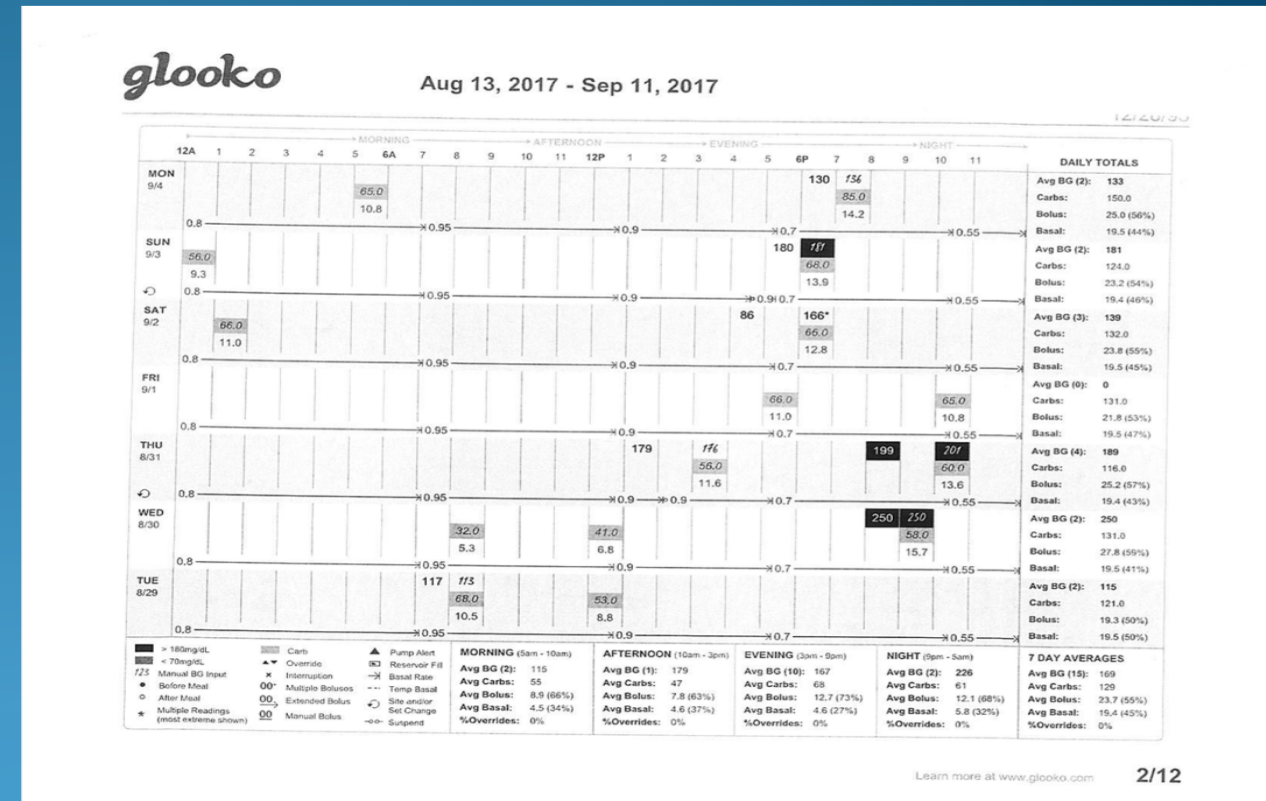
Basal vs. Bolus %

1. Goal is 50-50 distribution
2. Basal heavy may lead to nocturnal and early am hypoglycemia
3. Bolus heavy may lead to post prandial hypoglycemia
4. Can be found in several places in the download



Logbook

1. Summary comparing glucose, CHO, bolus, and basal rates
2. Can see the # of glucose tests
3. Can see the response to a meal bolus
4. Can see if the bolus is manual or per pump calculator – overriding of bolus
5. Can see glucose values superimposed on the basal rate



Set Change Frequency, etc.

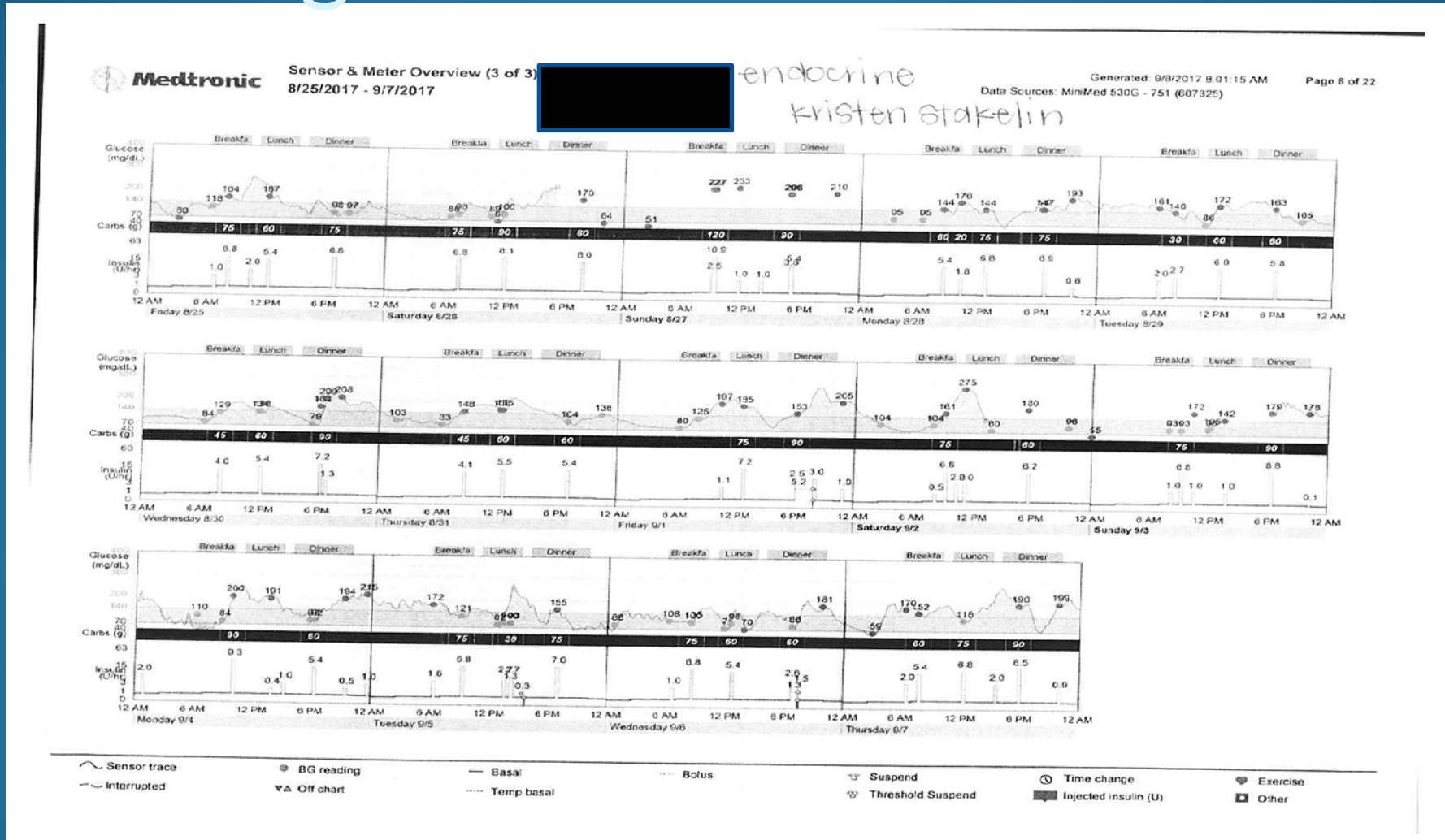
1. Optimal 3days or less
2. Is the patient trying to “stretch” the set change time
3. Omnipod has a “fixed” set change of 3 days
4. Is a cannula fill being done at set change- and lead to post set change highs
5. # of suspends

Medtronic Adherence (1 of 1) [Redacted] Generated: 9/14/17 3:32 PM Page 1 of 6
 9/1/17 - 9/14/17 Data Sources: Paradigm Revel - 723 (556642)

	Glucose Measurements		Bolus Events				Fill Events					Suspend Duration (h:mm)	
	BG Readings	Sensor Duration (h:mm)	Manual Boluses	Bolus Wizard Events	With Food	With Correction	Overridden	Rewind	Cannula Fills	Cannula Amount (U)	Tubing Fills		Tubing Amount (U)
Friday 9/1/17	14			14	6	13	2						
Saturday 9/2/17	13			13	8	9	4						
Sunday 9/3/17	15			15	9	11	6						
Monday 9/4/17	9			9	5	7	3	1	1	1	1	7.7	
Tuesday 9/5/17	11			11	7	8	2						
Wednesday 9/6/17	12			12	6	10	5						
Thursday 9/7/17	15			15	8	11	3						
Friday 9/8/17	11			11	8	8	4	1	1	1	1	6.9	
Saturday 9/9/17	10			10	6	7	2						
Sunday 9/10/17	7			10	7	4	4						
Monday 9/11/17	7			7	4	4	1						
Tuesday 9/12/17	12			12	5	8	5	1	1	1	1	7.1	
Wednesday 9/13/17	6			6	5	3	2						
Thursday 9/14/17	2			2	2								
Summary	10.9/day	0m	0.0/day	11.2/day	58.5%	70.1%	29.3%	3	3	1.0U /fill	3	7.2U/fill	0m

Partial day Suspend Note: Partial days will not be included in summary averages. Days on which a time change occurred are considered to be partial days.

Finger stick glucose vs sensor values



Insulin Pumps and the Older Adult

Concerns

- Decreased or impaired vision
- Decreased hearing or hearing loss
- Limited dexterity
- Consider risk of hypoglycemia

Advantages

- Color screens/touch screens
- Can choose audio, vibrate or combo
- Newer pumps are easier to navigate.



Insulin Pump and Pregnancy

- Tight glycemic control during pregnancy reduces the risk of fetal malformations
- Ideally, pump therapy started pre-pregnancy
- Close monitoring and intensive support
- May get less postprandial hyperglycemia and less hypoglycemia
- 1st trimester, post-prandial bolus with morning sickness
- May need a more aggressive breakfast I:C ratio

Insulin Pumps and Children

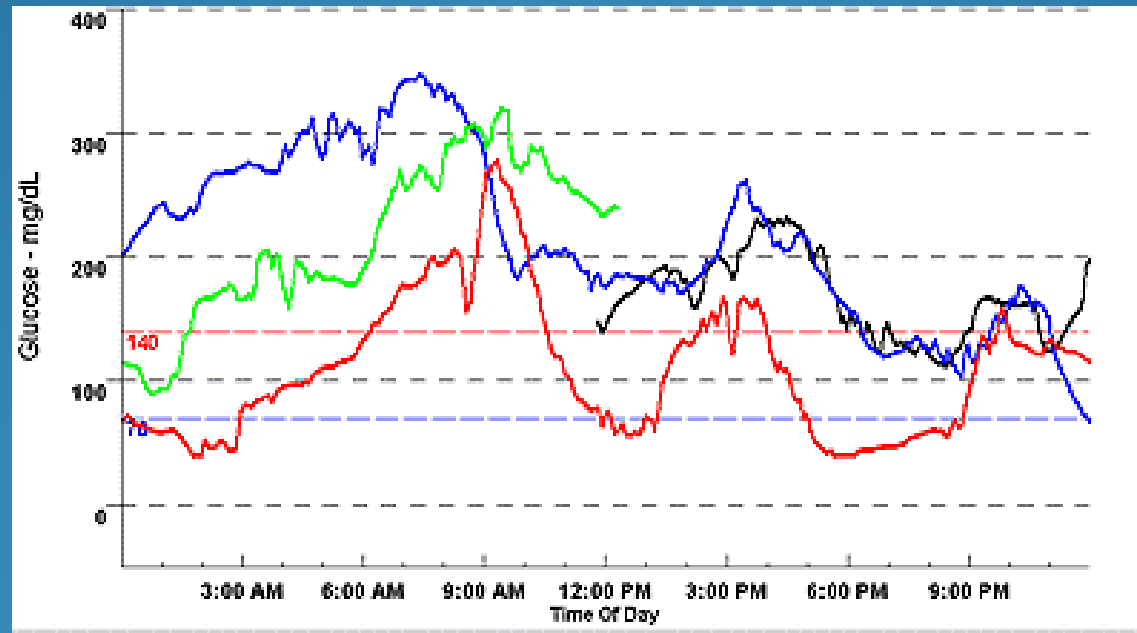
Advantages

- Ability to meet physiologic insulin needs (often ½ unit and 1 unit increments do not meet patient needs): MORE PRECISE DOSING
- Ability to fine-tune insulin doses: multiple basal rates, multiple carb ratios/correction factors
- Ability to prevent hypoglycemia
- Allows for more independence and freedom

Concerns

- Risk for DKA due to no long-acting “backup” insulin
- Requires troubleshooting ability
- Risk for skin infections
- Cost

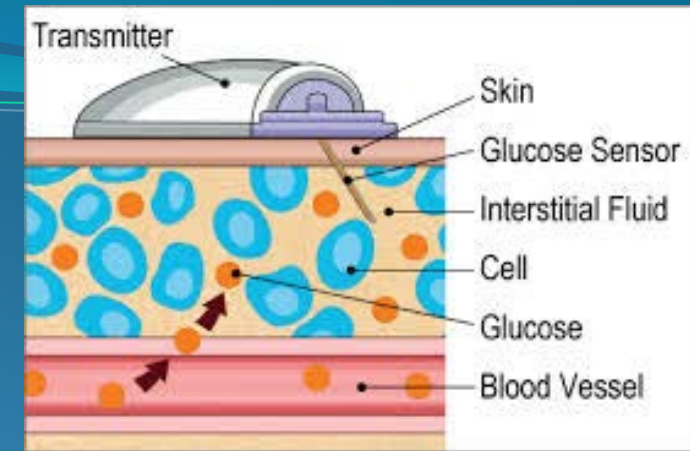
Continuous Glucose Monitoring



Continuous Glucose Monitoring (CGM)

- A device that measures glucose levels constantly (about every 5 minutes)
 - Measures interstitial blood glucose
- Helps to identify trends and patterns to blood glucose levels
- Who might benefit from CGM?
 - Someone with hypoglycemia unawareness
 - Someone who fears lows so badly they purposely run their blood sugar high
 - Someone whose blood sugar overnight is unpredictable
 - Someone who desires better control

Parts of CGM



- 1) Sensor— thin, flexible piece of wire inserted into the skin with a needle; contains enzymes that react with glucose. The reaction sends electrical signal to transmitter.
- 2) Transmitter—small plastic pod that sits on the sensor. Waterproof and reusable. Collects data from sensor and “transmits” to the receiver.
- 3) Receiver—display for the glucose readings. Displays results every 5 minutes. Shows trends, directional arrows, sounds alarms

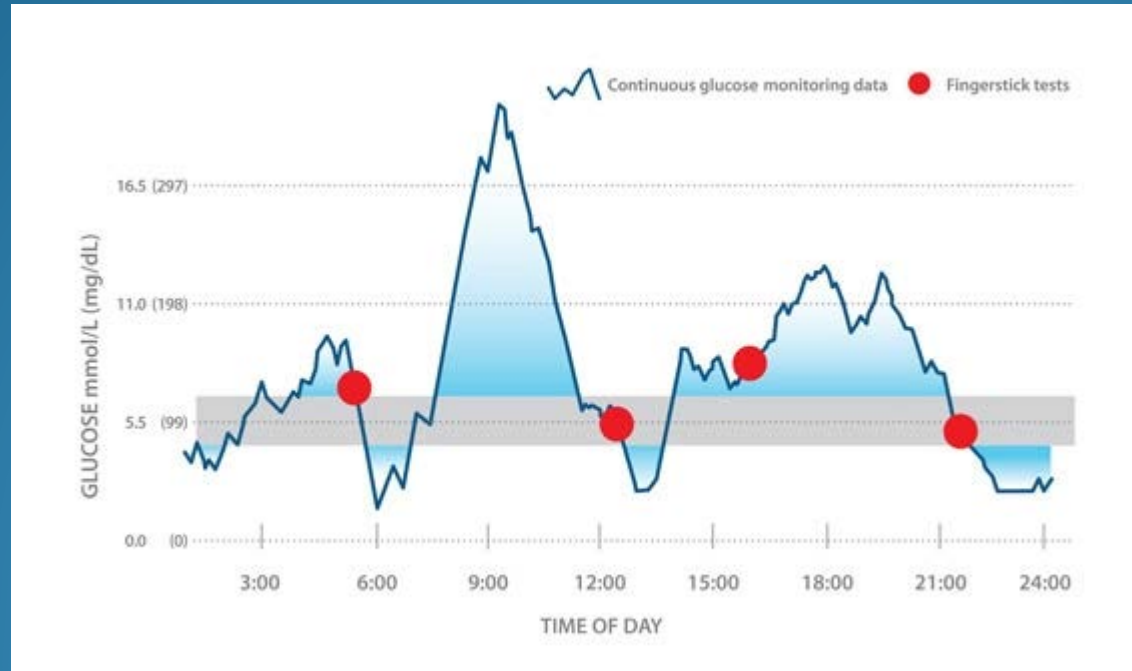
History of CGM

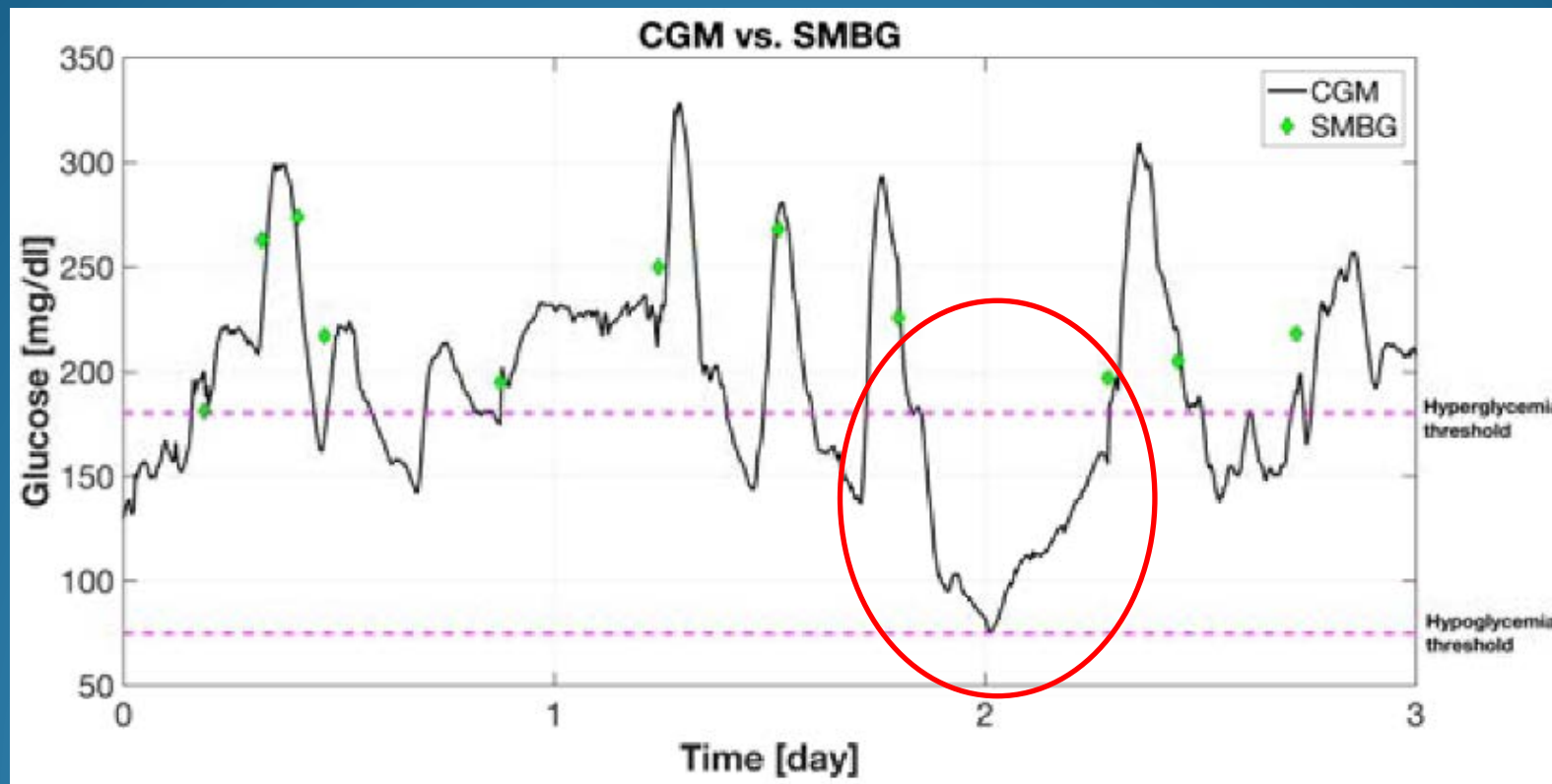


Current CGM Systems Available

- Dexcom G5 Mobile (G4 with Share)
- Medtronic Enlite
- Medtronic Guardian
- Freestyle Libre

Why CGM versus FSBS?





PROFESSIONAL VERSUS PERSONAL

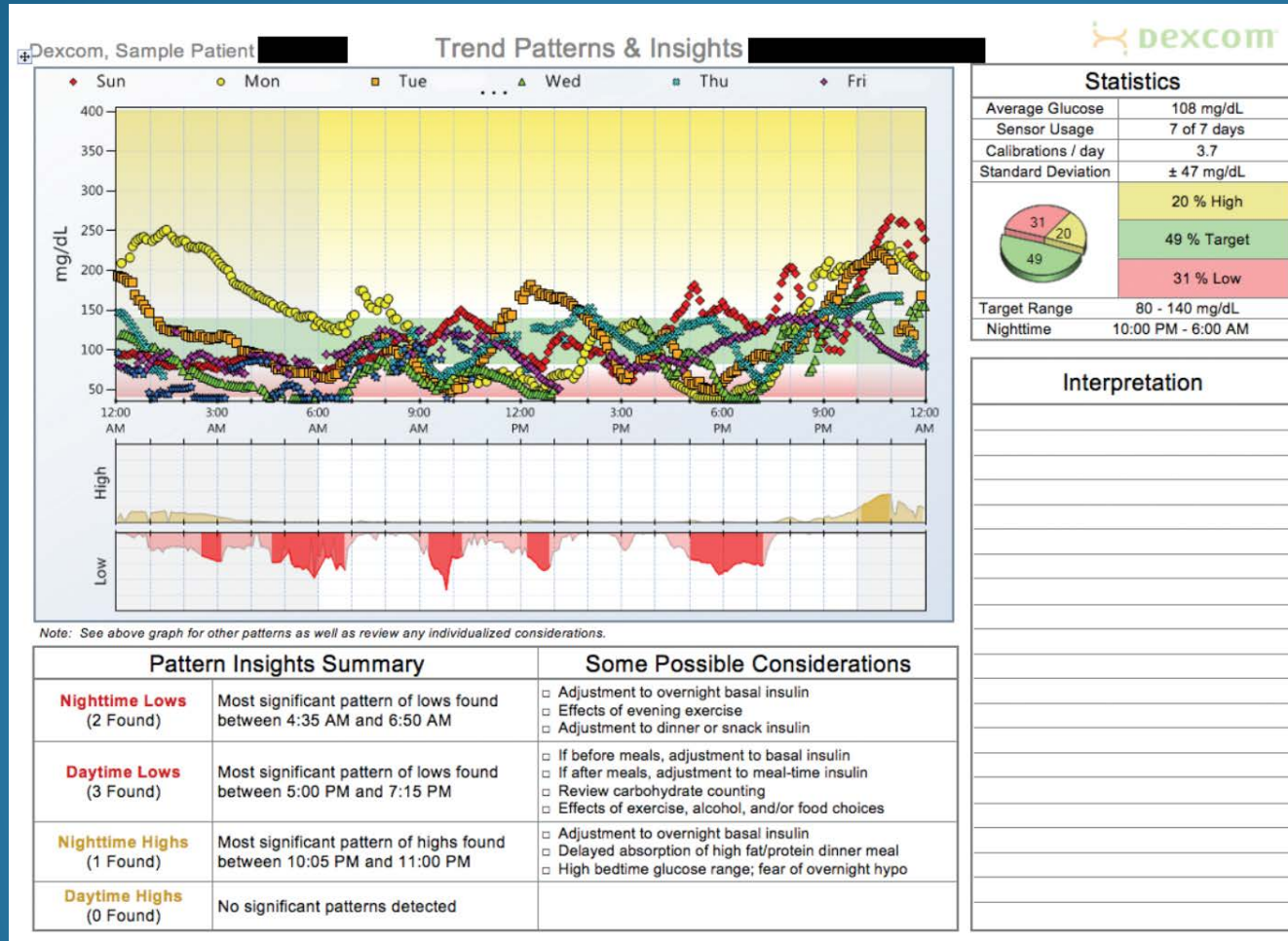
- Professional

- Primarily for practitioners
- Blinded
- Retrospective therapy adjustments
- Worn 3-7 days
- Practitioner can bill for insertion and interpretation

- Personal

- Pt owns device
- Pt can see data and respond
- Real time decision making
- Worn 6-7 days
- Can bill for interpretation at visit

CGM Evaluation





Sensor Daily Overlay

Dec 1 – Dec 7, 2013

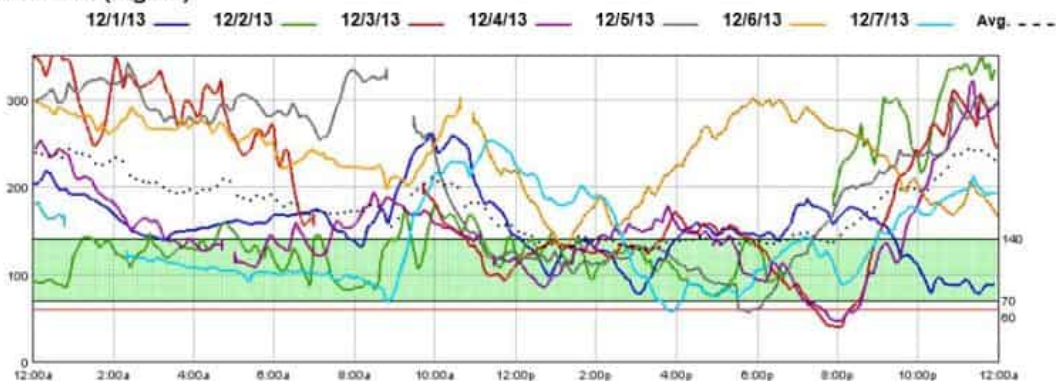
(7 days)

HbA1c: No Data

Pump: MiniMed 530G - 751
Sensor: In use

#602067

Sensor Data (mg/dL)

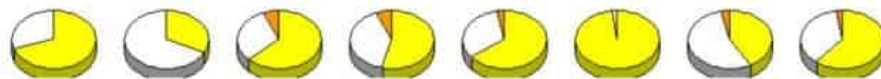


	Sun Dec 1	Mon Dec 2	Tue Dec 3	Wed Dec 4	Thu Dec 5	Fri Dec 6	Sat Dec 7	Average / Total
# Sensor Values	288	274	257	282	281	285	270	1,937
High SG (mg/dL)	261	350	370	321	342	301	252	370
Low SG (mg/dL)	77	75	40	46	56	130	57	40
Average SG (mg/dL)	155	150	194	150	211	236	139	176
Standard Dev.	39	68	87	52	86	43	50	72
MAD %	18.3	56.2	37.4	16.4	34.7	5.7	15.7	23.8
# Valid Calibrations	5	2	4	4	3	3	3	24

Excursion Summary

	Sun Dec 1	Mon Dec 2	Tue Dec 3	Wed Dec 4	Thu Dec 5	Fri Dec 6	Sat Dec 7	Average / Total
# Excursions	2	9	3	6	2	1	4	27
# High Excursions	2	9	2	5	1	1	3	23
# Hypo Excursions	0	0	1	1	1	0	1	4
AUC Above Limit	23.1	27.4	65.9	23.8	82.2	95.9	21.7	48.6
AUC Below Limit	0.0	0.0	1.1	0.8	0.3	0.0	0.2	0.3

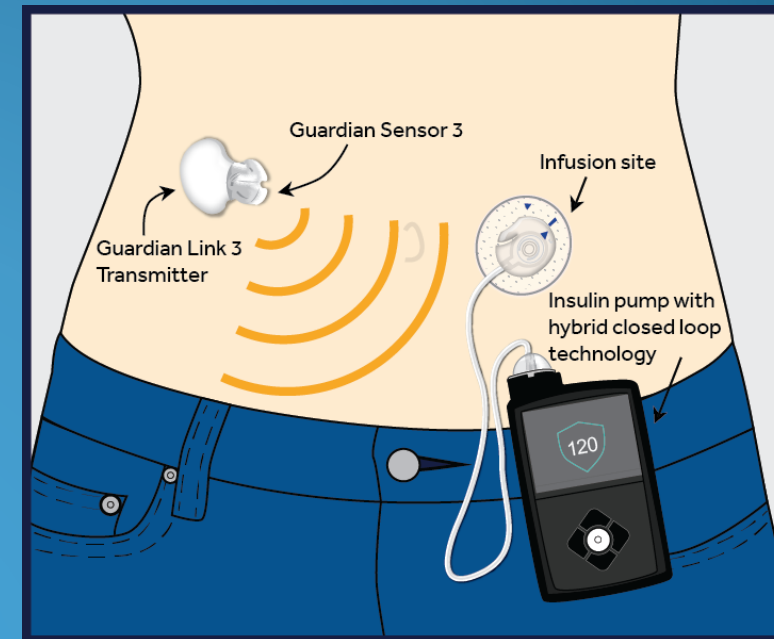
Duration Distribution (hh:mm)



	Sun Dec 1	Mon Dec 2	Tue Dec 3	Wed Dec 4	Thu Dec 5	Fri Dec 6	Sat Dec 7	Average / Total
Above 140	16:45 70%	7:20 32%	13:25 63%	12:35 54%	15:05 64%	23:20 98%	9:25 42%	97:55 61%
Within (70 - 140)	7:15 30%	15:30 68%	6:45 31%	9:30 40%	7:40 33%	0:25 2%	12:20 55%	59:25 36%
Below 70	0:00 0%	0:00 0%	1:15 6%	1:25 6%	0:40 3%	0:00 0%	0:45 3%	4:05 3%

Medtronic 670G: The First Hybrid Closed Loop System

- First system that can be programmed to:
 - Automatically adjust delivery of basal insulin based on continuous glucose monitor sensor glucose values
 - Can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values.
- 670G pump
- Guardian Link 3 transmitter
- Guardian Sensor 3
- Bayer Contour Next Link 2.4 meter



3 Modes of the 670G

- **Manual Mode**

- Suspend on low suspends insulin delivery when glucose goes low
- Suspend before low suspends insulin delivery before glucose drops low, to help prevent lows from occurring.

- **Safe Basal**

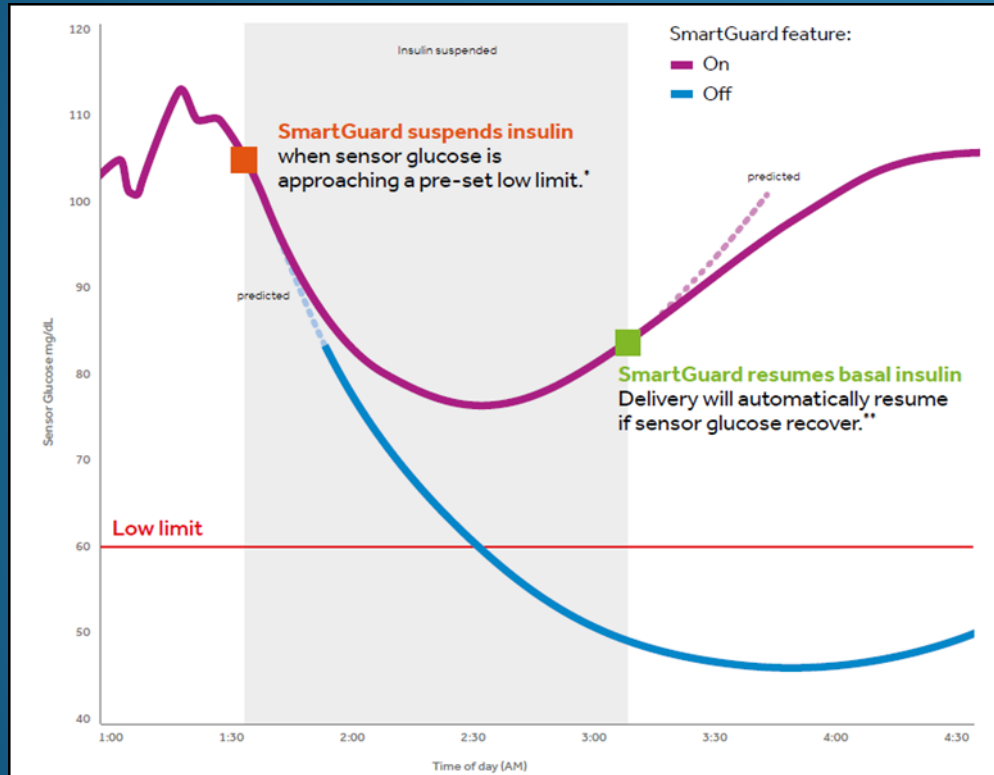
- Provides a fixed basal delivery based on recent deliver needs

- **Auto Mode**

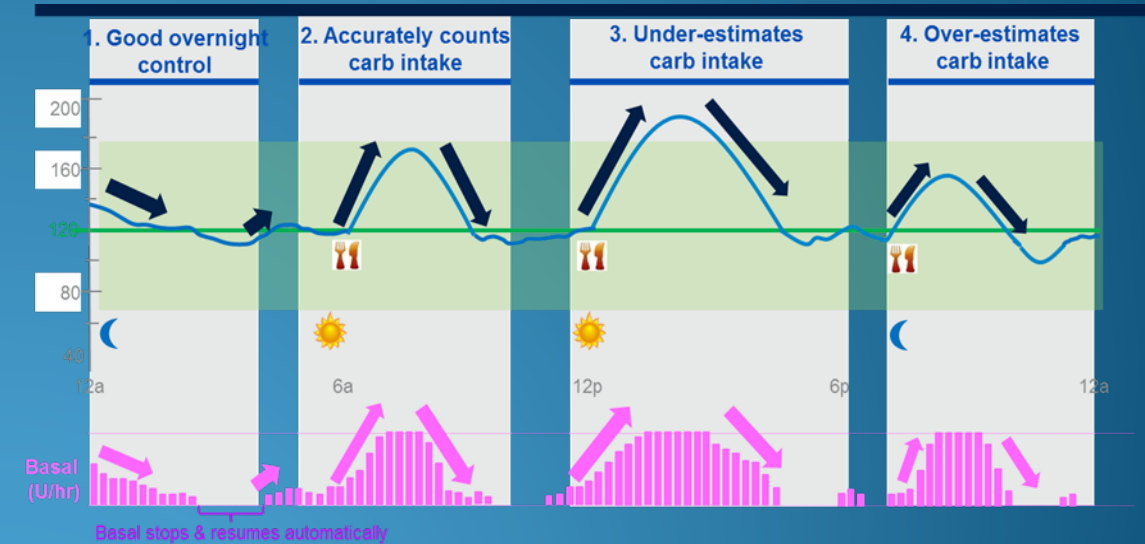
- Can automatically adjust basal insulin delivery based on sensor glucose data to maximize time in range
- Can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values.

670G Features

Suspend before low

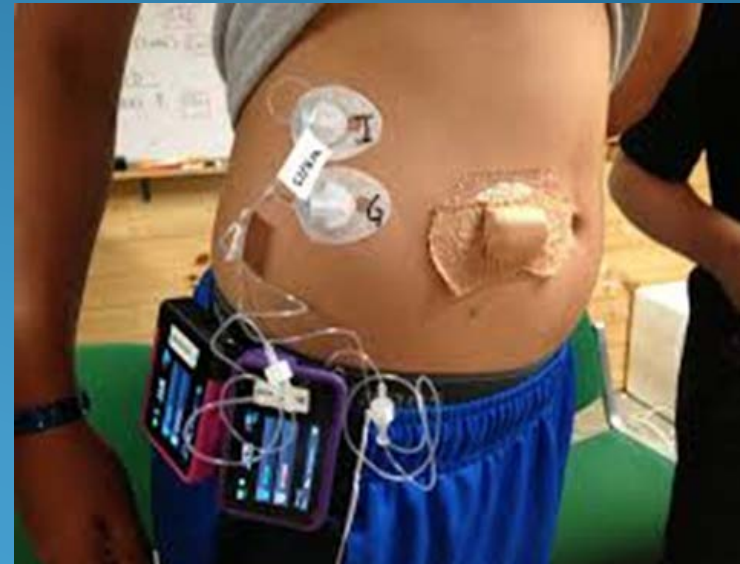
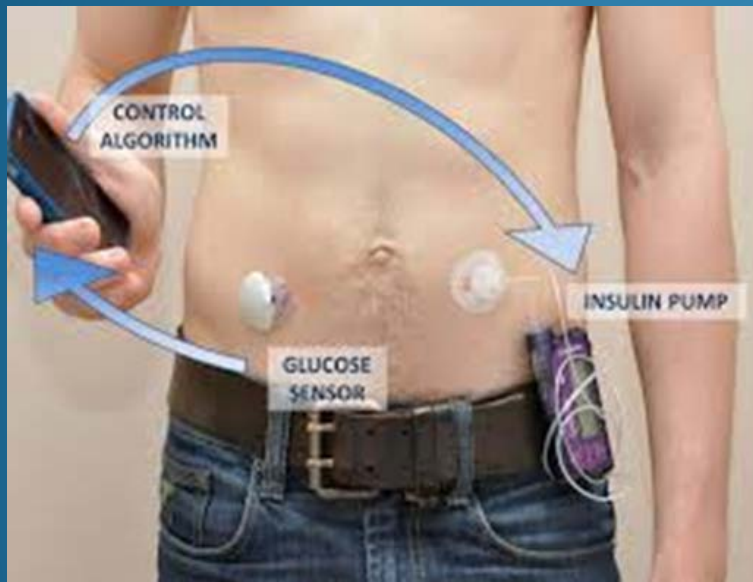


Auto Mode Basal Adjustment



The future of diabetes technology

- There is still a long way to go!



Conclusion

- Diabetes technology is rapidly changing.
- It can be utilized in patients throughout the lifespan.
- The keys to success:
 - Identifying the appropriate pump candidate
 - Education, education, education
 - Interpreting data with patient regularly
 - Lifelong learning

