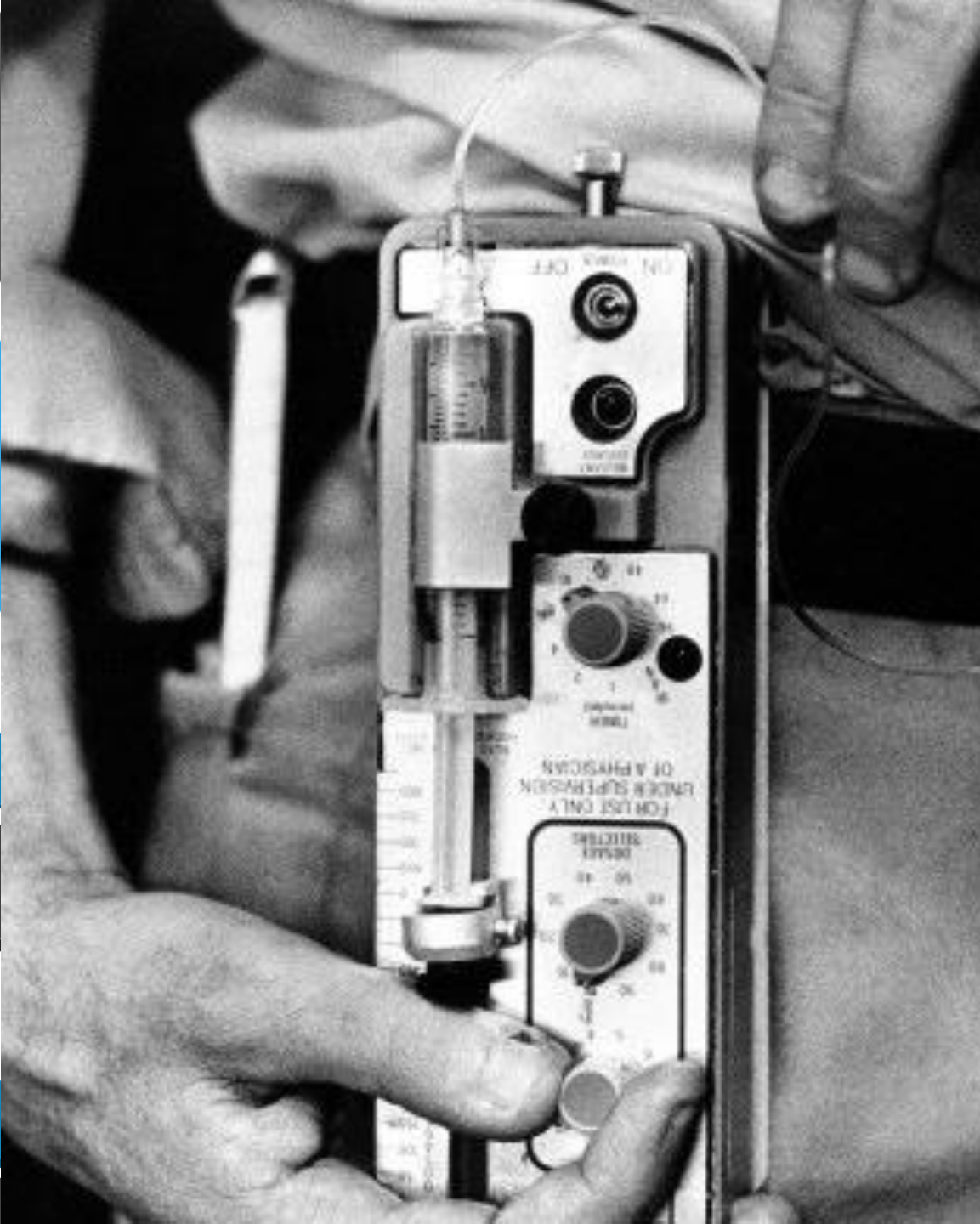


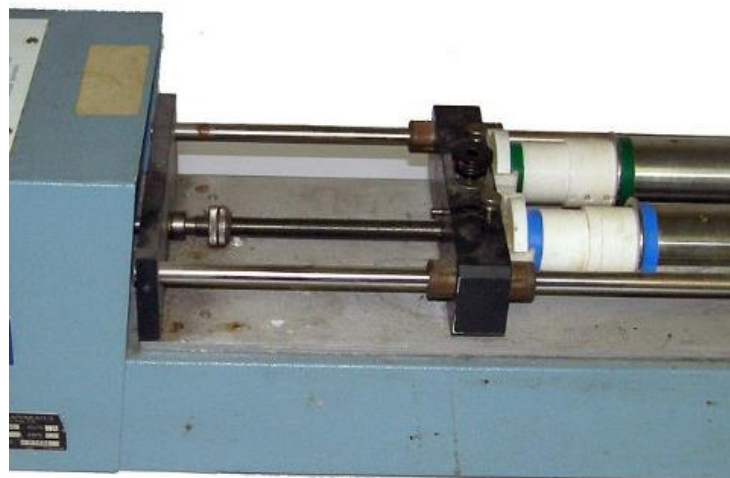


Diabetes Technology

Michigan Medicine
C.S. Mott Children's Hospital
Pediatric Endocrinology



Early Insulin Pumps
(early 1970s)



Objectives

Attendees will be able to verbalize

- The 4 essential elements for successful insulin pumping
- The basic function and components of an insulin pump, and special considerations for pump selection.
- Disease management specific to insulin pump therapy
- What is a continuous glucose monitor (CGM) and its primary function

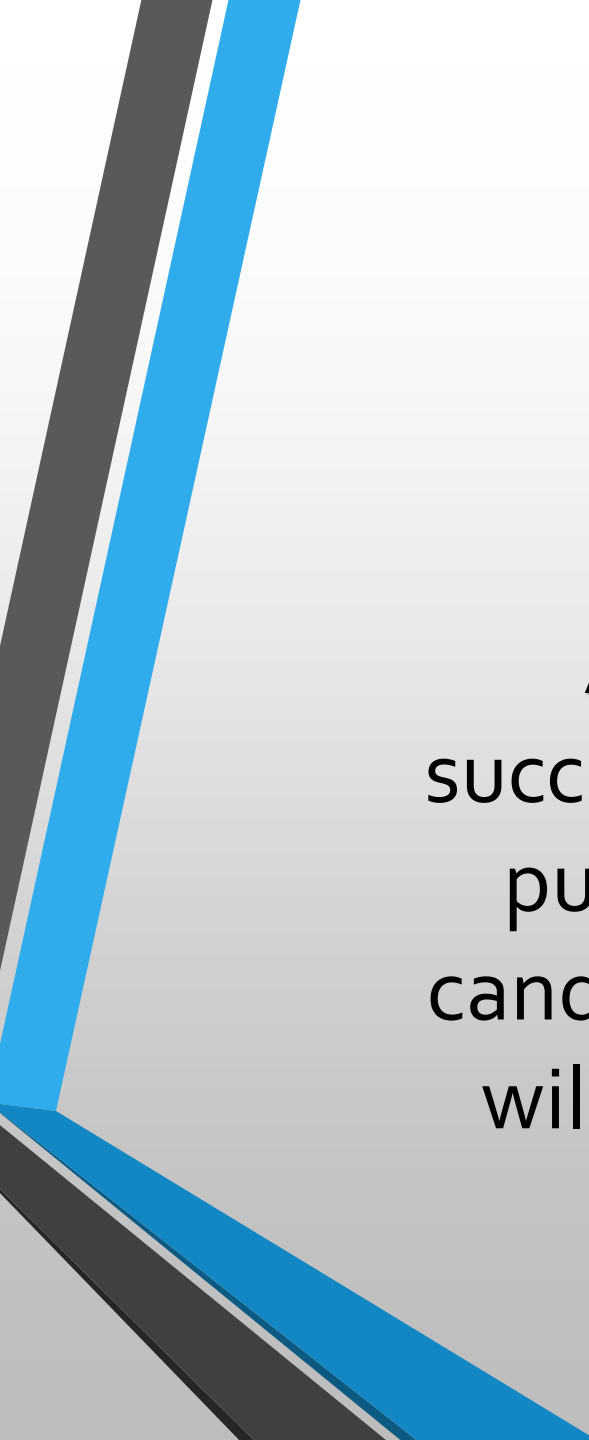
A
successful
pump
candidate
will:

Patient and parent agree to pump therapy and assigned responsibilities

Parents/legal guardians have working knowledge of the insulin pump regardless of the age of the youth and are responsible for daily use of the pump

Monitor and log blood sugar (BG) at least 4 times per day every day

Pump therapy requires monitoring and recording of blood sugars 8-12 times per day at initiation and with dose changes




A
successful
pump
candidate
will be:

Able to interpret
Nutrition Fact Labels

Determine carbohydrate
in foods (“Calorie King”
book & phone apps)


Count the carbohydrate
in every item that is eaten
and dose for all carbs



A
successful
pump
candidate
will be:

Demonstrate knowledge of
diabetes care and management:


- Basic diabetes education must have been completed
- Strong knowledge in how insulin works/action
- Knowledge of blood sugar targets
- Knowledge of A1c target
- How to prevent hypoglycemia & diabetic ketoacidosis (DKA)



A
successful
pump
candidate
will:

Maintain active communication
with the diabetes team:

- Minimum of quarterly clinic visits
- Contact diabetes team when blood sugar goals not being met
- Contact diabetes team when moderate or large ketones are present




What is an Insulin Pump?

A microcomputer
designed to deliver rapid
acting insulin in two ways:

A programmed **basal** rate delivered
in small amounts every few minutes

A user initiated **bolus** dose of insulin
given before meals and snacks, or to
correct a high blood sugar



Key Pump Advantages

- Insulin on Board (IOB)/Active Insulin = how long a bolus lowers the sugar
 - Prevent stacking of insulin doses
- Different Basal Rates
 - Different amounts of basal insulin at different times of the day
- Temporary basal
 - Useful for exercise, illness, stress



Pump Companies

Medtronic

800-646-4633 www.minimed.com

Dexcom (CGM)

877-339-2664 www.dexcom.com



OmniPod

800-591-3455 www.myomnipod.com



Tandem

877-801-6901 www.tandemdiabetes.com

Components



Pump



Insulin – Humalog, Novolog, Admelog, or Apidra (No Long acting)



Reservoir/cartridge to hold the insulin

Every 2-3 days, the insulin, reservoir, tubing, and cannula are changed.



Cannula (tube in the skin)



Tubing

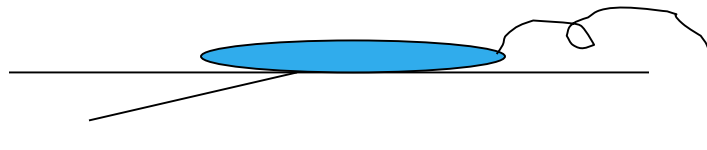


Infusion set

Infusion Sets

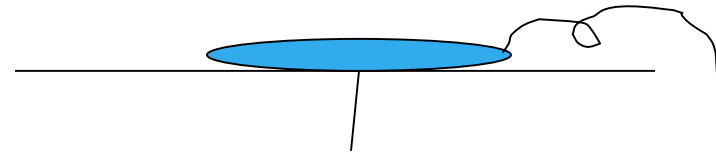
Angled (30°)

- Inserter available for most sets
- Able to use in areas of little subcutaneous fat
- Less likely to kink
- Less likely to be pulled off

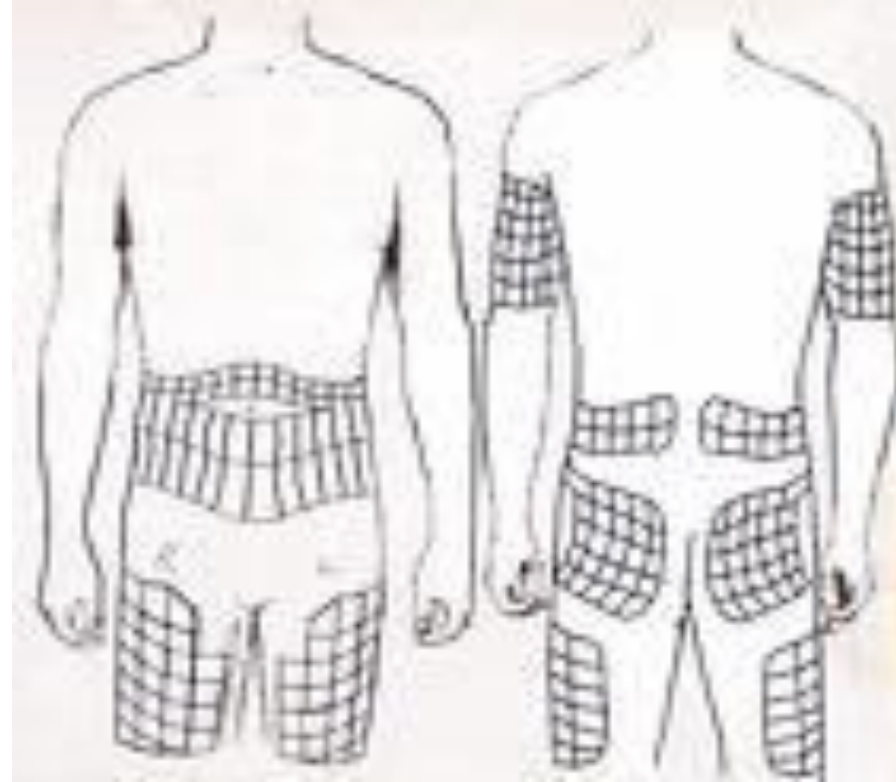


Straight-In (90°)

- Inserter is available for most sets
- Easier to insert in hard-to-reach places



Pump Infusion Set Sites



- Infusion sites are the same as you use for injections
- Rotate sites!
- Change sites every 2 to 3 days (insulin stability)
- If a site infection occurs, the patient needs to see their PCP for antibiotics

Pros and cons

Pros

- Improved blood sugar control
- Fewer shots
- Availability and convenience of insulin delivery
- Ease of covering snacks
- Ease of corrections
- Computer software for blood sugar analysis

Cons

- **Increased risk for ketones**
- Expense
- Risk for skin infections
- Physical/psychological considerations
 - Wearing something 24 hours per day

Special
consideration
for pump
selection



Cartridge size



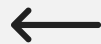
Waterproof vs water resistant



Lowest available basal rate



Tubing vs no tubing



Continuous Glucose Monitoring
Capabilities

Increased risk for ketones

Blood Sugar >300mg/dl or if ill,
check urine for ketones


If moderate or
large ketones

Call the office to determine the insulin dose.

Administer insulin dose via syringe/pen

- Change cartridge, insulin, tubing and infusion set
- Trouble-shoot pump
- Push fluids
- Recheck BG in 1-2 hours

Call every 3 hours until ketones clear



Returning to injections

Patient will need to switch back to the use of a syringe and vial (or insulin pen) for the following situations

- If ketones are present
- If off the pump for >24 hours, you must resume Lantus, Basaglar, Tresiba, or Levemir

Medical
Discontinuation
of Pump
Therapy may
occur if:

Quarterly clinic visits are missed

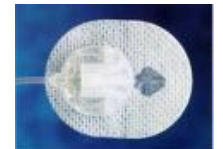
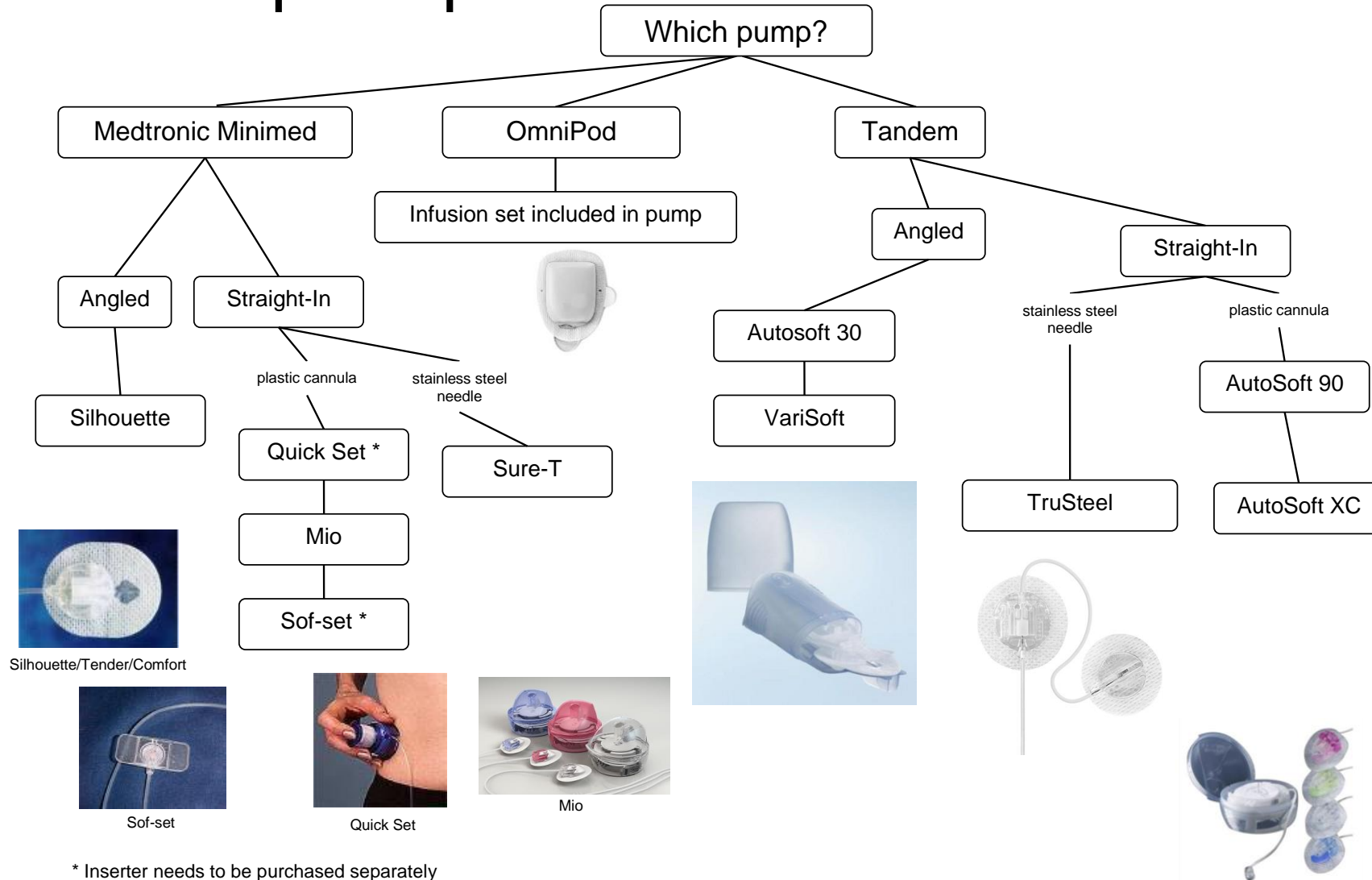
Blood sugars are not monitored at
least 4 times per day

Ketones are not monitored if ill or
blood sugar >300

Pump and meter(s) are not brought to
clinic visits

Hospital admissions as a result of not
following pump therapy guidelines

Multiple options in Infusion Sets



Silhouette/Tender/Comfort



Sof-set



Quick Set



Mio



* Inserter needs to be purchased separately

Continuous Glucose Monitoring (CGM)

Glucowatch first CGM



Continuous Glucose Monitors



Abbott Libre



Dexcom G6



Medtronic Guardian Connect



Medtronic Guardian 3

Continuous Glucose Monitors (CGM)

Continuous glucose monitors are medical devices that monitor a person's glucose levels every 5-10 minutes. They measure the glucose (sugar) in the fluid underneath the skin (the **interstitial fluid**).

The primary function of the CGM is to provide additional information to the user about blood glucose (sugar) levels and trends in real time.

May replace finger pokes

Continuous Glucose Monitors (CGM)

Uses a small sensor that is inserted subcutaneously, similar to a pump catheter/cannula. Two separate sites if on pump therapy.

Confirm blood sugar with finger poke when questioning accuracy of CGM

Continuous Glucose Monitors (CGM)

Follow calibration guidelines per device

Calibration – Blood sugar meter readings are entered into the pump/monitor and are used for calibrations. Calibrations are essential to making sure the glucose sensor maintains its accuracy over time.

Next Steps

Wear your infusion set that was placed today for 3 days.

Skin reaction

Notify the office for the following:

Infusion set falls off

If patient is not present at class, an infusion set must be inserted prior to submitting pump

Technology Breakthroughs in Pediatrics

- Medtronic 670G Closed Loop in June receiving FDA Pediatric Indication for 7 and above, currently researching 2 to 6 year olds.
- Tslim x 2 insulin pump and Dexcom G6 in research process for Closed Loop
- Libre FDA approved for 18 years and up – used off!



Disclosures

- The *Hybrid Closed-Loop Trial in Type 1 Diabetes* (NCT02463097) and *Safety Evaluation of the Hybrid Closed-Loop (HCL) System in Pediatric Subjects with Type 1 Diabetes* (NCT02660827) trials were funded by Medtronic.
- All principal investigators in both clinical trials received support and compensation for conducting the studies, not Study Coordinators. 😊

Background

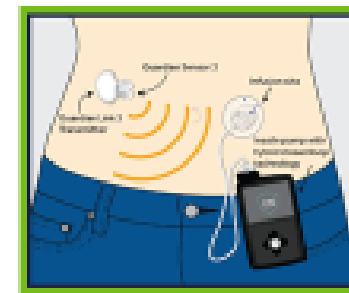
- Achieving and maintaining glycemic control as set by the ADA remains a challenge for many, especially children,¹ with type 1 diabetes (T1D).
- Automated insulin delivery systems that help maintain normoglycemia throughout the day are, now, a reality.
- Three-month, in-home use of the MiniMed™ 670G hybrid closed-loop system in T1D patients, 14-75 years old:²
 - Reduced A1C from 7.4% to 6.9%
 - Increased time in target glucose range (>70-180 mg/dL) from 67% to 72%
 - Decreased time <70 mg/dL from 5.9% to 3.3%
 - Reduced day and night time glucose variability
- This study investigated the safety of the MiniMed™ 670G system in children with T1D, 7-13 years old.

1. Wood JR, Miller KM, Maahs DM, et al. *Diabetes Care*. 2013;36:2035-2037.

2. Bergenstal RM, Garg S, Weinzimer SA, et al. *JAMA*. 2016;316:1407-1408

Insulin Delivery System

- MiniMed™ 670G insulin pump with SmartGuard™ technology.
- Guardian™ Sensor 3 glucose sensor and Guardian™ Link 3 transmitter.
- CONTOUR®NEXT LINK blood glucose meter for calibrations.



WARNING: Indicated for type 1 diabetes patients ≥ 14 years. Medtronic performed an evaluation of the MiniMed™ 670G closed-loop system and determined that it may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. Therefore, this device should not be used in anyone under the age of 7 years old. This device should also not be used in patients who require less than a total daily insulin dose of 8 units per day, because the device requires a minimum of 8 units per day to operate safely.

The MiniMed™670G System is, currently, approved for use only in the US for T1D patients ≥ 7 years. A prescription is required.

MiniMed™ 670G Pivotal trials

BASELINE PATIENT CHARACTERISTICS

- Single arm, multicenter, at-home, and in-clinic or hotel investigations
 - A1C <10%, minimum TDD requirement of >8 units/day
 - Pump therapy for >6 months, +/- CGM
 - For ages 7-13 years, diagnosis of T1D for ≥1 year
 - For ages 14-75 years, diagnosis of T1D for ≥2 years

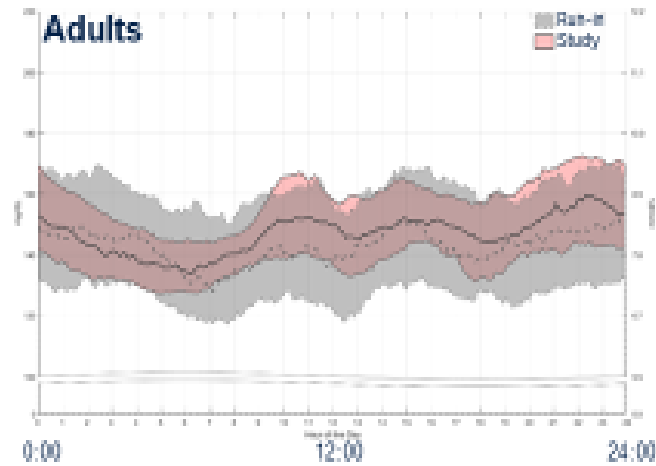
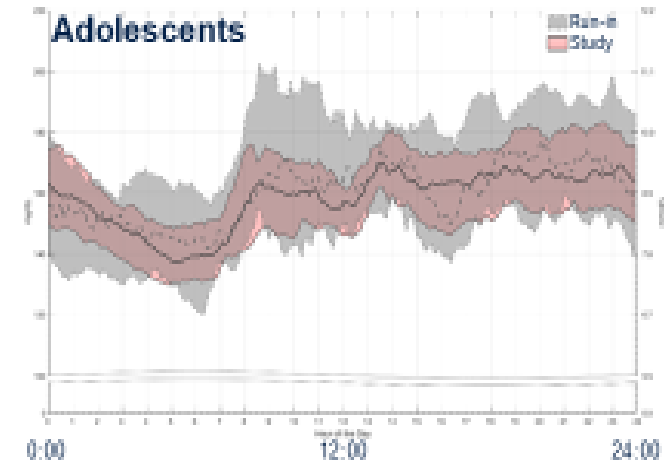
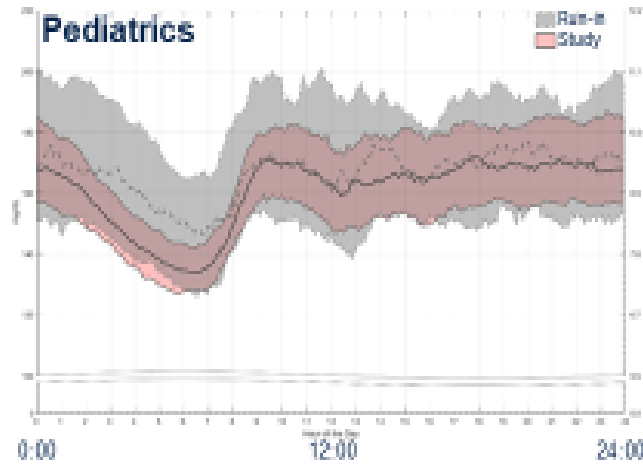
| | Pediatrics (7-13 years) N=105 | Adolescents (14-21 years) N=30 | Adults (22-75 years) N=94 |
|-----------------------------|-------------------------------------|--------------------------------------|---------------------------------|
| Age, years | 10.8 ± 1.8 | 16.5 ± 2.3 | 44.6 ± 12.8 |
| Sex | 49F / 56M | 16F / 14M | 53F / 41M |
| Weight, kg | 42.8 ± 13.0* | 67.4 ± 13.0 | 79.9 ± 18.2 |
| BMI, kg/m ² | 19.1 ± 4.3* | 23.7 ± 3.8 | 27.1 ± 5.4 |
| Duration of diabetes, years | 5.6 ± 2.9 | 7.7 ± 4.2 | 26.4 ± 12.4 |
| TDD, units/kg/day | 0.8 ± 0.2* | 0.8 ± 0.2 | 0.6 ± 0.2 |
| A1C at screening, % | 7.9 ± 0.8 | 7.7 ± 0.8 | 7.3 ± 0.9 |

*One patient's height and weight were not measured at enrollment.

The MiniMed™670G System is, currently, approved for use only in the US for T1D patients ≥ 7 years. A prescription is required.

RESULTS

24-HOUR SENSOR GLUCOSE PROFILES



Median and interquartile range of SG values are shown.

The MiniMed™ 670G System is, currently, approved for use only in the US for T1D patients ≥ 7 years. A prescription is required.

The Libre – 14 day wear CGM device

Designed to be dispensed at pharmacy, more affordable out of pocket. Scans the sensor as often as desired. Initial 12 hour warm up. Phone app receiver





Tslim x 2 with Basal IQ

Basal IQ Feature

- 31% relative time below 70 mg/dL
- Predicts a low <70 mg/dL 30 minutes prior to be less than 70 mg/dL
- Automatically suspends based on Dexcom sensor information
- Automatically resumes once glucose levels rise



References

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- By H. Peter Chase, MD

Pumping Insulin: Everything you Need for Success with an Insulin Pump, 6th edition, 2017

- By John T. Walsh & Ruth Roberts

Think Like a Pancreas: A Practical Guide to Managing Diabetes with Insulin, 2011

- By Gary Scheiner, MS, CDE

Practical CGM: A Guide to Improving Outcomes through Continuous glucose Monitoring, 2015

- By Gary Scheiner, MS, CDE
- Standards of Medical Care in Diabetes. Diabetes Care, Jan 2019;vol 42:sup 1.

Questions or Concerns?



thank you