
INSULIN PUMP THERAPY FROM THE PRIMARY CARE PERSPECTIVE

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AUGUST 2019



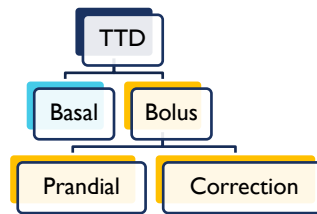
OBJECTIVES

- Describe approaches to intensive insulin therapy.
- Gain historical perspective of insulin pump therapy.
- Identify components of an insulin pump.
- Understand the insulin pump delivery of basal and bolus insulin.
- Describe the basics of carbohydrate counting.
- Identify appropriate candidates for insulin pump therapy.
- Recognize limitations of insulin pump therapy.
- Discuss the advantages and disadvantages of insulin pump therapy.
- Know the myths associated with insulin pump therapy.
- Understand the role of continuous blood glucose monitoring in intensive insulin therapy.

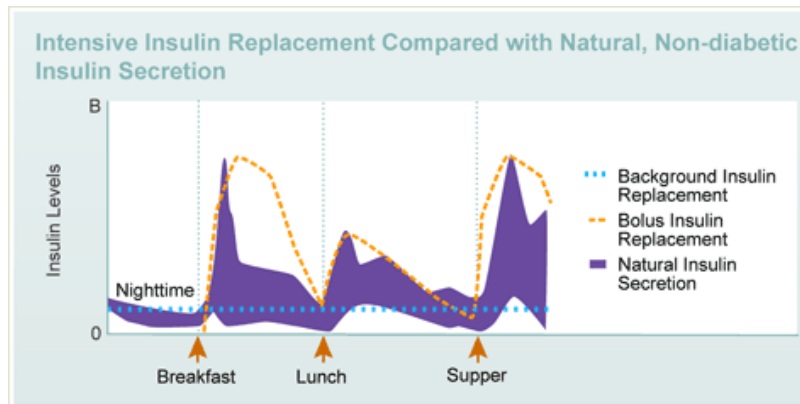
*In the adult patient.

TERMINOLOGY

- MDI-Multiple daily injections
- CSII-Continuous subcutaneous insulin infusion
- TDD-Total Daily Dose (of insulin)
- Basal
- Bolus
 - Prandial
 - ICR-Insulin to Carbohydrate Ratio
 - Correction
 - ISF-Insulin Sensitivity Factor
- SMBG-self-monitoring blood glucose
- CGM-continuous glucose monitoring



INTENSIVE INSULIN REPLACEMENT



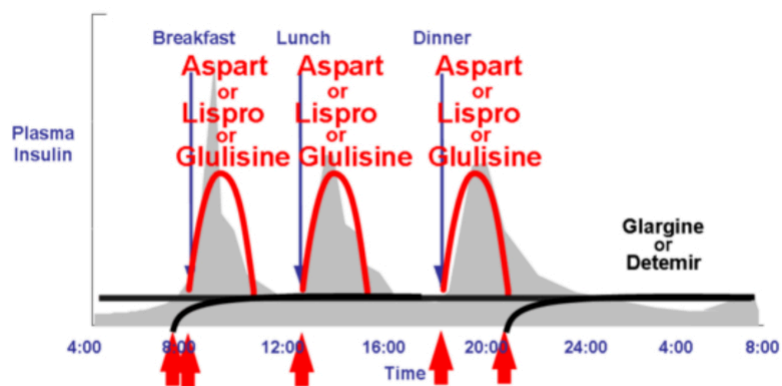
Diabetes Education Online. Diabetes Teaching Center at the University of California, San Francisco. Learning Library Resource Materials. Illustrations. Diabetes Treatment. Type 2 Diabetes. Intensive insulin replacement. Retrieved from website <http://dte.ucsf.edu/learning-library/resource-materials/>.

INSULIN DELIVERY IN TYPE I DM AND INTENSIVE DM MANAGEMENT

- Multiple daily insulin injection therapy
- Continuous subcutaneous insulin infusion

INSULIN DELIVERY IN TYPE I DM AND INTENSIVE DM MANAGEMENT

- Multiple daily insulin injection therapy

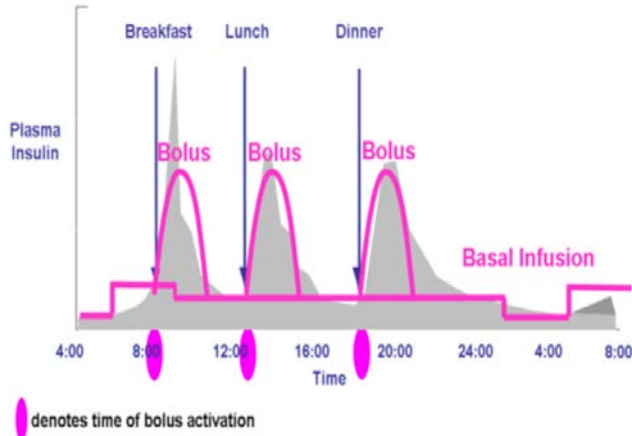


↑ denotes time of insulin injection

Subramanian S, Baidal D, Skyler JS, et al. (Updated 2016 Nov 16) The Management of Type 1 Diabetes. In: Feingold KR, Anawalt B, Boyce A, et al., editors. Endotext [Internet]. South Dartmouth (MA): MDTText.com, Inc.; 2000-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK279114/>

INSULIN DELIVERY IN TYPE I DM AND INTENSIVE DM MANAGEMENT

- Continuous subcutaneous insulin infusion



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HISTORICAL PROSPECTIVE

<p>1963</p> <p>First insulin pump prototype</p>	<p>1977</p> <p>First commercial "artificial pancreas" device</p>	<p>1978</p> <p>"Big Blue Brick" First commercially available insulin pump called the Autosyringe</p>	<p>1983</p> <p>MiniMed introduces their first insulin pump</p>	<p>2017</p> <p>World's first hybrid closed loop system for Type 1 DM</p>
<p>Designed by Dr. Arnold Kadish</p>	<p>Invented by Dean Kamen</p>			<p>Medtronic</p>

INSULIN PUMPS

- ~400,000 patients with type I DM in US use an insulin pump for disease management
- 30-40% of patients with type I DM are using insulin pump and sensor technology

Umperierrez, G.E., Klonoff, D.C. (2018) Diabetes Technology Update: Use of Insulin Pumps and Continuous Glucose Monitoring in the Hospital. *Diabetes Care*. 41(8)15791589.
DOI: 10.2337/dci18-0002

COMMON MYTHS ASSOCIATED WITH INSULIN PUMP THERAPY

- Wearing an insulin pump is uncomfortable.¹
- You can “forget” you have diabetes.¹
- Anyone can use an insulin pump.¹
- Only patients with Type I DM can use an insulin pump.
- I don’t know a lot about technology, so I could never use an insulin pump.²
- If I wear the pump, everyone will know that I have diabetes.²
- You still have to do shots with a pump, and it’s painful.²
- Wearing an insulin pump will interfere with daily activities.²
- Insulin pumps and/or insertion sites are surgically implanted.

¹Myths and Facts About Insulin Pump Therapy

By Joel Shpigel R.Ph. on July 9, 2013

Posted in Insulin Pumps. Accessed <https://www.medtronicdiabetes.com/products/guardian-sensor-3>. July 2019.

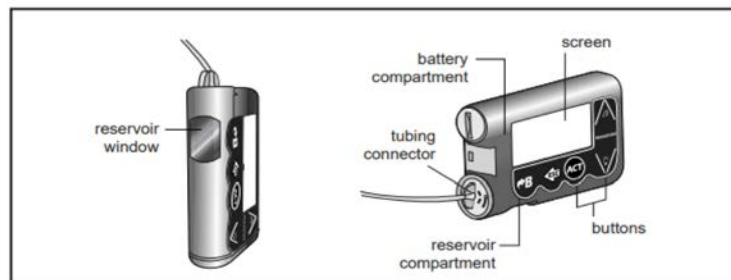
²MYTH VS REALITY: INSULIN PUMPS AND CONTINUOUS GLUCOSE MONITORS
Posted by Editorial Team On July 31, 2013 In Education and Information. The Loop Blog.
Accessed www.Medtronic.com July 2019.

COMPONENTS OF THE TRADITIONAL INSULIN PUMP

- The pump
- Infusion set
- Tubing
- The insulin

COMPONENTS OF THE TRADITIONAL INSULIN PUMP

- The pump
 - Battery powered programmable device with multiple settings (most are about the size of a pager)
 - Reservoir to hold in:
 - Pumping mechanism
 - Battery
 - Computer chip
 - Screen



https://www.medtronicdiabetes.com/sites/default/files/library/download-library/user-guides/Paradigm_Revel_user_guide.pdf

COMPONENTS OF THE TRADITIONAL INSULIN PUMP

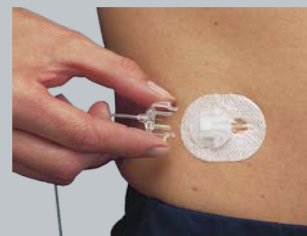
- Infusion set
 - Allows insulin to flow to the subcutaneous tissue via a cannula that is self inserted by the patient via a needle insertion
 - Cannula is then secured to the skin
 - Changed every 3 days



MiniMed™ Quick-set™ infusion set



MiniMed™ Quick-serter™



MiniMed™ Silhouette infusion set



AutoSoft 90™

<https://www.tandemdiabetes.com/products/infusion-sets>



True Steel™

TYPES OF INSULIN PUMPS

- Insulin pumps with tubing
- Tubeless insulin pumps

WHAT IS AN INSULIN PUMP SYSTEM WITH TUBING?

- Small device programmed to deliver insulin subcutaneously via a small cannula



WHAT IS A TUBING FREE INSULIN PUMP SYSTEM?

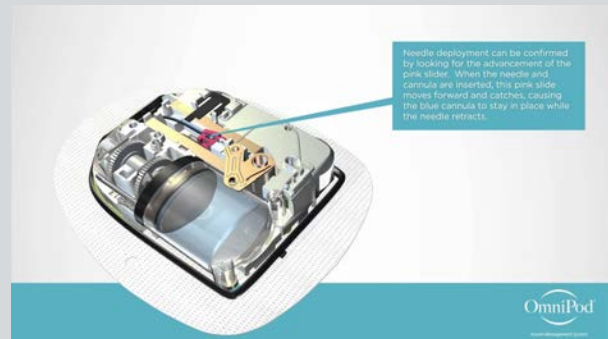
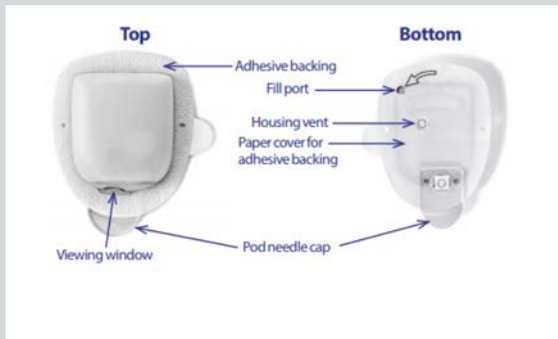


<https://www.myomnipod.com/Omnipod-system>



<https://www.myomnipod.com>

TUBELESS INSULIN PUMP INSERTION

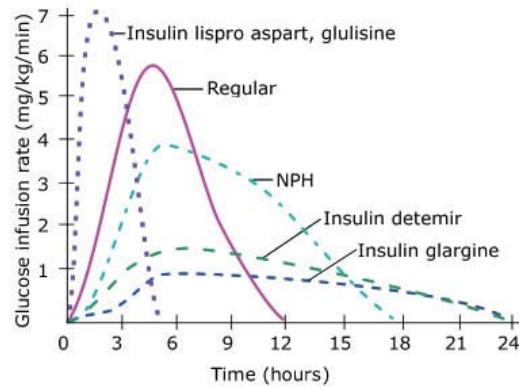


<https://www.myomnipod.com/sites/default/files/inline-files/17845-5A%20Guide%2C%20Eros%20US%20User%20Guide%20Rev%20B.pdf>

COMPONENTS OF THE TRADITIONAL INSULIN PUMP

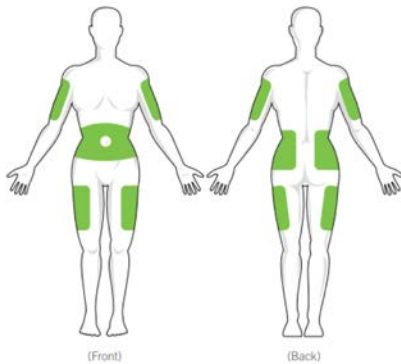
- The insulin
 - Rapid acting insulin

Activity Profiles of Different Types of Insulin

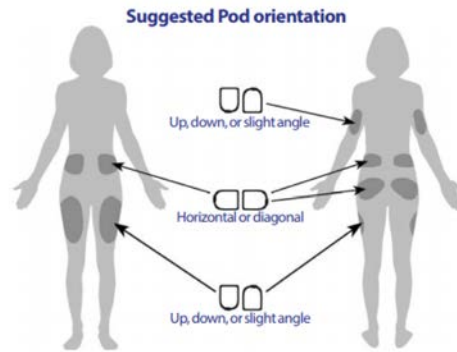


<https://dtk.ucsf.edu/images/charts/4.f.i.jpg>

INSULIN INSERTION SITES



<https://www.tandemdiabetes.com/docs/default-source/product-documents/t-slim-insulin-pump/updated-t-slim-user-guide.pdf>



<https://www.myomnipod.com/sites/default/files/inline-files/17845-5A%20Guide%2C%20Eros%20US%20User%20Guide%20Rev%20B.pdf>

DELIVERY OF INSULIN USING INSULIN PUMP

- **Basal rate-continuous infusion of insulin that is delivered automatically based on settings. Purpose is cover hepatic glucose production and maintain euglycemia during fasting.**

- Programmable basal rate tailored to patient's 24 hour glucose profile and insulin needs
- Single or multiple rates over 24 hour period
- Can be modified for a different rate every hour
 - Dawn phenomenon
 - Daily activity
 - Exercise
 - Work schedule
 - Sleep
- Temporary rate

Basal 1		
24 hr Total: 18 U		
Start	End	U/hr
12:00 A	12:00 A	0.750
Save		

<https://www.medtronicdiabetes.com/customer-support/minimed-630g-system-support/basal-patterns>

Basal 1		
24 hr Total: 20.6 U		
Start	End	U/hr
12:00 A	4:00 A	0.650
4:00 A	12:00 A	0.900
Save		

<https://www.medtronicdiabetes.com/customer-support/minimed-670g-system-support/add-basal-rate>

DAWN PHENOMENON

- Nocturnal spikes of growth hormone secretion result in increase blood sugar without ability of insulin to compensate
- Occurs between 2AM and 8AM (depending on patient's sleep schedule)



https://www.tandemdiabetes.com/docs/default-source/general-guides/005023_b-guide-to-successful-pumping.pdf?sfvrsn=a8553bd7_4

DELIVERY OF INSULIN USING INSULIN PUMP

- **Bolus rate-a dose of rapid acting insulin to cover food intake and/or lower an elevated blood sugar**
 - Prandial-bolus dose of insulin with each meal or snack based on planned carbohydrate intake
 - Insulin to carbohydrate ratio
 - Correction-bolus of insulin to “correct” an elevated blood sugar
 - Insulin sensitivity factor
 - Calculators
 - Individualized prandial and correction insulin dosing algorithms, blood glucose targets and active insulin time

INSULIN TO CARBOHYDRATE RATIO

- The amount of carbohydrate in grams that one unit of insulin will cover
- ICR 1:10

Goals:

- ✓ Match insulin more closely with planned intake
- ✓ Increase flexibility and timing of food intake

COUNTING CARBOHYDRATES

- Steps:
 1. Develop a meal plan
 2. Learn which foods contain carbohydrates
 3. Use measuring tools

COUNTING CARBOHYDRATES

- Utilize resources for counting carbohydrates

CORRECTION BOLUS

- The amount of blood glucose lowered by one unit of insulin.
- ISF= 1:50

CURRENT INSULIN PUMP MARKET

- Medtronic
- Omnipod
- Tandem

WHAT DOES THE RESEARCH SAY ABOUT INSULIN PUMP THERAPY COMPARED TO MDI?

- Mildly reduced HbA1C
- Improved quality of life
- Reduced incidence of hypoglycemia

Peters, A.L., Ahmann, A.J., Battelino, T., Evert, A., Hirsch, I.B., Murad, M.H., Winter, W.E., Wolpert, H. (2016). Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*, 101(11):3922-3937.

ENDOCRINE SOCIETY CLINICAL PRACTICE GUIDELINES

- Recommendations for CSII over MDI (basal-bolus with analog insulin):
 - Patients with type 1 DM who have not achieved their A1C goal, as long as the patient and caregivers are willing and able to use the device.
 - Patient with type 1 DM who have achieved their A1C goal but continue to experience hypoglycemia or high glucose variability, as long as the patient patient and caregivers are willing and able to use the device.
- Suggestions:
 - Patients with type 1 DM who require increased insulin delivery flexibility or improved satisfaction and are capable of using the device.
 - CSII with good adherence to monitoring and dosing in patients with type 2 DM who have poor glycemic control despite intensive insulin therapy, oral agents, other injectable therapy, and lifestyle modifications .

Peters, A.L., Ahmann, A.J., Battelino, T., Evert, A., Hirsch, I.B., Murad, M.H., Winter, W.E., Wolpert, H. (2016). Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, 101(11):3922-3937.

ENDOCRINE SOCIETY CLINICAL PRACTICE GUIDELINES

- Common themes:
 - “as long as the patient and caregivers are willing and able to use the device”
 - “are capable of using the device”
 - “CSII with good adherence to monitoring and dosing”

Peters, A.L., Ahmann, A.J., Battelino, T., Evert, A., Hirsch, I.B., Murad, M.H., Winter, W.E., Wolpert, H. (2016). Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, 101(11):3922-3937.

PATIENT REQUIREMENTS FOR INSULIN PUMP USE

- Motivated
- Responsible
- Knowledgeable about diabetes self care
- Desires better glycemic control
- Psychologically stable
- Willingness to monitor blood sugars a minimum of four times daily
- Willing to learn and utilize carbohydrate counting
- Willing to undergo insulin pump training to safely use technology
- Appropriate expectations of capabilities of insulin pump therapy
- Understands that success of insulin pump therapy is reliant on knowledgeable user
- Acknowledges that the insulin pump is not autonomous
- Adherence to blood glucose monitoring and interaction with insulin pump team is paramount to success
- Recognizes as a longer term therapy
- Willingness to comply with medical follow-up

Bode, B.W. Medtronic Pumping Protocol. A Guide to Insulin Therapy Initiation.

LIMITATIONS OF INSULIN PUMP THERAPY

- Limitation of intensive blood glucose control
- **Hypoglycemia**

ADVANTAGES OF INSULIN PUMP THERAPY

- Increased flexibility in lifestyle.
- Predictable insulin delivery.
- Precise insulin delivery.
- Ability to accurately deliver 1/10th of a unit of insulin.
- Tighter blood glucose control, while reducing the risk of low blood glucose.
- Reducing episodes of severe hypoglycemia.
- Reducing wide fluctuations in blood glucose.
- Helping manage the "dawn phenomenon."

The Advantages and Disadvantages of an Insulin Pump. Diabetes Information & Resources » Managing Diabetes » The Advantages and Disadvantages of an Insulin Pump? © 2019 by Joslin Diabetes Center. Accessed www.joslin.org July 2019.

DISADVANTAGES OF INSULIN PUMP THERAPY

- Risk of skin infections at the catheter site.
- Risk of diabetic ketoacidosis (DKA) from pump malfunction or absorption problems.
- Cost: pumps are expensive, plus the continuing cost of supplies.
- Checking blood glucose at least 4 times per day.
- Letting others know that you have diabetes.

The Advantages and Disadvantages of an Insulin Pump. Diabetes Information & Resources » Managing Diabetes » The Advantages and Disadvantages of an Insulin Pump? © 2019 by Joslin Diabetes Center. Accessed www.joslin.org July 2019.

COMPLICATIONS OF INSULIN PUMP THERAPY

- Failure to deliver the required amount of insulin
 - Disruption of insertion site (visible or invisible), kink in tubing, machinery malfunction
 - User error (inadvertent or incorrect changes to pump settings or bolus delivery calculations)
- Hypoglycemia

DAY TO DAY

No matter the delivery system

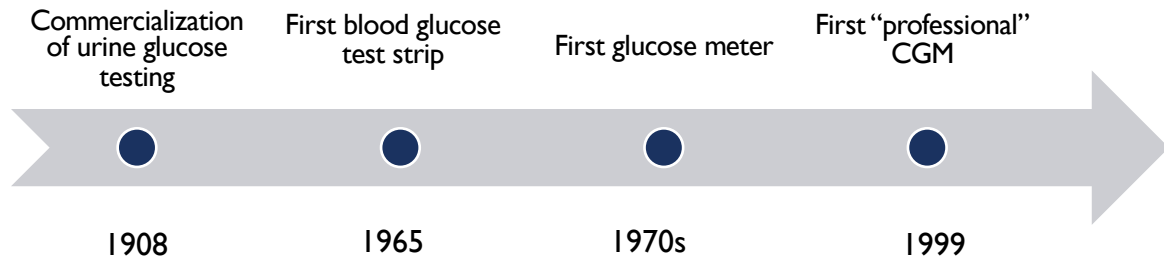
- Blood glucose testing supplies
- Insulin
- Fast acting carbohydrate to treat hypoglycemia
- Extra snack
- Medical alert identification
- Injectable glucagon for emergency treatment
- Back up MDI plan if pump failure
 - With insulin, supplies, prescriptions
- Sick day plan
 - Ketone test strips



Insulin Pump users

- Pump supplies
- Infusion set supplies

HISTORY OF GLUCOSE MONITORING



Hirsch, I.B. History of Glucose Monitoring. Accessed from <https://professional.diabetes.org> July 2019

CONTINUOUS GLUCOSE MONITORING (CGM)

- Real time measurement of glucose levels 24 hours daily
 - Provides comprehensive picture of glycemic variability
 - Allows glucose fluctuations to be linked to daily events
 - Data can be downloaded to observe glucose trends

CONTINUOUS GLUCOSE MONITORING (CGM)

- Two types
 - Real time
 - Continuously report glucose levels
 - Alarm for hypoglycemic and hyperglycemic excursions
 - Intermittently scanning
 - Does not communicate continuously
 - Communicates on demand
 - Does not have alerts
 - Approved for adults only

American Diabetes Association. 7. Diabetes technology: Standards of Medical Care in Diabetes—2019. Diabetes Care 2019;42(Suppl. 1):S71–S80

CONTINUOUS GLUCOSE MONITORING (CGM)

3 parts:

1. Sensor
 - Measures glucose concentration in interstitial fluid every five minutes
 - Delay between blood glucose value and interstitial value
 - Inserted under the skin by user with an applicator
 - Can be worn for 7-14 days depending on system
2. Transmitter
 - Sits on top of the sensor and transmits data wirelessly to receiver
3. Receiver (insulin pump, device, smart device)
 - Displays real-time glucose number, trend and history

CONTINUOUS GLUCOSE MONITORING (CGM)

- Generates downloadable data
 - Provides a measure of time blood glucose in within range
 - Duration and severity of hypoglycemia
 - Trends
 - Relationships to other activities
- Can alert to high and low blood sugars
- Newer devices require fewer or no calibration

Aijan, R., Slattery, D. & Wright, E. (2019) Continuous Glucose Monitoring: A Brief Review for Primary Care Practitioners. *Advances in Therapy*. 36(3): 579-596.

CONTINUOUS GLUCOSE MONITORING (CGM)

- Integration of CGM with insulin pumps includes both threshold and predictive hypoglycemia suspend feature.
- Some devices allow data to be shared with others (example-allow a parent to remotely monitor the child's blood sugars)

Rodbard D. (2016). Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities. *Diabetes technology & therapeutics*, 18 Suppl 2(Suppl 2), S3-S13. doi:10.1089/dia.2015.0417

CGM DEVICES CURRENTLY AVAILABLE IN THE US

	Freestyle Libre 14-day	Dexcom G6	Medtronic Guardian Sensor 3	Senseonics Eversense
Fingerstick calibration	0	0	2/day	2/day
Treatment decisions	No additional fingerstick	No additional fingerstick	Requires fingerstick confirmation before treatment	Requires fingerstick confirmation before treatment
Wear length	14 days	10 days	7 days	90 days
Alarms for high and low blood sugars	No	Yes	Yes	Yes

<https://diatribe.org/continuous-glucose-monitors>

ARTIFICIAL PANCREAS-CLOSED LOOP SYSTEM

- Automated basal insulin delivery based on sensor data
 - Insulin pump, CGM device and algorithms
 - “Threshold suspend” feature
 - “Auto mode” feature

Subramanian S, Baidal D, Skyler JS, et al. (Updated 2016 Nov 16) The Management of Type 1 Diabetes. In: Feingold KR, Anawalt B, Boyce A, et al., editors. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK279114/>

COMMON MYTHS ASSOCIATED WITH INSULIN PUMP THERAPY- REVISITED

- Wearing an insulin pump is uncomfortable.¹
- You can “forget” you have diabetes.¹
- Anyone can use an insulin pump.¹
- Only patients with Type I DM can use an insulin pump.
- I don't know a lot about technology, so I could never use an insulin pump.²
- If I wear the pump, everyone will know that I have diabetes.²
- You still have to do shots with a pump, and it's painful.²
- Wearing an insulin pump will interfere with daily activities.²
- Insulin pumps and/or insertion sites are surgically implanted.

¹Myths and Facts About Insulin Pump Therapy

By Joel Shpigel R.Ph. on July 9, 2013

Posted in Insulin Pumps. Accessed <https://www.diabetespharmacist.com/2013/07/articles/insulin-pumps/myths-and-facts-about-insulin-pump-therapy/> July 2019.

²MYTH VS REALITY: INSULIN PUMPS AND CONTINUOUS GLUCOSE MONITORS

Posted by Editorial Team On July 31, 2013 In Education and Information. The Loop Blog. Accessed www.Medtronic.com July 2019.

REALITIES OF INSULIN PUMP THERAPY

- “The one absolute requirement for using a pump is that you and/or your caregivers are ready and willing to do what it takes to use the pump safely.”
- The insulin pump does not eliminate the need to check blood glucose and give insulin before a meal.
- There is more technology involved with insulin pump use than using injections.
- It only contains short acting insulin.
 - Must have a back up plan (and insulin and supplies) if pump malfunction.
- It is expensive but covered by insurance.
- It is an extra piece of hardware.
- It is a choice.
- It is not lifelong but does require commitment.

Insulin Pumps. American Diabetes Association. www.diabetes.org. Accessed July 2019.

- “Important to note, success of these devices and technologies is directly linked to the level to which people are educated, capable, and willing to use them.”

Peters, A.L., Ahmann, A.J., Battelino, T., Evert, A., Hirsch, I.B., Murad, M.H., Winter, W.E., Wolpert, H. (2016). Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, 101(11):3922-3937.

- “Only providers whose practice can assume full responsibility for a comprehensive pump management program should offer this technology.”

Grunberger, G., Abelseith, J.M., Bailey, T.S., Bode, B.W., Handelsman, Y., Hellman, R., Jovanovic, L., Lane, W.S., Raskin, P., Tamborlane, W.V., Rothermel, M.A. (2014). Consensus Statement by the American Association of Clinical Endocrinologists/American College of Endocrinology Insulin Pump Management Task Force. *Endocrine Practice*. 20(5):463-489.

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