

Pumps and Sensors

**-The Bionic Patient-**

MY OTHER PANCREAS

**Is Battery Operated**

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Subcutaneous Continuous Insulin Infusion (CSII)

Computerized Basal/Bolus Insulin Delivery

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Where We Stand

- 20-30% of pts with T1DM and 1-2% of insulin-treated patients with T2DM use an insulin pump
- 2016: ~500,000 pts using CSII in the U.S.
- 2017/2018: 40,000 670G pumps shipped
- From 2009-2016 CGM users have increased 35%
- 2050: Up to 1/3 of US residents may have T2DM; many will be insulin-requiring
- **Clinicians must develop a comprehensive understanding of these devices**

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Technological Features of CSII

<p><b>Insulin Delivery</b></p> <p>(not all options available on all pumps)</p>	<ul style="list-style-type: none"> <li>• Small bolus increments: 0.05-0.10 units</li> <li>• Extended boluses for delayed digestion or grazing</li> <li>• Multiple insulin-to-carbohydrate ratios, sensitivity factors, BG targets</li> <li>• Bolus calculators (based on BG level and carbohydrate quantity)</li> <li>• Low basal rates: 0.025-0.05 units/h</li> <li>• Multiple basal rates</li> <li>• Temporary basal rates and suspension mode</li> <li>• Automated delivery based on CGM data</li> </ul>
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Technological Features of CSII

<p><b>Safety Features</b></p> <p>(not all options available on all pumps)</p>	<ul style="list-style-type: none"> <li>• Alarms for occlusion and low insulin reservoir</li> <li>• Active insulin to prevent insulin stacking</li> <li>• Keypad lock</li> <li>• Waterproof or watertight</li> <li>• Auto-suspends insulin delivery when a CGM value reaches or falls below a pre-set threshold.</li> </ul>
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Technological Features of CSII

<p><b>Miscellaneous</b></p> <p>(not all options available on all pumps)</p>	<ul style="list-style-type: none"> <li>• Electronic logbook software (insulin doses, BG levels, carbohydrates)</li> <li>• Integrated food databases with customization</li> <li>• Reminder alarms for BG checks, bolus doses</li> <li>• Wireless communication with remote glucose meter</li> <li>• Integration with continuous glucose monitoring technology</li> </ul>
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**Pumps DO NOT . . .**

- Take over care of patient's diabetes
- Make diabetes perfect
- Lessen the work of diabetes (it's just different)




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**Patient Selection for CSII**

- ~ Ideal Candidates ~
- ~ Patient Selection ~

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**Ideal CSII Candidate**

- Pt with T1DM or intensively managed insulin-dependent T2DM
- Currently performing  $\geq 4$  insulin injections and  $\geq 4$  SMBG measurements daily
- Willing and intellectually able to undergo the rigors of insulin pump therapy initiation and maintenance
- Willing to maintain frequent contact with their health care team

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CSII Candidates of Concern

- Unable/unwilling to perform MDI injections, frequent SMBG and to carb count
- Lack of motivation to achieve tighter glucose control
- Hx of serious psychological or psychiatric condition(s) (e.g., psychosis, severe anxiety, or depression)

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CSII Candidates of Concern

- Substantial reservations about pump usage interfering with lifestyle
- Unrealistic expectations of pump therapy (e.g., belief that it eliminates the need to be responsible for diabetes management)

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Patient Selection Criteria

- Self-motivated
- Acceptance of diabetes
- Ability to problem solve
- Financial resources



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Finances

- More expensive than multiple daily injections
- Initial expense
  - Pump: ~\$7,000
  - Start-up: \$1,500 - \$10,000
- Ongoing expense
  - Supplies: \$3,600/year
- Financial assistance???




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Medicare Requirements  
On CSII BEFORE Enrollment

- Has documented SMBG  $\geq 4$  times per day during the month before enrollment
- Fasting C-peptide  $\leq 110\%$  lower limit of normal or  $\leq 200\%$  lower limit of normal if CrCl  $\leq 50$  ml/min with concurrent FPG  $\leq 225$  mg/dL; OR beta-cell autoantibody positive (+ICA or GAD antibodies)

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Medicare Requirements  
Qualifications if CSII AFTER Enrollment

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|--|---|
| <ul style="list-style-type: none"> <li>• Has completed a comprehensive DM ed program</li> <li>• On MDI with self-adjustments for at least 6 months</li> <li>• Documented SMBG <math>\geq 4x/d</math> during the previous 2 mo</li> </ul> | <ul style="list-style-type: none"> <li>• Meets <math>\geq 1</math> of the following criteria:               <ul style="list-style-type: none"> <li>• HbA1c <math>&gt; 7.0\%</math></li> <li>• Hx recurrent hypoglycemia</li> <li>• Fluctuating BGs before meals</li> <li>• Dawn phenomenon</li> </ul> </li> </ul> |
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### Programming the Pump

~ Basal Rates ~

~ Bolus Rates ~

~ Active Insulin/Insulin on Board ~

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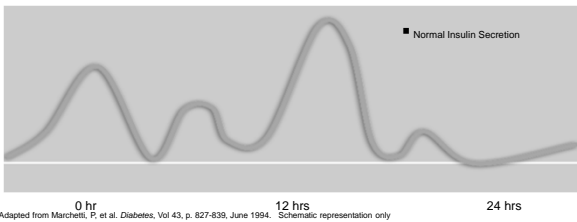
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### Normal Insulin Production



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### Insulin Regimen with an Insulin Pump (CSII)



### Examples of different meal bolus profiles with an insulin pump



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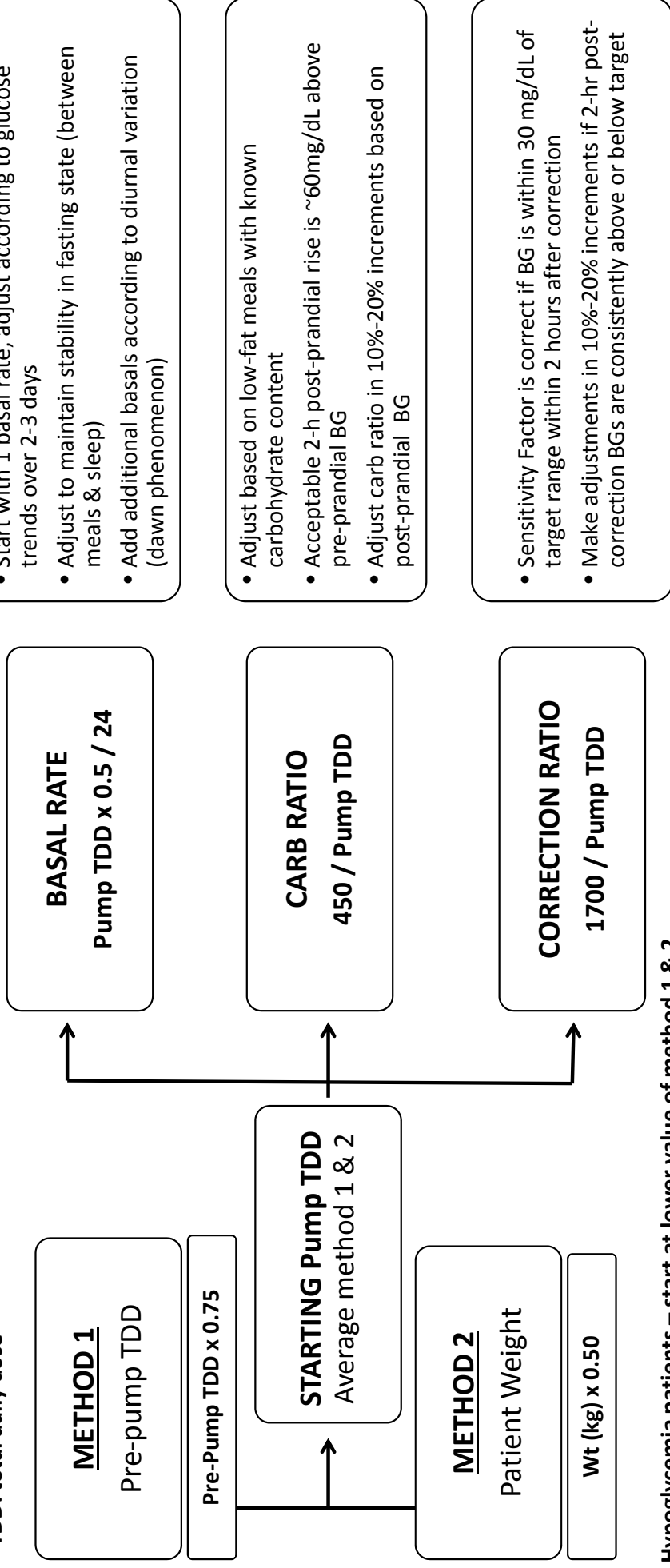
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# Initial Calculations for CSII

TDD: total daily dose



**Hypoglycemia patients – start at lower value of method 1 & 2**  
**Hyperglycemic, elevated A1C or pregnant – start at higher value of method 1 & 2**

Consensus Statement by AACE/ACE insulin pump management task force. Endocr Pract. 2014 May; 20(5):463-89.

Initial Calculations for CSII

- Active Insulin (IOB)
  - Generally set from 3-4 hours (shorter in 670G)
- Auto Mode of 670G
  - Carb ratio and IOB **ONLY VALUES** set by provider
  - Carb ratio calculation closer to 300/TDD
- **IMPORTANT** to assess the manual mode settings for patients using the 670G auto mode

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Ideal CSM Candidate

- Anyone with T1D
- Anyone with T2D on intensive insulin management
- Everyone else with A1C >goal
- Medicare limits CGM to devices with dosing approval only (currently) and to people with DM who test 4 times per day and use intensive insulin management

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CGMS DOES . . .

- Less BG variability – more time in range
- Less apprehension at work, at school, while sleeping, or driving
- Give great data a majority of the time
- Glucose value every 5 minutes
- Eliminate SMBG (for some systems) most of the time

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CGMS DOES NOT . . .

- Completely eliminate the need for SMBG (for some systems)
- 'Take over' all diabetes control (getting closer)
- Give 100% data all of the time



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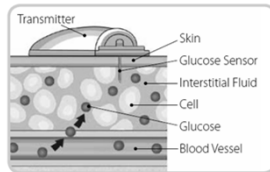
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Sensor Glucose ≠ Blood Glucose

- **Sensor** measures glucose in the **interstitial fluid**
- **BG meter** measures glucose in the **blood**



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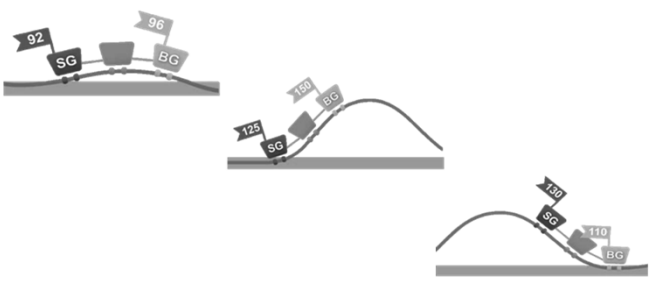
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Sensor Glucose ≠ Blood Glucose



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CGM Systems

- Offer alarms for glucose highs and lows
- Ability to download data and track trends over time and share data
- Offers ability to easily observe how any given food, exercise or insulin dose affects control over the course of a few hours
- Allows immediate feedback - pts able to modify behaviors to gain better control

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CGM Systems

- Supplements A1C
- Identify post-prandial glucose excursions
- Identify undetected nocturnal hypo
- Visual patient teaching tool
- Stop insulin delivery when BG < set value (integrated systems only)
- Allow patient to improve dosing (based on arrows)

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CGM Systems

- Directional arrows available
- Key aid to control
- Blood glucose levels in a state of flux
- Info regarding direction of glucose
- Predictive alarms based on rate of change
- **Allows for adjustments in insulin dosing**



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	<b>Glucose not rising or falling &gt;1mg/dL/minute</b>
	Glucose rising 1-2 mg/dL per minute**
	Glucose rising 1-2 or 2-3 mg/dL per minute*
	Glucose rising 2-3 or >3 mg/dL per minute*
	Glucose rising 3 or more mg/dL per minute**

\* Varies based on system    \*\*Not available on all systems

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	<b>Glucose falling 1-2 mg/dL per minute**</b>
	Glucose falling 1-2 or 2-3 mg/dL per minute*
	Glucose falling 2-3 or >3 mg/dL per minute*
	Glucose falling 3 or more mg/dL per minute**

\* Varies based on system    \*\*Not available on all systems

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**Dexcom G5 & G6 / Abbott Freestyle Libre Dosing Off CGM Values**

- Use Caution:
  - First 24 hours
  - Last 24 hours
  - Higher-carb meals
  - Stressful situations
  - Lows and rebound highs




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**Pump & CGM Combo**

- Medtronic and Tandem have combination pump/CGM systems
- The sensor is a separate site on the skin from the pump
  - The sensor's glucose information is visible on the pump screen
- Life-changing future pump technology relies heavily on CGM technology



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**670G Hybrid Insulin Pump**

- Suspend before low – stops insulin 30 minutes before set low limit and restarts when level recovers
- Auto Mode
  - Adjusts basal insulin based on BG to keep glucose at 120 mg/dL
  - Adjusts correction based on learned history



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**Costs**

- Systems
  - \$360 to \$1,400 for the hardware
  - \$3000 when initially introduced
- Sensors
  - Costs vary from \$100-300 per month (\$3.60-10/day) for continuous use
- Does not include the cost of the test strips needed for calibration and BG confirmations (if needed)



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Use of CGM

- Improvements in DM management
  - Decreased variability
  - Decreased hypoglycemia
  - Decreased A1C
- Improvements in lifestyle
- Reinforces education
- Increased understanding of self-management choices



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Alarm Fatigue

- Patient will say to you:  
“These alarms are going off ALL THE TIME!”  
“I hate this sensor!”
- Issues:
  - 1) **Too many** alarms turned on
  - 2) **MOST likely due to . . .**  
**Insulin/activity/food behaviors**  
**Actions, delivery, rates and/or ratios are what need to be changed**



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Future Systems and Sensors



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