

The Latest on Pumps and Exercise



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John Walsh, PA, CDTC, jwalsh@diabetesnet.com, Advanced Metabolic Care + Research; 700 West El Norte Pkwy; Escondido, CA 92126 (760) 743-1431

View slides at www.diabetesnet.com/diabetes-resources/diabetes-presentations

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Highlights

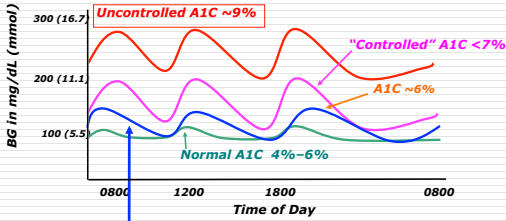
- Introduction to Exercise and Pumps
- Line and Patch Pumps
- Tuning The Bolus Calculator
- Infusion Set Issues
- On the Horizon



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The Challenge Of Diabetes

Bringing the A1c down smoothly takes effort



...for this you need **ADVANCED** therapy

Courtesy Tim Bailey, MD, FACE, CPI

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Ways To Get There



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Things That Affect Glucose in Exercise


- Current glucose and trend
- BOB at start
- Carbs on board and carb intake
- Length and intensity of exercise
- Training/glycogen level
- Recent lows
- Aerobic versus anaerobic exercise
- Stress hormones/competition



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Pump Advantages


- Convenience (fewer missed doses)
- Less insulin, less insulin stacking
- Easier to exercise and match varying insulin needs
- Lower A1c & less severe hypoglycemia, less BG variability *
- More social freedom
- Better data (clinicians, pumpers, parents)



* Pickup JC, Sutton AJ. Severe hypoglycaemia and glycaemic control in Type 1 diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion. Diabet Med 2008 Jul;25(7):765-74.

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Performance With Optimal BGs



Team Type 1 set a new RAAM course record in 2009
 3,021 miles (4,861 km)
 5 days, 9 hrs and 5 min
 23.41 mph

Plus 1st place in 2007 and 2nd in 2008

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Infusion Line Pumps



Accu-Chek Combo

Asante Snap

Animas Ping

Medtronic Revel

Tandem t.slim

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Patch Pumps



Valeritas V-Go


Accu-Chek Solo

Insulet Omnipod

Calibra Finesse

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Accu-Chek Solo




- Precise dispensing screw
- Auto-inserter
- 200 units
- Weighs 1 oz
- Bolus button on pump
- Remote with color screen
- Accurate bolus calculations

FDA approved

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CellNovo Wax Motor Pump




- Small wax cube is heated to pump 0.05 u of insulin
- ? slow bolus delivery
- Controller sends data via phone lines to internet site/cell phone
- Connects to short infusion set
- 2 rechargeable pumps
- Unclear operation in heat/cold

CE approved in Europe

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Debiotech Jewel




- Micro-Electro-Mechanical Systems tiny silicon motor
- Silicon wafer nanotechnology for mass production of motor
- Very light, 0.02 u delivery
- Separate infusion site
- Current 400 u insulin bladder makes it large
- ? Cost

CE approved

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Finesse Type 1 or 2 Bolus Device




Calibra

- Simple, low cost design
- Manual bolus, no basal
 - 0.5, 1, 2, & 5 unit options
- Convenient for those who also use a long-acting insulin
- 200 u reservoir, 27 gauge metal needle, 2" x 1" x 0.25"
- No electronics
- Acquired by J&J in July, 2012

FDA approved


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Remote Controls – PDA + Meter



Accu-Check Combo Animas Ping


- Discreet bolus delivery (and basal in some) from PDA
- Sends BG and bolus dose to pump via radio wave or Bluetooth
- All data in one location
- Some remotes (Cellnovo and Omnipod) must be present to give a bolus



Cellnovo Omnipod

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Why The Glucose Falls With Exercise



- Excess basal or bolus insulin
- Excess BOB at start
- Too few carbs
- Longer, more intense exercise
- Lack of training

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Why The Glucose Rises With Exercise




- Too little basal or bolus insulin*
- Too many carbs
- Anaerobic exercise
- Competition/stress
- Dehydration
- Muscle trauma (extreme sports)

* Limits exist for the duration and degree for insulin reductions

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Benefits Of Training



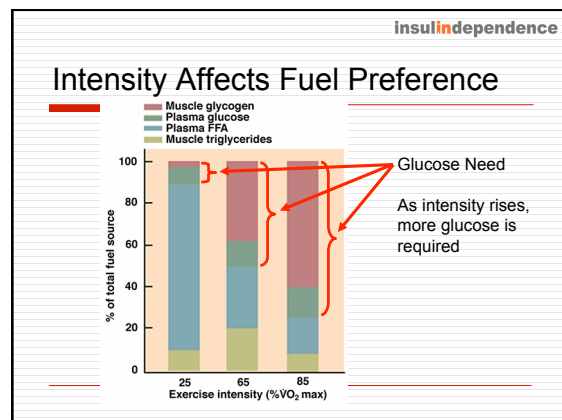
Basals and boluses are already lowered

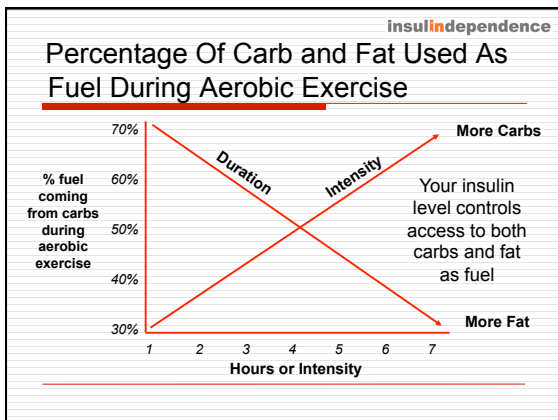
- Better access to internal glucose and fat stores

Muscle glycogen stores are already enlarged

- About 25% less glucose is removed from blood after exercise because glycogen stores are already enlarged

Glycogen – nature's glucose shock absorber

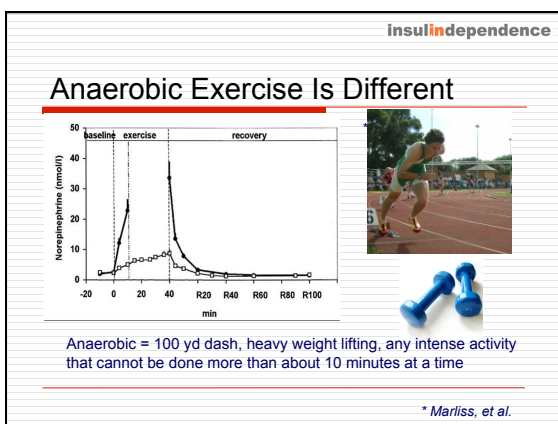




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When Insulin Levels Need To Change

The LONGER you exercise,
The MORE INTENSELY you exercise, and
The LESS TRAINED you are,
The MORE likely you'll need to lower your basals and boluses



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Glucose Regulation – Aerobic vs Anaerobic

VO _{2max}	
30% 40% 50% 60% 70% 80% 90% 100%	
Regulation by: <i>insulin</i>	<i>catecholamines – epi, norepi</i>
Type: aerobic	anaerobic
Intensity: mild to high	very high
Duration: hours	10 to 15 minutes
Fuel: 30-70% glucose	up to 100% glucose
Glucose: usually falls	usually rises
ExCarbs: yes	no

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Anaerobic Spurts Help Prevent Lows

- Use anaerobic exercise to your advantage for longer aerobic activities
- Short periods of anaerobic effort – 10 to 30 seconds – may be sufficient to raise your glucose and minimize hypoglycemia
- If the insulin level is not excessive

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Competition May Raise The Glucose

Competitive events release stress hormones

- Hard to predict
- Bolus as needed

Short anaerobic events do the same

- Bolus after event

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Glucose Sources And Timing

Ideally, during exercise most glucose will not come out of the blood

	During	After
Local muscle glycogen	- 85%	+ 85%
Blood glucose	- 15%	- 85%
Carb intake	~15%*	~85%

* More carbs are needed DURING exercise if insulin level is too high

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Reload Glycogen Rapidly

- Glycogen stores in muscle and liver are reduced during exercise
- It is much easier to rebuild glycogen stores in the first 2 hours after exercise
 - Glycogen rebuilding is 2-3 times faster
 - **Less risk of night lows**
 - 1 gr carb and 1/4 gr protein per lb during 1st 2 hrs
- Use fast carbs: chocolate milk, bagels, potatoes, cereals, dried fruit

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Tuning the Bolus Calculator

The BC helps user find bolus recommendations that better match carb intake and the current glucose while minimizing insulin stacking



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Bolus Calculator Settings

This Setting	Assists
Basal rates	Safe sleep (~50% of TDD)
CarbF or I:C ratio	Cover carbs well
CorrF or ISF	Lower highs safely
Target glucose	Correct to specific goal
DIA	Minimize insulin stacking

The average TDD controls the frequency of highs and lows

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Training Impacts Your TDD & Settings

As your TDD falls with improved physical fitness, keep your basals and boluses balanced

Example: 160 lb person in good control:

	Change in BC Settings from Training				
	TDD	Basal	CarbF	CorrF	Ins Sens
Before Training	40 u	0.8 u/h	10.4	49	96%
After Training	30 u	0.6 u/h	13.6	65	125%

When TDD changes, so should your pump settings

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Bolus Calculator

User Inputs: Glucose Grams of carb






Photo courtesy www.sixuntime.com Photo courtesy emilybolter.com

BC Output: Recommended bolus with list of units for carbs, correction (if any), and BOB (if any)

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APP Study – Carb Factors are Often Incorrect^{1,2}

CarbF settings found in pumps

Pump carb factors from 400 pumps are not evenly distributed.

People like "Magic" numbers – 5, 10, 15, and 20 g/unit.

Always use formulas to get more accurate pump settings → better than WAG!

Many use "magic" numbers for their CarbF!

1. J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010
2. J. Walsh, D. Wroblewski, and TS Bailey: Insulin Pump Settings – A Major Source For Insulin Dose Errors, Diabetes Technology Meeting 2007

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APP Study – Use the TDD to Find Pump Settings¹

Basal = ~ 48% of TDD or 0.02 x TDD

CarbF = $5.7 \times \frac{Wt(kg)}{TDD}$ or $2.6 \times \frac{Wt(lbs)}{TDD}$

Corr. Factor = 110/TDD (mmol/L) or 1960/TDD (mg/dl)

CorrF is inversely related to TDD and to avg. BG

Or use the Pump Settings Tool at www.diabetesnet.com/diabetes_tools/pumpsettings/

¹J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010

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Verify Bolus Recommendations

BOB = glucose-lowering activity that remains from recent boluses

Almost all pumps cover carbs fully regardless of BOB.

If BOB exceeds correction bolus, consider reducing recommended bolus, especially before events and before going to sleep.

If you have 4.35 u of BOB from a bolus given 3 hrs earlier, would you give 2.9 more units for a bedtime snack?

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Avoid Short DIAs

A short DIA hides your true BOB and leads to

- Hidden insulin stacking and "unexplained" lows
- Errors in adjustments of basal rates, carb factors, and correction factors
- Ignoring your "smart" pump's advice

Set DIA for real action time: 4.5 to 6 hrs.

Don't modify DIA time to fix control problems

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How To Reduce Boluses

- Bolus reductions are ideal for exercise that takes place shortly after a meal and lasts less than 60 to 90 minutes
- For exercise before meals, eat extra free carbs and reduce bolus for the meal that follows
- For long and more strenuous exercise, meal boluses can be greatly reduced and sometimes eliminated.

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Clever Pump Trick – Super Bolus – Shift Basal To Bolus

Helps when eating over 30 to 40 grams of carb

Max carbs/meal = Wt(lb) X 0.36 to stay in control²

Future: Super Bolus shifts part of the next 2 to 3.5 hrs of basal insulin into the bolus with less risk of a low later.^{1,2}

¹J. Walsh: http://www.diabetesnet.com/diabetes_presentations/super-bolus.html September, 2004
²J. Bondia, E. Dassau, H. Zisser, R. Cairn, J. Vehli, L. Jovanovic, F.J. Doyle III. Coordinated basal-bolus for lighter postprandial glucose control in insulin pump therapy, Journal of Diabetes Science and Technology, 3(1), 89-97, 2008

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How Many Basals?

Number of Basals	Percentage of Pumpers
1	~8%
2	~14%
3	~20%
4	~18%
5	~21%
6	~15%
7	~10%
8	~4%
9	~2%
10	~1%

Percentage of pumpers who use 1 to 10 basals per day from self reports of several hundred pumpers at insulin-pumpers.org

Basal changes take at least 3-5 hours to have their full effect* when basal rates are doubled, so >5 basals has dubious benefit

* Heinemann L, Nosek L, Kapitza C, et al. Changes in basal insulin infusion: time until a change in metabolic effect is induced in patients with type 1 diabetes. Diabetes Care. 2009;32(8):1437-1439.

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Temp Basal Reduction

- Short, large basal reductions can be used right before exercise to offset excess BOB
 - ~80% reduction for up to 90 min
- Smaller reductions for exercise that lasts over 90 min
 - Max reduction usually 50%
 - Reduce basal an hour or so before activity starts
- After a long exercise, glucose may fall for 12 to 36 hrs
 - Temp basal reductions are often needed
 - Plus additional carbs to rebuild glycogen stores

Don't suspend your pump!

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Multiple Temp Basal Reductions

3 hrs activity at 5 of 5 intensity

Adjust basals long before the need arises

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Disconnect Bolus

- Disconnect up to 2 hrs for sports, mini-vacation, etc.
- User estimates time off and pump gives up to 50% of missed basal as bolus
- Alarm reminds user to re-connect
- After reconnecting, pump shows how much basal was lost and offers to supply the missing amount

Pump Plumbing

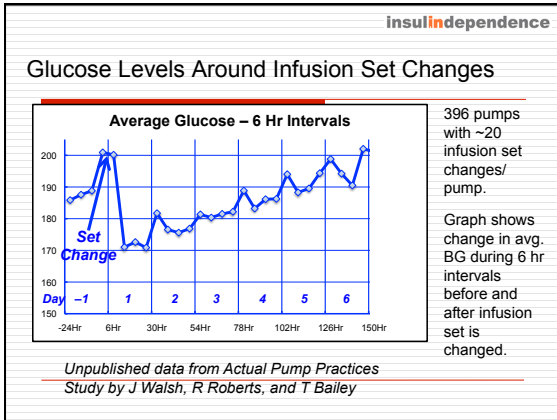
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Infusion Sets – The Achilles Heel Of Pumps

Survey of 1142 pump wearers seen in 40 German diabetes clinics

- 54% reported an increase in glycemia for unknown reasons until their infusion set was changed
- 26% of patients report that their auto-insertion device did not always work (in 10% ± 12% of all cases)
- 19% reported kinking, 12% had leakage, 12% air bubbles, and 33% had other issues
- 58% use Teflon and 39% use steel needle, with 82% straight and 12% bent sets

G Heinemann and L Heinemann: Reality of insulin pump treatment in Germany: Results from a survey with 1142 patients treated in 40 specialized practices: Abstract 2013 ADA Meeting, winDiab, Scientific Institute of the Specialized Diabetes Practices, Düsseldorf, Germany

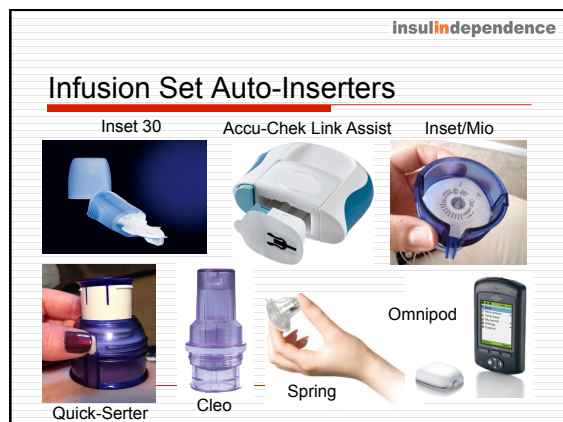


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- ### Reasons that Infusion Sets Fail
- Complete pullout
 - Insulin leak along Teflon to skin
 - Hematoma (pool of blood)
 - Occlusion
 - Cannula kink
 - Loose hub
 - Punctured line
-
- ALL should rarely or never happen*

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- ### Anchor Your Infusion Line!
- Place a strip of 1" tape across infusion line to:**
- Stop tugging on Teflon catheter under the skin to reduce skin irritation or "pump bumps"
 - Stop "unexplained highs" caused by insulin leaking back to skin surface
 - Prevent most pull outs
-
- Use tape so you don't lose insulin!

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- ### Tapes
- Some 1" tapes that work well
- Transpore
 - Micropore
 - Durapore
 - Hypafix
 - Blenderm


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- ### Tackies
- Tincture of Benzoin
 - Toupee glue
 - Skin-Tac
 - Mastisol
- Remove with Goo B Gone or Detechol




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Line Disconnect Mechanisms

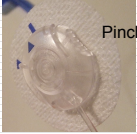
With motion and degree of manual dexterity



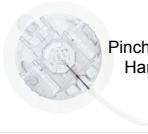
Twist & pull;
Easiest



Pinch & pull;
Easier



Pinch, twist, & lift;
Hardest




Pinch & lift;
Harder

Tubing lengths: 24", 32", and 43" for most sets

On The Horizon

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Easy Adjustment for Exercise



Enter planned exercise into pump:

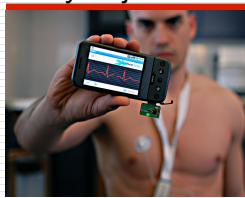
1. Intensity (1-7 scale)
2. Duration (15-480 min)
3. Training level for activity (1-5 scale)

With your current BOB and CGM BG/trend, pump calculates likely carb intake and insulin reduction needed during and after the exercise

Future Pump Feature

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Easy Adjustment for Exercise



Add activity monitor to pump


Combined with your current BOB and CGM BG/trend, this lets your pump calculate likely basal and bolus reductions after exercise

Future Pump Feature

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Future Pump Features


- How setting change impacts TDD (& BG)
- Temp basal plus bolus doses
- Super Bolus
- Meal-size boluses
- Excess BOB alert (bolus without BG but BOB is ++)
- Low BG predictor (HypoManager)
- Exercise compensator
- Infusion set monitor/leak detector
- Automated basal and bolus testing



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Early Closed Loop – Animas Vibe


- Insulin pump with high contrast color screen
- 1 week Dexcom G4 sensor with smallest needle
- Internet access via Diasend software



CE approved in Europe

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Early Closed Loop – Medtronic Veo



- Low Glucose Suspend (LGS)
- Uses CGM to suspend basal for up to 2 hrs when low
- User can reactivate basal
- Reduce prolonged nighttime lows
- Ability to detect low BGs remains an issue

CE approved in 2009, submitted for FDA approval

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Challenges to an Artificial Pancreas

JDRF Closed Loop – 2012

- ① Develop alternate glucose sensing for reliability
 - a) Multiple sensors on one platform
 - b) Alternate technologies: fluorescence, etc.
- ② Develop dual delivery pump (insulin + other drug)
- ③ Evaluate alternate non-insulin drugs to prevent hypoglycemia (glucagon, Symlin, GLP-1 agonist, leptin, or ?)
- ④ Modular testing of software control algorithms

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Faster Insulins

Problem: Carb digestion is often < 2 hrs
Insulin action lasts > 5 hrs

- Ultra-fast insulin analogs
 - Novo Nordisk FIAsp
 - Bidel
 - MannKind Afrezza (inhaled)
- Micro-needle intradermal delivery
- Hyaluronidase
- Warming of infusion site

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Microneedle Intradermal Delivery

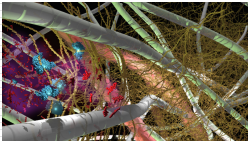


- Becton Dickinson 1.5 mm intradermal needle speeds up insulin action
- Painless
- Reliable attachment of infusion set is critical to success

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Hyaluronidase

- Recombinant human hyaluronidase temporarily degrades local hyaluran, a structural protein in the interstitial space
- Faster insulin uptake
- DIA ~4 to 4.5 hrs – Phase 3 clinical testing with 435 pump wearers now underway
- Release in early 2014?

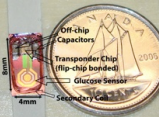


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Long-Lasting Implanted CGMs




Dexcom G1 2004




Off-chip Capacitors
Transducer Chip (Fig-clip bonded)
Glucose Sensor
Secondary Pad


- Few disposables
- Minor surgery
- Funded as rental?



Sensors For Medicine




MicroCHIPS Illume



GlySens

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Implanted Fluorescent CGM



血糖値の変化によって光の強さを測るファイバー

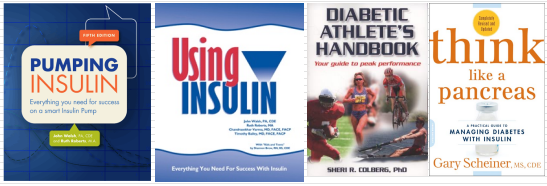
Molecules fluoresce & change color as glucose rises or falls

- Small size, low power, low cost, long life, great accuracy, minimal lag time

From Y. J. Heo et al: Institute of Industrial Science at the University of Tokyo

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Life Gets Easier When You Know More!



PUMPING INSULIN
Everything you need for success on a smart insulin Pump

Using INSULIN
Everything You Need For Success With Insulin

DIABETIC ATHLETE'S HANDBOOK
Your guide to peak performance

think like a pancreas
A PRACTICAL GUIDE TO MANAGING DIABETES WITH INSULIN
Gary Scheiner, MS, CDE

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