Beta Bionics

iLet Bionic Pancreas

BETABIONICS.COM

Letter from Ed Damiano

Inventor of the iLet Bionic Pancreas

More than twenty years ago, my wife diagnosed our son, David, with type 1 diabetes when he was just 11 months old. As a pediatrician, she recognized there was something gravely wrong with him, and we soon found ourselves in the pediatric intensive care unit coming to grips with how his life and ours had suddenly and forever changed.

In the years that followed, we checked his blood sugar 10 to 15 times a day and continually adjusted his insulin doses. We lived with the constant worry that one night he would have a little bit too much insulin at bedtime and hypoglycemia would take him from us while we slept.

So, as a father, and a professor of biomedical engineering, I set out to create a better way to deliver insulin with a device that would determine 100% of every insulin dose delivered. My hope was that such a technology would automatically deliver safe and effective glucose control and thus make type 1 diabetes less burdensome and less stressful.

On David's 24th birthday, the FDA cleared the iLet Bionic Pancreas and helped realize my vision of the device I wish I'd had when David was a child, but which he now has as a young adult. It has improved his glucose control and dramatically reduced his hypoglycemia[+], making him safer, healthier, and happier in the process.

The iLet eliminates the need to carbohydrate count[*] or to set and adjust carb ratios, correction factors, or basal rates. It is already positively impacting people's lives, including ours. I hope you find it helpful, too.

Ed Damiano, PhD
Founder and Executive Chairman
Beta Bionics

[+]Individual results may vary. [*]User must be carb aware.

Is the iLet Bionic Pancreas right for your family?

Is your child:

- Newly diagnosed with type 1 diabetes?
- Using multiple daily injections (MDI)?
- Frustrated with the work their pump requires?
- Open to using a CGM?
- Someone who doesn't want to focus too much on their diabetes?
- Not comfortable with carb counting?
- Suffering from diabetes burnout?

Are you:

- Overwhelmed with the work that your child's diabetes management requires?
- Apprehensive about your child taking care of their diabetes while away at college?
- Hesitant to allow other adults (school nurse, teacher, another parent, etc.) to manage your child's diabetes?
- Worried about your child attending sleepovers, sporting events, or school trips without you?

If you answered yes, the iLet Bionic Pancreas may be right for your family.

WHY GO BIONIC?

The iLet Bionic Pancreas automatically adjusts to your child's insulin needs so you don't have to.

It's designed to reduce the burden of diabetes management for the whole family so you can spend less time worrying about diabetes and more time doing the things you love.

No carb counting

Instead of carb counting everything on your child's plate, the iLet just needs an estimate of the carbs in the meal – Usual for me, More or Less.

No corrections

The iLet makes the corrections for you so you can focus on other things. If your child is trending high, it will automatically give them more insulin to bring them back into range. If they're trending low, it will reduce the current insulin dosage.

Dosing decisions made for them

The "Bionic" part of the iLet communicates with your child's CGM and makes all of the insulin dosing decisions—no carb counting, no correction factors, no adjustments.

Algorithms that learn your child

Unlike other systems that simply react, the iLet is constantly learning and adapting to determine the right settings for your child. It's like having a diabetes expert in their pocket!

Consistent care everywhere

Can you imagine sending your child to school or a sleepover without worrying about their ability to carb count and calculate a meal dose? Since the iLet determines 100% of insulin doses, you can have peace of mind knowing their care is consistent wherever they go.

Small but mighty

Small (2.3" x 3.5" x 0.6"), lightweight and easy to put in a pocket or clip onto clothing.

Talks to the Dexcom CGM

The iLet communicates directly with your child's Dexcom CGM (G7 and G6) to know where their glucose is headed.

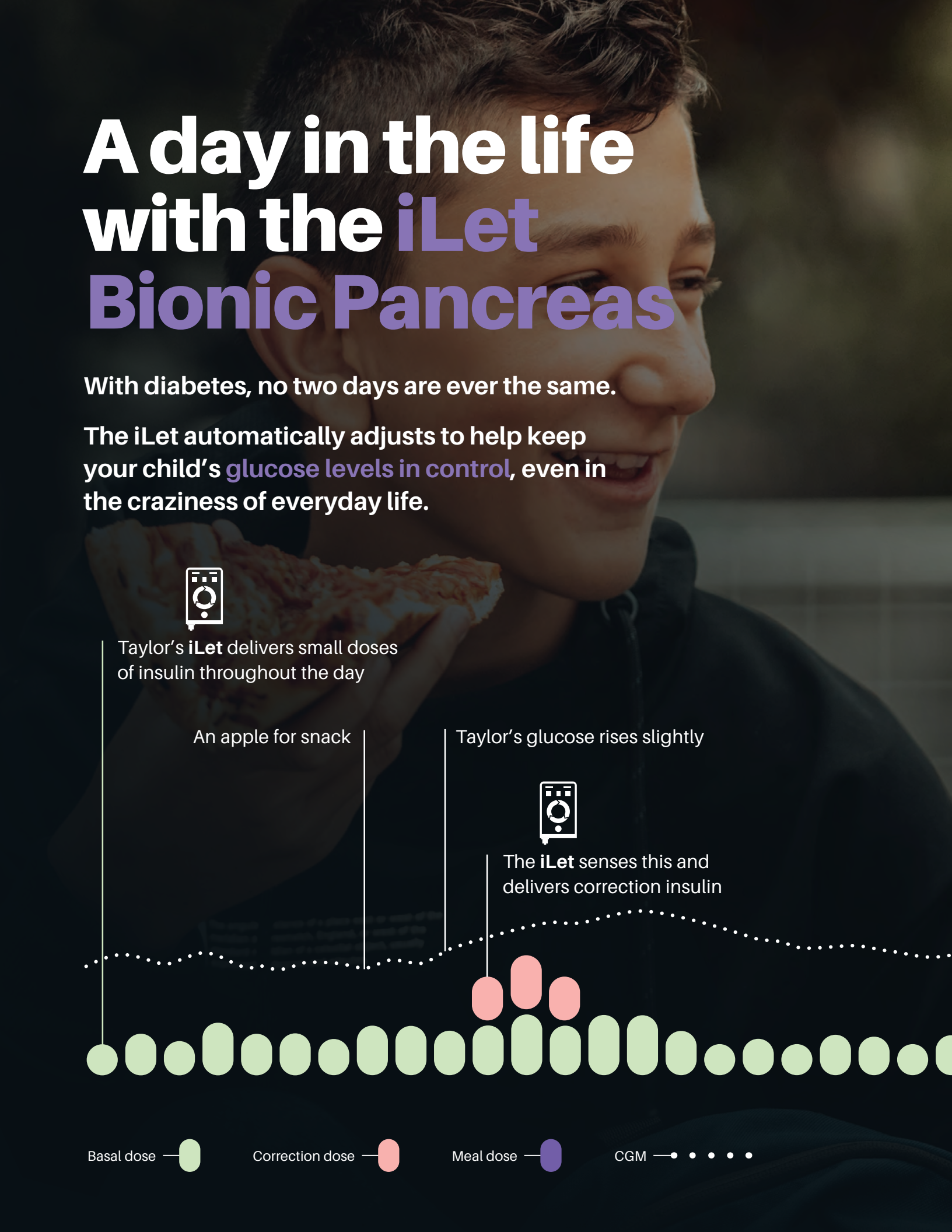
Water resistant

If the iLet is dropped into water—no problem! It's protected in up to 12 feet of water for up to 30 minutes.

A day in the life with the iLet Bionic Pancreas

With diabetes, no two days are ever the same.

The iLet automatically adjusts to help keep your child's glucose levels in control, even in the craziness of everyday life.




Taylor sits down to eat dinner and chooses “Usual for me” for her meal announcement. The **iLet** determines a meal dose and delivers it.
The **iLet** continues to deliver insulin to adjust for the meal, as needed
Taylor’s levels come back into range

Pivotal Trial Results

Based on clinical trial results, children using the iLet could experience almost 900 extra hours of time in range each year.[1]

"...it doesn't mean we never talked about it (diabetes), but the iLet left more room for other conversations. And I think the lack of questioning all the time meant there was less frustration even in those conversations that you did have."

- PARENT OF TEEN PARTICIPANT, BIONIC PANCREAS PIVOTAL TRIAL

The iLet helped those kids the most, who needed it the most

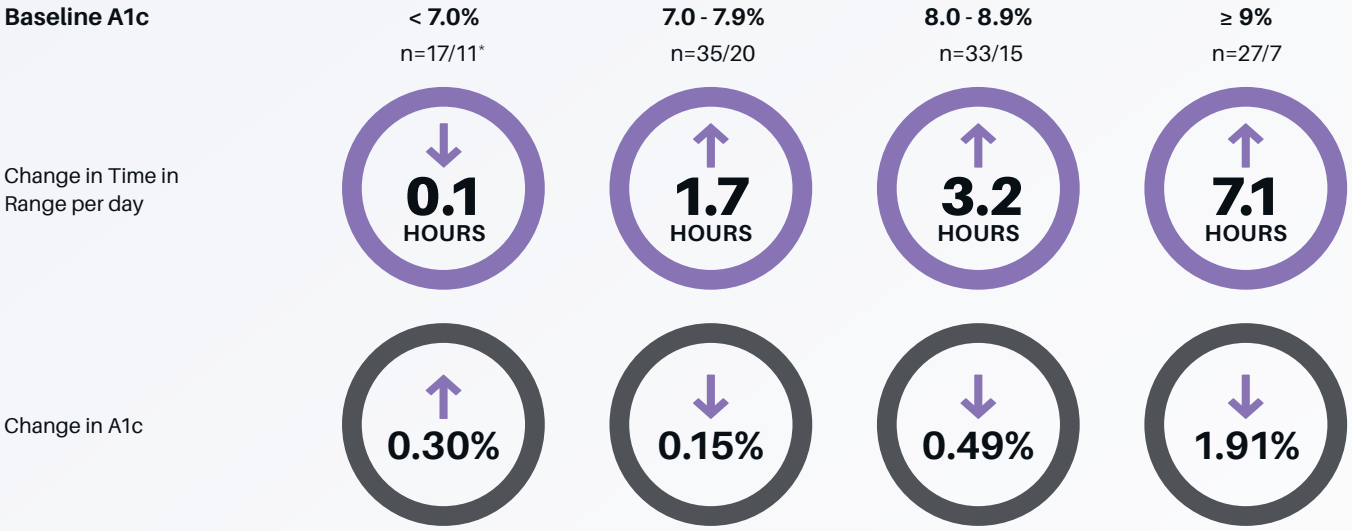
Our clinical partners conducted the largest and most diverse clinical study of an automated insulin delivery system to date.

16 world-class diabetes centers across the country conducted the pivotal trial where hundreds of adults and children with type 1 diabetes used the iLet paired with a Dexcom G6 in everyday life for 3 months.

The results were published in the September 29, 2022 issue of The New England Journal of Medicine.[2]

Parents of children on the iLet are more satisfied with their treatment than those on Standard of Care.[4]

Time in Range and A1c improvement in Children using the Bionic Pancreas with Humalog or Novolog[3]



Values are Mean Baseline Adjusted Difference. The study was not designed to evaluate the effect of the iLet Bionic Pancreas in subgroups by baseline HbA1c. Individual user results may vary from the average values shown here. *n=iLet/Standard of Care.

Mia, 9

3rd Grader
Diagnosed with T1D 5 years ago

Previous Treatment Plan:
Hybrid closed loop and CGM - A1C: 9% TIR: 52%
Individual user results may be different than those depicted here

Results on iLet and Dexcom G7:
A1C: 6.8% TIR: 71%

Despite their best efforts, Mia's parents couldn't improve her TIR or reduce her HbA1c, even though she was on a hybrid closed loop system. Mia's parents were overwhelmed by the decisions they needed to make daily that impact Mia's health. They needed a solution that fits their family.

Mia's pediatric endo recommended trying the iLet Bionic Pancreas and Dexcom G7 CGM. Because the iLet makes 100% of the dosing decisions, it took the pressure off of Mia's parents to constantly try to manage what she's eating, meal doses, corrections, etc. Also, because the iLet doesn't require carb counting, Mia's able to input her meal dose while she's in school – Usual for me, More or Less. Then the iLet takes care of the rest. Mia's mom explained, "Now I can let her just be a kid. I actually let her go to a sleepover last week because I knew she'd be ok with the iLet."

Damon, 15

10th grade Sophomore
Diagnosed with T1D 11 years ago

Previous Treatment Plan:
MDI and CGM - A1C: 11.2% TIR: 35%
Individual user results may be different than those depicted here

Results on iLet and Dexcom G7:
A1C: 7.3% TIR: 68%

Damon is an active sophomore in high school who is in clubs, plays baseball and has a new girlfriend—he is not focused on his diabetes. His mom, Sharon, didn't know what to do to help keep him on track with his diabetes. "He wouldn't dose for meals because he didn't want to prick his finger in front of his friends. Sometimes he'd take an insulin dose, sometimes he wouldn't – but he had no idea how his sugar levels were throughout the day." Damon said, "I just don't want to deal with it at school. I have so many things going on with classes, clubs and baseball practice that I just don't have time. I wanted something that does it for me."

Damon's endocrinologist suggested he try the iLet Bionic Pancreas with Dexcom G7. The Dexcom G7 allows Damon to see how he's doing throughout the day and the iLet Bionic Pancreas makes all of the dosing decisions for him. Damon explained, "It's so nice to not have to try to calculate my carbs for a meal – because I'm always wrong anyway! I just pick Usual for me, More or Less and it does it for me. And if I need any corrections, it just takes care of it. And I'm able to wear the iLet while playing baseball – it doesn't get in the way."

Hear from parents of iLet users on how the iLet has helped their families.

"The iLet has changed our lives by allowing us to return to our true selves. It has brought back joy, hope, and humor! By no longer making decisions on carb counting, correction tracking, and dosage amounts, Catherine has been able to lower her A1C and become more independent with her own care. It has allowed me, her mother, to remove worry knowing she is making great decisions towards her long-term health. Success and happiness - for her and for our family - are the sweetest gifts the iLet gives us EVERY DAY!"

– Tracy, mother of iLet user Catherine

"Introducing our incredible son, Houston-Cutter, affectionately known as 'Cutter.' At the age of 6, he bravely faced the challenge of a type 1 diabetes diagnosis, swiftly followed by celiac disease. Surprisingly, these conditions haven't dimmed his spirit; instead, they've ignited his resilience.

Cutter's dedication to sports and the joy of a regular childhood is made possible by the blessing of the Beta Bionics iLet Bionic Pancreas. This remarkable device has transformed his life, granting our family a sense of normalcy. With the iLet, Cutter's blood sugar levels have found newfound stability, even after adding celiac disease to his diabetic journey.

As both Cutter's mom and a healthcare professional deeply invested in researching and consulting colleagues nationwide, selecting the Beta Bionics iLet was an easy decision. Beta Bionics embodies everything a healthcare company should be—putting the patient at the forefront. Their unwavering support has been phenomenal, and we're immensely grateful."

– Courtney, mother of iLet user Cutter

Are you ready to GO Bionic?

betabionics.com/get-started

Scan the QR Code

or call 855.745.3800 to get started.

Safety Information
The iLet® Bionic Pancreas System is indicated for use by people with type 1 diabetes 6 years of age and older. The iLet Bionic Pancreas requires prescription by a physician. Refer to the iLet Bionic Pancreas System User Guide at www.betabionics.com/user-guides, or for complete safety information including indications, contraindications, warnings, cautions, compatible devices, compatible drugs and instructions, refer to www.betabionics.com/safety. DO NOT start to use the iLet Bionic Pancreas System without adequate training. Incorrect use may result in over-delivery or under-delivery of insulin, which could lead to hypoglycemia or hyperglycemia.

Medical Disclaimer
This handout is for information only and is not a substitute for medical advice and/or services from a healthcare provider. All personal health care decisions and treatment should be discussed with a healthcare provider who is familiar with your individual needs.

1. Messer, L.H., et al.(2022) Positive impact of the Bionic Pancreas on Diabetes Control in Youth 6-17 Years Old with Type 1 Diabetes: A Multicenter Randomized Trial. Diabetes Technology and Therapeutics 2022; 24:712–725.

2. Russell, S.J., et al. (2022) Multicenter, Randomized Trial of a Bionic Pancreas in Type 1 Diabetes. New England Journal of Medicine. doi.org/10.1056/NEJMoa2205225.

3. Data on file.

4. Weissberg-Benchell J et al. Psychosocial Impact of the Insulin-Only iLet Bionic Pancreas for Adults, Youth, and Caregivers of Youth with Type 1 Diabetes. Diabetes Technology and Therapeutics 2023; 25:705-717.

Image shown does not include required overpatch. Please be sure to follow instructions for using the overpatch.

Beta Bionics

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