iLet® Bionic Pancreas System Quick Reference Guide

Beta Bionics

℞ ONLY

LA000082_C

Manufacturer

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Equipment covered in this User Guide

iLet® Bionic Pancreas
iLet Cartridge
iLet Connect
iLet Charge

This section serves as notice under 35 U.S.C. §287(a) that the products listed at www.betabionics.com/us-patents/ are protected by one or more U.S. patents. Each product also may be covered by one or more foreign patents, and additional patent application(s) may be pending. The list of product and U.S. patents may not be all inclusive, and other products not listed may be protected by one or more patents.

Date of Issuance

2023-12-14

Welcome to the Beta Bionics family!

The iLet® Bionic Pancreas System is an insulin delivery system that automatically regulates blood glucose (BG) levels. The iLet Bionic Pancreas System is the same as the iLet System, which uses autonomous lifelong learning to calculate and deliver insulin doses and to continually adapt these doses to your changing insulin needs.

Read and follow the instructions in this quick reference guide before you start to use the iLet System.

Need any help? Contact your healthcare provider or contact our Beta Bionics customer service team.

Use this Quick Reference Guide to help remind you of some key tasks that you will need to complete in your daily life with the iLet System. Please complete your training before using the iLet Bionic Pancreas System.

You can access the user guide at betabionics.com or scan this code with your smartphone's camera.

If you would like a copy of a paper user guide, you may call Beta Bionics customer service to request one at no additional cost.

> **WARNING:** Consult the iLet Bionic Pancreas User Guide for important safety information, indications, contraindications, warnings, precautions, and detailed instructions before you start using your iLet System.

> **WARNING**: Consult the manufacturer's instructions that accompany your iCGM and insulin infusion set for important information on proper handling, contraindications, warnings, and precautions.

Important Contacts and Numbers

iLet Bionic Pancreas Pre-Training Checklist

We are excited to get you started on the iLet Bionic Pancreas System!

To prepare for your training visit, please follow the steps below. Complete and sign this checklist and bring it to your training. Contact Beta Bionics Customer Service if you have any questions or concerns at: +1-855-745-3800

- ☐ **Do not** open your iLet Bionic Pancreas Device or supplies. **Do not** start to use your iLet System without adequate training from your healthcare provider and/or a Certified iLet Trainer (CiT).
- ☐ **Do not** charge or turn on your iLet Device. If you put the iLet Device on the charging pad, it will turn on. If you mistakenly turn it on, follow the steps listed below to turn it off:
  - Set the date, time, and name to access the iLet home screen and menus.
  - In the upper left-hand corner, tap the Menu icon.
  - Tap the Settings icon.
  - Tap Other.
  - Select Shut Down.
  - Swipe right to shut down your iLet Device.

Make your iLet training kit with the following supplies and bring them to your scheduled training visit:

- ☐ iLet Device
- ☐ iLet charger and cable
- ☐ One of the following rapid acting insulins (U100):
  -A vial of Humalog or Novolog
  -Prefilled Fiasp PumpCart cartridges
- ☐ If you are using a vial of insulin, you also need:
  -iLet Cartridges (at least 2)
  -Syringe and needle to fill the cartridge (at least 2)
- ☐ iLet Connects (at least 2)
- ☐ iLet Quick Reference Guide
- ☐ Glucose meter and test strips
- ☐ Ketone testing supplies (urine strips or blood ketone meter and test strips)
- ☐ iLet Infusion sets (at least 2, either Inset or Contact Detach)
- ☐ CGM supplies (at least 1 back up sensor in addition to the one you are wearing to the visit)

- [ ] If you're new to your CGM, complete the following steps:
  - Review the manufacturer's instructions.
  - Set up the CGM on your phone OR the CGM receiver (if you do not have a compatible smartphone or device).
  - Complete the CGM training.

- [ ] You need to have a CGM sensor running at the start of your iLet training visit. Start your sensor the day before your scheduled training visit or at least a few hours before. Your CGM sensor needs time to warm up.

  You will need your transmitter ID or sensor pairing code to connect your CGM sensor to your iLet Device.

  Record it here: _____

- [ ] Weigh yourself at home before your training visit if you have a scale.

  Current weight: _____

- [ ] Download the iLet mobile application from the Apple App Store or the Google Play Store and set up your account. Make sure you know your username and password for your training visit.

- [ ] Review the iLet Mobile App User Guide at www.betabionics.com/user-guides for instructions.

If you're interested in learning more about the iLet before your training visit, visit our website at www.betabionics.com/resources.

Questions to ask my trainer:

Sign here: **Date:**

Contact your prescribing healthcare provider if anything occurs before your training that may make it difficult for you to start the iLet System or may require the training to be rescheduled (e.g., severe hyperglycemia or a DKA event, hospitalization, or another new diagnosis).

Table of Contents

1. Important User Information

1.1 About this Quick Reference Guide

1.1.1 Overview

The iLet Bionic Pancreas System consists of the iLet bionic pancreas (iLet ACE Pump with iLet Dosing Decision Software), its disposables, a continuous glucose monitor and an infusion set (see **Section 2.1 Parts of Your iLet System** for details).

This quick reference guide provides important information on how to operate your iLet Bionic Pancreas System (iLet System). It provides step-by-step instructions on how to safely set up, manage, and care for your iLet System. It also provides important safety information including warnings, and precautions.

Read and follow the instructions in this quick reference guide before using your iLet System and consistently throughout your future use. Changes in equipment, software, or procedures occur periodically. Information describing these changes will be included in future editions of this quick reference guide. Contact Beta Bionics to obtain a replacement copy.

WARNING: Do not use your iLet System and its components before reading this quick reference guide and participating in training. Failure to follow the instructions in the quick reference guide can result in over/under delivery of insulin. This can cause very low or very high BG, which could result in serious injury or death.

WARNING: Consult the manufacturer's instructions that accompany your drug product, insulin infusion set, iCGM, and SMBG for important information on dosage, administration, proper handling, contraindications, warnings, and precautions.

CAUTION: Touchscreen images and illustrations of the iLet System components in this quick reference guide are examples only. The specific settings and information presented should not be considered as suggestions for your individual needs.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

1.1.2 Safety Statements

In this quick reference guide there are two kinds of safety statements:

> **WARNING:** Statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

> **CAUTION:** Statement that alerts the user to the possibility of a problem with the device associated with its use or misuse (i.e., device malfunction).

1.1.3 Abbreviations

Abbreviation	Explanation
BG	Blood Glucose
BP	Bionic Pancreas
CGM	Continuous Glucose Monitor
iCGM	Integrated Continuous Glucose Monitoring System
CT	Computed Tomography
FCC	Federal Communications Commission
HCP	Healthcare Provider
iAGC	Interoperable Automated Glycemic Controller
BF	Body Floating

Abbreviation	Explanation
GUI	Graphical User Interface
MRI	Magnetic Resonance Imaging
PET	Positron Emission Tomography
RF	Radiofrequency
SMBG	Self-monitoring blood glucose
SN	Serial Number
CF	Correction Factor
ACE	Alternate Controller Enabled
EMC	Electromagnetic Compatibility

1.2 Indications for Use

The person with diabetes is an intended operator of the iLet bionic pancreas, which consists of the iLet ACE Pump and the iLet Dosing Decision Software. The iLet bionic pancreas is for use according to the following:

- For a single person only
- For home use
- For people with type 1 diabetes mellitus
- For people 6 years of age or older
- For use with a compatible iCGM
- For use with a prescription

The Indications for Use for the iLet ACE Pump and iLet Dosing Decision Software are explained here:

1.2.1 Indications for Use: iLet ACE Pump

The iLet ACE Pump is an alternate controller enabled (ACE) pump intended to deliver insulin under the skin based on input from an integrated continuous glucose monitor (iCGM) and an interoperable automated glycemic controller (iAGC), in people 6 years of age or older with diabetes mellitus. The iLet ACE Pump is intended for single-person use; it is not to be shared.

1.2.2 Indications for Use: iLet Dosing Decision Software

The iLet Dosing Decision Software is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps. A self-monitoring of blood glucose (SMBG) meter may also be used for manual input of blood glucose values to continue insulin dosing for a limited period of time when input from the iCGM is temporarily not available.

The iLet Dosing Decision Software autonomously determines and commands an increase, decrease, maintenance, or suspension of all basal doses of insulin and autonomously determines and commands correction doses of insulin based on input from an iCGM, and it autonomously determines and commands meal doses of insulin based on meal announcements.

iLet Dosing Decision Software is intended for the management of type 1 diabetes mellitus in people 6 years of age or older. iLet Dosing Decision Software is intended for single patient use and requires a prescription.

1.3 Working With Your Healthcare Provider

Your healthcare provider (HCP) can help you establish diabetes management guidelines that best fit your lifestyle and health needs.

> **WARNING**: DO NOT start to use your system without adequate training from your HCP and/or a certified iLet trainer. DO NOT change your settings without guidance from your HCP.

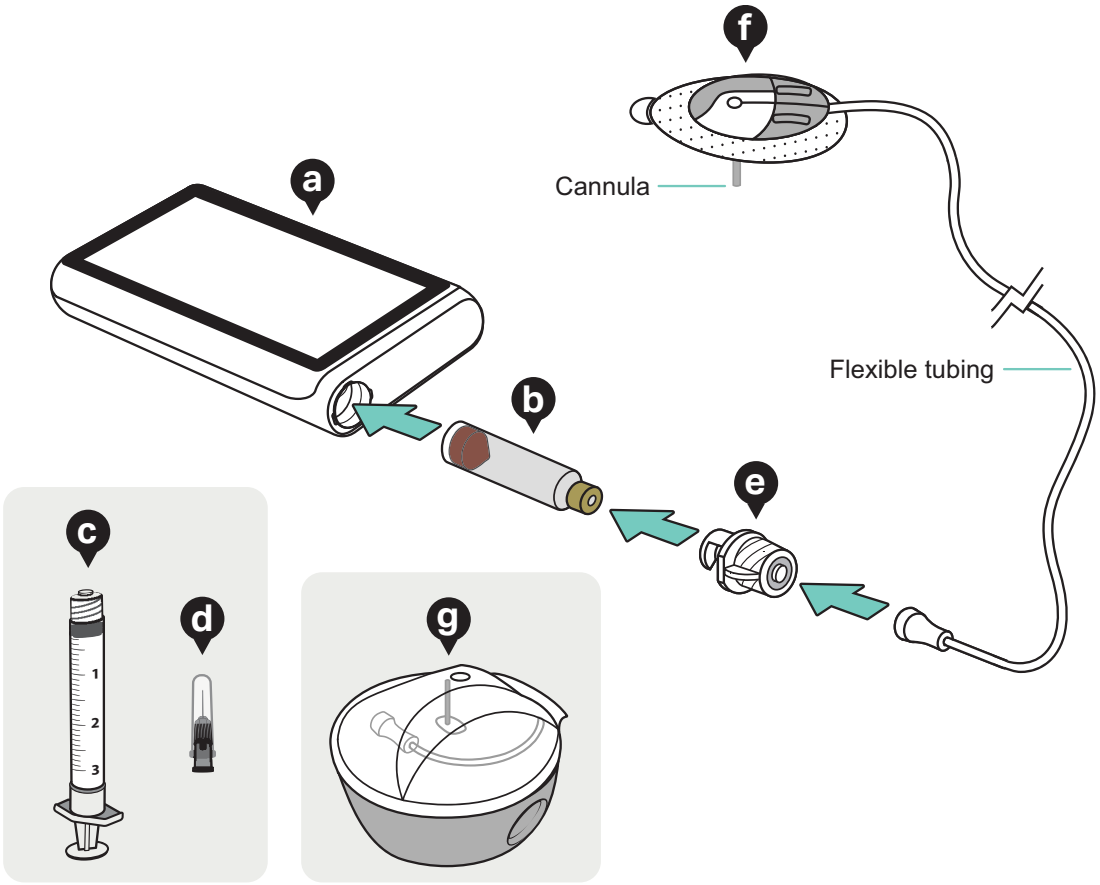
> **WARNING:** Monitor your BG with the guidance of your healthcare provider. Improper or inadequate monitoring may result in undetected hyperglycemia or hypoglycemia.

> **WARNING:** Always notify your healthcare provider about your diabetes and your iLet System. If you need to discontinue the use of your iLet System for medical procedures, follow your healthcare provider's instructions on how to disconnect your iLet System.

2. Home Screen and Device Navigation

2.1 Parts of your iLet System

The iLet System consists of the iLet Device with iLet Dosing Decision Software, and disposable parts.



a. iLet Device: Device that automatically delivers insulin subcutaneously based on input from an integrated continuous glucose monitor (iCGM) transmitter and an interoperable automated glycemic controller (iAGC).

b. iLet Cartridge: Glass container with a soft membrane on top called a septum and a red rubber plunger. iLet Cartridge is filled with insulin and inserted into your iLet Device.

c. Syringe: Plastic syringe (3 mL) that connects to the needle and is used to transfer insulin from a vial into the cartridge.

d. Needle: Needle (3/8-inch) with needle guard (i.e. protective needle cap).

e. iLet Connect: Plastic Luer connector that attaches the flexible tubing of the insulin infusion set to your iLet Device.

f. Infusion Set Base: adhesive patch that sticks on the body with a plastic housing on top and the tiny tube called a cannula that sits under the skin to deliver insulin. Flexible tubing connects the infusion set base to the iLet Device, using the iLet Connect.

g. Infusion Set: Contains the infusion set base, flexible tubing, and inserter, and is used to attach the insulin infusion set base to your body.

2.2 Touchscreen and Backlight

The iLet Device's touchscreen has a high contrast black and white LCD, with a backlight available.

Always On Touchscreen Display: the touchscreen will automatically go to sleep after 45 seconds of inactivity. During this time, your iLet will continue dosing insulin, the display will continue to provide basic status information, but the touchscreen cannot be activated by finger taps.

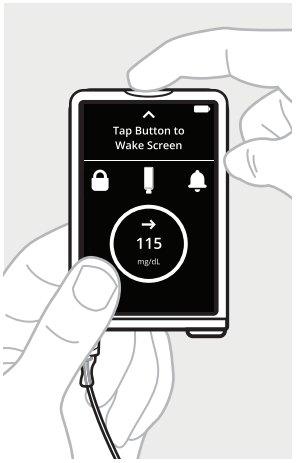


Figure A

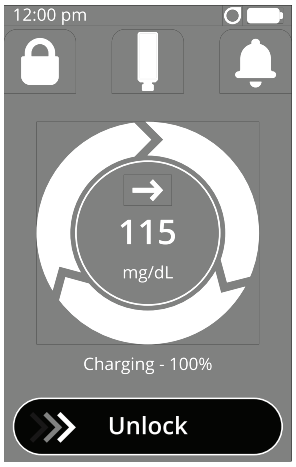


Figure B

The Always On Display may be disabled under **Settings**, **General**. When the Always On Display is disabled, basic status information will be hidden after the touchscreen goes to sleep. During this time, the iLet Device will continue dosing insulin, and you can view basic status information by taping the ***Sleep/Wake*** button.

To turn the touchscreen on, tap the ***Sleep/Wake*** button (see Figure A). Drag the Unlock slider to the right to unlock to the touchscreen (see Figure B).

2.3 Home Screen

Status Bar

Menu
Access features like Enter BG, CGM, Settings, History, Mobile Device, and Volume

Insulin Cartridge
View the number of units remaining in your insulin cartridge, or access the options to change out your insulin cartridge or infusion set

Notifications
View and respond to the alerts and reminders for your iLet Device

Glucose Status
Shows your current CGM glucose value and trend arrow if available. Tapping this brings you to the Graph and Therapy Summary, which includes recent CGM glucose trends and recent insulin delivery

Meal Announcements
Deliver insulin for meals with carbohydrates

2.4 Status Bar

Icon	Feature	Description
	Searching for CGM or Mobile Device	Currently searching for a CGM or Mobile device.
	Dexcom CGM Paired	Dexcom CGM has been paired.
	Mobile Device Paired	Mobile device has been paired.
	Alert Present	An alert is present. View details under the Notifications feature.
	Battery	View the level of your iLet Device's battery charge. The battery icon will display an animation when the iLet Device is charging. The home screen will display a % level when the iLet Device is charging.

2.5 Notifications

Always read and respond to alerts to ensure your iLet System is working correctly. The number of currently active alerts will display in the Notifications icon. When several Alerts occur at once, they will appear in order of priority on the Alerts screen.

Figure C

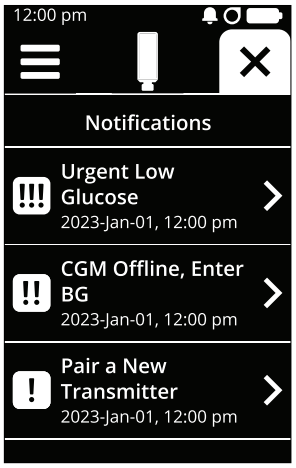
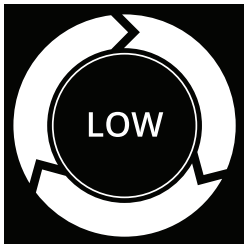
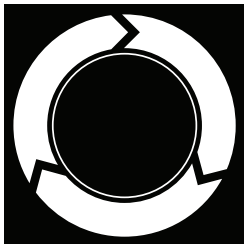
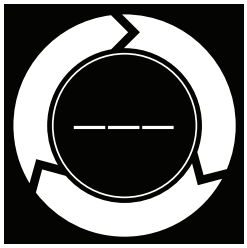
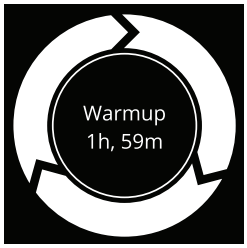


Figure D

2.6 Glucose Status

Status	Description
	CGM glucose value will be displayed in the center of the circle. It may display a trend arrow if enough information is available. The circle will spin when your iLet System is running.
	CGM glucose is below 40 mg/dL. It may display a trend arrow if enough information is available.
	CGM glucose is above 400 mg/dL. It may display a trend arrow if enough information is available.
	CGM sensor has never been paired with your iLet Device.
	CGM sensor data is not available. CGM sensor is not connected. CGM sensor is stopped. CGM glucose value is not available.
	CGM sensor is warming up.

2.7 Glucose Trend Arrows

Your CGM glucose value will be accompanied by a glucose trend arrow which can help you anticipate the rate of change in your glucose values.

Icon	Description
→	Glucose is steady, and changing less than 1 mg/dL each minute. Glucose may change up to 15 mg/dL in 15 minutes.
↗ ↘	Glucose is slowly rising or falling, and changing 1 - 2 mg/dL each minute. Glucose may change up to 30 mg/dL in 15 minutes.
↑ ↓	Glucose is rising or falling, and changing 2 - 3 mg/dL each minute. Glucose may change up to 45 mg/dL in 15 minutes.
↑↑ ↓↓	Glucose is rapidly rising or falling, and changing more than 3 mg/dL each minute. Glucose may change by more than 45 mg/dL in 15 minutes.
None	System can't calculate the speed and direction of your glucose change.

2.8 Graph and Therapy Summary Screens

Your recent CGM patterns, insulin dosing, and time in range will be displayed by pressing the CGM glucose value on the Home screen. Use the arrows on the top of the screen to change the time period displayed. Use the chart and graph icons in the upper right hand corner of the screen to toggle between the screens.

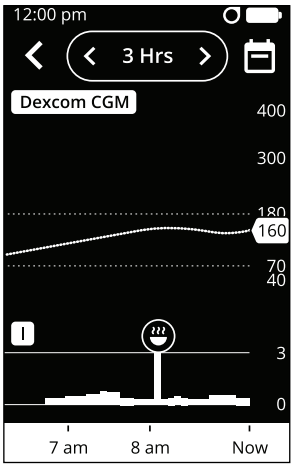


Figure E

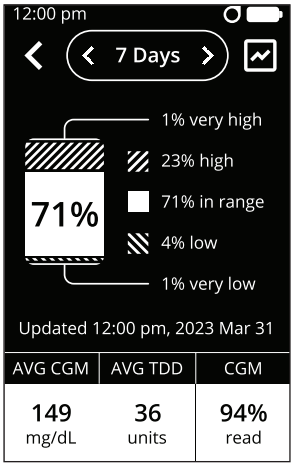


Figure F

2.9 Menu Screen

Icon	Feature	Description
✕	Close	Close the currently open screen

	Enter BG	Enter a BG reading and/or calibrate your CGM
	CGM	View options for pairing or managing a CGM sensor with your iLet Device
	Mobile Device	Pair a compatible smart device (phone or tablet) to your iLet Device using the iLet Mobile App
	Settings	View and adjust your iLet Device settings
	History	View past Alerts, Meal Announcements, insulin cartridge and insulin infusion set changes, Algorithm Steps, and Insulin History
	Volume	View and adjust the volume level of your iLet Device

2.10 Limited Access

Put your iLet Device into Limited Access mode. To activate, you will need to set a passcode between 4 and 8 digits (see Figure G). This function can limit access to features like meal announcements, cartridges, and settings. Autonomous dosing will continue while the iLet Device is passcode protected.

If you forget your passcode, please contact Beta Bionics customer service for more information.

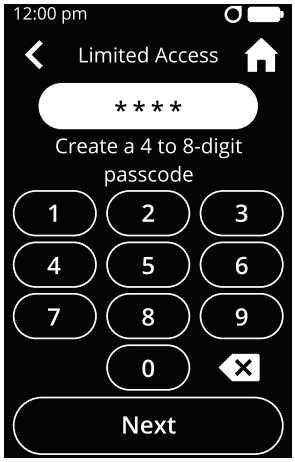


Figure G

2.11 Settings Menu

Settings allow you to adjust features of your iLet Device (see Figure H).

2.11.1 About iLet

View details about your iLet Device in a scrollable list (see Figure I). Your iLet Device's Serial Number is located here for reference. The Serial Number may also be found on the back panel of the iLet Device.

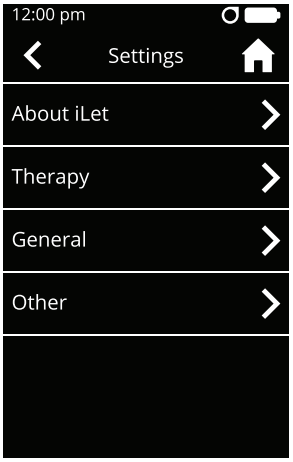


Figure H

Figure I

NOTE that content on this screen is for demonstrative purposes only and actual content may differ slightly.

2.11.2 Body Weight

Adjust the body weight that the iLet uses to dose (see Figure J), if your body weight changes by more than 15%. Contact your healthcare provider for guidance.

CAUTION: Do not adjust the body weight without your healthcare provider's guidance.

CAUTION: Always check that the body weight entered is accurate. The iLet will prompt you to verify the body weight every 3 months.

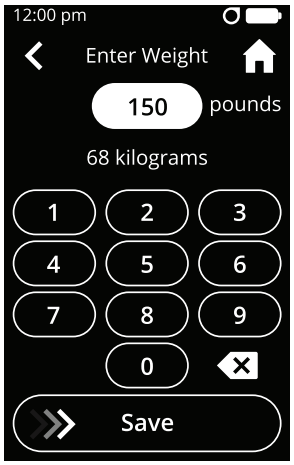


Figure J

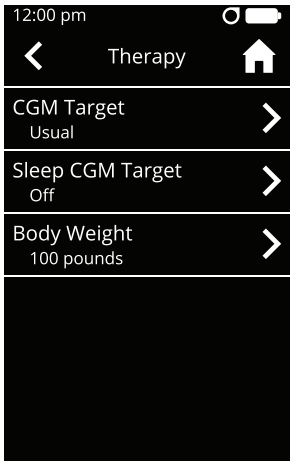


Figure K

2.11.3 Therapy

Adjust settings which may affect your iLet Device's dosing (see Figure L).

2.11.3.1 CGM Target

The default CGM Target setting is Usual.

Adjust the CGM Target to a higher or lower point (see Figure M).

CAUTION: Do not adjust the CGM Target or Sleep CGM Target without your healthcare provider's guidance.

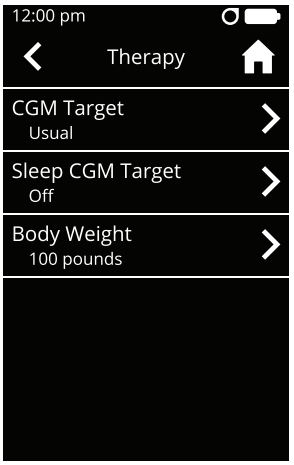


Figure L

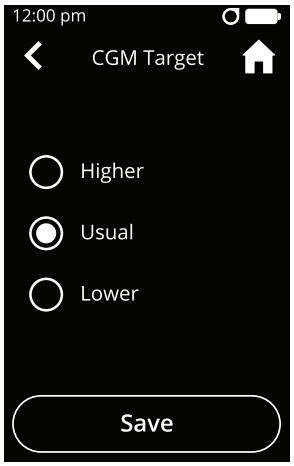


Figure M

CGM Target	Numeric Value
Higher	130 mg/dL
Usual	120 mg/dL
Lower	110 mg/dL

3. Maintaining Your iLet System

3.1 Charging Your iLet Device

WARNING: Do not run your iLet Device on low power for too long. If your iLet Device runs out of power, it will not dose insulin or provide you with CGM values, and the ***Sleep/Wake*** button will not turn the touchscreen on or off. See **Section 7.2.1 Troubleshooting Device Power** for what to do if your iLet Device has run out of power. If your iLet runs out of power, the time of powering down and data contents of the alarm system log shall be saved. If the log reaches capacity, your iLet will alert you, and will also discard the oldest data as newer data is generated. Do not position the power adapter, USB Cable and charging so that it is difficult to operate the iLet Device.

WARNING: Install, remove and handle only dry charging components with dry hands. Make sure that no liquids are present when charging your iLet Device.

WARNING: Use only the AC power adapter and USB cable provided with the iLet Device when charging the iLet Device. Use of another power supply could damage the iLet Device or create the **risk of fire or burns.**

WARNING: Take care when plugging and unplugging your USB cable. Do not force or bend the end of the USB cable into the charging port.

WARNING: Choose a location for charging where you can easily access the power adapter and quickly disconnect to prevent the potential **risk of electrical shock.**

WARNING: Do not expose the USB cable or power adapter to water or other liquids as this may cause. them to not function properly and may lead to **risk of fire or burns.**

WARNING: If your AC power adapter or USB cable is damaged or lost, please contact Beta Bionics Customer Support for a replacement to ensure safe operation of the iLet Device.

Place your iLet Device onto the charging pad to charge it (see Figure N).

Be sure to remove your device clip (iLet Clip) from the iLet Device before placing it on the iLet Charge. The charging pad status light will be solid and the battery icon in the status bar will animate when the iLet is charging properly.

Never let your iLet battery run out of power! Charge your iLet Device for 15 minutes every day.

When charging, maintain an appropriate distance of 7 inches from other magnets and inductive chargers.

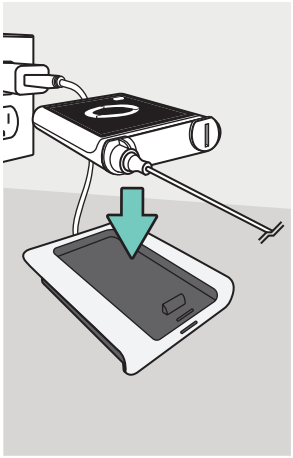


Figure N

3.2 Replacing Your CGM Sensor

Replace your CGM sensor according to your CGM manufacturer's instructions. The Dexcom G6 CGM requires sensor replacement every 10 days and transmitter replacement every 90 days. The Dexcom G7 CGM requires sensor replacement every 10 days.

Manage your CGM sensor from the Main Menu (see Figure O).

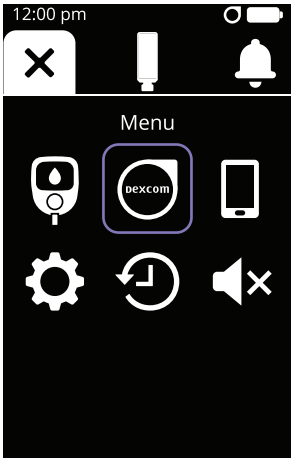


Figure O

3.3 Switching CGM Sensor Types

Switch the CGM sensor that your iLet Device will pair with (see Figure P). If you have a sensor session active, switching the sensor type will stop the sensor session. You will not receive glucose readings, glucose alerts or CGM alerts until you start a new sensor.

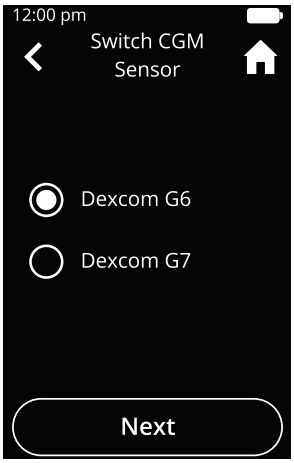


Figure P

3.4 Replacing Your Insulin Cartridge, Tubing and Infusion Set

> **WARNING:** It can be unsafe to use accessories, detachable parts and materials not described in the instructions for use.

> **WARNING:** After installation, do not remove and reinstall the cartridge, tubing line, and/or Luer connector. If these components are removed from the iLet Device, they should be discarded. Replace the cartridge, tubing line, and/or Luer connector with new components following the appropriate procedures in this quick reference guide.

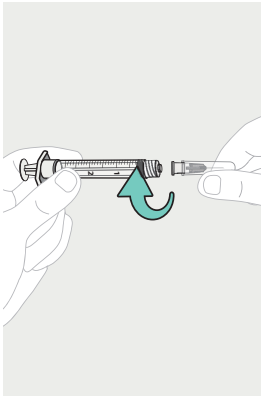
> **CAUTION:** Do not reuse the iLet Connect, insulin cartridge, tubing set, or insulin infusion set.

Replace your iLet insulin cartridge when it runs out of insulin or every 3 days, whichever occurs sooner. Replace your iLet Connect and infusion set tubing every time you replace your iLet insulin cartridge.

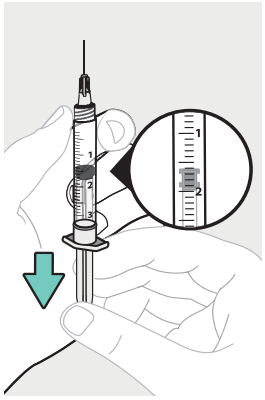
Replace your iLet infusion set at least every 3 days. Always replace your iLet infusion set (as well as cartridge, tubing and connector) if you have any doubt it is not working!

3.5 Preparing the Insulin Cartridge and Insulin Tubing

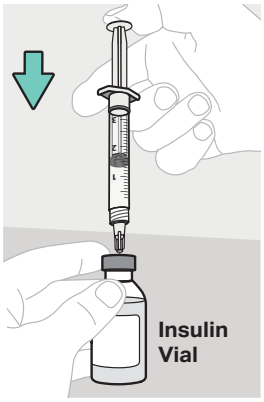
In order to prepare the insulin cartridge, you need to fill an iLet Cartridge with insulin if you are not using a Fiasp® PumpCart® (insulin aspart) prefilled insulin cartridge.



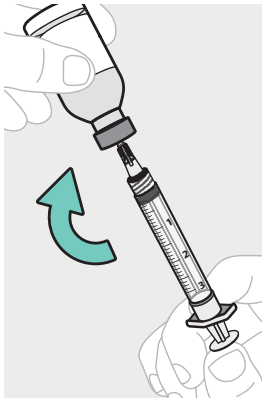
1. Attach syringe to needle.



2. Pull back the plunger of the syringe to 1.8 mL.



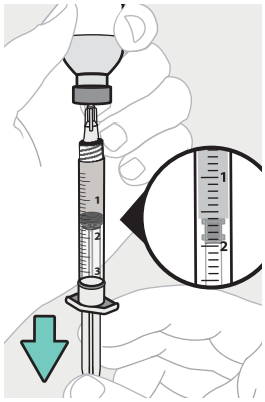
3. Insert needle into vial and depress air into the vial.



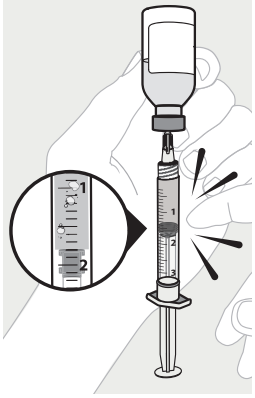
4. Invert insulin vial.

> **CAUTION:** Do not overfill the cartridge. The rubber plunger in the cartridge might get pushed out of the back of the cartridge if too much insulin is transferred. If the plunger is removed from the cartridge, dispose of the cartridge and use a new cartridge.

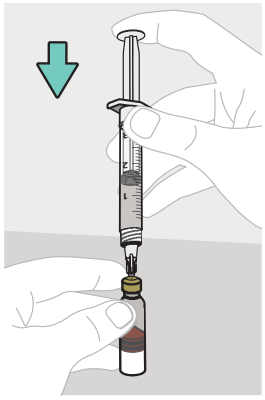
NOTE: The cartridge does not hold more than 1.8mL of insulin.



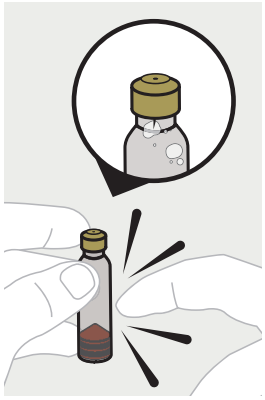
5. Fill the syringe with insulin.



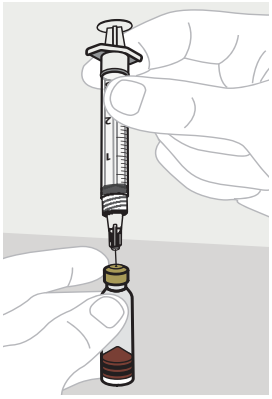
6. Remove air bubbles from the syringe.



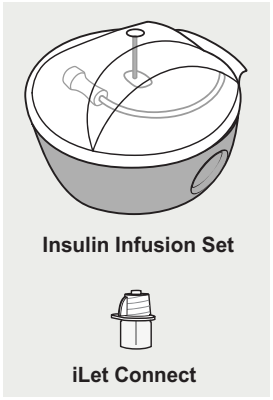
7. Insert needle into empty prepared cartridge and fill with insulin.



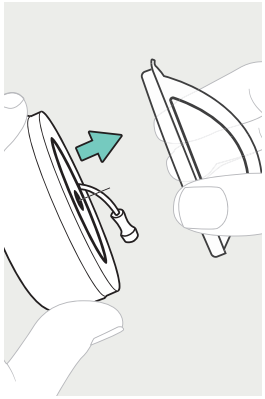
8. Remove the needle and tap the cartridge to loosen any air bubbles inside.



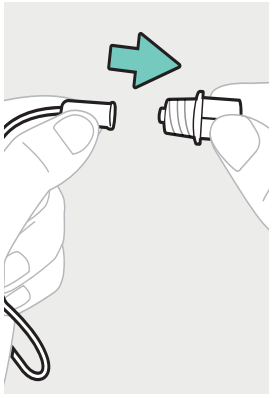
9. Reinsert the syringe and carefully remove any air bubbles. Set aside the cartridge for now.



10. Gather an insulin infusion set and an iLet Connect.



11. Gently unpack the tubing from the insulin infusion set.



12. Connect the iLet Connect to the insulin infusion set tubing and twist to secure.

WARNING: Keep the needle straight, and do not angle the needle to try and remove bubbles on the sides. This can tear the septum of the cartridge , which can cause insulin to leak out of the cartridge. This can cause high BGs, and if prolonged, may cause very high BGs or DKA. If the septum tears, discard the cartridge and restart the fill process.

NOTE: If a bubble is still present near the top of the cartridge, slowly withdraw the syring needle from the cartridge while maintaining pressure on the plunger. The needle tip should now be surrouned by the air bubble. Pull back on the plunger until the air bubble has been removed.

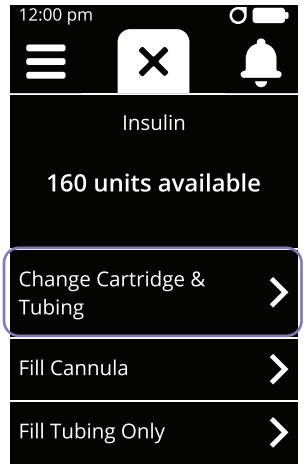
NOTE: Your infusion set may look different from what is pictured.

3.6 Preparing the Device for a New Insulin Cartridge

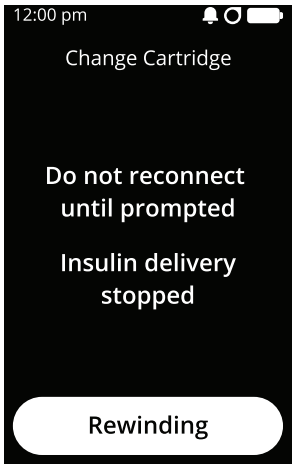
Once the insulin tubing is ready, prepare the iLet Device for the new insulin cartridge. Disconnect any current insulin infusion set tubing from your body, and follow the on-screen instructions to rewind the iLet Device.

CAUTION: Disconnect from your insulin infusion set base prior to beginning the rewind process.

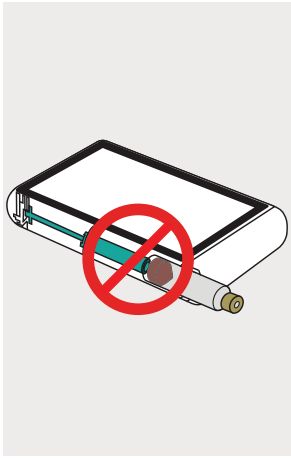
From the home screen, select the Insulin Cartridge icon.



Select Change Cartridge & Tubing. Disconnect any current insulin infusion set tubing from your body.

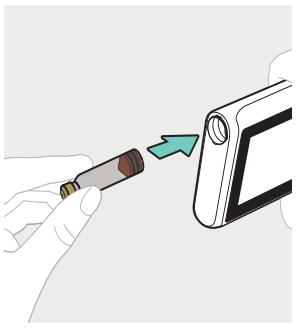


Allow the iLet Device to complete the rewind process. Then remove the old insulin cartridge and attached tubing.

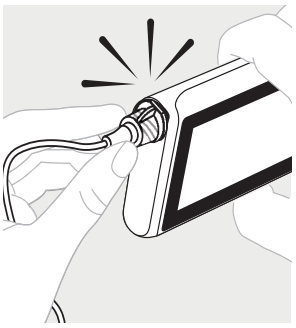


Only insert the insulin cartridge once the rewind process is complete.

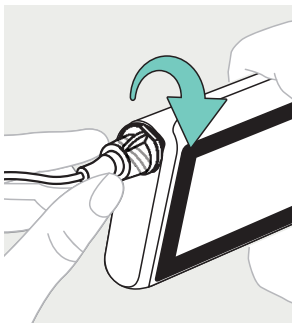
3.7 Insert New Insulin Cartridge



Insert the new insulin cartridge into the insulin chamber of the iLet Device.



AFTER the cartrirdge has been inserted, insert the iLet Connect into the chamber of the iLet Device to lock the filled insulin cartridge into place.



While continuing to push the iLet Connect into the chamber, rotate the connector a quarter turn to the right until the iLet Connect is fitted tightly.

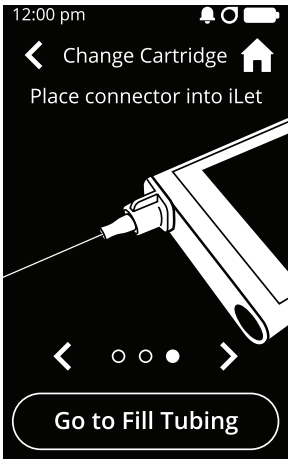
WARNING: Do not attach a filled insulin cartridge and Luer adapter outside of your iLet Device. This

can tear the septum of the cartridge, which can cause insulin to leak out of the cartridge. This can cause high BGs, and if prolonged, may cause very high BGs or DKA. If you attach the filled cartridge and the iLet Connect Luer adapter outside of your iLet Device, discard the cartridge and adapter and restart the fill process.

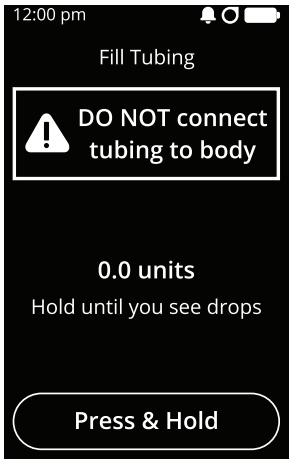
3.8 Fill Insulin Tubing

WARNING: Do not fill tubing while it is connected to your insulin infusion set. Always disconnect the insulin tubing from the insulin infusion set base before using the "Fill Tubing" feature.

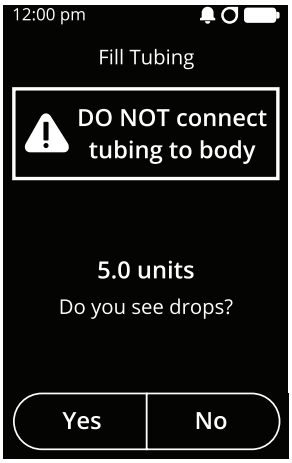
CAUTION: Always remove all air bubbles from the device before insulin delivery. Ensure there are no air bubbles when drawing insulin into the cartridge. Hold your iLet Device with the cartridge connector pointed upward when priming the tubing. Ensure that there are no air bubbles in the tubing when filling. Air takes space where insulin should be so it can affect insulin delivery.



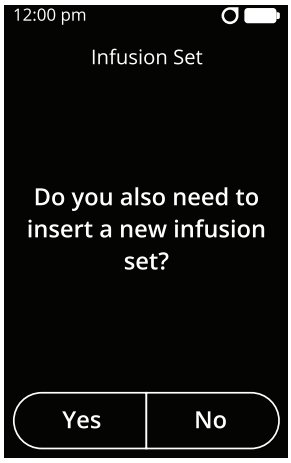
Once the new insulin cartridge is in place, tap "Go to Fill Tubing" on the iLet Device screen.



Press and hold the "Press & Hold" button until the tubing is filled, clear of bubbles, and you see drops at the end of the insulin infusion set.



Once the insulin tubing is filled and you see drops at the end, tap "Yes" on the screen to complete the process.

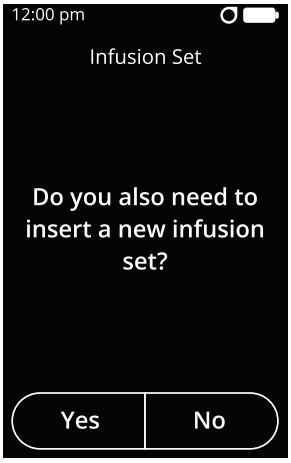


If you do not need to insert a new insulin infusion set base, select "No" and connect the new insulin infusion set tubing to the insulin infusion set base already on your body.

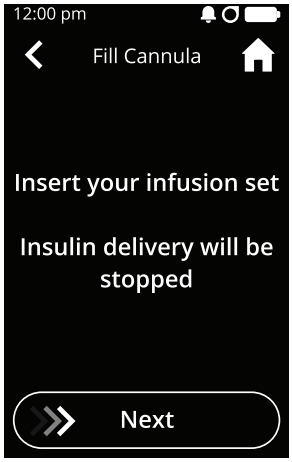
3.9 Insert Insulin Infusion Set

WARNING: Do not place your insulin infusion set on any scars, lumps, moles, stretch marks, or tattoos. Placing your insulin infusion set in these areas can cause swelling, irritation, or infection. This can affect insulin absorption and cause high or low BG.

> **CAUTION:** Change insulin infusion set every 2 to 3 days or as recommended by your healthcare provider. Wash your hands with antibacterial soap. Thorougly clean the insertion site on your body before handling the insulin infusion set to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.



If you do need to insert a new insulin infusion set base, select "Yes" and refer to the insulin infusion set manufacturer's instructions for insertion.



Once the insulin infusion set base is inserted and your insulin tubing is connected to it, drag "Next" to go to the Fill Cannula screen.

Drag "Fill" to theright to fill the cannula. When the cannula is done filling, you'll see a screen confirming the process is complete! Nice job!

4. Meal Announcements

1. Tap the Meal Announcement icon at the bottom of the home screen.
2. Select the meal type you're announcing: "Breakfast", "Lunch", or "Dinner" (see Figure P)
3. The carbohydrate amount will default to "Usual for me", but you can change it by tapping on the option (see Figure Q). This selection adjusts your dose based on the amount of carbohydrate you are eating

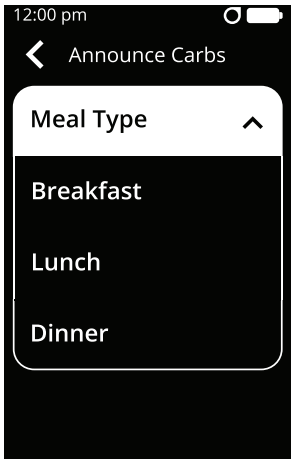


Figure Q

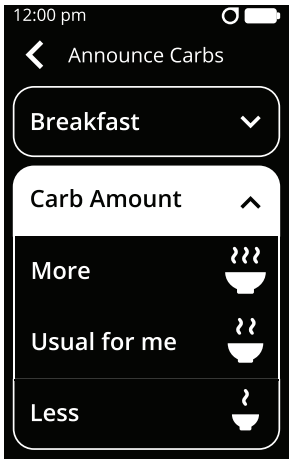


Figure R

   a) "Usual for me" is the usual amount of carbohydrates you would typically eat for that meal type

   b) "More" is around 50% more carbs than your "Usual for me" meal (1.5 times as many carbs as your

"Usual for me" meal)

c) "Less is around half as many carbs as your "Usual for me" meal (50% of your "Usual for me" meal)

NOTE: These options are for the carbohydrates in your meal, not for fats and proteins.

4. Once you select your Meal Type and Carb Amount, drag the "Deliver" slider to the right to complete the meal announcement. Notice a vibration to confirm delivery

5. You can cancel the delivery of insulin by dragging the "Cancel" slider to the left

NOTE: During the initial use period of the meal announcement, the Less carb amount will initially be marked as unavailable for selection. Once the iLet System has undergone the initial adaptation for that meal (through use of the "Usual for me" or "More" carb amount options), the Less option will become available to select.

When do I announce?

- Announce a meal right when you start eating.
- You can announce up to 15 minutes before you start eating. Only do this if you are certain that you will start eating within 15 minutes to avoid hypoglycemia.
- You can announce a meal up to 30 minutes after you start eating. If you forget to meal announce, and more than 30 minutes have passed since you started eating, do not meal announce to avoid insulin "stacking".
- If you announce a meal and then decide to eat more, you can announce again for the additional carbohydrates (carbs). Only consider the amount of additional carbs you are eating when choosing the meal size, not the carbs you have already announced for.

CAUTION: If eating more and announcing again, do not include carbs that you have already announced when deciding the meal size. This could result in severe hypoglycemia.

CAUTION: After 30 minutes, your glucose is already rising, and the iLet System has already dosed insulin according to your CGM levels, even without a meal announcement. If you announce a meal during this time, you will "stack" insulin and be at risk for severe hypoglycemia, as well as confuse the iLet System, causing future meal doses to be less effective.

CAUTION: Do not announce a meal for carbohydrates used to treat low blood glucose. This could cause additional hypoglycemia and is dangerous.

CAUTION: Announcing a larger meal than the actual size could lead to severe hypoglycemia and confuse the iLet System, causing future meal doses to be less effective.

CAUTION: Not announcing meals may lead to hypoglycemia later due to the corrections algorithm adding more insulin.

CAUTION: Using the meal announcing to bring your glucose level down if you are not eating could lead to severe hypoglycemia and confus the iLet System, causing future meal doses to be less effective.

5. Enter BG

WARNING: The iLet is intended to dose insulin based on CGM data. In the events where CGM stops providing glucose data to the iLet, BG-run mode will serve to continue a safe level of insulin delivery, but it will not provide the same level of glucose control as the iLet with CGM. BG-run use **SHOULD BE TEMPORARY** and always for the shortest duration possible with the goal to resume CGM-guided iLet insulin dosing **AS SOON AS POSSIBLE**.

If the CGM sensor is online, you do not need to enter BG values for autonomous dosing. You may enter a BG to calibrate the Dexcom G6 sensor or Dexcom G7 sensor. Refer to the Dexcom G6 or Dexcom G7 user guide for calibration guidance.

When your CGM is offline, your iLet Device will enter BG-run mode, which is limited to a maximum of 48 hours in the first 7 days after initializing the iLet, and a maximum of 72 hours thereafter. This mode requires frequent entry of BG values to continue insulin dosing. You will be alerted when BG values need to be entered. After the maximum allowable period (48 or 72 hours), BG-run mode will expire and CGM values are required to resume dosing. When BG-run mode expires and CGM values are not available, ALL insulin dosing will stop. You must switch to alternative therapy as advised by your healthcare provider.

CAUTION: If your CGM is offline for an extended period of time, ALL dosing will stop and you should switch to alternative therapy until you are able to reconnect to a CGM sensor. A countdown timer will appear before dosing would stop.

CAUTION: The iLet Device cannot connect wirelessly with a self-monitoring blood glucose device,

and manual BG value entries must be performed when the iLet Device alerts you for a BG entry.

For more information about the BG-run mode, please refer to the iLet BIonic Pancreas user guide, **Section 4.3.1 BG-Run Mode**.

During BG-run mode, you can expect the following to happen:

- Your iLet Device will continue dosing basal insulin based on its previously learned basal rate as long as you enter the required BG values. If an entered BG value is low, the iLet will shut off your basal insulin for an hour, or until a BG value that is not low is entered.
- If an entered BG value is high, the iLet will give you correction insulin.
- You can continue to announce meals and the iLet will give you meal insulin.

a. Use a BG meter to check your BG.

b. From the ***Home*** screen, tap the ***Menu*** icon in the upper left corner.

c. Tap the ***Enter BG*** icon (see Figure R).

d. Type in a BG value. Tap ***Next*** to continue (see Figure S).

e. Check if the BG entered is correct. Tap ***Confirm*** to proceed.

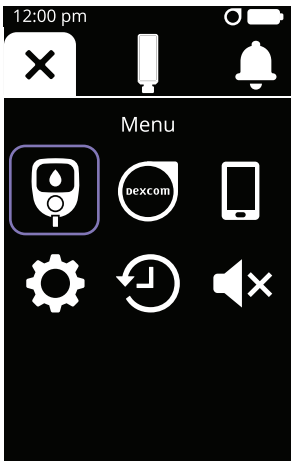


Figure S

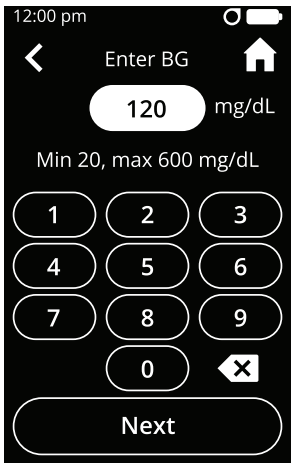


Figure T

6. Responding to Alerts

6.1 iLet System Alerts Overview

Your iLet Device will alert you when important issues need to be addressed. There are several alert levels (see Figure T). When multiple alerts occur at the same time, alerts with the highest priority will be displayed first.

You may encounter other alerts that are not described in this quick reference guide. If you encounter such alerts, follow the instructions on the screen and contact Beta Bionics.

When an alert occurs, your iLet Device will:

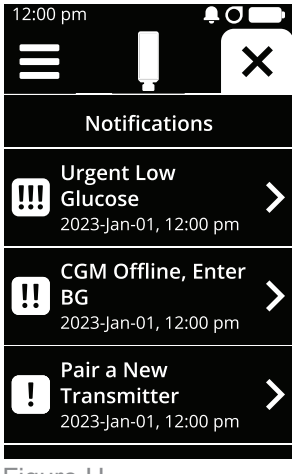


Figure U

a. Emit a series of audible sounds and vibrations.

b. Display a bell icon in the status bar.

c. Display a number in the Notifications icon on the Lock, Home, and Always On screens.

d. Display a symbol with an exclamation point in the Notifications list.

e. Display an alert message.

> **CAUTION:** Check your iLet Device regularly for any displayed alerts. Respond as soon as possible to conditions that may affect insulin delivery or require immediate action.

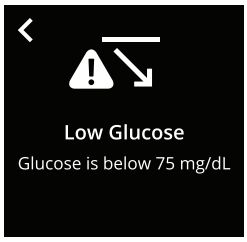
Priority	Level	Behavior	What It Means	What to do
Low 	Level 0	Alert with no beeps and no vibrations.	A reminder about an upcoming event, or a component of your iLet System may stop functioning soon.	Acknowledge the alert by tapping the button at the bottom of the alert message.
	Level 1	Will alert every 5 minutes with 2 beeps and 1 vibration. These will not escalate to the next volume level.		
	Level 2	Will alert every 5 minutes with 2 beeps and 1 vibration. These will not escalate to the next volume level.		

Medium 	Level 3	Will alert every 5 minutes with 12 beeps (if volume is on) and 3 vibrations. These will escalate to the highest volume level after 15 minutes. The alert will not stop until acknowledged or resolved.	Your iLet Device may have stopped delivering insulin. It requires attention as soon as possible.	Fix the issues that trigger the alert. You may need to contact Beta Bionics for further resolution.
	Level 4	Will alert every 5 minutes with 12 beeps (if volume is on) and 3 vibrations. These will escalate to the highest volume level after 15 minutes. The alert will not stop until acknowledged or resolved.		
High 	Level 5	Will alert every 5 minutes with 20 beeps (if volume is on) and 5 vibrations. These will escalate to the highest volume level after 5 minutes. The alert will not stop until acknowledged or resolved.	Your glucose is urgently low. It requires immediate attention or action.	Treat your low glucose level with rapid-acting carbohydrates and monitor your CGM glucose until it returns to range.

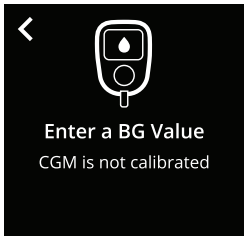
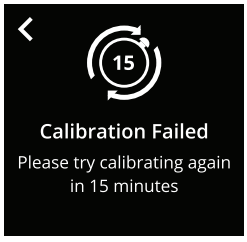
6.2 CGM and Glucose Alerts

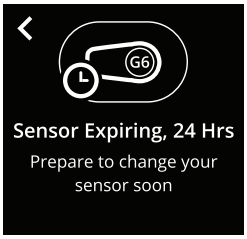
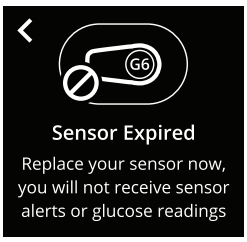
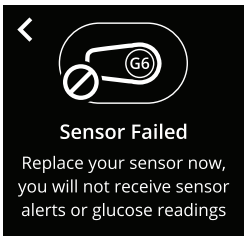
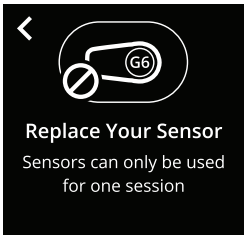
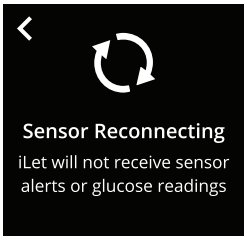
6.2.1 CGM and Glucose Alerts

Screen	Alert	Priority (Level)	What to do
	Urgent Low Soon	Medium (Level 3)	Your glucose is predicted to drop below 54 mg/dL in the next 20 minutes. Prepare to treat your low glucose as advised by your healthcare provider. Monitor your BG levels closely.

	Urgent Low Glucose	High (Level 5)	Treat your low glucose with up to 15 grams of rapid-acting carbohydrates, as advised by your healthcare provider. Monitor your BG levels closely.
	Low Glucose	Medium (Level 3)	Treat your low glucose with up to 15 grams of rapid-acting carbohydrates, as advised by your healthcare provider. Monitor your BG levels closely.
	High Glucose	Medium (Level 3)	Inspect your cartridge, tubing, and infusion set for any leaks or occlusions. Check for ketones and contact your healthcare provider if your high glucose continues.
	Glucose Falling Quickly	Medium (Level 3)	Prepare to treat your low glucose as advised by your healthcare provider. Monitor your BG levels closely.

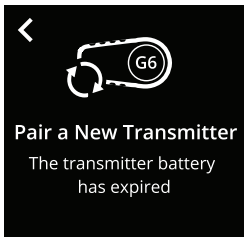
6.2.2 Dexcom G6 Sensor Alerts

Screen	Alert	Priority	What to do
	Enter a BG Value	Medium (Level 3)	Enter a BG value measured by a finger-stick test.
	Calibration Failed	Low (Level 1)	Calibrate your sensor again in 15 minutes with a BG value.

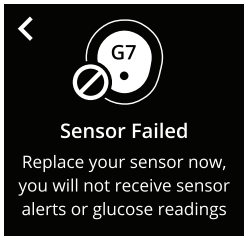
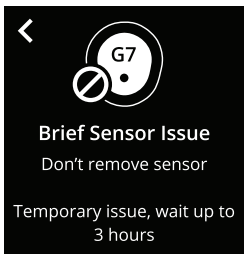
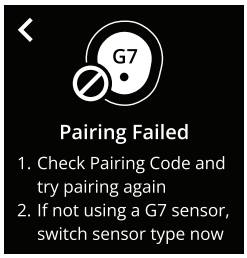
	Sensor Expiring, 24 Hrs	Low (Level 0)	You may see alerts within: 24 hours, 6 hours, 2 hours, or 30 minutes. Be prepared to change your sensor when it expires.
	Sensor Expired	Low (Level 1)	Change your sensor now.
	Sensor Failed	Low (Level 1)	Change your sensor now.
	Replace Your Sensor	Low (Level 1)	Replace with a new CGM and start a new sensor session.
	Sensor Reconnecting	Low (Level 1)	Wait up to 3 hours for your sensor to reconnect. If more than 3 hours have elapsed, please contact Beta Bionics.

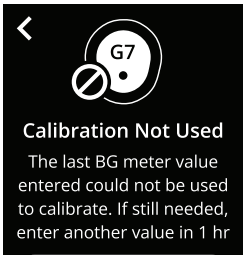
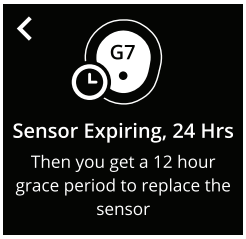
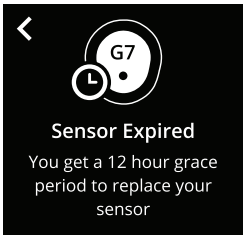
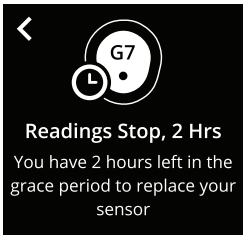
6.2.3 Dexcom G6 Transmitter Alerts

Screen	Alert	Priority	What to do
	CGM Battery Low	Low (Level 0)	Confirm that you have another transmitter available for when your transmitter battery expires.

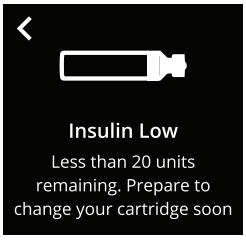
	Pair a New Transmitter	Low (Level 1)	Your transmitter's battery has expired. Pair a new transmitter now.
	Pair a New Transmitter	Low (Level 1)	Your transmitter has failed. Pair a new transmitter now.
	Transmitter Not Found	Low (Level 1)	Check your transmitter SN. Pair again. If the issue continues, contact Beta Bionics. If not using a G6 sensor, switch your sensor type to the appropriate sensor.

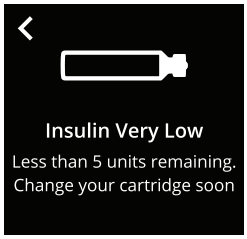
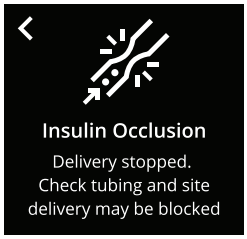
6.2.4 Dexcom G7 Alerts

Screen	Alert	Priority	What to do
	Sensor Failed	Low (Level 1)	Replace your sensor now, you will not receive sensor alerts or glucose readings.
	Brief Sensor Issue	Low (Level 0)	This is a temporary issue, don't remove your sensor. Wait up to 3 hours. If more than 3 hours have elapsed, please contact Beta Bionics.
	Pairing Failed	Low (Level 1)	Check the Pairing Code entered and try pairing again. If not using a G7 sensor, switch your sensor type to the appropriate sensor.

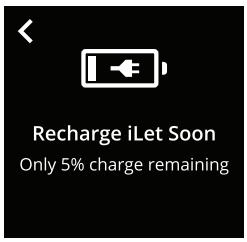
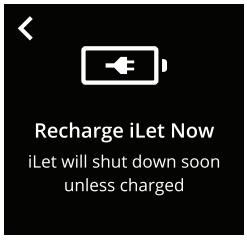
	Calibration Not Used	Low (Level 1)	The last BG meter value entered could not be used to calibrate. If still needed, enter another value in 1 hr.
	Sensor Expiring	Low (Level 0)	You may see alerts within: 24 hours and 2 hours. After this you will get a 12 hour grace period. Be prepared to change your sensor when the grace period ends.
	Sensor Expired	Low (Level 1)	You get a 12 hour grace period to replace your sensor. The sensor will continue to function as normal during this time. Change your sensor within the next 12 hours.
	Readings Stop	Low (Level 1)	You may see alerts within: 2 hours and 30 minutes that the sensor grace period is ending. Be prepared to change your sensor when the grace period ends.
	Replace Sensor Now	Low (Level 1)	Replace with a new sensor and start a new sensor session.

6.3 Insulin Delivery Alerts

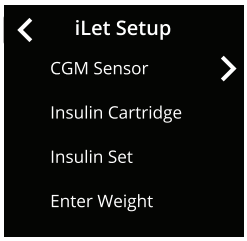
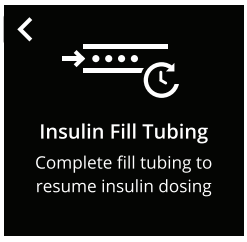
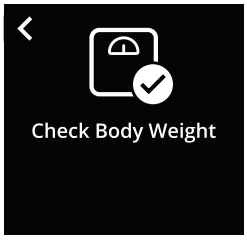
Screen	Alert	Priority	What to do
	Insulin Low	Low (Level 1)	Only 20 units of insulin remaining. Prepare to change your cartridge soon.

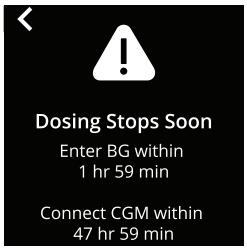
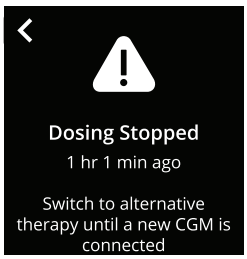
	Insulin Very Low	Medium (Level 3)	Less than 5 units of insulin remain. Change your cartridge soon.
	Change Insulin	Medium (Level 3)	Your insulin cartridge is empty. Change your cartridge now.
	Insulin Occlusion	Medium (Level 3)	Check your tubing and infusion set. Follow your healthcare provider's recommended troubleshooting procedures. Tap Resume Delivery to continue therapy. If another occlusion occurs, contact Beta Bionics. For more information on how occlusions and doses are handled, please refer to **Section 9.1 iLet Dosing Decision Software**.

6.4 Battery Alerts

Screen	Alert	Priority	What to do
	Recharge iLet Soon	Medium (Level 3)	Only 5% or lower charge remaining. Charge your iLet as soon as possible.
	Recharge iLet Now	Medium (Level 3)	Only 2.5% or lower charge remaining. Charge your iLet as soon as possible to avoid shutdown.

6.5 Reminders

Screen	Alert	Priority	What to do
	iLet Setup	Low (Level 1)	Follow the on-screen directions to set up your iLet for therapy.
	Insulin Set Expired	Low (Level 2)	Your infusion set has expired, tap Change Set to change it and fill cannula.
	Change Insulin	Medium (Level 3)	You started but have not completed the insulin cartridge change process. Tap Finish Now to complete it.
	Insulin Fill Tubing	Medium (Level 3)	You started but have not completed the Fill Tubing process. Tap Finish Now to complete it.
	Insulin Fill Cannula	Medium (Level 3)	You started but have not completed the fill cannula process. Tap Finish Now to complete it.
	Check Body Weight	Low (Level 0)	This reminder appears every 3 months. Follow the on-screen instructions to confirm or update your body weight. Not updating your body weight may result in less effective control if it is outside the current range provided in the reminder.

	Dosing Stops Soon	Medium (Level 3)	Connect a CGM before either timer runs out or enter a BG before the first timer runs out to continue dosing.
	Dosing Stopped	Medium (Level 3)	Dosing has stopped. Connect a CGM or enter a BG to resume dosing.
	Dosing Stopped	Medium (Level 3)	Dosing has stopped. The iLet must receive a CGM value to resume dosing. Entering a BG value will not resume insulin dosing. If the iLet will not be receiving a CGM value soon, switch to alternative therapy as advised by your healthcare provider and disconnect from the iLet.
	iLet Malfunction	Medium (Level 4)	Contact support and switch to alternative therapy as advised by your healthcare provider.

7. Troubleshooting

7.1 Always Have an Emergency Kit

> **CAUTION:** Always have an alternative method of administering insulin either a vial and syringe or insulin pen. Because your iLet Device uses only rapid-acting insulin, you will not have any long-acting insulin in your body.

> **CAUTION:** In the event that your iLet Device malfunctions, not having long-acting insulin in your body is dangerous. Lack of long-acting insulin may lead to severe hyperglcyemia or DKA.

> **CAUTION:** Always have an alternative method of monitoring your BG in case your CGM malfunctions. Your iLet Device relies on BG entries when your CGM is unavailable.

Always have an appropriate emergency kit with you. Talk with your healthcare provider regarding what

items the kit should include.

Supplies to carry every day include:

- BG testing supplies: meter, strips, control solution, lancets, and meter batteries
- CGM supplies: sensor (and transmitter if applicable)
- Fast-acting carbohydrates to treat low BG
- Ketone meter
- Ketone testing strips
- Extra snack for longer coverage than fast-acting carbohydrate
- Glucagon rescue kit
- Rapid-acting insulin vial and syringes or a rapid-acting insulin pen
- Basal insulin vial and syringes or a basal insulin pen
- Insulin infusion sets (minimum of 2)
- iLet insulin cartridges (minimum of 2)
- Infusion set preparation products (e.g., antiseptic wipes, skin adhesive)
- Diabetes identification card or jewelry

7.2 Verify Proper Functionality

- Once per day, check to see if insulin is leaking around the insulin chamber, Luer adapter, tubing, or infusion set.
- Once per day, touch the ***Sleep/Wake*** button. Confirm that the system is on and no alerts are displayed on the touchscreen.
- Once per day, check that basic features and the iLet Device's alerts, such as vibration and sound notifications are working. Turn on the touchscreen or backlight to check vibration. Select a volume to check sound.
- Monitor your CGM for unusual changes in BG levels.

- Place your iLet Device on the charger and confirm that it is charging.
- Try to keep your iLet Device from exceeding the rated fluid exposure level. The iLet Device has an IPX8 moisture ingress protection rating. If your iLet Device has exceeded the rated fluid exposure level, examine the iLet Device for signs of moisture ingress as the iLet Device may not function properly. If you see signs of moisture ingress, contact Beta Bionics customer service.
- Try to keep your iLet Device from exceeding excessive handling conditions. If your iLet Device has been exposed to excessive handling conditions, examine the iLet Device for signs of damage as the iLet Device may not function properly. If you see signs of damage, contact Beta Bionics customer service.

7.2.1 Troubleshooting Device Power

If your iLet Device is not on, place it on the iLet Charge. If your iLet Device remains off while on the iLet Charge, check your power supply to ensure that it is connected correctly and ensure that the iLet Device is sitting on the iLet Charge correctly (See **Section 3.1 Charging your iLet Device**).

If your power supply is working but the iLet Device still does not turn on, contact Beta Bionics for additional assistance.

8. Care Information

8.1 General Handling

> **CAUTION:** Do not insert any objects or fluids into the insulin chamber. This could damage the device and cause it not to function properly.

> **CAUTION:** Do not use your iLet Device if it has been dropped or encounters other significant shock as it may not function properly. Inspect your iLet Device for any signs of damage if it has been dropped. If you are unsure about potential damage, discontinue the use of your iLet System and contact your healthcare provider.

> **CAUTION:** Dispose of your iLet Device and its accessories per local laws and rules for medical electrical hazards and bio-hazard waste to prevent risk of harm. Always wash your hands after handling used components and accessories.

- Check your iLet Device and iLet Device's alerts at least once a day to make sure that it is working properly.

8.2 Cleaning Your iLet Device

CAUTION: Never dry any component of your iLet System in a microwave oven or baking oven as this may cause it not to function properly.

CAUTION: Do not clean the inside of the cartridge chamber as this may cause it not to function properly.

CAUTION: Do not wash any component of your iLet System in the dishwasher. Do not use household or industrial cleaners, solvents, bleach, scouring pads, chemicals, or sharp instruments to clean your iLet System as this may cause it not to function properly.

- Clean your iLet Device and touchscreen once per week.
- Clean your iLet Device and touchscreen with a soft, lint-free cloth. You can use a damp cloth with water if necessary. You can also use 70% Isopropyl Alcohol, CaviCide™ (or similar disinfectant) or diluted dish detergent for up to 1 minute per week.
- Keeping your touchscreen clean makes it more responsive to touch.
- Use a soft towel to dry your iLet Device. Wipe the outside of the Dexcom G6 transmitter with a damp lint-free cloth or isopropyl alcohol wipe between uses. Refer to your Dexcom User Manual for additional instructions.

9. Technical Information

9.1 iLet Dosing Decision Software

The iLet System only needs your body weight to get started (for initialization). It automatically delivers insulin to control glucose levels based on your CGM readings. You do not need to know your basal insulin rates, correction factors, or carbohydrate-to-insulin ratios to use the iLet System.

The iLet Dosing Decision Software is a set of mathematical formulas that calculate and predict how much insulin is needed based on your CGM values and how they have been trending. An algorithm is a set of steps that help solve a problem as efficiently as possible. An algorithm may also be used to automate the steps of a solution for a particular problem. The iLet Dosing Decision Software is made up of three algorithms that work together to figure out how much insulin you need at any time:

1. The first algorithm is called the **basal insulin algorithm**. This algorithm calculates how much insulin "baseline" you should always have; This algorithm will autonomously make a decision

about delivering a basal insulin dose, whether a CGM glucose or BG value is available or not.

2. The second algorithm is called the **bolus correction algorithm**. This algorithm makes adjustments or "corrections" that you might need to the basal insulin dose to adjust for all kinds of things that come up during the day such as stress, sleeping, etc. It also prevents something called insulin stacking which can lead to hypoglycemia.

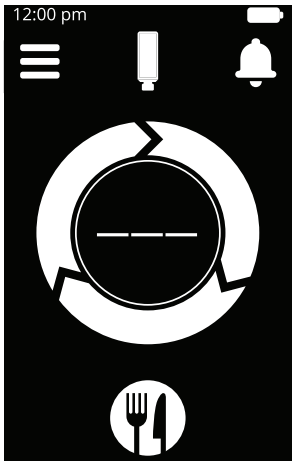
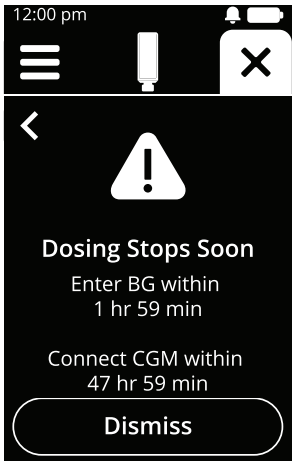
3. The third algorithm is called the **meal announcement algorithm** and is specifically for making sure you have the right insulin dosing for meals. You will learn how to "announce" a meal to the system or tell the iLet that you are having a meal. The third algorithm will then figure out how much insulin you need. This algorithm will learn and adapt as you use the system more. Insulin meal doses are capped at 24 U.

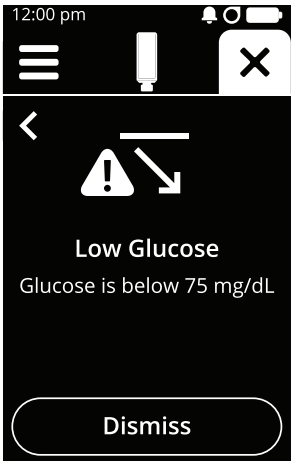
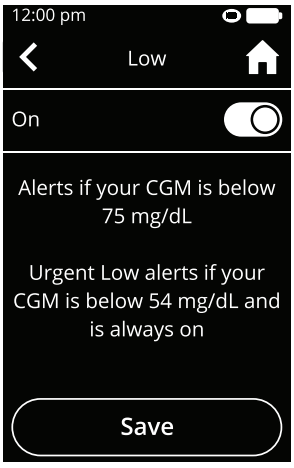
Finally, when the CGM is offline, the iLet Dosing Decision Software remembers the latest basal dosing that it learned, allows you to make meal announcements in exactly the same way as when the CGM was online, and then automatically responds to entered BG values by issuing a correction dose of insulin when needed.

When an occlusion occurs during an autonomous delivery, the iLet System will attempt to make up the rest of the dose at the next opportunity if appropriate. When an occlusion occurs during a Meal Announcement, the remainder of the dose is not delivered. The amount of the dose that was partially delivered is used by the iLet Dosing Decision Software in future dose calculations.

The iLet Dosing Decision Software is a Physiological Closed-Loop Control System (PCLCS), with various modes. A summary of each mode and their indicators below describes when the iLet Dosing Decision Software changes its mode of operation.

PCLCS Mode	Indicators	Description
CGM Mode		The iLet Dosing Decision Software will respond to CGM glucose values with autonomous insulin doses.

BG Mode, No CGM		The iLet Dosing Decision Software will respond to BG glucose values with autonomous insulin doses.
No CGM, No BG		The iLet Dosing Decision Software will respond with autonomous basal insulin doses even if no CGM or BG value is provided. The iLet Device will also alert the user to enter a BG value.

No Delivery, Low CGM / BG Limit Mode	 	The iLet Dosing Decision Software will respond by shutting off insulin doses in response to a low CGM or BG entry. Insulin doses (excluding meal doses) are set to 0 in response to a low glucose level ≤60 mg/dL.
User Settable Mode		The iLet Device will respond by alerting the user when CGM or BG values are below 75 mg/dL.

The iLet Dosing Decision Software has additional means of providing dose safety. These are:

1. Insulin doses are globally capped at 30 units.

2. Routine autonomous insulin doses in response to CGM glucose values are limited to 3 units.

3. If a low glucose level occurs (such as less than or equal to 60 mg/dL), the autonomous insulin doses will stop until glucose levels have returned to a better range.

Individual autonomous 5-minute doses, including both bolus and basal, are actually limited to 3 units in response to a CGM glucose value when the CGM is online and to 6 units in response to a BG value when the CGM is offline (there are no additional hard limits on dosing that are imposed over a specific amount of time). The global dose limit of 30 units is relevant / available to allow a simultaneous meal dose, which has its own limit of 24 units, to be delivered along with the maximum possible autonomous (basal + bolus) dose, should such a circumstance occur.

9.2 iLet System Specifications (iLet Device, CGM Sensor, and CGM Transmitter)

Name	Specification
Operating Conditions (iLet Device, CGM sensor, CGM transmitter)	Temperature: 50°F (10°C) to 98.6°F (37°C) Humidity: 15% to 90% RH non-condensing
Storage Conditions (if iLet Device, CGM sensor and CGM transmitter stored together)	Temperature: 36°F (2°C) to 86°F (30°C) Humidity: 20% to 90% RH non-condensing
Operating Altitude	-1200 feet to 10,000 feet
Moisture Protection for iLet Device only	IPX8: Protected against immersion in water for up to 12 feet for 30 minutes
Moisture Protection G6 Receiver	IP22: Protected against vertically falling water drops and insertion of large objects
Moisture Protection G6 Transmitter	IP28 Protection against insertion of large objects and immersion in water for up to 8 feet for 24 hours
Moisture Protection G7 Sensor	IP58 Protection against insertion of large objects and immersion in water for up to 8 feet for 24 hours
Protection Against Electrical Shock	Type BF applied part

9.3 iLet Device Specifications

The iLet Device and power supply accessories have an expected typical use service life of 4-years,

including the internal electrical power source. During the service life of your iLet Device you may need to replace charging accessories or other consumable components. Call customer service for charging issues and to ask for a replacement charger. Do not use third party chargers with the iLet Device.

The specified accuracy may not be maintained outside of specified operating conditions or use of insulin infusion sets other than those defined in this quick reference guide.

Name	**Specification**
Classification	External Inductive PSU: Class II, Infusion Device. Internally-powered Type BF applied part.
Size (without disposables)	59 W X 91 L X 15 H millimeters
Weight (with full cartridge–no set)	110 grams
Operating Conditions	Temperature: 41°F (5°C) to 104°F (40°C) Humidity: 15% to 90% RH non-condensing Atmospheric Pressure, operating: 10.2 to 15.4 psia (Relative altitude 10,000 to -1,300 feet)
Storage Conditions	Temperature: -4°F (-20°C) to 140°F (60°C) Humidity: 15% to 90% RH non-condensing Atmospheric Pressure, operating: 10.2 to 15.4 psia (Relative altitude 10,000 to -1,300 feet)
Reservoir Volume, Insulin	1.8 mL (180 units)
Drug Concentration, Insulin	U-100
Alarm Indication	Audible, Vibratory, and Visual
Minimum Audible Alarm Volume	45 dBA at 1 meter, for all alarms
Typical Audible Alarm Volume	49 dBA at 1 meter, for all alarms
Residual Remaining in the Cartridge (unusable), Insulin	15 units
Frequency of Delivery	Every 5 minutes

Basal Delivery Accuracy at all Flow Rates, Insulin (tested per IEC 60601-2-24)	± 5% Max (10 U/hr) and Intermediate (1.0 U/hr) / ± 15% Min Basal (0.1U/hr)
Bolus Delivery Accuracy at all Volumes Insulin (tested per IEC 60601-2-24)	± 5% Max (30 U)/Intermediate (5 U)/Min (0.5U)
Maximum Infusion Pressure Generated and Occlusion Alarm Threshold, Insulin	30 PSI
Patient Protection from Air Infusion	The drug delivery route to interstitial tissue is subcutaneous, not intravenous Priming process eliminates almost all air. Clear tubing aids in the detection of air.
Typical Operating Time (0.7 units/hr, 18 unit total bolus/day with CGM)	5 days typical between charge (Full charge to total discharge state)
Bolus Volume at Release of Occlusion, Insulin	Less than 4 units
USB Wall Charger, Model No. Means to Isolate Wall Mains Power	GTM86100-1005-W2
Wall Charger Input Voltages/ Current	100-240V~. 50/60 Hz, 0.3A
Wall Charger Output Voltages Current	5 VDC/2.0A
Wall Charger Output Cable/ Connector	1530 mm, 22/2 Cond, UL 2468, Micro-B USB 5 Pin Type "B" or Equal, Ferrite Core
Wall Charger Ingress Protection	IP22
Inductive Charging Pad w/USB	T511 Choetech
Input Volt/Current	5V/2A
Output Power	5W (Max)
Output Type	Qi Inductive Charger
Inductive Charging Pad w/USB	T511-S Choetech
Input Volt/Current	5V/2A, 9V/1.8A

Output Power	10W (Max)
Output Type	Qi Inductive Charger
Prime Rate (Tested in 110 cm length set)	< 60 seconds No alarms are disabled
Bolus Rate	1 Unit / 5 ±0.5 seconds No alarms are disabled
Compatible Administration Sets with Luer Lock Connectors	iLet inset™, iLet inset™ 30, iLet Contact™ Detach
Maximum Volume That May Be Infused Under Single Fault Conditions	Maximum 3.0 units

Time to Occlusion Alert*

Operating Rate	Typical	Maximum
Bolus (4 units or greater)	11 seconds	15 seconds
Basal (1 unit/hr)	2 hours 51 minutes	3 hours 52 minutes
Basal (0.1 unit/hr)	29 hours 29 minutes	39 hours 25 minutes

* The time until an occlusion alert occurs is based on the insulin volume not delivered. A bolus of less than 4 units might not trigger an occlusion alert until additional basal or bolus deliveries occur.

9.4 iLet System Delivery Accuracy

The iLet System delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Beta Bionics. The iLet inset™ I infusion set was used for all the testing performed.

All testing was performed with the following quantities:

N =	Min Basal	Int Basal	Max Basal	Min Bolus	Int Bolus	Max Bolus
Pumps	29	15	15	15	15	15
Cartridges	29	15	15	15	15	15
Infusion Sets	15	15	15	15	15	15

9.4.1 Basal Delivery

To assess basal delivery accuracy, iLet Devices were tested by delivering at minimum (29 devices), intermediate (15 devices), and maximum (15 devices) basal rates (0.1, 1.0, and 10.0 units/hr). All devices for minimum basal, intermediate basal and maximum basal were new. An additional 15 devices for minimum, intermediate, and maximum basal had been aged to simulate four years of regular use. Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy. The following tables report the typical basal performance (median) observed, along with the minimum and maximum results observed for minimum, intermediate, and maximum basal rate settings for all devices tested. For the minimum, medium and high basal rates, accuracy is reported from the time basal delivery started with no warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Minimum Basal Rate Delivery Performance (0.1 units/hr, n = 29 new devices)

Basal Duration (Number of Units Delivered with 0.1 units/hr Setting)	**1 hour (0.1 units)**	**6 hours (0.6 units)**	**12 hours (1.2 units)**
Amount Delivered (Median) [min, max]	0.09 units [0.02, 0.12]	0.56 units [0.29, 0.65]	1.12 units [0.77, 1.25]

Minimum Basal Rate Delivery Performance (0.1 units/hr, n = 15 aged devices)

Basal Duration (Number of Units Delivered with 0.1 units/hr Setting)	**1 hour (0.1 units)**	**6 hours (0.6 units)**	**12 hours (1.2 units)**
Amount Delivered (Median) [min, max]	0.09 units [0.02, 0.11]	0.55 units [0.30, 0.63]	1.11 units [0.79, 1.20]

Intermediate Basal Rate Delivery Performance (1.0 units/hr, n = 15 new devices)

Basal Duration (Number of Units Delivered with 1.0 units/hr Setting)	**1 hour (1.0 units)**	**6 hours (6.0 units)**	**12 hours (12.0 units)**
Amount Delivered (Median) [min, max]	0.99 units [0.61, 1.37]	5.94 units [5.56, 6.35]	11.90 units [11.39, 12.33]

Intermediate Basal Rate Delivery Performance (1.0 units/hr, n = 15 aged devices)

Basal Duration (Number of Units Delivered with 1.0 units/hr Setting)	1 hour (1.0 units)	6 hours (6.0 units)	12 hours (12.0 units)
Amount Delivered [min, max]	0.98 units [0.61, 1.33]	5.88 units [5.33, 6.28]	11.74 units [11.04, 12.31]

Maximum Basal Rate Delivery Performance (10.0 units/hr, n = 15 new devices)

Basal Duration (Number of Units Delivered with 10.0 units/hr Setting)	1 hour (10.0 units)	6 hours (60.0 units)	12 hours (120.0 units)
Amount Delivered (Median) [min, max]	9.98 units [9.70., 10.36]	60.00 units [58.93, 60.67]	120.021 units [118.63, 121.01]

Maximum Basal Rate Delivery Performance (10.0 units/hr, n = 15 aged devices)

Basal Duration (Number of Units Delivered with 10.0 units/hr Setting)	1 hour (10.0 units)	6 hours (60.0 units)	12 hours (120.0 units)
Amount Delivered (Median) [min, max]	9.98 units [9.69, 10.32]	59.90 units [59.07, 60.78]	119.81 units [118.62, 121.12]

9.4.2 Bolus Delivery

To assess bolus delivery accuracy, 15 iLet Devices were tested by delivering consecutive minimum, intermediate, and maximum bolus volumes (0.5, 5.0, and 30 units). All devices were new, and 15 additional devices had been aged to simulate four years of regular use. Water was used as a substitute for insulin for this testing. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy. Delivered bolus volumes were compared to the requested bolus volume delivery for minimum, intermediate, and maximum bolus volumes. The tables below show average, minimum and maximum bolus sizes observed as well as the number of boluses which were observed to be within the specified range of each target bolus volume.

Minimum Bolus Delivery Performance (0.5 units, n = 375 boluses, n = 15 new devices)

	Units of Insulin Delivered After a 0.5 unit Bolus Request							
Number and Percent of Boluses Within Range	<0.125 (<25%)	0.125-0.375 (25-75%)	0.375-0.475 (75-95%)	0.475-0.525 (95-105%)	0.525-0.625 (105-125%)	0.625-0.875 (125-175%)	0.875-2.5 (175-250%)	>2.5 (>250%)
	0/375 (0.0%)	4/375 (1.1%)	84/375 (22.4%)	253/375 (67.5%)	34/375 (9.1%)	0/375 (0.0%)	0/375 (0.0%)	0/375 (0.0%)

Intermediate Bolus Delivery Performance (5.0 units, n = 375 boluses, n = 15 new devices)

	Units of Insulin Delivered After a 5.0 unit Bolus Request							
Number and Percent of Boluses Within Range	<1.25 (<25%)	1.25-3.75 (25-75%)	3.75-4.75 (75-95%)	4.75-5.25 (95-105%)	5.25-6.25 (105-125%)	6.25-8.75 (125-175%)	8.75-12.5 (175-250%	>12.5 (>250%)
	0/375 (0.0%)	0/375 (0.0%)	8/375 (2.1%)	362/375 (96.5%)	5/375 (1.3%)	0/375 (0.0%)	0/375 (0.0%)	0/375 (0.0%)

Intermediate Bolus Delivery Performance (5.0 units, n = 375 boluses, n = 15 aged devices)

	Units of Insulin Delivered After a 5.0 unit Bolus Request							
Number and Percent of Boluses Within Range	<1.25 (<25%)	1.25-3.75 (25-75%)	3.75-4.75 (75-95%)	4.75-5.25 (95-105%)	5.25-6.25 (105-125%)	6.25-8.75 (125-175%)	8.75-12.5 (175-250%	>12.5 (>250%)
	0/375 (0.0%)	0/375 (0.0%)	8/375 (2.1%)	366/375 (97.6%)	1/375 (0.3%)	0/375 (0.0%)	0/375 (0.0%)	0/375 (0.0%)

Maximum Bolus Delivery Performance (30.0 units, n = 240 boluses, n = 15 new devices)

	Units of Insulin Delivered After a 30.0 unit Bolus Request							
Number and Percent of Boluses Within Range	<7.5 (<25%)	7.5-22.5 (25-75%)	22.5-28.5 (75-95%)	28.5-31.5 (95-105%)	31.5-37.5 (105-125%)	37.5-52.5 (125-175%)	52.5-75 (175-250%)	>75 (>250%)
	0/240 (0.0%)	0/240 (0.0%)	0/240 (0.0%)	240/240 (100.0%)	0/240 (0.0%)	0/240 (0.0%)	0/240 (0.0%)	0/240 (0.0%)

9.5 Explanation of Symbols

Symbol	Meaning of Symbol	Standard/Reference Number

	Warning (a hazard alert which, if not avoided, could result in death or serious injury)	IEC 60601-1 Table D.2 ISO 7010-W001
	Refer to Instructions for Use	IEC 60601-1 Table D.2 ISO 7010-M002 Table 5
	Refer to instruction manual/booklet	ISO 7010-M002
IPX8	Protected against up to 12 feet of water for up to 30 minutes	IEC 60601-1 Table D.3
	Manufacturer	ISO 15223-1 Ref 5.1.1 ISO 7000-3082
	TYPE BF APPLIED PART	IEC 60601-1 Table D.1 IEC 60417-5333 IEC 60601-1 Table D.1
	CLASS II equipment	IEC 60417-5172 IEC 60601-1 Table D.1
	Do not reuse	ISO 7000-1051 ISO 15223-1 Ref 5.1.6
	Part Number	ISO 7000-2493 ISO 15223-1 Ref 5.1.7
	Serial Number	ISO 7000-2498
	Date of manufacture	ISO 15223-1 Ref 5.1.3 ISO 7000-2497
	Use-by date	ISO 15223-1 Ref 5.1.4 ISO 7000-2607
	Batch code	ISO 15223-1 Ref 5.1.5 ISO 7000-2492
	Non-pyrogenic	ISO 15223-1 Ref 5.6.3 ISO 7000-2724

	Non-Ionizing Radiation	IEC 60417-5140
	Alternating Current	IEC 60417-5032
	Sterilized using irradiation	ISO 15223-1 Ref 5.2.4
	Do not use if package is damaged	ISO 15223-1 Ref 5.2.8
	Keep dry	ISO 15223-1 Ref 5.3.4
	Direct Current	IEC 60417-5031
	Federal law restricts this device to sale by or on the order of a physician	No Standard for symbol but is per FDA 21CFR part 801
	MR Unsafe	ASTM F2503
	Bluetooth Low Energy	Bluetooth
	Inductive charging	NA
	Two-Sided Operating Atmospheric Pressure Limit	ISO 15223-1 Ref 5.3.9
	Two-sided Storage Temperature Limits	ISO 15223-1 Ref 5.3.7
	Two-sided Storage Humidity Limit	ISO 15223-1 Ref 5.3.8
	Two-Sided Storage Atmospheric Pressure Limits	ISO 15223-1 Ref 5.3.9

	Two-sided Operating Temperature Limits	ISO 15223-1 Ref 5.3.7
	Two-sided Operating Humidity Limits	ISO 15223-1 Ref 5.3.8

10. Electromagnetic Compatibility

The information contained in this section is specific to the iLet Bionic Pancreas System. This section provides reasonable assurance of normal operation. However, it does not guarantee such outcomes under all conditions. If your iLet System must be used near other electrical equipment, it should be observed in this environment to verify normal operation. Take special precautions for electromagnetic compatibility when using medical electrical equipment. The iLet System shall be placed into service with adherence to the Electromagnetic Compatibility information provided here.

> **WARNING:** Using cables and accessories not specified in this Quick reference guide may adversely impact safety and performance, and electromagnetic compatibility, including increased emissions and/or decreased immunity. This may cause your iLet Device not to function properly.

For IEC 60601-1 testing, under the definition of Essential Performance, the iLet System is defined as follows:

- The iLet System will not over deliver a clinically significant amount of insulin.
- The iLet System will not under deliver a clinically significant amount of insulin.
- The iLet System will not deliver a clinically significant amount of insulin after occlusion release.
- The iLet System will not discontinue reporting CGM data without notification to the user.

This section contains the following tables of information:

- Electromagnetic Emissions
- Electromagnetic Immunity
- Distances Between the System and RF Equipment
- Quality of Wireless Services and Data Security

- FCC Notice Concerning Interferences

10.1 Electromagnetic Emissions

The iLet System is intended for use in the electromagnetic environment specified below. Always make sure that the iLet System is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment–Guidance
RF Emissions, CISPR 11	Group 1	The iLet System uses RF energy only for its internal function. Therefore, RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment.
RF Emissions, CISPR 11	Class B	The iLet System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions, IEC 61000-3-2	Complies	
Voltage Fluctuations/ Flicker Emissions, IEC 61000-3-3	Complies	

10.2 Electromagnetic Immunity

The iLet System is intended for use in the electromagnetic environment specified below. Always make sure that the iLet System is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment–Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines (100 kHz repetition frequency)	± 2 kV for power supply lines ± 1 kV for input/ output lines (100 kHz repetition frequency)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: 150 kHz to 80MHz, d = 1.20√P 80 MHz to 800 MHz, d = 1.20√P 800 MHz to 2.5GHz, d = 2.30√P Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range†. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	
Proximity Field from Wireless Transmitters	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz:28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation	

Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	70% UT (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	70% UT (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery. NOTE: Ur is the rated voltage.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

∗Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the System.

† Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

WARNING: Portable RF communications equiment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of

the iLet Device, including cables specificed by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Immunity Test	Transmitter Compliance Level	Reciever Compliance Level
Radiated and Conducted Fields Aircraft use	FAA RTCA /DO-160 edition G Section 20 Category T. Can be used on aircraft according to the directions provided by the operator of the aircraft	

Compliance Statement (Part 15.19)

Emissions Test	Compliance
Radio Frequency Emissions CISPR 11/FCC part 15	Group 1, Class B
Radio Frequency Emissions Aircraft Use	Meets FAA RTCA /DO-160 edition G Section 21, Category M for in-cabin use.

10.3 Quality of Wireless Service and Data Security

The manufacturer defines the wireless quality of service for the iLet System as the percentage of readings successfully received by the iLet Device, where the iLet Device and the CGM transmitter attempt to communicate every 5 minutes. One of the iLet System essential performance requirement states that the iLet System will not discontinue reporting data or information from the CGM transmitter to the user without notification.

For information about when your CGM is offline and related alerts see the iLet Bionic Pancreas User Guide, **Section 4.3 When Your CGM Sensor is Offline.**

The iLet Device is expected to receive at least 90% of CGM readings sent by the transmitter while the

iLet Device and transmitter are located within 20 feet of each other. Wireless communication is assured unless there is wireless interference caused by other devices in the 2.4GHz band. This interference may impact the iLet System's ability to maintain this quality of wireless service. To improve the quality of service in the presence of other devices in the 2.4GHz band, decrease the distance between the iLet Device and the CGM transmitter, or move away from other devices operating in the 2.4GHz band.

The iLet Device only accepts communications from a known linked device. You must link the device with your iLet Device. The iLet Device uses encryption and proprietary means to ensure data integrity.

Specification Type	Specification Detail
Wireless Technology	Bluetooth Low Energy (BLE) version 5.1
Tx/Rx Frequency Range	2360-2500 MHz
Bandwidth (per channel)	2 MHz
Radiated Output Power	+8 dBm (maximum)
Modulation	Gaussian Frequency-Shift Keying (GFSK)
Data Rate	2 Mbps
Data Communication Range (maximum)	20 feet

10.4 FCC Notice Concerning Interference

The transmitter covered by this quick reference guide has been certified under FCC ID: XPYBMD380.

The transmitter has been approved by the Federal Communications Commission. There is no guarantee that it will not receive interference or that any particular transmission from the transmitter will be free from interference.

Compliance Statement (Part 15.19)
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received. This includes interference that may cause undesired operation.

Warning (Part 15.21)
Changes or modifications unapproved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Interference Statement (Part 15.105 (b))
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy. If not installed and used following the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference using one of the following methods:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and receiver.
- Connect the equipment to an outlet on a circuit that the receiver is not connected with.

Consult the dealer or an experienced radio or a TV technician for help.This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population.

Replacement of POWER SUPPLY CORDS and other parts
Call Beta Bionics if any component or accessory of the iLet System needs replacement.

11. Additional Information

11.1 Insulin Compatibility

The iLet ACE Pump and iLet Dosing Decision Software are designed to use rapid-acting U-100 insulin. The following U-100 rapid acting insulin analogs have been tested and found to be safe for use in the iLet Device:

- NovoLog (insulin aspart) and Humalog (insulin lispro) for ages 6 years and older
- Fiasp® PumpCart® (insulin aspart) in a pre-filled 1.6mL cartridge for ages 6 years and older.

NovoLog, Humalog, and Fiasp are compatible with the system for use up to 72 hours (3 days). If you

have questions about using other insulins, contact your healthcare provider. Fiasp has a faster initial absorption than other rapid-acting U-100 insulins. Always consult your healthcare provider and refer to the insulin labeling prior to use.

Please refer to the drug manufacturer's labeling for drug related information including dosage and administration contraindications, warnings and precautions.

11.2 Compatible iCGMs

Compatible CGMs with the ACE Pump and iAGC include the following iCGMs:

- Dexcom G6 CGM
- Dexcom G7 CGM

For information about Dexcom G6 CGM product specifications and performance characteristics and Dexcom G7 CGM product specifications and performanace characteristics, visit the manufacturer's website.

The Dexcom G6 sensors and transmitters and Dexcom G7 sensors are sold and shipped separately by Dexcom. The Dexcom G7 sensor has a built-in transmitter.

> **WARNING:** Do not ignore symptoms of hyperglycemia and hypoglycemia. If your sensor glucose alerts or readings do not match your symptoms, measure your BG with a BG meter.

> **WARNING:** Do not expect CGM alerts when the CGM sensor is warming up. You will NOT get any sensor glucose readings or alerts until the warmup ends. During this time, you might miss severe hyperglycemia or hypoglycemia events. Check your BG with a meter.

> **WARNING:** Do not use any component of your CGM system if it is damaged/cracked. This could cause electrical safety hazards or malfunction, e.g., electrical shocks.

> **WARNING:** Do not ignore broken CGM sensors or detached sensor wires. If a sensor wire breaks off under your skin and you cannot see it, do not try to remove it. Contact your healthcare provider. Seek professional medical help if you have symptoms of infection or inflammation – redness, swelling, or pain – at the insertion site.

> **WARNING:** Do not insert the CGM sensor in sites that have not been studied or approved. Use in other sites might cause inaccurate sensor glucose readings. This could result in missing severe hyperglycemia or hypoglycemia events. See the CGM manufacturer's Instructions for Use for details.

WARNING: Do not inject insulin or insert an insulin infusion set within 3 inches from the CGM Sensor. The insulin delivered through the insulin infusion set might affect sensor accuracy, resulting in over/under delivery of insulin. This can cause missing severe hypoglycemia or hyperglycemia events.

CAUTION: Do not separate the CGM sensor and iLet Device by more than 20 feet. The range from the transmitter to the iLet Device is less than 20 feet without obstruction.

CAUTION: Consult the manufacturer's instructions that accompany your iCGM for important information on proper handling, contraindications, warnings, and precautions.

11.3 Important Pediatric and Caregiver User Information

The following recommendations are meant to help younger users and others who require a caregiver and their caregivers to program, manage, and maintain the iLet System.

- It is the responsibility of the healthcare provider and caregiver to decide if the user is appropriate for treatment with the iLet System.
- Users may accidentally press or tap the touchscreen, leading to unintentional insulin delivery. Consider using the Limited Access feature, which is an optional, user-settable passcode, to additionally guard against accidental presses and taps, and to prevent unauthorized access to the iLet Device. For more information about Limited Access, see **Section 2.10 Limited Access**.
- Review the Meal Announcement feature to determine how it best fits with the user's care plan.
- The insulin infusion set may become dislodged more often with younger users and may need to be secured. Consult with your child's healthcare provider about how to safely secure the components of the iLet System.

WARNING: Keep all parts of the iLet System out of the reach of children. The iLet System contains small parts (i.e., USB cables, insulin infusion sets with flexible tubing, needles, syringes, and cartridges). These parts can pose a strangulation or choking hazard or cause internal injury if swallowed.

WARNING: Do not allow young children to hold the CGM sensor, transmitter, or transmitter kit box without adult supervision. The sensor and transmitter include small parts that may pose choking hazards.

CAUTION: Check the iLet System's personal settings regularly to make sure they are correct, especially if the iLet Device has been left unattended. Incorrect settings can result in over delivery or under delivery of insulin.

11.4 General Warnings and Precautions

WARNING: Do not use the iLet ACE Pump and Dosing Decision Software if you are unable or unwilling to test blood glucose (BG) levels with an SMBG meter when input from the iCGM is not available.

WARNING: Do not use the iLet ACE Pump and Dosing Decision Software if you are unable or unwilling to recognize and respond to iLet Device safety alerts.

WARNING: Do not use the iLet System if you are taking hydroxyurea, also known as Hydrea. This medication is sometimes used in the treatment of blood disorders and some kinds of cancer. The use of hydroxyurea can result in falsely elevated sensor glucose readings. The iLet System relies on sensor glucose readings to adjust insulin, provide insulin doses, and provide high and low glucose alerts. If the iLet System receives sensor readings that are higher than actual glucose levels, it could result in missed hypoglycemia alerts and potential errors in diabetes management, such as too much insulin being delivered. Hydroxyurea can also result in errors when reviewing, analyzing, and interpreting historical patterns for assessing glucose control.

WARNING: Do not use the iLet ACE Pump and Dosing Decision Software in people under 6 years of age. The iLet ACE Pump and Dosing Decision Software have not been studied in these populations.

WARNING: Do not use the iLet ACE Pump and Dosing Decision Software in people who are pregnant, on dialysis or critically ill. The iLet ACE Pump and Dosing Decision Software have not been studied in these populations.

WARNING: The iLet System is only for use with U-100 insulin lispro (Humalog), U-100 insulin aspart (Novolog), or U-100 insulin aspart in prefilled 1.6mL cartridge (Fiasp® PumpCart® (insulin aspart)).

WARNING: The iLet System is only for use with a compatible iCGM. When using the iLet Device, wear an iCGM.

WARNING: The iLet ACE Pump and Dosing Decision Software are only for use with U-100 Fiasp insulin in the prefilled Fiasp PumpCart. Do not use U-100 Fiasp insulin from a vial with the iLet ACE

Pump and Dosing Decision software, as that has not been studied.

WARNING: Do not expose your iLet System, including your iLet Device, steel infusion set, CGM transmitter, and CGM sensor, to X-ray (screening at airports or other facilities and procedures), Computed Tomography (CT) scan, Magnetic Resonance Imaging (MRI), or Positron Emission Tomography (PET) scan.

WARNING: Remove the iLet Device, steel infusion set, CGM sensor, and CGM transmitter before undergoing radiation therapy, Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment procedures. Exposure of the iLet Device, steel infusion set, CGM sensor, or CGM transmitter to any of these may damage them.

WARNING: Your iLet System, including your iLet Device, steel infusion set, CGM transmitter, and CGM sensor, is not magnetic resonance (MR) safe. Your iLet System must be left outside of the procedure room if you are receiving an MRI scan.

WARNING: Do not expose your iLet Device, steel infusion set, CGM transmitter, or CGM sensor to equipment used in procedures for Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming, Cardiac Catheterization, or Nuclear Stress Test.

WARNING: Depending on the equipment being used during general anesthesia, your iLet System may need to be removed. You do not need to remove iLet System components for electrocardiograms (EKGs) or colonoscopies. Metal detectors and body scanners at airports are also acceptable. Remove your iLet System prior to any laser surgery as some lasers can create interference and cause your iLet System to alert you.

WARNING: Do not try to open or repair your iLet Device. It is a sealed device that should not be opened. Modification could result in improper functioning and safety risks. If your iLet Device seal is broken, your iLet Device is no longer watertight and the warranty is voided. If you are unsure about potential damage, discontinue the use of your iLet Device and contact Beta Bionics.

WARNING: Your iLet System is for single patient use only. Sharing any part of your iLet System may lead to transfer of germs, infection, or over/under delivery of insulin.

WARNING: Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: The iLet ACE Pump and Dosing Decision Software were evaluated in an outpatient setting for home use. The system has not been evaluated in hospitalized people.

WARNING: Never fill your tubing while your tubing set is connected to your body. Always make sure that the tubing set is disconnected from your body before filling the tubing. Failure to do so can result in over delivery of insulin. This can cause serious injury or death from very low BG.

WARNING: Do not reuse iLet Cartridges.

WARNING: Do not disconnect the iLet Connect from the iLet Device while your insulin infusion set is connected to your body. Always disconnect your insulin infusion set tubing from your body before removing the iLet Connect Luer adapter and iLet Cartridge.

WARNING: Do not add insulin to a filled iLet Cartridge after loading it into your iLet Device. Do not remove insulin from your iLet Cartridge after loading it into your iLet Device. This will result in an inaccurate display of the insulin level on the Home Screen. You could run out of insulin before the iLet Device detects that your iLet Cartridge is empty. This can cause very high BG or Diabetic Ketoacidosis (DKA).

WARNING: Do not change your body weight in your iLet Device without consulting your healthcare provider first. If your body weight changes significantly, contact your healthcare provider to determine if an adjustment to your body wegith setting is required.

WARNING: Do not take insulin from other sources (e.g., via injection or another device) unless you have been advised to do so by your healthcare provider. Low BG levels may occur if insulin delivery outside of your iLet System is used because your iLet System will not be able to include it in its calculations, which may result in over-delivery of insulin. Contact your healthcare provider if you have concerns.

WARNNG: Do not use cartridges other than those manufactured by Beta Bionics or the prefilled pharmacy dispensed drugs on the recommended list. Use of cartridges not recommended may affect the performance of your iLet System. It can be unsafe to use accessories, detachable parts and materials not described in the instructions for use. Secure the iLet Device to your body in any orientation of your choosing to avoid the iLet Device falling, dropping or damaging the tubing line.

CAUTION: Managing your BG using your iLet Device is different from managing your BG on your own. Follow the instructions as provided in this user guide. Always ask your healthcare provider for

additional guidance if you are unsure.

CAUTION: Always check that your iLet Cartridge has enough insulin to last through the night. You could miss the Change Insulin alert and insulin deliveries when sleeping.

CAUTION: Always make sure your hands are clean when handling components. Fill the sterile iLet Cartridge on a clean surface.

CAUTION: The packaging and contents of the iLet Cartridge are supplied sterile and sealed. When using a cartridge, check for damage. In the event that the packaging is already opened, do not use the cartridge. Contact Beta Bionics for additional assistance.

CAUTION: Avoid exposure of your iLet Device to temperatures below 40°F (5°C) or above 104°F (40°C). Insulin can freeze at low temperatures and degrade at high temperatures. Insulin exposed to conditions outside of the manufacturer's recommended ranges can affect the safety and performance of your iLet System.

CAUTION: Do not place any part of your iLet System in water. If your iLet System has been exposed to water, check for any signs of water entering your iLet System. If there are signs of water entry, stop using your iLet System and use an alternative therapy.

CAUTION: Disconnect the tubing set from your body while on amusement park thrill rides. Rapid changes in altitude or gravity can affect insulin delivery and cause injury.

CAUTION: Disconnect the tubing set from your body before entering an aircraft without cabin pressurization or in planes used for aerobatics or combat simulation. Rapid changes in altitude or gravity can affect insulin delivery and cause injury.

CAUTION: Do not force the insulin cartridge into the bottom right-side chamber. This side chamber is smaller than the insulin chamber. The bottom right-side chamber may have a cap or be closed off.

CAUTION: The packaging and contents of the insulin infusion set and the iLet Connect are supplied sterile and sealed. When using an insulin infusion set or an iLet Connect, check for damage. In the event that the packaging is already opened, do not use the insulin infusion set or iLet Connect. Contact Beta Bionics for additional assistance.

CAUTION: Always monitor glucose levels regularly during sports, activiites, and exercise.

CAUTION: If you disconnect from your iLet, you may need to consider, with guidance from your healthcare provider, the potential need for carbohydrates relative to the amount of insulin on board and activity you may engage in. You may view your Insulin On Board within Algorithm Steps under the History feature. Check your BG before disconnecting from and after reconnecting to your iLet System.

CAUTION: The iLet Mobile App is compatible with the iOS platform and Android platform. The iLet Mobile App provides the ability to perform over-the-air updates and / or pull data from an iLet Device to share with the Beta Bionics Cloud.

CAUTION: Do not install apps on your smartphone from untrusted sources. These apps may contain malware that may impact use of the iLet Mobile App. Install apps only from trusted sources (i.e. Apple App store or Google Play store). If you do not know what an App is, do not install it, regardless of the source.

It is not advised to install any app from a source other than the Apple App Store or Google Play store on your smartphone that is running the iLet Mobile App. Doing so may put you at risk of unintentionally installing malware on your device.

CAUTION: Malware, or "malicious software" from unknown third-parties, is designed to damage your device and/or read your private information. Unknown Apps and unknown downloads are the most common method for spreading malware. Malware could prevent the iLet Mobile App from functioning as intended.

CAUTION: Depending on the length of time and reason you disconnect from your iLet System, you may need to replace missed insulin doses. Treat high and low BG levels as recommended by your healthcare provider when disconnected from your iLet System**.**

CAUTION: The iLet Mobile App performs a check to ensure that your device is not rooted, jaibroken or installed via sideloading. Rooted or jailbroken means the removal of limitations and security measures set by the manufacturer of a smart device. The removal of these poses a security risk and data may become vulnerable. Sideloading means the loading of an application from an app binary file or downloading a file that can install an executable on a smartphone.

If the iLet Mobile App determines your device is rooted, jailbroken and/or has applications installed via sideloading, you will be blocked from iLet Mobile App use.

CAUTION: If you believe you may have an App installed from a third-party source, take steps to

delete that App. If you believe you may have malware on your device, discontinue use of your iLet Mobile App, and contact Beta Bionics customer service.

CAUTION: Bluetooth Low Energy technology is a type of wireless communication used in cell phones and many other devices. Your iLet Device and CGM transmitter wirelessly pair together with other devices using Bluetooth wireless communication technology. When paired, this allows the iLet Device and CGM transmitter to communicate securely and only with each other.

CAUTION: Check your iLet System's settings regularly to ensure they are correct. Incorrect settings can result in over or under delivery of insulin. Consult with your healthcare provider as needed.

CAUTION: Confirm that the correct time and date are set on your iLet Device. When editing 12-hour time, always check that the AM/PM setting is accurate. The incorrect time or date settings may affect safe insulin delivery.

CAUTION: Confirm that the touchscreen display turns on. You will hear audible beeps and feel your iLet Device vibrate. Confirm that you can see the battery charging indicator on the charger and on your touchscreen wiehn your iLet Device is placed on the charger. If any of these features are not working, discontinue the use of your iLet System and contact your healthcare provider and Beta Bionics.

CAUTION: Do not use the vibration feature by itself during sleep unless otherwise directed by your healthcare provider. Set a high volume for alerts and alarms so you do not miss an important alert or alarm.

CAUTION: Always look at the touchscreen to confirm you select the correct icon.

CAUTION: When using the Dexcom G6 sensor, confirm that your CGM transmitter's serial number (SN) is programmed into your iLet Device before use. Your iLet Device cannot communicate with your transmitter unless the correct CGM transmitter's SN is entered. If your iLet Device and transmitter are not communicating, you will not receive the sensor's glucose readings. You might miss alerts regarding severe hypoglycemia or hyperglycemia events. If you receive a replacement iLet Device, make sure that your new device is programmed with the correct SN.

CAUTION: When using the Dexcom G6 sensor, do not discard your CGM transmitter when you change your sensor. The transmitter is reusable. The same transmitter is used with multiple sensors until the transmitter battery life reaches its end.

CAUTION: Do not use your iLet System if you think your iLet Device might be damaged due to

dropping, hitting against a hard surface, or subjecting it to significant vibration. If you are unsure about potential damage, discontinue the use of your iLet System and contact your healthcare provider.

CAUTION: Nearby devices, such as mobile phones or other wireless devices, may interfere with your CGM readings. If radiofrequency communication is lost or interrupted, increase distance between your device and the interfering device to see if communication is reestablished. If needed, remove or turn off the nearby device.

CAUTION: Do not change the insulin infusion set before bedtime or if you are not available in the next 2 hours to confirm that the insulin infusion set is inserted correctly and no occlusions (blockages) are present. Respond quickly to any problems with the insertion to ensure continued insulin delivery.

CAUTION: Check the insulin infusion set daily for proper placement and leaks. Replace your insulin infusion set if you notice leaks. Improperly placed insulin infusion sets or leaks can result in under-delivery of insulin and high BG could occur.

CAUTION: Check the insulin infusion set and tubing set daily for any leaks, air bubbles, or kinks. These may restrict or stop insulin delivery. This could result in under-delivery of insulin and high BG could occur.

CAUTION: Check the tubing connections between cartridge and tubing set daily to ensure they are tight and secure. Leaks around the tubing connections can result in under delivery of insulin and high BG could occur.

CAUTION: Check to make sure tubing is not connected to your body. Always disconnect iLet Device from the insulin infusion set when using the Fill Tubing function.

CAUTION: Your iLet Device will notify you when your iLet Cartridge is low (20 units) or empty. When this happens, be prepared to change your iLet Cartridge soon. When your iLet Cartridge is empty, your iLet Device cannot dose insulin. Not having insulin will cause your BG to rise, and if prolonged, may cause very high BG or DKA.

CAUTION: Check that the body weight you entered matches the guidance provided by your healthcare provider. An incorrect body weight entry may result in the over-delivery or under-delivery of insulin relative to your insulin needs.

11.5 Potential Risks

11.5.1 Potential Risks Related to Using Your iLet System

Potential interruption of insulin delivery caused by a system failure (hardware or software defects) may present risks. These general risks may include:

- Hypoglycemia (low BG)
- Hyperglycemia (high BG)
- Diabetic Ketoacidosis (a potentially life-threatening complication during which the body produces excess amount of blood acids, called ketones)
- Seizure
- Coma
- Death

Users may accidentally press or tap the touchscreen, leading to unintentional insulin delivery. Consider using the Limited Access feature, which is an optional, user-settable passcode, to additionally guard against accidental presses and taps, and to prevent unauthorized access to the iLet Device. For more information about Limited Access, see **Section 2.10 Limited Access**.

11.5.2 Potential Risks Related to Using an Insulin Infusion Set

Read and follow the instructions that accompany your insulin infusion set to determine safe and proper handling. General risks related to the insulin infusion set may include:

- Local infection
- Skin irritation, redness, itching, or swelling
- Bruising
- Discomfort or pain
- Bleeding
- Rash or skin discoloration
- Occlusions (blockages) or air bubbles that can interrupt insulin delivery and lead to hyperglycemia or diabetic ketoacidosis

There is a small chance that an insulin infusion set cannula (the tube that remains after the insulin infusion set needle is removed) could break and remain under your skin. If that occurs, contact your healthcare provider immediately.

If an infusion site becomes irritated or inflamed, the insulin infusion set should be removed and replaced in a new location on your body.

11.5.3 Potential Risks Related to Using a CGM

Read and follow the instructions that accompany your CGM to determine safe and proper handling, including contraindications, warnings and precautions.

CGM Inaccuracies

- Your iLet Device relies on CGM values to dose appropriately. Inaccurate CGM values could lead to under or over delivery of insulin (e.g., when your BG values are rapidly rising or falling).
- CGM inaccuracies are usually related to your sensor only and not to your transmitter or iLet Device. If your CGM values do not match your symptoms, always check your glucose using a SMBG meter. Consider treatment and/or CGM sensor calibration if necessary.
- Your CGM and iLet Device will alert you when a CGM calibration is needed.
- Your CGM and infusion set should be placed at least 3 inches apart on the body.

General risks related to CGM sensor use, due to its insertion into the skin or skin adhesive, may include:

- Local infection
- Bruising
- Bleeding
- Skin irritation, redness, itching, or swelling
- Discomfort or pain
- Rash or skin discoloration

There is a small chance that the CGM sensor wire could break while you are wearing it and remain under your skin. If you think this occurs, contact your healthcare provider immediately.

You will not get sensor alerts on the iLet Device under the following conditions:

- When an alert is snoozed after acknowledgement
- When your sensor is not within range
- When your iLet Device is not receiving sensor glucose readings
- When you are unable to notice the alert or vibration

The CGM takes readings from the fluid below the skin (interstitial fluid), instead of blood. Measuring glucose in the interstitial fluid (the fluid that surrounds the cells of your tissue below your skin) differs from measuring it in the blood. Glucose is absorbed into the interstitial fluid more slowly than it is absorbed into the blood. Therefore, CGM readings lag from the BG meter readings. Talk to your healthcare provider about the difference between CGM readings and BG meter readings or refer to the CGM manufacturer's instructions.

12. Clinical Performance

12.1 Introduction

The following data represent an overview of the clinical performance and safety results of the iLet Bionic Pancreas System (iLet System).

12.1.1 The Bionic Pancreas Pivotal Trial

The Bionic Pancreas Pivotal Trial (Reference 1) included people with type 1 diabetes 18 years of age and older (Reference 2, Reference 3) and people with type 1 diabetes 6 to 17 years of age (Reference 4). Results from a randomly selected cohort of these participants who used the iLet System to deliver insulin was compared to the results from a Standard of Care cohort consisting of participants who used their usual method of delivering insulin with real-time continuous glucose monitoring (CGM) using the Dexcom G6 added if it was not already part of their usual care. A more detailed summary of the study and study results is provided in the User Guide.

12.1.2 The Insulin-Only Bionic Pancreas Extension Study

12.1.2 The Insulin-Only Bionic Pancreas Extension Study: The Insulin-Only Bionic Pancreas Extension Study was an extension study that included people with type 1 diabetes 6 years of age and older who participated in the Standard Care Group (control group) of the Bionic Pancreas Pivotal Trial (Reference 5). Results compared the performance of the insulin-only (IO) configuration of the iLet Bionic Pancreas (BP) System using Fiasp at the end of the 13-week extension phase to the same participants' results in the SC Group during the RCT pivotal study phase.

12.2 The Bionic Pancreas Pivotal Trial

The goal of the research study was to assess the efficacy and safety of using the iLet System to deliver insulin compared to Standard of Care. The study was done at 16 clinical sites in the US and included 440 participants (275 users 18 years of age and older, and 165 users 6-17 years of age).

Participants who met all study criteria were enrolled in the 13-week study and were randomly assigned to either:

- the iLet group that used the iLet System to deliver insulin, or
- the Standard of Care (SC) group that used their usual method to deliver insulin (multiple daily injections, insulin pump therapy, or a hybrid closed-loop system) with Dexcom G6 CGM added if it was not already part of their usual care. All participants in the Standard of Care group were provided with Dexcom G6 CGM supplies and were trained in the use of CGM data for diabetes management.

Of the 275 people ≥ 18 enrolled, 221 were randomly assigned to the iLet group and 54 were randomly assigned to the Standard of Care group. People ≥ 18 in the iLet group (n=221) were randomly assigned to use either Novolog or Humalog with the iLet System, whichever they used as part of their usual care (n=107), or Fiasp* (n=114).

Of the 165 people 6-17 years of age enrolled, 112 were randomly assigned to the iLet group and 53 were randomly assigned to the Standard of Care group. People 6-17 years of age in the iLet group all used Novolog or Humalog, whichever they used as part of their usual care (n=112).

The primary endpoint for the randomized study was HbA1c at 13 weeks. Secondary endpoints included the percentage of time the CGM glucose was below 54 mg/dL, the average CGM glucose, and the percentage of time the CGM glucose was in the range of 70 – 180 mg/dL.

The primary analysis was done using the combined group of people 6 years of age or older randomized to the iLet System using Novolog or Humalog versus Standard of Care. Additional analyses were performed for the subgroup of people ≥ 18 using the iLet System with Novolog or Humalog, the subgroup of people ≥ 18 using the iLet with Fiasp, and the subgroup of people 6-17 years of age using iLet System with Novolog or Humalog.

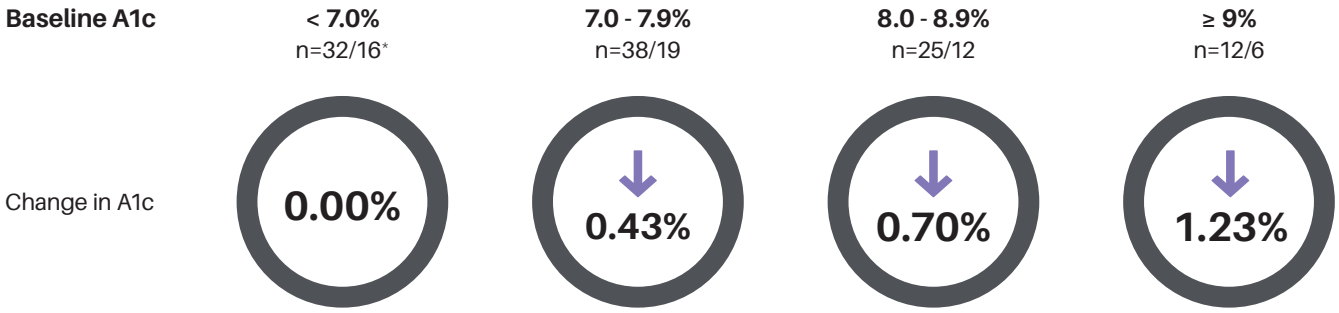
12.2.1 Primary Endpoint

Across both groups of participants 6-17 and ≥ 18 years of age, and across the types of insulin used by participants ≥ 18 (the Novolog/Humalog group or the Fiasp group) the baseline-adjusted difference in

HbA1c was –0.5% after 13 weeks in the iLet group relative to the Standard of Care group (p<0.001).

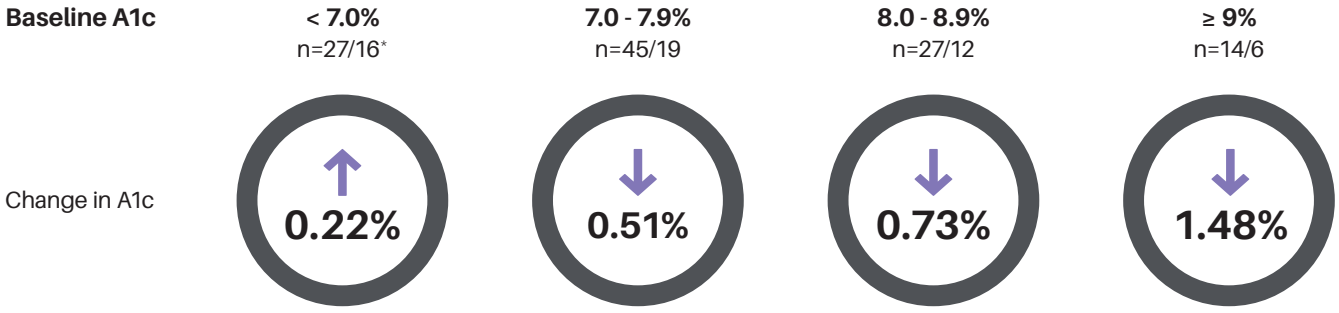
- In people ≥ 18, the average baseline-adjusted difference in HbA1c was –0.5% in the iLet group using Novolog or Humalog versus the Standard of Care group after 13 weeks.
- In people ≥ 18, the average baseline-adjusted difference in HbA1c was –0.5% in the iLet group using Fiasp versus the Standard of Care group after 13 weeks.
- In people 6-17 years of age, the average baseline-adjusted difference in HbA1c was –0.5% in the iLet group using Novolog or Humalog versus the Standard of Care group after 13 weeks.

12.2.1.1 Change in HbA1c over 13 Weeks in People ≥ 18 According to Baseline HbA1c – iLet System with Novolog or Humalog versus Standard of Care



*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.*

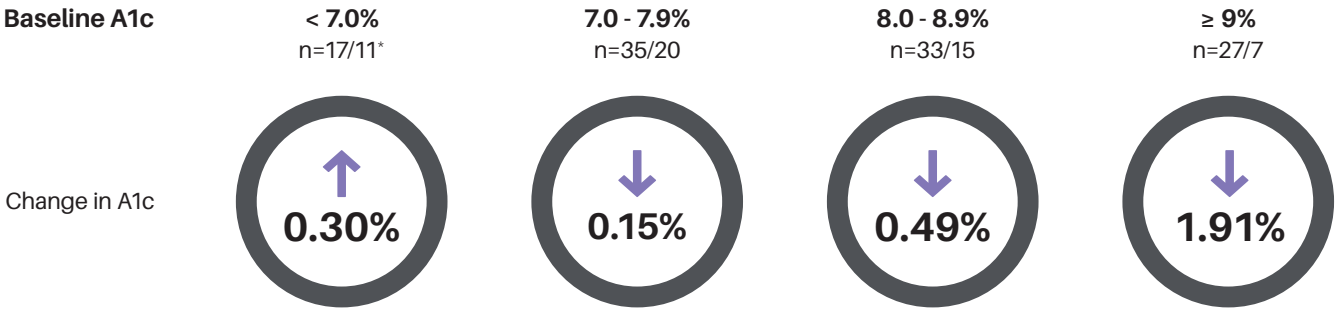
12.2.1.2 Change in HbA1c over 13 Weeks in People ≥ 18 According to Baseline HbA1c – iLet System with Fiasp versus Standard of Care



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.*

12.2.1.3 Change in HbA1c over 13 Weeks in People 6-17 Years of Age According to Baseline HbA1c – iLet System with Novolog or Humalog versus Standard of Care



*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.*

12.2.2 Secondary Endpoints

12.2.2.1 Time with CGM Glucose Levels Less Than 54 mg/dL

There was no increase ($p<0.001$) in the median percentage of time that CGM glucose levels were less than 54 mg/dL in the combined group of people 6 years of age or older using the iLet System with Novolog or Humalog compared with the Standard of Care group over 13 weeks. The baseline-adjusted difference in the median percentage of time that CGM glucose levels were less than 54 mg/dL between the iLet System and Standard of Care groups was 0.00%.

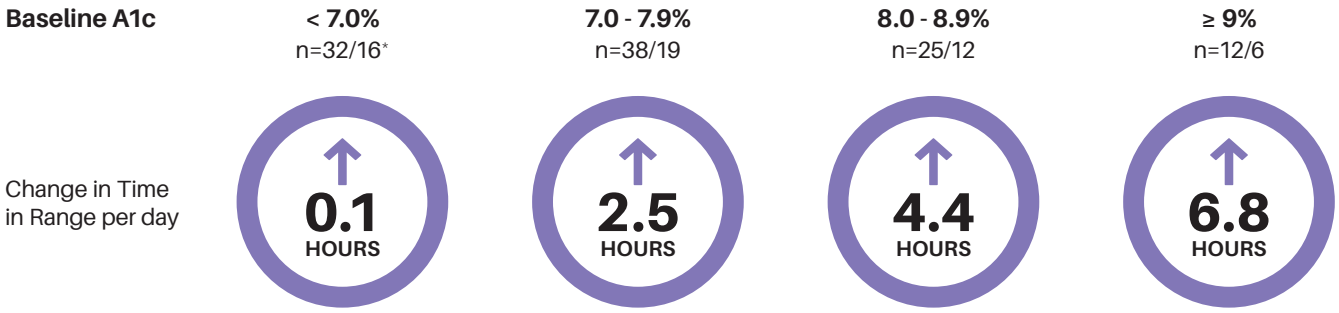
The baseline-adjusted difference in the median percentage of time that CGM glucose levels were less than 54 mg/dL in just the group of people ≥ 18 using the iLet System with Novolog or Humalog compared with the Standard of Care group was 0.02% (an increase of less than one minute per day). This difference was not statistically significant. The baseline-adjusted difference in the median percentage of time that CGM glucose levels were less than 54 mg/dL in just the group of people ≥ 18 using the iLet System with Fiasp and compared with the Standard of Care group was 0.00%. The baseline-adjusted difference in the median percentage of time that CGM glucose levels were less than 54 mg/dL in just the 6-17 years of age group using the iLet with Novolog or Humalog compared with the Standard of Care group was -0.04% (a decrease of less than one minutes per day). This difference was not statistically significant.

12.2.2.2 Time in Range (70-180 mg/dL)

There was an increase in time in range (70–180 mg/dL) in the iLet groups compared with the Standard of Care groups.

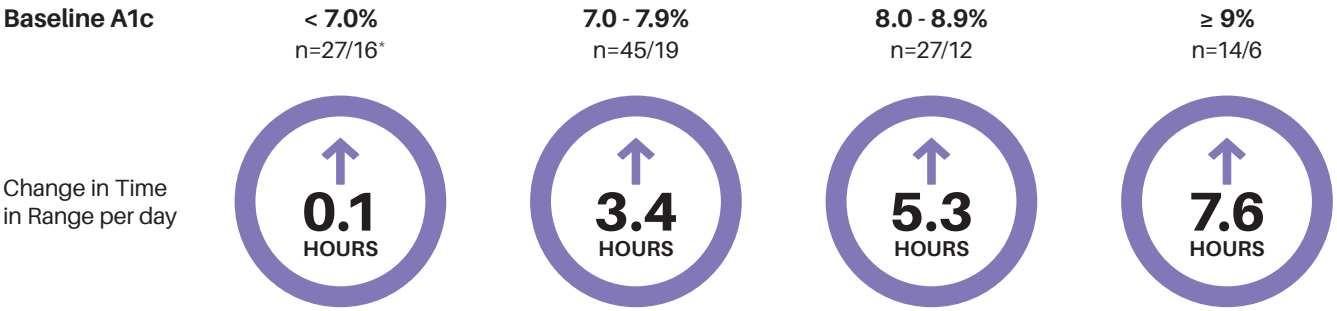
In people ≥ 18, there was a baseline-adjusted difference of +11% in the average time in range between the iLet group using Novolog or Humalog and the Standard of Care group (an increase of 2.6 hours per day). The baseline-adjusted difference in the average time in range between the people ≥ 18 in the iLet group using Fiasp and the Standard of Care group was +14% (an increase of 3.4 hours per day). The baseline-adjusted difference in the average time in range between the people ≥ 18 in the iLet group using Novolog or Humalog and the Standard of Care group was larger in study participants with higher baseline HbA1c.

12.2.2.3 Change in Time in Range (70-180 mg/dL) over 13 Weeks in People ≥ 18 According to Baseline HbA1c – iLet System with Novolog or Humalog versus Standard of Care



*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.*

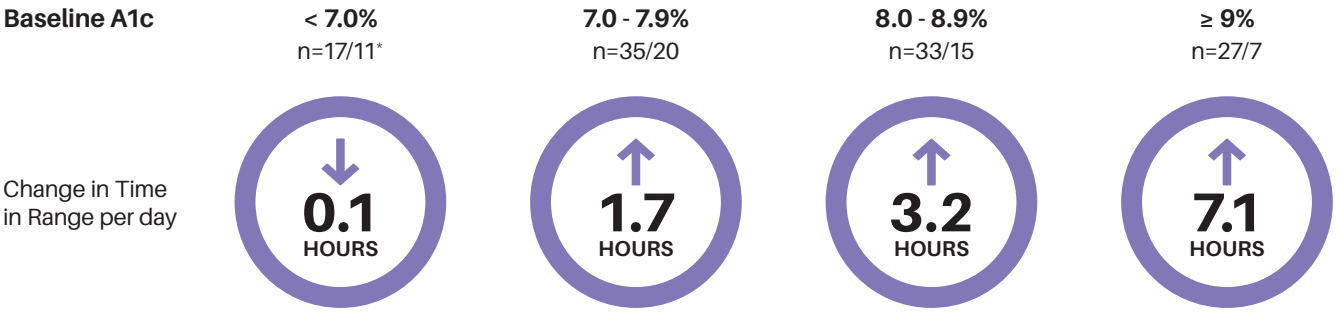
12.2.2.4 Change in Time in Range (70-180 mg/dL) over 13 Weeks in People ≥ 18 According to Baseline HbA1c – iLet System with Fiasp versus Standard of Care



*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.*

12.2.2.5 Change in Time in Range (70-180 mg/dL) over 13 Weeks in People 6-17 Years of Age According to Baseline HbA1c – iLet System with Novolog or Humalog versus Standard of Care

In people 6-17 years of age, there was a baseline-adjusted difference of +10% in the average time in range between the iLet group using Novolog or Humalog and the Standard of Care group (an increase of 2.4 hours per day). The baseline-adjusted difference in the time in range between the participants 6-17 years of age in the iLet group using Novolog or Humalog and the Standard of Care group was larger in study participants with higher baseline HbA1c.



*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.*

12.2.2.6 Average CGM Glucose Levels

There was a decrease in average CGM glucose level in the iLet groups as compared to the Standard of Care groups.

In people ≥ 18, there was a baseline-adjusted difference of –16 mg/dL in the average CGM glucose level between the iLet group using Novolog or Humalog and the Standard of Care group. The baseline-adjusted difference in the average CGM glucose level between the people ≥ 18 in the iLet group using Fiasp and Standard of Care group was –18 mg/dL. In people 6-17 years of age, there was a baseline-adjusted difference of –15 mg/dL in the average CGM glucose level between the iLet group using Novolog or Humalog and the Standard of Care group.

12.2.3 Adverse Effects

The Serious Adverse Events table below provides a list of adverse events that occurred during the randomized comparative period of the study. There were no significant differences in the number of events of severe hypoglycemia between the iLet groups and Standard of Care groups. There were two events of diabetic ketoacidosis and they were both determined to be caused by infusion set failures.

There were substantially more adverse events reported in the iLet groups than in the Standard of Care groups, primarily related to hyperglycemia with or without ketosis. Most of these events were attributed to a presumed or confirmed infusion set failure. The difference in events reported between the groups was due to study design, and in particular, the procedural differences in the way adverse event were reported between the groups.

Of the 223 device issues related to an Adverse Event, the majority (80%) were attributed to infusion set issues. Two of the cases of infusion set failure resulted in diabetic ketoacidosis. All CGM-measured hyperglycemic outcomes consistently showed that hyperglycemia occurred less often in the iLet groups than in the Standard of Care groups and that prolonged hyperglycemia events (defined as CGM glucose levels >300 mg/dL for at least 90 minutes during a 120-minute period) occurred significantly less frequently in the iLet groups than in the Standard of Care groups.

There were no other device issues or adverse events that were of concern with respect to the safety profile of the iLet. System

12.2.3.1 Serious Adverse Events

	People ≥ 18			People 6-17 years of age	
	iLet (Humalog® or Novolog®) (N=107)	**iLet (Fiasp®) (N=114)**	**Standard of Care (N=54)**	**iLet (Humalog® or Novolog®) (N=112)**	**Standard of Care (N=53)**
Severe Hypoglycemic (SH) Events					
Number of SH Events per Participant n (%)					
0	100 (93%)	111 (97%)	53 (98%)	109 (97%)	52 (98%)
1	7 (7%)	3 (3%)	0 (0%)	3 (3%)	1 (2%)
2	0 (0%)	0 (0%)	1 (2%)	0 (0%)	0 (0%)
Incidence Rate per 100 Person-Years	25.5	10.2	14.2	10.4	7.3
Diabetic Ketoacidosis (DKA) Events					
Number of DKA Events per Participant n (%)					
0	107 (100%)	112 (98%)	54 (100%)	112 (100%)	53 (100%)
1	0 (0%)	2* (2%)	0 (0%)	0 (0%)	0 (0%)
Incidence Rate per 100 Person-Years	0	6.8	0	0	0
Other Serious Adverse Events (SAEs)					
Number of SAEs per Participant n (%)					
0	106 (>99%)	114 (100%)	53 (98%)	110 (98%)	52 (98%)
1	1 (<1%)	0 (0%)	1 (2%)	2 (2%)	1 (2%)
Incidence Rate per 100 Person-Years	3.6	0	7.1	6.9	7.3
Participants with Worsening of HbA1c from baseline to 13 weeks by >0.5% *n (%)*	4 (4%)	7 (6%)	4 (8%)	13 (12%)	4 (8%)
Total Number of Overall Adverse Events (AEs) *n Events*	63	83	6	181	4

** both DKA events were related to infusion set failures*

12.3 The Insulin-Only Bionic Pancreas Extension Study

The Insulin-Only Bionic Pancreas Extension Study was an extension study for people ≥6 years old with type 1 diabetes (T1D) who participated in the Standard Care Group (SC/control group) in the Bionic Pancreas Pivotal Trial, a prior 13-week multi-center, parallel group randomized controlled trial (RCT). Throughout this section, the Bionic Pancreas Pivotal Trial is referred to as the RCT. In the Extension Study, the RCT SC group had the opportunity to use the IO configuration of the iLet BP System for 13 weeks. All participants 6-17 years old (at time of consent for the RCT) used study-provided U-100 Fiasp® PumpCart® (insulin aspart) in a pre-filled 1.6mL cartridge during the Extension Study.

One of the objectives of the extension study was to evaluate the safety and usability of the IO BP using fast-acting insulin aspart (Fiasp) and its impact on study subject's quality of life. In the 6-17 years of age cohort of the Extension Study, the change from baseline (the SC arm of the RCT) that occurred using fast-acting insulin aspart in the BP System was comparable to the change from baseline observed in the 6-17 years of age cohort in the RCT, during which insulin aspart (Novolog) or insulin lispro (Humalog) was used in the BP System. There was no increase in severe hypoglycemia or hyperglycemia measured with CGM and no new findings relative to the preceding RCT that impact the safety profile of using the BP with Fiasp PumpCart (insulin aspart) in people 6-17 years of age.

12.3.1 Study Design

A 13 week single-arm intervention trial (extension of randomized controlled trial [RCT] for the control group) with 90 participants with Type 1 diabetes at 16 clinical sites in the United States (42 participants ≥18 years of age and 48 participants 6-17 years of age). 46 participants were analyzed. Data for participants ≥18 years of age not presented in labeling.

12.3.2 Methods

Participants were trained in the use of the BP. Participants 6-17 years of age used U-100 Fiasp® PumpCart® (insulin aspart) in a pre-filled 1.6mL cartridge.

Phone contacts occurred after 1-2 days and 7 (±2) days and visits occurred at 2 weeks (±4 days), 6 weeks (±4 days), 10 weeks (±4 days), and 13 weeks (±4 days). Visits could be conducted virtually. At the 13-week visit, a blood sample was obtained for central lab HbA1c determination and psychosocial questionnaires were completed.

12.3.3 Endpoints

All participants who initiated use of the BP with Fiasp were included in the analyses. The 13-week

HbA1c measurement at the end of the RCT and the 13 weeks of CGM data during the RCT were used as baseline metrics for the analyses. For outcomes, HbA1c was measured at the end of 13 weeks and CGM data were collected over the full 13 weeks.

12.3.4 Key outcomes

- HbA1c
- Mean CGM glucose
- Time 70-180 mg/dL
- Time >180 mg/dL
- Time >250 mg/dL
- Hyperglycemic event rate
- Time <70 mg/dL
- Time <54 mg/dL
- Hypoglycemic event rate
- Standard deviation of mean CGM glucose
- Coefficient of variation

12.3.5 Other Key Outcomes

- Psychosocial questionnaires
- Insulin metrics
- Other HbA1c and CGM metrics

Safety outcomes included severe hypoglycemia, diabetic ketoacidosis, and non-serious adverse events.

12.3.6 Participants 6-17 Years of Age Results

46 of the 48 participants 6-17 years of age initiated BP with Fiasp and were included in this analysis (two participants were assigned aspart insulin and were therefore excluded from the analysis). In the 6-17 years of age cohort of the extension study which used Fiasp with the iLet System, the study found a decrease in HbA1c from baseline to 13 weeks of 0.56%. There was an increase in TIR from baseline

by 12.0% and mean glucose decreased by 18 mg/dL. These changes occurred without an increase in CGM-measured time <54 mg/dL (decreased 0.15%). Time <70 mg/dL showed a slight decrease of 0.82% from baseline.

A comparison of RCT data for participants 6-17 years of age (which used insulin aspart or insulin lispro) with Extension study data for participants 6-17 years of age (which used Fiasp) was descriptively assessed. The change that occurred using fast-acting insulin aspart (Fiasp) in the 6-17 years of age cohort was comparable to the amount of change from baseline observed in the 6-17 years of age cohort in the prior RCT during which insulin aspart (Novolog) or insulin lispro (Humalog) was used in the bionic pancreas.

Mean Change in HbA1c from Baseline to 13 Weeks (6-17 years)

	Extension Study			
	Baseline (SC)	**Week 13 (BP-F)**	**Change from Baseline to Week 13**	**P-Value [a]**
Overall	N=45 7.8 (1.1)	N=43 7.2 (0.7)	N=42 -0.56 (0.69)	<0.001
6-12 years	N=23 8.0 (0.9)	N=22 7.2 (0.5)	N=21 -0.65 (0.68)	–
13-17 years	N=22 7.6 (1.3)	N=21 7.1 (0.8)	N=21 -0.47 (0.71)	–

⁎a- P-values for the change in means were calculated from a paired t-test comparing the week 13 extension phase value to the extension baseline value. P-values were adjusted to control the false discovery rate.

Out of 46 subjects 6-17 y/o who were on Fiasp, 1 subject had missing HbA1c data at baseline and 3 subjects had missing HbA1c data during follow-up for a total of 4 subjects missing HbA1c data, therefore change from baseline to Week 13 was analyzed in a total of 42 subjects.

Key CGM Outcomes (6-17 years)

	Extension Study			
	Baseline (SC)	**Week 13 (BP-F)**	**Change from Baseline**	**P-Value [a]**
Overall	N=46	N=45	N=45	
Hours of CGM Data	2042 (132)	1877 (270)	–	–
% Time in range 70-180 mg/dL	51% (16%)	63% (10%)	12.0% (11.8%)	<0.001
Mean glucose (mg/dL)	187 (34)	168 (16)	-18 (24)	<0.001
% Time > 180 mg/dL	46% (17%)	35% (10%)	-11.2% (12.3%)	<0.001
% Time > 250 mg/dL	21.2% (14.7%)	11.6% (6.5%)	-9.8% (10.7%)	<0.001
Hyperglycemic event rate per week (≥90 min >300 mg/dL in 120 minutes) [b]	3.1 (2.5)	1.7 (1.5)	-1.5 (1.8)	<0.001
% Time <70 mg/dL	2.89% (2.66%)	2.13% (1.46%)	-0.82% (2.13%)	0.01
% Time <54 mg/dL	0.67% (0.90%)	0.54% (0.51%)	-0.15% (0.69%)	0.17
Hypoglycemic event rate per week [c]	1.23 (1.56)	1.11 (1.12)	-0.14 (1.04)	0.41
Glucose SD (mg/dL)	72 (15)	63 (12)	-9.5 (9.1)	<0.001
Glucose Coefficient of Variation (%)	39% (5%)	37% (5%)	-1.6% (4.3%)	0.02
6-12 years	N=24	N=24	N=24	
Hours of CGM Data	2035 (150)	1902 (319)	–	–
% Time in range 70-180 mg/dL	49% (15%)	62% (6%)	13.1% (13.6%)	–
Mean glucose (mg/dL)	187 (30)	166 (10)	-20 (26)	–
% Time > 180 mg/dL	47% (16%)	35% (6%)	-12.6% (14.1%)	–
% Time > 250 mg/dL	22.5% (12.6%)	11.4% (3.8%)	-11.1% (11.2%)	–
Hyperglycemic event rate per week (≥90 min >300 mg/dL in 120 minutes) [b]	3.4 (2.1)	1.5 (0.8)	-1.9 (1.9)	–
% Time <70 mg/dL	3.43% (2.83%)	2.91% (1.54%)	-0.52% (2.15%)	–
% Time <54 mg/dL	0.88% (1.09%)	0.77% (0.58%)	-0.10% (0.84%)	–
Hypoglycemic event rate per week [c]	1.60 (1.84)	1.63 (1.29)	0.03 (1.11)	–
Glucose SD (mg/dL)	76 (13)	65 (9)	-10.8 (9.9)	–
Glucose Coefficient of Variation (%)	41% (5%)	39% (4%)	-1.8% (3.9%)	–

13-17 years	N=22	N=21	N=21	
Hours of CGM Data	2049 (113)	1848 (203)	–	–
% Time in range 70-180 mg/dL	52% (18%)	63% (12%)	10.8% (9.4%)	–
Mean glucose (mg/dL)	186 (39)	170 (21)	-16 (23)	–
% Time > 180 mg/dL	45% (19%)	36% (13%)	-9.7% (9.9%)	–
% Time > 250 mg/dL	19.8% (16.9%)	11.8% (8.7%)	-8.4% (10.2%)	–
Hyperglycemic event rate per week (≥90 min >300 mg/dL in 120 minutes) [b]	2.8 (2.8)	2.0 (1.9)	-1.0 (1.6)	–
% Time <70 mg/dL	2.31% (2.39%)	1.24% (0.64%)	-1.16% (2.10%)	–
% Time <54 mg/dL	0.45% (0.58%)	0.27% (0.19%)	-0.20% (0.48%)	–
Hypoglycemic event rate per week [c]	0.83 (1.10)	0.52 (0.39)	-0.34 (0.95)	–
Glucose SD (mg/dL)	69 (17)	61 (14)	-8.1 (8.0)	–
Glucose Coefficient of Variation (%)	37% (4%)	35% (4%)	-1.5% (4.7%)	–

a- P-values for the change in means were calculated from a paired t-test comparing the week 13 extension phase value to the extension baseline value. Missing data were handled using multiple imputation. P-values were adjusted to control the false discovery rate.

b- A CGM-measured hyperglycemic event is defined as ≥90 cumulative minutes with a CGM sensor value >300 mg/dL within a 120-minute period. The event ends when there is ≥15 consecutive minutes with a CGM sensor value ≤180 mg/dL, at which point the participant becomes eligible for another hyperglycemic event.

c- A CGM-measured hypoglycemic event is defined as ≥15 consecutive minutes with a CGM sensor value <54 mg/dL. The event ends when there is ≥15 consecutive minutes with a CGM sensor value ≥70 mg/dL, at which point the participant becomes eligible for another hypoglycemic event.

12.3.7 Summary of Participants 6-17 Years of Age Adverse Events

In the 6-17 years of age cohort of the extension study, there were fifty-three (53) adverse events (AEs) reported by 25 (54%) of the 46 6-17 years of age participants who initiated BP with Fiasp insulin (The 53 adverse events were: 1 DKA, 1 other SAE (hospitalization for abdominal pain), 48 hyperglycemia/ketosis not meeting the definition for DKA, and 3 other (ankle injury, contact dermatitis, and bruise). Two (2) of the AEs were SAEs. A complete recovery occurred after each event. There were no UADEs. No deaths occurred during the study.

12.3.8 Summary of Participants 6-17 Years of Age Serious Adverse Events

One participant in the 6-17 years of age cohort developed DKA related to an infusion set failure. The participant was hospitalized and fully recovered. The participant was discontinued due to home circumstances. Aside from the infusion set issue, there was no evidence of a malfunction with the BP.

The only other SAE was hospitalization for abdominal pain in a participant in the 6-17 years of age cohort that was unrelated to the study.

Severe Hypoglycemia, Diabetic Ketoacidosis, and Other Serious Adverse Events (6-17 years)

	Overall	6-12 years	13-17 years
	During 13 weeks of Extension (BP-F)	During 13 weeks of Extension (BP-F)	During 13 weeks of Extension (BP-F)
Number of participants	46	24	22
Severe Hypoglycemic (SH) Events [a]			
Number of events	0	0	0
Participants with ≥1 event	0 (0%)	0 (0%)	0 (0%)
Number of events per subject			
0	46 (100%)	24 (100%)	22 (100%)
1	0 (0%)	0 (0%)	0 (0%)
Incidence rate per 100 person-years	0.0	0.0	0.0
Diabetic Ketoacidosis (DKA) Events [b]			
Number of events	1	1	0
Participants with ≥1 event	1 (2%)	1 (4%)	0 (0%)
Number of events per subject			
0	45 (98%)	23 (96%)	22 (100%)
1	1 (2%)	1 (4%)	0 (0%)
Incidence rate per 100 person-years	8.9	16.9	0.0
Other Serious Adverse Events (SAEs) [c]			
Number of events	1	0	1
Participants with ≥1 event	1 (2%)	0 (0%)	1 (5%)
Number of events per subject			
0	45 (98%)	24 (100%)	21 (95%)
1	1 (2%)	0 (0%)	1 (5%)
Incidence rate per 100 person-years	8.9	0.0	18.9

a- A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.

b- A hyperglycemic event is classified as DKA if the following are present: a) symptoms such as polyuria, polydipsia, nausea, or vomiting; b) serum ketones >1.5 mmol/L or large/moderate urine ketones; c) either arterial blood pH <7.30 or venous pH <7.24 or serum bicarbonate <15; and d) treatment provided in a health care facility.

c- A serious adverse event is defined as any untoward medical occurrence that a) results in death, b) is life-threatening, c) requires inpatient hospitalization of prolongation of existing hospitalization, d) results in persistent or significant disability/incapacity or substantial disruption of the ability to conduct normal life functions (sight threatening), e) is a congenital anomaly or birth defect, or f) is considered a significant medical event by the investigator based on medical judgment.

12.4 References

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