iLet® Bionic Pancreas System User Guide

Beta Bionics

℞ ONLY

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Equipment covered in this User Guide
iLet® Bionic Pancreas
iLet Cartridge
iLet Connect
iLet Charge

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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 user guide before you start to use the iLet System.

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

Important Contacts and Numbers

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1. Important User Information

1.1 About This User 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 2.2 Parts of Your iLet System** for details).

This user 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. It also provides the terms of your product warranty.

Read and follow the instructions in this user 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 user guide. Contact Beta Bionics to obtain a replacement copy.

WARNING: Do not use your iLet System and its components before reading this user guide and participating in training. Failure to follow the instructions in the user 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 user 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 user 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 Definitions

The "iLet Bionic Pancreas System" is the same as the "iLet System". The "iLet Device" is made of the "iLet ACE Pump" and "iLet Decision Dosing Software".

1.1.4 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

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

iAGC	Interoperable Automated Glycemic Controller	ACE	Alternate Controller Enabled
BF	Body Floating	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 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.

1.4 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.

1.5 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 2.5.4.3 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.

1.6 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 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 aspart insulin 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.

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: 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.

1.7 Potential Risks

1.7.1 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 2.5.4.3 Limited Access**.

1.7.2 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.

1.7.3 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.

1.8 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 sensor to the iLet Device is less than 20 feet without obstruction.

2. Getting to Know Your iLet System

2.1 iLet System Overview

The iLet Bionic Pancreas System is a closed-loop system that delivers insulin based on input from an integrated continuous glucose monitor (iCGM) in order to automatically regulate blood-glucose (BG) levels (see Figure 1). The iLet System uses autonomous lifelong learning to calculate and deliver insulin doses and to continually adapt these doses to your changing insulin needs.

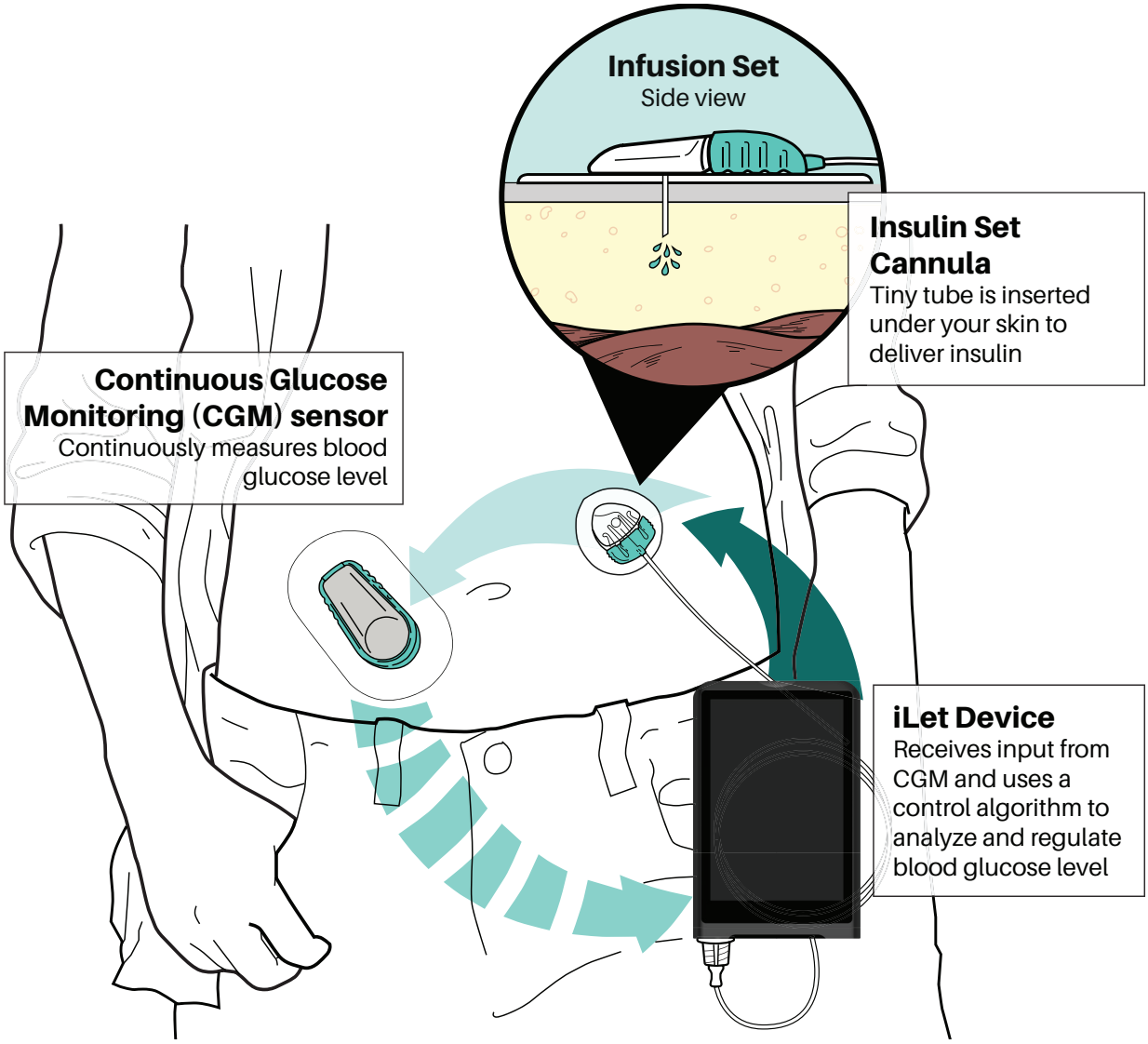


Figure 1

2.2 Parts of Your iLet System

The iLet System consists of the iLet ACE Pump with iLet Dosing Decision Software and disposable parts (see Figure 2):

a. **iLet Device:** Device that automatically delivers insulin subcutaneously based on input from an integrated continuous glucose monitor (iCGM) and/or an SMBG meter, and an interoperable automated glycemic controller (iAGC). In the absence of input from an iCGM, the iAGC can instead use blood glucose entries from an SMBG meter.

Replace the following disposable parts (b, e, f, and g) every 2-3 days:

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. **Insulin 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 insulin infusion set base to the iLet Device using the iLet Connect.

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

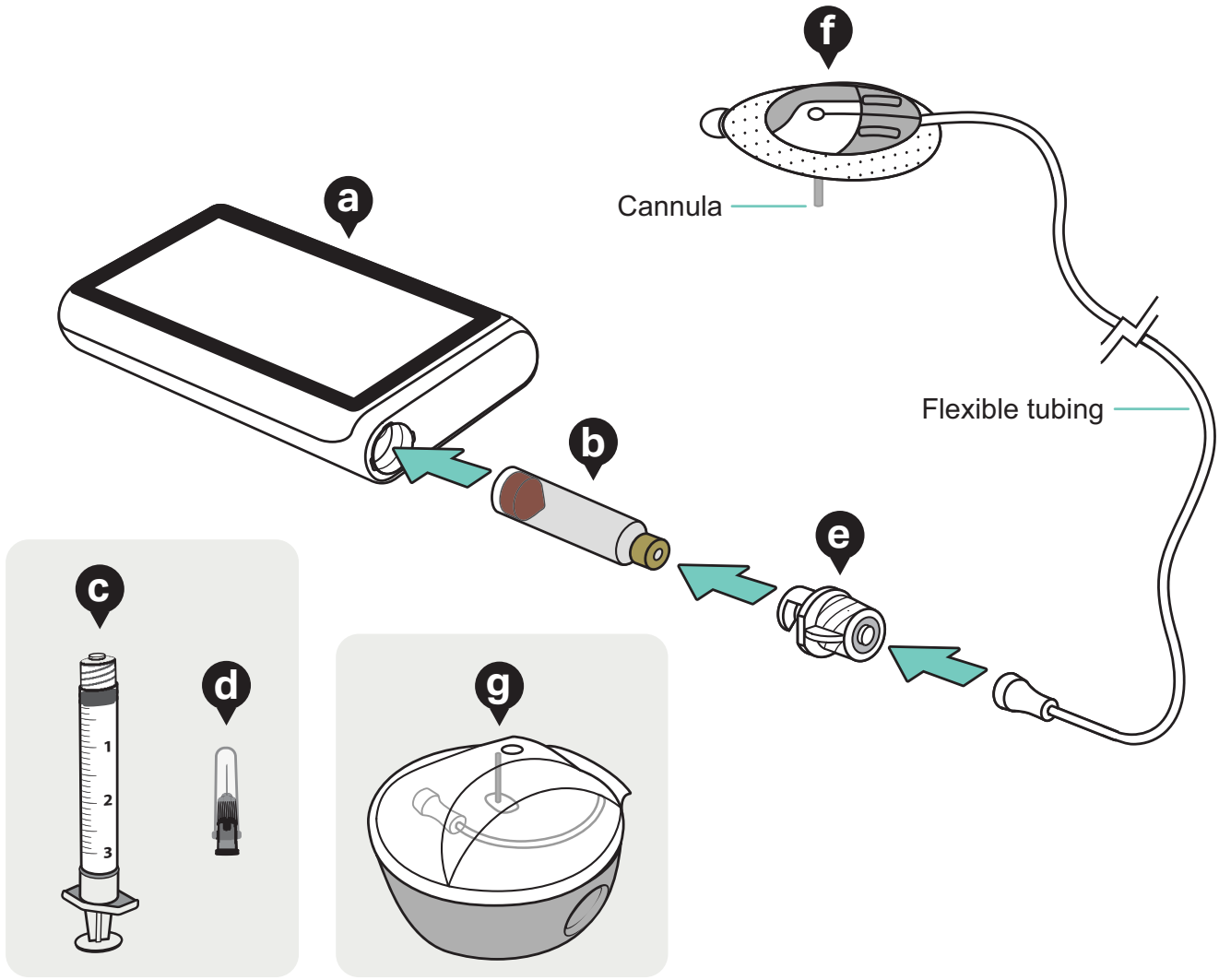


Figure 2

2.3 iLet Device

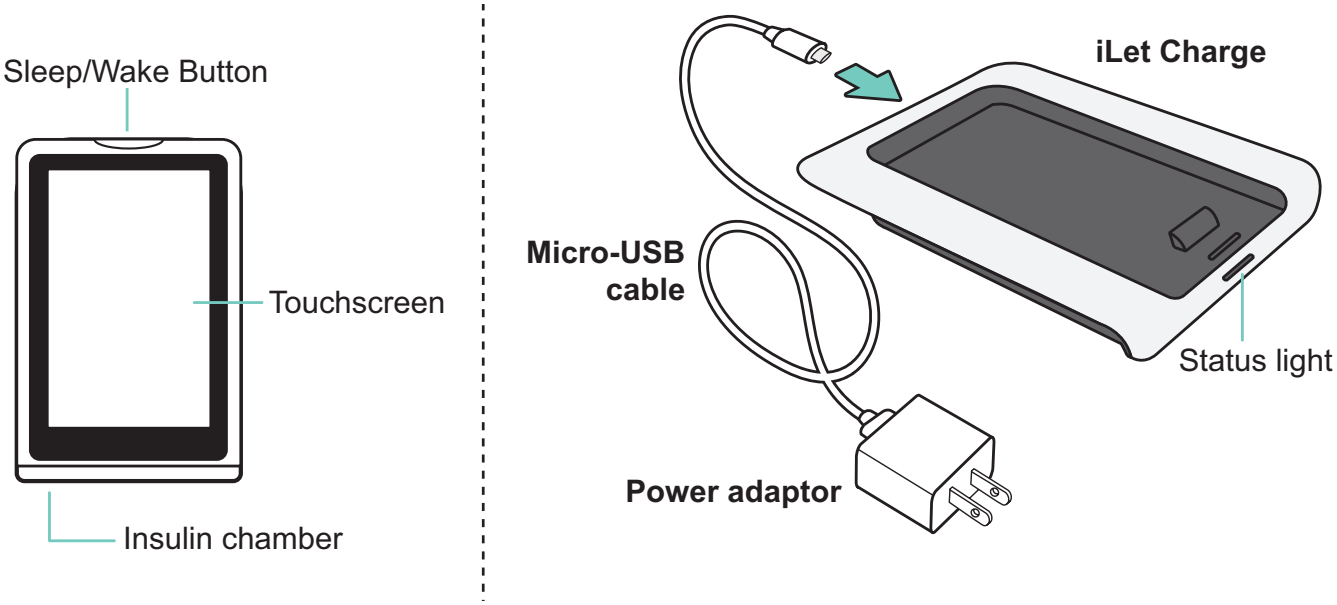


Figure 3

It is important to insert your insulin infusion set and CGM in locations on your body per the recommendations provided by the manufacturer of your insulin infusion set and CGM.

The iLet Device may be worn in any orientation. It may be placed in a pocket, or worn supported in any manner as long as the method of wearing the iLet Device does not impede access for monitoring alerts or cause damage or occlusion to the infusion tubing line.

2.3.1 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 6.2.1 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.

Your iLet Device contains a rechargeable battery that is not replaceable. Charge the battery daily to maximize battery lifespan. It typically takes approximately 2 hours to charge a depleted battery. A fully charged iLet Device will stay on for 4 to 5 days. A fully charged iLet Device with color display will stay on for 3 days. Your iLet Device's battery life depends on the amount of usage, including the backlight and the amount of insulin delivered. The iLet is operational and will dose insulin while charging. The iLet will play a unique audio tone when it is placed on a charger and is receiving power.

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

Try to charge at times which will limit the disruption of insulin therapy. For example, charging while bathing or showering will allow the iLet Device to maintain an optimum battery level.

a. Connect the charger to the power adapter with the micro-USB cable and plug it into an electrical outlet (see Figure 4).

b. Place your iLet Device onto the charger (see Figure 5). Be sure to remove your device clip (iLet Clip) from the iLet Device before placing it on the iLet Charge.

c. Make sure that the iLet Device is charging properly.

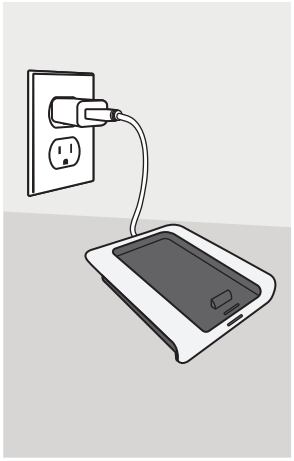


Figure 4

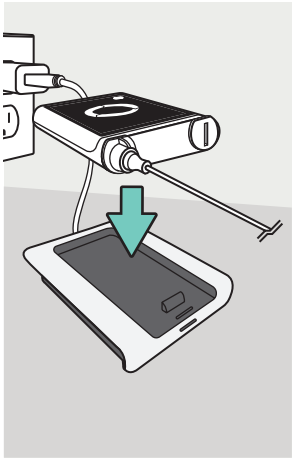


Figure 5

- If the charger status light is solid and the battery indicator animates on the touchscreen, your iLet Device is charging properly.

- If the charger status light is blinking, your iLet Device is not charging properly. Remove your iLet Device from the charger for at least 10 seconds and then place it back on the charger.

2.3.2 Using the Touchscreen

You can navigate the touchscreen with your fingers. Common gestures that you may use to interact with your iLet Device include:

Tap	Use your finger to touch an icon on the touchscreen or a button.
Press/Hold	Keep pressing a button or icon until its function is complete.
Drag	Place your finger on the touchscreen and move it in the direction indicated.

2.3.3 Turning on the Touchscreen and Backlight

The iLet Device's touchscreen has a high contrast black and white LCD, with a backlight available for dark environments. Alternately, the iLet may have a color display.

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.

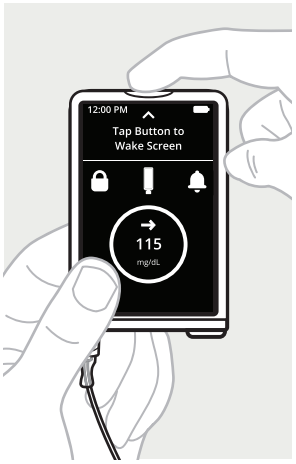


Figure 6

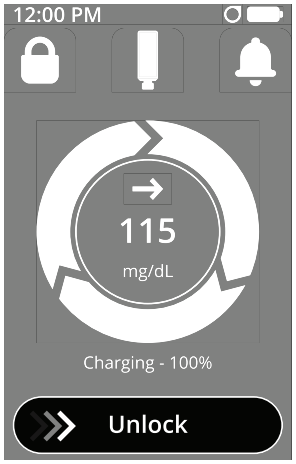


Figure 7

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 6).

To turn the backlight on, lightly press and hold the ***Sleep/Wake*** button for one second.

For iLet devices with a color display, there is no Always On feature. When the display is turned off, it will be black.

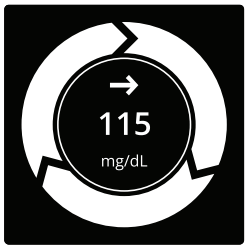
2.3.4 Unlocking the Touchscreen

Drag the ***Unlock*** slider to the right to unlock the touchscreen (see Figure 7).

2.4 Features and Icons

2.4.1 Home Screen

Figure 8

Icon	Feature	Description
	Menu	View the Menu screen.
	Insulin Cartridge	View the insulin remaining in your cartridge. Change your insulin cartridge, change your infusion site, and fill your tubing.
	Notifications	View and respond to the alerts and reminders for your iLet System.
	Glucose Status	View your current CGM glucose and trend. The circle will spin when the iLet is running. Tap to view a graph of CGM and insulin dosing data and a therapy summary screen.
	Meal Announcement	Deliver insulin for meals with carbohydrates.

2.4.2 Notifications

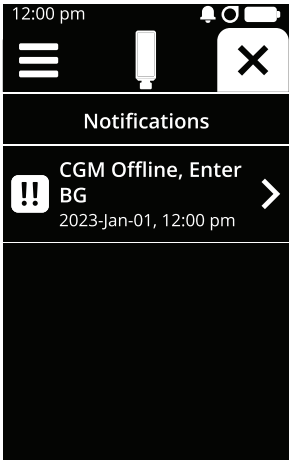


Figure 9

Your iLet Device will notify you with audio tones and/or vibration alerts when attention is required. A visible message will appear in the ***Notifications*** icon (see Figure 9). The number of currently active alerts will appear in the ***Notifications*** icon. A bell icon will also appear in the status bar, next to the battery icon (see **Section 5.1 iLet System Alerts Overview** for a list of alerts).

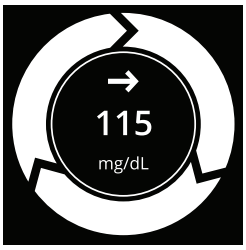
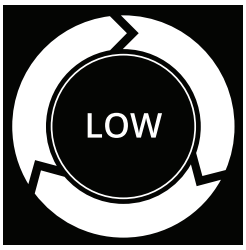
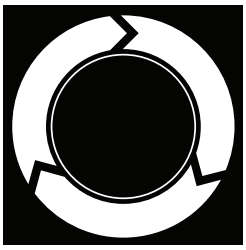
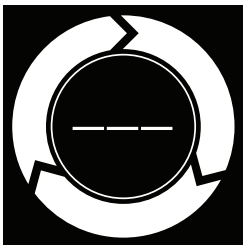
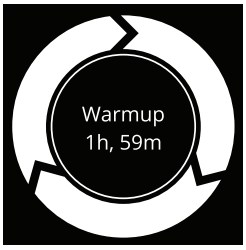
Acknowledging alerts may be required to resume insulin delivery, so always check, respond to, and dismiss active alerts.

Check if any alerts are present throughout the day and respond to all alerts promptly. Not responding to alerts can result in low or high blood glucose levels lasting longer than they should or even becoming severe events that could have been avoided if you responded sooner.

2.4.3 Glucose Trend Arrows

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.

2.4.4 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.

2.4.5 Graph and Therapy Summary

Tapping on the CGM glucose value in the center of the Home screen will display the Graph screen (see Figure 10). You may tap this when the device is locked or unlocked.

The Graph screen displays recent CGM glucose data (small dots) and insulin dosing (vertical bars).

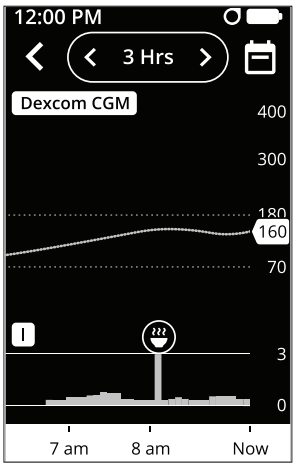


Figure 10

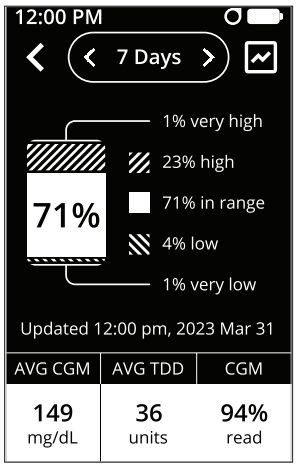


Figure 11

The CGM chart displays glucose values between 40 and 400 mg/dL, with an 'in range' section between 70 and 180 mg/dL (dotted line section in Figure 11).

You can choose between 3, 6, 12, and 24-hour views by tapping on the left and right arrows at the top of the screen.

Occasionally, small gaps between the CGM glucose values may occur. The gaps represent periods of missing CGM data. This indicates that the CGM sensor and iLet Device have lost connection briefly. If you notice large gaps between the CGM glucose values, make sure your iLet Device and the CGM sensor are connected. The iLet Device will alert you when it has lost connection with your CGM sensor for 30 minutes or more.

Tap anywhere on the graph to zoom in, and tap anywhere to zoom out.

To toggle to the Therapy Summary screen, tap the chart icon in the top righthand side of the screen.

The Therapy Summary screen will show summaries of glucose and dosing data (see Figure 11). You can choose between 1, 7, 30 and 90-day views by tapping on the left and right arrows at the top of the screen. Tap on the graph icon in the upper righthand corner to switch back to the Graph screen.

2.4.6 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 is charging. The home screen will display a % level when the iLet is charging.

2.4.7 Menu Screen

Tap the ***Menu*** icon in the upper left of the Home Screen to access the menu (see Figure 12). To close the ***Menu*** screen, tap the **X** tab (see Figure 13).

Figure 12

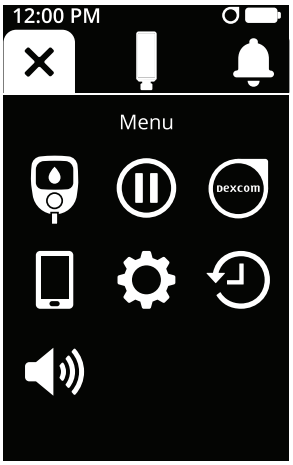


Figure 13

Icon	Feature	Description
	Close	Close the menu screen.
	Enter BG	Enter a BG reading and/or calibrate your CGM (see **Section 4.3.2 Enter BG** for instructions).
	Pause Insulin	Pause insulin delivery and set a reminder to resume (see **Section 4.8 Pause Insulin** for instructions)..
	CGM	View options for pairing or managing a CGM sensor and transmitter with your iLet Device (see **Section 4.2.4 Replacing your CGM sensor and transmitter** for instructions).
	Mobile	Pair a compatible smart device (phone or tablet) to your iLet Device using the iLet Mobile App (see **Section 4.4 Mobile Device** for instructions).
	Settings	View and adjust your iLet Device settings (see **Section 3.1.2 Enter Your Settings** for instructions).
	History	View Alerts, Meal Announcements, Cartridge Changes, Infusion Set Changes, Algorithm Steps, and Insulin History (see **Section 2.6 History** for instructions).
	Volume	View and adjust the volume level of your iLet Device (see **Section 2.7 Volume** for instructions).

2.5 Settings Menu

Settings allow you to adjust features of your iLet Device (see Figure 14).

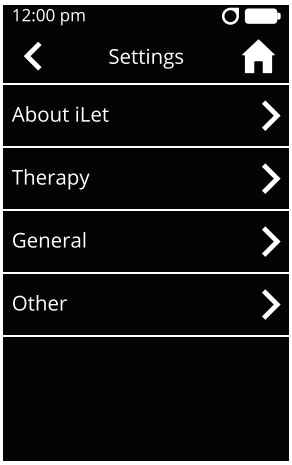


Figure 14

Figure 15

2.5.1 About iLet

View details about your iLet Device in a scrollable list (see Figure 15). 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.

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

2.5.2 Therapy

Adjust settings which may affect your iLet Device's dosing (see Figure 16).

2.5.2.1 CGM Target

The default CGM Target setting is Usual.

Adjust the CGM Target to a higher or lower point (see Figure 17).

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

Figure 16

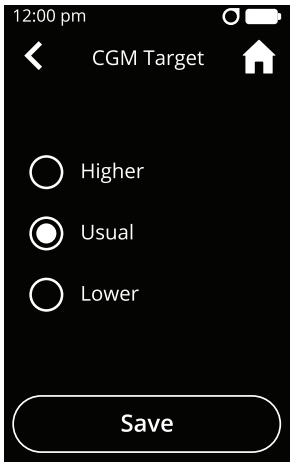


Figure 17

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

2.5.2.2 Secondary CGM Target

The Secondary CGM Target allows you to set a different target for a part of the day. Turn on the Secondary CGM Target using the On/Off toggle (see Figure 18). The default Secondary CGM Target setting is Usual. You can adjust the Secondary CGM Target to be Higher or Lower, and you can customize the start and end times.

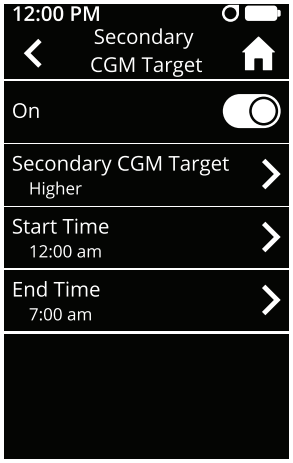


Figure 18

Figure 19

2.5.2.3 Body Weight

Adjust the body weight that the iLet uses to dose (see Figure 20), 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.

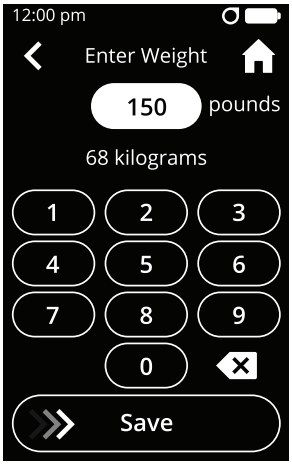


Figure 20

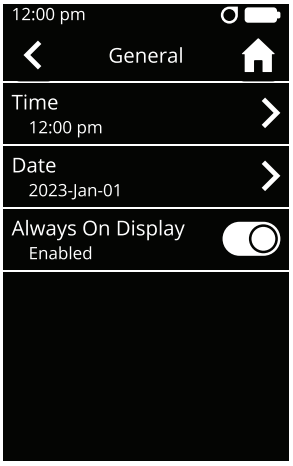


Figure 21

2.5.3 General

Change device settings (see Figure 21).

Time - Adjust the time displayed on your iLet Device's clock.

Date - Adjust the date of your iLet Device.

Always On Display - Enable or disable the Always On Display, which provides info at a glance.

2.5.4 Other

(see Figure 22).

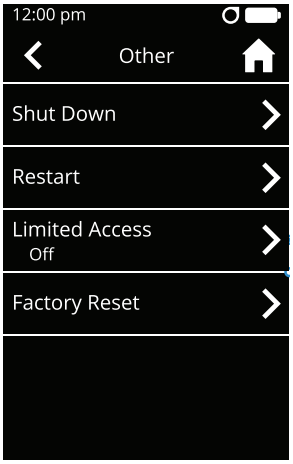


Figure 22

2.5.4.1 Shut Down

Turn off your iLet Device for storage. Go into Settings and choose Other, then choose Shutdown (see Figure 23). All dosing will stop. To turn the iLet Device back on, place the iLet Device on the charger.

Upon waking up if the battery has been fully depleted, the iLet Device may require you to go through the iLet Startup Sequence again. In that case, a new treatment session will be started using a new body weight entry, but all other user settings on the iLet Device will be retained.

Figure 23

2.5.4.2 Restart

Similar to restarting a computer, this will cycle power and restart your iLet Device (see Figure 24). Your iLet Device's existing settings, learnings, cartridge level, CGM session, and autonomous dosing will resume after the restart is complete.

Figure 24

2.5.4.3 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 25). 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.

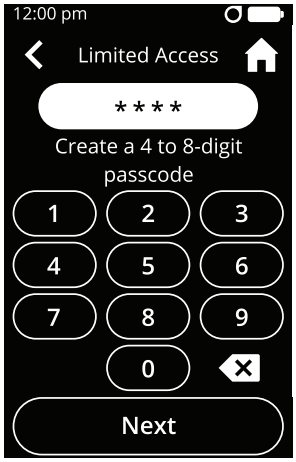


Figure 25

2.5.4.4 Factory Reset

Return your iLet Device to factory settings. This will erase all settings, learnings, and CGM sessions. You will need to set up your iLet Device again (see Figure 26).

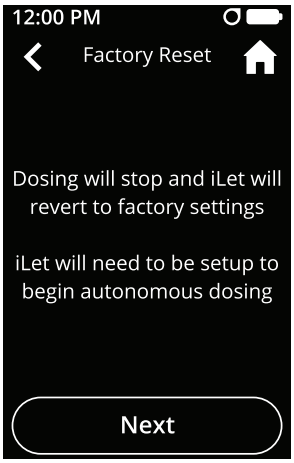


Figure 26

2.6 History

Tap the ***History*** icon in the ***Menu*** to view the event history (see Figure 27).

2.6.1 Alerts

Tap ***Alerts*** to view a scrollable list of alarms over the past 24 hours.

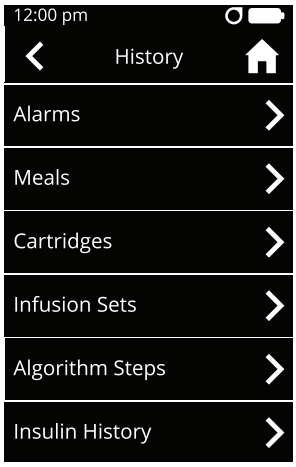


Figure 27

2.6.2 Meals

Tap ***Meals*** to view a scrollable list of meal announcements over the past 24 hours.

2.6.3 Cartridges

Tap ***Cartridges*** to view information of the last insulin cartridge change. It will also display how much insulin the tubing was filled with during the last insulin cartridge change.

It will also display how many occlusions (blockages) have occurred since starting the current algorithm session.

2.6.4 Insulin Infusion Sets

Tap ***Infusion Sets*** to view information of the last insulin infusion set change.

2.6.5 Algorithm Steps

Tap ***Algorithm Steps*** to view your current Insulin On Board (e.g., how much active insulin is in your body), a list of the last 36 delivery steps (3 hours) and the information that was used to calculate the amount of insulin to deliver. Algorithm Steps provides the following information in each step (see Figure 28):

1. CGM (numeric value)
2. Insulin (dose delivered)
3. Requested Insulin (dose calculated by the algorithm)
4. BG Entered (numeric value, if applicable)
5. Meal Size (carb amount chosen, if applicable)

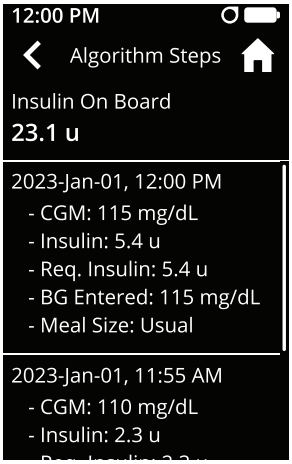


Figure 28

2.6.6 Insulin History

Tap Insulin History to view a list of iLet insulin history for total daily basal insulin and meal announcements (see Figure 29).

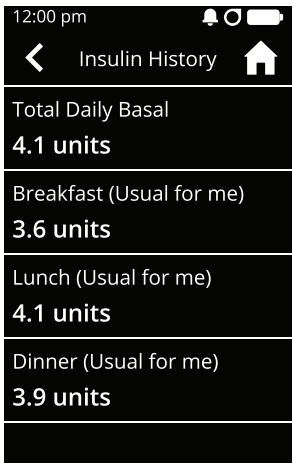


Figure 29

2.7 Volume

You can adjust the volume level of alerts. More urgent alarms will escalate to the highest volume level if they are not acknowledged.

Follow the instructions below to adjust the volume.

a. From the ***Home*** screen, tap the ***Menu*** icon in the upper left corner (see Figure 30)

b. Tap the ***Volume*** icon (see Figure 31).

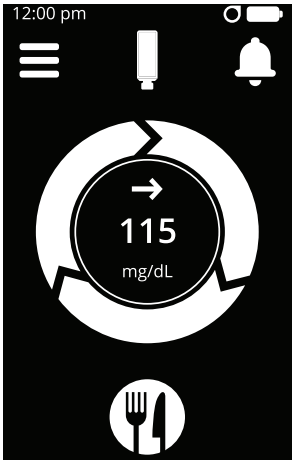


Figure 30

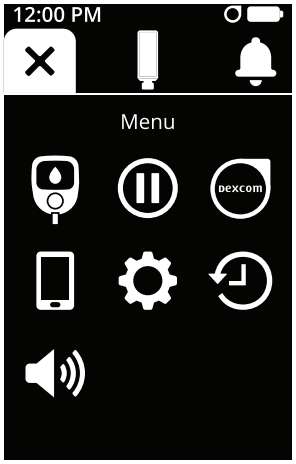


Figure 31

Select the volume you want. Tap any of the four options to play the volume. iLet will still vibrate when the volume is set to Off, and will still beep when charging begins (see Figure 32).

Tap ***Save*** to confirm selection.

Remember, whatever volume level you set, you need to make sure you are able to hear and respond to alerts. It is recommended you keep the volume on high.

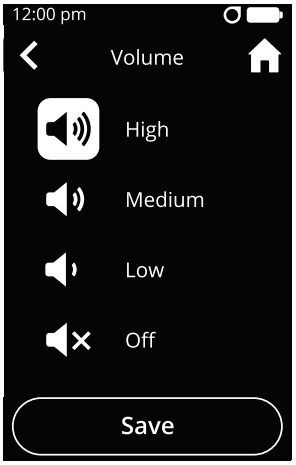


Figure 32

3. Getting Started With Your iLet System

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

3.1 Preparing to Set Up Your iLet System

When you turn on your iLet Device for the first time, instructions on the touchscreen will guide you on how to get started.

3.1.1 Turn on Your iLet Device

a. Place your iLet Device onto the charger an turn it on (see Figure 33).

b. Make sure that the charger status light and the iLet touchscreen are on.

- The iLet logo should appear and spin.

c Tap ***Begin*** on the Welcome screen (see Figure 34).

Figure 33

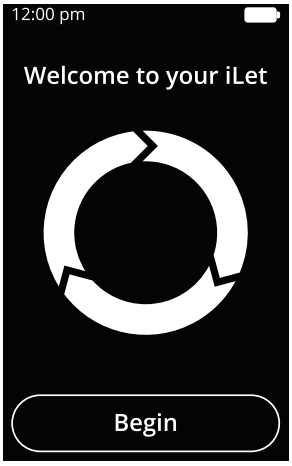


Figure 34

3.1.2 Enter Your Settings

c. Set the time to the current time and tap ***Next*** (see Figure 35).

d. Set the date to the current date and tap ***Next*** (see Figure 36).

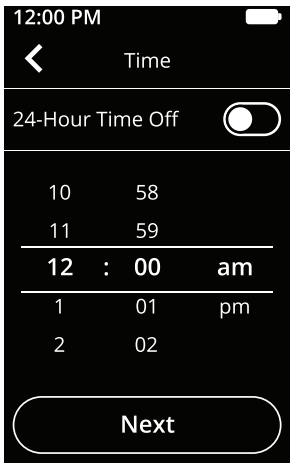


Figure 35

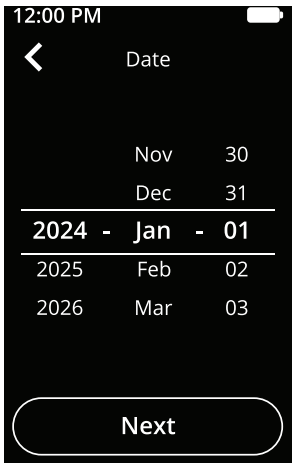


Figure 36

3.2 Setting Up Your iLet System

3.2.1 iLet Setup Alert

After you have finished entering your settings, an alert will appear on the touchscreen. Tap the ***iLet Setup*** alert (see Figure 37).

- A list of tasks to complete will appear on the touchscreen (see Figure 38).
- Use this list to guide you if you are setting up your iLet Device for the first time or if you are setting up a replacement iLet Device.

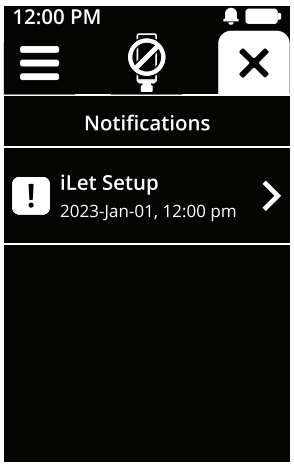


Figure 37

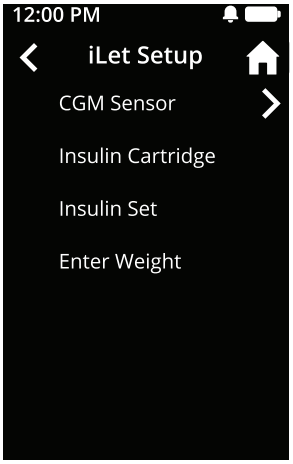


Figure 38

- If you navigate away from the ***iLet Setup*** list, you can return by tapping the ***Alert*** icon and then tapping ***iLet Setup*** again.

> **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.

3.2.2 CGM Sensor

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

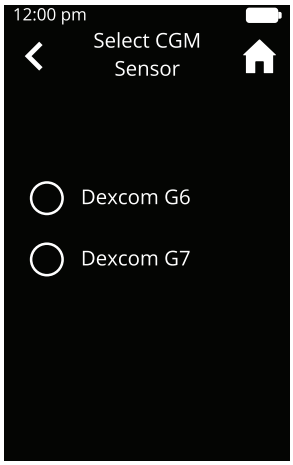


Figure 39

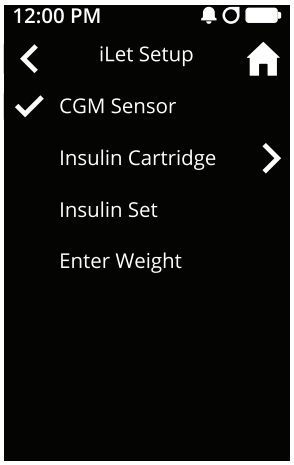


Figure 40

Set up your CGM before setting up the iLet Device with enough time to allow your CGM sensor time to warm up. Follow the CGM manufacturer's instructions for how to insert the sensor and start the sensor session on a compatible device (smartphone or receiver). The iLet Device cannot be initiated until the CGM sensor is warmed up and displaying a glucose value.

First, select your CGM Sensor. You can choose between Dexcom G6 or Dexcom G7 (see Figure 39).

a. Tap ***CGM Sensor*** in the iLet Setup menu

b. Select your CGM Sensor. You can choose between Dexcom G6 or G7.

3.2.2.1 Pair Dexcom G6 CGM Sensor

a. Tap ***No Code***

    a. If you need to start a new sensor, enter the sensor code found on the adhesive paper

b. Enter the CGM transmitter serial number and tap ***Next***

c. Tap ***Next*** on the ***Insert Sensor*** screen

    a. If you need to start a new sensor, follow the prompts on this screen and insert the sensor according to the manufacturer's instructions before tapping Next

The iLet Device will return to the iLet Setup Menu, and the CGM sensor row will be checked off.

The status bar will show a searching symbol while it is pairing with the transmitter. It will show the CGM icon when the transmitter is paired. It can take up to 30 minutes for the transmitter to pair with the iLet Device. If your sensor is currently running on a CGM receiver or insulin pump,

it will need to be unpaired from that device before it can be paired with the iLet Device. Your transmitter can remain paired to a smartphone.

Once the transmitter is paired, your iLet Device will start displaying your current CGM glucose and trend arrow if available on the home screen.

If your sensor needs to warm up first, the iLet Device will display the time remaining in the warmup period on the home screen. When the warmup period is complete, your CGM glucose will be displayed. The iLet Device cannot be initiated until the CGM sensor is warmed up and displaying a glucose value. Use self-monitoring of blood glucose (SMBG) readings as needed until the two-hour period has passed.

3.2.2.2 Pair Dexcom G7 CGM Sensor

a. If you need to start a new sensor, insert your sensor first

a. Tap ***Next*** on the ***Insert Sensor*** screen and find the 4-digit pairing code located on your applicator

b. Enter the pairing code located on your applicator and tap ***Submit***

The iLet will return to the iLet Setup Menu, and the CGM sensor row will be checked off.

The status bar will show a searching symbol while it is pairing with the sensor. It will show the CGM icon when the sensor is paired. It can take up to 30 minutes for the sensor to pair with the iLet Device. If your sensor is currently running on a CGM receiver or insulin pump, it will need to be unpaired from that device before it can be paired with the iLet Device.

Once the sensor is paired, your iLet Device will start displaying your current CGM glucose and trend arrow if available on the home screen.

If your sensor needs to warm up first, the iLet Device will display the time remaining in the warmup period on the home screen. When the warmup period is complete, your CGM glucose will be displayed. The iLet Device cannot be initiated until the CGM sensor is warmed up and displaying a glucose value. Use self-monitoring of blood glucose (SMBG) readings as needed until the warm up period has passed.

3.2.3 Insulin Cartridge

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 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.

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 User Guide.

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).

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.

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 User Guide.

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.

3.2.3.1 Preparing to fill the iLet cartridge

- If you use Humalog® or Novolog® vials, you will need to fill the iLet Cartridge with insulin prior to installing it.
- If you use Fiasp® PumpCart® (insulin aspart) prefilled insulin cartridges, proceed to **Section 3.2.3.6** Prepare the Tubing.
- When you are done changing your insulin cartridge, the Insulin Cartridge row will be checked off on the ***iLet Setup*** alert screen.

a. To fill the iLet Cartridge with insulin, gather the following supplies (see Figure 41).
   - iLet Cartridge
   - Syringe
   - Needle
   - Humalog or Novolog Insulin vial
   - Alcohol wipe

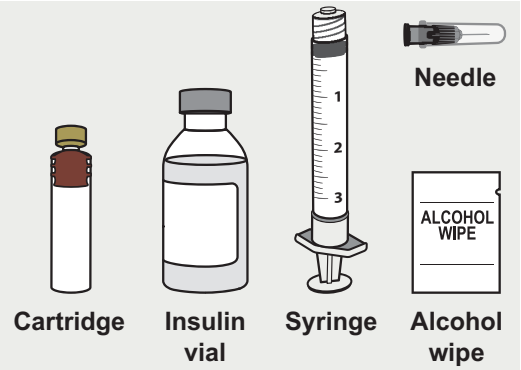


Figure 41

b. Wipe the top of the insulin vial with an alcohol wipe and let dry (see Figure 42).

> **NOTE:** If the vial is new, remove and discard the cap before wiping the vial top.

c. Open the iLet Cartridge package and remove the empty iLet Cartridge from the packaging (see Figure 43).

d. Open the syringe package and remove the syringe from the packaging (see Figure 44).

e. Open the needle package and remove the needle from the packaging (see Figure 45).

> **WARNING:** Do not remove the needle guard yet.

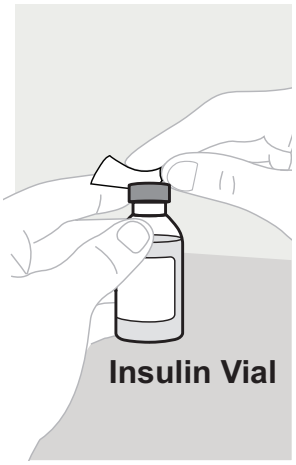


Figure 42

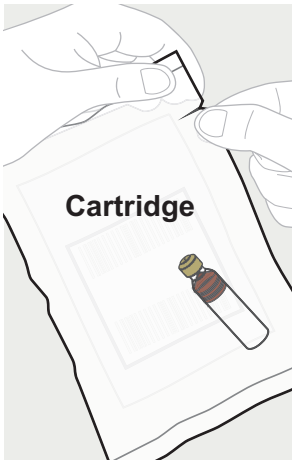


Figure 43

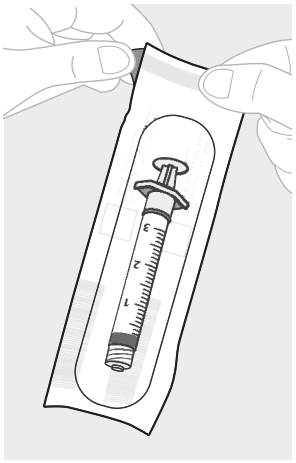


Figure 44

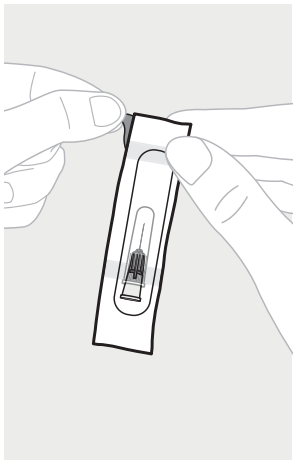


Figure 45

f. Attach the syringe to the needle by twisting one into the other (see Figure 46).

g. Remove the needle guard without touching the needle.

h. Pull back the plunger of the syringe (see Figure 47). Make sure the plunger of the syringe is at 1.8 mL (about halfway between the 1.5 mL and 2 mL marks).

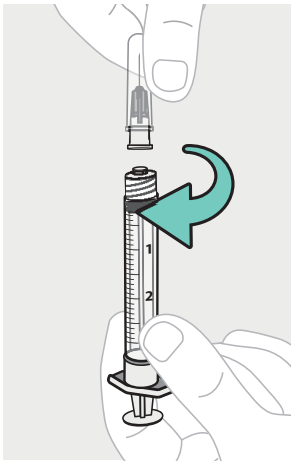


Figure 46

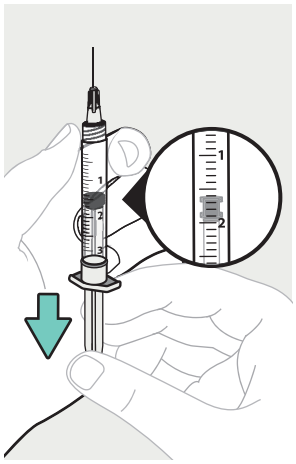


Figure 47

i. Insert the syringe needle into the insulin vial while the vial is placed upright on a table or countertop. Push down on the syringe plunger rod to fill the vial with the air from the syringe (see Figure 48). Try not to insert air directly into the insulin.

j. Without letting go of the syringe plunger rod, keep pressure on the plunger rod and invert (turn upside down) the insulin vial and syringe (while the syringe needle is still in the vial) (see Figure 49).

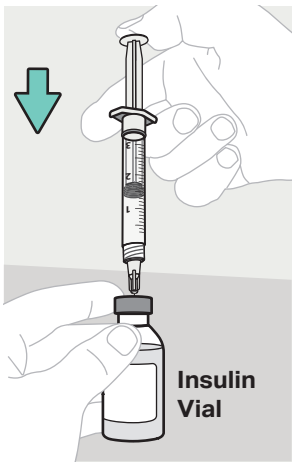


Figure 48

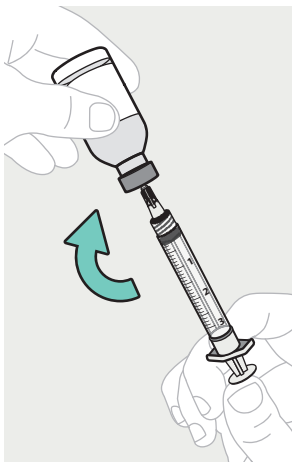


Figure 49

3.2.3.2 Filling the Syringe with Insulin

a. Carefully and slowly pull back the syringe plunger rod to fill the syringe with about 1.8 mL of insulin (about halfway between the 1.5 mL and 2 mL marks) (see Figure 50).

b. Remove any remaining air from the syringe by flicking it with your finger and pushing on the syringe plunger rod to get rid of air bubbles (see Figure 51). Pull back on the syringe plunger rod again if needed to fill the syringe to about 1.8 mL.

c. Remove the syringe needle from the insulin vial and set the vial aside.

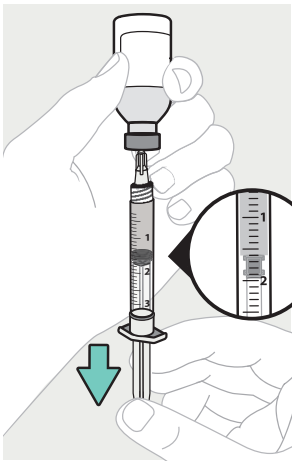


Figure 50

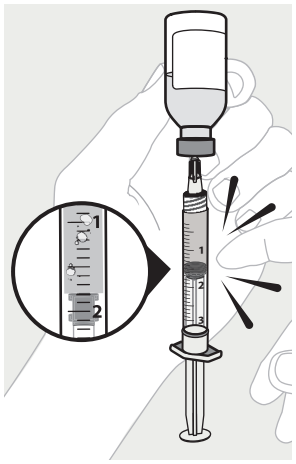


Figure 51

3.2.3.3 Filling the iLet Cartridge

a. Place the base of the empty cartridge upright on a flat surface and hold the cartridge with one hand. With the other hand, insert the syringe needle into the empty cartridge's septum (see Figure 52).

b. Pressing down slowly on the syringe plunger rod, transfer the insulin from the syringe into the cartridge.

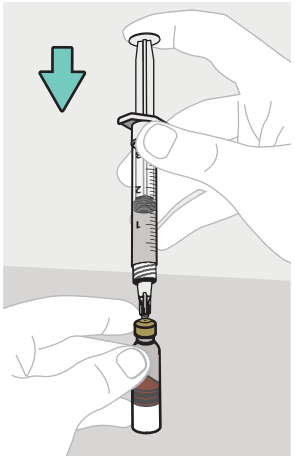


Figure 52

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 1.8 mL of insulin.

c. If needed, pull back slightly on the syringe plunger rod and remove as much air from the cartridge as you can. See **Section 3.2.3.4 Removing Air Bubbles from the iLet Cartridge**, and **Section 3.2.3.5 Adding More Insulin After Bubbles Have Been Removed**.

d. Once there are no air bubbles remaining inside the cartridge, remove the syringe from cartridge and discard the syringe and needle in a sharps disposal container.

3.2.3.4 Removing Air Bubbles From the iLet Cartridge

a. If there are any large air bubbles remaining inside the cartridge, remove the syringe from the cartridge and set it aside avoiding any contact with the needle to keep the needle sterile. Loosen any remaining air bubbles in the cartridge by tapping the cartridge with your finger or tapping the cartridge on the table until air bubbles float up into the neck of the cartridge (see Figure 53). The air bubbles may combine into one or more larger bubbles.

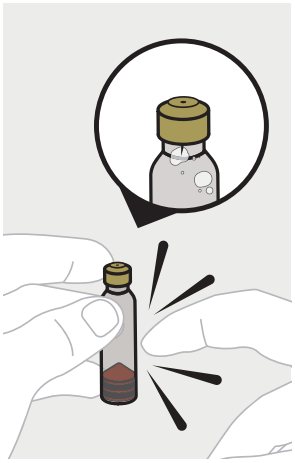


Figure 53

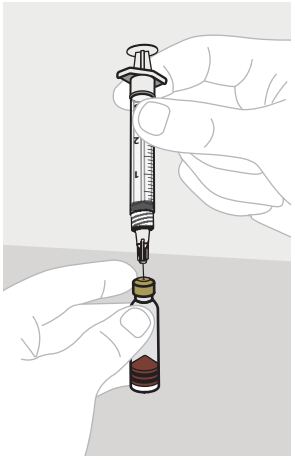


Figure 54

b. Reinsert the syringe until the needle is touching the air bubble (see Figure 54). Draw back on the plunger until the air bubble is fully removed from the cartridge.

> **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 syringe needle from the cartridge while maintaining pressure on the plunger. The needle tip should now be surrounded by the air bubble. Pull back on the plunger until the air bubble has been removed.

3.2.3.5 Adding More Insulin After Bubbles Have Been Removed

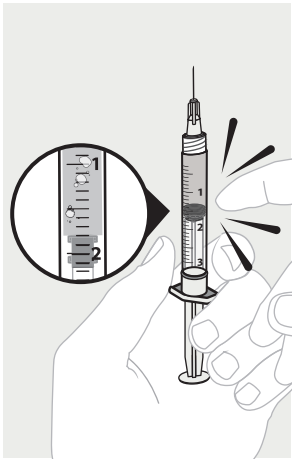


Figure 55

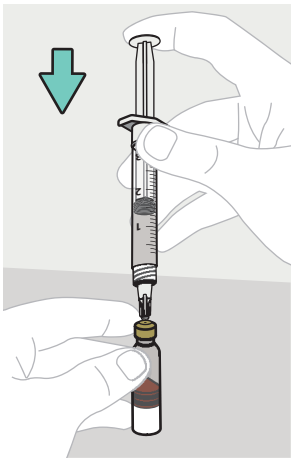


Figure 56

a. Invert the syringe so that the needle is pointing up. Tap on the side of the syringe to loosen any air bubbles until they float to the needle hub (see Figure 55). Press on the plunger until air is expelled.

b. Reinsert the syringe into the cartridge septum and push down slowly on the syringe plunger rod to transfer additional insulin from the syringe into the cartridge such that the cartridge is filled to your satisfaction (see Figure 56).

> **CAUTION:** Do not overfill the cartridge. The red 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 1.8 mL of insulin.

c. Remove the syringe and needle from the cartridge. Dispose of the syringe and needle in a sharps disposal container.

3.2.3.6 Prepare the Tubing

> **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.

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

To prepare your insulin infusion set, gather the following supplies (see Figure 57).

- iLet Connect
- Insulin Infusion Set

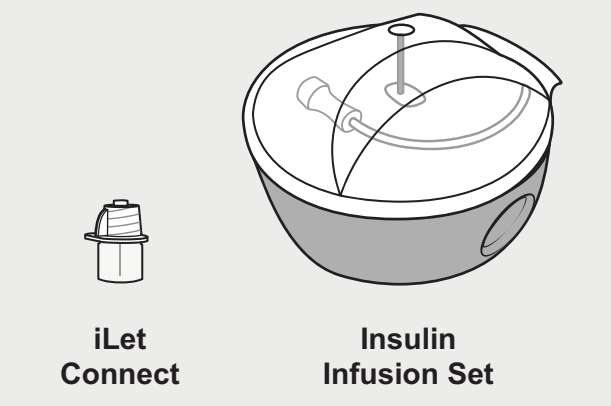


Figure 57

a. Open the insulin infusion set packaging according to the insulin infusion set instructions to access the tubing (see Figure 58).

b. Gently unpack the tubing from the insulin infusion set packaging.

c. Your insulin infusion set may look different from what is pictured.

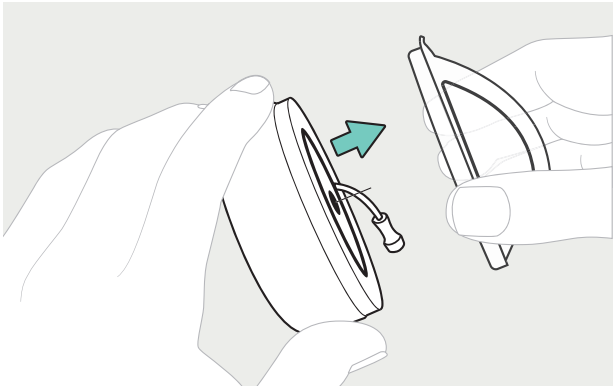


Figure 58

d. Unpack the iLet Connect Luer adapter from the packaging.

e. Connect the iLet Connect Luer adapter and insulin infusion set flexible tubing by twisting one into the other until tight (see Figure 59). Make sure this connection is straight and tight. If this connection is not tight, insulin can leak out causing hyperglycemia, or air can get it in and push insulin into your body, causing hypoglycemia. Do not connect the iLet Connect to the insulin cartridge yet.

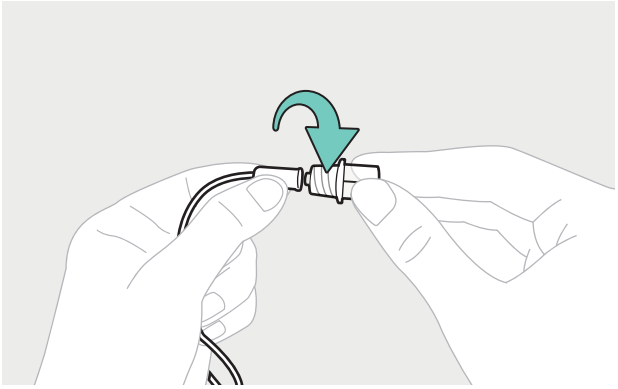


Figure 59

3.2.3.7 Prepare the iLet Device

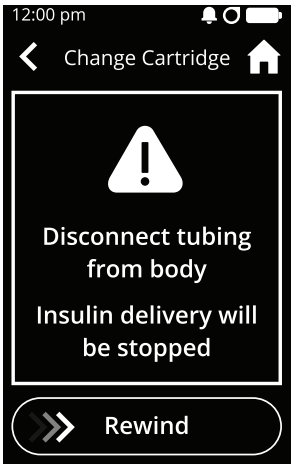


Figure 60

a. Tap the Insulin Cartridge row of the iLet Setup alert

b. Drag the Rewind slider to the right (see Figure 60).

c. Allow the iLet Device to complete the rewind process. Only insert the filled insulin cartridge once the rewind process is complete. Failure to do so can damage the cartridge and the iLet, as well as cause unintentional insulin delivery through the tubing.

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

3.2.3.8 Insert the Cartridge

> **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.

a. Insert the cartridge into the insulin chamber (see Figure 61).

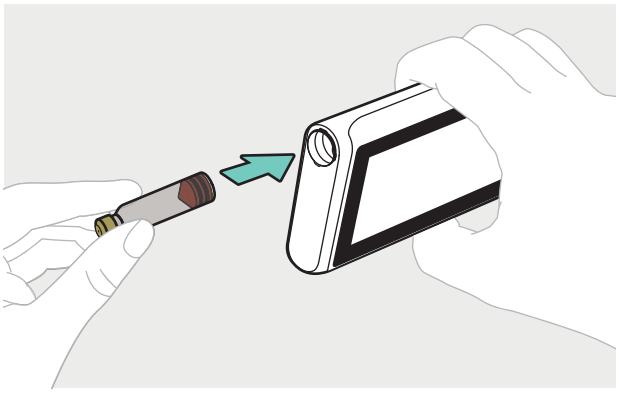


Figure 61

b. After the cartridge has been inserted, insert the iLet Connect into the iLet device's insulin chamber (see Figure 62).

   - You will hear a click when the Luer adapter attaches to the cartridge (see Figure 63).

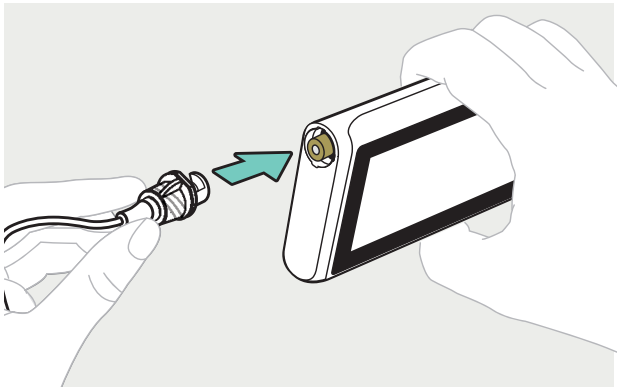


Figure 62

c. Once the Luer adapter is touching the iLet device, quarter turn the Luer adapter to the right (see Figure 64).

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

> **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.

Figure 63

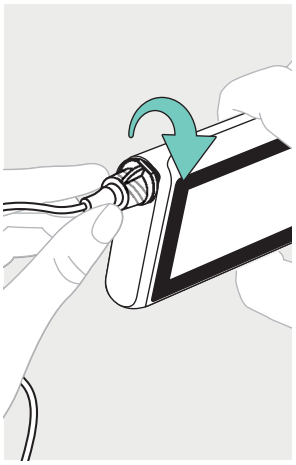


Figure 64

d. Your cartridge is now installed. When you have completed all the steps, tap ***Go To Fill Tubing*** to continue. You may press ***Go To Fill Tubing*** at any time to proceed during the animation.

3.2.3.9 Fill the Tubing

> **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.

a. Tap and hold the ***Press & Hold*** button to begin filling your tubing with insulin (see Figure 65). You will see drops appear from the needle of the insulin infusion set.

b. Hold the ***Press & Hold*** button until you see drops. No air bubbles should occur in the tubing.

c. Tap ***Yes*** if you see drops without air bubbles in your tubing (see Figure 66). Tapping ***No*** will take you back to the ***Press & Hold*** screen.

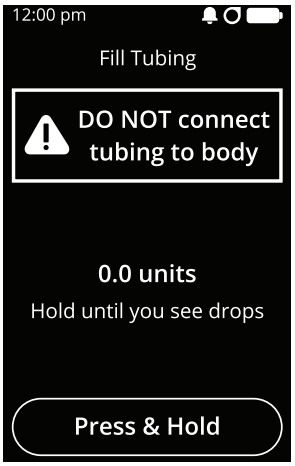


Figure 65

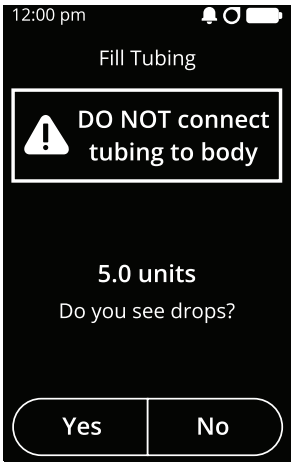


Figure 66

d. Tap ***Next*** to finish.

> **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.

e. When you are done changing your insulin cartridge, the Insulin Cartridge row will be checked off (see Figure 67) and the iLet Device will ask you if you need to change your insulin set. Tap ***Yes*** to proceed to placing your new infusion set.

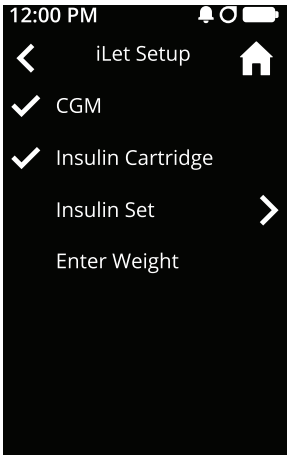


Figure 67

3.3 Insulin Set

> **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.

> **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 anti-bacterial soap. Thoroughly 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.

CAUTION: Check 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.

3.3.1 Inserting Your Insulin Infusion Set and Filling the Cannula

a. Insert your new insulin infusion set base. Refer to the instructions for use provided in your insulin infusion set box

b. Drag the ***Next*** slider to confirm that you have inserted a new insulin infusion set (see Figure 68).

c. Select the type and length of your infusion set cannula. Refer to the manufacturer's instructions to find this information. Drag the ***Fill*** slider to the right (see Figure 69).

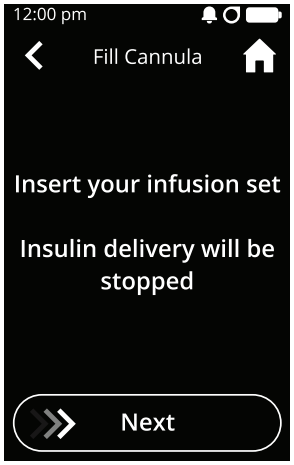


Figure 68

Figure 69

d. The iLet will begin filling your insulin infusion set cannula with insulin. You will see a progress bar until the fill is complete.

3.3.2 Compatible Infusion Sets

Insulin Infusion Set	Cannula Length	Cannula Type	Duration of Use
Inset™I	6mm, 9mm	Teflon	2 to 3 days
Inset™ 30	13mm	Teflon	2 to 3 days
Contact™ Detach	6mm, 8mm	Steel	1 to 2 days

Note that not all insulin infusion sets or cannula lengths may be available at the time of product launch.

3.4 Enter Weight and Go Bionic

Your healthcare provider will provide guidance on how to accurately measure your body weight and enter the value with their oversight. When you ***Go Bionic***, your iLet System will begin regulating your glucose levels autonomously and adapt to your insulin needs.

a. Enter your body weight to the nearest pound. Tap ***Next*** to continue (see Figure 70).

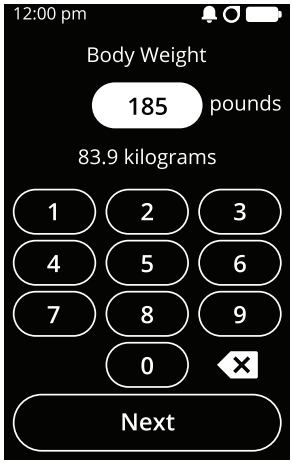


Figure 70

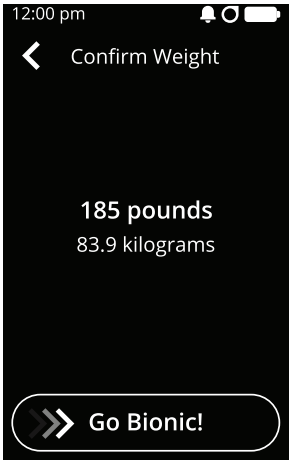


Figure 71

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.

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 weight setting is required.

b. Confirm the body weight you entered is correct, and then drag the ***Go Bionic!*** slider to the right (see Figure 71).

Congratulations! Your iLet System will begin dosing and learning about your insulin needs. After a few seconds, the home screen will appear.

4. Living with Your iLet System

4.1 What to Expect from Your iLet System

The iLet System works differently than other insulin delivery systems as it responds to your CGM glucose levels and trends. However, you will still experience high and low CGM glucose levels that require your attention while using the iLet System.

It can be hard to let your iLet System manage your BG levels. **Remember to be patient with your iLet System as it adapts to you.** Your iLet System will continue to adapt to meet your changing insulin needs. Contact Beta Bionics Customer Service, your healthcare provider and/or your certified iLet trainer if you have concerns.

> **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.

4.1.1 Automated Insulin Delivery

Once you have entered your body weight, your iLet Device begins regulating glucose levels automatically. The iLet Device does not require you to count carbohydrates, program basal rate settings, program insulin to carbohydrate ratios, program correction factors, or make corrections for high BG levels.

When connected to CGM, your iLet Device decides how much insulin to deliver every 5 minutes. It calculates how much insulin you need for basal needs, high or rising CGM glucose levels, and meals with carbohydrates. If your iLet Device detects your CGM glucose level dropping too rapidly or to an unsafe level, it will decrease or stop insulin delivery.

> **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.

Your iLet Device cannot regulate your glucose levels if the insulin cartridge is empty or if the insulin infusion set is not working properly. **Your iLet System will have limited functions when the CGM sensor is offline.** Refer to **Section 4.3 When Your Sensor Is Offline** for more details.

4.2 Maintaining your iLet System

There are important steps you must take to maintain your iLet System to ensure your device is working properly and avoid interruptions to your diabetes care. If the iLet System is not maintained properly, it could lead to hyperglycemia and DKA..

4.2.1 Replacing your iLet insulin cartridge, iLet connect and tubing

> **WARNING:** Do not fill tubing while it is connected to your insulin infusion set. Always disconnect the tubing set from the insulin infusion set before filling the tubing.

Replace your iLet insulin cartridge, iLet connect and tubing when the cartridge runs out of insulin or at least every three days. Avoid planned replacements before bed, or any time when you are not able to monitor your glucose levels for several hours after the change.

Always replace your iLet insulin cartridge, iLet connect and tubing if you have any suspicion that something is not working or if there is any leaking at any of the connections.

Always replace your iLet insulin cartridge, iLet connect and tubing together. Do not reuse any of these components, and do not separate them once connected.

DO NOT let your iLet run out of insulin or leave an empty cartridge in for too long! This will cause hyperglycemia, as the iLet will not be able to dose insulin in response to your rising CGM glucose levels. This may cause hypoglycemia later, because the iLet will have to deliver correction insulin once it is able to again. Consider putting a reminder in your calendar or your smartphone to remind you to change your infusion set and replace your insulin cartridge.

If you need to disconnect from the iLet, ALWAYS disconnect at the infusion site base on your body. NEVER disconnect from the iLet by removing the cartridge from the device while staying connected to the tubing or unscrewing the tubing from the iLet Connect and staying connected to the tubing.

ALWAYS disconnect from the iLet at your infusion site base when replacing your iLet cartridge and tubing. Stay disconnected until you have finished the cartridge change and tubing fill process.

To change your cartridge, connector and tubing:

a. From the ***Home*** screen, tap the ***Cartridge*** icon (see Figure 72).

b. Tap ***Change Cartridge and Tubing*** (see Figure 73).

c. Disconnect the tubing from the infusion set base on your body. Remove the infusion set base if you will also be replacing your insulin infusion set at this time.

Figure 72

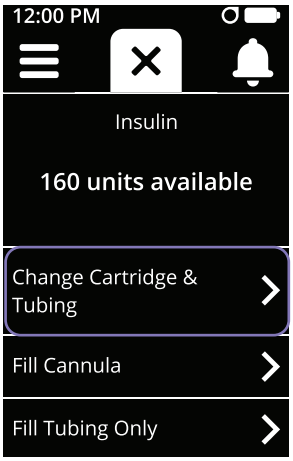


Figure 73

d. Drag the ***Rewind*** slider to the right to rewind the iLet Device.

e. Remove the old cartridge. Discard the old cartridge, iLet connect and tubing.

> **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.

f. When the rewind process is complete, load the new filled insulin cartridge into the iLet Device. Do not insert the new cartridge until the rewind process is complete. This can damage the cartridge and the iLet, as well as cause unintentional insulin delivery through the tubing.

g. Attach the tubing to the iLet Connect. Make sure this connection is straight and tight. If this connection is not tight, insulin can leak out causing hyperglycemia, or air can get it in and push insulin into your body, causing hypoglycemia. Do not connect the iLet Connect to the insulin cartridge yet.

h. Install the new iLet Connect.

i. Tap ***Go to Fill Tubing*** on the iLet Device.

j. Tap and hold the ***Press and Hold*** Button until the tubing is clear of bubbles and you see drops at the end of the infusion set connector.

k. Once you see drops at the end of the tubing, release the ***Press and Hold*** button and then tap Yes.

It is not required to replace your cartridge, connector and tubing at the same time as when you change your insulin infusion set. These can be changed separately.

- If you are also replacing your insulin infusion set, tap ***Yes*** and proceed to the next section.
- If you are not replacing your insulin infusion set, tap ***No***. Connect the newly primed tubing to the infusion set base on your body.

4.2.2 Replacing your insulin infusion set

Replace your insulin infusion set at least every three days. Avoid planned replacements before bed, or any time when you are not able to monitor your glucose levels for several hours after the change.

Always replace your infusion set immediately if it falls out or is pulled out, if you have any suspicion that it is not working, or if there is any evidence of leaking.

To replace your infusion set:

a. Disconnect the tubing from the infusion set base on your body. Remove the infusion set base from your body by gently peeling the adhesive off your skin.

b. Insert your new infusion set base.

c. Connect your tubing to your new infusion set base.

d. From the ***Home*** screen, tap the ***Cartridge*** icon (see Figure 74).

e. Tap ***Fill Cannula*** (see Figure 75).

f. Select the cannula type and length.

g. Drag the ***Fill*** slider to the right. The iLet Device will deliver insulin to fill the cannula.

h. Make sure your infusion set is inserted and your tubing is connected to your new infusion set before filling the cannula!

Figure 74

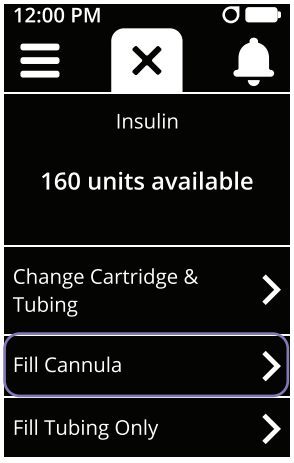


Figure 75

It is not required to replace your insulin infusion set at the same time as when you change your iLet cartridge, iLet Connect and tubing. These can be changed separately.

- If you are replacing your iLet cartridge, iLet connect and tubing but not your infusion set, make sure to connect your newly filled tubing to your existing infusion set base on your body.
- If you are replacing your infusion set but not your iLet cartridge, iLet connect and tubing, connect your existing tubing to your new infusion set base on your body.

4.2.3 Filling Tubing Only

> **WARNING:** Do not fill tubing while it is connected to your insulin infusion set. Always disconnect the tubing set from the insulin infusion set before filling the tubing.

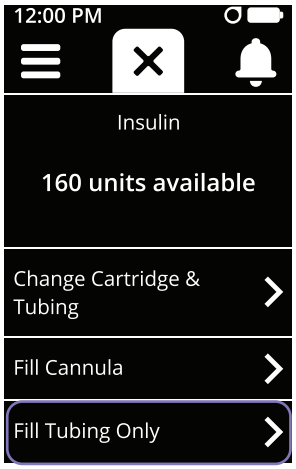


Figure 76

Occasionally you may see air bubbles in your tubing line. You can use the ***Fill Tubing Only*** feature (see Figure 76) to prime out air from the tubing. You can also use this, with other methods, to troubleshoot occlusions (blockages). Always consult with your healthcare provider before doing so. Follow the on-screen instructions to fill tubing as described in **Section 3.2.3.9 Filling the Tubing**.

4.2.4 Replacing your Dexcom G6 CGM sensor and transmitter

Replace your Dexcom G6 CGM sensor and transmitter according to your manufacturer's instructions. Avoid planned replacements before bed, or any time when you are not able to monitor your glucose levels for several hours after the change.

- Dexcom G6 CGM sensors need to be replaced every 10 days
- Dexcom G6 transmitters need to be replaced every 90 days

To replace your Dexcom G6 sensor:

a. From the ***Home*** screen, tap the ***Menu*** icon

b. Tap the ***CGM*** icon (see Figure 77)

c. If needed, tap ***Stop Sensor***

d. Remove your CGM sensor by gently peeling the adhesive from your skin. Do not discard the transmitter!

e. Discard the old sensor

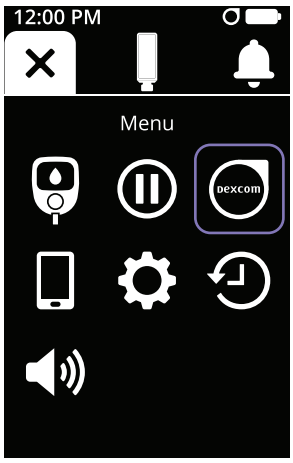


Figure 77

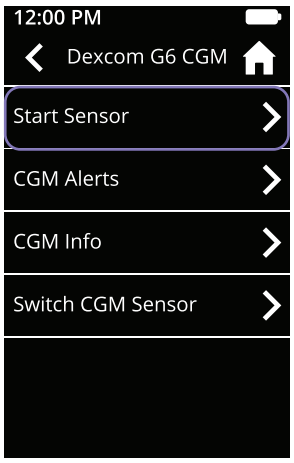


Figure 78

f. Return to the CGM menu on your iLet Device. Tap ***Start Sensor*** (see Figure 78)

g. Enter your sensor code from the adhesive paper and tap ***Next***

h. Insert your sensor and attach your transmitter according to your CGM manufacturer's instructions

i. Tap ***Next*** to complete the process

Remember: only use FDA approved insertion sites for your CGM sensor

To replace your Dexcom G6 transmitter:

a. From the Home screen, tap the ***Menu*** icon

b. Tap the ***CGM*** icon

c. Tap ***CGM*** Info

d. Tap ***Transmitter SN*** (see Figure 79)

e. Tap ***Pair New*** (see Figure 80)

f. Enter the Sensor Code from the adhesive paper

g. Enter the transmitter serial number found on the bottom of the transmitter, or the box the transmitter came in

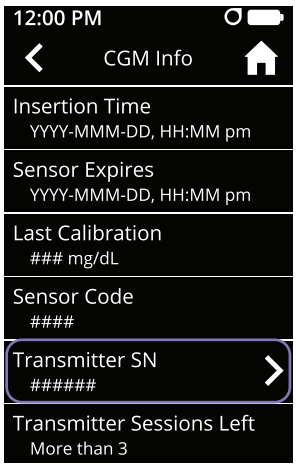


Figure 79

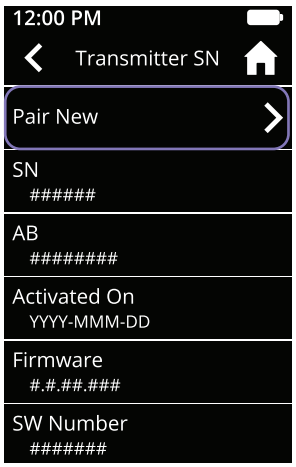


Figure 80

h. Insert your sensor and attach your transmitter according to your CGM manufacturer's instructions

i. Tap ***Next*** to complete the process

The status bar will show a searching symbol while it is pairing with the transmitter. It will show the CGM icon when the transmitter is paired. It can take up to 30 minutes for the transmitter to pair with the iLet Device.

Once the transmitter is paired, the warmup period for the sensor will begin. The iLet Device will display the time remaining in the warmup period on the home screen. When the warmup period is complete, your CGM glucose will be displayed. Use self-monitoring of blood glucose (SMBG) readings and enter BG values into the iLet Device as needed until the two-hour period has passed.

4.2.5 Replacing your Dexcom G7 Sensor

Replace your Dexcom G7 CGM sensor according to your manufacturer's instructions. Avoid planned replacements before bed, or any time when you are not able to monitor your glucose levels for several hours after the change.

- Dexcom G7 CGM sensors need to be replaced every 10 days

To replace your Dexcom G7 sensor:

a. From the ***Home*** screen, tap the Menu icon

b. Tap the ***CGM*** icon (see Figure 81)

c. If needed, tap ***Stop Sensor***

d. Remove your CGM sensor by gently peeling the adhesive from your skin

e. Discard the old sensor

f. Return to the CGM menu on your iLet Device. Tap ***Start Sensor*** (see Figure 82)

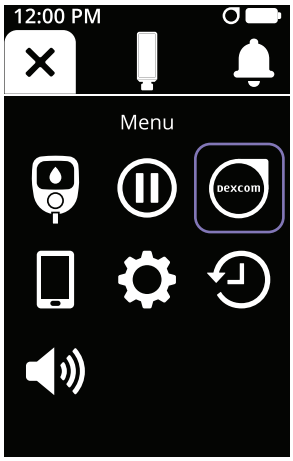


Figure 81

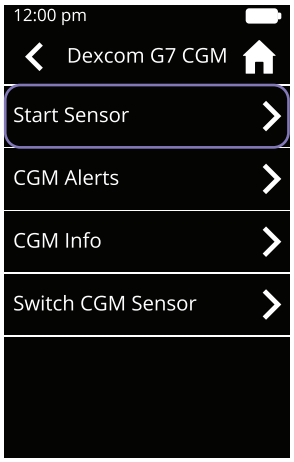


Figure 82

g. Insert your sensor according to the Dexcom G7 instructions and find the 4-digit pairing code from the Dexcom G7 applicator. Tap ***Next*** when ready

h. Type in the 4-digit pairing code from the applicator, and tap ***Submit*** to complete the process

Remember: only use FDA approved insertion sites for your CGM sensor

The status bar will show a searching symbol while it is pairing with the sensor. It will show the CGM icon when the sensor is paired. It can take up to 30 minutes for the sensor to pair with the iLet Device.

Once the sensor is paired, the warmup period for the sensor will begin. The iLet will display the time remaining in the warmup period on the home screen. When the warmup period is complete, your CGM glucose will be displayed. Use self-monitoring of blood glucose (SMBG) readings and enter BG values into the iLet as needed until the warmup period has passed.

4.2.6 Switch CGM Sensor

Switch the CGM sensor that your iLet Device will pair with (see Figure 83). 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.

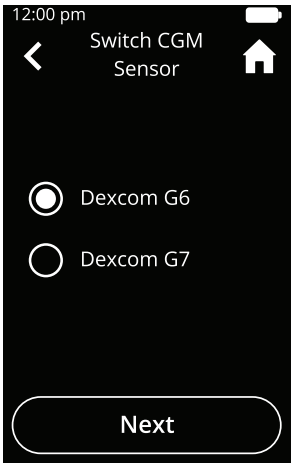


Figure 83

4.2.7 CGM Connectivity

Your iLet Device and CGM sensor communicate with each other via Bluetooth. Your iLet Device and sensor may disconnect briefly and reconnect automatically. This is expected during typical use of the iLet System. You can help to maintain this Bluetooth connection by wearing the sensor and the iLet Device on the same side of your body and keeping the screen of the iLet Device facing out when it is in your pocket.

If your iLet Device has not received a CGM glucose reading from the sensor for 30 minutes, it will alert you.

- Bring your sensor and your iLet Device closer to each other to see if communication automatically resumes within 15 minutes.
- Make sure your sensor (and transmitter if applicable) are both securely in place

- Make sure the transmitter serial number and/or sensor pairing code in your iLet Device is correct
- If you continue to have trouble connecting your sensor, you may need to replace your CGM sensor and/or transmitter. Contact Beta Bionics Customer Service and your CGM manufacturer for assistance.

> **CAUTION:** Nearby devices, such as mobile phones or other wireless devices, may interfere with 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.

4.3 When Your CGM Sensor is Offline

Occasionally, your CGM sensor may stop communicating or stop working. When your CGM sensor is offline:

What Will Happen	What to do
An alert of loss of CGM readings within 30 minutes will display. If your sensor session is stopped, this alert will stop.	See Section 4.2.7 CGM Connectivity for instructions.
An alert to enter a BG value will display. This will continue to appear until your CGM sensor is back online.	Enter a BG value when alerted.
Basal delivery.	You do not need to do anything to ensure that the basal is being delivered. While your CGM is offline, your iLet Device will use the most recently adapted basal doses and continue to dose basal insulin every 5 minutes.
If you enter a BG and your BG entry is high.	Your iLet Device will deliver a dose of correction insulin.
If you enter a BG and your BG entry is low.	Your iLet Device will stop all insulin dosing for one hour. After one hour, your iLet will automatically restart insulin delivery. If another low BG is entered before one hour has passed, your iLet will restart the one-hour suspend period. If a BG is entered that is no longer low before one hour has passed, your iLet will restart all insulin delivery.
If you eat a meal with carbohydrates	You will need to announce a meal. Without CGM glucose readings, your iLet cannot increase or decrease insulin delivery after your meal like it usually would. Enter a BG at the start of your meal and 2 hours after for optimal glucose control. As always, if you treat a low glucose with rapid-acting carbohydates, do NOT announce that as a meal.

4.3.1 BG-Run Mode

> **WARNING:** The iLet System is intended to dose insulin based on CGM data. In the events where CGM stops providing glucose data to the iLet System, 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 System with CGM. BG-run use **SHOULD BE TEMPORARY** and always for the shortest duration possible with the goal to resume CGM-guided iLet System insulin dosing **AS SOON AS POSSIBLE**.

> **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.

Your iLet Device relies on a CGM sensor for CGM values.

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.

Additionally, if you know in advance that you will not have access to CGM for longer than the 48 or 72 hours, you may choose to switch to the alternative therapy at any time with guidance from HCP for insulin dosing.

> **CAUTION:** If your CGM is offline for an extended period of time, 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.

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 System 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 System will give you correction insulin.
- You can continue to announce meals and the iLet System will give you meal insulin.

During BG-run mode, the following alerts may occur.

a. When your CGM is offline for an extended time, the "Dosing Stops Soon" alert will appear (see Figure 84). Connect to a CGM or enter a BG to avoid insulin suspension. Both the home screen (see Figure 85) and alert screen will provide the time remaining until insulin is suspended. The alert screen will show the time remaining to enter a BG to avoid insulin suspension as well as the time remaining until the iLet System must receive a CGM value to continue dosing.

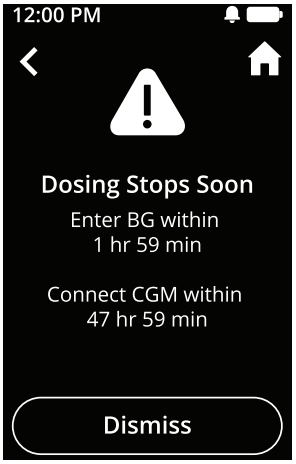


Figure 84

Figure 85

b. When insulin is suspended, the "Dosing Stopped" alert will appear (see Figure 86). The "Dosing Stopped" alert will provide the time since insulin was suspended. Enter a BG to resume insulin dosing. Insulin dosing will also resume if the iLet System receives a CGM value.

Figure 86

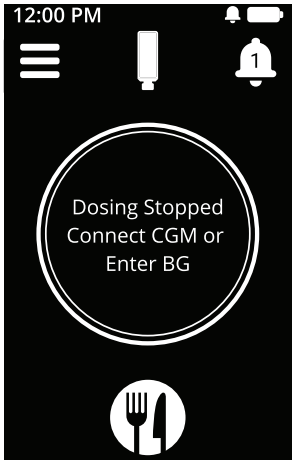


Figure 87

c. After 48 or 72 hours, the BG-run mode will expire and the "Dosing Stopped" alert will appear (see Figure 88). The iLet System must receive a CGM value to resume dosing. Entering a BG value will not resume insulin dosing. If the iLet System will not be receiving a CGM value soon, switch to alternative therapy as advised by your healthcare provider and disconnect from the iLet System.

Figure 88

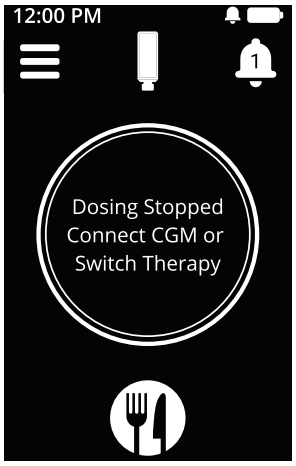


Figure 89

4.3.2 Enter BG

If the CGM sensor is online, you do not need to enter BG values for autonomous dosing. You may enter a BG to calibrate your CGM sensor. Refer to the your CGM manufacturer's instructions for calibration guidance. Refer to **Section 4.3 When Your CGM Sensor is Offline**.

Figure 90

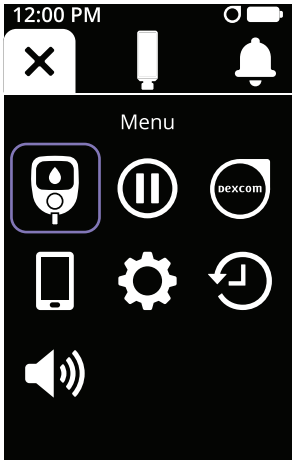


Figure 91

a. Use a BG meter to check your BG.

b. From the ***Home*** screen, tap the ***Menu*** icon in the upper left corner (see Figure 90).

c. Tap the ***Enter BG*** icon (see Figure 91).

d. Type in a BG value. Tap ***Next*** to continue (see Figure 92).

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

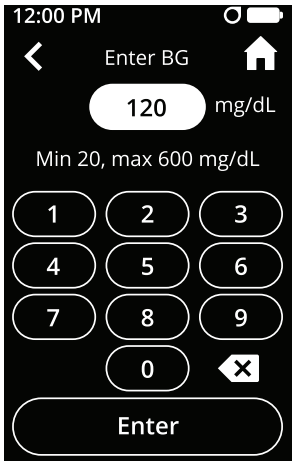


Figure 92

4.4 Mobile Device

Mobile device allows you to pair your iLet Device with a smartphone via the iLet Mobile App which can be installed on your smartphone from the Apple App store or Google Play store. The iLet Mobile App will allow you to download software updates and upload your data to the cloud. Please refer to the iLet Mobile App user guide for more information at betabionics.com/resources.

Figure 93

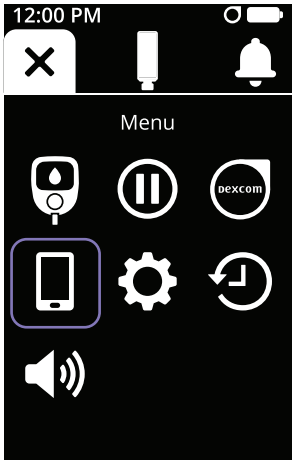


Figure 94

a. From the ***Home*** screen, tap the ***Menu*** icon in the upper left corner (see Figure 93).

b. Tap the ***Mobile*** icon (see Figure 94).

c. Open the iLet Mobile App on your compatible device (see Figure 95).

d. Enter the 6-digit code into the iLet Mobile App (see Figure 96).

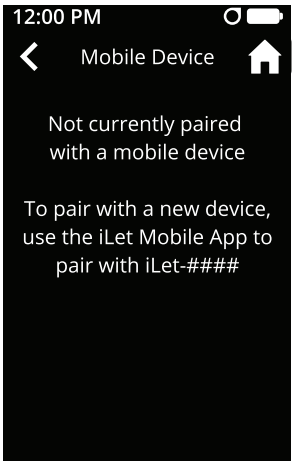


Figure 95

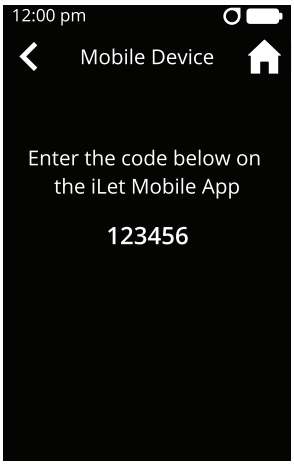


Figure 96

CAUTION: The iLet Mobile App is compatible with the iOS platform or 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: The iLet Mobile App performs a check to ensure that your device is not rooted, jailbroken 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.

4.5 Managing Highs and Lows

4.5.1 General Tips

- The iLet System works differently than other insulin delivery systems as it responds to your CGM glucose values and trends. You will still experience high and low CGM glucose values that require your attention while using the iLet System.
- It is important to be patient with the iLet System as it adapts to your insulin needs and responds to your changing glucose levels.
- It is also critically important to maintain your iLet Device properly, and promptly respond to all alarms.
- You will still experience low glucose levels (hypoglycemia) that require treatment with rapid-acting carbohydrates (juice, glucose tabs, etc). You may need to treat with fewer carbs than you are used to, because your iLet System will have already decreased and/or stopped insulin dosing.
- You will still experience high glucose levels (hyperglycemia) that may require you to replace your insulin infusion site or take other steps to resolve a problem with your device.
- Make sure your CGM alarms are turned on, and the volume is set to a level you can hear.
- Not responding to glucose alerts quickly can cause low and high glucose events to become longer and more serious than they otherwise might have been.
- If your CGM is reading high or low, or you are feeling symptoms of high or low glucose levels, it is always a good idea to confirm with a fingerstick blood glucose reading.
- If your CGM is inaccurate compared to your fingerstick blood glucose reading, calibrate your CGM according to the manufacturer's instructions.
- Make sure the iLet Connect Luer adapter is on straight and tightly attached to the tubing. If this connection is not tight, insulin can leak out causing hyperglycemia, or air can get in and push insulin into your body, causing hypoglycemia.
- Call your health care provider if you have any questions and for assistance in managing your glucose levels while using the iLet System.

4.5.2 When your Glucose Level is High

Your iLet System will automatically deliver insulin in response to rising and high CGM glucose levels to bring your glucose level back down into range safely. This may take longer than you expect. DO NOT take additional insulin via injections, inhaler, or another pump while using the iLet System unless directed by your healthcare provider.

Always check to confirm that your iLet System is working as it should.

Make sure your iLet System:

- Is reading your CGM glucose level every five minutes and make sure your CGM is calibrated
- Is delivering insulin doses in response to your CGM glucose level
- Has enough battery power
- Has enough insulin in the cartridge. Consider changing the insulin if it has been more than 3 days since you filled the cartridge
- Does not have an active alarm that has stopped insulin dosing (i.e. occlusion alarm, complete cartridge change process, dosing stopped)
- Is connected to the tubing and your infusion set
- Is not leaking insulin anywhere between the iLet System and your body (make sure there is no evidence of wetness or smell of insulin anywhere along the tubing and at the infusion site)
- Has the "High Glucose" alarm turned on. This will alert you when your CGM glucose has been more than 300 mg/dl for 90 minutes
- If everything looks like it's working, give the iLet System time to respond to your glucose levels. Continue to monitor your glucose until it returns to a normal range.

Change your insulin infusion site if you have any suspicion that it is not working.

Signs that the infusion site is not working include:

- The device is working properly (charged, has insulin, is reading CGM glucose levels) but CGM glucose levels continue to rise and/or stay high despite insulin dosing by the device
- CGM glucose is above 300 mg/dl for 90 minutes or above 400 mg/dl once

- Any evidence the site may be kinked, dislodged, or is leaking insulin (is wet, smells like insulin)

Consider changing your insulin cartridge, tubing, and cartridge connector in addition to your infusion site if there is any suspicion of leaking at the cartridge connector as well.

If your CGM glucose is above 300 mg/dl for 90 minutes or more

- Your iLet System will alarm for your high glucose reading, and you should respond immediately! If your glucose level is this high for this long, that likely means that something is not working as it should
- Check a fingerstick blood glucose reading to confirm your hyperglycemia
- Check a fingerstick or urine ketone level as directed by your healthcare provider
- Change your infusion set if you have ketones or as directed by your healthcare provider
- Consult with your healthcare provider and your ketone action plan
- Pay attention to high BG levels and respond to this alert quickly. Prolonged high BGs can cause late correction insulin dosing, and may cause the iLet to temporarily be more aggressive with insulin dosing to try and bring your glucose level back down. This can lead to hypoglycemia later.
- Avoid long periods of high BGs by:
    - Announcing for meals with carbohydrates.
    - Maintaining the device so it always has enough insulin and battery.
    - Keeping the High Glucose alert turned on.
    - Setting the volume set to a level you can hear.
    - Changing the infusion set if you have any doubt it is not working.
- Unless specifically directed to do so by your healthcare provider, DO NOT take additional insulin the iLet System does not know about (via injections, inhaler, or another pump). This is dangerous and can result in severe hypoglycemia
- NEVER use the meal announcement to correct a high blood glucose level. This is dangerous and can result in severe hypoglycemia. It will also affect your iLet System's learning about you, causing future meal announcement doses to be less effective

- NEVER use the "Fill Tubing" feature to correct a high blood glucose level. This is EXTREMELY DANGEROUS and will result in severe hypoglycemia

4.5.3 When your Glucose Level is Low

Your iLet System will reduce or stop insulin dosing in response to low or falling CGM glucose levels. Always make sure to have rapid-acting carbohydrates and emergency glucagon available to respond to low glucose levels. Make sure your CGM alarms are turned on and you can hear them.

Your iLet System has four different alarms for low CGM glucose readings:

Alert	Meaning	Response
Urgent Low Glucose	CGM glucose < 54 mg/dl	• Check a fingerstick blood glucose reading to confirm hypoglycemia • Treat with up to 15 grams of rapid-acting carbohydrates. You may need to treat with fewer carbs than you are used to, because your iLet System will have already decreased and/or stopped insulin dosing • Always wait and give your glucose level a chance to respond to the rapid-acting carbohydrates before treating again • Check a fingerstick blood glucose reading approximately 15 minutes after treating. Your fingerstick glucose reading may show a rise in glucose level before your CGM glucose rises • Treat again with rapid-acting carbohydrates if your glucose level remains low • Continue to monitor until your glucose remains above 70 mg/dl
Low Glucose	CGM glucose < 75 mg/dl	
Glucose Falling Quickly	CGM glucose < 100 mg/dl and falling 2 mg/dl/min or more	Treat with rapid-acting carbohydrates to prevent a hypoglycemic event from happening. You may not need the full amount of carbohydrates you would usually use to prevent this low glucose event from happening
Urgent Low Soon	CGM glucose will be < 54 mg/dl within 20 minutes	

If you see your CGM glucose level dropping, but your glucose is still above 100 mg/dl:

- Do not treat with rapid-acting carbohydrates right away
- Monitor your CGM glucose levels and be patient. Let the iLet System respond to your falling glucose levels
- Make sure your Glucose Falling Quickly and Urgent Low Soon alarms are turned on. Consider treating with some rapid-acting carbohydrates when those alarms are triggered

Do not take too many carbohydrates to treat a low glucose level. This can cause your glucose to respond too much, leading to a high glucose level and triggering more insulin dosing from the iLet System. This may end up causing a "roller coaster" effect while your iLet System responds to both rising and falling glucose levels.

4.5.4 How to Treat Low Glucose Levels

- Make sure to treat low glucose levels with only rapid-acting carbohydrates. These include juice, glucose tablets, Skittles, fruit chews, etc. These will provide the quick rise in BG that you need and, if taken in moderation, will not cause your BG to go too high or stay high for a long time.
- Do not use slower acting carbohydrates to treat a low glucose level. These include things with more fat or protein, such as chocolate, peanut butter, crackers, etc. These types of foods will cause your BG to rise more slowly, leaving your BG too low for too long, and may cause higher BGs later when you don't need it.
- Do not take too many carbohydrates to treat a low glucose level. This can cause your glucose to respond too much, leading to a high glucose level and triggering more insulin dosing from the iLet. This may end up causing a "roller coaster" effect while your iLet responds to both rising and falling glucose levels.
- NEVER announce a meal for carbohydrates used to treat a low BG.
- If your BG is low before a meal, treat the low glucose with rapid-acting carbohydrates and allow the glucose to rise before you eat and announce for your meal. Once your glucose is within range, eat and announce the meal as planned. Choose the meal size based on the carbohydrate content of the meal, and do not consider the carbs used to treat the low.
    - Do not include carbs used to treat lows in your meal announcement size. This will cause additional hypoglycemia.

  - Do not announce your meal as smaller than what it actually is to get less insulin as a "reverse correction". This will cause hyperglycemia because you won't get enough insulin for the meal you are eating now. It may also cause the meal dose to adapt upwards, delivering too much insulin the next time you announce a meal and causing future hypoglycemia.

- REMEMBER: Your CGM glucose may lag behind your blood glucose level when you are treating lows. Consider checking a fingerstick blood glucose level using a meter 15 minutes after treating and before deciding to treat again, as your glucose may have already returned to range.

4.6 Meal Announcements

Although the iLet System does not require a user to enter an exact carb amount to calculate and administer a meal bolus, it does require that the user announce the meal as "Breakfast", "Lunch", or "Dinner" AND provide an estimate of the carb content as "Usual for me", "More", or "Less" for that meal type.

Why do I need to announce my meals?

Announcing a meal will give you insulin at the time of your meal to help limit the glucose rise after eating. The iLet System will add more insulin as needed.

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".

> **CAUTION:** Announcing more than 30 minutes after you have started eating can result in severe hypoglycemia.

- 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.

What is the meal type?

- Select the meal type based on what you consider to be breakfast, lunch, or dinner.
- You are free to decide the meal type based on carbohydrate content, time of day, or whatever you find works best for you.
- Being consistent with what you consider breakfast, lunch, and dinner will help the iLet System learn how to treat your meals.

What is the meal size?

- **It is important to choose your meal size based on the amount of carbs in the meal, NOT the total size of the meal or the amount of protein, fiber, or fat.**
- Although the iLet System does not require you to count carbs, meals are announced as having Usual for me, More, or Less carbs.
- Choose the meal size compared to the usual amount of carbs you eat for the chosen meal type.
- You should be choosing "Usual for me" MOST of the time.
- Use "Less" if your meal has around half the carbs (50%) of your "Usual for me" meal.
- Use "More" if your meal has around 50% more carbs than your "Usual for me" meal (1.5 times as many carbs as your "Usual for me" meal)
- All that matters is what you consider to be Usual, More, or Less for yourself and for the chosen meal type.
- Announce snacks the same way you would announce meals.
    - If the snack you are eating has as many carbs as your meals for that meal type, then announce that snack as a meal.
    - If your snack does not have as many carbs are your "Less" meal type, then you should not announce that snack as a meal.

4.6.1 Delivering a Meal Announcement

Tap the Meal Announcement icon at the bottom of the home screen (see Figure 97).

a. Choose Meal Type. You can select Breakfast, Lunch, or Dinner (see Figure 98).

b. Confirm that the correct Meal Type is selected (see Figure 99). You may change it by tapping on the meal you selected previously.
The Carb Amount defaults to Usual for me. You may change it by tapping on Usual for me.

Figure 97

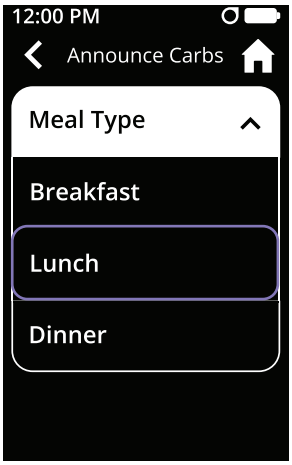


Figure 98

c. Tap Usual for me. Choose from 3 Carb Amounts: More, Usual for me, and Less (see Figure 99).

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

More and Less are relative to the Usual amount of carbohydrate you eat for the selected Meal Type.

> **NOTE:** During the initial use period of the meal announcement, the Less carb amount option 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.

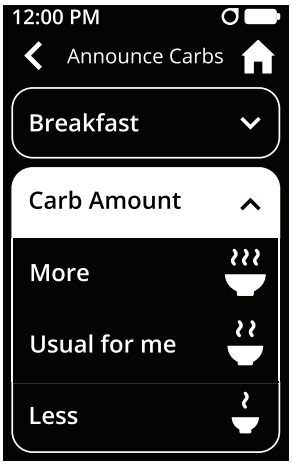


Figure 99

d. Drag the Deliver slider to the right (see Figure 100). You will notice a vibration to confirm that the delivery is successful.

e. The iLet Device will begin to deliver an insulin dose. No further action is needed. Occasionally, the delivery may take several seconds to start.

f. When your iLet Device begins delivering insulin, the screen will lock.

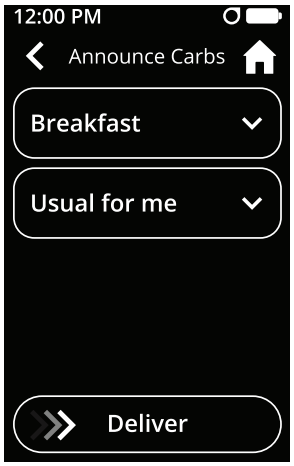


Figure 100

Figure 101

A message will appear to show delivery in progress (see Figure 101). You can unlock the screen at any time during the delivery to cancel a delivery.

4.6.2 Cancelling a Meal Announcement

Sometimes you may need to cancel a delivery in progress.

a. Drag the Unlock slider to the right (see Figure 102).

A progress bar will show how much of the insulin dose has been delivered. Drag the Cancel slider to the left (see Figure 103). Meal insulin delivery will be stopped. The percentage of delivery will be shown. Tap OK to return to the Lock screen. Note that you will see the following screen if you try to enter more than two meal announcements within five minutes (see Figure 104). If this occurs, tap Dismiss. Wait up to five minutes before trying again.

Figure 102

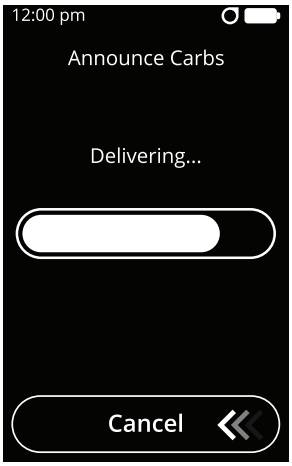


Figure 103

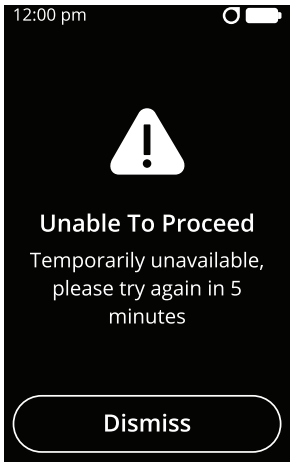


Figure 104

4.6.3 How can I help the iLet System learn my meals?

- Be consistent with how you decide the meal type and size.
    - Only select breakfast if you are eating your breakfast, lunch for your lunch, and dinner for your dinner.
    - Only think about the carbs in your meal when selecting the size, not fat or protein.
- The iLet System has an initial learning period while it is learning how much insulin you need for meals.
    - The "Less" option will be available once the iLet System has learned how much insulin you need for your "Usual for me" meal. This will happen separately for Breakfast, Lunch and Dinner. This can happen after one meal announcement, or it may take several meal announcements. Once this happens, the "Less" option will no longer be marked as unavailable and you will be able to select this size in the drop down list.
    - If the "Less" option is not yet available and you are eating less carbs than your "Usual for me" meal, do not announce that meal. The iLet System will deliver insulin in response to your rising CGM glucose.
- In the first few days, try to eat meals that have carbs in the "Usual for me" range and wait at least 4 hours before eating and announcing again. This will help the iLet System learn how much insulin you need for your "Usual for me" meal.
- If your BG is low before a meal, treat the low glucose with rapid-acting carbohydrates and allow the glucose to rise before you eat and announce for your meal. Once your glucose is within range, eat and announce the meal as planned. Choose the meal size based on the carbohydrate content of the meal, and do not consider the carbs used to treat the low.
    - Do not include carbs used to treat lows in your meal announcement size. This will cause additional hypoglycemia.
    - Do not announce your meal as smaller than what it actually is to get less insulin as a "reverse correction". This will cause hyperglycemia because you won't get enough insulin for the meal you are eating now. It may also cause the meal dose to adapt upwards, delivering too much insulin the next time you announce a meal and causing future hypoglycemia.

- If your BG is low after a meal:
    - Consider your glucose trend and the circumstances around when you announced the meal. The low BG may not be related to the meal announcement.
    - Consider the amount of carbs that were in the meal and whether you selected the correct meal type and size for what you ate.
        - ♦ If the low BG happened within an hour of the meal announcement, and without a period of high glucose levels after the meal, you may have overestimated the carb content of the meal.
        - ♦ If the low BG happened several hours after the meal announcement, and after an extended period of high glucose levels, you may have underestimated the carb content of the meal.
    - Do not over-treat the low. Taking too many carbs to treat this low will cause the BG to rise too much, leading to additional insulin dosing. This will prevent the iLet from learning that the initial meal dose was too big, so it might not adapt the dose downward.
- The iLet System never stops learning and is always adapting to your insulin needs. It will continue to adapt your insulin dose sizes for meals as your insulin needs change.

4.6.4 Meal Announcement Frequently Asked Questions

Q. What happens if I do not announce my meals?

A. The iLet System will automatically give you insulin as your blood glucose rises, but it will not be able to track and learn from your meals. Your blood glucose may go higher and stay higher for longer than if you had announced the meal.

> **CAUTION:** This may lead to hypoglycemia later due to the correction algorithm adding more insulin.

Q. I ate or drank carbohydrates to treat a low blood glucose. Should I announce these carbs as a meal?

A. No.

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

Q If I forgot to announce my meal and I already finished eating, should I announce that meal?

A. 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 announce the meal.

> **CAUTION:** After 30 minutes, your glucose is already rising, and the iLet System has already dosed insulin according to your rising 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.

Q. I usually have a snack before bed to keep my blood sugar in range overnight. Do I need to do this while using the iLet System? If so, should I announce my bedtime snack?

A. You do not need to eat a bedtime snack to keep your blood glucose in range overnight while using the iLet System.

If you chose to eat before bed, you should announce it to the iLet System the same as you would during the day. This will give you insulin up-front and help prevent additional dosing in response to the rise in glucose after you eat and reduce the risk of hypoglycemia during the night.

Q. I do not eat foods with carbohydrates and if I do, they are very low carb. Should I still announce my meals?

A. No. If you eat a very low carb diet or no carbs at all, you should not announce meals.

Q. Can I use the meal announcement to bring my glucose level down if I am not eating?

A. No. This can be dangerous.

> **CAUTION:** It could lead to severe hypoglycemia and confuse the iLet System, causing future meal doses to be less effective.

Q. If my glucose is high and I am about to eat, should I announce a meal that is larger than my actual meal to get more correction insulin up front?

A. No. Do not announce a meal that is larger than the actual meal size to correct high glucose levels.

- The iLet System will have already delivered correction insulin in response to your high glucose.

> **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.

Q. I am used to counting carbohydrates. I saw how much insulin the iLet System gave me for my last meal. Should I work backwards to figure out my meal size based on my old insulin to carbohydrate ratio?

A. No. The iLet System does not use insulin to carbohydrate ratios to dose insulin for meals.

Do not calculate the amount of carbohydrates you need based on the insulin dose your iLet System gave you. This will affect the iLet System's ability to learn about your insulin needs and confuse the iLet System, causing future meal doses to be less effective.

Q. I think the iLet System has not learned my meal doses because my glucose is high after meals. Is there anything I can do?

A. You may need to take a few days and focus on helping the iLet System learn about your meals.

- Be consistent with how you decide the meal type and size.
    - Only select breakfast if you are eating your breakfast, lunch for your lunch, and dinner for your dinner.
    - Only think about the carbs in your meal when selecting the size, not fat or protein.
- Avoid over-treating any lows that occur after meals to help the iLet learn if meal doses are too big.
- Try to eat meals that have carbs in the "Usual for me" range and wait at least 4 hours before eating and announcing again

After a few days, your meal dose(s) should adapt. Consult your healthcare provider and/or certified iLet trainer with questions.

4.7 Exercise

> **CAUTION:** If you disconnect from your iLet Device, 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:** Always monitor glucose levels regularly during sports, activities, and exercise.

When you exercise, your insulin needs can change significantly. Your iLet System does not know that you are exercising. Your iLet System will continue to increase or decrease insulin dosing in response to your changing CGM glucose levels as usual.

There are things you can do to help prevent hypoglycemia during and after exercise:

- Before exercising, make sure your CGM glucose is in range and not falling
- Always make sure to have rapid-acting carbohydrates available to prevent or treat hypoglycemia. Carry an emergency glucagon kit with you to treat severe hypoglycemia.
- Make sure your CGM alarms are turned on and the volume is set to a level you can hear on your iLet System, and your CGM app on your smartphone if applicable. Respond to CGM alarms immediately.

Can I eat carbohydrates in preparation for exercise while using the iLet System?

On your previous therapy, you may be used to eating a large carbohydrate meal or snack before exercise when your blood glucose is not low (otherwise known as “pre-loading”), to prevent it from dropping, hoping to avoid hypoglycemia during and after exercise. This will NOT work on the iLet System.

- If you do this before exercise while still connected to the iLet System, the iLet System will automatically increase insulin delivery in response to your rising CGM glucose levels. This will cause you to have more insulin working in your body while you are exercising, increasing your risk of hypoglycemia during and after exercise – which is exactly what you were trying to avoid!

- Instead, if you want to "pre-load" with carbs, make sure to eat your carbohydrate meal or snack AFTER DISCONNECTING from the iLet System. This way, the iLet System cannot deliver insulin and your glucose will rise from the carbs in the meal or snack as you intended.

Option 1: Disconnect from the iLet System

You and your care team may decide to stop insulin dosing before, during and/or after exercise. To stop insulin delivery, disconnect from the iLet tubing and set the device aside. Leave your infusion set base on your skin so you can easily reconnect to the iLet Device when you are ready. You can pause insulin delivery while you are disconnected from the iLet to prevent insulin from being wasted. Remember to resume insulin delivery on your iLet when you reconnect. See **Section 4.8** for details.

- Be sure to do this for all water related activities (e.g. swimming). Your iLet Device should not get wet.
- Disconnect from your iLet Device up to 30 minutes before exercise, at the direction of your care team.
- Make sure you can still monitor your CGM glucose and hear your CGM alarms using your CGM app on a smartphone. Keep your iLet Device close by to hear the alarms if you do not have a smart phone.
- DO NOT "pre-load" with carbs BEFORE disconnecting from the iLet Device.
- If you choose to "pre-load" with carbs, only do so AFTER disconnecting from the iLet Device.
- Remember to reconnect to the iLet Device when you are finished.
- Staying disconnected for too long can result in hyperglycemia and development of ketones. Consult with your healthcare team about how long you should be disconnected from the iLet Device.

Option 2: Stay Connected to the iLet Device

You may wish to remain connected to your iLet Device during exercise. The iLet Device will continue to increase or decrease insulin dosing in response to your CGM glucose levels.

- DO NOT “pre-load” with carbs.
- ALWAYS make sure to have rapid-acting carbohydrates available to prevent or treat hypoglycemia. Carry an emergency glucagon kit with you to treat severe hypoglycemia.
- If your CGM glucose is low or is dropping fast during or after exercise, treat with rapid acting carbs as needed. Continue to monitor your blood glucose until it remains above 70 mg/dL.
- DO NOT take too many carbohydrates to treat a low glucose level. This can cause your glucose to respond too much, leading to a high glucose level and triggering more insulin dosing from the iLet Device. This may end up causing a “roller coaster” effect while your iLet Device responds to both rising and falling glucose levels.

4.8 Pause Insulin

When disconnected from your iLet infusion set, you can pause insulin delivery to prevent insulin from being wasted. Always remember to resume insulin delivery when reconnecting.

a. Tap the Menu icon (see Figure 105)

b. Tap the Pause Insulin icon (see Figure 106).

Figure 105

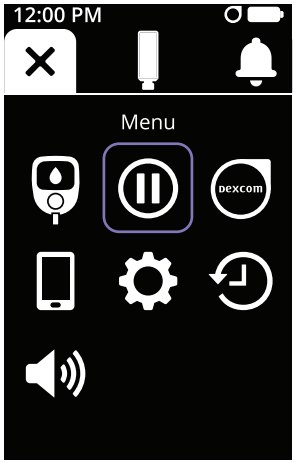


Figure 106

c. Select a time to be reminded to resume insulin after pausing insulin (see Figure 107).

d. The home screen will have a banner indicating that insulin is paused (see Figure 108).

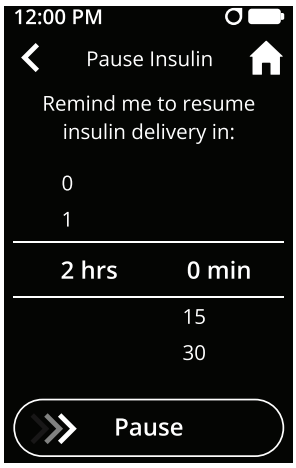


Figure 107

Figure 108

Resuming Insulin

e. You can resume insulin at any time by tapping the Insulin Paused banner or by going to the Menu and tapping the Pause Insulin icon. Then tap Resume Delivery (see Figure 109).

f. You will also get a reminder to resume after the timer expires, you can resume directly from the alert (see Figure 110).

Figure 109

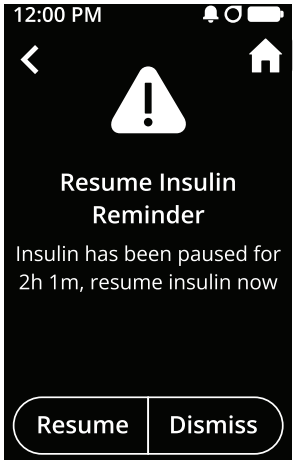


Figure 110

4.9 Illnesses

If you become ill, follow these instructions.

- Notify your healthcare provider if you notice significant CGM fluctuations.
- Notify your healthcare provider if you are unable to eat for more than one day.

5. Responding to Alerts

5.1 iLet System Alerts Overview

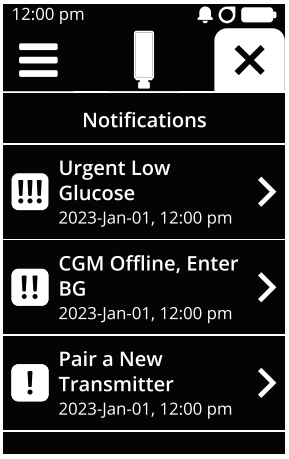


Figure 111

Your iLet Device will alert you when important issues need to be addressed. There are several alert levels (see Figure 105). 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 user guide. If you encounter such alerts, follow the instructions on the screen and contact Beta Bionics.

When an alert occurs, your iLet Device will:

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.

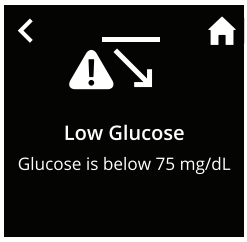
e. Display an alert message.

> **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.

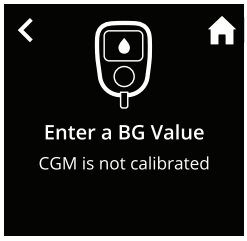
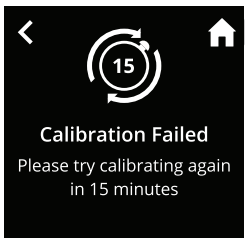
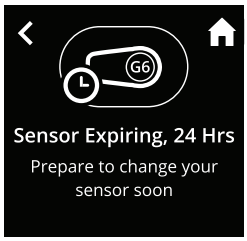
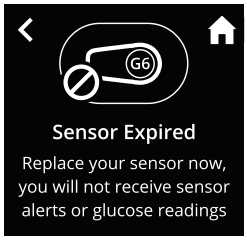
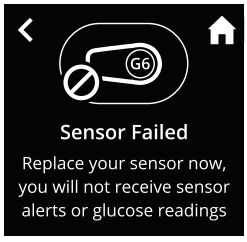
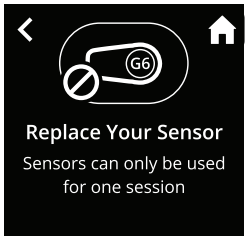
Priority	Level	Behavior	What It Means	What to do
Low 	Level 0	Alert with no beeps and no vibrations.	A reminder about an upcoming event, or a component of your iLet System may stop functioning soon.	Acknowledge the alert by tapping the button at the bottom of the alert message.
	Level 1	Will alert every 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.

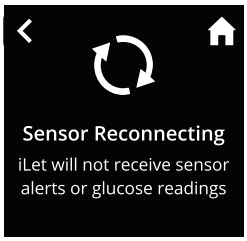
5.2 CGM and Glucose Alerts

5.2.1 CGM and Glucose Alerts

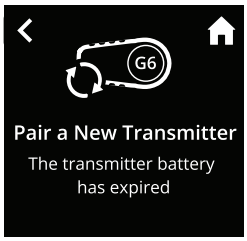
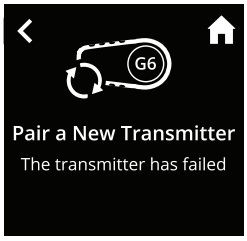
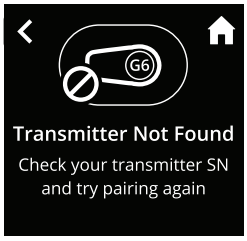
Screen	Alert	Priority (Level)	What to do
	Urgent Low Soon	Medium (Level 3)	Your glucose is predicted to drop below 54 mg/dL in the next 20 minutes. Prepare to treat your low glucose as advised by your healthcare provider. Monitor your BG levels closely.
	Urgent Low Glucose	High (Level 5)	Treat your low 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.

5.2.2 Dexcom G6 Sensor Alerts

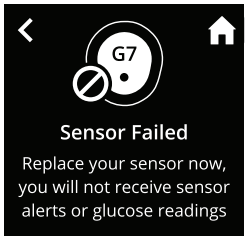
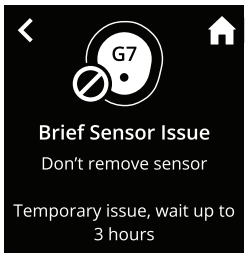
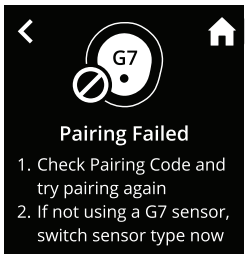
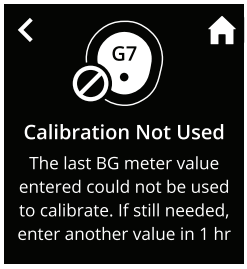
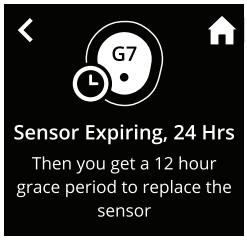
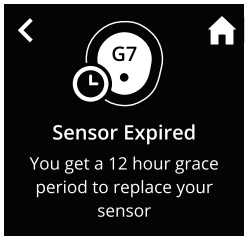
Screen	Alert	Priority	What to do
	Enter a BG Value	Medium (Level 3)	Enter a BG value measured by a finger-stick test.
	Calibration Failed	Low (Level 1)	Calibrate your sensor again in 15 minutes with a BG value.
	Sensor Expiring, 24 Hrs	Low (Level 0)	You may see alerts within: 24 hours, 6 hours, 2 hours, 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.

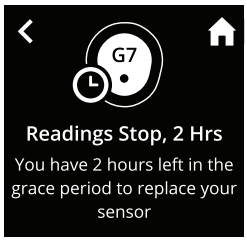
	Sensor Reconnecting	Low (Level 1)	Wait up to 3 hours for your sensor to reconnect. If more than 3 hours have elapsed, please contact Beta Bionics.

5.2.3 Dexcom G6 Transmitter Alerts

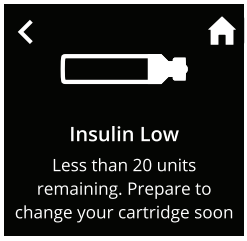
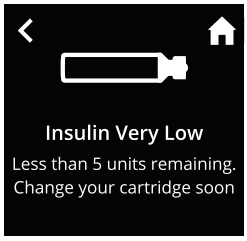
Screen	Alert	Priority	What to do
	CGM Battery Low	Low (Level 0)	Confirm that you have another transmitter available for when your transmitter battery expires.
	Pair a New Transmitter	Low (Level 1)	Your transmitter's battery has expired. Pair a new transmitter now.
	Pair a New Transmitter	Low (Level 1)	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.

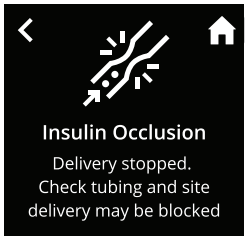
5.2.4 Dexcom G7 Sensor Alerts

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.

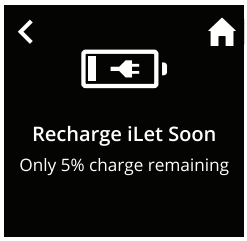
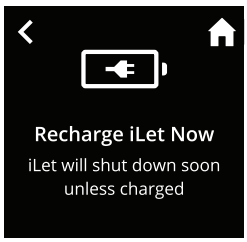
	Readings Stop	Low (Level 1)	You may see alerts within: 2 hours and 30 minutes that the sensor grace period is ending. Be prepared to change your sensor when the grace period ends.
	Replace Sensor Now	Low (Level 1)	Replace with a new sensor and start a new sensor session.

5.3 Insulin Delivery Alerts

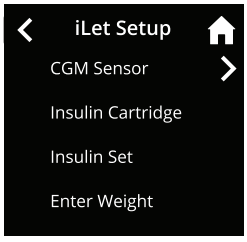
Screen	Alert	Priority	What to do
	Insulin Low	Low (Level 1)	Only 20 units of insulin remaining. Prepare to change your cartridge soon.
	Insulin Very Low	Medium (Level 3)	Less than 5 units of insulin remain. Change your cartridge soon.
	Change Insulin	Medium (Level 3)	Your insulin cartridge is empty. Change your cartridge now.

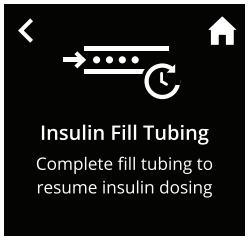
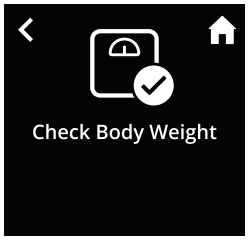
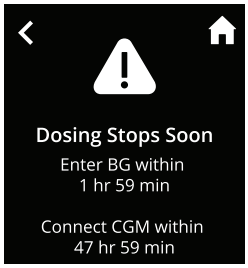
	Insulin Occlusion	Medium (Level 3)	Check your tubing and infusion set. Follow your healthcare provider's recommended troubleshooting procedures. Tap Resume Delivery to continue therapy. If another occlusion occurs, contact Beta Bionics. For more information on how occlusions and doses are handled, please refer to **Section 9.1 iLet Dosing Decision Software**.

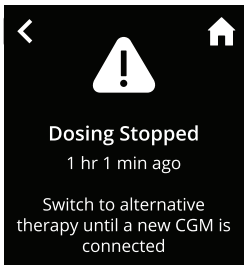
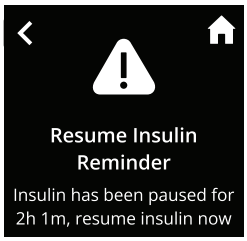
5.4 Battery Alerts

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

5.5 Reminders

Screen	Alert	Priority	What to do
	iLet Setup	Low (Level 1)	Follow the on-screen directions to set up your iLet Device 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 Device must receive a CGM value to resume dosing. Entering a BG value will not resume insulin dosing. If the iLet Device will not be receiving a CGM value soon, switch to alternative therapy as advised by your healthcare provider and disconnect from the iLet Device.
	iLet Malfunction	Medium (Level 4)	Contact support and switch to alternative therapy as advised by your healthcare provider.
	Resume Insulin Reminder	Medium (Level 3)	The timer you set for the resume insulin delivery reminder has elapsed. Resume insulin delivery now.

6. Troubleshooting

6.1 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

6.2 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, as described in **Section 2.7 Volume**.
- 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. 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. If you see signs of damage, contact Beta Bionics customer service.

6.2.1 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 2.3.1 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.

7. Care Information

7.1 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.

7.2 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 transmitter with a damp lint-free cloth or isopropyl alcohol wipe between uses. Refer to your Dexcom User Manual for additional instructions.

8. Clinical Performance

8.1 Introduction

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

8.1.1 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.

8.1.2 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.

8.2 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).

People 6 years of age or older who were diagnosed with type 1 diabetes and were using insulin for at least a year were eligible for the study. Potential participants were excluded if they had a history of cystic fibrosis, pancreatitis, or other pancreatic disease, if they were pregnant,

breast feeding, planned to become pregnant in the next 3 months, were sexually active without use of contraception, or had end-stage kidney disease. There was no upper limit on HbA1c. Potential participants were not excluded because of a recent history of severe hypoglycemia, diabetic ketoacidosis, or hospitalization related to problems with glucose management.

Participants who met all study criteria and were enrolled in the study 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).

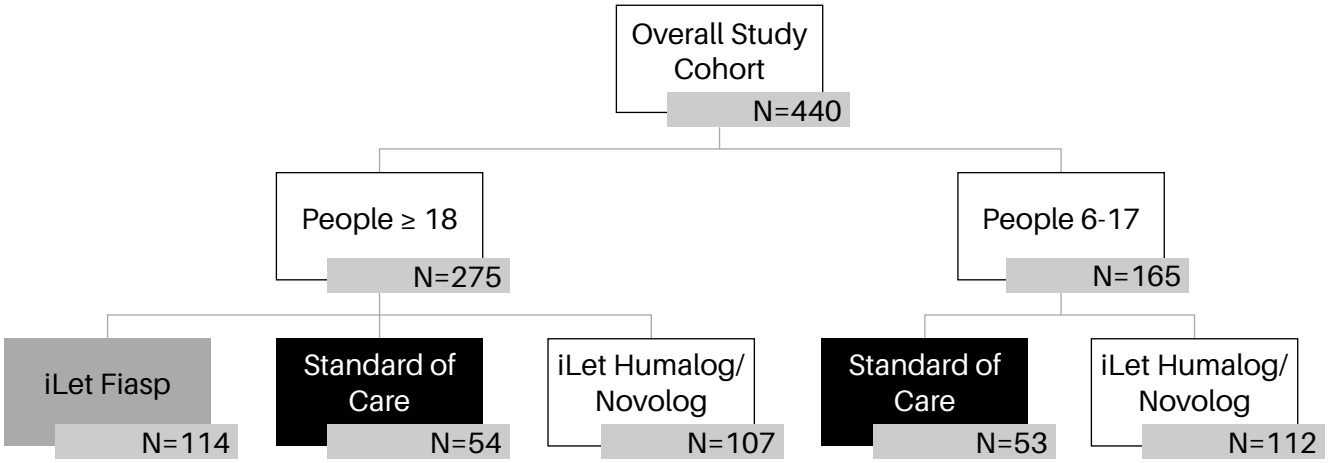
Participants assigned to the iLet group were trained on the use of the iLet System and used it for 13 weeks. Participants in the Standard of Care group were trained on the use of the Dexcom G6 and how to use CGM data for glucose management, they continued their usual method of insulin delivery with either Novolog or Humalog for 13 weeks.

At the end of the 13-week randomized comparative period of the study, patients in the iLet group had the option to participate in a 2-3-day study to test the safety of running the iLet System using manually entered blood glucose (BG) values from fingersticks while wearing a blinded CGM, rather than using CGM as input to the iLet System.

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 overall enrolment by age and insulin used in the iLet group are detailed in Figure 1.



Assignment of Participants to Study Groups

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 System with Fiasp, and the subgroup of people 6-17 years of age using iLet System with Novolog or Humalog.

8.2.1 Demographics

The characteristics of the participants at baseline for the four different analyses are shown in Tables 1 and 2.

Table 1. Characteristics of Participants at Baseline – People ≥ 18. Standard of Care (SC), iLet System with Fiasp (iLet-F), or iLet System with Novolog or Humalog (iLet-N/H)

	SC (N=54)	**iLet-F (N=114)**	**iLet-N/H (N=107)**
Age (yrs)			
Mean (SD)	44 (16)	42 (16)	44 (15)
<18	NA	NA	NA
18 to <25	7 (13%)	21 (18%)	16 (15%)
25 to <45	21 (39%)	46 (40%)	38 (36%)
45 to <60	13 (24%)	29 (25%)	33 (31%)
≥60	13 (24%)	18 (16%)	20 (19%)
Range	18 to 79	18 to 83	18 to 73

	SC (N=54)	iLet-F (N=114)	iLet-N/H (N=107)
Diabetes Duration (yrs) *Mean (SD)*	29 (14)	24 (14)	26 (14)
HbA1c Level at Randomization (%)*			
Mean (SD)	7.6 (1.2)	7.8 (1.2)	7.6 (1.2)
<7.0	18 (34%)	31 (27%)	37 (35%)
7.1-7.4	6 (11%)	17 (15%)	17 (16%)
7.5%-<9.5	26 (49%)	56 (50%)	46 (43%)
≥9.5	3 (6%)	9 (8%)	7 (7%)
Range	5.5 to 11.3	5.3 to 14.9	5.5 to 13.1
Sex – Female *n (%)*	26 (48%)	62 (54%)	52 (49%)
Race/Ethnicity Group *n (%)*			
White non-Hispanic	47 (87%)	98 (86%)	85 (79%)
Black non-Hispanic	2 (4%)	10 (9%)	14 (13%)
Hispanic or Latino	3 (6%)	6 (5%)	7 (7%)
Asian	1 (2%)	0 (0%)	0 (0%)
American Indian/Alaskan Native	1 (2%)	0 (0%)	0 (0%)
More than one race	0 (0%)	0 (0%)	1 (<1%)
Unknown	0 (0%)	0 (0%)	0 (0%)
Annual Household Income *n (%)*			
< $25,000	1 (2%)	1 (<1%)	3 (3%)
$25,000 - <$35,000	5 (9%)	7 (6%)	3 (3%)
$35,000 - <$50,000	2 (4%)	4 (4%)	4 (4%)
$50,000 - <$75,000	4 (7%)	14 (12%)	18 (17%)
$75,000 - <$100,000	8 (15%)	19 (17%)	9 (8%)
$100,000 - <$200,000	12 (22%)	38 (33%)	41 (38%)
≥ $200,000	12 (22%)	15 (13%)	17 (16%)
Unknown	10 (19%)	16 (14%)	12 (11%)
Education *n (%)*			
<Bachelor's	21 (39%)	47 (41%)	35 (33%)
Bachelor's	22 (41%)	47 (41%)	40 (37%)
>Bachelor's	10 (19%)	19 (17%)	30 (28%)
Unknown	1 (2%)	1 (<1%)	2 (2%)
Health Insurance *n (%)*			
Private	45 (83%)	98 (86%)	94 (88%)
Medicare/Medicaid	6 (11%)	10 (9%)	9 (8%)
Other Government Insurance	2 (4%)	2 (2%)	2 (2%)
None	1 (2%)	2 (2%)	0 (0%)
Unknown	0 (0%)	2 (2%)	2 (2%)
Body-Mass Index			
Mean (SD)	29.1 (6.9)	28.6 (5.1)	28.9 (5.5)
<18.5 n (%)	2 (4%)	0 (0%)	0 (0%)
18.5 to 24.9 n (%)	16 (30%)	32 (28%)	29 (27%)
25.0 to 29.9 n (%)	14 (26%)	41 (36%)	40 (37%)
>30.0 n (%)	22 (41%)	40 (35%)	38 (36%)

	SC (N=54)	iLet-F (N=114)	iLet-N/H (N=107)
Insulin/CGM Device Use *n (%)*			
MDI without CGM	6 (11%)	7 (6%)	13 (12%)
MDI with CGM	12 (22%)	32 (28%)	21 (20%)
Pump without CGM	3 (6%)	10 (9%)	5 (5%)
Pump with CGM (without automation)	14 (26%)	22 (19%)	21 (20%)
Pump with CGM with predictive low glucose suspend feature	2 (4%)	5 (4%)	6 (6%)
Hybrid closed loop system	17 (31%)	38 (33%)	41 (38%)
Currently Using CGM *n (%)*	45 (83%)	97 (85%)	89 (83%)
c-Peptide * *(ng/mL)*			
Mean (SD)	0.009 (0.023)	0.025 (0.070)	0.046 (0.185)
<18.5 n (%)	46 (92%)	80 (78%)	77 (78%)
Total Daily Insulin (U/kg/day) *Median (IQR)*	46 (92%)	80 (78%)	77 (78%)
Time Since Last Severe Hypoglycemia Event [a] *n (%)*			
Never had an event	17 (31%)	57 (50%)	48 (45%)
<3 months ago	0 (0%)	1 (<1%)	4 (4%)
3 to <6 months ago	1 (2%)	1 (<1%)	0 (0%)
≥ 6 months ago	36 (67%)	55 (48%)	55 (51%)
Time Since Last Diabetic Ketoacidosis Event *n (%)*			
Never had an event	22 (41%)	46 (40%)	57 (53%)
<3 months ago	0 (0%)	0 (0%)	1 (<1%)
3 to <6 months ago	0 (0%)	0 (0%)	0 (0%)
≥ 6 months ago	32 (59%)	68 (60%)	49 (46%)
Non-Insulin Blood Sugart Control Medications Taken *n (%)*			
None	52 (96%)	107 (94%)	98 (92%)
SGLT2 Inhibitor	0 (0%)	1 (<1%)	0 (0%)
Metformin	2 (4%)	4 (4%)	7 (7%)
GLP1 Agonist	0 (0%)	2 (2%)	2 (2%)

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.

** HbA1c missing for 1 iLet-F and 1 SC participant. BMI missing for 1 iLet-F participant. C-Peptide missing for 11 iLet-F participants, 4 SC participants, and 8 iLet-N/H participants. Total daily insulin missing for 1 iLet-F participant.*

Table 2. Characteristics of Participants at Baseline – People 6-17 years of age. Standard of Care (SC), iLet System with Novolog or Humalog (iLet-N/H)

	iLet-N/HSC (N=112)	SC (N=53)
Age (yrs)		
Mean (SD)	12 ± 3	12 ± 3
6 to <12	47 (42%)	23 (43%)
12 to <18	65 (58%)	30 (57%)
Range	6 to17	6 to17
Diabetes Duration (yrs)		
Mean (SD)	6 ± 4	7 ± 4
Range	1 to 15	1 to 16
HbA1c Level at Randomization (%)*		
Mean (SD)	8.1 ± 1.2	7.8 ± 1.1
≤ 7.0%	18 (16%)	12 (23%)
7.1-7.9	34 (30%)	19 (36%)
8.0%-8.9	33 (29%)	15 (28%)
≥9.0	27 (24%)	7 (13%)
Range	6.1 to 12.2	5.8 to 10.6
Sex – Female *n (%)*	55 (49%)	15 (28%)
Race/Ethnicity Group *n (%)*		
White non-Hispanic	72 (64%)	36 (68%)
Black non-Hispanic	13 (12%)	3 (6%)
Hispanic or Latino	16 (14%)	8 (15%)
Asian	2 (2%)	2 (4%)
American Indian/Alaskan Native	1 (<1%)	0 (0%)
More than one race	6 (5%)	4 (8%)
Unknown	2 (2%)	0 (0%)
Annual Household Income *n (%)*		
< $25,000	3 (3%)	1 (2%)
$25,000 - <$35,000	4 (4%)	1 (2%)
$35,000 - <$50,000	7 (6%)	2 (4%)
$50,000 - <$75,000	8 (7%)	5 (9%)
$75,000 - <$100,000	18 (16%)	8 (15%)
$100,000 - <$200,000	35 (31%)	17 (32%)
≥ $200,000	31 (28%)	11 (21%)
Unknown	6 (5%)	8 (15%)
Education *n (%)*		
<Bachelor's	37 (33%)	16 (30%)
Bachelor's	36 (32%)	17 (32%)
>Bachelor's	38 (34%)	18 (34%)
Unknown	1 (<1%)	2 (4%)
Health Insurance *n (%)*		
Private	90 (80%)	40 (75%)
Medicare/Medicaid	16 (14%)	8 (15%)
Other Government Insurance	6 (5%)	4 (8%)
None	0 (0%)	0 (0%)
Unknown	2 (2%)	1 (2%)

	iLet-N/HSC (N=112)	SC (N=53)
Body-Mass Index		
BMI Percentilea (%) Mean (SD)	74% ± 24%	66% ± 27%
<5th percentile n (%)	0 (0%)	2 (4%)
5th to <85th percentile n (%)	64 (57%)	37 (70%)
85th to <95th percentile n (%)	26 (23%)	8 (15%)
>95th percentile n (%)	22 (20%)	6 (11%)
Insulin/CGM Device Use *n (%)*		
MDI without CGM	7 (6%)	0 (0%)
MDI with CGM	30 (27%)	21 (40%)
Pump without CGM	0 (0%)	1 (2%)
Pump with CGM (without AID or PLGS)	45 (40%)	13 (25%)
Pump with CGM and PLGS	3 (3%)	3 (6%)
Pump with CGM and AID Pump	27 (24%)	15 (28%)
Currently Using CGM *n (%)*	105 (94%)	52 (98%)
c-Peptide * *(ng/mL)*		
Mean (SD)	0.039 ± 0.115	0.042 ± 0.098
<0.007 n (%)	77 (79%)	34 (72%)
Total Daily Insulin (U/kg/day) *Median (IQR)*	0.90 (0.75, 1.14)	0.87 (0.70, 1.10)
Time Since Most Recent SH Event [b] *n (%)*		
Never had an event	93 (83%)	40 (75%)
<3 months ago	1 (<1%)	0 (0%)
3 to <6 months ago	1 (<1%)	1 (2%)
≥ 6 months ago	17 (15%)	12 (23%)
Time Since Last DKA Event *n (%)*		
Never had an event	65 (58%)	29 (55%)
<3 months ago	0 (0%)	1 (2%)
3 to <6 months ago	1 (<1%)	0 (0%)
≥ 6 months ago	46 (41%)	23 (43%)
Non-Insulin Blood Sugar Control Medications Taken *n (%)*		
Metformin	7 (7%)	2 (4%)

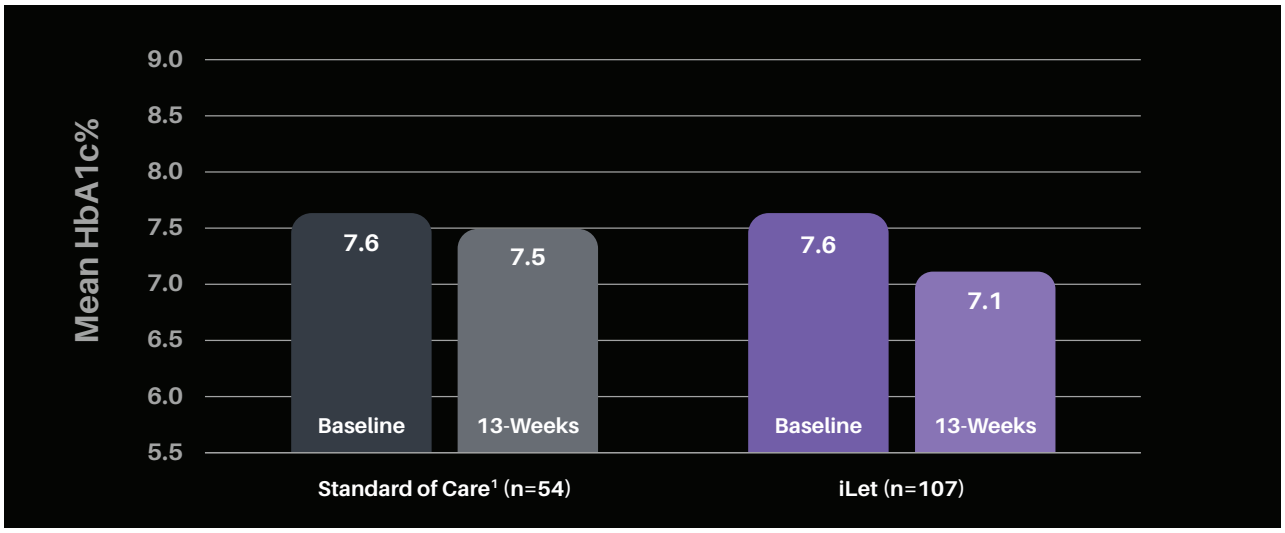
** Highest education level of parent or guardian*

b – 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.

8.2.2 Primary Endpoints

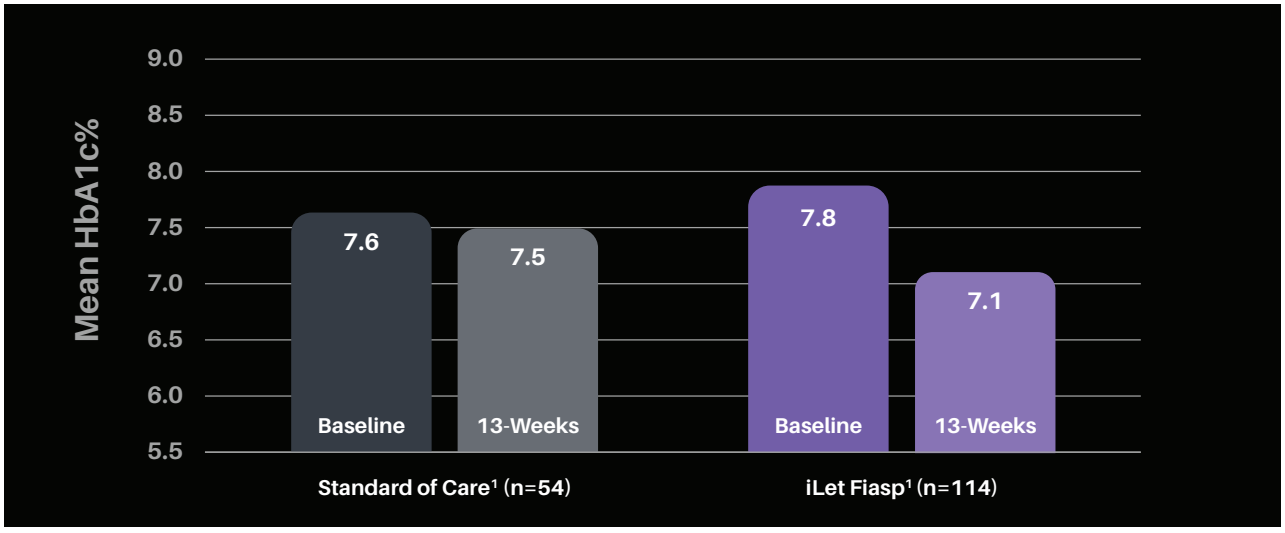
Across both groups of participants 6-17 and ≥ 18 years of age, and across the types of insulin used by participants ≥ 18 (the Novolog/Humalog group or the Fiasp group) the baseline-adjusted difference in HbA1c was –0.5% after 13 weeks in the iLet group relative to the Standard of Care group (p<0.001).

8.2.2.1 Change in HbA1c after 13 Weeks in People ≥ 18 – iLet System with Novolog or Humalog versus Standard of Care



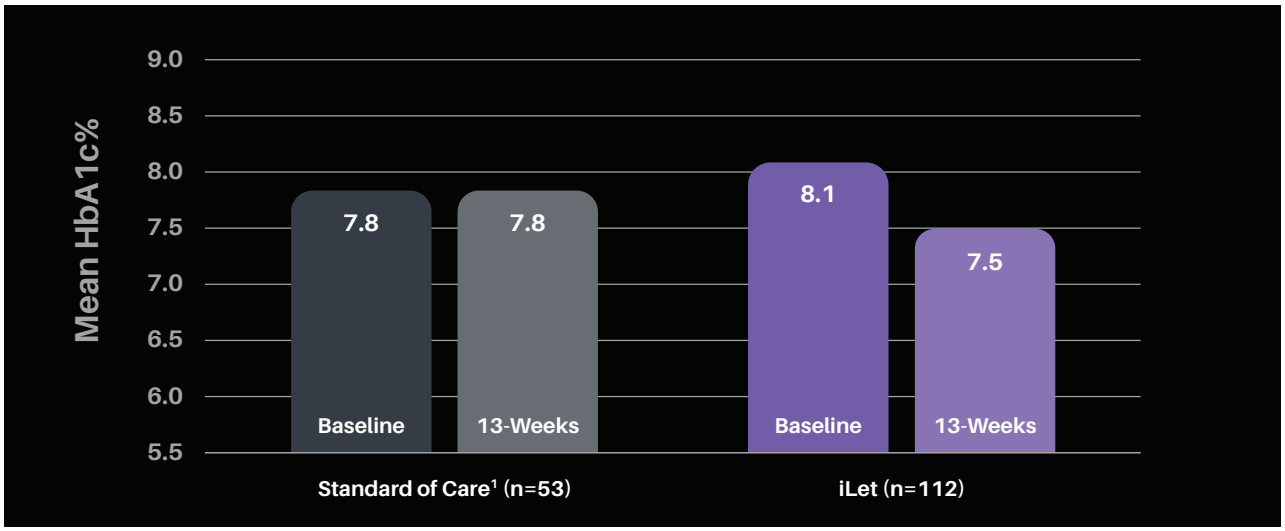
In people ≥ 18, the average baseline-adjusted difference in HbA1c was –0.5% in the iLet group using Novolog or Humalog versus the Standard of Care group after 13 weeks.

8.2.2.2 Change in HbA1c after 13 Weeks in People ≥ 18 – iLet System with Fiasp versus Standard of Care



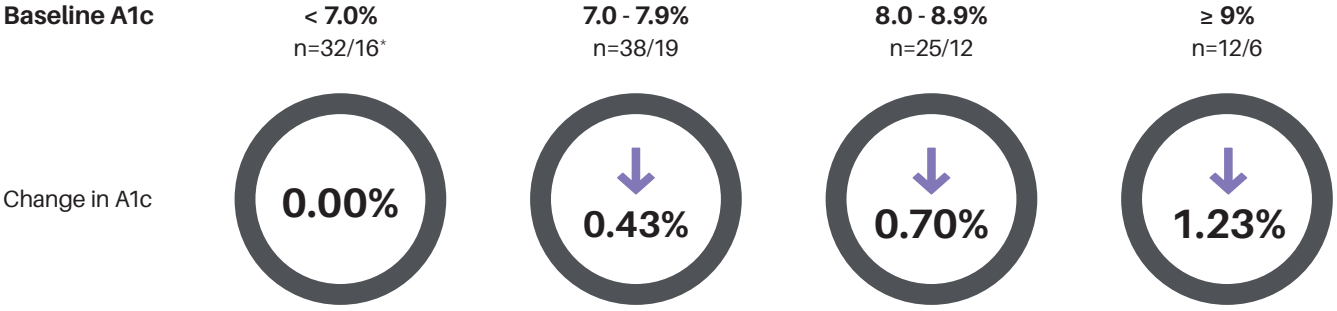
In people ≥ 18, the average baseline-adjusted difference in HbA1c was –0.5% in the iLet group using Fiasp versus the Standard of Care group after 13 weeks.

8.2.2.3 Change in HbA1c after 13 Weeks in People 6-17 years of age – iLet System with Novolog or Humalog versus Standard of Care



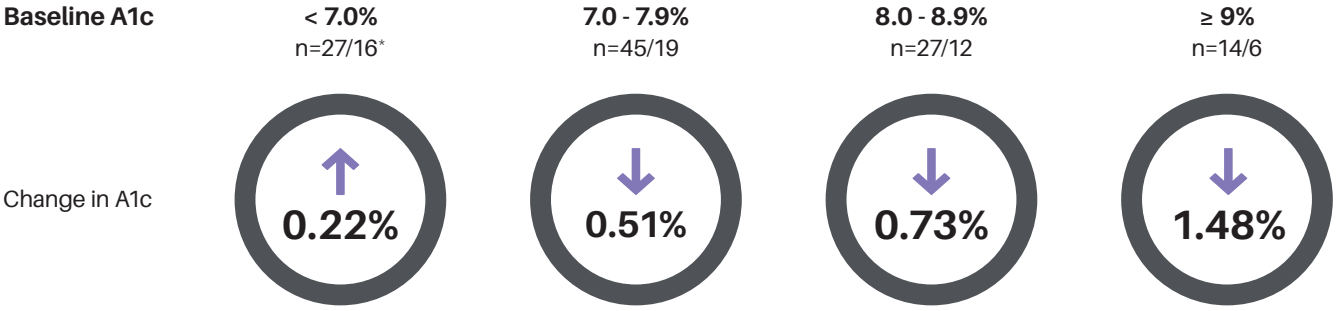
In people 6-17 years of age, the average baseline-adjusted difference in HbA1c was –0.5% in the iLet group using Novolog or Humalog versus the Standard of Care group after 13 weeks.

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



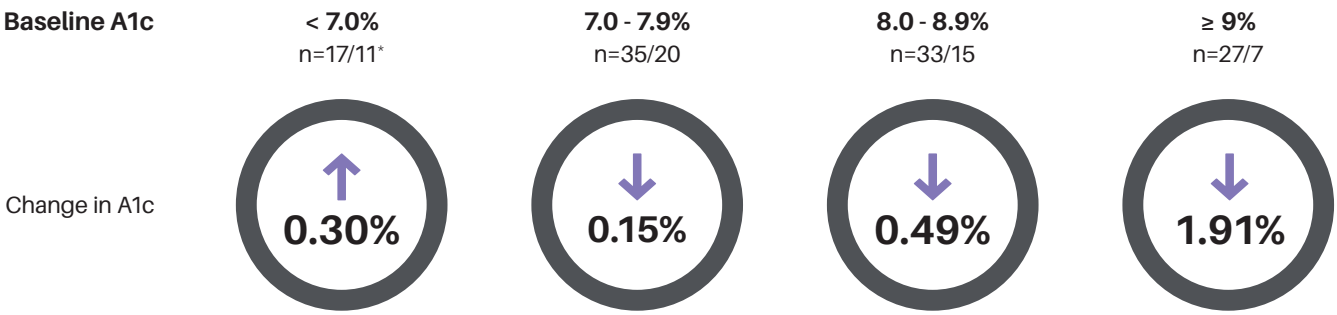
*Values are Mean Baseline Adjusted Difference. The study was not designed to evaluate the effect of the iLet Bionic Pancreas in subgroups by baseline HbA1c. Individual user results may vary from the average values shown here. *n=iLet/ Standard of Care.*

8.2.2.5 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.*

8.2.2.6 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.*

8.2.2.7 Secondary Endpoints

Percent of time CGM glucose levels were below 54 mg/dL, were between 70–180 mg/dL, and mean CGM glucose levels over 13 weeks are shown in Table 3.

Table 3 Glucose results at baseline and over 13 weeks

	Participants ≥ 18			People 6-17 years of age	
	iLet (Humalog® or Novolog®) (N=107)	**iLet (Fiasp®) (N=113) †**	**Standard of Care (N=54)**	**iLet (Humalog® or Novolog®) (N=112)**	**Standard of Care (N=53)**
% Time<54 mg/dL					
Baseline median (IQR)	0.21% (0.02%, 0.57%)	0.12% (0.02%, 0.68%)	0.11% (0.00%, 0.37%)	0.20% (0.03%, 0.59%)	0.22% (0.03%, 0.46%)
Week 13 median (IQR)	0.33% (0.14%, 0.52%)	0.26% (0.12%, 0.48%)	0.18% (0.08%, 0.58%)	0.33% (0.18%, 0.63%)	0.37% (0.16%, 0.66%)
13w Adjusted Group Difference (95% CI) [p-value]	0.02% (-0.04%, 0.08%)	0.00% (-0.07%, 0.05%)**	n/a	-0.04% (-0.13%, 0.03%) [0.24]	n/a
% Time 70-180 mg/dL					
Baseline mean (SD)	56% (19%)	54% (18%)	53% (21%)	47% (17%)	48% (19%)
Week 13 mean (SD)	69% (8%)	71% (8%)	58% (17%)	60% (8%)	50% (16%)
13w Adjusted Group Difference (95% CI) [p-value]	11% (8%, 13%) [<0.001]	14% (11%, 17%) [<0.001]	n/a	10% (7%, 13%) [<0.001]	n/a
Mean CGM Glucose (mg/dL)					
Baseline mean (SD)	179 (41)	181 (34)	186 (42)	195 (39)	195 (42)
Week 13 mean (SD)	157 (12)	155 (11)	174 (30)	172 (14)	187 (34)
13w Adjusted Group Difference (95% CI) [p-value]	-16 (-20, -11) [<0.001]	-18 (-22, -14) [<0.001]	n/a	-15 (-21, -9) [<0.001]	n/a

†1 participant dropped immediately after randomization. Participant was not included in this table

8.2.2.8 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%.

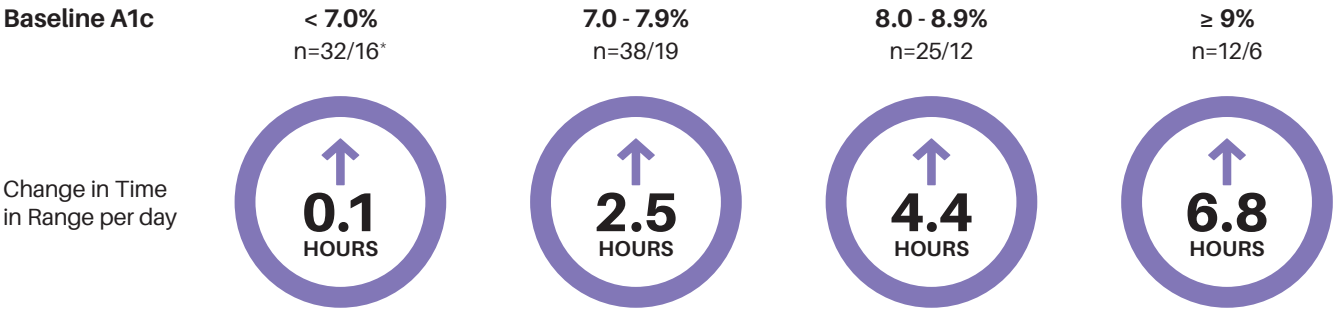
The baseline-adjusted difference in the median percentage of time that CGM glucose levels were less than 54 mg/dL in just the group of people ≥ 18 using the iLet System with Novolog or Humalog compared with the Standard of Care group was 0.02% (an increase of less than one minute per day). This difference 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 System 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.

8.2.2.9 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.

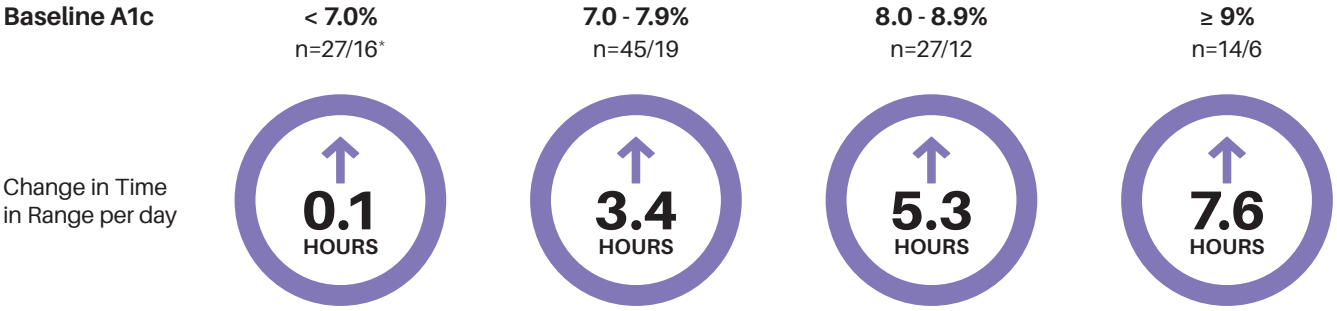
8.2.2.10 Change in Time in Range (70-180 mg/dL) over 13 Weeks in People ≥ 18 According to Baseline HbA1c – iLet System with Novolog or Humalog versus Standard of Care

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.



*Values are average baseline 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.*

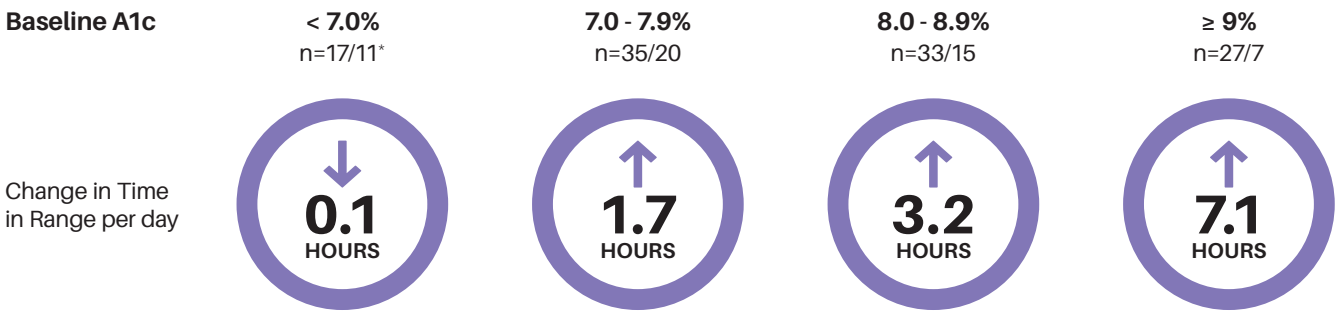
8.2.2.11 Change in Time in Range (70-180 mg/dL) over 13 Weeks in People ≥ 18 According to Baseline HbA1c – iLet System with Fiasp versus Standard of Care



*Values are average baseline 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.*

8.2.2.12 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 average baseline 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.*

8.2.2.13 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.

8.2.3 Adverse Effects

Table 4 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. Hyperglycemia with or without ketosis was a reportable adverse event only in the iLet groups. The iLet groups were provided with a BG meter and a blood ketone meter, and were given specific instructions for when to check their blood glucose and ketone levels and when to contact the clinical site

for prolonged hyperglycemia or ketosis. These devices and instructions were not provided to the participants in the Standard of Care group, who were instead instructed to continue their diabetes management with their personal health care provider. As a result, hyperglycemia with or without ketosis was not routinely reported to the clinical sites by participants in the Standard of Care group.

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. Table 5 summarizes device issues reported during the randomized comparative part of the study.

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

Table 4. 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)**
Total Number of Adverse Events (AEs) *N Events*	63	83	6	181	4
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%)

	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)**
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%)
Other Adverse Events *N Events / N Participants*					
Hyperglycemia with or without Ketosis Related to Study Device	34 / 27	52 / 40	0 / 0	126 / 68	0 / 0
Hyperglycemia with or without Ketosis Not Related to Study Device	13 / 12	14 / 12	0 / 0	41 / 32	2 / 1
Non-Severe Hypoglycemia	1 / 1	0 / 0	0 / 0	1 / 1	0 / 0
Other Reportable Adverse Events	7 / 7	12 / 10	3 / 3	8 / 7	0 / 0

** both diabetic ketoacidosis (DKA) events were related to infusion set failures*

8.2.3.1 Device Issues

There were 472 device issues reported over 13 weeks of the RCT in the iLet Groups, of which 223 were associated with an Adverse Event.

Table 5. Device issues

		People 6 years of age or older iLet (Humalog® or Novolog®) (N=219 randomized)		People ≥ 18 only iLet (Fiasp®) (N=114)	
		No. of Reported Issues			
Device	**Device Issue**	**Related to AE**	**Not Related to AE**	**Related to AE**	**Not Related to AE**
Dexcom G6	**Dexcom G6 Applicator Release**	0	7	0	7
	Dexcom G6 Sensor Accuracy	1	1	1	8
	Dexcom G6 Sensor Failure	1	15	0	6
	Dexcom G6 Transmitter Issue	1	15	2	11
iLet	**iLet Alarm Issue**	2	1	0	1
	iLet Algorithm-related Issue	4	0	1	0
	iLet Algorithm-related Issue User Error	1	3	0	0
	iLet Case Issue	0	1	0	0
	iLet Connectivity Issue	0	3	0	1
	iLet Downloading Issue	0	0	0	1
	iLet Infusion Set Issue	132	26	49	24
	iLet Infusion Set Skin Irritation	2	1	0	0
	iLet Memory Chip Failure	0	0	0	1
	iLet Screen Issue	0	22	0	4
	iLet Battery/Charging Issue	5	23	0	7
	iLet Cartridge Issue	16	26	0	7
	iLet Motor Issue	3	10	1	3
	iLet Waking Issue	0	6	0	1
	Fiasp Cartridge Issue	NA	NA	0	3

		People 6 years of age or older iLet (Humalog® or Novolog®) (N=219 randomized)		People ≥ 18 only iLet (Fiasp®) (N=114)	
		No. of Reported Issues			
Other	**Cell phone for G6 Clarity App**	0	2	0	0
	Dexcom Clarity Issue	1	1	0	0
	Ketone Meter Data Storage Issue	0	0	0	1
Total		169	163	54	86

In iLet (Humalog or Novolog) , greater than 1 device issue with AE in 98 participants and without AE in 103 participants. In iLet (Fiasp), greater than 1 device issue with AE in 40 participants and without AE in 49 participants. Not included above is (1) 1 device issue form in iLet (Humalog or Novolog) that should not have been submitted as a device issue for 'bad insulin' leading to hyperglycemia and ketosis (it was reported as an AE) and (2) 3 device issue forms submitted by the site for discomfort with Fiasp bolus that should not have been submitted as a device issue.

8.2.4 Intervention Compliance

The trial completion rate was extremely high, with 99% of the 440 participants completing the 13-week final visit. Use rate of the iLet Bionic Pancreas System was very high and the iLet System delivered insulin autonomously a median of 97% of the time in people ≥ 18 and 96% of the time in people 6-17 years of age.

8.2.5 Safety of the iLet System using BG entries only

Fifty-four participants in the randomized comparative period of the study tested the safety of utilizing BG values obtained by fingerstick instead of CGM as input into the iLet System. Median number of hours using BG measurements as input for the iLet System was 49.5, with all participants having at least 46.5 hours. Median number of BG measurements entered during the first 24 hours was 9 and during the second 24 hours was 10. There were no cases of severe hypoglycemia, DKA, or other SAEs. CGM-measured (blinded) hypoglycemia frequency appeared similar during the BG-run period as in the pre-randomization baseline period and randomized comparative period of the study. Hyperglycemia metrics generally were higher during the BG-run period than in the randomized comparative period of the study but not higher than in the pre-randomization baseline period.

8.3 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.

8.3.1 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.

8.3.2 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.

8.3.3 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.

8.3.4 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

8.3.5 Other Key Outcomes

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

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

8.3.6 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 changes 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.

8.3.7 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.

8.3.8 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.

8.4 References

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3. Bionic Pancreas Research Group; Beck RW, Russell SJ, Damiano ER, et al. A multicenter randomized trial evaluating fast-acting insulin aspart in the bionic pancreas in adults with type 1 diabetes. Diabetes Technology and Therapeutics 2022; 24:681–696. DOI: 10.1089/dia.2022.0167.

4. Bionic Pancreas Research Group; Messer LH, Buckingham BA, Cogen F, et al. Positive impact of the bionic pancreas on diabetes control in youth 6–17 years old with type 1 diabetes: A multicenter randomized trial. Diabetes Technology and Therapeutics 2022; 24:712–725. DOI: 10.1089/dia.2022.0201.pub.

5. Bionic Pancreas Research Group; Russell SJ, Beck RW, Damiano ER, et al. The Insulin-Only Bionic Pancreas Pivotal Trial Extension Study: A Multi-Center Single-Arm Evaluation of the Insulin-Only Configuration of the Bionic Pancreas in Adults and Youth with Type 1 Diabetes. Diabetes Technology and Therapeutics 2022. 24:726-736. DOI: 10.1089/dia.2022.0341.

9. Technical Information

9.1 iLet Dosing Decision Software

> **WARNING:** The iLet Device is intended to dose insulin based on CGM data. In the events where CGM stops providing glucose data to the iLet Device, 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 Device with CGM. BG-run use **should be temporary** and always for the shortest duration possible with the goal to resume CGM-guided iLet System insulin dosing **as soon as possible**.

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.

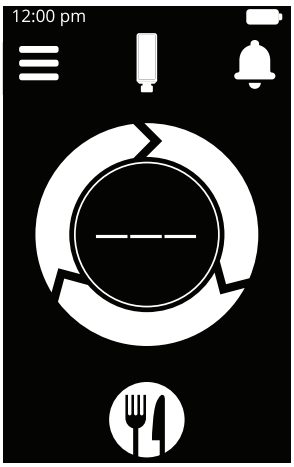
2. The second algorithm is called the **bolus correction algorithm**. This algorithm makes adjustments or "corrections" that you might need to the basal insulin dose to adjust for all kinds of things that come up during the day such as stress, sleeping, etc. It also prevents something called insulin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

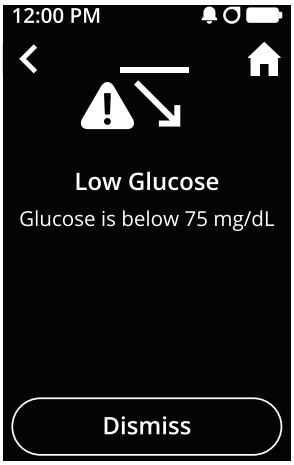
3. The third algorithm is called the **meal announcement algorithm** and is specifically for making sure you have the right insulin dosing for meals. You will learn how to "announce" a meal to the system or tell the iLet System that you are having a meal. The third algorithm will then figure out how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

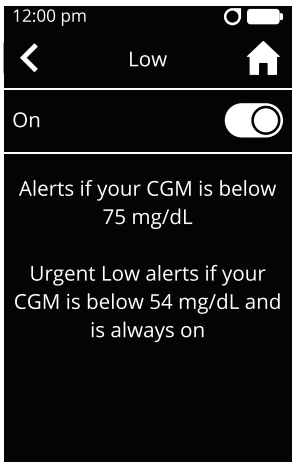
Finally, when the CGM is offline, the iLet Dosing Decision Software remembers the latest basal dosing that it learned, allows you to make meal announcements in exactly the same way as when the CGM was online, and then automatically responds to entered BG values by issuing a correction dose of insulin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

**Values marked with an asterisk are specific to the iLet device with a color display.*

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 *49 W X 91 L X 15 H millimeters**
Weight (with full cartridge–no set)	110 grams *95 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, transport: 0.7 to 15.4 psia(Relative altitude up to 63,000 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 *58 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 *3 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[1]

Operating Rate	Typical	Maximum
Bolus (4 units or greater)	11 seconds *29 seconds**	15 seconds *1 minute**
Basal (1 unit/hr)	2 hours 51 minutes *2 hours 30 minutes**	3 hours 52 minutes *3 hours 20 minutes**
Basal (0.1 unit/hr)	29 hours 29 minutes *25 hours 2 minutes**	39 hours 25 minutes *37 hours 30 minutes**

[1] 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.

**Rows marked with an asterisk are specific to the iLet device with a color display.*

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]
*Amount Delivered (Median) [min, max]**	*0.092 units [0.001, 0.129]*	*0.556 units [0.294, 0.672]*	*1.12 units [0.794, 1.307]*

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]
*Amount Delivered (Median) [min, max]**	*0.092 units [0.003, 0.122]*	*0.553 units [0.238, 0.639]*	*1.108 units [0.707, 1.230]*

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]
*Amount Delivered (Median) [min, max]**	*0.99 units [0.80, 1.17]*	*5.95 units [5.50, 6.15]*	*11.90 units [11.23, 12.15]*

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]
*Amount Delivered (Median) [min, max]**	*0.99 units [0.79, 1.28]*	*5.95 units [5.47, 6.28]*	*11.93 units [11.17, 12.22]*

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]
*Amount Delivered (Median) [min, max]**	*9.92 units [9.20, 10.50]*	*59.52 units [58.36, 60.49]*	*118.97 units [117.43, 120.46]*

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]
*Amount Delivered (Median) [min, max]**	*10.00 units [9.74, 10.19]*	*60.04 units [59.29, 60.54]*	*120.02 units [118.65, 120.84]*

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.

**Rows marked with an asterisk are specific to the iLet device with a color display.*

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%)

*	*0/375 (0.0%)*	*2/375 (0.5%)*	*36/375 (9.6%)*	*316/375 (84.3%)*	*34/375 (5.6%)*	*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%)
*	*0/375 (0.0%)*	*0/375 (0.0%)*	*0/375 (0.0%)*	*375/375 (100.0%)*	*0/375 (0.0%)*	*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%)
*	*0/375 (0.0%)*	*0/375 (0.0%)*	*9/375 (2.4%)*	*365/375 (97.3%)*	*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%)
*	*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
REF	Part Number	ISO 7000-2493 ISO 15223-1 Ref 5.1.7
SN	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 Storage 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 Operating 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
	Keep Away From Sunlight	ISO 15223-1 Ref 5.3.4
	Rechargeable Lithium-ion Battery	IEC 60417-5639

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 User Guide may adversely impact safety and performance, and electromagnetic compatibility, including increased emissions and/or decreased immunity. This may cause your iLet System 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 = $1.20\sqrt{P}$ 80 MHz to 800 MHz, d = $1.20\sqrt{P}$ 800 MHz to 2.5GHz, d = $2.30\sqrt{P}$ 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 *30 V/m*[*] 80 MHz to 2.7 GHz	10 V/m *30 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 *400 A/m**	30 A/m *400 A/m**	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**Rows marked with an asterisk are specific to the iLet device with a color display.*

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 **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 user 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. Warranty

11.1 iLet Device Warranty

The warranty is valid only in the United States. Beta Bionics, Inc. ("Beta Bionics") expressly warrants for a period of four (4) years from the original date of shipment of the device to the initial purchaser of the iLet Bionic Pancreas Device ("original end use purchaser") that the iLet Bionic Pancreas Device shall meet the specifications set forth in the applicable official operating instructions for use provided with each iLet Bionic Pancreas Device (the "Instructions") and against defects in materials and workmanship, under normal use. The sole remedy for this warranty is that Beta Bionics will, at its sole discretion, repair the or replace the iLet Bionic Pancreas Device with a new or refurbished iLet Bionic Pancreas Device. Repair or replacement of an iLet Bionic Pancreas Device will not extend the original four (4) year warranty, which will continue to apply. If your iLet Bionic Pancreas Device is replaced, then you must return your original iLet Bionic Pancreas Device to Beta Bionics in accordance with Beta Bionics' instructions. In the event the original iLet Bionic Pancreas Device is not returned, then this warranty shall be void and you will not be entitled to future replacement or repairs.

The warranty is valid only if the iLet Bionic Pancreas Device is used in accordance with Beta Bionics' instructions. The warranty set forth herein shall become null and void if:

- damage results from changes or modifications made to the iLet Bionic Pancreas Device by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the iLet Bionic Pancreas Device by any person or entity other than Beta Bionics;
- the iLet Bionic Pancreas device seal is broken by user or third persons;
- a non-Beta Bionics approved insulin cartridge is used with the iLet Bionic Pancreas;
- damage consists of scratches and wear to surfaces and other externally exposed parts due to wear and tear;
- damage results from an event or accident beyond the control of Beta Bionics; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse.

From time-to-time Beta Bionics may offer software updates for the iLet Bionic Pancreas Device

that are intended to add new features and functionality to, and to help ensure the up-to-date functionality of, your iLet Bionic Pancreas Device. Beta Bionics reserves the right to offer those updates, if any, in its sole discretion either at no charge or for an additional fee to be determined at a future date. To the extent that an update is offered at no charge, it is considered to be included in the original cost of your iLet Bionic Pancreas Device. Any future software updates will be subject to your acceptance of other terms and conditions that may be applicable at that time, including additional terms that may modify or limit the terms of this warranty.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the iLet Bionic Pancreas Device covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the iLet Bionic Pancreas Device and does not apply to other products, accessories, to any third party pre-filled insulin cartridges, or CGM sensors or transmitters.

EXCEPT AS EXPRESSLY SET FORTH ABOVE, BETA BIONICS MAKES NO WARRANTY, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE PRODUCTS OR ANY OTHER ITEMS PROVIDED BY BETA BIONICS, AND HEREBY EXPRESSLY DISCLAIMS ANY OTHER FORM OF WARRANTY, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THIS STATED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES PROVIDED BY LAW.

11.2 iLet Cartridge Warranty

The warranty is valid only in the United States. Beta Bionics, Inc. (“Beta Bionics”) warrants that the Beta Bionics’ iLet Bionic Pancreas insulin cartridge (“Beta Bionics Cartridge”) for one (1) use during the period of three (3) days after the individual cartridge sterile package has been opened, not to exceed beyond the expiration date of the cartridge, to the initial purchaser of the Beta Bionics Cartridge (“original end use purchaser").

The warranty is valid only if the Beta Bionics Cartridge is used in accordance with the accompanying Instructions. The warranty set forth herein shall become null and void if:

- the Beta Bionics Cartridge has been used for more than one use by a single end-user;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the accompanying Instructions;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;

- damage results from changes or modifications made to the Beta Bionics Cartridge by the original end use purchaser or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the Beta Bionics Cartridge by any person or entity other than Beta Bionics;
- damage is caused by use of the Beta Bionics Cartridge with any non-Beta Bionics products;
- damage results from an event or accident beyond the control of Beta Bionics; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the Beta Bionics Cartridge covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the Beta Bionics Cartridge and does not apply to other products, accessories, any third party pre-filled insulin cartridges, or CGM sensors or transmitters.

EXCEPT AS EXPRESSLY SET FORTH ABOVE, BETA BIONICS MAKES NO WARRANTY, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE PRODUCTS OR ANY OTHER ITEMS PROVIDED BY BETA BIONICS, AND HEREBY EXPRESSLY DISCLAIMS ANY OTHER FORM OF WARRANTY, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THIS STATED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES PROVIDED BY LAW.

11.3 iLet Infusion Set Warranty

This warranty is valid only in the United States. Beta Bionics, Inc. (“Beta Bionics”) warrants that the Beta Bionics’ insulin infusion sets (“Infusion Sets”) for one (1) use during the period of three (3) days after the individual Infusion Set sterile package has been opened, not to exceed beyond the expiration date of the Infusion Set, to the initial purchaser (“original end use purchaser”) shall meet the specifications set forth in the applicable official operating instructions for use provided with each Infusion Set (the “Instructions”) and against defects in materials and workmanship, under normal use. During the warranty period, Beta Bionics will replace any defective Infusion Set, subject to the conditions and exclusions stated herein.

The warranty is valid only if the Infusion Set is used in accordance with the accompanying Instructions. The warranty set forth herein shall become null and void if:

- the Infusion Sets has been used for more than one (1) use by a single end-user
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the original end use purchaser at the time of intended product use;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the accompanying Instructions;
- damage results from changes or modifications made to the Infusion Set by the original end use purchaser or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the Infusion Set by any person or entity other than Beta Bionics;
- damage is caused by use of the Infusion Set with any non-Beta Bionics insulin cartridge;
- damage results from an event or accident beyond the control of Beta Bionics; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the Infusion Set and does not apply to other products, accessories, any third party pre-filled insulin cartridges, or CGM sensors or transmitters.

EXCEPT AS EXPRESSLY SET FORTH ABOVE, BETA BIONICS MAKES NO WARRANTY, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE PRODUCTS OR ANY OTHER ITEMS PROVIDED BY BETA BIONICS, AND HEREBY EXPRESSLY DISCLAIMS ANY OTHER FORM OF WARRANTY, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THIS STATED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES PROVIDED BY LAW.

11.4 iLet Connect Warranty

This warranty is valid only in the United States. Beta Bionics, Inc. (“Beta Bionics”) warrants that the Beta Bionics’ Luer adapters for one (1) use during the period of three (3) days after the individual Luer adapter sterile package has been opened, not to exceed beyond the expiration date of the Luer adapter, to the initial purchaser (“original end use purchaser”) shall meet the

specifications set forth in the applicable official operating instructions for use provided with each Luer adapter (the "Instructions") and against defects in materials and workmanship, under normal use. During the warranty period, Beta Bionics will replace any defective Luer adapter, subject to the conditions and exclusions stated herein.

The warranty is valid only if the Luer adapter is used in accordance with the accompanying Instructions. The warranty set forth herein shall become null and void if:

the Luer adapters has been used for more than one (1) use by a single end-user;

the sterile package is compromised while in the control of the user by any means other than purposeful opening by the original end use purchaser at the time of intended product use;

damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the accompanying Instructions;

damage results from changes or modifications made to the Luer adapter by the original end use purchaser or third persons after the date of manufacture;

damage results from service or repairs performed to any part of the Luer adapter by any person or entity other than Beta Bionics;

damage is caused by use of the Luer adapter with any non-Beta Bionics insulin cartridge;

damage results from an event or accident beyond the control of Beta Bionics; or

damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the Luer connector and does not apply to other products, accessories, any third party pre-filled insulin cartridges, or CGM sensors or transmitters.

EXCEPT AS EXPRESSLY SET FORTH ABOVE, BETA BIONICS MAKES NO WARRANTY, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE PRODUCTS OR ANY OTHER ITEMS PROVIDED BY BETA BIONICS, AND HEREBY EXPRESSLY DISCLAIMS ANY OTHER FORM OF WARRANTY, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THIS STATED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES PROVIDED BY LAW.

For product returns, please reference https://www.betabionics.com/support/.

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