Addendum: Eversense 365 and Beta Bionics Mobile App

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Precedence Statement

This Addendum modifies the iLet Bionic Pancreas System Quick Reference Guide (LA000155, Rev D). Where this Addendum conflicts with the enclosed Guide, this Addendum governs. Retain with your Quick Reference Guide.

Summary of Changes

- **App name.** The iLet Mobile App is now the Beta Bionics Mobile App. Wherever the Guide says "iLet Mobile App," "iLet mobile application," or "iLet App," read "Beta Bionics Mobile App." Beta Bionics Cloud is unchanged.
- **Eversense 365.** The Senseonics Eversense 365 CGM System is now a compatible iCGM. The updates on the following pages add it to the Guide.

For complete instructions, including Eversense 365 setup, see the current iLet Bionic Pancreas System User Guide at **www.betabionics.com/user-resources.**

Updated Language & App Name Updates

- **Page 5:** Download the Beta Bionics Mobile App from the Apple App Store or the Google Play Store and set up your account. Make sure you know your username and password for your training visit. Review the Beta Bionics Mobile App User Guide at www.betabionics.com/user-resources for instructions.
- P**age 17 (2.9 Menu Screen): Mobile Device:** Pair a compatible smart device (phone or tablet) to your iLet Device using the Beta Bionics Mobile App.
- **Page 43 (7.2.5): Pairing Failed:** Try and scan your sensor again with the Beta Bionics

Mobile App. Contact customer support if this issue continues.

- **Pages 84-85:** Replace every "iLet Mobile App" in the CAUTION statements with "Beta Bionics Mobile App." No other wording changes.

2.4 Status Bar

Page 13: add the following row after Abbott CGM Paired.

Icon	Feature	Description
	Eversense CGM Paired	Eversense CGM has been paired.

3.2 Replacing your CGM Sensor

Page 21-22: add after 3.2.1 CGM Accuracy, Calibration and Replacement.

To disconnect your current transmitter, tap the Menu icon on the home screen, tap the CGM icon, and then tap Disconnect Transmitter. A warning will appear stating that you will no longer receive glucose readings if you disconnect. Slide Disconnect to confirm. The CGM icon will disappear from the status bar.

To pair your new transmitter, tap Pair Transmitter on the Eversense CGM menu. The iLet will remind you to pair your Eversense transmitter with the Eversense 365 app first. Once paired with the Eversense 365 app, return to the iLet and tap Next. You will then be prompted to tap the button on your smart transmitter 3 times until a pink light is blinking.

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

Using the Eversense 365 App with Your iLet

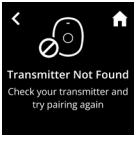
Page 22: add after 3.3 Switching CGM Sensor Types.

Keep the Eversense 365 app open and running on your phone while you use your iLet. The app is needed to receive Eversense system alerts and to enter calibrations.

The iLet provides its own glucose alerts. It is recommended that you disable all optional glucose alerts on the Eversense 365 app before use. If glucose alerts are left enabled in the Eversense 365 app, you may receive additional alerts that must be acknowledged through the Eversense 365 app. For information on updating Eversense alert settings, see the Eversense 365 CGM System User Guide.

7.2.6 Senseonics Eversense 365 Alerts (new)

Page 43: add after the 7.2.5 table.

Screen	Alert	Priority	What to do
	Transmitter Not Found	Low (Level 1)	Check your transmitter and try pairing again.

10.2 iLet System Specifications

Pages 55-56: add the following row after Moisture Protection FreeStyle Libre 3 Plus Sensor.

Specification	Value
Moisture Protection Eversense 365 Transmitter	Refer to the Eversense 365 CGM System User Guide

12.2 Compatible iCGMs

Page 77: replace the list and the paragraph that follows it.

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

- Dexcom G6 CGM
- Dexcom G7 CGM, Dexcom G7 15 Day CGM (generally referred to as Dexcom G7 CGM)
- Abbott FreeStyle Libre 3 Plus Sensor
- Eversense 365 CGM System

For information about Dexcom G6 CGM, Dexcom G7 CGM, Abbott FreeStyle Libre 3 Plus

Sensor, or Eversense 365 CGM product specifications and performance characteristics, visit the manufacturer's website.

12.2.4 Senseonics Eversense 365 CGM System (new)

Page 79: add after 12.2.3.1 Contraindications.

For information about Eversense 365 CGM product specifications and performance characteristics, refer to the manufacturer's user guide.

12.3 Interfering Substances

Page 79: add after the FreeStyle Libre 3 Plus Sensor Users paragraph.

Eversense 365 CGM System Users:

Antibiotics of the tetracycline class (such as tetracycline, doxycycline, minocycline, and tigecycline) may falsely lower sensor glucose readings. Do not rely on sensor glucose readings while taking tetracyclines. Mannitol or sorbitol, when administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, may falsely elevate sensor glucose readings. See the Eversense 365 CGM System User Guide for more information.

12.6.3 Potential Risks Related to Using a CGM

Page 88: replace the calibration bullet and add the following bullet after the infusion set bullet.

- The Dexcom G6 CGM, Dexcom G7 CGM, and FreeStyle Libre 3 Plus sensors are factory calibrated. Dexcom G6 CGM and Dexcom G7 CGM can be calibrated by entering a BG value. FreeStyle Libre 3 Plus sensors cannot be calibrated. Eversense 365 CGM calibrations must be entered in the Eversense 365 app. Contact your CGM manufacturer for any questions about CGM accuracy, calibration, and replacement.
- For Eversense 365, refer to the manufacturer's user guide for the recommended distance between your sensor and infusion set.

Trademarks

Page 108: add after the Dexcom trademark statement.

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