

# iLet Bionic Pancreas System: Camp Diabetes Care Plan

## 1. INTENDED USE OF THIS FORM

This plan is intended solely for the use of the camp healthcare team or other qualified personnel caring for the camper wearing the iLet Bionic Pancreas. This plan may be used to supplement existing camp protocols. Beta Bionics recommends that the camp healthcare team or other qualified personnel be familiar with the use of the iLet and refer to the User Guide, product label and or instructions for use before providing diabetes care to campers using the iLet.

The following documents should be provided to and reviewed by the camp healthcare team and other qualified personnel:

- iLet Bionic Pancreas User Guide <https://www.betabionics.com/resources/user-guides/>
- iLet Bionic Pancreas User Educational Resource Guide
- Beta Bionics Standard Ketone Action Plan (if applicable)

The camp healthcare team and other qualified personnel may request training and support from Beta Bionics: 1-855-745-3800

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*Sections 2 and 3 may be completed by the camper's parent/guardian*

## 2. CAMPER INFORMATION

Camper Name: \_\_\_\_\_ Cabin/Group: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Age: \_\_\_\_\_ Plan valid from: \_\_\_\_\_ to \_\_\_\_\_

## 3. CAMPER'S SELF-CARE SKILLS ON THE iLet

| Skill   | Full Support             | Supervision              | Independent              |
|---|--------------------------|--------------------------|--------------------------|
| Select meal type and size for carbohydrates to be consumed and deliver the meal announcement  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Manage the iLet related to exercise/physical activity   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Recognize and treat hypoglycemia  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Manage hyperglycemia/ketones using the prescribed Ketone Action Plan  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Change insulin cartridge, cartridge connector, tubing, and prime the tubing   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Insert a new infusion set (includes removing the old infusion set and inserting a new one)  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Disconnect/reconnect the iLet tubing from infusion set  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Troubleshoot alarms   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Insert a new CGM sensor and connect to the iLet   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Charge the iLet   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| For any self-care skill that the camper is not able to perform independently the camp healthcare team or other qualified personnel must assist or provide supervision to ensure the task is completed safely and correctly. |                          |                          |                          |

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*Sections 4 and 5 should be reviewed and completed by the camper's healthcare team with input from the parent/guardian*

#### 4. INSULIN, GLUCOSE TARGET, AND CGM ALERTS TO BE USED AT CAMP

|   |  |
|---|--|
| <b>Insulin Type</b>   |  |
| <input type="checkbox"/> insulin lispro (Humalog)   | <input type="checkbox"/> insulin aspart (Novolog)  |
| <input type="checkbox"/> Fiasp prefilled PumpCart   | <input type="checkbox"/> Other: _____  |
| <b>Infusion Set Type</b>  |  |
| <input type="checkbox"/> Contact Detach (change at least every 2 days or as needed)   | Note: Only use supplies compatible with the iLet   |
| <input type="checkbox"/> Inset (change at least every 3 days or as needed)  |  |
| <b>Initial iLet CGM Glucose Target Settings to be used at camp</b>  |  |
| Use the camper's parent/guardian report of pre-camp activity level to determine if the initial target setting for camp should be adjusted: <ul style="list-style-type: none"><li>• If the activity level at camp is expected to be <u>higher</u> than the camper's activity level at home, raise the target one step (i.e. from Usual to Higher). This includes the secondary glucose target if enabled.</li><li>• If expected camp activity level is <u>similar to or lower</u> than camper's home activity level, no change required.</li></ul> |  |
| Use the Sleep (secondary) Target setting to change the target during a specified time period if needed.   |  |
| Default CGM glucose target to be used at camp: <input type="checkbox"/> Lower <input type="checkbox"/> Usual <input type="checkbox"/> Higher  | Sleep glucose target enabled during camp: <input type="checkbox"/> Yes <input type="checkbox"/> No<br>Sleep CGM glucose target: <input type="checkbox"/> Lower <input type="checkbox"/> Usual <input type="checkbox"/> Higher<br>Starts at: _____ Ends at: _____ |
| <b>iLet CGM Glucose Alert settings to be used at camp (check box if alert should be set to "on")</b>  |  |
| <input type="checkbox"/> High Glucose (CGM glucose > 300 mg/dl for 90 minutes)  | NOTE: It is strongly recommended to keep AT LEAST the High Glucose and Urgent Low Soon Alerts on. Urgent low (CGM glucose < 54 mg/dl) cannot be turned off.  |
| <input type="checkbox"/> Low Glucose (CGM glucose < 75 mg/dl)   |  |
| <input type="checkbox"/> Urgent Low Soon (CGM glucose will be < 54 mg/dl in 20 minutes)   |  |
| <input type="checkbox"/> Fall Rate (CGM glucose < 100 mg/dl and falling 2 mg/dl/min or more)  |  |
| <b>Limited Access setting to be used during camp</b>  |  |
| Limited Access passcode required to access meal announcements, cartridge menus and settings during camp? <input type="checkbox"/> Yes <input type="checkbox"/> No      Passcode: _____  |  |

#### 5. DIABETES MANAGEMENT ON THE iLet WHILE AT CAMP

|   |
|---|
| <b>Responding to Alerts</b>   |
| <ul style="list-style-type: none"><li>• The camper's high and low glucose alerts should be kept "On" according to instructions in section 4. Volume should be set at a level they and/or camp personnel can hear.</li><li>• <u>ALWAYS</u> read, respond to, and dismiss active alerts on the iLet. Acknowledging the alerts may be required to resume insulin dosing.</li><li>• If the camper is not independent in troubleshooting alarms, the camp healthcare team or other qualified personnel must be notified to assist.</li></ul>   |
| <b>High Glucose (Hyperglycemia)</b>   |
| <ul style="list-style-type: none"><li>• <u>ALWAYS</u> allow unrestricted access to water or sugar free beverages and the restroom.</li><li>• Ketone Action Plan should only be followed when the camper has ketones and is hyperglycemic. Ketones may be present during euglycemia due to fasting, following a "keto" diet and/or exercise.</li><li>• <i>If the camper's BG is high but has not been above 300 for 90 minutes confirm the following:</i><ul style="list-style-type: none"><li>◦ The iLet has enough battery, is reading the CGM glucose, and has insulin in the cartridge.</li><li>◦ The camper's insulin infusion set is in place and not leaking. <b><u>WHEN IN DOUBT, CHANGE IT OUT!</u></b></li><li>◦ The High Glucose alert is set to "On" in the iLet.</li></ul></li><li>• <u>DO NOT</u> give additional insulin outside of the iLet unless instructed by the parent/guardian or qualified camp healthcare provider</li></ul> |

|  |   |   |
|--|---|---|
| If the camper's BG is above 300 mg/dl for more than 90 minutes:  |   |   |
| <input type="checkbox"/>   | Follow the Beta Bionics Standard Ketone Action Plan for hyperglycemia on the iLet. (Appendix A)   |   |
| <input type="checkbox"/>   | Follow the instructions below for all episode of hyperglycemia on the iLet.   |   |
|  |   |   |
| Notify the parent/guardian if:   |   |   |
| <ul style="list-style-type: none"><li>• The camper has ketones in Zone 3 OR</li><li>• EMS is called due to persistent ketosis with nausea, vomiting or abdominal pain and/or altered mental status or labored breathing.</li></ul>   |   |   |
| Low Glucose (Hypoglycemia)   |   |   |
| <ul style="list-style-type: none"><li>• ALWAYS have rapid-acting carbohydrates available to prevent or treat hypoglycemia and emergency glucagon to treat severe hypoglycemia.</li><li>• If the camper is symptomatic without receiving a low CGM glucose alert:<ul style="list-style-type: none"><li>◦ confirm CGM alerts are on.</li><li>◦ check a fingerstick BG to confirm hypoglycemia. If the camper is hypoglycemic, treat accordingly to the instructions listed in this plan.</li></ul></li></ul> |   |   |
| For Urgent Low Glucose or Low Glucose CGM Alerts or any fingerstick BG less than 70 mg/dL:   | Alert:  | Start to treat with:                      |
|  | Urgent Low<br><br>CGM glucose < 54 mg/dl  | _____ grams of rapid-acting carbohydrates |
|  | Low Glucose<br><br>CGM Glucose < 75 mg/dl   | _____ grams of rapid-acting carbohydrates |
| For Glucose Falling Quickly or Urgent Low Soon Alerts:   | Alert:  | Start to treat with:                      |
|  | Glucose Falling Quickly<br><br>CGM glucose < 100 mg/dl and falling 2 mg/dl/min or more (CGM glucose will be < 70 mg/dl within 15 minutes) | _____ grams of rapid-acting carbohydrates |
|  | Urgent Low Soon<br><br>CGM glucose will be < 54 mg/dl within 20 minutes   | _____ grams of rapid-acting carbohydrates |

*If the CGM glucose is dropping but still above 100 mg/dL:*

- Do not treat with rapid-acting carbohydrates right away. Monitor the camper's CGM glucose levels and be patient. If the Low Glucose alerts are turned on, the iLet will alert and the camper can treat with rapid-acting carbs as needed.
- Do not treat with more carbohydrates than needed. This can cause the blood glucose to rise too much, leading to a high glucose level and triggering more insulin dosing from the iLet.

### **Severe Hypoglycemia**

Hypoglycemia is considered severe if the camper is unable to take oral carbohydrates, is unconscious, or is having a seizure.

Steps for responding to severe hypoglycemia:

- Administer the prescribed glucagon.
- Place the camper on their left side (recovery position) and monitor for vomiting.
- Call 911 and notify the camper's parent/guardian.
- If a BG meter is accessible, confirm hypoglycemia with fingerstick BG measurement. DO NOT delay treatment if a meter is not accessible.
- Disconnect the camper from the iLet but keep it with the camper.
- Always send the iLet with EMS to the hospital.

Consult the prescribed glucagon labeling and package insert for the most up to date drug information including route and dosing

| Type of glucagon to be administered                                  | Injection Site | Route        | Dose |
|--|----------------|--------------|------|
| <input type="checkbox"/> Gvoke PFS (pre-filled syringe)              |                | Subcutaneous |      |
| <input type="checkbox"/> Gvoke Hypopen (auto-injector)               |                | Subcutaneous |      |
| <input type="checkbox"/> Gvoke Kit (ready to use vial and syringe)   |                | Subcutaneous |      |
| <input type="checkbox"/> Zegalogue (dasiglucagon) Auto-Injector      |                | Subcutaneous |      |
| <input type="checkbox"/> Zegalogue (dasiglucagon) Pre-Filled Syringe |                | Subcutaneous |      |
| <input type="checkbox"/> Baqsimi (Nasal Glucagon)                    |                | Nasal        |      |

### **Adjusting iLet CGM Glucose Target Settings during camp**

Consider user behavior in addition to changing the target to address hypoglycemia and hyperglycemia.

- Confirm meals are being announced correctly, hypoglycemia is not being over-treated, alarms are being addressed promptly and the device is being correctly maintained, and the camper is not disconnected for extended periods of time.

Raise the CGM target one step (i.e., from "Usual" to "Higher") if the user is experiencing more than 1% of time with glucose less than 54 mg/dL OR they are consuming carbs for preventing or treating lows more than 2 times per day.

- This works best for users that are experiencing a normal or low mean glucose, and a normal or high time in range but still experiencing excessive hypoglycemia.
- The "Higher" target usually works well to address "drifting" hypoglycemia.

Lower the CGM target one step (i.e., from "Usual" to "Lower") if the user's average glucose is high but they are still experiencing excessive hypoglycemia.

- This may seem counterintuitive, but it can help give more insulin up front with glucose excursions, rather than later, and potentially reduce the amount of hypoglycemia that may result from the late correction insulin dosing.
- The "Lower" target usually works well to address post-prandial hyperglycemia as well as hypoglycemia that follows periods of hyperglycemia.

Use the Sleep (secondary) Target setting to change the target during a specified time period if needed.

| Meal Announcements  |   |
|---|---|
| <ul style="list-style-type: none"> <li>Only announce meals and snacks that have carbohydrates. <u>DO NOT</u> announce meals or snacks that have no carbohydrates or are very low carb.</li> <li><u>DO NOT</u> announce carbohydrates that are used to treat hypoglycemia.</li> <li>There is no designated snack announcement. Announce snacks as meals if they have similar carbohydrate content to one of the meal types. If the meal or snack does not have enough carbohydrates to be considered a "Less" meal, <u>DO NOT</u> announce it.</li> <li>Meals and snacks should be announced right when the camper is about to eat. If it has been more than 30 minutes since the camper started eating, <u>DO NOT</u> announce.</li> <li>A bedtime snack is not needed to prevent hypoglycemia overnight when using the iLet.               <ul style="list-style-type: none"> <li>If the camper is going to eat before bed, the meal or snack should be announced as it would be during the day following the guidance above and outlined in their Camp Meal Announcement Guide.</li> <li>Eating an unannounced snack before bed could cause the camper's glucose to rise and trigger more insulin dosing from the iLet. This can result in hypoglycemia overnight.</li> </ul> </li> </ul> |   |
| <i>Select one of the following options for meal announcements at school:</i>  |   |
| <input type="checkbox"/>  | The camper may independently select the meal type and size according to the amount of carbohydrates in the meal   |
| <input type="checkbox"/>  | The camp healthcare team or other qualified personnel will help the camper select meal type and size based on the amount of carbohydrates in the meal using the Camp Meal Announcement Guide. The Camp Meal Announcement Guide must be completed by the camp healthcare team or other qualified personnel. ( <i>Appendix B</i> )  |
| Exercise/Physical Activity  |   |
| <ul style="list-style-type: none"> <li><u>DO NOT</u> "pre-load" with carbs BEFORE disconnecting from the iLet.</li> <li>If the camper will "pre-load" with carbs, this should only be done <u>AFTER disconnecting</u> from the iLet.</li> <li><u>ALWAYS</u> have rapid-acting carbohydrates available to prevent or treat hypoglycemia and emergency glucagon to treat severe hypoglycemia.</li> </ul>  |   |
| <i>Select one of the following options for physical activity at camp:</i>   |   |
| <input type="checkbox"/>  | Disconnect from the iLet before physical activity (campers should disconnect from the iLet for any water related activities). <ul style="list-style-type: none"> <li>Disconnect from the iLet _____ minutes before physical activity.</li> <li>Take _____ grams of carbs before physical activity.</li> <li>Reconnect to the iLet _____ minutes after physical activity.</li> <li>The iLet should not be disconnected for longer than _____ minutes for physical activity.</li> </ul> |
| <input type="checkbox"/>  | Stay connected to the iLet during physical activity. <ul style="list-style-type: none"> <li><u>DO NOT</u> "pre-load" with carbohydrates prior to physical activity.</li> <li>Treat hypoglycemia as needed.</li> </ul>   |
| BG-Run Mode & Back Up Therapy Plan  |   |
| <ul style="list-style-type: none"> <li>It is very important to always have a backup CGM sensor to avoid going into BG-run mode.</li> <li>The iLet will go into BG-run mode when it is not receiving CGM glucose readings.</li> <li>The iLet will alert when a fingerstick BG is required.</li> <li>If a BG is not entered within the required interval, <u>insulin dosing will stop</u> until a BG is entered or the camper is connected to a CGM.</li> <li>This mode is temporary. After 72 hours BG-run mode will end, and all insulin dosing will stop.</li> <li>Once BG-run mode ends, the camper will need to connect to a CGM or switch to their back up therapy plan.</li> </ul>   |   |

| <i>Select one of the following for managing BG-run mode:</i>         |  |
|--|--|
| <input type="checkbox"/>   | Place a new CGM sensor immediately and enter a BG as requested by the iLet until CGM has completed the warm-up and the iLet is reading CGM glucose values. If the camper does not have a backup CGM sensor contact the parent or guardian. |
| <input type="checkbox"/>   | Notify the parent or guardian for guidance on managing BG-run mode or transitioning to back up therapy plan.   |
| <input type="checkbox"/>   | Disconnect from the iLet and transition to the camper's back up therapy plan outlined below:   |
| Instructions for transitioning to the camper's back up therapy plan: |  |

**This iLet Bionic Pancreas System: Camp Diabetes Care Plan has been approved by:**


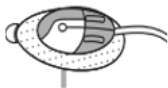


| CAMPER'S PARENT/GUARDIAN   |      |
|----------------------------|------|
| PARENT/GUARDIAN NAME:      |      |
| PARENT/GUARDIAN SIGNATURE: | DATE |

| CAMP HEALTHCARE PROVIDER            |      |
|-------------------------------------|------|
| CAMP HEALTHCARE PROVIDER NAME:      |      |
| CAMP HEALTHCARE PROVIDER SIGNATURE: | DATE |




## Appendix A: Beta Bionics Standard Ketone Action Plan

Use this form if the camper has been prescribed the standard ketone action plan.

### Ketone Action Plan

| Test your BG and ketones if:  |   |
|---|---|
| you are nauseous, vomiting or have diarrhea.  |    |
| you think your infusion set is not working.   |    |
| your CGM glucose has been above 300 mg/dL for 90 minutes.   | <br><b>High Glucose</b><br>Glucose has been above 300 mg/dL for more than 90 minutes |
| your CGM glucose is above 400 mg/dL.  | <br><b>HIGH</b>   |
| <b>Always keep these supplies with you:</b> <ul style="list-style-type: none"> <li>• Glucose meter and strips</li> <li>• Urine ketone strips OR blood ketone meter and strips</li> <li>• Extra CGM sensor</li> <li>• Extra infusion set and cartridge</li> <li>• Insulin vial and syringe, or insulin pen and pen needle</li> </ul> |   |

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|   |  |   |
|---|--|---|
| <b>ZONE 1</b><br> | Urine Ketones:<br>Negative<br><br>OR<br><br>Blood Ketones:<br>less than<br>0.6 mmol/L  | <b>Check to make sure:</b> <ul style="list-style-type: none"> <li>• your <u>iLet</u> is charged, has insulin, and is displaying CGM values.</li> <li>• your infusion set is in place and not leaking.</li> </ul> <b>Continue to monitor your BG:</b> <ul style="list-style-type: none"> <li>• If your BG is still high after 90 minutes, check ketones again.</li> </ul>  |
| <b>ZONE 2</b><br> | Urine Ketones:<br>Trace – Moderate<br><br>OR<br><br>Blood Ketones:<br>0.6 – 2.5 mmol/L | <ol style="list-style-type: none"> <li>1. <b>CHANGE</b> your <u>iLet</u> infusion set.</li> <li>2. <b>DRINK</b> extra fluids.</li> <li>3. <b>RECHECK</b> BG and ketones in 90 minutes.               <ul style="list-style-type: none"> <li>• If BG is less than 180 mg/dL and ketones are in <b>ZONE 1</b>, you do not need to do anything else.</li> <li>• If BG is more than 180 mg/dL and ketones are not in <b>ZONE 1</b>, <b>GO TO ZONE 3</b>.</li> </ul> </li> </ol>   |
| <b>ZONE 3</b><br> | Urine Ketones:<br>Large<br><br>OR<br><br>Blood Ketones:<br>2.5 mmol/L or higher        | <b>CALL YOUR HEALTHCARE PROVIDER IMMEDIATELY!</b><br><b><u>If your healthcare provider has told you to take an insulin injection, it is important to follow these steps:</u></b> <ol style="list-style-type: none"> <li>1. <b>DISCONNECT</b> from the <u>iLet</u> at the time of the injection.</li> <li>2. Give the injection of rapid acting insulin as instructed by your healthcare provider.</li> <li>3. <b>DRINK</b> extra fluids.</li> <li>4. <b>RECHECK</b> BG and ketones in 90 minutes.               <ul style="list-style-type: none"> <li>• If BG is less than 180 mg/dL and ketones are in <b>ZONE 1</b>, <b>CHANGE</b> your <u>iLet</u> infusion set and <b>RECONNECT</b> to the <u>iLet</u>.</li> <li>• If your BG is more than 180 mg/dL and ketones are not in <b>ZONE 1</b>, <b>CALL YOUR HEALTHCARE PROVIDER, GO TO THE EMERGENCY ROOM, OR CALL 911.</b></li> </ul> </li> </ol> |



## Appendix B: iLet Camp Meal Announcement Guide

Camper Name: \_\_\_\_\_

Cabin/Group: \_\_\_\_\_

This form should be used for any camper who requires assistance with announcing meals and snacks. This form must be completed by the camp's healthcare team or other qualified personnel with the camper's parent/guardian.

| Meal Type   | Meal Size to choose during camp  | Carbohydrate Ranges (grams)   |
|---|--|---|
| Breakfast   | Announce meal as "Usual for me" if carbohydrate content is 75%-125% of estimated typical meal  |   |
| Typical amount of carbohydrates in a "Usual for me" Breakfast before camp:<br><br>_____ grams   | Announce meal as "More than Usual" if carbohydrate content is 125%-175% of estimated typical meal  |   |
|   | Announce meal as "Less than Usual" if carbohydrate content is 25%-75% of estimated typical meal  |   |
|   | Do not announce meal if carbohydrate content is less than 25% of estimated typical meal  |   |
|   | Lunch  | Announce meal as "Usual for me" if carbohydrate content is 75%-125% of estimated typical meal |
| Typical amount of carbohydrates in a "Usual for me" Lunch before camp:<br><br>_____ grams   | Announce meal as "More than Usual" if carbohydrate content is 125%-175% of estimated typical meal  |   |
|   | Announce meal as "Less than Usual" if carbohydrate content is 25%-75% of estimated typical meal  |   |
|   | Do not announce meal if carbohydrate content is less than 25% of estimated typical meal  |   |
|   | Dinner   | Announce meal as "Usual for me" if carbohydrate content is 75%-125% of estimated typical meal |
| Typical amount of carbohydrates in a "Usual for me" Dinner before camp:<br><br>_____ grams  | Announce meal as "More than Usual" if carbohydrate content is 125%-175% of estimated typical meal  |   |
|   | Announce meal as "Less than Usual" if carbohydrate content is 25%-75% of estimated typical meal  |   |
|   | Do not announce meal if carbohydrate content is less than 25% of estimated typical meal  |   |
|   | To calculate the carbohydrate ranges, multiply the percent value listed in the Meal Size column by the grams provided in the Meal Type column for that meal. For a Usual meal, this would be $0.75 \times \#$ and $1.25 \times \#$ . |   |
| For example: The reported typical meal is 30 grams of carbohydrates. Announce as usual if meal at camp is between $0.75 \times 30$ and $1.25 \times 30$ , or between 22.5 and 37.5 grams. |  |   |

### This iLet Camp Meal Announcement Guide has been approved by:

|                                     |      |
|-------------------------------------|------|
| CAMPER'S PARENT/GUARDIAN            |      |
| PARENT/GUARDIAN NAME:               |      |
| PARENT/GUARDIAN SIGNATURE:          | DATE |
| CAMP HEALTHCARE PROVIDER            |      |
| CAMP HEALTHCARE PROVIDER NAME:      |      |
| CAMP HEALTHCARE PROVIDER SIGNATURE: | DATE |