



Customer Care:
1.888.BDCARES

BD Strive™

Insulin Management System (IMS)

User Guide



IMPORTANT: It is important to receive training prior to using the BD Strive™ Insulin Management System. If you have not received training, call Customer Care at **1.888.BDCARES**.

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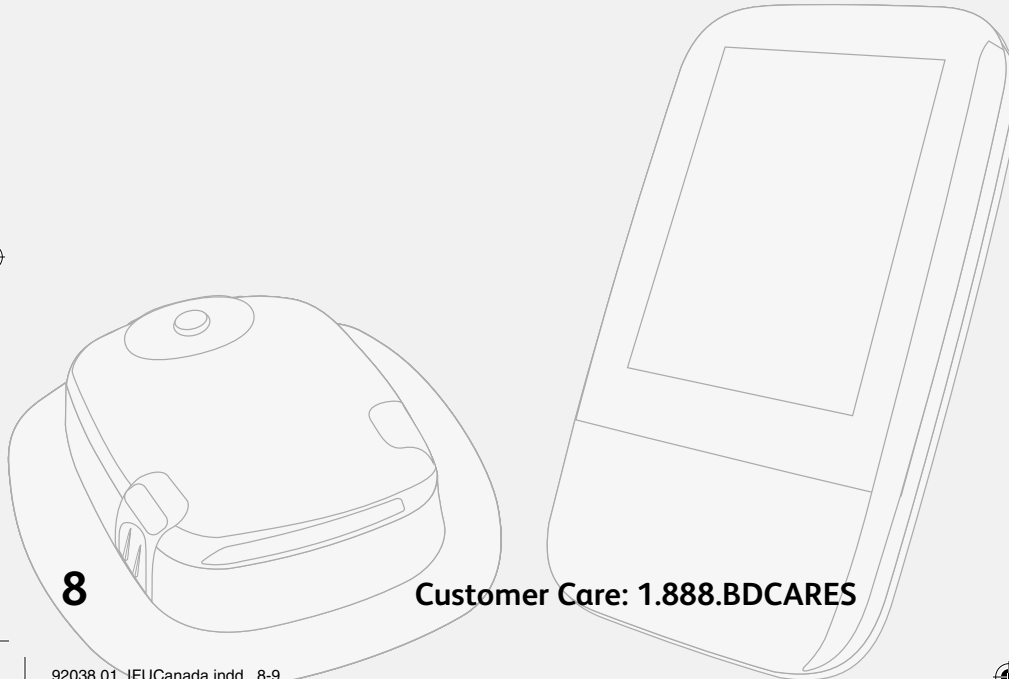
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1. Before you start



1.1 About this guide

Customer care information:

Make sure you read and understand this User Guide, and be sure to retain this User Guide for future reference. Speak to your healthcare team if you have questions or concerns about using your BD Strive™ Insulin Management System (BD Strive™) correctly.

If you need assistance in setting up, using or maintaining the BD Strive™, or to report a malfunction or an unexpected event, call Customer Care at **1-888-BDCARES**.

IMPORTANT: It is important to receive training prior to using the BD Strive™. If you have not been trained on the system, please call Customer Care.

1.1 About this guide (continued)

Healthcare Team: Working with HCP to train patients

Your Healthcare Team will include:

- **Your doctor or Healthcare Provider (HCP)**
- **Certified Diabetes Educator (CDE)**

Your team will help you learn how to use the BD Strive™ system. They will teach you how to set your:



- **Blood glucose target goals**
- **Insulin doses**

1.2 Symbols and terms

In this section:



This section provides information about the symbols you will find on the device or instructions (such as this User Guide and the Quick Start Guide). This section also defines terms and abbreviations used in this User Guide.




Safety-related symbols:



Term	Explanation
 WARNING	Indicates a hazardous situation that, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.
<u>IMPORTANT</u>	Indicates instructions that are important to follow to ensure proper use of the system.

Product-specific symbols:

The following are symbols (and what they mean) which might be on your wireless Remote, Insulin Delivery Device (IDD), and/or its packaging, you can also refer to: www.bd.com/symbols-glossary for additional details.

Symbol	What it means
	Catalog Number/ Model Number. Indicates the manufacturer's catalog number so that the medical device can be identified.
	Batch Code. Indicates the device's batch code so that the medical device can be identified.

Symbol	What it means
	<p>Device Serial Number. Indicates the device's serial number so that the medical device can be identified.</p>
	<p>Use-by date. Indicates the device's use-by date so that the medical device will not be used after the date accompanying the symbol.</p>
	<p>Date of Manufacture. Indicates the date on which the device was manufactured.</p>

Symbol	What it means
	<p>Manufacturer. Indicates the manufacturer of the device.</p>
	<p>Storage Temperature Limits. Indicates the temperature limits to which the medical device can be safely exposed.</p>

Symbol What it means



CE Mark.
Indicates the mandatory conformity mark for products sold within the European Economic Area.



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



Refer to Manual.
Indicates that the user needs to refer and follow the instructions in the manual/booklet.



Symbol What it means







Do Not Reuse.
Indicates that the device is for single use only and must not be used more than once.






MR Unsafe.
Indicates that the device is known to pose hazards in all MRI environments.

Symbol	What it means
	Type BF Medical Device. Indicates that the device is protected against electric shock.
	Sterilized Using Ethylene Oxide. Indicates that the device is provided sterile and has been sterilized using ethylene oxide.

Symbol	What it means
IP22	IP Code (on Remote). Level of ingress protection. The Remote is protected against solid foreign objects of 12.5 mm diameter and greater and protected against vertically falling water drops when tilted up to 15 degrees.
IP27	IP Code (on Insulin Delivery Device). Level of ingress protection. The IDD is protected against solid foreign objects of 12.5 mm in diameter and greater. It also protects against vertically falling water drops. The IDD can be immersed in 1m (3.28 ft) of water for 30 minutes.
	General Warning Sign. Indicates warnings applicable to this device.

Symbol	What it means
	Non-Pyrogenic. Indicates a medical device that is non-pyrogenic..
	Authorized European Representative. Indicates the Authorized representative in the European Community.
	Do Not Use if Package Is Damaged. Indicates a medical device that should not be used if the package has been damaged or opened.

Symbol	What it means
	Storage Humidity Limits. Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric Pressure Limits. Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Environmental Protection Waste. Electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your Local Authority or retailer for recycling advice.

Terminology and abbreviations:

The following are terms and abbreviations used in this User Guide along with their explanations.

Term	Explanation
Icon	A picture on your touchscreen, back of Remote, IDD, or package that points to a choice or information.
IDD	Insulin Delivery Device. The component of the BD Strive™ System that delivers insulin and attaches to your body.
HCP	Healthcare Provider.
Menu	A list of choices on your touchscreen.


Term	Explanation
Press (squeeze)	Use your fingers to press (squeeze) the buttons on the IDD at the same time.
Swipe	Quickly and lightly slide your finger across the Remote's touch screen.
Tap	Quickly and lightly touch the Remote's touchscreen with your finger.


1.3 Important safety information

Important safety information


In this section:


This section provides general safety information about using BD Strive™. Follow all instructions in this section and throughout this User Guide to ensure proper use and avoid injury.


 **CAUTION:** Federal law (United States) restricts this device to sale by or on the order of a physician.

 **WARNING: You must be trained before using BD Strive™.** Before using BD Strive™, ensure that you have been appropriately trained on its use. Incorrect use of your BD Strive™ or failure to follow the appropriate instructions in this User Guide can lead to serious injury or even death.

If you have questions or need further clarification on using BD Strive™, ask your HCP or call Customer Care at **1-888-BDCARES**.

 **WARNING:** The BD Strive™ System is not recommended for patients with type 1 Diabetes Mellitus.

 **WARNING:** If the device stops working it will not deliver insulin. You should carry an emergency kit of insulin supplies in case the Insulin Delivery Device (IDD) unexpectedly stops your insulin delivery.

 **WARNING:**
If you have a medical emergency, call 911 (US only) or call 112 (EU only).

You may also call your HCP or go directly to the hospital. For non-medical emergencies or for technical questions about your BD Strive™ setup or operation, you can call Customer Care at **1.888.BDCARES**, or you can visit the website at: bd-BD Strive™.com.

1.4 Indications for use

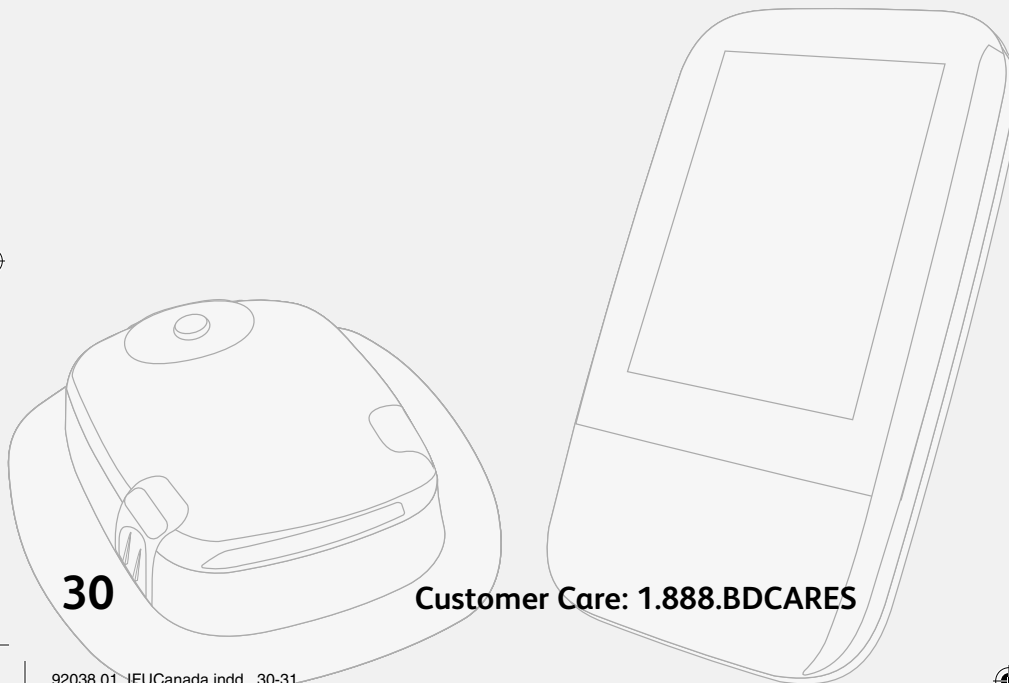
The BD Strive™ Insulin Management System (BD Strive™) is intended for the continuous subcutaneous delivery of insulin, at set and adjustable rates, for the management of type 2 diabetes mellitus in adult patients requiring insulin.

1.5 Contraindications

Contraindications:

- none known

2. BD Strive™ System Overview



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2.1 Introduction

Welcome to BD Strive™!

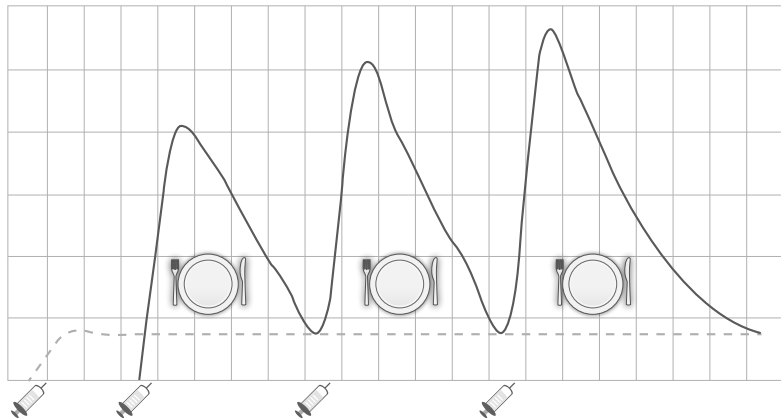
The BD Strive™ Insulin Management System (BD Strive™) provides you with a new way to deliver insulin.

If you have any questions about BD Strive™, you can call Customer Care at: **1.888.BDCARES.**

Before BD Strive™, you may have been giving your insulin with different types of insulins in separate pens or vials.

Previous insulin injection schedule using pens or syringes

--- Basal Insulin injection — Food dose Insulin injection



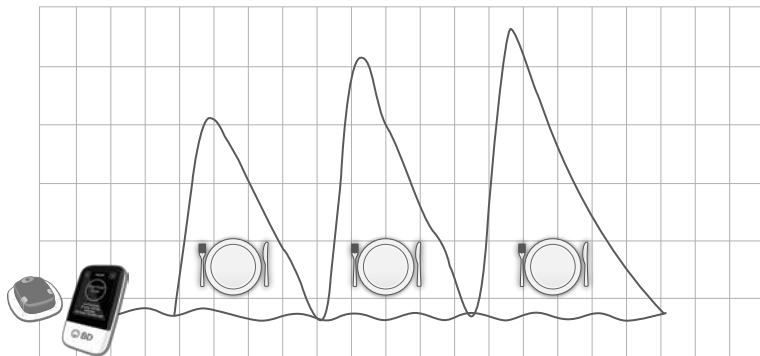
What to expect from BD Strive™:

BD Strive™ delivers insulin to the fat under the skin for up to 3 days.

Once you program your preset basal insulin during setup, BD Strive™ will automatically give you small amounts of insulin throughout the day to replace your basal (i.e. long-acting) insulin needs. When it is time for a meal, you can easily and discretely give yourself more insulin when needed before meals by delivering a food dose.

New insulin infusion using BD Strive™ (U-100 Humalog® ONLY)

—— Basal INFUSION with Swatch —— Food doses with Swatch



You will work with your Healthcare Provider (HCP) to adjust the insulin doses to meet your specific needs.

BD Strive™ has **2** main components:

- The Insulin Delivery Device (IDD), which delivers insulin.
- The wireless Remote, which can program and control the IDD

Insulin Delivery Device
(IDD)



Wireless
Remote



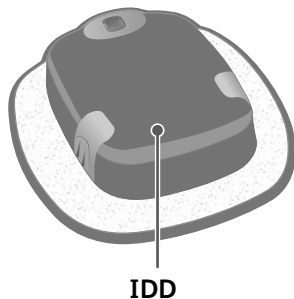
IMPORTANT: Equipment and accessories not specified within this User Guide are not authorized, and might impact safety and performance. If products have been damaged or modified, do not use. Call Customer Care at **1-888-BDCARES**.

2.2 About the IDD

About the IDD

Overview of Insulin Delivery Device (IDD):

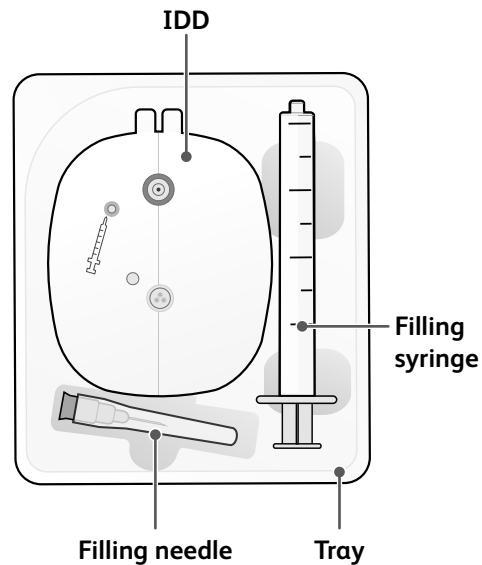
The IDD can be worn on the body for up to three days. It is designed to be worn during all your activities (see exceptions on page 188 and page 222). The IDD precisely delivers insulin from its internal reservoir once filled.

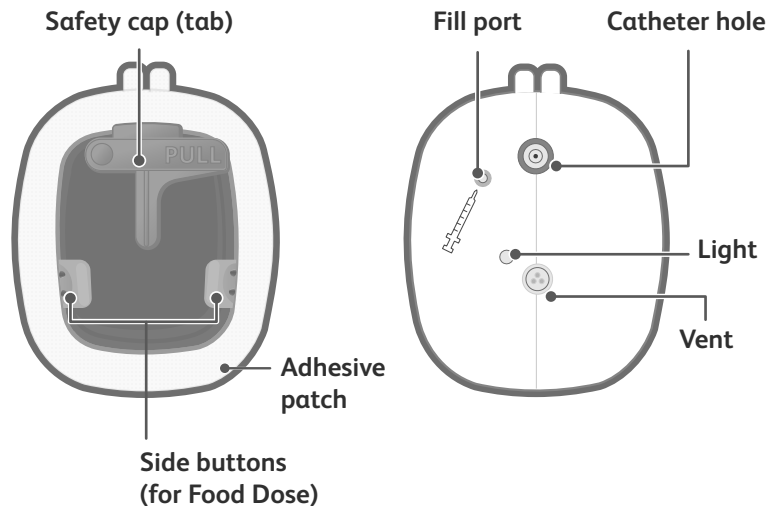


IDD

IDD package:

IDDs are provided in individual sterile packages which include the Filling syringe and Filling needle. You will use this each time you fill the IDD with your prescribed insulin amount.



IDD details:**Description of details:**

The following table lists each detail on the IDD and package alphabetically, and describes its function.

Detail	Description
Adhesive patch	Medical adhesive that keeps the device attached to your body for up to 3 days
Catheter	Small, flexible tube that delivers insulin from the IDD to your body
Catheter hole	The site where the catheter comes out of the IDD when inserted on your body

Detail	Description
Filling syringe	Used to fill the IDD with insulin.
Filling needle	Used to fill the IDD with insulin.
Light	Green light will blink during IDD setup.
Safety cap (tab)	Shields the insertion button and prevents you from accidentally activating the needle.

Detail	Description
Side buttons	Used when pairing device during IDD setup, and for delivering a food dose when your controller is not available.
Tray	Package also used to help you hold the IDD stable during filling.
Vent	Allows for proper operation of the device.

2.3 About the Remote

Safety tips for the IDD:

- ✓ **Keep the system and accessories away from young children**, as they contain small parts that might be dangerous if swallowed.
- ✓ **Change IDD every 3 days**, or when insulin runs out.
- ✓ **One-time use only (cannot be reused)**. IDDs are designed for one-time use. DO NOT attempt to refill or reapply a used IDD.
- ✓ **DO NOT use if the package has been opened or damaged**. This device is sterile, non-toxic, and non-pyrogenic unless the package has been opened or damaged.
- ✓ **To stop therapy, remove the IDD from the skin**. In order to pair a new IDD, you must deactivate per Section 5.8.

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Overview of Remote:

The wireless Remote looks much like a smartphone. Its purpose is to:

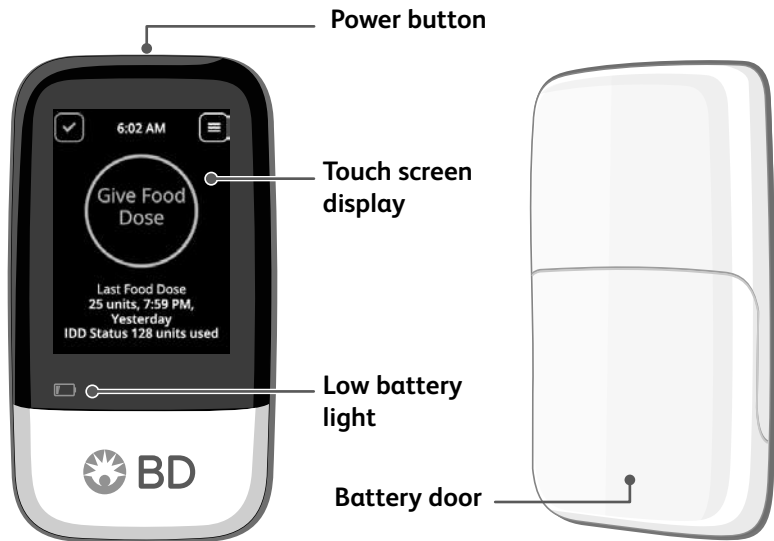
1. Program and control the IDD.
2. Keep a record of how much insulin you have used.

Use the Remote to program the Insulin Delivery Device (IDD), track insulin delivery, and deliver meal time insulin doses.



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Remote details:



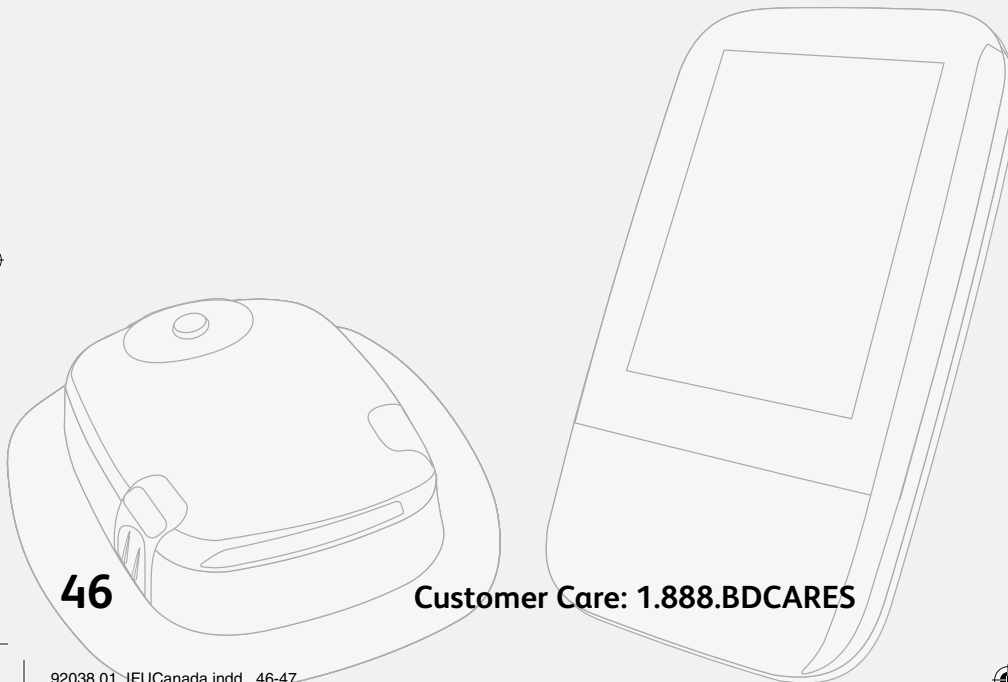
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Safety tips for the Remote:

- ✓ **DO NOT use someone else's Remote.** Remember to check your Remote name when unlocking the screen before initiating pairing, changing basal setting, changing IDD button amount setting, or starting a Food Dose. This ensures that you are using your personal Remote.
- ✓ **Remote Life.** Use life for the Remote is 2 years.
- ✓ **Disposal.** When disposing of any waste (IDDs, Remote, battery, etc.), be sure to follow your local disposal regulations.

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3. Insulin therapy



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3.1 Target blood glucose value

The target blood glucose value is a single number that falls within your blood glucose goals. The target blood glucose value is used to adjust your insulin dose.

Your target blood glucose value should be determined by your Healthcare Provider.

3.2 Using insulin with BD Strive™

Using insulin with BD Strive™

Insulin action:


The duration of insulin action is the amount of time that insulin remains active and available for use in your body. Different types of insulin will have different durations of action. Rapid acting insulins typically have a duration of action from 3 to 5 hours.

WARNING:

DO NOT take insulin injections while using BD Strive™.

Insulin types you can use with BD Strive™:

Only use the U-100 rapid-acting insulins with BD Strive™ listed below.

 **WARNING:** BD Strive™ is not for use with all types of insulin. Your BD Strive™ is designed only for use with this U-100 insulin:

- Humalog® (insulin lispro)

BD Strive™ is not intended for use with any other delivery substance.

While using BD Strive™, you no longer need to inject basal (long-acting) insulins such as Lantus®, Levemir®, Toujeo®, Tresiba®, etc., unless specifically instructed to do so by your healthcare provider.

For any questions, please confirm with your Healthcare Provider.

3.3 Understanding basal rate

Handling insulin:

Follow the warnings below when using BD Strive™ and handling insulin.

WARNINGS:

- **DO NOT** use expired insulin
- **DO NOT** use insulin that looks cloudy or discolored
- **Store insulin in a well-controlled environment** as recommended per the insulin manufacturer's labeling

What is a basal rate?

The BD Strive™ Insulin Management System releases a small amount of insulin every few minutes. This is called basal or background insulin. The dose or amount of insulin delivered is called the basal rate. You need basal insulin, between meals and at night, to cover glucose being released by your liver. This helps your blood glucose to stay level between meals and during the night.

3.4 Understanding Food Doses

What is a Food Dose?

When you eat or drink, the body breaks down the food into glucose and releases it into the blood. The pancreas releases a burst of insulin to match the rapid rise in blood glucose that occurs after a meal. Before each meal, you will deliver a Food Dose to match the glucose from your meal.

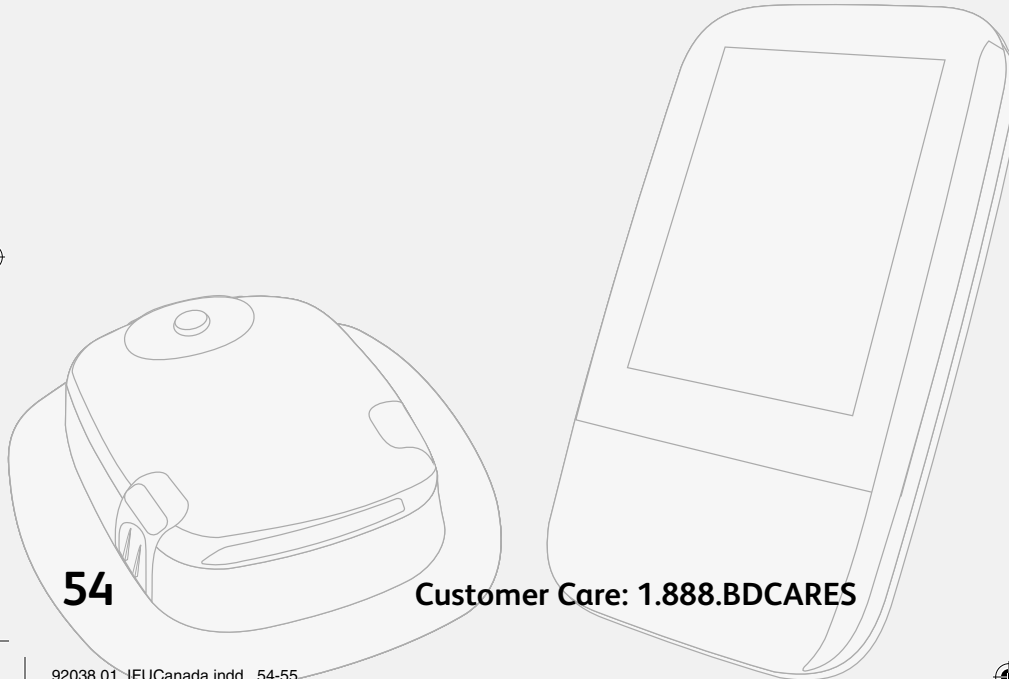
Guidelines from Healthcare Provider (HCP):

Your HCP will tell you the correct basal rate and Food Dose for each meal. You will learn how to program the Remote and IDD to deliver the correct doses. BD Strive™ delivers a constant background basal rate, and when you eat a meal you can deliver Food Doses using your Remote or the buttons on the IDD (if the Remote is unavailable).

Use of Food Dose data: insulin adjustment and pattern management

Adjusting insulin doses based on a pattern of blood glucose readings over three days or more is called “Pattern Management”, or “Pattern Control”. If your blood glucose is too high or too low at certain times of the day or night, you might need to adjust your insulin dose. Your HCP will help you learn how to make adjustments to your Food Doses based on your blood glucose patterns and food diary.

4. Getting started



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4.1 Read before you begin

Your healthcare provider will teach you how to:

- Fill the IDD with insulin.
- Place IDD on your body correctly.
- Use the Remote to tell the IDD how much insulin to give yourself during the day and night.
- Use the Remote or the IDD to give you mealtime insulin.

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IMPORTANT:

You should have received training and your basal and Food Dose insulin settings from your Healthcare Provider (HCP). If you have **NOT** received training or your settings, contact your HCP before you proceed.

4.2 Set up Remote

In this section:

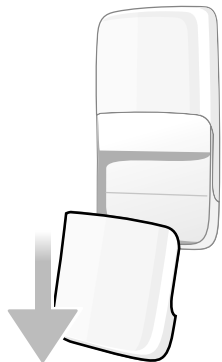
The steps in this section provide instructions for entering your insulin delivery settings and setting options such as language, date, and time.



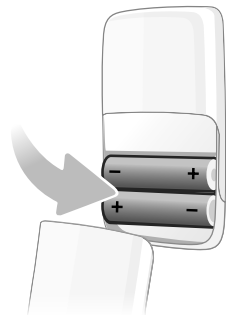
⚠ CAUTION: Use only new AAA alkaline batteries to power the wireless Remote. **NEVER** use re-chargeable, old, or used batteries; Remote might not work properly.

Step 1. Power on Remote

Set up Remote



a. Slide battery door off Remote.



b. Align + and - on batteries and compartment and install batteries.



c. Slide battery door on until it snaps into place.



d. The Remote automatically turns on. You can now start setting up the Remote. Continue with Step 2.

IMPORTANT: After 1 minute of inactivity the screen will automatically go to sleep. To unlock again, power on Remote, swipe your finger across arrows on screen, then tap **Confirm Unlock**. For more information see Section 4.3 on page 69.

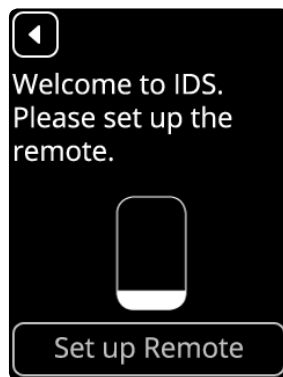
Step 2. Set language



- a.** Tap blue arrows to set your language. Tap **OK**.

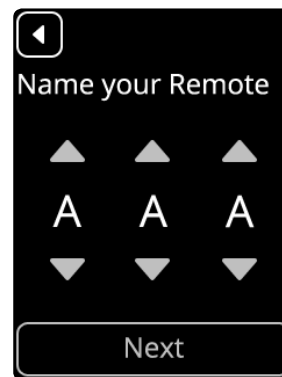
60

Step 3. Set Remote name



- b.** Tap **Set up Remote** to begin entering Remote settings.

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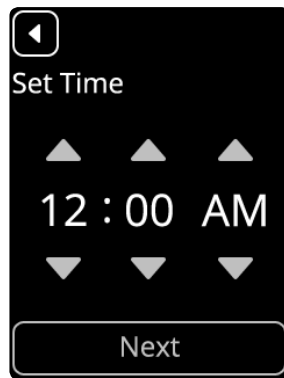


- c.** Tap blue arrows to set a 3-letter Remote name. Tap **Next**.

The Remote name you set appears on screen each time you turn on the Remote so that you can make sure you have the correct Remote.

Write the name here, as a reminder:

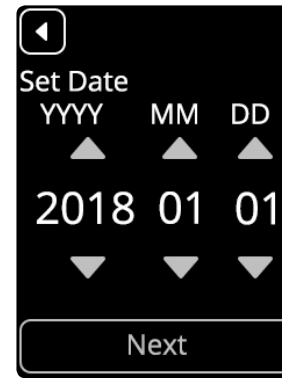
Step 4. Set time



- d.** Tap blue arrows to set the current time (hour, minute, and AM/PM).

Tap **Next**.

Step 5. Set date



- e.** Tap blue arrows to set the current date (year, YYYY; month, MM; and day, DD).

Tap **Next**.

Step 6. Set basal delivery

About basal insulin:

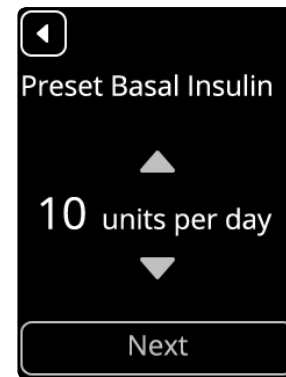
Basal insulin is the background insulin you receive in small doses throughout the day.

WARNING: Entering incorrect insulin delivery settings could lead to **low blood sugar (Hypoglycemia)** or **high blood sugar (Hyperglycemia)**. Make sure you set the basal insulin rate that your Healthcare Provider prescribed.

My prescribed basal insulin:

<div></div>	units per day
-------------	------------------

a. Write the number of insulin units you were prescribed for your basal insulin here.



(example value)

b. Tap blue arrows to set the basal insulin rate (units delivered per day). Tap **Next**.

Step 7. Set IDD Food Dose

(Amount per squeeze of IDD side buttons)

Set up Remote

About delivering Food Doses with the IDD:

If you do not have the Remote at meal times, you can still give insulin using your IDD. Each squeeze of the IDD side buttons will deliver a preset number of units.

Note: You might need to squeeze the IDD side buttons more than once to get your full Food Dose insulin. The maximum units per dose is 30 units.

⚠ WARNING: Entering incorrect insulin delivery settings could lead to **low blood sugar (Hypoglycemia)** or **high blood sugar (Hyperglycemia)**. Make sure you set the units per button press that your Healthcare Provider prescribed.

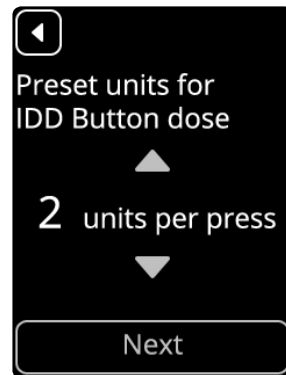
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My prescribed Food Dose insulin per press (squeeze):

_____	Units per press (squeeze)
-------	------------------------------

- a. Write number of insulin units you were prescribed for each press (squeeze) of IDD side buttons here.

	Food Dose (units)	number of presses
Breakfast	_____	_____
Lunch	_____	_____
Dinner	_____	_____

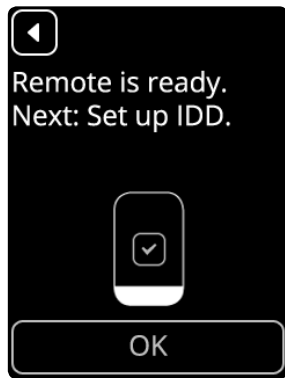


(example value)

- b. Tap blue arrows to set the number of units for each press (squeeze) of IDD side buttons. Tap **Next**.

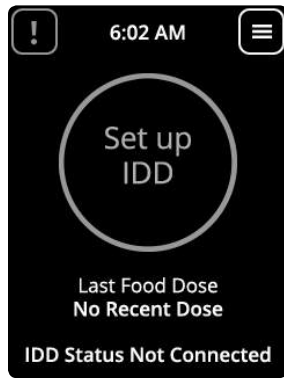
67

Step 7. Set IDD Food Dose (continued)



- C.** Setup is complete and Remote is ready.
Tap **OK**.

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- d.** The Remote Home screen is displayed. See Section 5.1 on page 82 when ready to set up an IDD.

4.3 About Remote's screen

In this section:

This section describes how to interact with the Remote's touchscreen, the information included on the Remote's Home screen, and an explanation of icons and buttons that appear on screen.

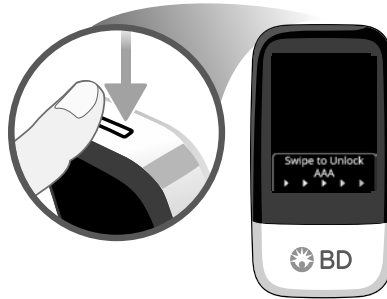


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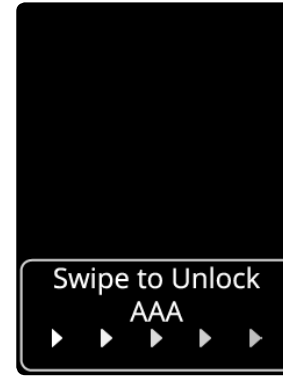
Remote's Sleep Mode:

After installing the batteries, the screen will automatically go to sleep after 45 seconds of inactivity.

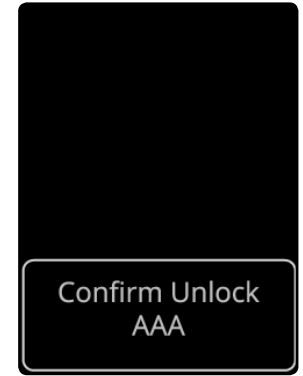
To unlock again, follow these instructions.



- a. If Remote is off, press (squeeze) and hold button on top of Remote until screen turns on.



- b. Always confirm that your Remote's name appears on the screen. Swipe your finger across arrows to unlock.

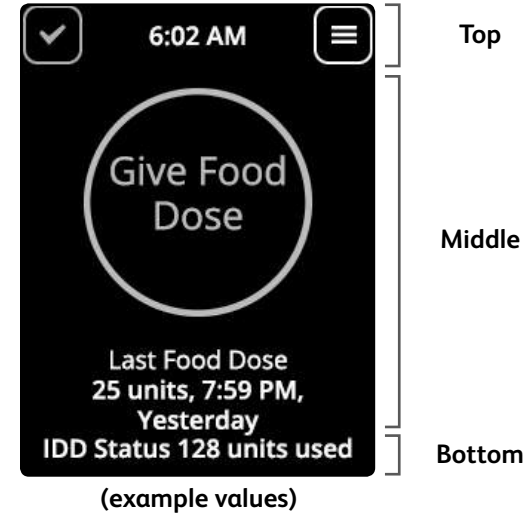


- c. Tap **Confirm Unlock** to unlock screen.

Screen areas:

Information and controls for each screen appear in three basic areas on the Remote screen:

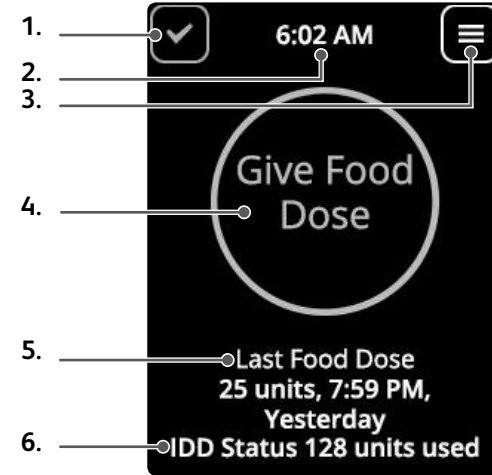
- **Top:** Includes navigation icons and time
- **Middle:** Includes primary information and/or functions for that screen
- **Bottom:** Includes more information, or a button that will send you to the next screen



Home screen:





After you have setup the Remote and IDD, the Home screen displays:



1. System's status
2. Time
3. Menu
4. Main button
5. Food Dose information
6. Total units of insulin delivered with current IDD









(example values)

Screen icons and buttons:

Icon	What it means
	Main button: This button provides different functions based on the button label:
	"Give Food Dose" to deliver insulin at meal times.
	"Press to Cancel" to cancel a Food Dose.
	"Setup IDD" to set up a new IDD.
	"Deactivate IDD" to deactivate your current IDD before setting up a new one.

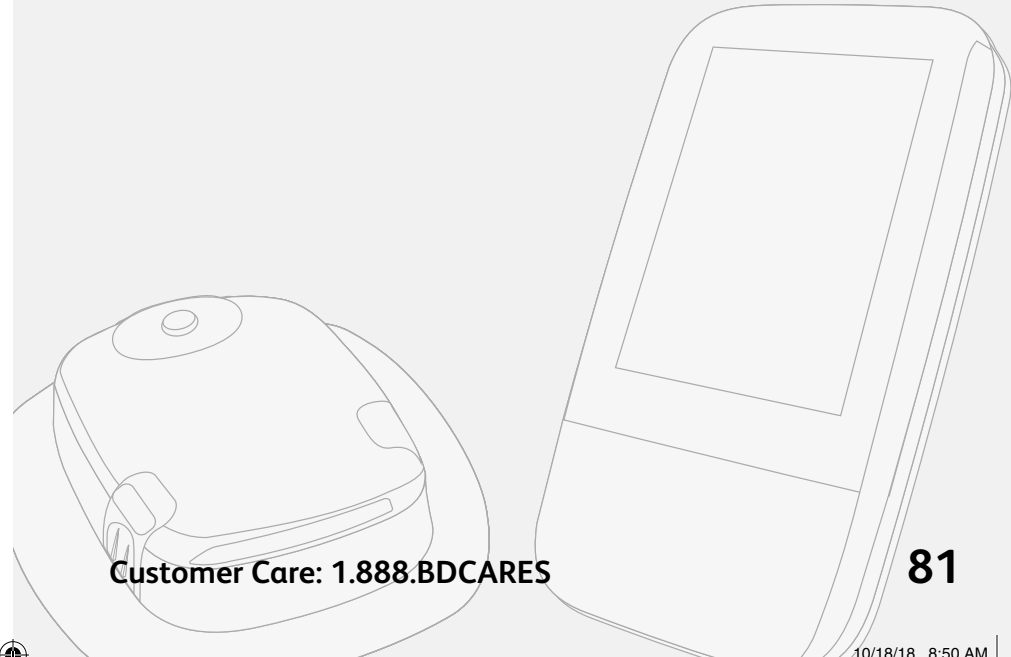
Icon	What it means
	Check mark status icon: The check mark icon means the IDD is operating normally. Tapping the icon displays information about the insulin delivered from the current IDD.
	Alert status icon: The "!" icon means the IDD Status has changed and needs attention. Tapping the icon will provide more information about the alert. Refer to Section 7.2 on page 228 for direction to use this icon.<DT>

Icon	What it means
	Menu icon: Tapping this icon will display the menu of all the system options.
	Home icon: Tapping this icon displays the Home screen.
	Back arrow: Tapping this icon displays the previous screen.
	Forward arrow: Tapping this icon will move you forward into a menu choice or onto another screen.

Icon	What it means
	Up/Down arrows: Tap these buttons to adjust a setting, such as date or Food Dose amount. Note: To make the counter advance faster, tap and hold the arrow.
	Bottom buttons: The large buttons at the screen's bottom provide different functions based on the button label (e.g., OK, Next).

5. Using BD Strive™

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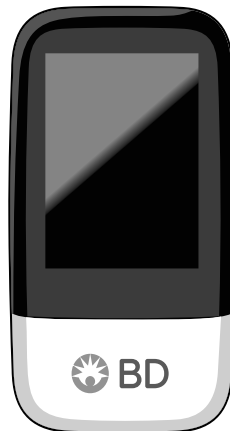
5.1 Prepare BD Strive™

Prepare BD Strive™

In this section:

The steps in this section provide instructions for connecting the IDD and filling the IDD with insulin.

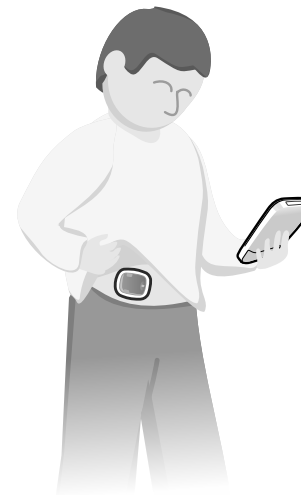
CAUTION: Make sure your Remote is properly set up, as described in Section 4.2 on page 57.



Before you start:

If you are currently wearing an IDD, you must deactivate and remove it before preparing a new IDD.

CAUTION: Before applying a new IDD, you must deactivate and remove the old IDD. See Section 5.8 on page 140 if you have not deactivated the current IDD.



Step 1. Gather supplies

Prepare BD Strive™



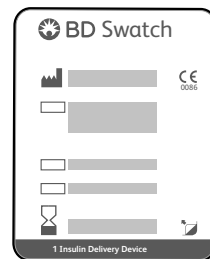
- a.** Wash your hands with soap and water, then dry them.



Remote



Your insulin
(Rapid acting Humalog®)



New IDD package



Alcohol
wipe



Sharps
container



WARNINGS:

- **DO NOT** use IDD if the package is damaged, if the IDD or insulin is past the expiration date. ⏰
- IDDs are designed for one-time use. **DO NOT** attempt to refill or reapply a used IDD.

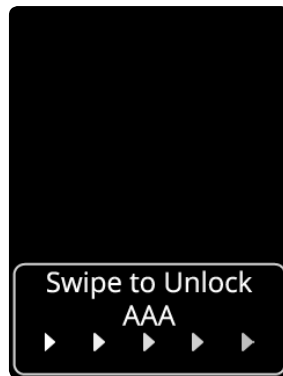
Step 2. Connect to IDD

Prepare BD Strive™

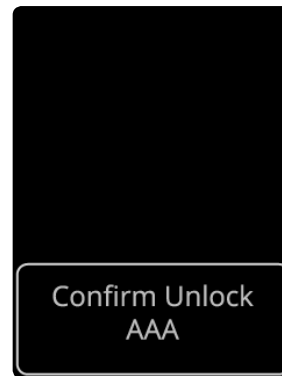


- a.** Press and hold button on top of Remote until screen turns on.

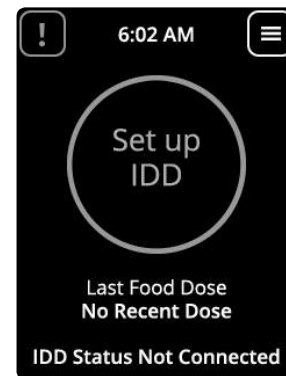
86



- b.** Always confirm that your Remote's name appears on the screen. Swipe your finger across arrows to unlock.



- c.** Tap **Confirm Unlock** to unlock Remote.

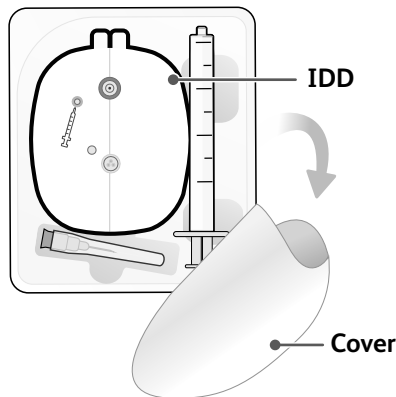


- d.** Tap **Set up IDD** circle to start setting up the IDD.

87

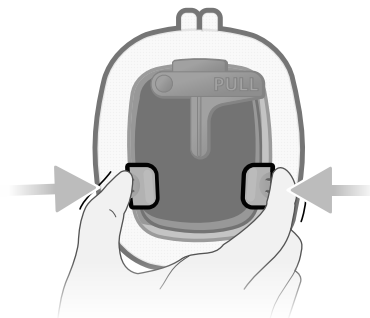
Step 2. Connect to IDD (continued)

Prepare BD Strive™



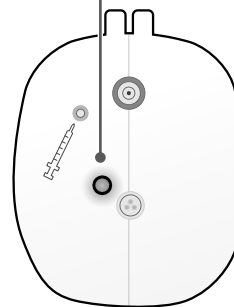
- e.** Peel IDD package cover from corner to open package. Remove IDD.

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- f.** Squeeze both IDD side buttons at the same time to wake up IDD. Look for the green light.

Green light



- g.** Once green light is on, the IDD is ready to pair. Place IDD back in the tray and place Remote on top of IDD.



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Step 2. Connect to IDD (continued)

Prepare BD Strive™



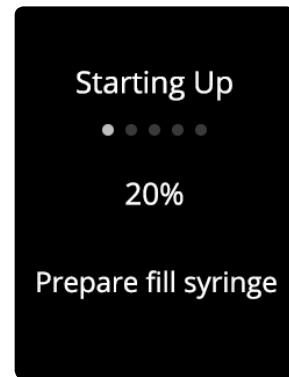
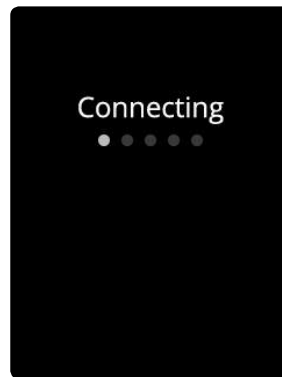
IMPORTANT:

For successful pairing, keep IDD and Remote in close range to each other (Remote above the IDD). Ensure you are at least 6 feet (2m) away from other Remotes, IDD's, or other equipment that might interfere with the pairing communication.

Once IDD is connected, you will have 60 minutes to complete setup step.

- h.** Tap **Yes** on Remote to connect to IDD. If a communication error occurs (Section on page 246) move to another room and try connecting again.

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- i.** Place IDD back into tray to help you hold IDD steady when filling. While the IDD is starting up, you can begin preparing the fill syringe. Proceed to step 3.

91

Step 3. Prepare Fill syringe

Prepare BD Strive™

My prescribed 3-day insulin name and amount:

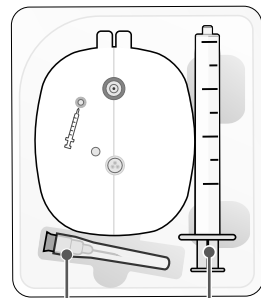
_____	U-100 insulin
_____	units

- a.** Write the insulin name and number of units your Healthcare Provider prescribed for 3 days here.

92

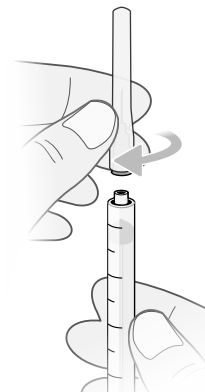


- b.** Clean insulin vial top with alcohol swab.



Filling needle
Filling syringe

- c.** Remove Filling syringe and Filling needle from IDD package.

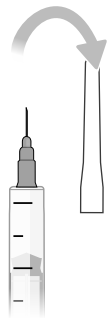


- d.** Screw Filling needle onto Filling syringe until it stops.

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Step 3. Prepare Fill syringe (continued)

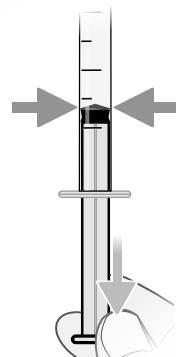
Prepare BD Strive™



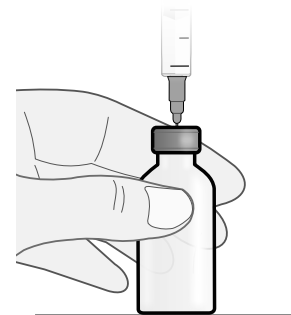
e. Remove needle guard.

IMPORTANT:

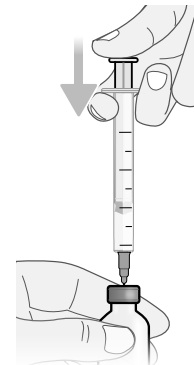
Use care after removing the needle guard and exposing the needle.



f. Pull plunger out until it aligns with the 3-day insulin amount you were prescribed.



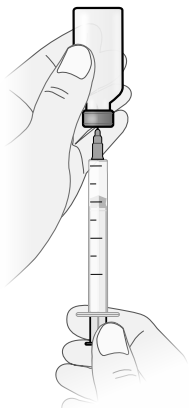
g. Place vial on table and insert needle into vial.



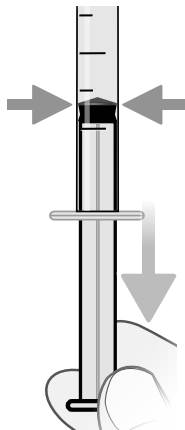
h. Press plunger all the way to push all air out of syringe and into vial.

Step 3. Prepare Fill syringe (continued)

Prepare BD Strive™



- i. Turn vial and syringe upside down together.

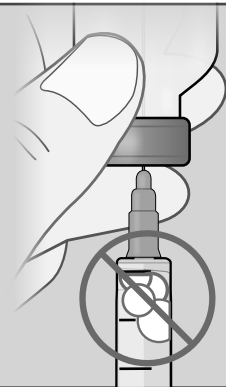


- j. Slowly pull plunger out until top ring of plunger aligns with the 3-day insulin amount you were prescribed.

WARNING:

If you see air bubbles (larger than a grain of rice):

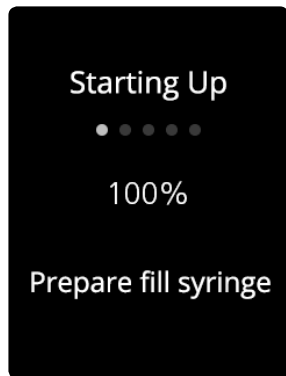
- a) Tap syringe with your finger to move bubbles to the top.
- b) Push plunger to push air back into vial.
- c) Pull plunger out again to withdraw insulin.



- k. Make sure there are no bubbles in the syringe that are larger than a grain of rice. If there are, follow instructions above.

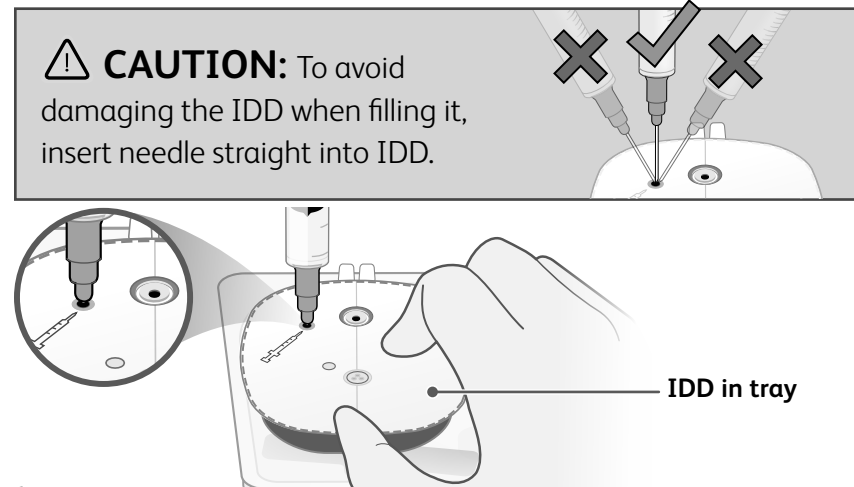
Step 4. Fill IDD with insulin


Prepare BD Strive™



- a.** Once Startup is complete, the Remote will prompt you to fill the IDD with insulin.

98

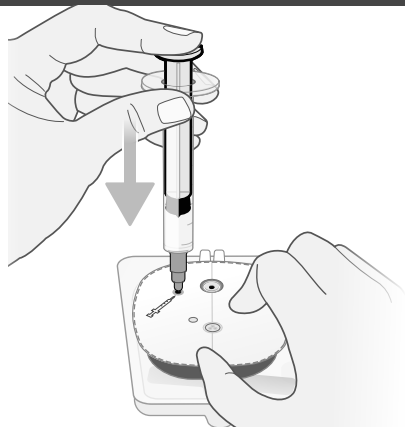


- b.** Insert needle straight into IDD fill port (marked with syringe icon ) until it stops.

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Step 4. Fill IDD with insulin (continued)

Prepare BD Strive™



- c.** Press plunger down all the way to inject entire syringe contents. Continue to **hold plunger down** and pull needle out of IDD.



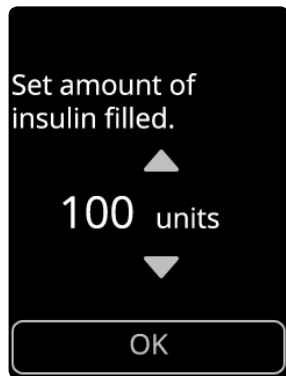
- d.** Fill syringe and needle are for single use only. Immediately dispose of the fill syringe and needle in the sharps container after use.



- e.** Tap **OK** on Remote after filling the IDD.

Step 5. Prepare IDD

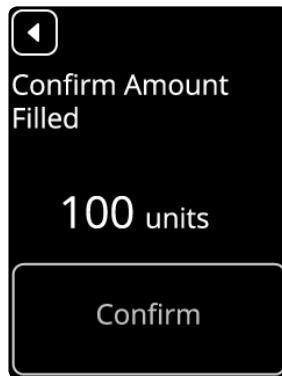
Prepare BD Strive™



(example value)

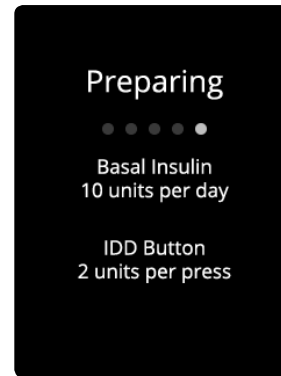
- a.** Tap blue arrows to enter the number of insulin units you put into the IDD, then Tap **OK**.

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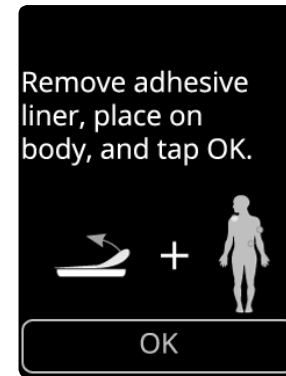
(example value)

- b.** Tap **Confirm** on Remote.



(example values)

- c.** Wait while IDD prepares itself. It is normal to hear sounds coming from the IDD.

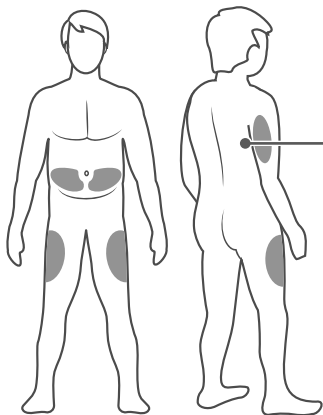


- d.** Wait until Remote prompts you to apply IDD, then proceed to step 6.

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Step 6. Select and prepare site

Prepare BD Strive™



Rotate to a different
site each time you
apply a new IDD

- a.** Before applying the IDD, you must first choose a site on your body. The graphic indicates in green the places on your body that you should use.

IMPORTANT:

- ✓ Although the abdomen might be easier to see and use, **it is important to rotate the sites you use to place the IDD.** Rotate to a different site each time you apply a new IDD. A new insertion site should be at least 1 inch (2.5 cm) away from the last site. You should not use the same insertion site again for 7-10 days.
- ✓ **Avoid** areas where belts, waistbands, or tight clothing might interfere with the IDD.
- ✓ **Avoid** placing the IDD near thick hairs, areas of infection, folds of skin, bony areas, scar tissue, visible blood vessels, body piercings, tattoos, or within 2 inches (5cm) of your navel.

Step 6. Select and prepare site (continued)



- b.** Clean site with an alcohol wipe and let it air-dry.

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IMPORTANT:

- ✓ **Cleaning the site will help prevent skin infection or irritation**, and keep your skin healthy.
- ✓ **Changing your IDD after a shower** is a good practice.

Step 7. Apply IDD and insert catheter

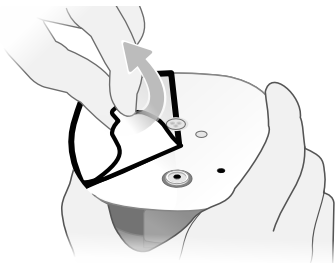
IMPORTANT:

- ✓ **DO NOT remove safety cap and do not press insertion button** until instructed on the Remote's screen. Removing the safety cap prematurely might result in unintended activation of the insertion mechanism needle. If the button is activated and the needle sticks out before applying the IDD to the body, discard the IDD and repeat setup with a new IDD.
- ✓ **Discard IDD** if needle is sticking out of IDD.
- ✓ **Dropping IDD** might trigger the insertion button.
- ✓ **DO NOT apply IDD** to wet skin.

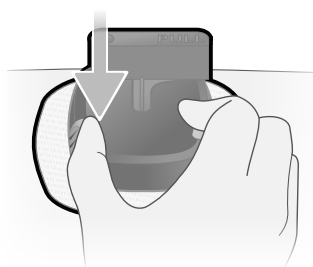
107

Step 7. Apply IDD and insert catheter (continued)

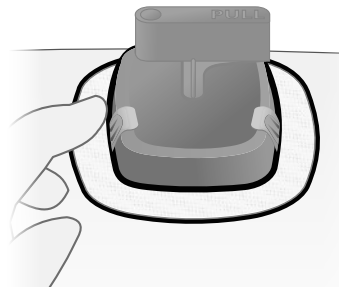
Prepare BD Strive™



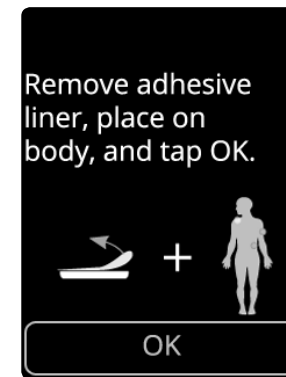
- a.** Remove paper pieces to expose adhesive on back of IDD.



- b.** Place IDD on insertion site and apply firm pressure for 10 to 15 seconds.



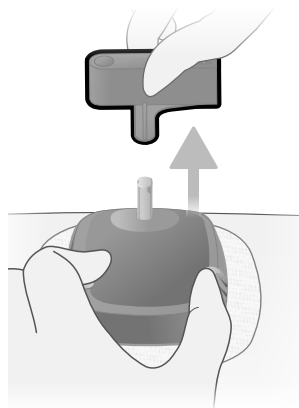
- c.** Press edges of adhesive pad down with your finger.



- d.** Tap **OK** on Remote.

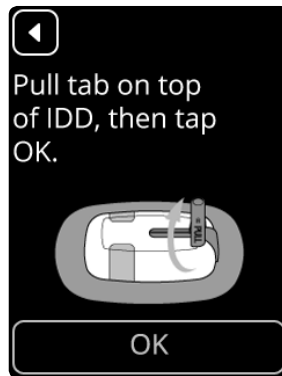
Step 7. Apply IDD and insert catheter (continued)

Prepare BD Strive™

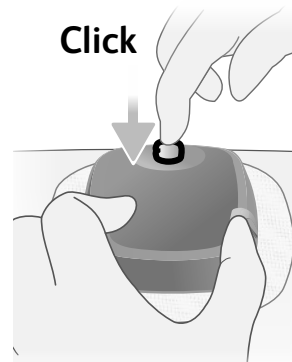


- e.** Remove orange IDD safety cap (tab) by pulling it straight out from IDD.

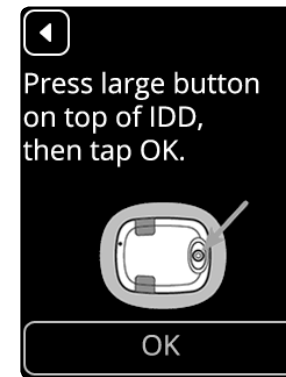
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- f.** Tap **OK** on Remote.



- g.** Press the button on top of IDD all the way down until it locks in place. This inserts the catheter into your skin.

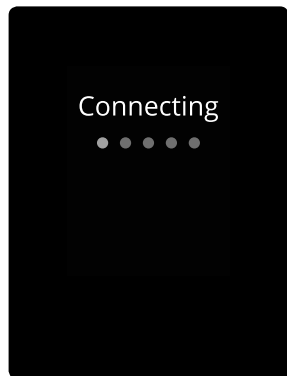


- h.** Tap **OK** on Remote.

111

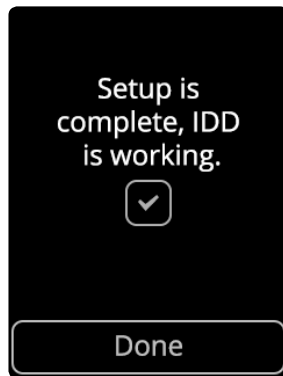
Step 8. Complete IDD setup

Prepare BD Strive™

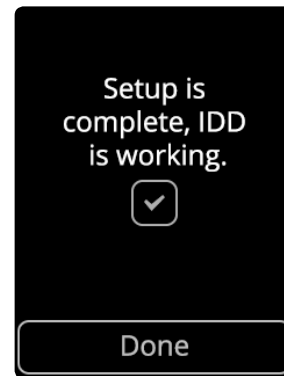


- a.** After you insert the catheter and tap **OK**, Remote will connect to IDD.

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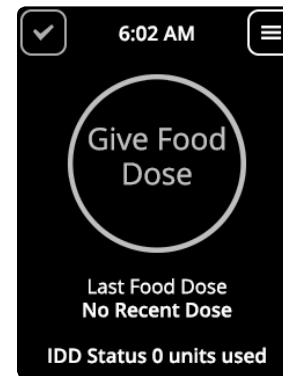


- b.** A green check mark should appear to show your IDD is working.



(example values)

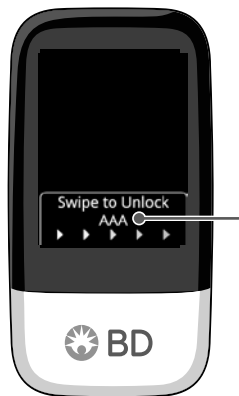
- c.** Tap **DONE** on Remote. **IDD Setup is complete.** Your IDD is now delivering basal insulin.



(example values)

- d.** The Remote's Home screen appears with "Give Food Dose" circle. See Section 5.3 or Section 5.4 if you need to deliver a Food Dose.

Step 8. Complete IDD setup (continued)



Remote
name

IMPORTANT: Once paired, your Remote is only communicating to your IDD. Be careful not to use another person's Remote. When unlocking the Remote screen, confirm your Remote name is correct prior to completing any action, such as delivering a dose or changing device settings.

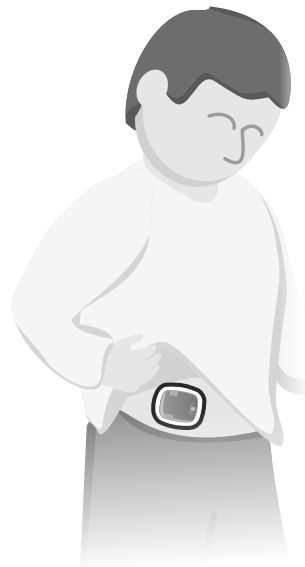
- e. After set up, each time you use the Remote, confirm your Remote name appears on the unlock screen.

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5.2 Safety tips when wearing your IDD

In this section:



Once you have set up the IDD, follow the warnings and tips in this section to ensure safe and proper use while wearing the IDD.



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 **WARNING:** If your device is damaged or dropped, it might not deliver insulin properly. Ensure that it is still working properly. If you are unsure as to potential damage, call Customer Care at **1.888.BDCARES**.

Safety tips for the IDD:

-  **Check to see that IDD is secure** throughout the day. **DO NOT loosen patch during use.** During use, do not loosen the IDD adhesive patch or dislodge the catheter. Check the insertion site often; if you do not insert the catheter properly Hyperglycemia might result.
-  **DO NOT apply to fragile/irritated skin.** If the insertion site becomes inflamed or shows signs of infection, remove the IDD and replace with a new IDD at a different insertion

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site until the first site has healed. Replace the IDD if the adhesive patch lifts from the skin, or if the catheter becomes fully or partially dislodged from the skin.



Avoid inadvertently pressing (squeezing) the side buttons. Inadvertent presses (squeezes) will lead to giving unintended doses of insulin, which could lead to Hypoglycemia. If you accidentally press (squeeze) side buttons, check your blood glucose immediately and follow the plan you made with your Healthcare Provider for treating Hypoglycemia. You can cancel doses given by button press using your Remote at any time, see Section 5.5 on page 128.



Disposal. IDDs should always be discarded in a sharps container. When disposing, be sure to follow your local disposal regulations.

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5.3 Delivering a Food Dose using Remote

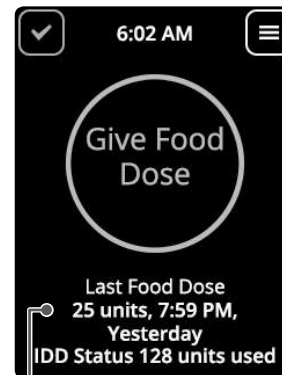
Delivering a Food Dose using Remote

In this section:

Follow the instructions in this section to set and start a Food Dose using the Remote.

Before you start:

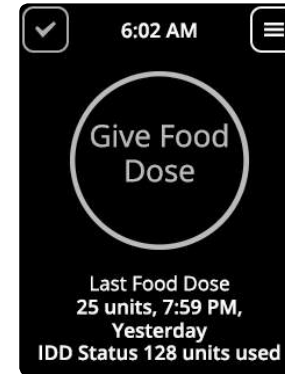
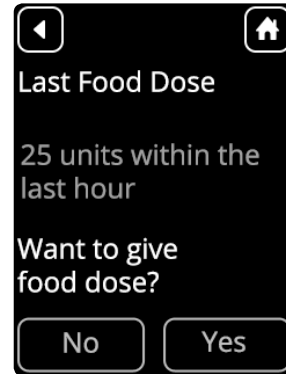
Before giving yourself a Food Dose, check the Food Dose information (time and amount of your last dose) on the Home screen.



(example values)

Food Dose
information

IMPORTANT: If it has been less than 1 hour since your last food dose, the following screen will appear to alert you that you have recently received a dose. If you still want to give an additional dose, then tap **Yes** to proceed.



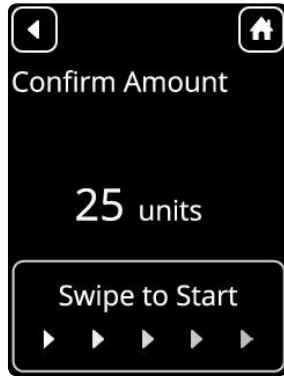
(example values)

a. Tap **Give Food Dose** circle on Remote's Home screen.

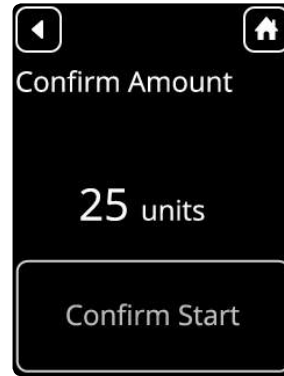


(example value)

b. Tap blue arrows to adjust Food Dose amount, then tap **OK**



(example value)



(example value)

- c. Swipe your finger across arrows, then tap **Confirm Start** to start dose.

122



(example value)

- d. Once started, the screen displays the Food Dose's progress.

IMPORTANT: Once the Food Dose has started, you can cancel the dose if needed by tapping **Press to Cancel** circle on the Remote's screen. See Section 5.5 on page 128 for more information on how to cancel your Food Dose.

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5.4 Delivering a Food Dose using IDD

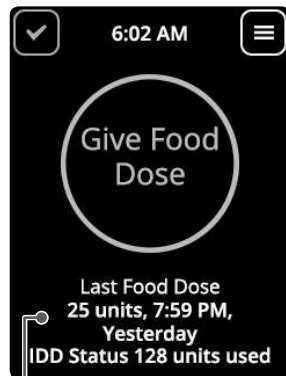
Delivering a Food Dose using IDD

In this section:

Follow the instructions in this section to set, confirm, and start a Food Dose using the IDD.

Before you start:

Before giving yourself a Food Dose, consider when you delivered your last dose. If you have your Remote, check the Food Dose information (time and amount of your last dose) on the Home screen.

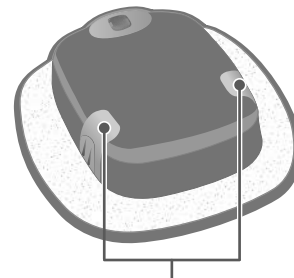


(example values)


Food Dose
information

- a. Make sure you know how much insulin is delivered each time you squeeze the side buttons.

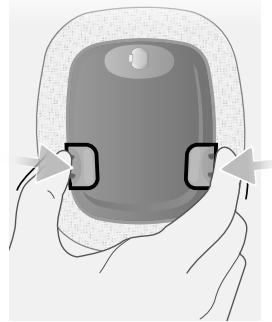
To view the current setting, or if your Healthcare Provider (HCP) advised you to change the amount of insulin delivered with each squeeze, see Section 5.11 on page 158 for more information.



IDD side buttons

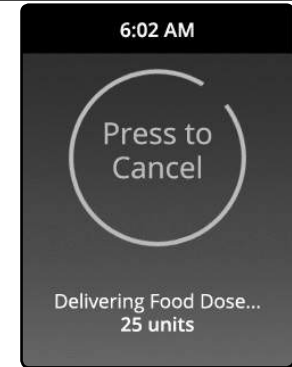
-  Use the IDD food dose button stickers and wallet card provided in your starter kit as helpful reminders of your units of insulin per button press setting.

- b.** To deliver your dose, **squeeze and release firmly and quickly both IDD buttons at the same time.** Each squeeze of the IDD buttons equals a preset number of units. For example, if your preset units is set at 5 units per press (squeeze) and you need 20 units, you would squeeze the side buttons 4 times. You can feel each squeeze, and may hear a click with each press.



⚠ CAUTION: If you lose count while squeezing IDD side buttons, **STOP, wait 30 minutes**, then check your blood glucose. Treat as instructed by your healthcare provider. For additional information on how to treat hypoglycemia, refer to page 185.

- c.** IDD will start delivering the dose about 5 seconds after your last squeeze. Once started, you will hear the pump begin to deliver and the Remote screen will display the Food Dose progress. **You can always verify your dose using the Remote if you are unsure of your IDD button presses (squeezes).**



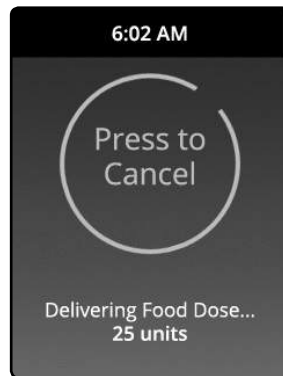
(example value)

IMPORTANT: Once the Food Dose has started, you can cancel the dose if needed by tapping **Press to Cancel** circle on the Remote's screen. See Section 5.5 on page 128 for more information on how to cancel your Food Dose.

5.5 Canceling a Food Dose

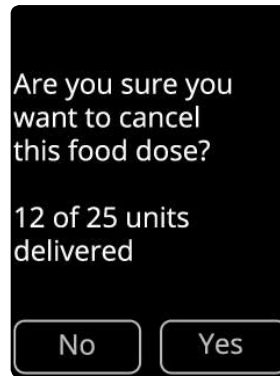
In this section:

This section explains how to cancel your Food Dose delivery if needed.



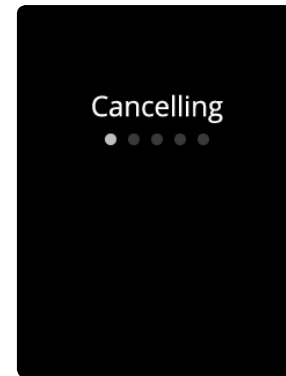
(example value)

- a.** Tap **Press to Cancel** circle on Remote's Home screen if you want to stop the Food Dose.



(example value)

- b.** Tap **Yes** to confirm.
Tap **No** to continue Food Dose.



- c.** After you confirmed, Remote will cancel the Food Dose.

5.6 Checking your insertion site regularly

In this section: This section explains the issues to look for when checking your insertion site.

As part of your daily routine, check the insertion site area around the IDD at least once per day. Each time you change the IDD, check the actual insertion site after removing the empty IDD.

Check for signs of an infection or adverse reaction, such as:

- Redness
- Heat
- Swelling
- Hardness
- Pain
- Soreness
- Discharge

In addition, check for signs of insulin leakage by looking for wetness around the insertion site.



WARNING:

If you notice any signs of infection or leakage:

1. Replace IDD with new IDD at a different site location.
2. Check your blood glucose level. Contact your **Healthcare Provider** and follow their instructions.

5.7 Checking IDD Status

In this section:

This section explains how to check your IDD Status from the Remote's home screen. For more information on different IDD Status notifications and errors, see Section 7.3 on page 240.

IDD Status and Food Dose information:

The Remote Home screen displays two types of information about the IDD at the bottom of the screen:

- **IDD Status.** The IDD Status displays the total units of insulin delivered since you set up your IDD.



IDD Status

(example values)

Food Dose
information

- **Food Dose information.** The Food Dose information displays information about the last Food Dose delivered within a given 24-hour period. The table on the next page will explain the different messages you might see.

Food Dose state

What it means

Last Food Dose

Provides the units and time of the last Food Dose delivered.

Partial Food Dose

A Food Dose started, but only part of the dose finished delivering. The units and time of the last Food Dose that were successfully delivered are provided.

No Recent Dose

No recent Food Dose has been delivered over the last 24 hours.

Status icon:

The status icon in the Home screen's top left corner provides information on the status of your IDD.

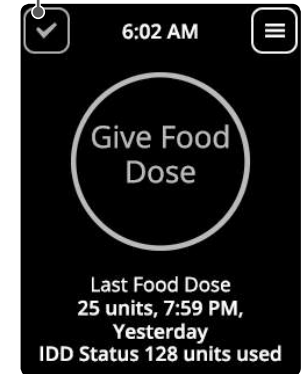


A check mark icon means the IDD is operating normally.



An alert icon “!” means the IDD Status has changed and needs attention.

Status icon

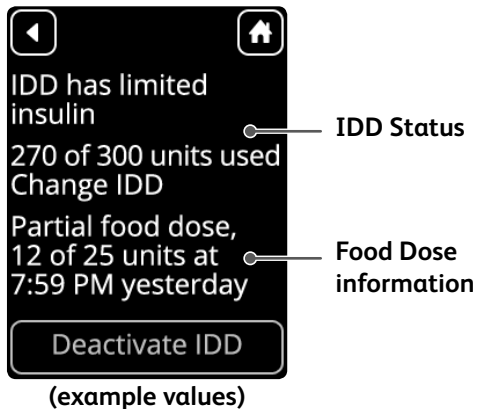


(example values)

To learn more about your Food Dose and status of your IDD, tap on the status icon in the Home screen's top left.

IDD Status screen:

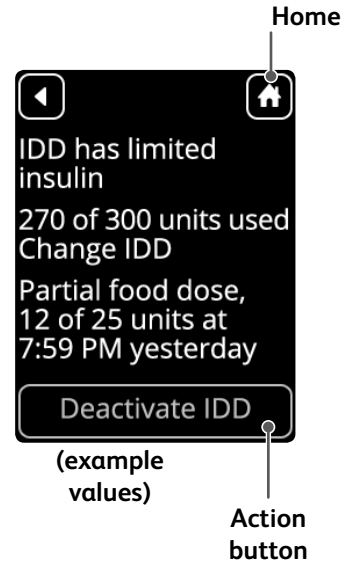
The IDD Status screen will be displayed.



The IDD Status screen displays two types of information:

- **IDD Status.** The IDD Status provides information on the status of your IDD, the amount of insulin used, and what action to take. For more information on different IDD Status notifications and errors, see Section 7.3 on page 240.
- **Food Dose information.** The Food Dose information displays the number of units and time of your last administered Food Dose for a 24-hour time period.

- **Action button** at the bottom of the screen enables you to deactivate your IDD or set up a new IDD.
- **Home icon** at the top of the screen enables you to return to the Home screen (e.g., if you do not want to take action from the IDD Status screen).



5.8 Replacing an IDD

Replacing an IDD

In this section:

When “IDD Status Empty,” “IDD Status Expired,” or “Deactivate IDD” appears on Remote (typically after 3 days), you must deactivate and replace the IDD.

Follow the instructions in this section to deactivate and remove your IDD.



CAUTION: When changing IDD, and before bedtime:

- Avoid changing your IDD before bedtime or if you will not be able to test your BG at least 1–2 hours after a new IDD is placed.
- Before bed, always check that your IDD has insulin to last through the night.

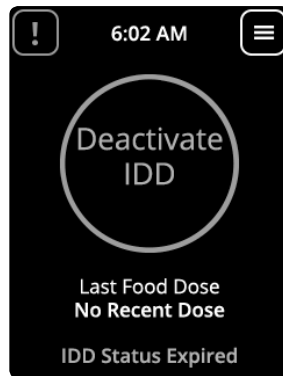
IMPORTANT: You cannot restart or reuse your IDD once you have deactivated the device.

Step 1. Deactivate current IDD

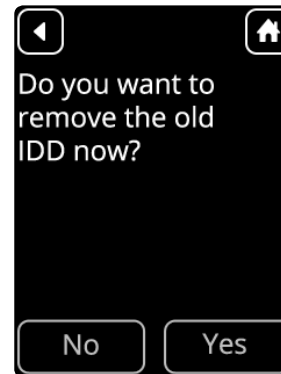
Replacing an IDD



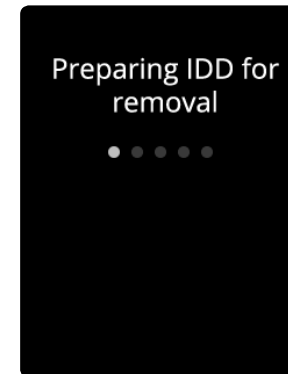
- a.** Wash your hands with soap and water, then dry them.



- b.** Tap **Deactivate IDD** circle.

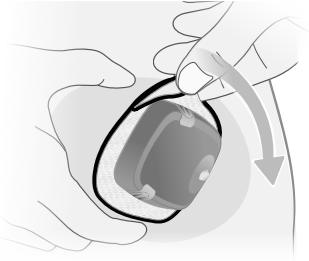


- c.** Tap **Yes** to confirm you want to remove the old IDD.



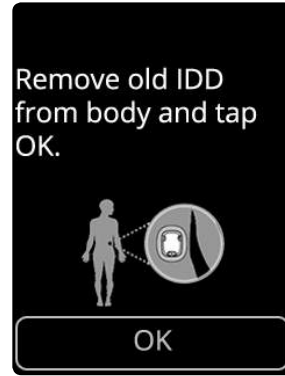
- d.** Wait while Remote deactivates IDD.

Step 1. Deactivate current IDD (continued)



- e.** When Remote prompts you to, gently peel adhesive edges and remove IDD from your skin.

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- f.** Tap **OK** on Remote.

Step 2. Safely dispose of IDD



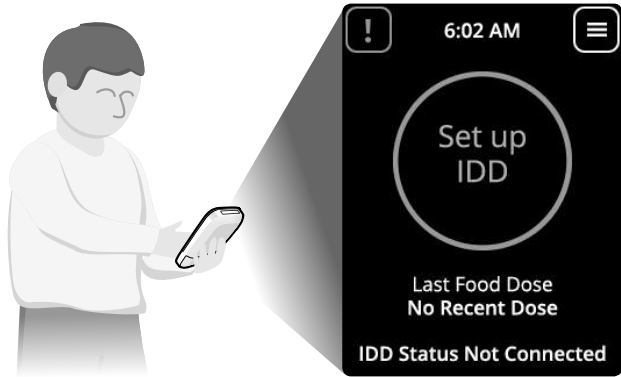
- a.** Discard IDD in sharps container.

⚠ WARNING: Please follow your local laws when disposing of the BD Strive™.

After use, parts of the BD Strive™ are considered biohazardous and can potentially transmit disease.

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Step 3. Prepare and apply new IDD



- a.** After tapping **OK** on the previous step, the Remote will display “Set up IDD.” Refer to Section 5.1 on page 82 to prepare and apply the new IDD.

5.9 Viewing dose history

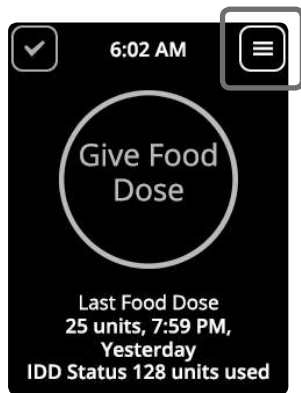
In this section:

This section provides instructions for viewing your dose history.


Your dose history helps you to keep track of your daily doses, as well as your Food Dose averages over the last 7, 14, and 30 days. It also helps you and your Healthcare Provider keep better track of your overall insulin and diabetes management.

Viewing today's doses

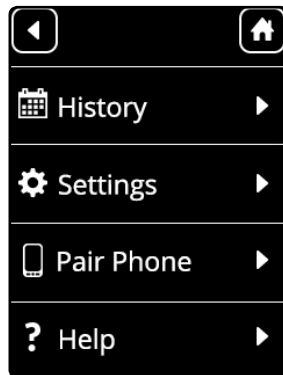
Viewing dose history



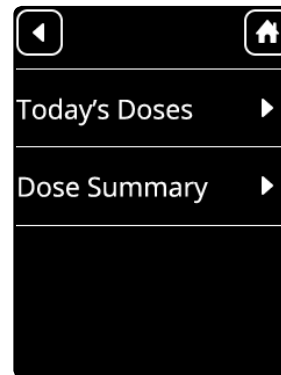
(example values)

- a.** On the Home screen, tap the Menu icon  in the top right corner.

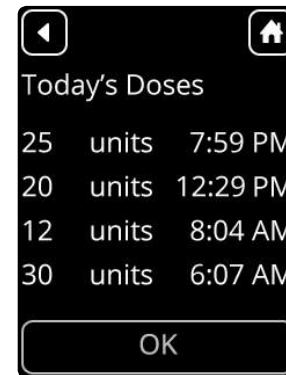
148



- b.** Tap on  **History**



- c.** To view your doses from today, tap **Today's Doses**.



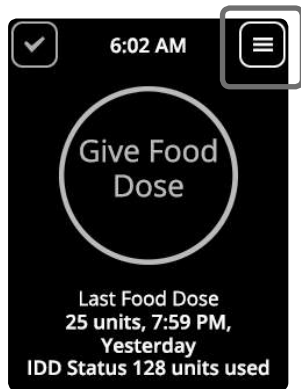
(example values)

- d.** Your Food Dose volumes and delivery times are displayed here. To exit the screen, tap **OK**.


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Viewing today's doses

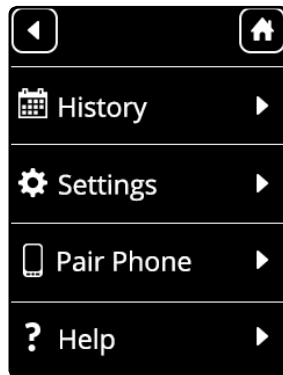
Viewing dose history



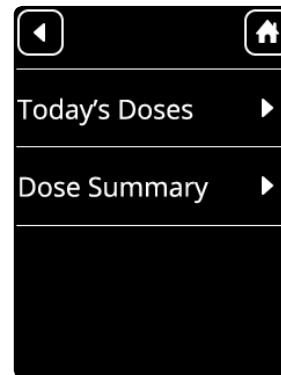
(example values)

- a.** On the Home screen, tap the Menu icon  in the top right corner.

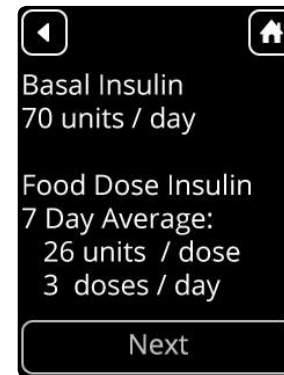
150



- b.** Tap on  **History**



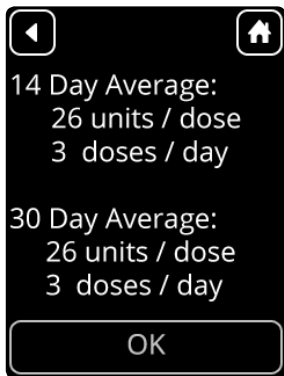
- c.** To view summaries of your average dose over 7, 14, and 30 days, tap on **Dose Summary**.



(example values)

- d.** Your basal insulin rate and Food Dose insulin averaged over the last 7 days is displayed. Tap **Next** 151

Viewing today's doses




(example values)

- e. Your Food Dose insulin averaged over the last 14 and 30 days is displayed. Tap **OK** to exit.

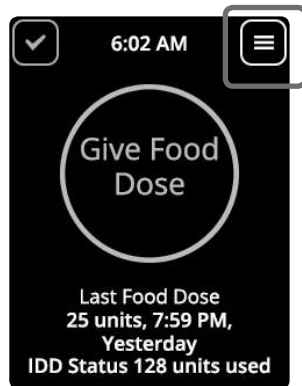
5.10 Changing basal insulin rate

In this section:


This section provides instructions on how to change the basal insulin rate. Basal insulin is the constant flow of insulin you receive each day.

 **WARNING:** Incorrect insulin delivery settings could lead to **low blood sugar (Hypoglycemia)** or **high blood sugar (Hyperglycemia)**.

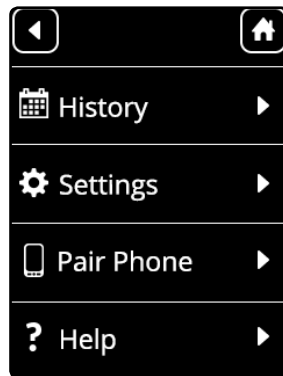
IMPORTANT: Before you make any changes to your insulin rate, consult with your Healthcare Provider.



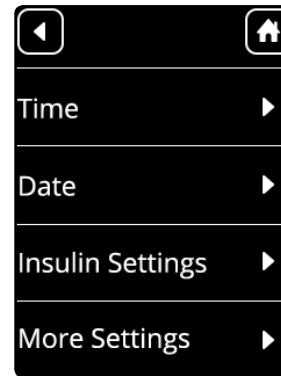
(example values)

- a.** On the Home Screen, tap the Menu icon  in the top right corner.

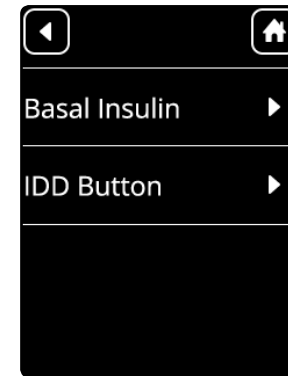
154



- b.** Tap  **Settings**

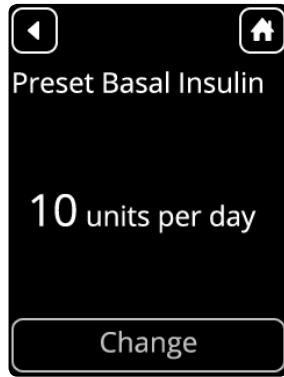


- c.** Tap **Insulin Settings**.




- d.** To change the basal insulin settings, tap **Basal Insulin**.

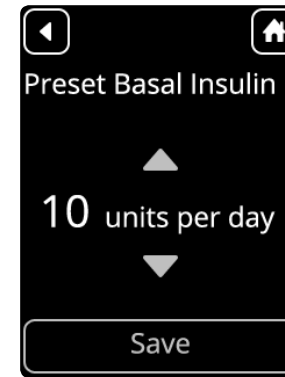
155



(example value)

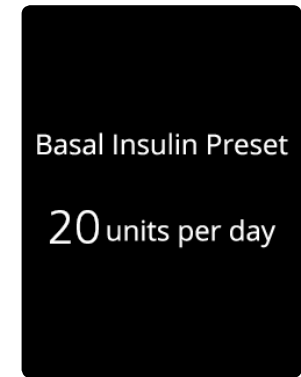
- e.** Screen displays current basal insulin rate. To change the rate, tap on **Change**.
 Note: if you do not want to change the current setting, tap the Home icon  to return to the Home screen.

156



(example value)

- f.** Tap blue arrows to change the basal insulin rate (units delivered per day). Tap **Save**.



(example value)

- g.** You have now changed the basal insulin rate.

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5.11 Changing IDD button insulin settings

Changing IDD button insulin settings

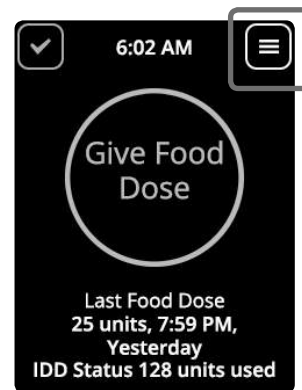
In this section:

This section provides instructions on how to change the amount of insulin delivered with each squeeze of the IDD buttons when you give yourself a Food Dose (extra insulin at meal times).


⚠ WARNING: Incorrect insulin delivery settings could lead to **low blood sugar (Hypoglycemia)** or **high blood sugar (Hyperglycemia)**.

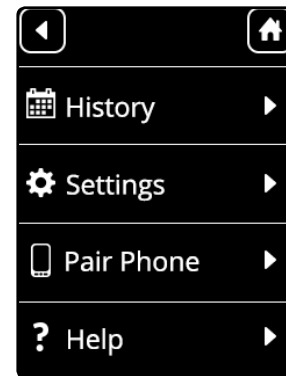
IMPORTANT: Before you make any changes to your insulin settings, consult with your Healthcare Provider.

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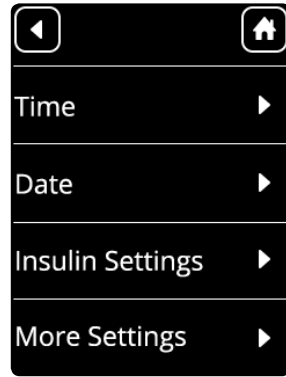
(example values)

- a. On the Home Screen, tap the Menu icon  in the top right corner.



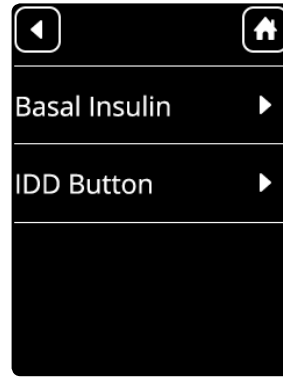
- b. Tap  **Settings**

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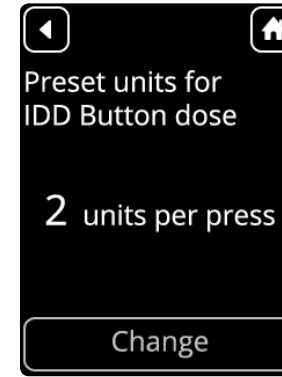


c. Tap on **Insulin Settings**.


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d. To change the IDD button insulin settings, tap **IDD Button**.

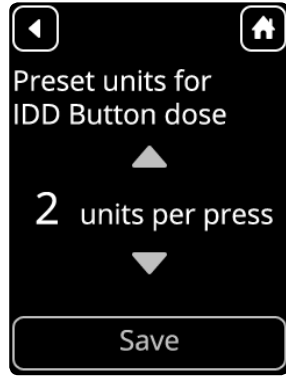


(example value)

e. Screen displays current preset units for the IDD button dose. To change the preset units, tap **Change**.
Note: if you do not want to change the current setting, tap the Home icon  to return to the Home screen.

161

5.12 Changing date



(example value)

- f.** Tap blue arrows to change the number of units for each press (squeeze) of IDD side buttons. Tap **Save**.

162

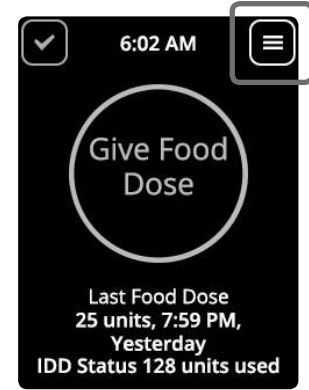


(example value)


- g.** You have now changed the IDD button preset.

In this section:

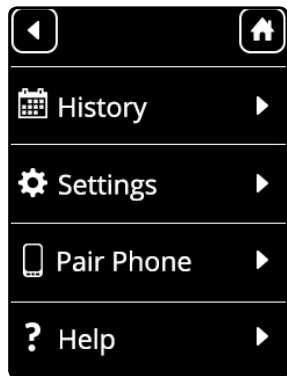
This section provides instructions on how to change the date setting (year, month, and day) on your Remote.



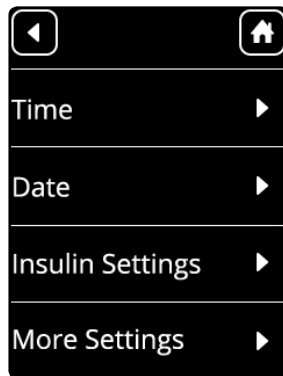
(example values)

- a.** On the Home screen, tap the Menu icon  in the top right corner.

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b. Tap on  **Settings**



c. Tap on **Date**.



d. Tap blue arrows to change the date (year, YYYY; month, MM; and day, DD).

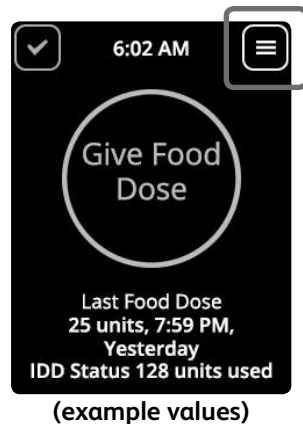



e. Tap **Save**. You have now set the date.

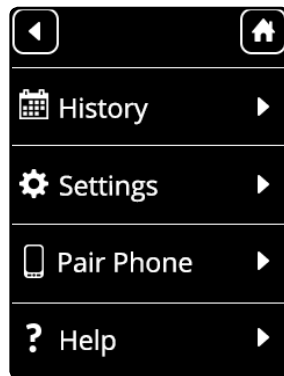
5.13 Changing time

Changing time

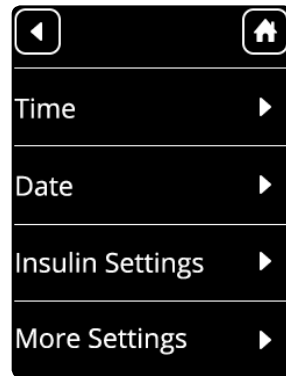
In this section: This section provides instructions on how to change the time format (12-Hour or 24-Hour) and time (hour, minute, and AM/PM) settings on your Remote.



- a.** On the Home screen, tap the Menu icon  in the top right corner.

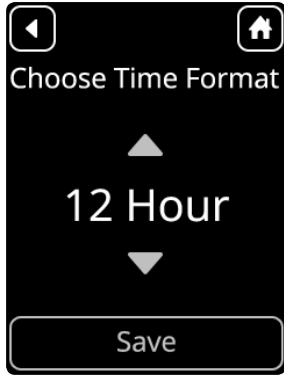


- b.** Tap on  **Settings**



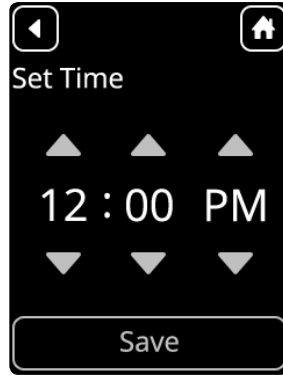
- c.** Tap on **Time**.

5.14 Changing language



- d.** Tap blue arrows to change the time format (12-Hour or 24-Hour). Tap **Save**.

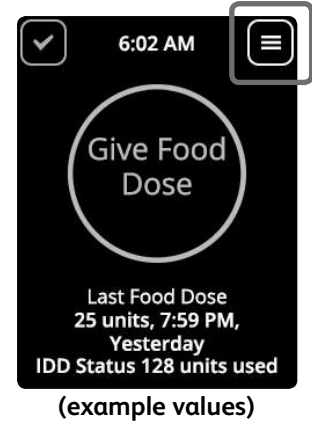
168




- e.** Tap blue arrows to change the time (hour, minute, and AM/PM). Tap **Save**.
You have now set the time.

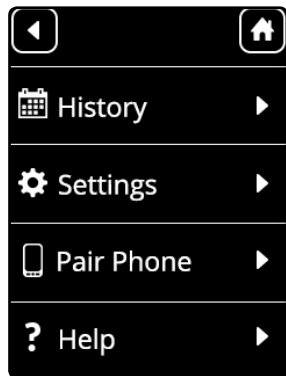
In this section:

This section provides instructions on how to change the language setting on your Remote.

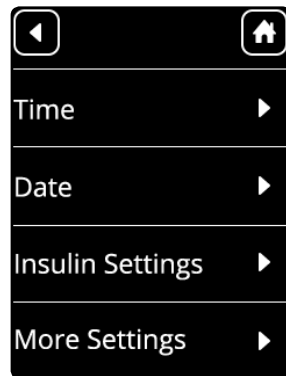


- a.** On the Home screen, tap the Menu icon  in the top right corner.

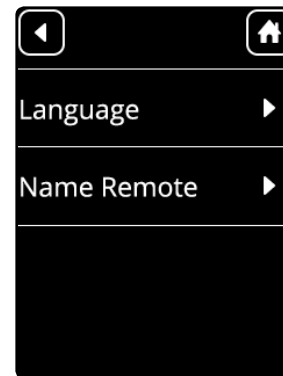
169



b. Tap on  **Settings**.



c. Tap on **More Settings**.



d. Tap on **Language**.



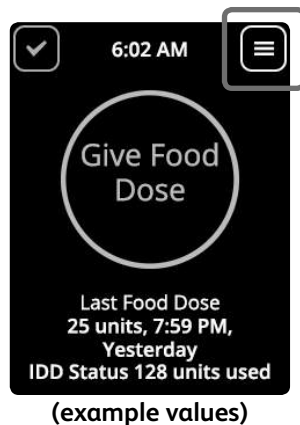
e. Tap blue arrows to change the language. Tap **Save**. You have now changed the language.


5.15 Changing Remote name

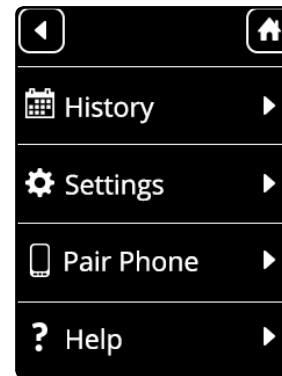
Changing Remote name

In this section:

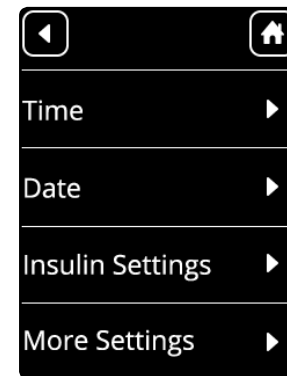
This section provides instructions to help you change the name of your Remote so you can recognize your own Remote.



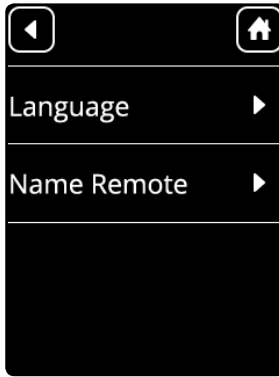
- a.** On the Home screen, tap the Menu icon  in the top right corner.



- b.** Tap on  **Settings**

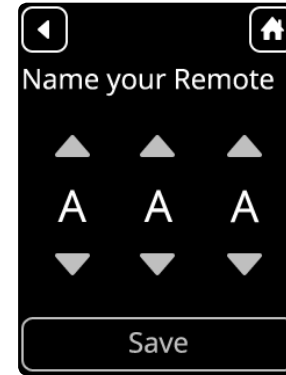


- c.** Tap on **More Settings**.



d. Tap on **Name Remote**.

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e. Tap blue arrows to set a 3-letter Remote name (three letters (A-Z) or numbers (0-9)).

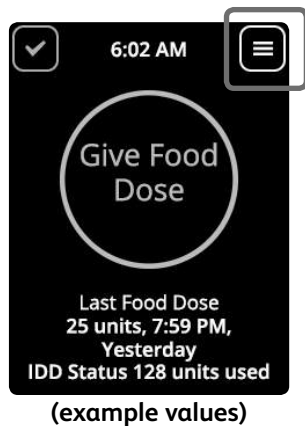
f. Tap **Save**. You have now set the Remote name.


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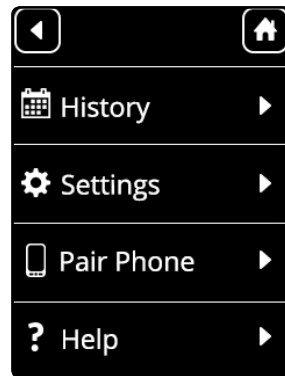
5.16 About Remote

In this section:

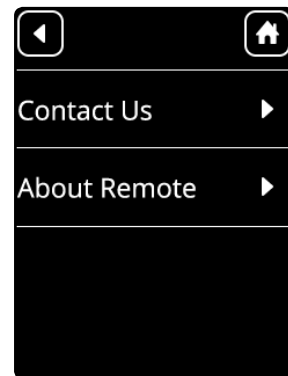
This section provides instructions on identifying the serial number and software version of your Remote.



- a.** On the Home Screen, tap the menu icon  in the top right corner.



- b.** Tap on  **Help**



- c.** Tap on **About Remote**.



(example values)

- d. The serial number of the Remote and software versions are displayed. If an IDD is not currently paired, no software version will be listed for the IDD.

5.17 Pairing Remote with Smartphone

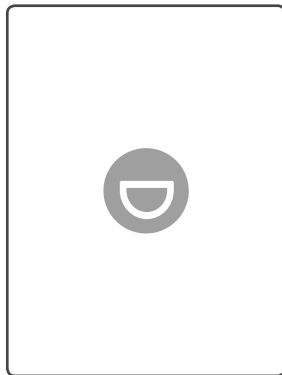
Pairing Remote with Smartphone

In this section:

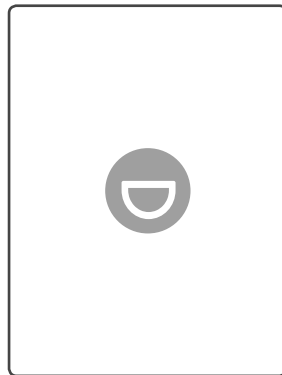
Follow the instructions in this section to pair your Remote to your smartphone and view your dose history on your smartphone.

Before you start:

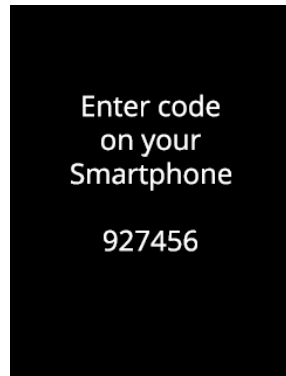
Make sure the Bluetooth is turned on in your smartphone settings



- a.** Download the mobile app from your App Store, and launch the application on your phone.



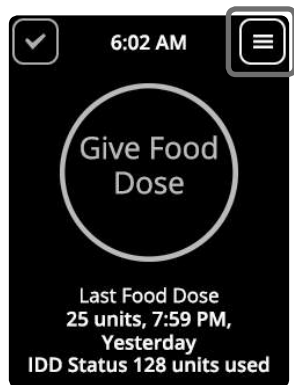
- b.** Follow the application instructions to connect to your Remote.



- c.** When prompted, enter the six digit code provided on your Remote into your smartphone

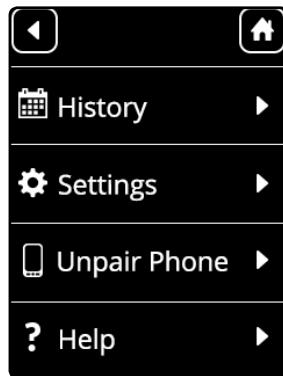
Unpair your Remote

Unpair your Remote

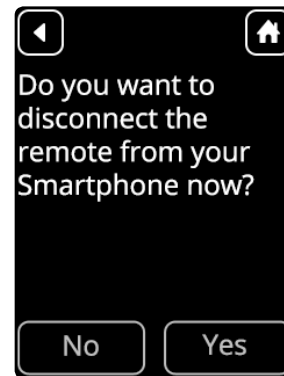


a. On your Remote home screen, tap the menu icon in the top.

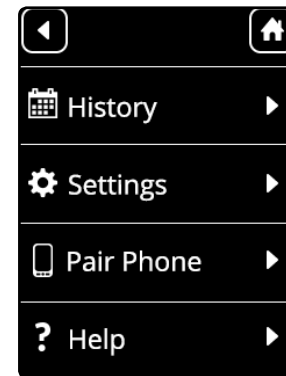
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b. Tap on  **Unpair Phone**



c. Tap on **Yes**.



d. Your Remote is now disconnected. Tap  or  to return to the home screen.

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5.18 Get the most from BD Strive™

Get the most from BD Strive™

In this section:

This section provides information about how to get the most from BD Strive™ by keeping the Remote accessible, communication with the IDD, and data security. This section also provides information on the temperature ranges in which you should use BD Strive™.

Remote should be accessible:

Since the IDD and Remote communicate wirelessly, you do not need to keep the Remote right next to the IDD for it to work.

Once you have paired your IDD for up to 72-hours, the IDD continues to deliver your basal insulin 24-hours a day, regardless of your Remote's location.

If you have forgotten your Remote somewhere, you can still deliver a Food Dose using the IDD buttons. Each squeeze of the IDD buttons will deliver the amount you set during setup.

You can use your Remote to deliver a Food Dose, check that your BD Strive™ system is working properly, change the basal rate, and check your insulin dose history, so remember to keep it with you so you can check your Remote at least 3 times a day and as often as you check your blood glucose.

Communicating with your IDD:

When you use your Remote to communicate with the IDD, hold the Remote at least 6 feet (2m) away from other Radio Frequency (RF) devices (other Remotes and IDDs, cell phones, etc).

During normal operation, the BD Strive™ system can withstand normal radio interference and electromagnetic fields.

However, as with all wireless communication technology, certain operating conditions can interrupt communication. In these cases, interruptions are easy to resolve (see "Communication error" on page 246246).

Data security:

Your IDD is programmed to only accept RF communications from the recognized Remote. This is programmed during the pairing step during "IDD Setup." The BD Strive™ ensures data security using encryption algorithms and data integrity checking.

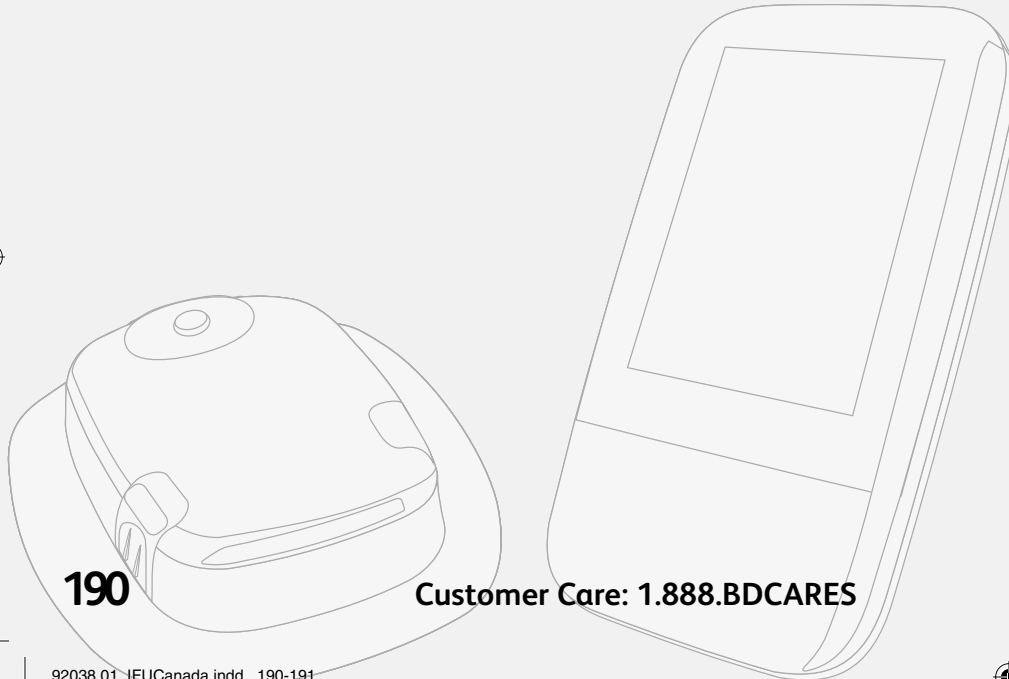
Temperatures:

Extreme operating temperatures can affect your BD Strive™. Extreme temperature conditions might also affect the insulin inside the IDD, which degrades at high temperatures. Follow the insulin manufacturer's instructions for use and the instructions on the following page.

- ✓ **DO NOT expose insulin** to extremes of hot and cold. Store insulin at room temperature.
- ✓ **Avoid** using the IDD in temperatures below 5°C (41°F) or above 37°C (98.6°F).
- ✓ **DO NOT store or leave** your Remote in extreme temperature conditions, such as inside a car.
- ✓ **DO NOT use IDD** at extreme temperature and humidity (IP27), exposure to water at depths greater than 1m (3.28 feet) or longer than 30 minutes.
- ✓ **Avoid** exposing the IDD to direct sunlight. **Remove** the IDD prior to using hot tubs, whirlpools and saunas.

6 Living with Diabetes

6.1 Diabetes management



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Check your blood glucose:

- Your Healthcare Provider (HCP) will help you set blood glucose goals or targets. These are the ranges of numbers that your blood glucose should fall within most of the time. When you self-monitor your blood glucose, you are checking to see if you are staying within your targets. If you are outside your targets you might need to take action.
- You will work with your HCP to decide how many times a day you should check your blood glucose. You might need to check more often if your treatment plan changes or if you are sick. You might also need to check your blood glucose more often if there is a change in your usual meal plan, if you feel symptoms of low or high blood sugar, before, during and/or after exercise, or if you think your BD

Strive™ is not working properly. This will give you and your HCP the necessary information needed to make changes to your treatment plan.

Avoiding highs and lows:

When you have diabetes, it is important to avoid high and low blood sugar. Out-of-control blood sugar can lead to short-term and long-term complications. The following chapters will provide you with more details regarding causes, detection and prevention, signs and symptoms, and treatment options.

6.2 Hypoglycemia (low blood sugar)

About Hypoglycemia:

Hypoglycemia occurs when there is not enough glucose in your blood to provide the energy your body needs. This is dangerous because your brain is not getting enough glucose to work properly. If there is not enough glucose for your brain to function, you might pass out or even have convulsions.

What causes Hypoglycemia?

Hypoglycemia or a low blood glucose reaction occurs when the blood glucose drops below the “normal” level. For most people a blood glucose reading below 70 mg/dl (3.9 mmol/l) is considered below normal.

This might happen if you took your insulin and:

- Did not eat enough food at a meal/snack or skipped/delayed a meal
- Took more insulin than needed for the meal that you ate
- Exercised or were more active than usual
- Drank alcohol prior to eating food

Signs and symptoms:

A low blood glucose reaction brings on very uncomfortable feelings. Once you have a reaction, you will know how to recognize it when it occurs again.

The signs and symptoms of Hypoglycemia are **mild, moderate**, or **severe**. See the charts on the following pages for the symptoms of mild, moderate, and severe Hypoglycemia.

Never ignore the signs of low blood sugar. If severe Hypoglycemia is left untreated, it can cause seizures or unconsciousness. If you are experiencing any signs and symptoms of low blood sugar, always check your blood glucose level to confirm.

Mild Hypoglycemia

In the early stages of Hypoglycemia you might feel all, some, or in some cases, none of these signs and symptoms.

- . Sudden hunger
- . Headache
- . Shaking
- . Fast or pounding heartbeat
- . Sweating
- . Tiredness
- . Dizziness
- . Blurred vision
- . Nervousness or excitement
- . Drowsiness
- . Numbness or tingling around mouth and lips

Moderate Hypoglycemia

If this reaction is not treated, the symptoms will progress to:

- . Personality change
- . Irritability
- . Confusion
- . Poor coordination
- . Difficulty concentrating
- . Slurred or slow speech

Severe Hypoglycemia

If the reaction is not treated and your blood glucose continues to fall, it can cause seizures or unconsciousness.

**SEVERE HYPOGLYCEMIA WILL REQUIRE
EMERGENCY TREATMENT.**

How do I detect and prevent Hypoglycemia?

Hypoglycemia causes high insulin levels that may cause the body to react poorly. Remember food raises blood glucose and insulin and exercise lowers blood glucose.

If you think you are having a low blood glucose reaction you should:

1. If possible, check your blood glucose level.
2. If your blood glucose is less than 70mg/dl (3.9mmol/l), treat with 15 grams of glucose or equivalent, such as 10 ounces (300ml) of skim milk, 4 ounces (120ml) of juice, or 3-4 glucose tablets. Do not eat chocolate or candy bars; they contain fat and will delay a fast rise in blood glucose.
3. Wait 15 minutes and retest your blood glucose level. If your blood glucose is still less than 70 mg/dl (3.9mmol/l), treat again with 15 grams of glucose
4. If you are away from home, you can take glucose tablets, 4 ounces (120ml) of fruit juice, or 6 ounces (180ml) of **REGULAR** soda.

6.3 Hyperglycemia (high blood sugar)

If you are unable to check your blood glucose, treat as described and wait 15 minutes. If you do not feel better, repeat the treatment. All treatment for Hypoglycemia should be followed by one of the following meals or snacks:

- If a meal is scheduled for 30–60 minutes, eat a snack that includes about 15 grams of carbohydrates (5 crackers, a piece of fruit, or a slice of bread).
- If your next meal is more than an hour away, eat about 15 grams of carbohydrate and 1 ounce (30 grams) of protein.

About Hyperglycemia:

Hyperglycemia occurs when the blood glucose level rises above your target range. It often happens when you do not have enough insulin in your body to use the glucose as fuel.

What causes Hyperglycemia?

Causes of Hyperglycemia include:

- Not taking enough insulin
- Eating too much food
- Infections and illness
- Stress
- Lack of exercise

Signs and symptoms of Hyperglycemia:

- Increased thirst
- Weakness, stomach pains, general aches
- Heavy, labored breathing
- Fatigue
- Loss of appetite, nausea, and vomiting
- Large amounts of sugar in the blood
- Frequent urination
- Ketones in the urine

How do I detect and prevent Hyperglycemia?

1. Check blood glucose levels often
2. Notify your Healthcare Provider when your blood glucose is above the targeted range for more than 2-3 readings in a row
3. Drink fluids without sugar and check blood glucose levels often

6.4 Diabetic Ketoacidosis (DKA)

Diabetic Ketoacidosis (DKA)

About DKA:

Diabetic Ketoacidosis is a condition that is rarely seen in people with type 2 diabetes. It happens in people whose pancreas no longer makes insulin. people with T1DM are at greater risk for DKA

If a person who requires insulin does not receive insulin for a period of time, DKA might occur. DKA is a serious but preventable condition that might result in diabetic coma or even death.

What causes DKA?

DKA is a condition that happens when a severe lack of insulin causes the body to break down fat to use as energy.



WARNING: DKA is a dangerous and serious condition.

If you have any of the signs and symptoms, **contact your Healthcare Provider IMMEDIATELY** or go to the nearest emergency room.

Signs and symptoms of DKA:

- Extreme thirst
- Frequent urination
- Feeling tired
- Nausea, vomiting, or abdominal pain
- Difficulty breathing
- Fruity odor on breath
- Confusion
- High blood glucose levels
- High ketone levels in the urine

How do I detect and prevent DKA?

DKA is a condition that happens when a severe lack of insulin causes the body to break down fat to use as energy. To avoid DKA make sure you check your blood sugar often, 2-4 times a day. Routine checking helps identify DKA before it develops.

Common causes of DKA are illness and high blood glucose. It results because there is not enough insulin in the body to control blood glucose. If you are at risk for DKA check the IDD Status on your Remote often to ensure it is delivering insulin.

6.5 Hyperosmolar Hyperglycemic Nonketotic Syndrome (HHS)

Hyperosmolar Hyperglycemic Nonketotic Syndrome (HHS)

About HHS:

Hyperosmolar Hyperglycemic Nonketotic Syndrome (HHS) is rarely seen in type 2 diabetes but might be serious if not discovered early. In HHS, there are very high blood glucose levels and severe dehydration. The body tries to rid itself of the large amounts of glucose by passing it into the urine. This might lead to severe dehydration.

What causes HHS?

HHS is a condition that is caused by severely high blood sugar levels.

Signs and symptoms of HHS:

- Blood sugar levels over 600 mg/dl (33.3 mmol/l)
- Frequent urination
- Extreme thirst
- Warm but dry skin that does not sweat
- High fever
- Loss of vision
- Confusion
- Hallucinations

IMPORTANT: If you are experiencing any of the signs and symptoms, **contact your Healthcare Provider (HCP) IMMEDIATELY** or go to the nearest emergency room at your local hospital.

6.6 Preparing for Emergencies

How do I detect and prevent HHS?

HHS occurs when your diabetes is uncontrolled. The best way to avoid HHS is to check blood glucose levels frequently, especially when ill. You should also check the IDD Status on your Remote often to ensure it is delivering insulin.

HHS might be avoided by checking blood glucose often (2-4 times a day) and reporting high readings to your HCP.

Keep an emergency kit with you at all times in the event that BD Strive™ is not working properly. The emergency kit should contain:

1. 1-2 sealed IDD's
2. Extra batteries for the Remote (at least two AAA alkaline)
3. A vial of U-100 insulin (see the warning in Section 3.2 on page 48)
4. Syringes for injecting insulin
5. Instructions for insulin dose replacement from your Healthcare Provider (HCP)

list continued on next page

6.7 Exercise / Sports

6. Blood glucose testing supplies
7. Glucose tablets, another fast acting carbohydrate, or if necessary, a glucagon emergency kit.
8. Alcohol prep swabs
9. HCP contact information
10. Letter from the HCP for airline security

Before you exercise:

Exercise is part of your treatment plan. It has the potential to lower blood glucose. Speak to your Healthcare Provider about your exercise goals and blood glucose targets before and after exercise in order to avoid Hypoglycemia.

When you exercise:

When exercising, avoid getting body lotion, creams, or oils near the insertion site. These products might loosen the adhesive. If the IDD adhesive becomes loose and begins to lift, remove and replace if needed, see Section 5.8 on page 140.

In this section:

This section provides information and tips about traveling with BD Strive™.

Time zones:

Traveling with BD Strive™ is easy! Your basal rate will stay the same, simply adjust your meal doses to the time zone you are now in. To adjust the time on your Remote, see Section 5.13 on page 166.

IMPORTANT: Remember to reset the time on your Remote to the local area when you get to your destination. The basal rate will run based on the rate programmed for the time of day regardless of your location.

Travel supplies:

- ✓ Bring at least double your usual amount of insulin and IDD's needed for the amount of time you will be away (to avoid running out or misplacing).
- ✓ Carry insulin and diabetes supplies with you in your carry-on bag. Storage on planes or trains can be above or below ideal temperature. Checked luggage can be lost or delayed.
- ✓ Take a list of your medications including generic name, trade name, and manufacturer.
- ✓ **Plan for IDD disposal.**
- ✓ **Emergency Kit.**

6.9 Sick days

Airport security:

In the United States: Make TSA workers aware that you have diabetes and are carrying medical supplies. Unused syringes and insulin IDD supplies are permitted when accompanied by insulin or other injectable medication. Medication and related supplies are normally X-rayed.

Outside the United States:

Check with your airline before your trip.

In this section:

This section provides information and tips about using BD Strive™ when you are sick.

When you are sick, your body releases stress hormones that help your body fight against your illness, but they will also raise your blood glucose.

IMPORTANT: If not treated quickly, high blood glucose levels caused by illness can lead to more serious problems like Diabetic Ketoacidosis (DKA) or Hyperosmolar Hyperglycemic State (HHS).

Sick Day Rules:

- ✓ **Drink fluids** even if you are able to eat food.
- ✓ **Every hour**, sip 8 ounces (240 ml) of sugar-free, caffeine-free drinks such as water, green tea, or black tea without milk or sugar free soft drinks.
- ✓ **Every third hour**, sip 8 ounces (240 ml) of broth, bouillon (clear, thin soup), or canned clear soup to provide sodium and other minerals your body needs.
- ✓ **Check your blood glucose every 2-4 hours** when you are sick, especially if you are vomiting. You should check your blood glucose at least 4 times a day. Report high blood glucose results to your Healthcare Provider. You might require more insulin.

- ✓ **Always take your insulin:** DO NOT discontinue your basal insulin rate. If you are not eating, you might not need to take your meal time doses. Work with your health-care provider to make a sick day plan.
- ✓ **If you have no appetite**, try to replace the carbohydrate portion of a meal with an equal amount of carbohydrates from semi-solid foods or fluids.
- ✓ **Take your temperature** because fever can cause you to become dehydrated.

6.10 Hospitalization and surgeries

✓ **If you cannot eat or keep food down**, you will need to alternate fluids that have calories with no-calorie/no carbohydrate drinks all day as follows:

1. First hour – drink 4-8 oz. (120-240ml) of regular soda
2. Next hour or two – drink 4-8 oz. (120-240ml) of water or seltzer
3. Check with your doctor or pharmacist before using over-the-counter medications

IMPORTANT:

If you feel sleepy or cannot think clearly, have someone call your doctor or take you to an emergency room.

Your insulin regimen:

Discuss with your Healthcare Provider (HCP) regarding adjustments to your insulin regimen. They will vary depending upon the medical procedure.

X-rays, MRIs, and CT scans:

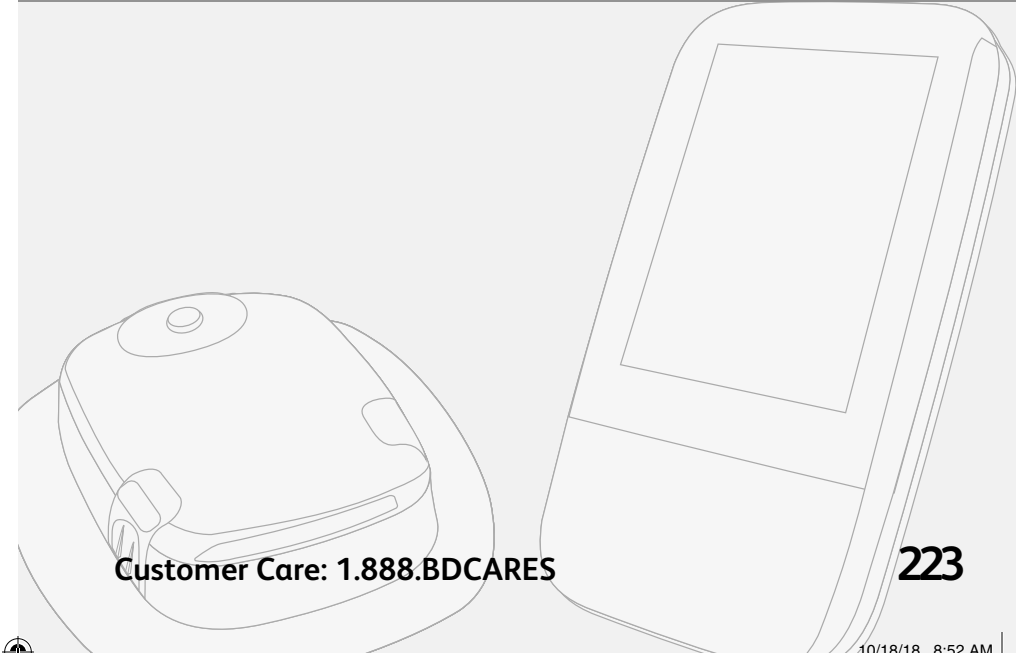
Before having an X-ray, MRI, or CT scan (or any similar test or procedure) remove your IDD, as the IDD may be affected by strong radiation or magnetic fields. Be sure to check with your HCP, and check your blood glucose levels before removing the IDD and after applying a new one.

7. Notifications and Troubleshooting

WARNING:

DO NOT use BD Strive™ in these environments:

- **Electromagnetic radiation.** During procedures involving strong electromagnetic radiation, such as CT, X-ray, MRI or similar scans, remove BD Strive™ and keep the system outside of the area of strong radiation. Strong electromagnetic radiation might damage BD Strive™ and cause it to malfunction.
- **Hyperbaric chamber.** BD Strive™ should NOT be used in a hyperbaric chamber, as there is a potential for explosion. There are active electronics inside the IDD and Remote, and the hyperbaric chamber has high concentrations of oxygen.



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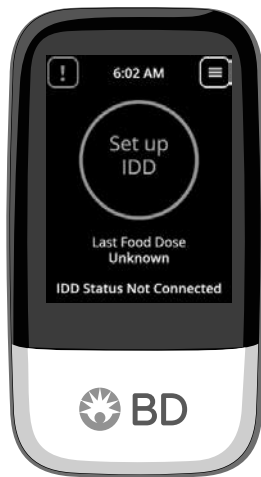
7.1 Remote Screen Notifications

In this section:

This section provides instructions for Remote screen notifications. The instructions explain what the notification means and what actions you should take to solve the notification.

IMPORTANT:

Always keep your Remote with you so that you can regularly monitor the IDD Status. Check your Remote at least 3 times a day and as often as you check your blood glucose.

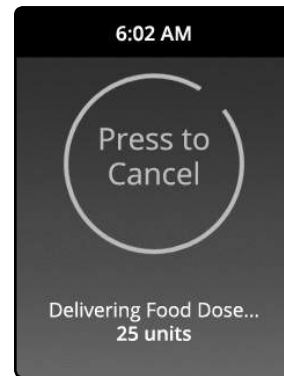


Delivering Food Dose

What it means:

- The delivering Food Dose screen will appear after you confirm a Food Dose from your Remote or after administering a manual Food Dose through the IDD buttons.
- The Remote will remain on this screen until your Food Dose has completed its delivery.

No action required.



(example value)

Connecting

Connecting



What it means:

- Remote and IDD are within range and are attempting to communicate with each other.
- Appears automatically after you wake up the display on your Remote or when you complete a screen prompt that attempts to establish communication between your Remote and IDD.

No action required.

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Syncing

Syncing



What it means:

- Remote and IDD are within range and are attempting to communicate with each other.
- Appears automatically after you wake up the display on your Remote or when you complete a screen prompt that attempts to establish communication between your Remote and IDD.

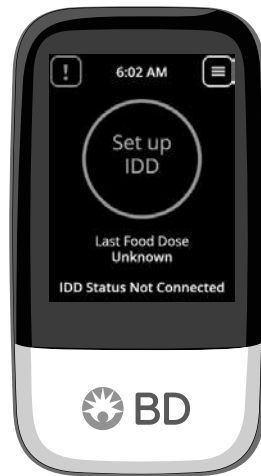
No action required.

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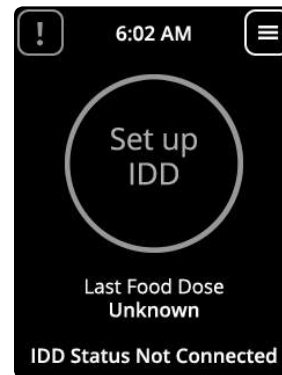
7.2 IDD Status Notifications

In this section:

This section provides instructions for IDD Status notifications. The instructions explain what the notification means and what actions you should take to solve the notification.



IDD not connected



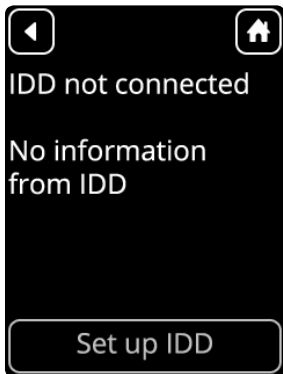
What it means:


- The “IDD Status Not Connected” message at the bottom of the screen means the Remote and IDD are not paired and connected.

What to do:

- Tap the orange **Setup IDD** circle and proceed with screen prompts to set up your new IDD, see Section 5.1 on page 82 for more instructions.

IDD not connected (continued)

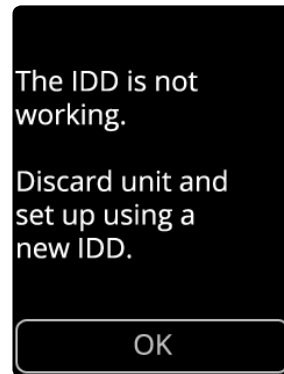


- For more information on your most recent Food Dose and current IDD Status, tap the orange Alert icon  to view the IDD Status screen.

Note: there might not be Food Dose information from the IDD.

- To set up a new IDD, tap **Setup IDD** at the bottom of the screen and proceed with the screen prompts to set up your IDD. See Section 5.1 on page 82 for more instructions.

IDD is not working



What it means:

- During IDD setup, your IDD is not able to complete the required steps to start up the system due to an internal hardware, software, or other non-recoverable error.

What to do:

- Follow the screen prompts, tap **OK**.
- Appropriately discard the IDD and try to setup with a new IDD.


IDD near empty



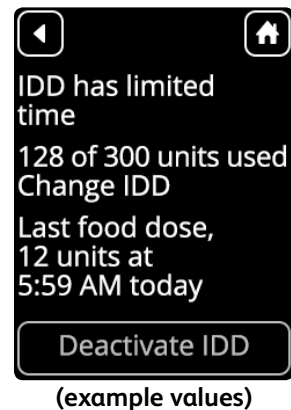
What it means:

- The “IDD Status Near empty” message at the bottom of the screen means your IDD is currently delivering insulin but will soon be empty.

What to do:

- For more information, tap the green check mark  on the Home screen. The IDD Status screen will display that the IDD has limited insulin left.

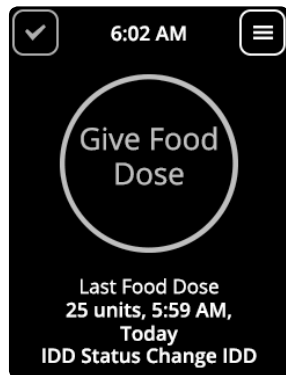
IDD near empty (continued)



- The screen also displays the amount of units that were used out of the total amount in the IDD. For example, if 270 of 300 units have been used, there are only 30 units left (i.e., 300 minus 270) to use in the IDD before the IDD is empty.
- If you want to deactivate your IDD, tap **Deactivate IDD** at the bottom of the screen and proceed with the screen prompts to deactivate your IDD and set up a new IDD. See Section 5.8 on page 140 for more instructions.

IMPORTANT: You cannot restart or reuse your IDD once you have deactivated the device.

IDD near expiry




(example values)

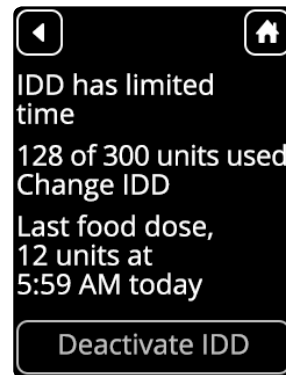
What it means:

- The “IDD Status Change IDD” message at the bottom of the screen means your IDD is currently delivering insulin but is nearing the end of the 3-day IDD life period.

What to do:

- For more information, tap the green check mark  on the Home screen. The IDD Status screen will tell you that the IDD has limited time left.

IDD near expiry (continued)



(example values)

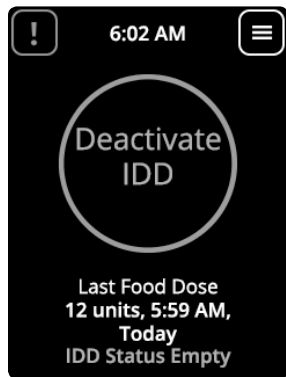
- The screen will also display the amount of unit that were used out of the total amount in the IDD.

Note: the 3-day IDD life period might expire before all the IDD insulin is used.

- If you want to deactivate your IDD, tap **Deactivate IDD** at the bottom of the screen and proceed with the screen prompts to deactivate your IDD. See Section 5.8 on page 140 for more instructions.

IMPORTANT: You cannot restart or reuse your IDD once you have deactivated the device.

IDD empty



(example values)

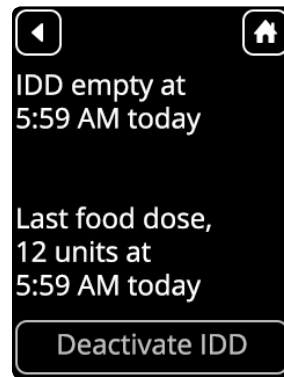
What it means:

- The “IDD Status Empty” message at the bottom of the screen means the IDD is empty and is no longer delivering insulin to you. The IDD must be deactivated.


What to do:

- Tap orange **Deactivate IDD** circle and proceed with screen prompts to deactivate your empty IDD and set up a new IDD. See Section 5.8 on page 140 for more instructions.

IDD empty (continued)

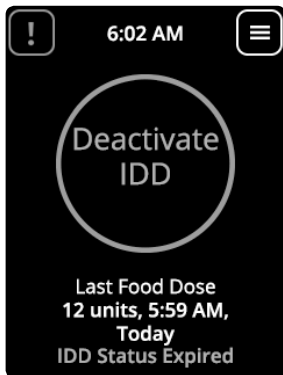


(example values)

- For more information on your most recent Food Dose and the time your IDD went empty, tap the orange Alert icon  to view the IDD Status screen.
- To deactivate your IDD, tap **Deactivate IDD** at the bottom of the screen and proceed with the screen prompts to deactivate your IDD and set up a new IDD. See Section 5.8 on page 140 for more instructions.

IMPORTANT: You cannot restart or reuse your IDD once you have deactivated the device.

IDD expired



(example values)

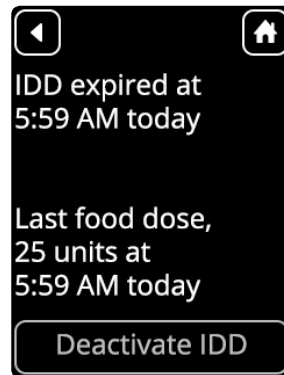
What it means:

- The “IDD Status Expired” message at the bottom of the screen means the IDD has reached its 3-day expiry and is no longer delivering insulin. The IDD must be deactivated.


What to do:

- Tap orange **Deactivate IDD** circle and proceed with screen prompts to deactivate your empty IDD and set up a new IDD. See Section 5.8 on page 140 for more instructions.

IDD expired (continued)



(example values)

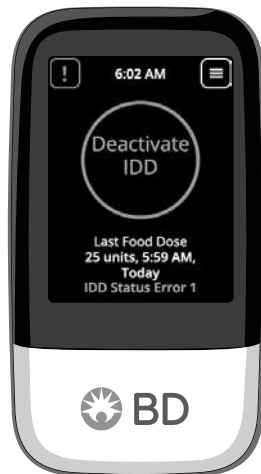
- For more information on your most recent Food Dose and the time your IDD expired, tap the orange Alert icon  to view the IDD Status screen.
- To deactivate your IDD, tap **Deactivate IDD** at the bottom of the screen and proceed with the screen prompts to deactivate your IDD and set up a new IDD. See Section 5.8 on page 140 for more instructions.

IMPORTANT: You cannot restart or reuse your IDD once you have deactivated the device.

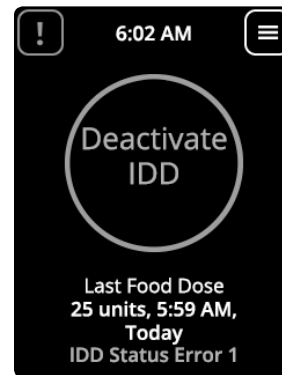
7.3 IDD Status Errors

In this section:

This section provides instructions for IDD Status errors. The instructions explain what the status error means and what to do to solve the status error.



IDD Status Error 1



(example values)

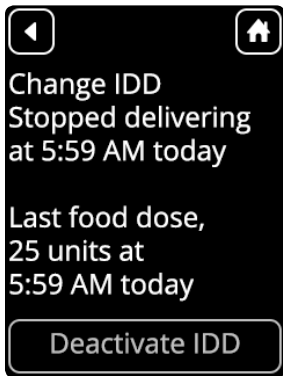
What it means:

- The “IDD Status Not Connected” message at the bottom of the screen means the Remote and IDD are not connected. This message appears once you have deactivated your old IDD and can set up your new IDD.


What to do:

- Tap orange **Set up IDD** circle and proceed with screen prompts to complete the new IDD setup process. See Section 5.1 on page 82 for more instructions.

IDD Status Error 1 (continued)



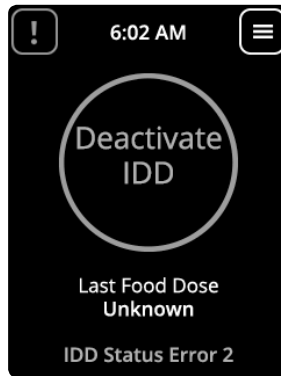
(example values)

- For more information on your most recent Food Dose and current IDD Status, tap the orange Alert icon  to view the IDD Status screen.
- To deactivate your IDD, tap **Deactivate IDD** at the bottom of the screen and proceed with the screen prompts to deactivate your IDD. See Section 5.8 on page 138 for more instructions.

IMPORTANT: You cannot restart or reuse your IDD once you have deactivated the device.

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IDD Status Error 2




(example values)

What it means:

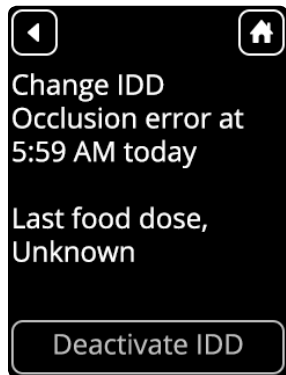
- The “IDD Status Error 2” message at the bottom of the screen means your IDD has occluded and may not be delivering insulin. The IDD must be deactivated.

What to do:

- Tap orange **Deactivate IDD** and proceed with screen prompts to deactivate your IDD, see Section 5.8 on page 138 for more instructions.
- For more information on your current IDD Status, tap the orange Alert icon  to view the IDD Status screen.

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IDD Status Error 2 (continued)



(example values)

- To deactivate your IDD, tap **Deactivate IDD** at the bottom of the screen and proceed with the screen prompts to deactivate your IDD.
- Check your blood glucose and treat as instructed by your healthcare provider.

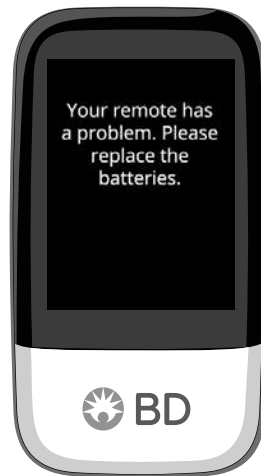
IMPORTANT: You cannot restart or reuse your IDD once you have deactivated the device.

CAUTION: If an occlusion error has been detected and the IDD has not yet been deactivated, the pump may appear to be functioning, but dose delivery is unknown for both basal delivery and IDD button press manual food dose delivery.

7.4 Communication and System Errors

In this section:

This section provides instructions for system and communication errors. The instructions explain what the error is and what the required actions are to solve the error.



Communication error

Communication error. Move to a different room, and hold remote near IDD.

Try connecting again?

No

Yes

What it means:

- Remote and IDD are not close enough to communicate.
- Remote and IDD are experiencing interference.
- Remote and/or IDD antenna are not working.

Communication error (continued)

What to do:

- Move Remote closer to IDD or move to a different room and tap **Yes**.
- Keep the IDD and Remote close to each other and away from other IDDs.
- If someone else with a BD Strive™ system is attempting to pair, ensure that you are at least 6 feet (2m) away before continuing with your attempt to pair your devices.

Communication error remains

Communication error remains.

Discard and forget this IDD?

No

Yes

What it means:

- Remote and IDD are not close enough.
- Remote and IDD are experiencing interference.
- Remote and/or IDD antenna are not working.
- Other system-related malfunction.

Communication error remains (continued)

What to do:

- Tap **No** to continue trying to establish communication between Remote and IDD.
- If you have tried to establish communication more than twice and the error remains, it is recommended that you tap **Yes** and proceed with deactivating your IDD.
- You will have to discard your IDD and set up a new IDD following the screen prompts. See Section 5.8 on page 140 for more instructions on deactivating your IDD.

IDD/Remote Compatibility Error

Your IDD is not compatible with your remote. Please call customer service.

1-888-BDCARES

OK

What it means:

- Remote and IDD software versions are incompatible.
- Your Remote and IDD will not work.

What to do:

Call the customer service number at **1.888.BDCARES**.

Customer Service Display

Your remote has a problem. Please call customer service.

1-888-367-9539

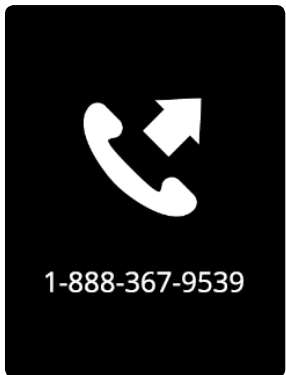
What it means:

- Remote has a software, hardware, or other issue that is causing it to malfunction.

What to do:

- Call the customer service number at **1.888.BDCARES**.

Customer Service Display (continued)



What it means:

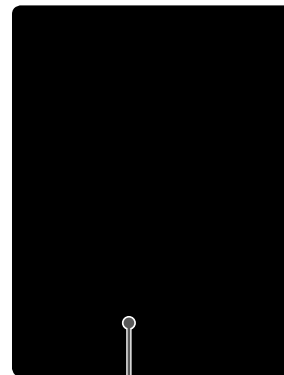
- Remote has a software, hardware, or other issue that is causing it to malfunction.

What to do:

- Call the customer service number at **1.888.BDCARES**

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No Display



Display will not turn on

What it means:

- Remote and IDD software versions are incompatible.
- Your Remote and IDD will not work

IMPORTANT: Remind to press and hold power button as described on page 70.

What to do:

- Check that you have put in fresh batteries.
- Check that batteries are installed and in the correct orientation.
- If your Remote is still having issues, call the customer service number at **1.888.BDCARES**.

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Battery issue

Your remote has a problem. Please replace the batteries.

What it means:

- Remote has a battery-related issue.
- Remote has software, hardware, or other issue that is causing it to malfunction.

What to do:

- Remove the battery cover and replace the old batteries with a fresh set.
- If your Remote is still having issues, call the customer service number at **1.888.BDCARES**.

7.5 Smartphone Pairing Errors

Smartphone connection failed.
Make sure BD app is running on Smartphone.

Try connecting again?

No

Yes

In this section:

This section provides instructions for smartphone pairing errors. The instructions explain what the error means and what actions you should take to solve the error.

Pairing to Smartphone Error

Smartphone connection failed. Make sure BD app is running on Smartphone.

Try connecting again?

No

Yes

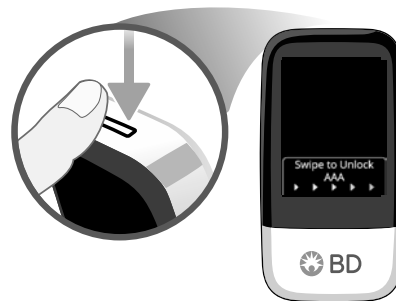
Issue:

- Remote is unable to pair and connect with Smartphone.

What to do:

- Tap **Yes** and follow instructions on Remote.

Syncing Data to Smartphone Issue



Issue:

- Recent dose data is not displayed on your mobile app

What to do:

- Turn your Remote on by pressing and holding the button on top of the Remote until the screen turns on.

Syncing Data to Smartphone Issue



- Swipe and tap to unlock. Once the home screen is displayed, press the button
- Press button again
- Press again to turn the Remote off

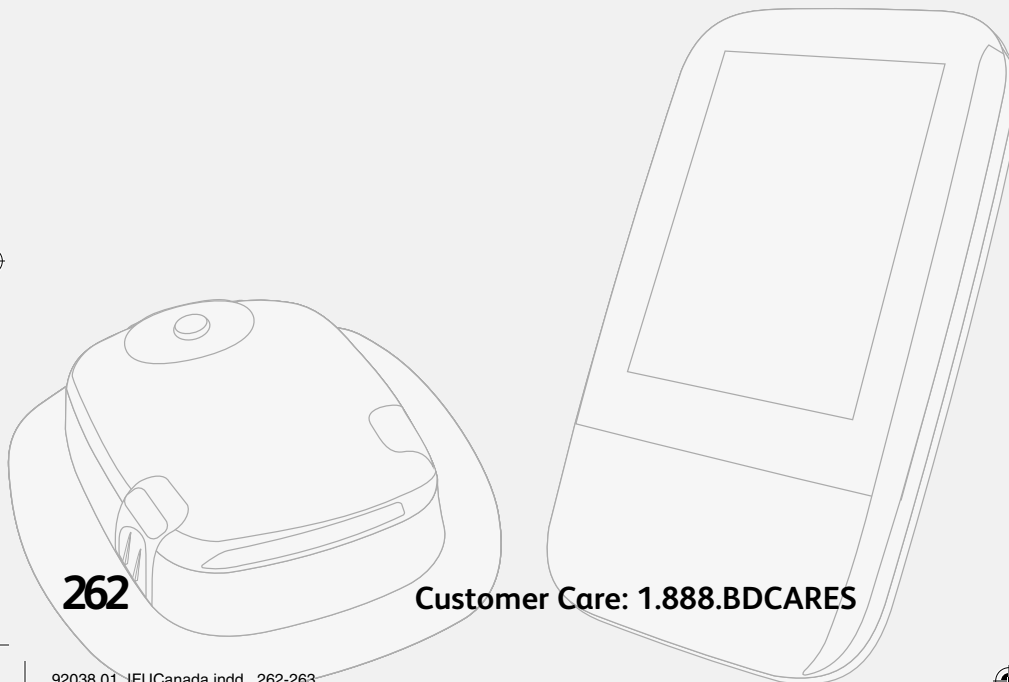
7.6 Troubleshooting

Issue	Instructions
Cannot see Remote screen when outside	If you are having trouble reading the display on the Remote, avoid intense sunlight and relocate.
Remote timed out before task completed	If the Remote screen has gone to sleep, press and hold the button on top of the Remote until the screen turns on. Check that your Remote name appears, and swipe across the arrows to unlock your Remote.

Issue	Instructions
Wrong language is displayed	If the wrong language is displayed, refer to Section 5.14 on page 169 to change the language.
Wrong time is displayed	When traveling to different time zones or to account for daylight savings time, refer to Section 5.13 on page 166 on how to change the time.
Blood glucose level increases	Change the IDD and monitor your blood glucose.

Issue	Instructions
Signs of infection	Change IDD if there are signs of infection or irritation.
Problems with Pairing	Keep IDD and Remote in close range to each other (Remote above the IDD). Ensure that your IDD is not positioned below the Remote and you are at least 6 feet (2m) away from other Remotes or equipment that might interfere with the pairing communication.

8. Appendix



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Customer Care: 1.888.BDCARES

8.1 Care and maintenance

In this section:

This section provides information on caring and maintaining your Remote, such as replacing the batteries and cleaning.



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Replacing Remote batteries:

The Remote requires two (2) AAA Alkaline Batteries. Batteries should be replaced approximately every 3 weeks.

CAUTION: Use only new AAA alkaline batteries to power the wireless Remote. Never use rechargeable, old, or used batteries; Remote might not work properly.

IMPORTANT: Use proper technique and avoid excessive force when handling the device.



When the orange, low battery light on the screen's bottom left turns on, you will have **12 hours** before the Remote display powers off. Replace the batteries as soon as possible.

When the low battery light flashes quickly for 10 seconds and the display does not turn on, replace batteries immediately.

CAUTION: If the batteries run out, Remote settings may be lost. **DO NOT** remove the old batteries until you have new ones on hand. The Remote protects settings for up to **2 hours** after the batteries run out or are removed.



Low battery life


To replace the batteries:


1. Remove the battery cover on the back of the Remote.
2. Remove the old batteries.
3. Replace the batteries using the diagram inside showing the proper direction of the batteries.
4. Replace the battery door. Your Remote is now ready to use.
5. Dispose of the old batteries in accordance with your local waste disposal regulations.

If your Remote settings were lost, see Section 4.2 on page 57 to set up your Remote settings.

Cleaning the Remote:


To clean the outside surface of the Remote, use a soft cotton cloth and water or mild soap-based solutions only.

 **WARNING:** The Remote is **NOT** waterproof (rated IP22). **DO NOT** immerse it or place it in or near water.

 **CAUTION: DO NOT** use IV Prep wipes, alcohol wipes, soap, detergent, or solvents to clean the screen or other parts of the Remote.

If your Remote becomes submerged or wet, dry the Remote with a clean lint-free cloth, open the battery compartment, and immediately discard the batteries, then dry the compartment with the cloth.

Leave the compartment open until the Remote is dry. DO NOT replace the batteries until the Remote is completely air-dried.

 **WARNING:** Never use a blow dryer to dry the Remote. Extreme heat can damage the electronics.

If you drop your Remote:

If you drop your Remote, inspect it for any visible signs of damage. Press and hold the power button to see if the Remote turns on and to inspect the screen for any damage. DO NOT use the Remote if it appears damaged or is not working correctly.

Call Customer Care for assistance at:

1.888.BDCARES

8.2 Ordering supplies

For product ordering information, please contact
1.888.BDCARES.

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8.3 BD Strive™ options and settings

Languages	English (US/UK), Spanish, Canadian French, Dutch, Danish, Finnish, Norwegian, Swedish, German, French
Remote name	3 alphanumeric characters (A-Z and 0-9) Default: AAA.
Time	12-hr or 24-hr - Default: 12:00 AM.
Date	yyyy/mm/dd - Default: 2018/01/01.
Basal Rates	10-70 units/day Default: 10 units/day.

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8.4 Technical Specifications

Food Dose Volumes

Up to 30 units in less than 10 minutes.

Food Dose Button Amount

0, 1, 2, or 5 units per button press. Default 2 units per press.

Reservoir Fill Amount

100, 150, 200, 250, or 300 units.

Dose History Averages

Available in 7, 14, and 30 day averages.

Duration of Use

Up to 3 days.

IDD specifications

Size

5.2 cm long x 4.1 cm wide x 1.5 cm high.

Weight (without insulin)

23 grams.

Operating Temperature Range

5 – 37°C.

Storage Temperature Range

5 – 30°C.

Operating Relative Humidity Range

20 – 90% relative humidity non-condensing.

Storage Relative Humidity Range	20 – 90% relative humidity non-condensing.
--	--

Operating Atmospheric Pressure Range	700 mbar to 1060 mbar.
---	------------------------

Storage Atmospheric Pressure Range	700 mbar to 1060 mbar.
---	------------------------

Waterproof Rating	1m (3.28 ft.) of water for 30 minutes (IPX7).
--------------------------	---

Reservoir Volume	up to 3ml (300 units).
-------------------------	------------------------

Compatible Insulin Type	Humalog®.
--------------------------------	-----------

Compatible Insulin Concentration	U-100 insulin (1 unit= 0.01mL)
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Cannula Insertion Depth	4.5 mm-8.0 mm.
--------------------------------	----------------

Residual Volume	≤ 300 ul (30 units)
------------------------	---------------------

Occlusion Detection	within 5 units.
----------------------------	-----------------

Flow capability

Basal: 0.5U pulses up to 70 units per day. Food Dose: 4 units per minute.

Delivery Accuracy (tested per IEC60601-2-24)

Basal: +/- 10%.
Food Dose: +/- 10%.

Non-pyrogenic

Fluid Pathway Only.

Protection from electrical shock

Type BF Medical Device.

Remote specifications**Size**

10.3 cm x 6.1 cm x 1.7 cm.

Weight (without batteries)

71 grams.

Screen

4.0 cm x 5.0 cm
LCD Color- display touch-screen.

Battery

2 AAA alkaline batteries.

Battery Life

Approximately 3 weeks.

Operating Temperature Range	5-37°C
Storage Temperature Range	5-30°C
Operating Relative Humidity Range	20 – 90% relative humidity non-condensing.
Storage Relative Humidity Range	20 – 90% relative humidity non-condensing.

Operating Atmospheric Pressure Range	700 mbar to 1060 mbar.
Storage Atmospheric Pressure Range	700 mbar to 1060 mbar.
Communication Distance	within a distance of up to 10 feet (~ 3 meters) utilizing the BLE Standard.
Warranty/Expected Service Life	24-months.
Protection from electrical shock	Type BF Medical Device.

BD Strive™ system notice concerning interference

This device complies with part 15 of the FCC Rules (US Only). Operation is subject to the following two conditions:

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

Changes or modifications not expressly approved by BD could void the user's authority to operate the equipment.

Both the IDD and Remote generate, use, and can radiate Radio Frequency (RF) energy, and might cause harmful interference to radio communications. There are no guarantees that interference will not occur in a particular installation. If the BD Strive™ System does cause harmful interference to radio and television reception, the

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interference might be corrected by one of the following measures:

- Move or relocate the BD Strive™ System.
- Increase the distance between the BD Strive™ System and the other device that is emitting or receiving interference.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- This device may not cause interference.
- This device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme aux normes RSS applicables aux dispositifs exemptés de licence édictées par Industrie Canada. Son fonctionnement est soumis aux deux conditions suivantes :

- (1) cet appareil ne peut pas causer d'interférence, et
- (2) cet appareil doit accepter toute interférence, notamment une interférence qui pourrait provoquer un fonctionnement indésirable.

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BD declares that the BD Strive™ System is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU. This ISM device complies with FCC Part 15, Canadian ICES-003, RSS-Gen, RSS-247, and RSS-102.

Electromagnetic Compatibility

The information contained in this section is written with regard to the BD Strive™ System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information might not be applicable to other medical electrical equipment.

General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed

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and put into service according to the EMC information provided in this document and the User Guide. Portable and mobile RF communications equipment can affect the function of medical electrical equipment.

The BD Strive™ system, including the IDD and Remote, communicates using wireless Bluetooth Low Energy (BLE) technology for RF communication. BD declares that the BD Strive™ System is in compliance with the essential requirements and other relevant provisions of Directive 93/42/EEC.

Accessories not specified within this User Guide are not authorized, and might adversely impact safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

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The BD Strive™ System communicates with the following characteristics: Frequency of 2.402-2.480 GHz using GFSK modulation with an effective isotropic radiated power of -10.6 dBm for Insulin Delivery Device and -7.0 dBm for Wireless Controller.

The data rate is 1Mbps, and general data transmission throughput is 1mb/sec with very low duty cycle.

Using BLE 4.1, the RF quality out-of-band pairing and AES128 encryption algorithm ensures data integrity. Extra three layers of CRC for data integrity checking and also one's complement checking for critical parameter checks.

The BD Strive™ System communicates using a low level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC Part 15, EN ETSI 300 328 requirements.

Care should be taken if the System is used in adjacent to other electrical equipment. Avoid conditions that might affect reliable data transmission of the system (eg: other IDD's, HF Surgical Equipment and RF shielded rooms, X-rays, magnetic resonance imaging (MRI), computed tomography (CT) scans, ultrasound, electromagnetic security systems, cellular telephones, RFID or other in-band transmitters).

If adjacent use is inevitable, the BD Strive™ System should be observed to verify normal operation in this setting.

The BD Strive™ System meets the immunity requirements of the general standard for electromagnetic compatibility (IEC 60601-1-2.)

Guidance and Manufacturer's Declaration Electromagnetic Emissions

The BD Strive™ system is intended for use in the electromagnetic environment specified below. The customer or user of the system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment
RF Emissions (CISPR 11)	Group 1	The BD Strive™ system uses RF Bluetooth low energy energy only for its internal communication. Therefore, the BD Strive™ system emits very low RF emissions and are not likely to cause any interference in nearby electronic equipment.

Guidance and Manufacturer's Declaration Electromagnetic Emissions (Continued)

Emissions Test	Compliance	Electromagnetic Environment
RF Emissions (CISPR 11)	Class B	The BD Strive™ 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 61000-3-2	Not Applicable	Requirements do not apply to BD Strive™ system because it is a battery powered device.
Voltage Fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration Electromagnetic Immunity

The BD Strive™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Immunity Test	IEC 60601 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	The BD Strive™ system should not be affected by electrostatic discharge that might occur under normal conditions of use.

Guidance and Manufacturer's Declaration Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 level	Compliance level	Electromagnetic Environment Guidance
Electrical fast transient/burst IEC 61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	Not Applicable	Requirements does not apply to BD Strive™ system because it is a battery powered device.
Power Line Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Requirements do not apply to BD Strive™ system because it is a battery powered device.

Guidance and Manufacturer's Declaration Electromagnetic Immunity

Immunity Test	IEC 60601 level	Compliance level	Electromagnetic Environment Guidance
Voltage Dips, Short Interruptions, and Voltage Variations IEC 61000-4-11	<5% U _T (>95% dip in U _T) for 0.5 cycle (U _T is ac mains voltage prior to application of the test level)	Not Applicable	Requirements do not apply to BD Strive™ system because it is a battery powered device.

Guidance and Manufacturer's Declaration Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 level	Compliance level	Electromagnetic Environment Guidance
Power Frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	Not Applicable	Requirements do not apply to BD Strive™ system because it is a battery powered device.

Guidance and Manufacturer's Declaration Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 level	Compliance level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3	10V/m for 80~2700 MHz, 10V/m 80% AM at 1 kHz	10V/m for 80~2700 MHz, 10V/m 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the BD Strive™ System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
IEC 60601-1-2 ed 4.0 Clause 8.10	Refer to table on page 284 for details	Refer to table on page 284 for details	

Guidance and Manufacturer's Declaration Electromagnetic Immunity (Continued)

Electromagnetic Environment Guidance (Continued)

Recommended separation distance:


$d = 1.17 \sqrt{P}$ 150 kHz to 80 MHz

$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz

$d = 0.7 \sqrt{P}$ 800 MHz to 2.5 GHz

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^a, should be less than the compliance level in each frequency range^b.

Interference may occur in the vicinity of equipment marked with the following symbol: 

For reference, please see table on page 284 for the compliance level of BD Strive™ system against common radio transmitters.

Guidance and Manufacturer's Declaration Electromagnetic Immunity (Continued)

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.

^a 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.

Guidance and Manufacturer's Declaration Electromagnetic Immunity (Continued)

^{a (continued)} If the measured field strength in the location in which the BD Strive™ System is used exceeds the applicable RF compliance level above, the BD Strive™ System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BD Strive™ System.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

**Radiated RF Test specifications including separation distances
for BD Strive™ system and common radio transmitters**

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment					Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (Continued)		
Test Frequency (MHz)	Band ^(a) (MHz)	Service ^(b)	Modulation ^(b)		Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^(b) 18 Hz		1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ^(c) ± 5 kHz deviation 1 kHz sine		2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^(b) 217 Hz		0,2	0,3	28
745							
780							

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (Continued)					Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (Continued)		
Test Frequency (MHz)	Band ^(a) (MHz)	Service ^(b)	Modulation ^(b)		Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^(b) 18 Hz		2	0,3	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^(b) 217 Hz		2	0,3	28
1 845							
1 970							

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (Continued)					Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (Continued)		
Test Frequency (MHz)	Band ^(a) (MHz)	Service ^(b)	Modulation ^(b)		Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^(b) 217 Hz		2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^(b) 217 Hz		0,2	0,3	9
5 500							
5 785							

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (Continued)

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- ^(a) For some services, only the uplink frequencies are included.
- ^(b) The carrier shall be modulated using a 50% duty cycle square wave signal.
- ^(c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended separation distances between portable and mobile RF communications equipment and the BD Strive™ System

The BD Strive™ System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BD Strive™ System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BD Strive™ System as recommended below, according to the maximum output power of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the BD Strive™ System (Continued)

Rated maximum output power of transmitter, in watts	Separation distance according to frequency of transmitter, in meters		
	<i>150 kHz to 80 MHz $d = 1.17 \sqrt{P}$</i>	<i>80 MHz to 800 MHz $d = 0.35 \sqrt{P}$</i>	<i>800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$</i>
0.01	0.12	0.035	0.070
0.1	0.37	0.11	0.22
1	1.17	0.35	0.7
10	3.7	1.11	2.21
100	11.7	3.5	7.0

Recommended separation distances between portable and mobile RF communications equipment and the BD Strive™ System (Continued)

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.

The BD Strive™ system complies with the following standards:

- IEC 60601-1 · EN 300 328; · FCC Part 15
- IEC 60601-1-11 · EN 301 489-1; · RSS-Gen
- IEC 60601-2-24; · EN 301 489-17; · RSS-102
- IEC 60601-1-2; · ICES-003; · RSS-247

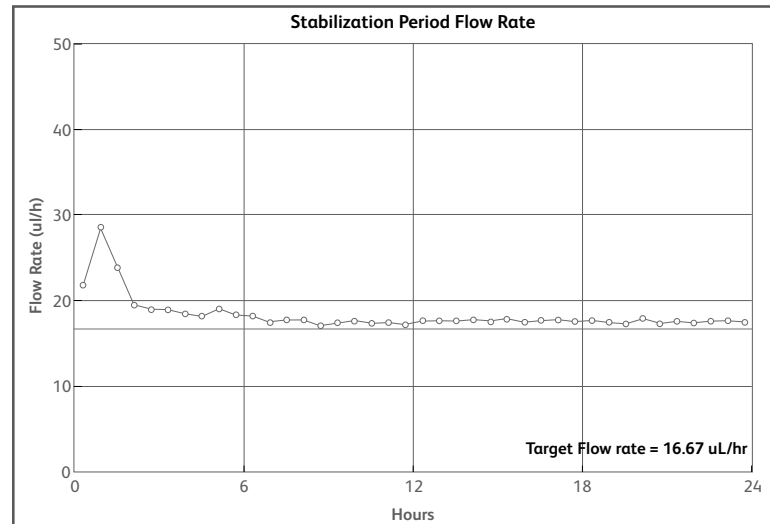
8.5 Dose accuracy

Dose accuracy

The basal dose accuracy was evaluated for three samples. The following graphs show the typical basal flow rate accuracy of the system against given time periods. The measurements were taken at an intermediate basal rate of 40U/day in accordance with 60601-2-24 at controlled room temperature.

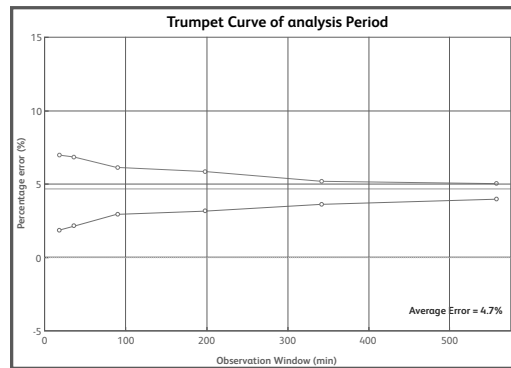
IDD flow rate upon initial startup (per IEC 60601-2-24)

Average flow rate during 24 hours period.



IDD flow accuracy after initial stabilization period (per IEC 60601-2-24)

The Trumpet curve shows the accuracy of the flow rate as a function of an averaging window. The reported percent deviation is calculated from the overall weight increase across the full T2 time period.



IDD flow accuracy after initial stabilization period (per IEC 60601-2-24) The average basal insulin and food dose delivered are expected to be within 10% of the requested dose. However, dose accuracy may be

affected by the presence of residual air in the IDD. Occasionally, the dose accuracy of 10% may not be maintained for the minimum food dose of 1U. The maximum food dose of 30U is expected to be within 10% of the requested dose. The Essential Performance of BD Strive™ system can be stated as “The BD Strive™ Insulin Management System maintains Insulin delivery accuracy of $\pm 10\%$ under specified operating conditions.” The measurements were taken for two IDD samples.

Bolus accuracy:

Set Bolus		Average Bolus (Actual)	Percentage average deviation from set Bolus	Maximum positive deviation from set bolus		Maximum negative deviation from set bolus	
(Units)	(uL)	(Units)	(%)	(Units)	(uL)	(Units)	(uL)
Maximum 30 U	300uL	30.86U	2.87%	1.44U	14.4uL	-0.52U	-5.2uL
Minimum 1 U	10uL	1.03U	3.00%	0.06U	0.6uL	-0.14U	-1.4uL

8.6 Glossary

The table in this section defines terms used in this User Guide.

Term	Definition
Adhesive patch	Medical adhesive that keeps your device attached to your body for up to 3 days.
Adverse reaction	An unwanted effect caused by a drug or medical device.
Alert status icon	The “!” icon means the IDD Status has changed and needs attention, Tapping the icon will provide more information about the alert.

Aseptic technique

A method for maintaining sterilization and preventing contamination.

Basal insulin rate

The insulin dose that is delivered at a low volume every few minutes, at a pre-set rate to keep blood glucose level between meals and during the night.

Battery life indicator

Located on the screen's bottom left which will notify you when the battery life is low. Batteries should be replaced approximately every 3 weeks.

Blood sugar target goals

The range your blood glucose should fall into most of the time. Your blood sugar goals should be determined by you and your health care provider.

Blood glucose (BG)

Another term for blood sugar.

Blood glucose (BG) level

The amount of glucose, sugar, in the bloodstream.

Calorie

A unit of measurement used to express the energy value of food. Calories come from carbohydrate, protein, fat, and alcohol.

Catheter

A small, flexible tube inserted below the skin, which serves to introduce a liquid medication into the body.

Catheter hole

The site where the catheter comes out of the IDD when inserted on your body.

Carbohydrate (carb)

Come from plants (fruits, vegetables, grains, cereal products, and desserts). Carbs convert 100 percent into glucose, 1 to 2 hours after eating.

Caution

Indicated a hazardous situation that, if not avoided, could result in minor or moderate injury.

Certified Diabetes Educator (CDE)

An experienced health care professional who specializes in prediabetes, diabetes prevention, and management.

Checkmark status icon

The checkmark icon means the IDD is operating normally. Tapping the icon displays information about the insulin delivered from the current IDD.

Communication error

An error which occurs when the Remote and IDD are not close enough, interference between Remote and IDD, and/or Remote or IDD antenna not working.

Contra-indications

Situation(s) in which an individual should not use a product.

Cream

A thick liquid or semisolid cosmetic or medical preparation applied to the skin.

CT Scan

Computer tomography scan combines a series of X-ray images obtained from different angles to reveal anatomic details of internal organs that cannot be seen with an X-ray.

Diabetes, diabetes mellitus

a disease in which the body's ability to produce or respond to the hormone insulin is impaired, resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood and urine.

Diabetic Ketoacidosis (DKA)

A serious complication that results from the buildup in the blood of potentially harmful products called ketones when not enough insulin is available to store glucose. It is rare among people with type 2 diabetes.

Discard

To dispose of or throw away.

Dose summary	Tap Dose Summary, to view your average dose over 7, 14, and 30 days.
Duration of insulin action	The length of time that certain types of insulin remain active and available in your body after an insulin dose is given. This duration can vary greatly depending on the type of insulin you take.
Emergency kit	A kit which contains: 1-2 sealed IDDs, batteries for the Remotes, a vial of U-100 insulin, syringes used for injecting insulin, instructions for insulin dose replacement from your Healthcare Provider, blood glucose testing supplies, glucose tablets or another fast-acting carbohydrate, alcohol prep swabs, HCP contact information.

Expiry	The end of a fixed period of time.
Fat	One of the three main nutrients in food. Excess calories are stored as body fat, providing the body with a reserve supply of energy and other functions.
Filling needle	Used to fill the IDD with insulin.
Filling syringe	Used to fill the IDD with insulin.
Food dose	Insulin that is taken before you eat.
Glucose	Another term for sugar, most commonly found in carbohydrates.

Glucose tablets

A sugar tablet that is most commonly used to increase blood glucose in episodes of low blood sugar (hypoglycemia)

Health Care Provider (HCP)

An individual who practices medicine and is authorized by the state to perform duties within the scope of their practice. This may include, a Nurse Practitioner, Physician's Assistant or CDE. This may include but is not limited to a Nurse Practitioner, Physician's Assistant, CDE, or MD.

Hyperglycemia

A reaction occurring when blood glucose is above normal levels.

**Hyperosmolar
Hyperglycemic
Nonketotic
Syndrome (HHS)**

A rare condition where very high blood glucose levels are seen with severe dehydration. The body tries to rid the body of the large amounts of glucose by passing it into the urine.

Hypoglycemia

A reaction occurring when blood glucose is below normal levels.

Icon

A picture on your touchscreen, back of Remote, Insulin Delivery Device (IDD), or package that points to a choice or information.

Inadvertently

Without intention; accidentally.

Increment

A unit of measure. As in 2 unit increments of insulin.

Infusion

Introducing a liquid substance to the body over a period of time at a specific rate.

Insertion site

The location on the body where the catheter is inserted under the skin for insulin delivery.

Insulin

A hormone made and secreted by the beta cells of the pancreas that helps control the glucose levels.

**Insulin
Delivery
Device (IDD)**

A device that is worn on the body for up to three days. It is designed to be worn during all your activities. The IDD precisely delivers insulin from its internal reservoir where the insulin is stored.

IDD light

Green light will blink during IDD setup.

**IDD
replacement kit**

IDDs are provided in individually-packaged replacement “kits” that include the Filling syringe and needle you will use each time you fill the IDD with your prescribed insulin amount.

**IDD side
buttons**

Buttons located on the side of the IDD that are used when pairing the device during IDD setup and for dispensing your full Food Dose when your Remote is not available (each squeeze equals preset number of units).

IDD vent

Allows for proper operation of the IDD.

Ketones

Weak acids produced when the body begins to break down fat for energy instead of glucose.

Lancet

A device used to puncture the tip of your finger to expel blood.

Leakage

An accidental escape of a fluid (insulin) from the IDD.

Lotion

A thick, smooth aqueous preparation with insoluble materials intended to be applied to the skin for medical or cosmetic purpose.

Menu

A list of choices on your touchscreen.

MRI

Magnetic resonance imaging is a technique that uses a magnetic field and radio waves to create detailed images of the organs and tissues within the human body.

Mild Hypoglycemia

In the early stages of hypoglycemia you might feel all, some, or in some cases, none of these signs and symptoms: sudden hunger, headache, shaking, fast or pounding heartbeat, sweating, tired, dizzy, blurred vision, nervous or excited, drowsy, numbness or tingling around mouth and lips.

Occlusion

A blockage or interruption in insulin delivery.

Operating Room Temperature

Temperature in which the device should be kept in when in use (5 – 30 degrees Celsius).

Pancreas

Organ in the body consisting of beta cells that make and release insulin in response to blood glucose.

**Pattern management/
Pattern Control**

Adjusting insulin doses based on a pattern of blood glucose readings over three days or more.

Press

Use your finger to squeeze a button.

Press to Cancel

Tap the “Press to Cancel” circle to cancel a Food Dose.

Protein

One of the three main nutrients in food. Foods that provide protein include meat, poultry, fish, cheese, milk, dairy products, eggs, and dried beans.

Radio Frequency (RF)

A frequency or band of frequencies that range 104 Hz to 1012 Hz, suitable for telecommunications.

Remote

Device used to set insulin rates and doses. It communicates and is used to control the IDD.

Residual volume

The volume of insulin still remaining in the insulin delivery device and/or infusion set after the wear duration.

Rotate

Infusion sites should be changed each time the IDD is changed. A new infusion site should be at least 1 inch (2.5 cm) away from the last site. You should not use the same insertion site again for 7 – 10 days.

Rx Only

For sale by or on the order of a physician only (US).

Safety cap

A cap that is shielding the needle insertion button and prevents you from accidentally activating the needle.

Self blood glucose monitoring

Regular blood checks to detect blood glucose levels. Blood glucose checks are used to make changes to one's treatment plan.

Severe Hypoglycemia

A low blood sugar reaction with symptoms that include: stupor, seizure, or unconsciousness. Medical help is highly advised.

Sharps

needles, lancets, and other sharp-pointed devices used to give injections or draw blood.

Sharps container

A puncture proof container used for the disposal and storage of used needles, syringes, and lancets.

Sick Day Rules

Advice to follow when you are sick. Your body releases stress hormones that help your body fight against your illness, but will also raise your blood glucose. Sick day rules will help you avoid diabetes complications from high blood glucose.

Sleep Mode

After installing the batteries, the screen will automatically go to sleep after 1 minute of inactivity.

Sterile

Free from bacteria or other living microorganisms.

Storage Temperature Range

The temperature range in which the device can be stored at (5 – 30 degrees Celsius).

Subcutaneous

Under the skin.

Submerged

Completely under water or any type of liquid.

Swipe

Quickly and lightly slide your finger across the Remote's touch screen.

Tap

Quickly and lightly touch the Remote's touchscreen with your finger.

Tip

Advice on how to keep BD Strive™ working properly.
Advice on getting the most out of BD Strive™.

Type 1 diabetes

The type of diabetes occurs primarily in children and young adults. The pancreas produces little to no insulin.

Type 2 Diabetes Mellitus

A metabolic disorder that is characterized by decreased insulin production, insulin resistance, and high blood sugars.

Rapid U-100 insulins

Humalog® (insulin lispro).

Warning

Indicated a hazardous situation that, is not avoided, could result in death or serious injury.

Wireless

Using waves to transmit signals opposed to wires or cables.

Withdraw

The act of removing.

X-ray

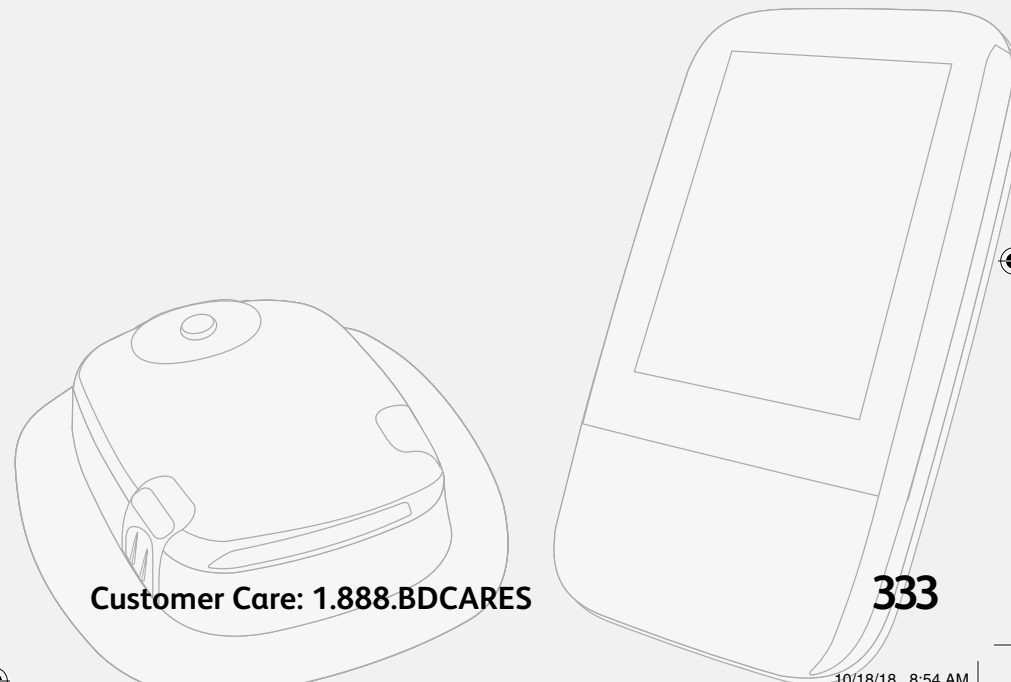
An electromagnetic wave of high energy that allows your HCP to see your internal organs and bones.

8.7 Recycling information for Remote

BD encourages recycling of its products. Since disposal facilities, environmental conditions, and regulations vary across states and countries, please consult qualified professionals and applicable regulations or authorities within your region to ensure proper disposal of your wireless Remote.

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Customer Care: 1.888.BDCARES

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Support

If you have any questions about using the BD Strive™ type 2 Insulin Management System, call Customer Care at **1.888.BDCARES.**

If you have any health questions or concerns about your diabetes treatment, contact your Healthcare Provider.

If you have a medical emergency, call 911 (US only) or 112 (EU only), your doctor, or go directly to the hospital.



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