

# inpen™

## InPen™ System

### Instructions for Use



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# Symbols in This User Guide

The following symbols are found on the InPen™ or the package labels. These symbols tell you about the proper and safe use of the InPen™ System.

	Non-ionizing Radiation
	Consult Instructions For Use
	Caution
	Do Not use if Package is Damaged
	Temperature Limitation
	Humidity Limitation
	Pressure Limitation
	Keep Dry
<b>IP22</b>	Protection Against Insertion of Large Objects and Dripping Water
	Type BF Applied Part
<b>CE</b>	Device Meets European Council Directive 93/42/EEC
	Manufacturer
<b>EC REP</b>	Authorized Representative in the European Community
	Expires On Date
	European Union WEEE Directive 2012/19/EU

# 1. Introduction

This user guide will explain how to use your InPen™ and the InPen™ Application (app). Read it carefully before you use your InPen™.



**You should read this manual before use – even if you have used the InPen™ before. Failure to follow the instructions may result in too much or too little insulin being delivered.**

**Important: Do not share your InPen™ or needles as infection or disease can be spread from one person to another.**

If any of the parts of your InPen™ appear broken or damaged, DO NOT USE. Contact Customer Service by tapping **Settings** from the Home screen and selecting **Help and Support** for a replacement.

InPen™ is not recommended for the blind or visually impaired without the assistance of a sighted individual trained to use it. Always carry a spare insulin delivery device in case your InPen is lost or damaged.

The InPen™ App is a diabetes management tool that helps track your insulin doses, calculate insulin doses using current glucose and carbohydrates, and share your therapy with your healthcare professional and family members.

The insulin dose calculations provided by the app are meant for patients undergoing subcutaneous multiple daily injection (MDI) therapy. Dose calculators have been shown to assist in the optimization of glycemic control in MDI patients under the supervision of healthcare professionals experienced in managing insulin-treated patients. Dose calculators have also been shown to reduce patient fear of hypoglycemia and improve patient confidence in diabetes management.

Dose calculators also track residual bolus insulin to mitigate insulin stacking.

## **System Description**

The InPen™ System includes the InPen™ smart insulin pen and the InPen™ App. The InPen™ System automatically records dose size and timing of insulin doses, provides reminders if insulin is not taken, includes an insulin dose calculator with personalized settings, tracks insulin on board, and has the ability to integrate with other diabetes technologies, including a continuous glucose monitor (CGM).

### **Key Features:**

- View simple, graphical visuals of your diabetes therapy and active insulin.
- Calculate insulin doses using current glucose and carbohydrates or meal type and/or size.
- Set reminders so you don't forget to take your insulin
- Import glucose data automatically from supported CGMs and BGMs
- View and share integrated diabetes therapy reports with your healthcare provider

### **Support:**

- Setup wizard within the app.
- User Guide links within the app
- Instructional videos within the app.

## **2. Indications for Use**

The InPen™ requires a prescription. It is a home-use reusable pen injector for single-patient use by people with diabetes under the supervision of an adult caregiver, or by a patient age 7 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Lilly Humalog® U-100 3.0 mL cartridges, Novo Nordisk Novolog® U-100 3.0 mL cartridges, and Novo Nordisk Fiasp® U-100 3.0 mL cartridges and single-use detachable and disposable pen needles (not included). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

The InPen™ dose calculator, a component of the InPen™ App, is indicated for the management of diabetes by people with diabetes under the supervision of an adult caregiver, or by a patient age 7 and older for

calculating an insulin dose or carbohydrate intake based on user entered data.

For an insulin dose based on amount of carbohydrates, a healthcare professional must provide patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software prior to use.

For an insulin dose based on fixed/variable meal sizes, a healthcare professional must provide patient-specific fixed doses/meal sizes to be programmed into the software prior to use.

### **3. Contraindications:**

The InPen™ System is not intended for anyone unable or unwilling to:

- Test blood glucose (BG) levels as recommended by a healthcare provider
- Maintain sufficient diabetes self-care skills
- Visit a healthcare provider regularly

User interaction, compatible device and proper device pairing and settings required.



**Caution: US law restricts the sale of the InPen™ System to sale by or on the order of a physician.**



#### **Important Pediatric User Information:**

Younger children may inadvertently play with the pen injector or the app, leading to unintentional logging or delivery of insulin. It is the responsibility of the healthcare provider and the caregiver to determine if the patient is appropriate for treatment with the InPen™ system.

Do not allow small children to chew on or ingest parts, such as the pen cap and cartridge components. Small parts could pose a choking hazard. If ingested or swallowed, these component pieces may cause internal injury or infection.

For patients who do not self-manage their disease, the smart device should always be under the supervision of a caregiver. Inadvertent button presses may lead

to unintentional dose logging or changes to therapy settings. These changes can potentially lead to hypoglycemic or hyperglycemic events which could result in serious injury or death.

## 4. Supported Devices

The InPen™ App is compatible with:

- iOS 10 or later
- Android 6 or later

This product should only be used with supported mobile devices. Refer to your local Medtronic® website or Helpline for information about supported devices and operating systems.

Periodically, the app needs to confirm that it is compatible with your smart device and operating system version. You may see system messages with instructions or warnings. Make sure you have an internet connection (ensure that Wi-Fi or cellular data is enabled) whenever possible.



**Caution: You must first pair your InPen™ with a smart device and the InPen™ App. This will ensure that doses from your InPen™ are sent wirelessly to the App on your smart device.**



**Warning: The Bluetooth® feature on your InPen™ sends dose information to your smart device. To prevent other people's doses from being sent to the smart device, do not let anyone else use your InPen to dose insulin. The InPen is for single patient use only.**



**Bluetooth® performance varies due to differences in phone hardware and operating systems. The InPen™ App is not recommended on Jailbroken or Rooted devices.**



**Your smart device must have enough memory storage or the InPen™ App will not be able to be installed or log dose. You may need to delete files or apps from your smart device.**

## 5. Getting Started

The following steps will get you started using the InPen™ App:

1. Download the InPen™ App from the App Store and install it on your smart device.
2. Open the app.
3. Log in to the app using an existing account or create a new one.
4. After you log in to the app, follow the steps in the setup wizard.

### 5.1 About You

1. Take a moment to tell us about you.

### 5.2 Therapy Setup

Before the app can be used, you will need your dose calculator and Long-acting insulin settings from your healthcare provider. Your healthcare provider may have already entered these for you at your visit. If not, you can find these on your InPen™ Prescription Form.

If you do not have your Therapy Settings you can skip this section of the wizard and complete it later. The dose calculator will be locked out until these settings are entered.



**IMPORTANT: To use the dose calculator safely, it is extremely important that Therapy Settings are correct. Proceed only after talking to your health care provider.**



**IMPORTANT: Once selected and confirmed, your Meal Therapy cannot be changed. Verify with your doctor if you are unsure of your Meal Therapy. If you choose the wrong meal therapy contact Customer Service by tapping Settings from the Home screen and selecting Help and Support.**





There are three different ways to calculate insulin doses using the InPen™ App. Your healthcare provider has prescribed you one of the following:

- Fixed Dosing
- Meal Estimation
- Carbohydrate Counting

Once you have your dose calculator settings, tap on each line to set the correct value. Once you have selected the correct value, tap the green check mark to save and the red X to cancel.

### **To change the Meal Therapy mode:**

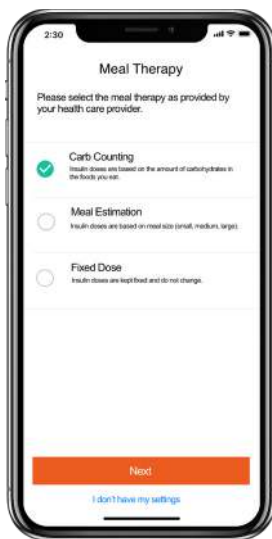
1. Go to Therapy Settings, then proceed after reading the disclaimer
2. Tap Meal Therapy and select the new Meal Therapy mode prescribed by your healthcare provider.
3. Tap on each line to set the value to match the settings provided by your healthcare provider.



**IMPORTANT: Before changing Meal Therapy Mode, you will need your current Meal Therapy settings from your healthcare provider. Previous Meal Therapy settings may be lost when you change to a new Meal Therapy type.**



**IMPORTANT: An updated prescription is required to increase the precision of your Meal Therapy mode.**



## 1. Fixed Dose Mode – Setup

The following settings must be set before you can begin fixed dosing:

**Maximum Calculated Dose** – The maximum calculated dose that your healthcare provider determines is safe for you. If a single dose recommendation or the total of recent doses plus the recommendation exceeds the maximum calculated dose setting, an alert will be displayed. Refer to the instructions given by your healthcare provider.

**Duration of Insulin Action** – This is the amount of time that insulin is actively lowering your blood glucose. It is used to calculate Active Insulin.

**Target Blood Glucose** – This is the blood glucose value you are trying to achieve. When entering a blood glucose value into the Dose Calculator, it will recommend insulin or carbohydrates to return to this target value.

**Insulin Sensitivity Factor** – This is the amount your blood glucose is lowered by 1 unit of insulin.

**Time of Day Settings** – By default, this is disabled and Target Blood Glucose and Insulin Sensitivity Factor are constant throughout the day. By sliding the switch to the right, you can set these values to four different values throughout the day. To disable this feature, slide the switch back to the left.

Each day at the time selected, the values in the column will be active until the next column's time is reached. Tap the time to adjust it. Note that the times must be in order and cannot overlap.

Time of Day settings are disabled by default. See Advanced App Features for instructions.

**Fixed Dose Settings** – This is the dose size your healthcare provider has determined for the different meals of the day.

## How to Use

- In Fixed Dose mode the Dose Calculator will provide a fixed dose insulin recommendation at meal times.
- After choosing your meal, you can enter a current glucose for a dose recommendation that includes a glucose correction if needed.
- Connected BGM may pre-populate through Apple Health. Only blood glucose values less than 10 minutes old will be pre-populated.
- After tapping Save, the dose recommendation is shown at the top of the home screen.
- You can tap Cancel to go back without saving the entry.

See Section 6.2 Calculate an Insulin Dose for more about the types of recommendations you may receive.

## 2. Meal Estimation Mode – Setup

The following settings must be set before you can begin meal estimation dosing:

**Maximum Calculated Dose** – The maximum calculated dose that your healthcare provider determines is safe for you. If a single dose recommendation or the total of recent doses plus the recommendation exceeds the maximum calculated dose setting, an alert will be displayed. Refer to the instructions given by your healthcare provider.

**Duration of Insulin Action** – This is the amount of time that insulin is actively lowering your blood glucose. It is used to calculate Active Insulin.

**Target Blood Glucose** – This is the blood glucose value you are trying to achieve. When entering a current glucose value into the Dose Calculator, it will recommend insulin or carbohydrates to return to this target value.

**Insulin Sensitivity Factor** – This is the amount your blood glucose is lowered by 1 unit of insulin.

**Meal Estimation** – Slide the switch to the right to select the dose size for low carb, medium carb, and high carb meals and snacks. Each day at meal times, the InPen™ App will ask you what size meal you are eating and recommend the correct dose. Tap the meal size to adjust it.

**Time of Day Settings** – By default, this is disabled and Target Blood Glucose and Insulin Sensitivity Factor are constant throughout the day. By sliding the switch to the right, you can set these values to four different values throughout the day. To disable this feature, slide the switch back to the left. Each day at the time selected, the values in the column will be active until the next column's time is reached. Tap the time to adjust it. Note that the times must be in order and cannot overlap.

Time of Day settings are disabled by default. See Advanced App Features for instructions.

### **How to Use**

- In Meal Estimation mode the Dose Calculator will provide an insulin recommendation based on meal size at meal times.
- After choosing your meal size, you can enter blood glucose (BG) for a dose recommendation that includes a glucose correction if needed.
- Connected BGM may pre-populate through Apple Health. Only BG values less than 10 minutes old will be pre-populated.
- After tapping Save, a revised dose recommendation is shown at the top of the home screen.
- You can tap Cancel to go back without saving the entry.

See Section 6.2 Calculate an Insulin Dose for more about the types of recommendations you may receive.

### 3. Carb Counting Mode – Setup

The following settings must be set before you can begin carb counting dosing:

**Maximum Calculated Dose** – The maximum calculated dose that your healthcare provider determines is safe for you. If a single dose recommendation or the total of recent doses plus the recommendation exceeds the maximum calculated dose setting, an alert will be displayed. Refer to the instructions given by your healthcare provider.

**Duration of Insulin Action** – This is the amount of time that insulin is actively lowering your blood glucose. It is used to calculate Active Insulin.

**Time of Day Settings** – By default, this is disabled and Target Blood Glucose, Insulin-to-carbohydrate Ratio, and Insulin Sensitivity Factor are constant throughout the day. By sliding the switch to the right, you can set these parameters to four different values throughout the day. To disable this feature, slide the switch back to the left.

**Time of Day (If Time of Day Settings are enabled)** – When enabled, these select the start time for each new set of parameters. Each day at the time selected, the parameters in the column beneath it will be active until the next column's time is reached. Tap the time to adjust it. Note that the times must be in order and cannot overlap.

**Target Blood Glucose** – This is the blood glucose value you are trying to achieve. When entering a current glucose value into the Dose Calculator, it will recommend insulin or carbohydrate to return to this target value.

**Insulin Sensitivity Factor** – This is the amount your blood glucose is lowered by 1 unit of insulin.

**Insulin-to-carbohydrate Ratio** – This is the number of grams of carbohydrate covered by 1 unit of insulin.

## How to Use

- In Carb Counting mode the Dose Calculator will provide a carbohydrate counting insulin recommendation once you have entered a current glucose or carbohydrates (Carbs) only, or both.
- Enter your current glucose and/or the number of grams of Carbs you are eating or plan to eat and tap Save.
- Connected BGM may pre-populate through Apple Health. Only blood glucose values less than 10 minutes old will be pre-populated.
- After tapping Save, a revised dose recommendation is shown at the top of the home screen.
- You can tap **Cancel** to go back without saving the entry.

See Section 6.2 Calculate an Insulin Dose for more about the types of recommendations you may receive.

When you have entered all values and carefully checked that they are correct, tap **Next**.

## 4. Long-acting Insulin

The app will remind you to take your Long-acting insulin. If you log a Long-acting dose prior to the reminder time the app will not remind you. If no long acting dose was logged, the app will remind you.

Once you have your long acting insulin settings, tap on each line to set the correct value. Once you have selected the correct value, tap the green check mark to save and the red X to cancel.

The values that must be set are:

**Insulin Type** – This is the type of Long-acting insulin that you take.

**Doses per Day** – This is the number of doses you take per day.

**Usual Amount** – This is the dose size you have been prescribed by your healthcare provider.

**Time** – This is the time of day that you are supposed to take your dose.

When you have entered all values and carefully checked that they are correct, tap **Next**.

## 5.3 Your Schedule

The app will also remind you to take your insulin at mealtimes and take any action before bed time.

The setup wizard will ask you to enter the **earliest** and **latest** times that you eat breakfast, lunch, and dinner. Make sure that you consider times during the week when going to work or school and times on the weekend which may be different.

NOTE: Long-acting insulin is not considered part of Active Insulin. Active Insulin applies to Rapid-acting or mealtime insulin only.

## 5.4 Bedtime

The setup wizard will next ask you when you typically go to bed. Consider the time before bed when you would be able to check your glucose and take any correction doses with InPen™ if needed.

InPen™ reminds you to check your blood glucose before bedtime and recommends additional insulin or carbohydrates if needed to help control your blood glucose.

## 5.5 Connect InPen



**IMPORTANT:** To ensure a secure connection, pair your InPen™ and smart device in a secure area with limited Bluetooth® devices in range.



**CAUTION:** Make sure you know which InPen™ you are pairing with your smart device.



**IMPORTANT:** The use of a security code on your mobile device is recommended.

1. Place the devices within 3 feet (~1 meter) of each other before you begin.
2. Make sure Bluetooth® is enabled on your smart device.
3. Follow the instructions in the app to pair your InPen™.
4. The InPen™ App will display **Pairing Successful** once InPen™ and your smart device are paired.
5. Follow the instructions to name your InPen™.
6. Read the important notes regarding treatment decisions.

## 5.5 Install an Insulin Cartridge

Follow the video instructions in the app for an overview of how to install an insulin cartridge. **See Section 11 Prepare your InPen™** for more detailed instructions.



**CAUTION: If the Cartridge Holder is not securely attached, the cartridge may be misaligned and you may not get your full dose.**

## 5.6 Taking an Insulin Dose

Follow the video instructions in the app for an overview of how to take an insulin dose. **See Section 12 Prime your InPen™ (Before Every Injection)** for more detailed instructions.

## 5.7 InPen Support

If you have product support questions, do not call your doctor. Help and support is available by phone or email or using our self-service Help Center any time through **Settings > Help and Support > Support**. Check Troubleshooting for explanations of app error messages and a list of other common issues and solutions.

## 5.8: Connect CGM

Select CGM to connected, Medtronic, Dexcom or Abbott. Currently, InPen is connected with Medtronic Guardian™ (connected) or Dexcom CLARITY (delay).



You will be prompted to enter username and password of CGM. Once the connection is established, changes may be done within the settings icon on the home screen.

## 5.9: Connect to Apple Health

If you are using an Apple iOS Device, you may connect to Apple Health for BG meters or CGM (delay). Follow the prompts to connect via Apple Health.

## 5.10 Tutorial

Tap through the tutorial for an overview of the features of the app. You can review the tutorial and this user guide at any time through **Settings > Help and Support > Support**.

## 6.0 Important Smart Device Setup



**IMPORTANT: Your smart device must be set up correctly to work properly and safely with the InPen™ System. Your device's internal settings override any InPen™ App setting. If the settings on your device are incorrect your InPen™ System may not function properly.**



**IMPORTANT: Enable the security features of your smart device to prevent unauthorized access to your data and settings.**

To ensure safety and security, utilize virus/malware scanning software on your smart device.

To receive Alarms or Alerts you must:

- Make sure the notifications are turned on in the settings menu
- Check that the app hasn't been shut down by your smart device
- Make sure to turn on Bluetooth® on your smart device
- Turn off the Do Not Disturb feature on your smart device (if available)
- Start the app after your smart device is restarted
- Set the volume on your smart device at a level you can hear

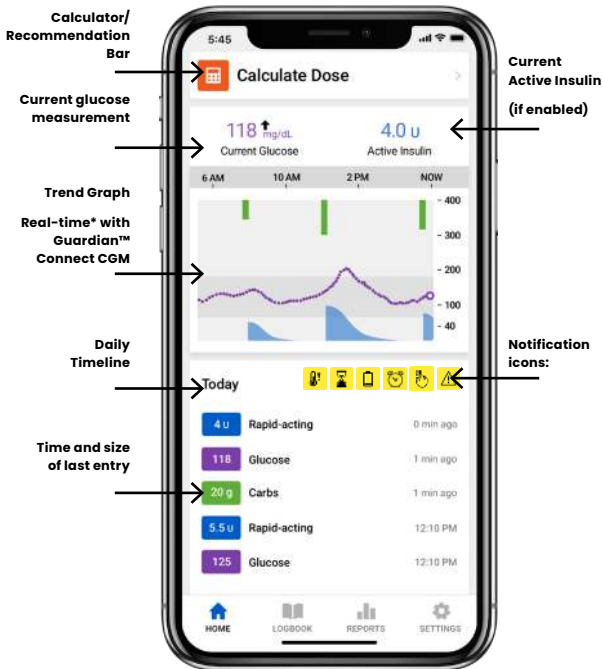
- Do not kill or force close the app; always run the app in the background
- Unplug your headphones when you are done using them; Alarms and Alerts from the app cannot be heard through your smart device's speakers if headphones are plugged in.

The InPen™ alarm and alert vibrations are not any different from other vibrating apps on your smart device. Medical device apps, like the InPen™ App, do not have any special priorities over your smart device's features. You cannot determine if a vibration is a notification from your InPen™ App or another app. The only way to know is to look at the screen of your device.







The smart device checks and updates the date and time in your InPen™. Check the date and time on your device often to be sure it is correct. Check the date and time on your device when you travel across time zones. Keep "set Automatically" enabled and let your smart device manage the date and time. For instructions on setting the date and time on your device, see the user manual for your device.

The InPen™ App is known to be free of malware.

# 7. Using the InPen™ App



## Notification icons:

-  Insulin Temperature
-  Insulin Age
-  Low InPen Battery
-  Rapid-acting Reminder
-  Long-acting Reminder
-  Alert

\*Data may not appear or be delayed in certain instances, including when there is no Internet connection. A confirmatory fingerstick is required prior to making adjustments to diabetes therapy.

## 7.1 Overview of Your Recent Glucose and Insulin Usage

The Home screen shows an overview of your recent glucose and insulin use.

**Current Glucose** shows the last glucose you entered or measured with a connected BGM or supported CGM. If the glucose is more than 10 minutes old, the value will show “---” and you will need to measure your glucose again.

**Active Insulin** is an estimate of the insulin from recent doses that is still being used in the body. It is based on the recent doses you’ve taken, and your Therapy Settings. If you take a 5 U dose, there will initially be a full 5 units in your body. Over several hours this will decrease as it is used by your body and Active Insulin will reach 0.0 units until more insulin is taken.



**NOTE: Long-acting insulin is not considered part of Active Insulin. Active Insulin applies to Rapid-acting or mealtime insulin only.**



The Daily **Timeline** is a graphical representation of glucose, carbohydrates meals, and insulin doses over the last 24 hours. Your most recent glucose, carbohydrates/meals and insulin doses will appear at the top, of the Timeline, and will move down the timeline as new logbook entries are saved. Only BGM values and glucose values entered and saved in the Dose Calculator are shown in the timeline.

The Trend Graph shows your glucose over time from CGM or BGM. Glucose data from BGM will be shown as individual points. Glucose data from CGM will be shown as a series of closely spaced points. Your most recent glucose will be shown as a hollow circle. By tapping the Trend Graph you can toggle between 3, 6, 12, and 24 hour views.

## 7.2 Calculate an Insulin Dose



**IMPORTANT:** Your Therapy Settings must be set correctly before using the Dose Calculator. Do not use the Dose Calculator if you have guessed settings or believe they may be set incorrectly.



**IMPORTANT:** All insulin you have recently taken must be entered to ensure that Active Insulin is correct. If you have taken any Rapid-acting or mealtime insulin from a device other than InPen™, it must be logged manually.



**IMPORTANT:** If you do not enter a current glucose value, Active Insulin will not be subtracted from the dose recommendation.



**WARNING:** Using the Dose Calculator with incorrect Therapy Settings or without all of your recent insulin logged may result in unsafe recommendations, which could lead to severe hyperglycemia, hypoglycemia, or injury.



**WARNING:** If your InPen™ is out of range of the smart device the Dose Calculator may not have all of your recent insulin logged and may result in unsafe recommendations, which could lead to severe hyperglycemia, hypoglycemia, or injury.

To use the Dose Calculator, tap the Dose Calculator icon on the Home screen.

The Dose Calculator will only provide an insulin recommendation once you have entered values. You can enter current glucose or carbohydrates/meal only, or both.

Enter your current glucose and/or carbohydrates/meal information for the meal you are eating or plan to eat and tap **Save**. Connected BGM may pre-populate through Apple Health. You can tap **Cancel** to go back without saving the entry.



Once you have entered current glucose and/or carbohydrates/meal information, you may see one of the following recommendations:



**Units of Insulin** – Based on your current Active Insulin and the current glucose and carbohydrates/meals entered; this is the recommended number of units of insulin to take now. You may give the dose using your InPen™ and it will be automatically logged.



**NOTE: Only prime your InPen™ after you have calculated your dose.**



**Grams of Carbs** – Based on your current Active Insulin, glucose and carbs/meals entered, these are the additional grams of carbohydrates to eat now to avoid low blood glucose in the near future.



**0 Units** – Based on your current Active Insulin, glucose and carbohydrates/meals entered; no additional food or insulin is recommended at this time.



**Eat fast-acting carbohydrates to treat your low blood glucose** – This message will be shown if you enter a low glucose value, regardless of Active Insulin or carbohydrates/meal entered. If your blood glucose is low, it is important that you eat fast-acting carbohydrates.

To view details about an insulin dose recommendation, you may tap the arrow in the recommendation banner at the top of the screen to see the math used in the calculation.

Calculator: Recommendation	
BG Correction	+3.10 U
Carb Dose	+5.50 U
IOB Adjustment	-2.00 U
Total	6.60 U
Max Dose	5.0 U
Recommended Dose	5.0 U

Tap the back arrow to return and save your dose. Note that dose recommendations are **rounded down** to the nearest half unit.



**IMPORTANT: The calculated dose is a suggestion. You decide whether to follow the suggestion or rely on your own judgment. The dose calculator cannot account for other factors like activity, illness, alcohol use, etc.**

## 7.3 Split Doses

The InPen™ can deliver a maximum of 30 units per injection. For doses greater than 30 units the dose must be split into multiple doses. If for any reason a dose is split into multiple doses, each dose that is delivered will be logged separately. To ensure that your insulin is tracked correctly, always take the larger dose first.

If you forget how much insulin was recommended, you may use the dose calculator again to calculate the remaining dose required.

When you are done using the calculator, you may tap **Cancel** to return to the Home screen or Save to automatically save what you entered, to the Logbook.

## 7.4 View Details in the Logbook

To view details of your recent doses and calculations, tap **Logbook** from the Home screen.

Here you will see your recent activity. You can scroll up and down to see details of different days. Each blood glucose value/meal type and/or size, carbohydrate value, dose calculation, prime dose, Rapid-acting insulin dose, Long-acting insulin dose, and cartridge replacement is listed with the time it occurred.

All doses taken from your InPen™ will be listed here, along with any doses of Rapid-acting or Long-acting insulin you have manually logged.



Manually logged Rapid-acting and Long-acting doses can be deleted from the logbook by tapping the dose.

If the insulin cartridge does not have enough insulin to complete your dose, the dose that was delivered will be logged. After changing the cartridge, deliver the remaining dose and it will be logged also. If you forget how much insulin was in the cartridge, you can use the dose calculator again to determine the remaining dose required.

Your InPen™ will automatically determine whether a dose was therapeutic (injected into your skin) or prime (clearing air out of the needle before a dose). It will also



automatically detect when you install a new cartridge.

## 7.5 Designate Dose or Prime if Needed



**IMPORTANT: Therapy doses and Prime doses must be correctly identified, because only therapeutic doses are included in Active Insulin and used by the Dose Calculator.**

InPen™ automatically determines if a dose was a Prime or a Therapeutic dose. If you need to adjust whether a dose was a Therapeutic dose or a Prime, tap the entry in the Logbook. A Dose or Prime selector will appear, and you can select the correct dose type.



## 7.6 Manually Log Rapid-acting Insulin



**WARNING: Log all insulin from all sources into the Logbook. The Dose Calculator does not account for manual injections that you do not enter and could recommend more insulin than needed. Too much insulin may cause hypoglycemia.**



**IMPORTANT: Your mobile device must be set to the current time to ensure that manual doses are logged correctly and your Active Insulin is correct. Incorrect time settings could result in unsafe recommendations, which could lead to severe hyperglycemia, hypoglycemia, or injury.**

For the Dose Calculator to work safely and accurately, it is critical that all Rapid-acting insulin be logged. If you take Rapid-acting insulin from a source other than your InPen™, it must be logged manually. Doses taken with your InPen™ are logged automatically.

To enter a manual dose, tap **Log Dose** in the Logbook. You can log Rapid-acting insulin or Long-acting insulin.

To enter the units of Rapid-acting insulin taken, tap **Dose Amount** and enter the number of units taken from a source other than your InPen™.

To enter the time of the dose, tap **Dose Time** and enter the time when the dose was taken. By default, the time is set to the current time, but it can be adjusted to any time within the last 24 hours to log a dose you previously took.



*If you have traveled across a time zone, adjust and enter the dose time as though it was taken in your current time zone.*

When you have entered the correct dose, tap **Save** to save it and return to the Home screen.

To exit without saving a dose, tap **Cancel**.

## 8.0 Advanced App Features

### 8.1 Reminders

The **Check BG 2hrs After Dose Reminder** helps you remember to check your blood glucose after each rapid acting insulin dose.

When enabled, it will alert you 2 hours after a Rapid-acting insulin dose is taken with the InPen or manually logged. To enable or disable the reminder, slide the switch.

The **Replace Cartridge After 28 Days Reminder** helps you remember to replace your insulin. When enabled, it will alert you 28 days after a cartridge is replaced in your InPen™. To enable or disable the reminder, slide the switch.

## 8.2 Insights by InPen™ Reports



**IMPORTANT: The Insights by InPen™ report is intended to supplement, not replace, medical expertise in the self-administration of insulin for the treatment of diabetes. The report provides information that can be used to identify trends to inform treatment decisions. Reports are not intended to produce medical advice and should not be relied upon for such purpose..**

To see a therapy summary for your own review or to share with a health care provider, tap **Reports** from the Home screen.

You can select 7, 14, 30, or 90-day time periods by clicking on the report settings icon in the upper left corner of the reports tab. The report covers through the end of the previous day, so the current day's activity will not be included.

To send this report to yourself or a health care provider, tap the share icon. Then select either **Fax or Email / Print / Share** and select from the available options to send the PDF report.

In addition to your current Therapy Settings, the contents of the report include:

**Total Daily Dose** – The average total insulin taken (Rapid and Long-acting) per day and percentage of each type taken per day. This excludes days where no doses were logged and does not include other doses not logged into the app.



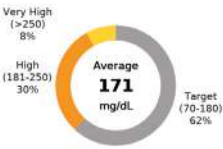
Use this chart to understand:

- Average total daily insulin dose (TDD) over the report period for days with at least one insulin dose and standard deviation of rapid acting doses only
- Percentages of Long-acting and Rapid-acting insulin within TDD

**Glucose** – The average glucose value entered into the dose calculator or imported from a connected BGM or CGM.

Use this chart to understand:

- Average and standard deviation of your glucose over report period
- Percentage of time spent in and out of the target glucose range

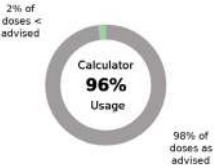


**64 mg/dL** the  
Glucose Standard  
Deviation

**Dose Calculator Usage** – The percentage of dose calculator usage and insulin doses where the dose calculator was used but the dose taken was different than the recommended dose.

Use this chart to understand:

- Percentage of doses in which the dose calculator was used within 10 min prior to the dose
- Percentage of doses taken within  $\pm 0.5$  U of the advised dose
- Percentage of doses taken 1 U over or under the advised dose

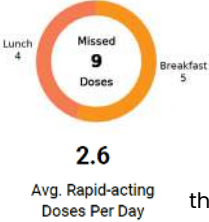


**Missed Doses** –

The average number of missed doses and when they occur per day.

Use this chart to understand:

- How many doses were missed, or meals skipped, over report period.
- Average number of Rapid-acting doses logged per day, over the report period.

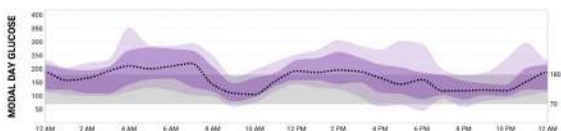


**Note:** Rapid-acting doses not logged within the time range configured in meal dose reminders are considered missed doses, unless you indicated that you did not eat that meal in the missed dose reminder response. If missed dose reminders are not enabled missed doses will still be reported.

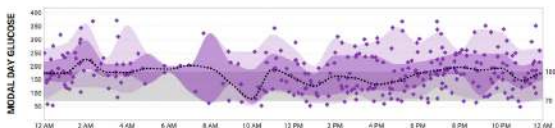
Long-acting doses not logged within three hours before or after the long acting reminder time are considered missed doses. Missed long acting doses are calculated only when the long acting reminder is enabled. The average number of doses taken per day is also shown. For BGM users, the average number of glucose checks per day is also displayed.

**Modal Day Glucose** – A graphical representation of patterns of daily glucose. The chart shows median values in black, quartile ranges in dark bands, and 10% – 90% values in lighter bands. A fixed target range of 70–180 mg/dL is shaded grey with the glucose data overlaying. This can be used to identify patterns and trends at different times of day.

CGM data will appear like this:



BGM data will appear like this:



**Note:** All glucose values saved to Logbook are plotted. The shaded bands are for reference only when viewing BGM data. Actual blood glucose between glucose points is unknown.

This chart may help identify:

- Variability in glucose levels by time of day
- Hyperglycemia trends
- Hypoglycemia trends

**Insulin Settings** – Insulin settings configured within the app will display beneath the Modal Day Glucose chart. The settings are aligned to the time of day they are programmed within the app.

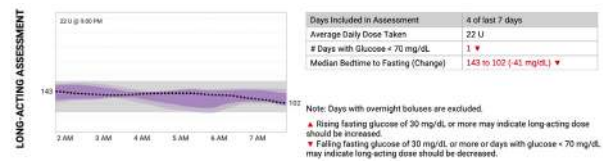
	12 AM	2 AM	4 AM	6 AM	8 AM	10 AM	12 PM	2 PM	4 PM	6 PM	8 PM	10 PM	12 AM
Target BG	120		100		100		100		100		120		mg/dL
ICR	12		8		10		10		10		12		g/U
FR	45		40		40		40		40		45		mg/dL/U

Max Dose: 10 U    Duration of Insulin Action: 2h

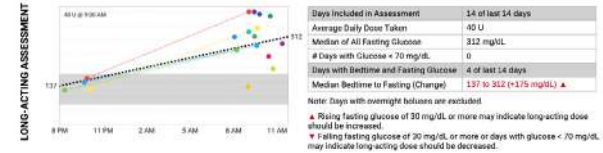
**Long-acting Assessment:** The fasting window is determined based on the time with the fewest Rapid-acting doses or you can specify your own. Glucose values entered into the dose calculator or imported from a connected BGM or CGM during the fasting window are shown. Days with Rapid-acting doses during the fasting window or in the 2 hours prior to the start of the fasting window are excluded.

- This assessment may help identify:
- The median bedtime glucose value (at least 2 hours after last meal of the day)
  - The median fasting glucose value (before first meal of the day)
  - Trends in glucose during the fasting window.
  - Flags to alert for rises and falls in glucose and frequency of hypoglycemia that may be of clinical significance.<sup>1,2</sup>

Long-acting Assessments with CGM data will appear like this:



Long-acting Assessments with BGM data will appear like this:



1. Walsh J, Roberts R. Pumping Insulin, 6 th ed. 2017, Torrey Pines Press

2. Walsh J, Roberts R, Bailey T. Guidelines for Optimal Bolus Calculator Settings in Adults. J DM Sci & Technol, 2011;5(1):129-135.

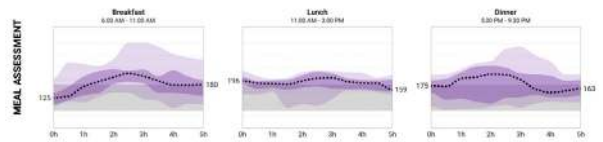
**Note:** Glucose values taken on the same day, are the same color and are connected with lines. The lines are for reference only when viewing BGM data. Actual blood glucose between glucose points is unknown.

**Meal Assessment:** Each meal window (Breakfast, Lunch, and Dinner) is based on the Meal Time window set within the App. Each chart shows the trends in glucose that occur after a Rapid-acting dose was logged. Doses delivered outside of the set Meal Time window are not included in the meal assessment.

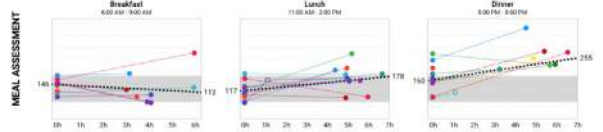
This assessment may help identify:

- The median glucose at the start of each meal.
- The median glucose at the end of each meal.
- Trends and patterns in glucose based on the time of day/type of each meal.

Meal Assessments with CGM data will appear like this:

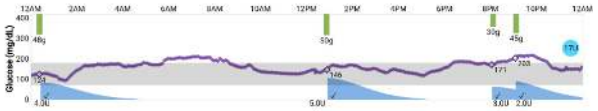


Meal Assessments with BGM data will appear like this:



**Note:** Glucose values taken on the same day, are the same color and are connected with lines. The lines are for reference only when viewing BGM data. Actual blood glucose between glucose points is unknown.

**Daily Charts** – Graphical representations of individual daily glucose, insulin doses, and carbohydrates/meal type.



Glucose from CGM or BGM is shown in purple with carbohydrates/meal shown in green. Rapid-acting insulin doses are shown as blue filled curves and Long-acting insulin doses are shown as blue circles. Use the daily charts to visualize and assess patterns in glucose, insulin, and carbohydrates on a daily basis for the last 7 or 14 days of the report period.

On each bolus:

- (✓) indicates the dose was within 0.5U of the recommendation
- (▲) indicates the dose was 1 U or more higher than the recommendation
- (▼) indicates the dose was 1 U or more lower than the recommendation
- No symbol indicates the dose calculator was not used

Daily charts may help identify:

- Effects of individual dosing decisions
- Causes of individual episodes of hypoglycemia or hyperglycemia

Daily charts may help verify:

- Insulin action time
- Insulin sensitivity factor
- Insulin-to-carbohydrate ratio



## 8.3 Dose Calculator Algorithm

To help you better manage and understand your therapy, the dose calculator algorithm is as follows:

$$DR = \frac{CE}{ICR} + \frac{BG - TG}{ISF} - AI$$

The fixed-dose calculator algorithm is as follows:

$$DR = \frac{MEAL\ DOSE}{DOSE} + \frac{BG - TG}{ISF} - AI$$

Where:

DR = Dose Recommendation

CE = Carbohydrates Entered

ICR = Insulin to Carbohydrate Ratio

BG = Blood Glucose

TG = Target Blood Glucose

ISF = Insulin Sensitivity Factor

AI = Active Insulin<sup>1</sup>

Meal Dose = Specified Meal Dose

If glucose is not entered, Active Insulin is not included in the calculation and only a carbohydrate dose is calculated per the following:

$$DR = \frac{CE}{ICR}$$

Where:

DR = Dose Recommendation

CE = Carbohydrates Entered

ICR = Insulin-to-carbohydrate Ratio

An "Eat X grams" recommendation is given if a value less than 0 is calculated per the following:

$$SC = - (DR) \times ICR$$

Where:

SC = Suggested Carbohydrates

DR = Dose Recommendation

ICR = Insulin-to-carbohydrate Ratio

---

<sup>1</sup>Adapted from Mudaliar et al, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501.

## 9. Troubleshooting

### 9.1 Notification Icons

During use of the app, you may see one or more alert icons on the Home screen. When an icon appears, it can be tapped for more information or to clear the notification.



**Dose Reminder** – This icon will appear when a Dose Reminder is enabled, and no dose was taken during the time window. It will clear automatically when the next dose of insulin is taken, or you can tap the icon for more information or to manually clear the alert.



**Low Battery** – This icon will appear when the InPen™ is reaching the end of its 1-year life and needs to be replaced. It will appear several times near the end of the lifetime and will remain visible until a new InPen™ is paired.



**Temperature** – This icon will appear when the InPen™ detects a very high or very low temperature. Based on the temperature of the InPen™, you may want to consider replacing your insulin cartridge. The icon will clear automatically when a new insulin cartridge is installed.



**Insulin Age** – This icon will appear if the Cartridge Replace Reminder is enabled, and the InPen™ has not detected a new cartridge being installed within the past 28 days. After this time, you should consider replacing the insulin cartridge. You can clear the icon manually or the icon will automatically clear when a new insulin cartridge is installed.



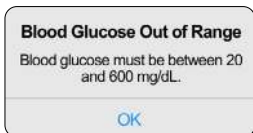
**Long-acting Reminder** – This icon will appear if the Long-acting Reminder is enabled, and no Long-acting dose was logged at the reminder time. You can tap the icon for more options or to manually clear the alert.

## 9.2 Messages

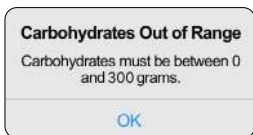
You may see the following messages when using the app:



If the blood glucose value entered is very low, then the dose calculator will not recommend a dose. It is important to eat Fast-acting carbohydrates to treat your low blood glucose. If you believe the message is in error, then check the blood glucose value you entered.



The dose calculator only accepts values between 20 – 600 mg/dl. If you believe the message is in error, then check the value you entered. If your blood glucose is outside this range, take immediate action to correct it prior to using the dose calculator.



The dose calculator only accepts values between 0 – 300g. If you believe the message is in error, then check the value you entered.

To use the dose calculator, you must have an InPen™ paired to your device. See the **Getting Started** section for pairing instructions.

To use the dose calculator, you must enter your personal settings into **Therapy Settings**.

If you do not have your therapy settings from your healthcare provider, then you need to obtain them before proceeding. It is critical for safety that therapy settings are set



correctly. See the Getting Started section for **Therapy Settings** setup instructions.

This important safety warning is shown every time you access **Therapy Settings**. Tap **Go Back** and contact your healthcare provider if you have not been given the correct settings to use.

If you have been provided with your correct therapy settings and are under the supervision of a healthcare provider, tap **Proceed**.

## 9.3 Common Problems and Solutions

The table below lists some potential issues that may arise during use of the InPen™ system and solutions to try.

Problem	Solutions to Try
I can't install the app.	Check that your smart device is compatible with the InPen™ App. See <b>Supported Devices</b> above.
	On your smart device, tap the App Store icon and search for "Companion Medical InPen" and follow the prompts to install the app.
	The InPen™ App may not be available in all locations.
I paired my InPen™ but doses are not appearing on the app.	Check that Bluetooth® is enabled on your smart device.
	Move the InPen™ and your smart device within 3 feet (1 m) of each other.
	Ensure that the InPen™ is still within its 1-year use life from the date of first use.
	Prime the InPen™ one or more times.
	Close and restart the InPen™ App.
	From your smart device's Bluetooth® Settings screen, if you see an InPen™ listing, tap it and select "Forget This Device." See Getting Started for instructions to pair if your InPen™ has been paired before.
	Close and restart the InPen™ App.

Problem	Solutions to Try
<p>After priming my InPen™, the prime amount is listed as a dose.</p>	<p>If you are using the dose calculator, ensure that you prime <b>after</b> calculating your dose.</p> <p>From the home screen, tap the Logbook tab to view the list of doses. Tap on the dose to designate it as a prime dose.</p> <p>Prime doses are not included in active insulin (IOB) or reports.</p>
<p>I left my InPen™ somewhere and I need to take insulin from another source.</p>	<p>You may take Rapid-acting insulin from sources other than your InPen™ if needed. When you do, be sure to manually log the dose into the InPen™ App. See <b>Manually Log Rapid-acting Insulin</b> for instructions on how to manually log a dose.</p> <p>For safety, it is important to log all Rapid-acting insulin taken. Doses taken from a paired InPen™ are logged automatically and do not need to be manually entered.</p>
<p>I paired my InPen™ to a new smart device, and now it won't connect with the original one.</p>	<p>Your InPen™ can only be paired to one smart device at a time. If necessary, follow the instructions in <b>Getting Started</b> to pair it to your original device again.</p> <p>Frequently pairing the InPen™ to different smart devices may decrease battery life and is not recommended.</p>

Problem	Solutions to Try
<p>I can't hear reminders on my smart device.</p>	<p>See <b>Important Smart Device Setup</b> for tips on properly setting up your smart device.</p>
<p>The Missed Dose Reminder isn't working.</p>	<p>Tap <b>Missed Dose</b> Reminders from <b>Settings &gt; Reminders</b> and ensure that the switch is enabled. Slide it to turn it on.</p> <p>The Missed Dose Reminder will only remind you if you have not taken a dose. If you use your InPen normally and take doses at your regular times each day, then the reminder will not appear.</p> <p>You can adjust the start and end times of the Missed Dose Reminder to fit your personal routine in <b>Settings &gt; Therapy Settings</b>.</p>
<p>I'm trying to adjust a date or time, but the selection keeps resetting.</p>	<p>To manually log an insulin dose, the time must be within the past 24 hours or the selection will reset.</p> <p>When setting a time-of-day setting, it must not overlap with another time period or the selection will reset.</p> <p>Adjust a different selector (e.g. date, hour, minute) first to avoid an invalid entry.</p> <p>Adjust another time period first to prevent overlap with the time you are trying to set.</p>

# 10. Compatible Insulin and Needles

InPen™ is compatible with 3 mL (U-100) insulin cartridges and disposable needles (supplied separately). Refer to the table below to determine compatible insulin and needles for use with your InPen™:



***Always check the insulin label before each injection to avoid medication errors.***

InPen™ Model	Compatible U-100 3 mL Cartridges	Compatible Needles
INPEN-100ELXX MMT-105ELXX	Lilly Humalog®	Compatible with BD Ultra Fine™ and Novo Nordisk NovoFine®
INPEN-100NNXX MMT-105NNXX	Novo Nordisk Novolog®	
	Novo Nordisk Fiasp®	

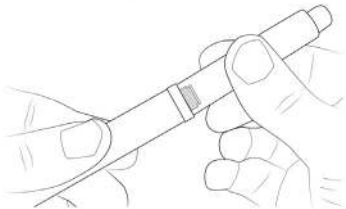
# 11. Getting Ready

Wash your hands and make sure you have the following items available before beginning:

- InPen™
- 3 mL U-100 Insulin Cartridge
- New Pen Needle

# 12. Prepare your InPen™

1. Pull Off Cap
2. Unscrew and Remove the Cartridge Holder.





3. Before inserting the Insulin Cartridge, be sure to inspect your Insulin Cartridge per the manufacturer's instructions. Do not use the cartridge if it has:
  - Expired
  - Unusual visual appearance
  - Cracks, breaks, or other damage
4. Insert the small end of the Insulin Cartridge into the Cartridge Holder.
5. Attach the Cartridge Holder by pushing the Cartridge Holder and InPen™ Body straight together. Screw the InPen™ Body onto the Cartridge Holder until it clicks and is secure.



**CAUTION: If the Cartridge Holder is not securely attached, the cartridge may be misaligned and you may not get your full dose.**



## Important Notes

- Your healthcare provider has prescribed the type of insulin best for you. Any changes in insulin should be made only under medical supervision.
- InPen™ is for use only with 3 mL U-100 Insulin Cartridges.
- Only use Insulin Cartridges compatible with your InPen™.
- Read and follow the instructions provided in your Insulin Cartridge Patient Information.
- Before each injection, read the Cartridge Label and be sure the InPen contains the correct Insulin Cartridge.
- The color of the InPen™ is not intended to indicate insulin type.

- The numbers on the Cartridge Holder give an estimate of the amount of insulin remaining in the Cartridge. Do not use these numbers for measuring an insulin dose.
- For more information on InPen™ and insulin, please refer to the Patient Information provided with your Insulin Cartridge or contact your healthcare provider.

## **Frequently Asked Questions about Preparing your InPen™**

### **1. What should I do if I can't attach the Cartridge Holder to the InPen™ body?**

Check that the Insulin Cartridge is fully inserted into the Cartridge Holder and the Screw is screwed all the way back inside the InPen™. Then carefully line up the Cartridge Holder with the InPen Body and screw together until secure.

### **2. Why do I pull the InPen™ apart when I try to remove the InPen™ cap?**

Twisting the InPen™ Cap may have unscrewed the Cartridge Holder.

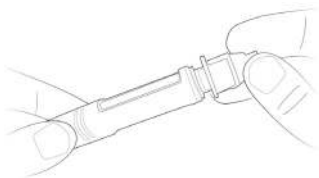
- Remove the cartridge holder and Insulin cartridge from the InPen™ cap.
- Place the Insulin cartridge into the Cartridge Holder and screw it back onto the InPen™ assembly.
- Be sure to prime the InPen™ again before the next use.

## 13. Prime your InPen™

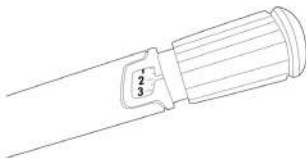


**CAUTION: If you do NOT prime, you may receive too much or too little insulin. Prime your InPen™ before every injection.**

1. Remove Paper Tab from the Needle
2. Attach the Needle by screwing the Needle straight onto the Cartridge Holder as shown.



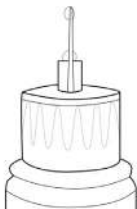
3. Pull off the Outer Cap and the Inner Cap.
  - Discard the Outer Cap.
  - Keep the Inner Cap to remove the Needle after your injection.
4. Turn the Dose Knob to select amount to prime:
  - Dial 2 units as shown.



5. Hold the InPen™ so the needle is pointing up and tap the cartridge to collect any air at the top.



6. Prime the InPen™ by pushing the Injection Button with your thumb and holding for eight (8) seconds. You should see a few drops of insulin.



7. If no stream is seen, repeat priming according to steps 4 through 6. A new Cartridge may need to be primed several times.



**CAUTION: If no insulin flows after several attempts, attach a new Needle, as the one on your InPen™ may be clogged.**



## **Important Notes**

- Only use needles compatible with your InPen™.
- The directions regarding Needle handling are not intended to replace local, healthcare provider, or institutional policies.
- Use a new needle for each injection. This will help ensure sterility. It will also help prevent leakage of insulin, keep out air bubbles, and reduce Needle clogs.
- You must PUSH the Injection Button straight down for the dose to be delivered.
- You will NOT receive your insulin by turning the Dose Knob.
- Do not attempt to change the dose while injecting.
- Always remove the used needle after each injection and store the InPen without a needle attached. This prevents contamination, infection, and leakage of insulin and will ensure accurate dosing.
- Always put the InPen™ cap back on after every use.
- Caregivers should be most careful when handling used needles to avoid hurting themselves.
- Only use your InPen™ as described in this manual.
- Handle it with care and do not drop it or knock it against hard surfaces.

- Do not try to wash, soak, or lubricate your InPen™ as this may damage it.
- Keep it away from direct sunlight, water, dust, and dirt.
- Do not expose your InPen™ (without cartridge) to temperatures below -5 °C (-23°F).
- Do not try to repair a broken InPen™.

## **Frequently Asked Questions about Priming Your InPen™**

### **1. Why is it important to prime before every injection?**

If you do NOT prime, you may get too much or too little insulin. Priming helps to ensure that the InPen™ and needle are working properly. Once the InPen™ is properly primed, insulin will flow from the needle. You may need to prime several times before you see insulin.

### **2. Why can it take several attempts to prime when a new Cartridge is inserted?**

There may be a gap between the Screw and the Cartridge Plunger. Repeating the priming steps will move the Screw out to touch the Cartridge Plunger. Once touching, insulin will flow from the needle when priming.

- Repeat the priming steps until insulin is seen.
- If you are still unable to see insulin flow from the Needle, go to Question 3.

### **3. Why can't I see insulin flow from the needle tip?**

Priming moves the Screw into contact with the Cartridge Plunger and gets the air out of the Cartridge. When you are priming the InPen™:

- You may see no flow at all. This may be because the Screw is moving forward to close a gap between the Screw and the Cartridge Plunger.
- If there is air in the Cartridge, the insulin may sputter or drip until all the air is removed.
- Insulin will flow as a stream only when the InPen is properly primed.

- If the Injection Button is hard to push, the needle may be clogged. Attach a new needle. Repeat the priming steps until a stream of insulin is seen.

If you are still unable to see a stream of insulin out of the needle, do NOT use the InPen™. Contact Customer Support for assistance or to obtain a replacement.

#### **4. What should I do if I have an air bubble in the Cartridge?**

Priming your InPen™ will remove air. Hold the InPen™ so that the needle is pointing up, and tap the Cartridge gently with your finger so any air bubbles can collect near the top. Repeat the priming steps until insulin is seen. A small air bubble may remain in the Cartridge after completion of the priming steps. If you have properly primed the InPen™, this small air bubble will not affect your insulin dose.

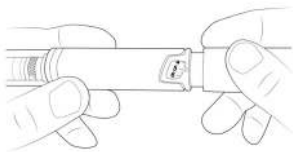
#### **5. Why does no drop of insulin appear at the needle tip when I check the insulin flow?**

The needle may be blocked.

- Screw on a new needle
- Check the insulin flow until insulin appears at the needle tip

## **14. Selecting Your Dose**

1. Select your dose by turning the Dose Knob until the desired dose is lined up with the Dose Indicator. Half units are shown as lines between the numbers.



If you select a wrong dose, simply change it by turning the dose button in either direction. If you change your mind and do not want to inject a dose, you may adjust the knob back to the 0 set point. No insulin will be dispensed until you press the button.



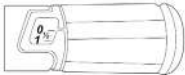
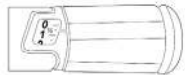
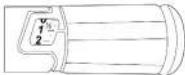
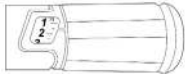

## Important Notes:

You cannot select a dose larger than 30 units. If you need more than 30 units, you must divide your dose into two injections.

## Frequently Asked Questions about Selecting Your Dose

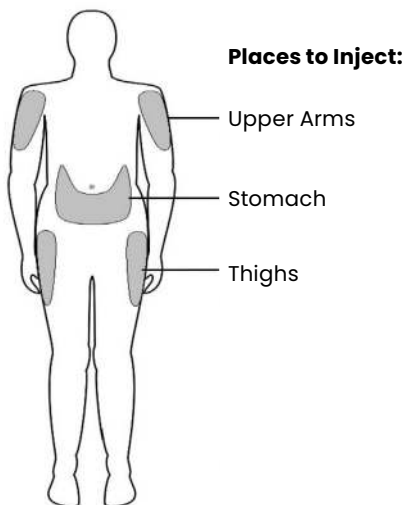
### 1. How do I read the dose indicator?

The InPen™ can be adjusted in steps (increments) of 0.5 ( $\frac{1}{2}$ ) units. Read the numbers shown in the indicator window to see the current dose setting. If the indicator is between numbers, this means that it is set at a  $\frac{1}{2}$  unit step between the numbers. See below for more examples.

Set to <b>0 units</b> . The indicator line is aligned with the “0” mark, which means nothing will happen if the button is pressed. Store the InPen this way.	
Set to <b><math>\frac{1}{2}</math> unit</b> . This is the smallest dose setting possible.	
Set to <b>1 unit</b> . The indicator line is lined up with the number “1”.	
Set to <b>1.5 units</b> . The indicator line is on the mark between the “1” and “2”.	
Set to <b>30 units</b> . This is the maximum dose setting possible.	

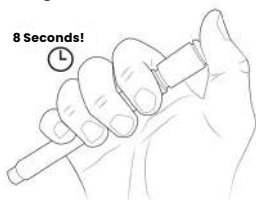
## 15. Injecting the Dose

1. Choose a place on your body to inject. Make sure your skin is clean and dry.



2. Insert the needle into your skin as your healthcare provider has instructed you.

3. To inject your insulin, place your thumb on the Injection Button, then slowly and firmly push the button until it stops moving.



4. Continue to hold the button for 8 seconds and then remove the Needle from your skin. Check to make sure you see a 0 in the Dose Window to confirm you received the complete dose.

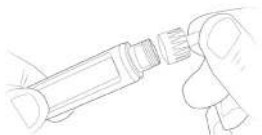


**Note: It is possible to set a dose larger than the amount of insulin left in the Cartridge. At the end of an injection, the number in the Dose Window should be 0. If it is not, this number is the amount of insulin you did NOT receive. Remember this number, because you will need to install a new cartridge and inject this much insulin to complete your full dose.**

5. After you remove the needle from the skin a drop of insulin may appear at the needle tip. This is normal and has no effect on the delivered dose.

**Note: To prevent air from entering the Cartridge, do not store the InPen™ with a needle attached.**

6. Place the cap back onto the needle, and remove the capped needle by twisting it off.



7. Put the used needle in a sharps container or a hard plastic container with a secure lid. Do not throw needles directly into your household trash.

8. Do not recycle the container of used needles. The full container must be disposed of according to your state and local laws.

**Note: For information on how to dispose of the container properly, ask your healthcare provider about options available in your area or go to the FDA website at: [www.fda.gov/safesharpsdisposal](http://www.fda.gov/safesharpsdisposal)**

9. Replace the cap on your InPen™.





## Important Notes

- You must PUSH the Injection Button straight down for the dose to be delivered.
- You will NOT receive your insulin by turning the Dose Knob.
- Do not attempt to change the dose while injecting.
- Always remove the used needle after each injection and store the InPen™ without a needle attached. This prevents contamination, infection, and leakage of insulin and will ensure accurate dosing.
- Always put the InPen™ cap back on after every use.
- Caregivers should be most careful when handling used needles to avoid hurting themselves.

## Frequently Asked Questions about Injecting the Dose

### 1. Why does the InPen not deliver any insulin when I turn the dose button to inject?

Turning the dose button will not deliver insulin. You have to press the dose button to inject.

### 2. Why is it difficult to push the Injection Button when I try to inject?

Your Needle may be clogged. Try attaching a new Needle, and then prime the InPen™.

Pushing the Injection Button down quickly may make the Button harder to push. Pushing the Button more slowly may make it easier.

Using a larger diameter Needle will make it easier to push the Injection Button during injection. Ask your healthcare provider which Needle is best for you.

If none of the above steps resolves the problem, your InPen™ may need to be replaced.

Your Injection Button may become harder to push if the inside of your InPen™ gets dirty with insulin, food, drink, or other materials. Following the HANDLING AND STORAGE instructions below should prevent this

### **3. Why doesn't the Dose Knob go to zero when I inject my dose?**

This can happen if the Insulin Cartridge does not have enough insulin left in it for your entire dose, or if the needle has become clogged. To get the rest of your dose:

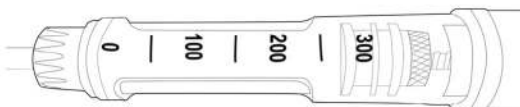
- The number in the Dose Window is the amount you did NOT receive. Remember this number, because you still need to inject this much to complete your dose.
- Adjust the knob back to the "0" setting.
- Remove the Needle from the InPen™.
- If the cartridge is empty, replace it with a new cartridge. If it is not empty, it is likely the needle was clogged.
- Install a new Needle.
- Prime the InPen™ until insulin is observed.

Complete your dose by dialing the amount that you did NOT receive and inject this amount.

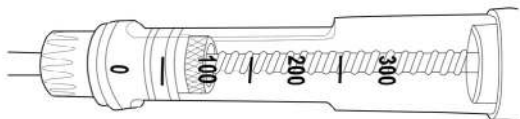
If you are not sure whether you have received your full dose, you should check your glucose level more frequently.

## **16. How Much Insulin is Left in Your InPen™?**

The cartridge scale shows an approximate number of units left in the Cartridge.



**FULL CARTRIDGE**



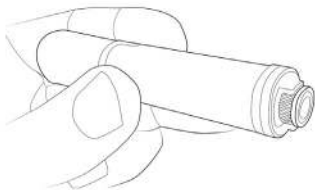
**EMPTY CARTRIDGE**

It is ok to set a dose greater than the amount of remaining insulin. The InPen™ will deliver as much insulin as is left in the cartridge and then you can complete the dose with a new cartridge. Refer to the INJECTING THE DOSE section above.

## 17. Replacing a Used Insulin Cartridge

**Note: Be sure the needle has been removed and disposed of properly.**

1. The Screw will be extended once you have used the entire insulin cartridge.
2. Hold the InPen™ knob and turn the Screw counterclockwise into the InPen™ Body until it stops.



3. Follow the instructions in PREPARING YOUR INSULIN INPEN™ section above. Dispose of the used cartridge before installing a new one.

## 18. Handling and Storage of Your InPen™

When an Insulin Cartridge is installed in your InPen™, store your InPen™ at room temperature. Refer to your insulin manufacturer or literature that came with your insulin for information on how to store the cartridges and how long to keep them.

Remove the Needle after every use. Do not store your InPen™ with the Needle attached.

Do not store the InPen™ in a refrigerator.

## 19. Cleaning of Your InPen™

Cleaning removes dirt from the surface of the device. It does not kill bacteria or viruses. The InPen™ should be cleaned whenever it is visibly dirty.

Clean your InPen™ as needed only with a soft cloth moistened with water, being careful not to get water inside. Never submerge the InPen™. If you get insulin on your InPen™, clean it off right away.



## **Important Notes:**

Only use your InPen as described in this manual.

- Handle it with care and do not drop it or knock it against hard surfaces.
- Do not try to wash, soak, or lubricate your InPen as this may damage it.
- Keep it away from direct sunlight, water, dust, and dirt.
- Do not expose your InPen (without cartridge) to temperatures below -5 °C (-23°F).
- Do not try to repair a broken InPen.

When you receive a battery warning or the InPen™ can no longer communicate with the Application, contact your healthcare provider to obtain a prescription for a new InPen™.

## **Frequently asked Questions about Caring for your InPen™**

### **1. What should I do if my InPen™ has been dropped or knocked against a hard surface, or if I am not sure that it is working properly?**

If you suspect that your InPen™ has been damaged or may not be working properly, discontinue using it immediately, and contact Customer Support for assistance or to obtain a replacement.

If you choose to continue using your InPen™, check that the Insulin cartridge is not damaged (see the information provided with the Insulin cartridge) and install a new needle.

Some disposable needles are supplied with a cap that may be filled to verify the correct volume of insulin is being dispensed. This may be used for added confirmation that the InPen™ is functioning properly. Refer to the Patient Information provided with the Needle for information on this feature.

## 20. Disposal

Your InPen™ contains a lithium battery and electronic parts, so you should not throw it out with your household waste, but do so in a safe and environmentally correct way:

- Remove the needle and cartridge, and throw them away as your doctor or nurse has instructed you.
- Throw your InPen™ away as specified by your local authorities.

## 21. Important Information

### Apple Legal Notice

Apple, iPad, iPhone, iPod, and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

### Android Legal Notice

Android is a registered trademark owned by Alphabet Inc.

### About Bluetooth®

Bluetooth is a type of wireless (RF) communication. Cell phones use Bluetooth technology as do many other devices. Your InPen™ uses Bluetooth to pair with your smart device and to send data to the InPen™ App.

Your InPen™ is subject to and complies with U.S. federal guidelines, Part 15 of the FCC rules for devices with RF capability. These rules state two conditions specific to the operation of the device. They are:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesirable operation.

These guidelines help ensure that your InPen™ will not affect the operation of other nearby electronic devices. With the exception of your smart device, other electronic wireless devices that are in use nearby, such as a cell phone or ™ a wireless network, may prevent or delay the transmission of data from your InPen™ to the InPen™ App. Moving away from or turning off these electronic devices may allow communication.

The InPen™ has been tested and found to be appropriate for use at home. In most cases, it should not interfere with other home electronic devices if used as instructed.

However, the InPen™ gives off RF energy and may interfere with your TV, radio, or other electronic devices that receive or transmit RF signals.

If you experience InPen™ interference problems, try moving your InPen™ away from the source of the interference. You can also move the electronic device or its antenna to another location to solve the problem. If you continue to experience interference, contact the support service for the manufacturer of the electronic device causing the interference.

The Bluetooth wordmark and logos are owned by the Bluetooth SIG, Inc. and any use of such marks by Companion Medical, Inc. is under license. Other trademarks and trade names are those of their respective owners.

## **22. Supplemental Information**

### **Essential Performance**

Essential Performance, as defined by IEC 60601-1, is not applicable to the InPen™ system.

### **Dose Accuracy**

InPen™ fulfils the functional requirements and specification limits for dose accuracy according to ISO 11608-1.

### **Applied Parts**

The InPen™ is a hand held device and is considered the applied part as defined by IEC 60601-1.

### **Declaration of Conformity**

Companion Medical declares that this product is in conformity with the essential requirements of Directive 1995/5/EC on Radio and Telecommunications Terminal Equipment and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (M5).

## **FCC Compliance**

This device complies with FCC Part 15 license exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

## **23. Warranty**

Companion Medical warrants the InPen™ System against defects in materials and workmanship for a period of 1 year from the date of purchase.

During the warranty period, Companion Medical will, at its discretion, replace any defective device, subject to the conditions and exclusions stated herein. In the event that a device is replaced, the warranty period will not be extended.

This warranty is valid only if the InPen™ System is used in accordance with the manufacturer's instructions and within the use-by-date. This warranty will not apply:

- If damage results from changes or modifications made to the device.
- If damage results from use of incompatible cartridges or needles.
- If damage results from a Force Majeure or other event beyond the control of the manufacturer.
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water or physical abuse, such as dropping or otherwise.

This warranty shall apply to the original user. Any sale or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Companion Medical nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.



All other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Use of the InPen™ system is subject at all times to the Companion Medical Inc. Terms of Service (<https://www.companionmedical.com/terms-of-service>) and Privacy Policy (<https://www.companionmedical.com/privacy-notice>).

## Product Specifications

The InPen™ System is intended for use by patients at home and in healthcare facilities.

### Operating Conditions

5 °C (41 °F) to 40 °C (104 °F)

15 % to 93 % RH (non condensing)

### Operating Altitude

-381 m (-1253 ft) to 3010 m (9878 ft)

### Operating Pressure

80 kPa – 105 kPa

### Storage Conditions

-5 °C (23 °F) to 40 °C (104 °F)

10 % to 98 % RH (non condensing)

### Dimensions

16.5 cm (6.5") x ø1.9 cm (0.8")

### Weight

35 g

### Power Supply

Li-Mn battery (not replaceable)

### Lifetime

1 year from activation

### Accuracy

Meets limits for dose accuracy according to ISO 11608-1

### Moisture Protection

IP22: Protection against insertion of large objects and dripping water

### Protection against Electrical Shock

Type BF applied part

**For information contact:**



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