inpen

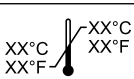
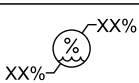
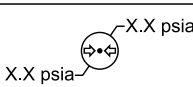
InPen™ System

User Guide

Medtronic

Symbols in this user guide

The following symbols are found on the InPen system or the package labels. These symbols tell you about the proper and safe use of the InPen system. For a more comprehensive description of the symbols displayed on the device and package labels, please refer to the Medtronic symbols glossary website: https://www.medtronicdiabetes.com/symbols-glossary.

	Non-ionizing electromagnetic radiation
	Consult instructions for use
	Caution
	Do not use if package is damaged and consult instructions for use
	Requires prescription in the USA
FCC ID	Complies with United States regulations for RF devices
	Temperature limits
	Humidity limits
	Atmospheric Pressure
	Keep dry
IP22	Protection against insertion of large objects and dripping water

	Type BF applied part
	Manufacturer
	Use-by date
	Date of manufacture (DoM)
	Batch code
	Catalogue number
	Medical device
	Do not dispose of this product in unsorted municipal waste stream

Contents

1 Introduction

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

Note: You should read this user guide before use – even if you have used the InPen system before. Failure to follow the instructions may result in too much or too little insulin being delivered.

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

Do not use your InPen system if any parts appear broken or damaged. Contact customer support for a replacement by tapping **SETTINGS** from the Home screen and selecting **Help and Support**.

The InPen system 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 system is lost or damaged.

The InPen smart insulin pen is designed to administer insulin in persons with diabetes mellitus.

The InPen system app is a diabetes management tool that helps track your insulin doses, calculates insulin doses based on your current glucose level and carbohydrates, or meal type and/or size, and shares your therapy with your healthcare team.

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 optimize glycemic control in MDI patients with the support 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 active insulin to lower the risk of insulin stacking.

1.1 System description

The InPen system includes the InPen smart insulin pen and the InPen system app. The InPen system automatically records dose size and timing of insulin doses, provides alerts and reminders if insulin is not taken, includes an insulin dose calculator with personalized settings, and tracks active insulin. The InPen system has the ability to receive blood glucose measurement data and display blood glucose measurements and data on the app and reports from compatible diabetes technologies, including a continuous blood glucose monitor (CGM).

1.2 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 alerts and reminders so you don't forget to take your insulin.
- Import glucose data automatically from supported continuous glucose monitors (CGMs) and blood glucose meters (BGMs).
- View and share integrated diabetes therapy reports with your healthcare provider.

1.3 Support within the App

- Setup wizard within the app.
- A link to the User Guide within the app.
- Instructional videos within the app.

2 Indications for use

The InPen system 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 InPen system 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 InPen system allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

The InPen system dose calculator, a component of the InPen system 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:

The following recommendations are meant to help younger patients and their caregivers manage and care for the InPen system. Patient caregivers should check with a healthcare provider to determine if the young 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

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

The app is available for Android™ (MMT-8061) and for iOS™ (MMT-8060) 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 system with a smart device and the InPen system app. This will ensure that doses from your InPen system are sent wirelessly to the app on your smart device.

WARNING: The Bluetooth® feature on your InPen system 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 system to dose insulin. The InPen system is for single patient use only.

Note: Bluetooth performance varies due to differences in phone hardware and operating systems. The InPen system app is not recommended on jailbroken or rooted devices.

Note: Your smart device must have enough memory storage or the InPen system app will not be installed or log doses. 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 system app:

1. Download the InPen system app from the App Store or Google Play 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 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 should provide your therapy settings.

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.

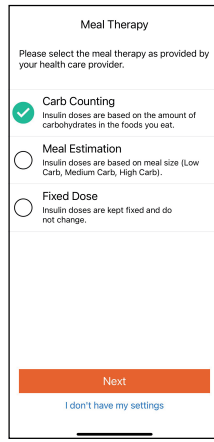
WARNING: Your dose calculator settings must be set correctly before using the dose calculator. Do not use the dose calculator if you have guessed settings or believe they may be set incorrectly. Incorrect dose calculator settings may result in recommendations, which could lead to hyperglycemic or hypoglycemic events, which could result in serious injury or death.

When selecting your meal therapy mode, choose the mode that is recommended by your healthcare provider. Choose the settings required to complete the setup of the selected mode. Verify with your doctor if you are unsure of your meal therapy mode.

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

- Fixed Dose
- Meal Estimation
- Carb Counting

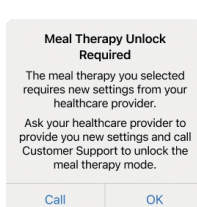
Once you have your dose calculator settings, tap on each line to set the correct value. Once you have selected the correct value, tap the green check mark to save or the red X to cancel.



To change the meal therapy mode:

1. Your healthcare provider should provide you with the therapy settings needed to change your meal therapy mode.
2. Go to **SETTINGS**. Tap **Therapy Settings**, then proceed after reading the disclaimer.

> **Note:** If you receive a pop-up indicating that a meal therapy unlock is required, contact your healthcare provider for assistance. Your healthcare provider will need to contact customer support to unlock the mode so that you can switch therapies.



3. Tap **Meal Therapy** and select the new meal therapy mode provided by your healthcare provider.
4. Tap on each line to set the value to match the settings provided by your healthcare provider.

WARNING: Before changing meal therapy mode, you will need your new dose calculator settings for the new meal therapy mode from your healthcare provider. Previous dose calculator settings may be lost when you change to a new meal therapy mode. A popup will warn users which settings will be lost if switching modes. Incorrect dose calculator settings may result in incorrect dose recommendations, which could lead to hyperglycemic or hypoglycemic events, which could result in serious injury or death.

5.1.1 Fixed Dose Mode - setup

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

Maximum Calculated Dose – This is 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 enabling this setting, you can set these parameters to four different values throughout the day.

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.

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

How to use

- In fixed dose mode the dose calculator provides 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.
- When a glucose value is available to be used for treatment decisions and is less than 10 minutes old, it will pre-populate in the dose calculator.
- If a CGM value is unavailable in the app, then sensor glucose values are not approved for making treatment decisions (also known as adjunctive values), and you must check and enter a blood glucose value from a glucose meter.
- 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 recommendation.

See *Section 6.2, Calculating an insulin dose, page 28* for more about the types of recommendations you may receive.

5.1.2 Meal Estimation Mode - setup

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

Maximum Calculated Dose – This is 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.

Meal Estimation – Enable this setting to select the dose size for low carb, medium carb, and high carb meals and snacks. Each day at meal times, the InPen system 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 enabling this setting, you can set these parameters to four different values throughout the day. 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.

How to use

- In Meal Estimation mode, the dose calculator provides an insulin recommendation based on meal size at meal times.
- When a glucose value is available to be used for treatment decisions and is less than 10 minutes old, it will pre-populate in the dose calculator.
- If a CGM value is unavailable in the app, then sensor glucose values are not approved for making treatment decisions (also known as adjunctive values), and you must check and enter a blood glucose value from a glucose meter.
- After choosing your meal size, you can enter a current glucose for a dose recommendation that includes a glucose correction if needed.
- 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* for more about the types of recommendations you may receive.

5.1.3 Carb Counting Mode - setup

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

Maximum Calculated Dose – This is 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 Carb Ratio, and Insulin Sensitivity Factor are constant throughout the day. By enabling this setting, you can set these parameters to four different values throughout the day.

Time of Day (If Time of Day Settings are enabled) – When enabled, these values indicate 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 carbohydrates 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 Carb 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 provides a carbohydrate counting insulin recommendation once you have entered a current glucose, carbohydrates, or both.
- Enter your current glucose, the number of grams of carbs you are eating or plan to eat, or both and tap **Save**.
- When a glucose value is available to be used for treatment decisions and is less than 10 minutes old, it will pre-populate in the dose calculator.
- If a CGM value is unavailable in the app, then sensor glucose values are not approved for making treatment decisions (also known as adjunctive values), and you must check and enter a blood glucose value from a glucose meter.
- 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, Calculating an insulin dose, page 28* 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**.

5.1.4 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 or 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 that is determined 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**.

5.2 Notifications and alerts on your smart device

The InPen system app will send you notifications to support your diabetes management and use of the InPen system. In the InPen system app Notifications settings, turn on Override Phone Settings to ensure you receive InPen system Notifications to your smart device. If these settings are not enabled, you may miss important notifications and alerts from the InPen system app.

For Apple users: After entering your therapy settings, the InPen system app prompts you to allow notifications and critical alerts from the InPen system app. Critical alerts appear even when you set your smart device to not disturb you or when the volume is turned all the way down.

For Android users: After entering your therapy settings, the InPen system app prompts you to allow the InPen system app Do Not Disturb access within your smart device settings. By allowing Do Not Disturb access, the InPen system app can send important dosing alerts even when you set your smart device to Do Not Disturb or when the volume is turned all the way down.

- Allow notifications to receive reminders and alerts from the InPen system app. These notifications will match the settings you have on your phone and will not override your other settings, such as vibrate only or Do Not Disturb.
- Allow critical alerts (iOS) or Do Not Disturb access (Android) to receive important dose alerts and reminders. These alerts can override your smart device Do Not Disturb and volume settings. While these settings are optional, if not enabled you may miss important alerts from the InPen system app. The following alerts and reminders may be delivered when Critical Alerts or Do Not Disturb access is ON:
  - Long-acting Dose Reminder
  - CGM-based Missed Dose Alert
  - CGM-based Correct High Glucose Alert

These dosing alerts will sound at the volume set within the notifications section within your InPen system app settings. All other notifications or reminders from the InPen system app will be delivered following your smart device settings and set volume.

If you do not allow notifications and critical alerts during setup of the InPen system app, be sure to enable these features in your smart device settings before using the InPen system.

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.

5.4 Bedtime

The setup wizard asks you when you typically go to bed.

The InPen system 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 Connecting your InPen system

Note: To ensure a secure connection, pair your InPen system and smart device in a secure area with limited Bluetooth devices in range.

WARNING: The InPen system is for single patient use only. The use of a security code on your mobile device is recommended. Do not allow others to pair their smart device to your InPen system, or dose with your InPen system, as this may lead to inaccurate dose logs and incorrect active insulin. This may result in incorrect dose recommendations, which could lead to hyperglycemic or hypoglycemic events, which could result in serious injury or death.

1. Place your InPen system and smart device 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 system.
4. The InPen system app will display that the pairing was successful once the InPen system and your smart device are paired.
5. Follow the instructions to name your InPen system.
6. Read the important notes regarding treatment decisions.

5.6 Connecting to a CGM

Refer to the CGM user guide for guidance before using SG values for your treatment decisions in the dose calculator.

1. Tap **SETTINGS**, then tap **Connections**.
2. Tap **Medtronic**.
3. Follow the instructions to log in to the CGM system.

Note: An internet connection is required for CGM-based features.

When the internet is unavailable, the InPen system app will not:

- Display a current CGM value
- Send Missed Dose alerts
- Send Correct High Glucose alerts

5.7 Installing an insulin cartridge

Follow the video instructions in the app for an overview of how to install an insulin cartridge. See *Chapter 11, Preparing your InPen system, page 58* for more detailed instructions.

5.8 Taking an insulin dose

Follow the video instructions in the app for an overview of how to take an insulin dose. See *Chapter 12, Priming your InPen system, page 61* for more detailed instructions.

5.9 InPen system support

Help and support is available by phone or email through **SETTINGS > Help and Support**. Check the Troubleshooting section for explanations of app error messages and a list of other common issues and solutions.

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 > Tutorial**.

5.11 Connecting InPen Reports to CareLink™

You can use the CareLink system to transmit data from the InPen system app to your healthcare provider.

You can allow your healthcare provider to view your insights by InPen Reports. To allow this, you must: create a CareLink Personal account if you do not already have one, connect your CareLink Personal account using the InPen system app, and link your CareLink Personal account with your healthcare provider's account.

Creating a CareLink Personal account:

1. Go to https://carelink.minimed.com/
2. Select **Create an Account**.
3. Select your country and language. Click **Next**.
4. Select **Patient** and click **Next**.
5. Read and accept the Terms of Use and Privacy Statement for CareLink Personal. Click **Next**.
6. Confirm you are the proper legal age. Click **Next**.
7. Read the consent agreements and select **Yes** or **No**, as necessary. Click **Next** when prompted.
8. Create a username and password and enter a valid email address. Be sure to save your username for linking your CareLink Personal account with your healthcare provider's CareLink system account.
9. If you are prompted to enable two-factor authentication, you can select this option, then click **Next**.
10. Fill out the required patient information and click **Submit**.
11. Enter the verification code sent to the provided email address to confirm your identity.
12. When finished you will see the enrollment completed screen.

Once your CareLink Personal account is created, link your account with the InPen system app.

Connecting your CareLink Personal account using the InPen system app:

1. Open the InPen system app and tap **SETTINGS**.
2. Tap **Connections**.
3. Tap **InPen Reports in CareLink**.
4. Tap **Connect Now**. Read the terms and conditions and then tap **Continue**.
5. Enter your CareLink Personal username and password and tap **Log in**.
6. Tap **Done** to finish the process and return to the Home screen.

To share reports with your healthcare provider, you must link your CareLink Personal account with your healthcare provider's CareLink system account.

Linking your CareLink Personal account with your healthcare provider's account:

1. Provide your CareLink Personal username to your healthcare provider.
2. Ask your healthcare provider to request linking the accounts from their CareLink system account.
3. Once your healthcare provider requests linking the accounts, you will receive an email to log in to your CareLink Personal account.
4. After you log in, go to the **Data Sharing** tab on the left panel.
5. Select **Approve** to complete linking.

Once the accounts are linked and your InPen system app and CareLink Personal account are linked, your healthcare provider will be able to generate Insights reports.

5.12 Important information about smart device setup

CAUTION: 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 system app setting. If the settings on your device are incorrect your InPen system may not function properly. Your InPen system app will follow your smart device notification settings if Override Phone Settings was not enabled during the initial setup or enabled in the Notification Menu within the InPen system app settings. Therefore, if your phone is set to Do Not Disturb, you may not receive notifications. If your phone mute switch is enabled or volume is too low, you may not hear notifications.

WARNING: Set your smart device to automatically update date and time. If your phone time is set incorrectly, doses may be logged with an incorrect time, which may affect your active insulin and dosing recommendations, which may lead to hyperglycemia, hypoglycemia, or injury.

Note: The use of a passcode on your mobile device is recommended to prevent unauthorized changes to dose calculator settings or the logbook.

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 notifications or alerts you must do the following:

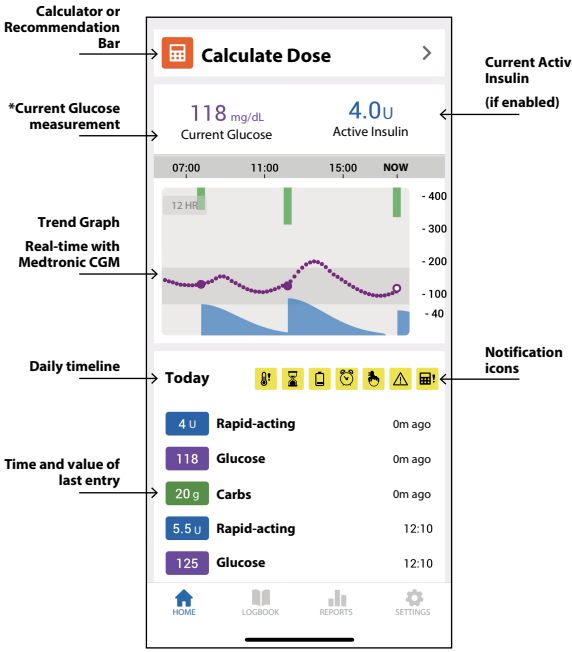
- Make sure the notifications are turned on in the settings menu. For more information, see *Section 5.2, Notifications and alerts on your smart device, page 19*.
- Check that the app hasn't been shut down by your smart device.
- Make sure to turn on Bluetooth on your smart device.
- Turn off the Do Not Disturb feature on your smart device (if available), or turn on Override Phone Settings to allow the app to override your smart device notification settings. For more information about setting up notifications, see *Section 7.1, Notifications, page 34*.
- Start the app after your smart device is restarted. Set the volume to a level you can hear on your smart device.
- Do not force close the app. Always run the app in the background.
- Unplug your headphones when you are done using them. Notifications and alerts from the app cannot be heard through your smart device's speakers if headphones are plugged in.

It is recommended to check your smart device periodically for notifications from the InPen system app. The InPen system alarm and alert vibrations are not any different from other vibrating apps on your smart device. Medical device apps, like the InPen system 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 system app or another app. The only way to know is to look at the screen of your device.

Check the date and time on your smart device often to be sure it is correct. Check the date and time on your device when you travel across time zones. Keep the setting enabled on your smart device that automatically manages the date and time settings. For instructions on setting the date and time on your device, see your smart device's user manual.

The InPen system app is known to be free of malware.

6 Using the InPen system app



Notification icons:

	Insulin Temperature
	Insulin Age
	Low InPen Battery
	Missed Dose Alert
	Long-acting Reminder

	Active Insulin Warning
	Correct High Glucose

*Medtronic CGM data may not appear or may be delayed in certain instances, including when there is no internet connection. With a Medtronic CGM, you will receive real-time CGM missed dose alerts and correct high alerts when enabled in app.

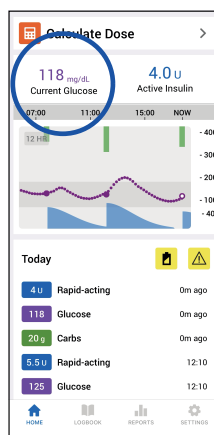
6.1 Overview of your recent glucose and insulin usage

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 a BG reading is more than 10 minutes old, the value will show "---" and you will need to take another BG reading.

If there is no value appearing for the Current Glucose, try one of the following:

- Check your CGM app for a current glucose value.
- Make sure your smart device has a stable internet connection.
- Make sure Bluetooth is enabled on your smart device and airplane mode is turned off.
- Verify your CGM connection in the InPen system app by tapping **SETTINGS** > **Connections**.

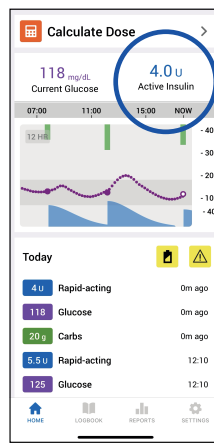


Note: Using the InPen system with an adjunctive CGM requires the user to verify glucose levels with a BGM before making treatment decisions.

When a current glucose from a connected CGM is unavailable, you will not receive Missed Dose alerts or Correct High Glucose alerts from the InPen system app.

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 or 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.

6.2 Calculating an insulin dose

WARNING: Your dose calculator 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. Incorrect dose calculator settings may result in incorrect dose recommendations, which could lead to hyperglycemic or hypoglycemic events, which could result in serious injury or death.

WARNING: If you have taken any rapid-acting insulin from a device other than your InPen system, it must be logged manually in the app. The dose calculator does not account for injections taken with other injectors that you do not manually log and could recommend more insulin than needed. Too much insulin may cause hypoglycemia, which could result in serious injury or death.

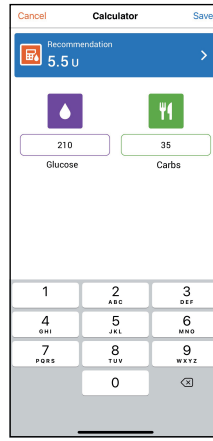
WARNING: Ensure doses taken with the InPen system are transferred to the app before your next dose calculation, or it may result in high dose recommendations, which could lead to hypoglycemia, which could result in serious injury or death.

WARNING: Always ensure that the glucose values and carb values you are entering into the dose calculator are current and accurate. Do not enter a BG value that is older than 10 minutes. Entering inaccurate glucose or meal values into the calculator may lead to inaccurate dose recommendations, which could lead to hyperglycemic or hypoglycemic events, which could result in serious injury or death.

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:

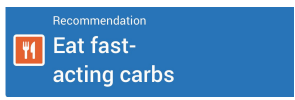
Units of insulin – Based on your current active insulin and the current glucose and carbohydrates/meals entered; this is the recommended number of units of insulin to take now. You may give the dose using your InPen system, and it will be automatically logged.

Note: Only prime your InPen system 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.

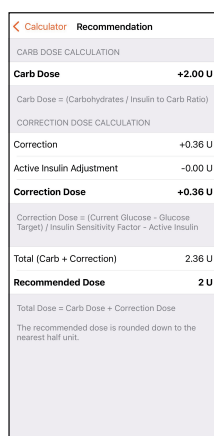
0 Units – Based on your current active insulin, glucose and carbohydrates/meals entered; no additional food or insulin is recommended at this time.



Eat fast-acting carbs – This message will be shown if you enter a low glucose value, regardless of active insulin or carbohydrates 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.

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



Note: 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.

6.3 Multi-part doses

The InPen system 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.

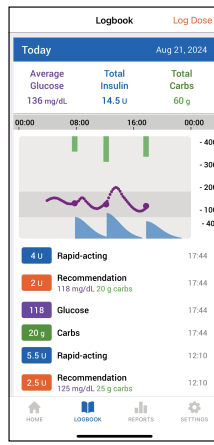
When you are done using the calculator, you may tap **Cancel** to return to the Home screen or **Save** to automatically save what you entered to the logbook.

6.4 Viewing 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 system 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 also be logged. If you forget how much insulin was in the cartridge, you can use the

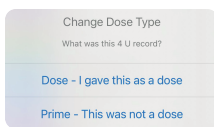
dose calculator again to determine the remaining dose required.

Your InPen system 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.

6.5 Designating a dose or prime if needed

WARNING: All InPen system doses must be correctly categorized as therapy or a prime. Only therapy doses are included in active insulin and used by the dose calculator. Incorrect active insulin may affect dose recommendations, which could lead to hyperglycemic or hypoglycemic events, which could result in serious injury or death.

The InPen system 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.



6.6 Manually logging rapid-acting insulin

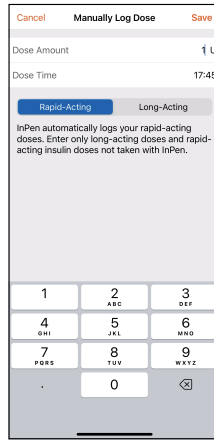
WARNING: If you have taken any rapid-acting insulin from a device other than InPen system, it must be logged manually in the app. The dose calculator does not account for injections taken with other injectors that you do not manually log and could recommend more insulin than needed. Too much insulin may cause hypoglycemia, which could result in serious injury or death.

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 system, it must be logged manually. Doses taken with your InPen system 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 InPen system.

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.**

7 Advanced App features

7.1 Notifications

The InPen system app provides notifications about the following alerts and reminders.

When connected to a Medtronic CGM:

- **Missed Dose** – When enabled, this alert appears when the InPen system app detects that the SG is rising quickly and there is no recent dose of rapid-acting insulin logged within the logbook. This alert can be enabled to detect missed doses and alert you during the day and night.
- **Correct High Glucose** – When enabled, this alert appears when your glucose is above your glucose target and the dose calculator would recommend a correction dose of rapid-acting insulin to get you back to your set glucose target. This alert considers your current sensor glucose and any active insulin to

determine if a correction dose is needed. This alert can be enabled to alert you during the day and night.

When enabled, this alert requires you to set an **Alert Me When I Need** unit threshold value. Set the value to when you will be notified that a correction dose of insulin will be recommended by the dose calculator to get your glucose back to your set glucose target.

Example: When your **Alert Me When I Need** threshold is set to 2 units, the Correct High Glucose alert appears when your current SG is above target and the dose calculator would recommend at least 2 units of rapid-acting insulin.

- **Long-acting Reminder** – When enabled and no long-acting insulin has been recently logged, a reminder appears at your scheduled dose time that it is time to take your long-acting insulin dose.

  The volume of the long-acting dose reminder can be configured in the InPen system app Notifications settings. When connected to a CGM, the long-acting dose reminder uses the configured day volume and configured Notification volume setting.
- **Replace Cartridge Reminder** – This reminder helps you remember to replace your insulin. This reminder occurs 28 days after a cartridge is replaced in your InPen system. This reminder cannot be configured.

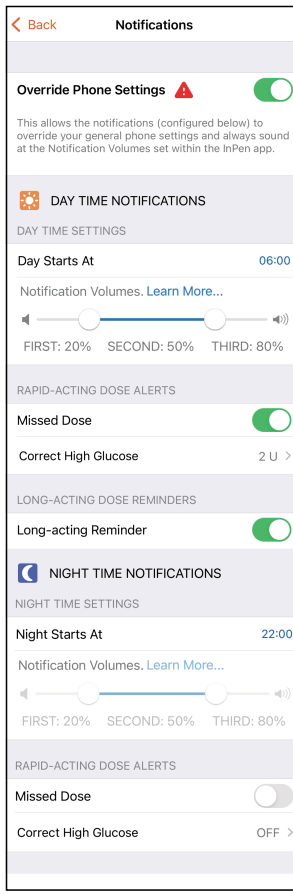
Users without a connected Medtronic CGM:

- **Missed Dose** – When enabled, this alert occurs at the end of your configured meal time window when no rapid-acting insulin dose was logged within the set meal time window.
- **Check Glucose 2hrs After Dose** – When enabled, this reminder helps you remember to check your blood glucose after each rapid-acting insulin dose and at bedtime. When enabled, an alert occurs 2 hours after a rapid-acting insulin dose is taken with the InPen system or manually logged, and at your bedtime.
- **Replace Cartridge Reminder**– This reminder helps you remember to replace your insulin. This reminder occurs 28 days after a cartridge is replaced in your system. This reminder cannot be configured.
- **Long-acting Reminder** – When enabled, and no long-acting insulin has been recently logged, a reminder occurs at your scheduled dose time that it is time to take your long-acting insulin dose.

The volume of the long-acting dose reminder can be configured in the InPen system app Notifications settings when Override Phone Settings is enabled.

To set up notifications when connected to a Medtronic CGM:

1. Tap **SETTINGS**, then tap **Notifications**.



2. In the DAY TIME NOTIFICATIONS section, enter the following settings:
    - **Override Phone Settings** – This allows the notifications to override your general phone settings and always sound at the Notification Volume set within the InPen system app.
    - **Day Starts at** – Enter the time to begin the daytime notification settings.
    - **Volume settings** – Certain notifications provide up to three notifications, with each one increasing in volume.

      Set the volume for the first notification (FIRST) and last notification (THIRD). The second notification volume will be halfway between the first and third volumes. If the first volume setting is set to 0%, it will vibrate only. To set the same volume for all notifications, move both sliders to the same value.

      Tap Learn More in the Notification Volumes section for further information on how to control the volume of your notifications.

      These volume settings apply only to Missed Dose alerts, Correct High Glucose alerts, and Long-acting Reminder. Other notifications use the volume set for your smart device.
    - **Missed Dose** – Enable this setting to turn on Missed Dose alerts.
    - **Correct High Glucose** – Tap this setting to open the Correct High Glucose screen. On this screen, you can turn on Correct High Glucose alerts and set the threshold unit value.

      Alert Me When I Need – Enter a value for the Correct High Glucose alerts. Set the value to when you will be notified that a correction dose of insulin will be recommended by the dose calculator to get your glucose back to your set glucose target.
    - **Long-acting Reminder** – Enable this setting to turn on Long-acting reminders.
3. In the NIGHT TIME NOTIFICATIONS section, enter the following settings:
    - **Night Starts at** – Enter the time to begin the night time notification settings. Night time

settings will be followed until the **Day Starts at** time.

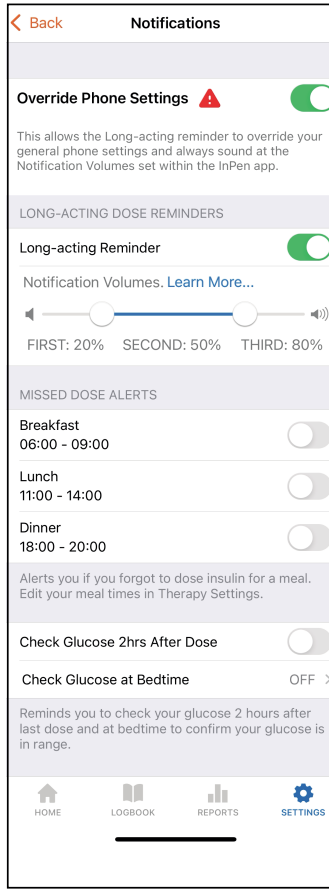
- **Volume Settings** – Enter the volume settings for the night time alerts.
- **Missed Dose** – Enable this setting to turn on Missed Dose alerts.
- **Correct High Glucose** – Tap this setting to open the Correct High Glucose screen. On this screen, you can turn on Correct High Glucose alerts and set the threshold unit value.

  Alert Me When I Need – Enter a value for the Correct High Glucose alerts. Set the value to when you will be notified that a correction dose of insulin will be recommended by the dose calculator to get your glucose back into target range.

4. Tap **Back** to exit the Notifications settings screen.

To set up notifications when not using a CGM:

1. Tap **SETTINGS**, then tap **Notifications**.



2. Enter the following settings:
   - **Override Phone Settings** – This allows the long-acting reminder to override your general phone settings and always sound at the Notification Volumes set within the InPen system app.
   - **Long-Acting Reminder** – Enable this setting to turn on long-acting reminders.
   - **Volume settings** – Certain notifications provide up to three notifications, with each one increasing in volume.

Set the volume for the first notification (FIRST) and last notification (THIRD). The second notification volume will be halfway between the first and third volumes. If the first volume setting is set to 0%, it will vibrate only. To set the same volume for all notifications, move both sliders to the same value.

Tap Learn More in the Notification Volumes section for further information on how to control the volume of your notifications.

These volume settings apply only to Missed Dose alerts, Correct High Glucose alerts, and Long-acting Dose reminders. Other notifications use the volume set for your smart device.

- **Breakfast**, **Lunch**, and **Dinner** – Enable these settings to receive Missed Dose alerts for each mealtime. The hours of the mealtimes can be configured in therapy settings.
- **Check Glucose 2hrs After Dose** – Enable this setting to receive reminders to check BG two hours after an insulin dose and before bedtime.
- **Check Glucose at Bedtime** – Enter the time that you want to be reminded to check BG before going to sleep.

3. Tap **Back** to exit the Notifications settings screen.

7.2 Insights by InPen Reports

Note: 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 healthcare provider, tap **REPORTS** from the Home screen.

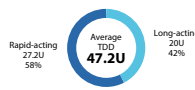
You can select 7, 14, 30, or 90-day time periods by clicking on the report settings icon in the upper left corner of the reports tab. The report covers through the end of the

previous day, so the current day's activity will not be included.

To send this report to yourself or a healthcare provider, tap the share icon. Then select **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:

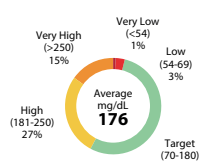
Total Daily Dose – The average total insulin taken (rapid-acting and long-acting) per day and percentage of each type taken per day. This excludes days when no doses were logged and does not include other doses not logged into the app.



Use this chart to understand the following:

- 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.

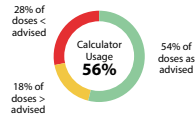


Use this chart and glucose data to understand the following:

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

64 SD (mg/dL)

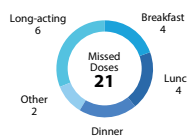
Dose Calculator Usage – The percentage of dose calculator usage and insulin doses where the dose calculator was used but the dose taken was different from the recommended dose.



Use this chart to understand the following:

- Calculator Usage % - Percentage of doses in which the dose calculator was used within 10 min prior to the dose
- Doses as advised - Percentage of doses taken as advised (within +/- 0.5 U of the recommended dose)
- Doses < advised/doses > advised - Percent of doses taken that were greater than or less than the advised dose (at least 1 U more or less than the recommended dose)

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



Use this chart to understand the following:

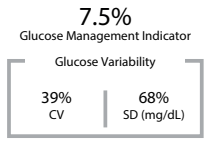
- How many doses were missed, or meals skipped, over the report period.
- Average number of rapid-acting doses logged per day, over the report period.
- Missed doses categorized as other indicate when a missed dose was detected outside a defined mealtime window. This only applies when connected to a CGM.

2.6
Avg. Rapid-acting Doses Per Day

Notes:

- **For users with a connected CGM**, if no insulin is logged within one hour after a potential missed dose is detected, the report will consider this a missed dose. It categorizes that missed dose into breakfast, lunch, dinner or other based on the defined meal times configured within the InPen system app.
- **For users without a connected CGM**, rapid-acting doses not logged within the meal times configured within the InPen system app are considered missed doses, unless you indicated that you did not eat that meal in the missed dose alert response. If missed dose alerts 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 blood glucose checks per day is also displayed.



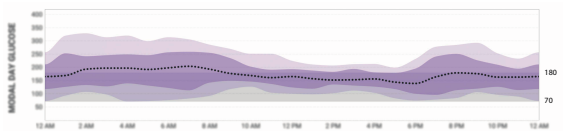
Between the round charts, you will find the Glucose Data Panel. In addition to providing information on standard deviation, this chart also provides your coefficient of variation to enhance understanding of glucose variability, as well as your Glucose Management Indicator (GMI).

Coefficient of Variation (%CV) provides your healthcare provider with additional information to help adjust your therapy.

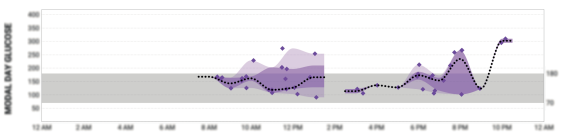
The Glucose Management Indicator (GMI) provides an approximate value of laboratory A1C levels based on average glucose values when at least 10 days of CGM data are available. It provides your healthcare provider with additional information to help adjust your therapy.

Modal Day Glucose – This is a graphical representation of patterns of daily glucose. The chart shows median glucose values in black, 50% of glucose values in the dark bands, and 10% - 90% of glucose values in the lighter bands. A fixed target range of 70-180 mg/dL is shaded gray 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 the following:

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

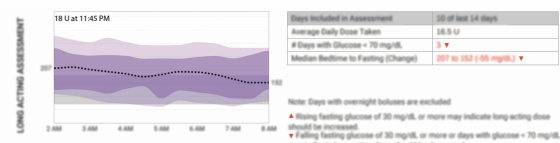
Insulin Settings – Insulin settings configured within the app will display beneath the modal day glucose chart. The settings are aligned to the time of day they are programmed within the app.

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 before the start of the fasting window are excluded.

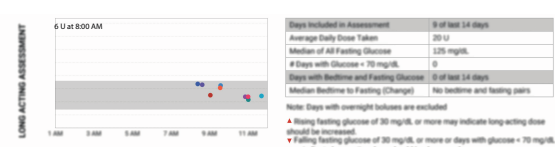
This assessment may help identify the following:

- 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.
- Rises and falls in glucose and frequency of hypoglycemia that may be of clinical significance.[1, 2]

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, 6th ed. 2017, Torrey Pines Press

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

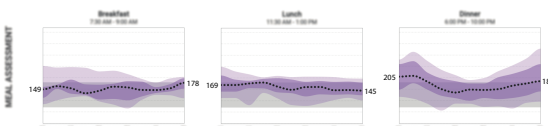
Note: Glucose values taken on the same day are the same color and are connected with lines. The lines are for reference only when viewing BGM data. Actual blood glucose between glucose points is unknown.

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 the set meal time window are not included in the meal assessment.

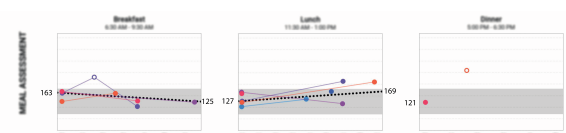
This assessment may help identify the following:

- 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 or type of each meal.

Meal Assessments with CGM data will appear like this:

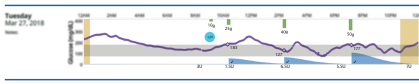


Meal Assessments with BGM data will appear like this:



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 turquoise circles. Missed doses are shown as gold bands. Use the daily charts to visualize and assess daily patterns in glucose, insulin, and carbohydrates for the last 7 or 14 days of the report period.

On each bolus, the following symbols may appear:

✔	Indicates the dose was within 0.5 U of the recommendation
▲	Indicates the dose was at least 1 U higher or more than the recommendation
▼	Indicates the dose was at least 1 U lower or more than the recommendation
No symbol	Indicates the dose calculator was not used

Daily charts may help identify the following:

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

Daily charts may help verify the following:

- Insulin action time
- Insulin sensitivity factor
- Insulin-to-carb ratio (ICR)

7.3 Dose calculator algorithm

There are four different formulas the dose calculator feature uses to estimate a bolus, depending on your current BG, and time since your last dose.

Glucose	**< 2 hours from last dose**	**≥ 2 hours from last dose**
Glucose > 180 mg/dL	Formula 1	Formula 1

Glucose	< 2 hours from last dose	≥ 2 hours from last dose
Target glucose ≤ glucose ≤ 180 mg/dL	Formula 1	Formula 3
55 mg/dL < glucose < target glucose	Formula 2	Formula 4
No glucose entered	Formula 4	

1. If your current glucose is above 180 mg/dL, or between target glucose and 180 mg/dL within 2 hours of your last dose, the dose calculator feature subtracts active insulin from the correction estimate, then adds this to the food estimate to get the total bolus estimate. However, if the result of subtracting active insulin from correction estimate is a negative number (less than zero), the total bolus estimate is based only on the food estimate.

$$\text{TBE} = \underbrace{\frac{\text{C}}{\text{CR}}}_{\text{(food estimate)}} + \underbrace{\frac{\text{CG} - \text{TG}}{\text{ISF}}}_{\text{(correction estimate)}} - \text{AI}$$

Where:

TBE = Total Bolus Estimate

C = Carbs

CR = Carb Ratio

CG = Current Glucose

TG = Target Glucose

ISF = Insulin Sensitivity Factor

AI = Active Insulin

2. If your current glucose is less than your target glucose, and it has been less than 2 hours since your last dose, the food estimate is reduced by the correction estimate to get the total bolus estimate.

$$\text{TBE} = \underbrace{\frac{\text{C}}{\text{CR}}}_{\text{(food estimate)}} + \underbrace{\frac{\text{CG} - \text{TG}}{\text{ISF}}}_{\text{(correction estimate)}}$$

Note: When the current glucose is below the target glucose, and it has been less than 2 hours since your last dose, active insulin is not considered in the total bolus estimate.

Where:

TBE = Total Bolus Estimate

C = Carbs

CR = Carb Ratio

CG = Current Glucose

TG = Target Glucose

ISF = Insulin Sensitivity Factor

3. If it has been more than 2 hours since your last dose and your current glucose is > 55 mg/dL and ≤ 180 mg/dL, the dose calculator feature adds the correction estimate and subtracts active insulin from the food estimate to get the total bolus estimate. Note if glucose is below target glucose, the food estimate will be reduced by the correction estimate and active insulin.

$$\text{TBE} = \underbrace{\frac{\text{C}}{\text{CR}}}_{\text{(food estimate)}} + \underbrace{\frac{\text{CG} - \text{TG}}{\text{ISF}}}_{\text{(correction estimate)}} - \text{AI}$$

Where:

TBE = Total Bolus Estimate

C = Carbs

CR = Carb Ratio

CG = Current Glucose

TG = Target Glucose

ISF = Insulin Sensitivity Factor

AI = Active Insulin

4. If you do not enter a glucose, the total bolus estimate is based only on the food estimate.

$$\text{TBE} = \underbrace{\frac{\text{C}}{\text{CR}}}_{\text{(food estimate)}}$$

Where:

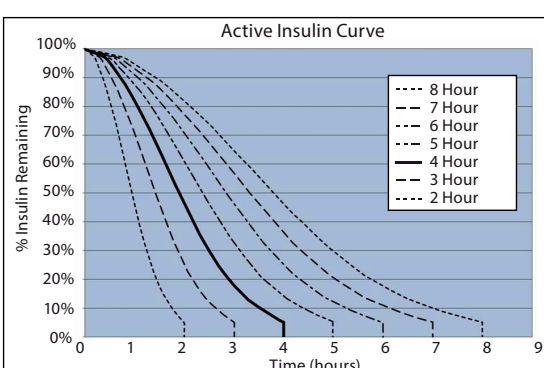
TBE = Total Bolus Estimate

C = Carbs

CR = Carb Ratio

Following are some notes about the dose calculator:

- Total bolus estimates are rounded down to the nearest 0.5U.
- If glucose is ≤ 55 mg/dL, the dose calculator will recommend eating fast acting carbohydrates to raise glucose.
- For fixed dose or meal estimation modes, the food estimate is the dose provided by the healthcare provider for the meal selected in the calculator.
- If the total bolus estimate is negative and the calculator is in carb counting mode, the calculator will recommend eating X grams of carbohydrates as calculated by **carbs = –(total bolus estimate) * ICR.**
- The following Active Insulin Curve represents how long a bolus of insulin lowers your glucose after the bolus is given. The percentage of insulin remaining lowers at varying rates depending on how long the insulin is active in your body.[3]



[3] Graph adapted from Mudaliar and colleagues, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501.

7.4 Changing Meal Therapy mode

If your healthcare provider recommends changing the Meal Therapy mode, use these steps to make the update in the InPen system app.

1. Tap **SETTINGS** > **Therapy Settings**.
2. Read the caution statement, then tap **Proceed**.
3. Tap **Meal Therapy**, then select the new meal therapy prescribed by your healthcare provider.
4. Tap the green check mark.

8 Troubleshooting

8.1 Notification icons

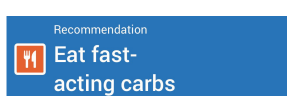
During use of the app, you may see one or more alert icons on the Home screen. When an icon appears, it can be tapped for more information or to clear the notification.

	**Missed Dose** – When not connected to a CGM, 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 InPen Battery** – This icon will appear when the InPen system 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 system paired.
	**Insulin Temperature** – This icon will appear when the InPen system detects a very high or very low temperature. Based on the temperature of the InPen system, 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 replace cartridge reminder is enabled, and the InPen system 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 automat-

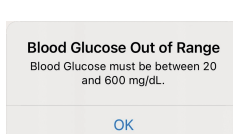
	ically clear when a new insulin cartridge is installed.
	**Long-acting Reminder** – This icon will appear if the long-acting reminder is enabled, and no long-acting dose was logged at the reminder time. You can tap the icon for more options or to manually clear the alert.
	**Correct High Glucose** – This icon will appear if your glucose is above the target range and a correction dose is needed to get you back into the target glucose range.
	**Active Insulin Warning** – This icon will appear when the InPen system is no longer logging insulin doses in the InPen system app due to reaching its end-of-life. The active insulin warning will be shown for a maximum of a week or until you pair a new InPen system or the expired pen is removed from the InPen system app.

8.2 Messages

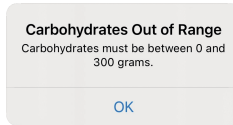
You may see the following messages when using the app:



If the blood glucose value entered is 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 and 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 before using the dose calculator.

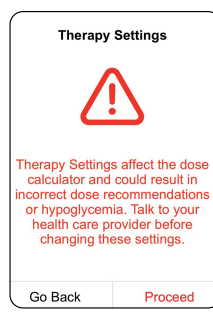


The dose calculator only accepts values between 0 and 300 g. If you believe the message is in error, then check the value you entered.

To use the dose calculator, you must have the InPen system paired to your device. See *Chapter 5* for pairing instructions.

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

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 *Chapter 5, Getting started, page 12* 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 therapy settings to use.

If you have been provided with your therapy settings tap **Proceed**.

8.3 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 system app. For more information, see *Chapter 4, Supported devices, page 12*.
	On your smart device, tap the icon for your device's app store and search for "InPen" and follow the prompts to install the app.
	The InPen system app may not be available in all locations.
I paired my InPen system, but doses are not appearing in the app.	Check that Bluetooth is enabled on your smart device.
	Move the InPen system and your smart device within 3 feet (1 m) of each other.
	Ensure that the InPen system is still within its 1-year use life from the date of first use. The Smart Start InPen system has a 30-day use life.
	Prime the InPen system one or more times.
	Close and restart the InPen system app.
	From your smart device's Bluetooth settings screen, if you see an InPen system listing, tap it and select the setting to forget the device. See *Chapter 5, Getting started, page 12* for instructions to pair if your InPen system was previously paired with your smart device.
	Close and restart the InPen system app.

Problem	Solutions to try
After priming my InPen system, the prime amount is listed as a dose.	If you are using the dose calculator, ensure that you prime after calculating your dose. From the Home screen, tap **LOGBOOK** to view the list of doses. Tap on the dose to designate it as a prime dose. Prime doses are not included in active insulin or reports.
I left my InPen system somewhere and I need to take insulin from another source.	You may take rapid-acting insulin from sources other than your InPen system if needed. When you do, be sure to manually log the dose into the InPen system app. See *Section 6.6, Manually logging rapid-acting insulin, page 33* for instructions on how to manually log a dose.
	For safety, it is important to log all rapid-acting insulin taken. Doses taken from a paired InPen system are logged automatically and do not need to be manually entered.
I paired my InPen system to a new smart device, and now it won't connect with the original one.	Your InPen system can only be paired to one smart device at a time. If necessary, follow the instructions in *Chapter 5, Getting started, page 12* to pair it to your original device again. Frequently pairing the InPen system to different smart devices may decrease battery life and is not recommended. Frequently pairing the InPen system to different smart devices may decrease battery life and is not recommended.
I can't hear reminders on my smart device.	See *Section 5.12, Important information about smart de-*

Problem	Solutions to try
	vice setup, page 24 for tips on properly setting up your smart device.
The Missed Dose reminder isn't working.	Tap **SETTINGS** > **Reminders**. In the **Missed Dose Reminders** section, turn on reminders for Breakfast, Lunch, or Dinner, as necessary.
	The **Missed Dose** reminder will only remind you if you have not taken a dose. If you use your InPen system normally and take doses at your regular times each day, then the reminder will not appear.
	You can adjust the start and end times of the missed dose reminder to fit your personal routine in **SETTINGS** > **Therapy Settings**.
I'm trying to adjust a date or time, but the selection keeps resetting.	To manually log an insulin dose, the time must be within the past 24 hours or the selection will reset. When setting a time of day setting, it must not overlap with another time period or the selection will reset. Adjust a different selector (e.g. date, hour, minute) first to avoid an invalid entry. Adjust another time period first to prevent overlap with the time you are trying to set.
The app is unresponsive.	Restart the app. If restarting the app doesn't work, uninstall and reinstall the app. If reinstalling the app doesn't work, contact customer support.
I can't create an account.	Contact customer support.

9 Compatible insulin and needles

The InPen system 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 system:

WARNING: Always check the insulin label before each injection to avoid medication errors. Injecting the wrong insulin type could lead to hyperglycemic or hypoglycemic events, which could result in serious injury or death.

InPen system model	Compatible U-100 3 mL cartridges	Compatible needles
MMT-105ELXX	Lilly Humalog	BD Ultra Fine and Novo Nordisk Novofine
MMT-105NNXX	Novo Nordisk Novolog	
	Novo Nordisk Fiasp	

10 Getting ready

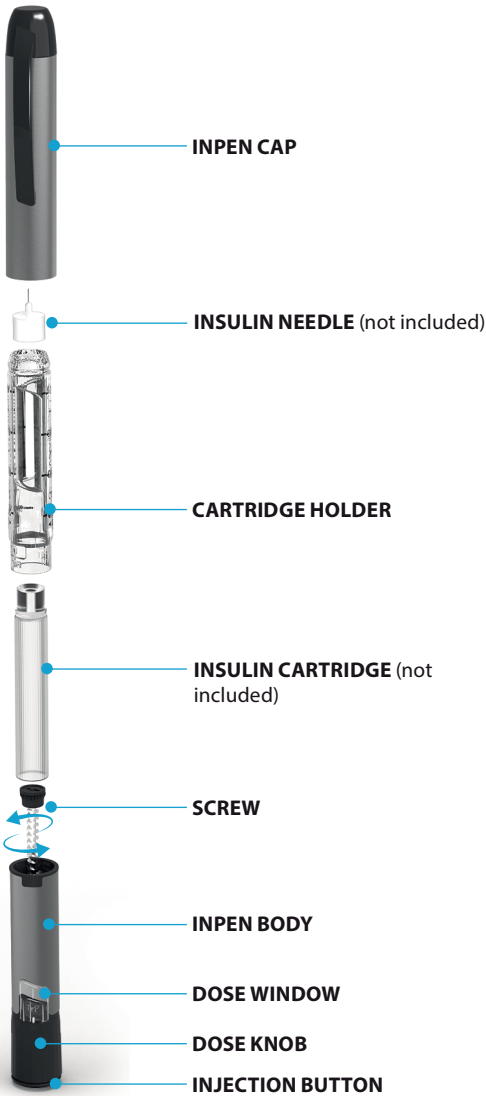
Check for adverse reactions where the InPen system comes into contact with skin. These reactions include redness, swelling, irritation, sensitization, rash, and other allergic reactions. Do not allow the InPen system to come into contact with skin wounds, as the InPen system materials have only been evaluated for safe contact with intact skin.

If a serious incident related to the device occurs, immediately report the incident to a healthcare professional, to the applicable competent authority, and to a local Medtronic support representative. Serious incidents may include death, temporary or permanent serious decline in health, or a serious public health threat.

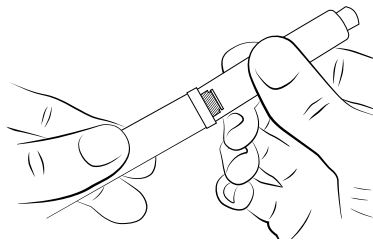
Wash your hands and make sure you have the following items available before beginning:

- InPen system
- 3 mL U-100 insulin cartridge
- New pen needle

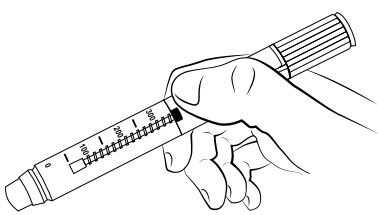
11 Preparing your InPen system



1. Pull off the 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 in the following cases:
   - The cartridge is expired.
   - The cartridge has an unusual visual appearance.
   - The cartridge has 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, which may result in hyperglycemia.

Notes:

- Your healthcare provider has prescribed the type of insulin best for you. Any changes in insulin should be made only under medical supervision.
- The InPen system is for use only with 3 mL U-100 rapid-acting insulin cartridges.
- Only use insulin cartridges compatible with your InPen system.
- Read and follow the instructions provided with your insulin cartridge.
- Before each injection, read the cartridge label and be sure the InPen system contains the correct insulin cartridge.
- The color of the InPen system 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 the InPen system and insulin, please refer to the patient information provided with your insulin cartridge or contact your healthcare provider.

11.1 Frequently asked questions about preparing your InPen system

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 body. Then carefully line up the cartridge holder with the InPen body and screw together until secure.

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

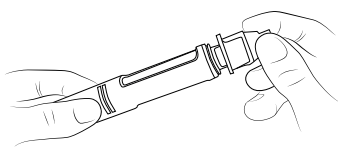
Twisting the InPen cap may have unscrewed the cartridge holder.

- 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 body assembly.
- Be sure to prime the InPen system again before the next use.

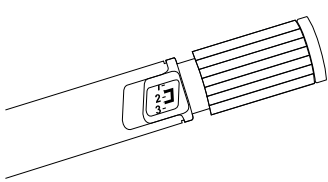
12 Priming your InPen system

CAUTION: If you do not prime, you may not receive a full dose. Prime your InPen system before every injection.

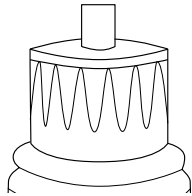
1. Remove the paper tab from the needle.
2. Attach the needle by screwing the needle straight onto the cartridge holder as shown.



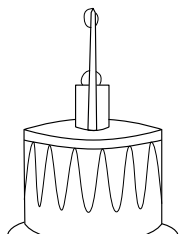
3. Pull off the outer cap and the inner cap.
   - Discard the inner cap.
   - Keep the outer cap to remove the needle after your injection.
4. Turn the dose knob to select amount to prime. Dial 2 units as shown.



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



6. Prime the InPen system 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 require the InPen system to be primed several times.

CAUTION: If no insulin flows after several attempts, attach a new needle, as the one on your InPen system may be clogged. If you do not change a clogged needle, you may not get your full dose, which may result in hyperglycemia.

Notes:

- Only use needles compatible with your InPen system.
- 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.

12.1 Frequently asked questions about priming your InPen system

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

   If you do not prime, you may not receive a full dose. Priming helps to ensure that the InPen system and needle are working properly. Once the InPen system 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 the screw and the cartridge are 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 system:

   - 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 system is properly primed.
   - If the injection button is difficult 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 system. 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 system will remove air. Hold the InPen system 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 system, this small air bubble will not affect your insulin dose.

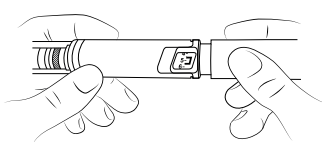
5. **Why doesn't a drop of insulin appear at the needle tip when I check the insulin flow?**

   The needle may be blocked.

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

13 Selecting your dose

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.



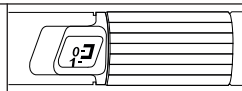
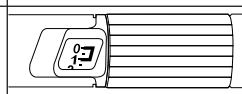
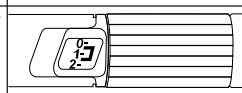
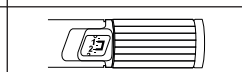
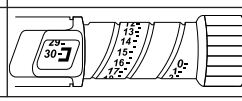
If you select a wrong dose, simply change it by turning the dose knob in either direction. If you change your mind and do not want to inject a dose, you may adjust the dose knob back to the 0 set point. No insulin will be dispensed until you press the injection button.

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

13.1 Frequently asked questions about selecting your dose

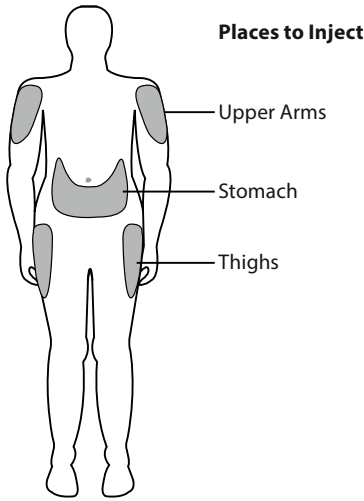
How do I read the dose indicator?

The InPen system can be adjusted in steps (increments) of 0.5 (½) 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 ½ unit step between the numbers. See the following table for more examples.

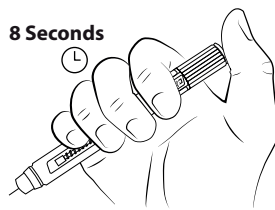
Set to **0 units**. The indicator line is aligned with the "0" mark, which means nothing will happen if the button is pressed. Store the InPen system this way.	
Set to **½ unit**. This is the smallest dose setting possible.	
Set to **1 unit**. The indicator line is lined up with the number "1".	
Set to **1.5 units**. The indicator line is on the mark between the "1" and "2".	
Set to **30 units**. This is the maximum dose setting possible.	

14 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 without touching the injection button, as indicated by your healthcare provider.
3. To inject your insulin, place your thumb on the injection button, then slowly and firmly push the button until it stops moving.



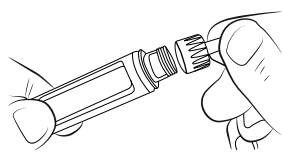
4. Continue to hold the button for 8 seconds and then remove the needle from your skin. Check to make sure you see a 0 in the dose window to confirm you received the complete dose.

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 system with a needle attached.

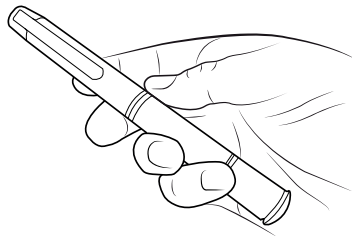
6. Place the outer cap back onto the needle and remove the capped needle by twisting it off.



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.

9. Attach the cap on your InPen system.



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 system 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.

14.1 Frequently asked questions about injecting the dose

1. **Why does the InPen system not deliver any insulin when I turn the dose knob to inject?**

   Turning the dose knob will not deliver insulin. You have to press the injection 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 system.

   Pushing the injection button down quickly may make the injection button harder to push. Pushing the injection 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 these steps resolves the problem, your InPen system may need to be replaced.

Your injection button may become harder to push if the inside of your InPen system gets dirty with insulin, food, drink, or other materials. Following the instructions in *Chapter 17, Handling and storage of your InPen system, page 71* should prevent this.

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

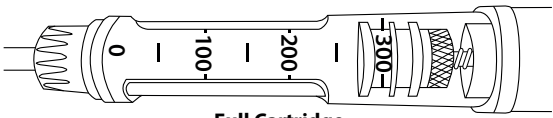
   This can happen if the insulin cartridge does not have enough insulin left in it for your entire dose, or if the needle has become clogged. To get the rest of your dose, do the following:

   - Check the number in the dose window. This is the amount that 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 system.
   - 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 system until insulin is observed. You should see a few drops of insulin.
   - Complete your dose by dialing the amount that you did not receive and inject this amount.

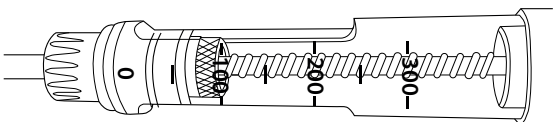
If you are not sure whether you have received your full dose, you should check your glucose level more frequently.

15 How much insulin is left in your InPen system?

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



Full Cartridge



Empty Cartridge

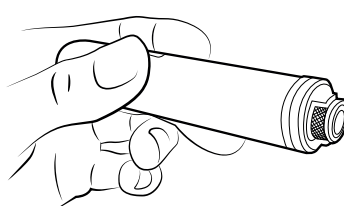
It is ok to set a dose greater than the amount of remaining insulin. The InPen system will deliver as much insulin as is left in the cartridge, and then you can complete the dose with a new cartridge. See *Chapter 14, Injecting the dose, page 65*.

16 Replacing a used insulin cartridge

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

See *Chapter 9, Compatible insulin and needles, page 57* for information about compatible insulin cartridges.

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



3. Follow the instructions in *Chapter 11*. Dispose of the used cartridge before installing a new one.

17 Handling and storage of your InPen system

When an insulin cartridge is installed in your InPen system, store your InPen system 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 system with the needle attached.

Do not store the InPen system in a refrigerator.

Your InPen system is designed to work accurately and safely, but you must still take good care of it.

Notes:

- Only use your InPen system 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 system as this may damage it.
- Keep it away from direct sunlight, water, dust, and dirt.
- Do not expose your InPen system (without cartridge) to temperatures below 5 °C (41 °F).
- Do not try to repair a broken InPen system.

Refer to *Chapter 24, Product specifications, page 75* for more information.

When you receive a battery warning or the InPen system can no longer communicate with the InPen system app, you will need to obtain a new InPen system.

18 Cleaning your InPen system

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

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

Frequently asked questions about caring for your InPen system:

What should I do if my InPen system 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 system 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 system, 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 system is functioning properly. Refer to the patient information provided with the needle for information on this feature.

19 Replacing your InPen system

Your InPen system has a use-life of 1 year. The Smart Start InPen system has a use-life of 30 days. Discontinue use of your InPen system after it has expired. At the end of the use-life, your InPen system will not communicate doses to the InPen system app, which may result in incorrect recommendations from the dose calculator.

Obtain a replacement pen before the use-life of the InPen system expires. To obtain a new InPen system, contact your healthcare professional.

Be sure to manually log insulin doses in the InPen system app until you receive your new InPen system.

20 Disposal

Your InPen system 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. Throw them away according to the instructions on the needle and cartridge labeling, and as your doctor or nurse has instructed you.
- Throw your InPen system 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 radio frequency (RF) communication. Cell phones use Bluetooth technology as do many other devices. Your InPen system uses Bluetooth to pair with your smart device and to send data to the InPen system app.

Your InPen system 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 system will not affect the operation of other nearby electronic devices. Except for 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 system to the InPen system app. Moving away from or turning off these electronic devices may allow communication.

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

If you experience interference problems with your InPen system, try moving your InPen system 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 Medtronic 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 applicable to the InPen system.

Operating frequency 2.4-2.4835 GHz band
Effective radiated power (ERP) 0.19 mW (-7.19 dBm)
Effective isotropic radiated power (EIRP) 0.31 mW (-5.04 dBm)

Dose accuracy

The InPen system fulfills the functional requirements and specification limits for dose accuracy according to ISO 11608-1.

±0.5 U below 10 U and ±5% at 10 U and above.

Applied parts

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

FCC compliance

This device complies with part 15 of the FCC Rules.

Operation is subject to two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

23 Warranty

Medtronic 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, Medtronic 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 Medtronic 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 Medtronic Terms of Use (https://www.medtronicdiabetes.com/terms-of-use) and Privacy Policy (https://www.medtronicdiabetes.com/privacy-policy).

24 Product specifications

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

Operating conditions (insulin loaded) 5 °C (41 °F) to 37 °C (98.6 °F) 10% to 95% RH (non condensing)
Operating altitude -381 m (-1253 ft) to 3010 m (9878 ft)
Operating pressure 80 kPa – 105 kPa

Storage and transportation conditions (no insulin loaded) 5 °C (41 °F) to 40 °C (104 °F) 10% to 95% RH (non condensing)
Dimensions 16.5 cm (6.5 in) x ø1.9 cm (0.8 in)
Weight 35 g
Power supply Li-Mn battery (not replaceable)
Use life **InPen system** - 1 year from activation **Smart Start InPen system** - 30 days from activation
Accuracy Meets limits for dose accuracy according to ISO 11608-1 ±0.5 U below 10 U and ±5% at 10 U and above
Moisture protection IP22: Protection against insertion of large objects and dripping water
Protection against electrical shock Type BF applied part
Operating range of Bluetooth connection 3 meters

Medtronic

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www.medtronicdiabetes.com

℞ *Only*

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