InPen® MOBILE APP
Healthcare Provider
INSTRUCTIONS FOR USE

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TABLE OF CONTENTS

Introduction.............................................................................................................................................................................3
InPen® Mobile App...........................................................................................................................................................3
Intended Use.........................................................................................................................................................................3
Indications for Use............................................................................................................................................................3
Contraindications...............................................................................................................................................................3
Start Orders.............................................................................................................................................................................4
General Notes......................................................................................................................................................................4
Definitions.................................................................................................................................................................................5
Dose Calculator Algorithm.......................................................................................................................................6
Basic Setup.............................................................................................................................................................................7
Calculate a Dose...............................................................................................................................................................9
Using the Dose Calculator with Blood Glucose Data......................................................................9
Low Blood Glucose......................................................................................................................................................10
Logging Doses without Using the Dose Calculator ..................................................................................11
Using the Dose Calculator without Blood Glucose Data........................................................................12
Split Doses.............................................................................................................................................................................12
Additional Dose Calculator Settings......................................................................................................................13
Time of Day Settings...................................................................................................................................................13
Dose Reminders..............................................................................................................................................................14
INTRODUCTION

InPen® Mobile App
The InPen® Application (App) is a diabetes management tool that tracks insulin doses from the InPen, calculates insulin doses, and shares therapy details with healthcare professionals and family members.

This guide provides important information for the safe use of the InPen.

Intended Use
The InPen App is intended for use by people with diabetes to view, calculate, track, trend, and share data to support diabetes management. The App is available for use on compatible Apple iOS devices, and is designed to work with the InPen smart injector pen.

Indications for Use
The InPen dose calculator, a component of the InPen app, is indicated for the management of diabetes by people with diabetes age 12 and older by calculating an insulin dose or carbohydrate intake based on user entered data. Prior to use, a healthcare professional must provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, insulin sensitivity parameters, duration of insulin action, and maximum dose to be entered into the app.

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

- Check blood glucose (BG) levels as recommended by a healthcare provider
- Demonstrate adequate carbohydrate-counting skills
- Maintain sufficient diabetes self-care skills
- Visit a healthcare provider regularly
CONTINUED

Start Orders

Be sure to complete the InPen Start Order. The start order includes the required and optional settings for customizing the dose calculator for each patient. The patient is given a copy of the start order and may enter their settings into the App.

General Notes

*Note: Refer to the Mobile App User Guide for instructions on how to pair the InPen to the Apple device.*

If the InPen is out of range of the Apple device the dose calculator may not have all recent doses logged which could result in unsafe recommendations, including hyperglycemia, hypoglycemia, or injury.

To receive Alarms or Alerts the patient must:

- Make sure notifications are turned on in the settings menu
- Check that the App hasn’t been shut down by the Apple device
- Make sure to turn on Bluetooth®
- **Turn off the Do Not Disturb** feature on the Apple device (if available)
- Restart the App after the Apple device is restarted
- Set the volume on the Apple device at a level the patient can hear
- Do not close the App; always run the App in the background
- Unplug headphones when not in use; Alarms and Alerts from the App cannot be heard through the Apple device if headphones are plugged in.

It is recommended to allow the Apple device set the date and time automatically. Medical device apps, like the InPen App, do not have any special priorities over the device’s features. You cannot determine if an alarm/alert is a notification from the InPen App or another app without looking at the screen of the Apple device.
DEFINITIONS

Active Insulin – Also known as IOB (Insulin On Board), is an estimate of the insulin from recent doses that is still being used in the body. It is derived from the recent doses taken and the Duration of Insulin Action parameter.

Maximum Calculated Dose – This is the largest dose of insulin the patient should normally take. When using the Dose Calculator, if a dose recommendation or the total of recent doses plus the recommendation exceeds this, an alert will be displayed.

Duration of Insulin Action – This is the amount of time that insulin is actively lowering blood glucose. It is used to calculate Active Insulin and the blue circles on the history arc of the Home Screen.

Time of Day Settings – By default, this is disabled and Target Blood Glucose, Carbohydrate Factor, and Correction Factor are constant throughout the day.

Time of Day (If Time of Day Settings are enabled) – Each day at the time selected, the parameters in the column beneath it will be active until the next column’s time is reached.

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

Insulin Sensitivity Factor – This is the number of grams of carbohydrate covered by 1 unit of insulin.

Insulin to Carb Ratio – This is the amount blood glucose is lowered by 1 unit of insulin.

Last Glucose and Last Dose – These are displays of the last glucose entered or measured with a connected BGM or CGM and the last insulin dose taken with an InPen or manually logged in the Logbook. How long ago is displayed in hours and minutes. If the value is older than 24 hours it is displayed as the number of days ago.
DOSE CALCULATOR ALGORITHM

The insulin dose calculations provided by the app are meant for patients undergoing subcutaneous multiple daily injection (MDI) therapy. Dose calculators also track residual bolus insulin to mitigate insulin stacking.

The dose calculator utilizes the current blood glucose measurement, carbohydrate consumption, active insulin, carbohydrate factor, correction factor, and target blood glucose to calculate the estimated dose.

The basic equation is as follows:

\[
\text{Dose Recommendation} = \frac{\text{Carbs Entered}}{\text{Carb Factor}} + \frac{\text{BG} - \text{Target BG}}{\text{Correction Factor}} - \text{Active Insulin}
\]

If BG is not entered, Active Insulin (IOB) is not included in the calculation, and only a carb dose is calculated:

\[
\text{Dose Recommendation} = \frac{\text{Carbs Entered}}{\text{Carb Factor}}
\]

If the calculated value is less than 0, then an “Eat” recommendation is given using the following equation:

\[
\text{Suggested Carbs} = - (\text{Dose Recommendation}) \times \text{Carb Factor}
\]

1Adapted from Mudaliar et al. Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501.
HOME SCREEN

Time and value of last glucose measurement

Time and size of last rapid acting insulin dose

History Arc

Current Insulin-on-Board (Active Insulin)

Dose Calculator

Notification icons:
- Rapid Acting Reminder
- Low InPen Battery
- Insulin Temperature
- Insulin Age
- Long Acting Reminder
BASIC SETUP

1. Provide a complete InPen Start Order to the patient. 

   **Note:** Insulin settings must be accurate and correct. If you are unfamiliar with insulin dosing or how to determine insulin settings, then do not prescribe the InPen System.

2. **Download and install** the InPen app from the Apple App Store.

3. Launch the App by tapping the icon.

4. Open the Settings page by tapping **Settings**. Open Insulin Settings by tapping on **Insulin Settings**.

5. Insulin setting values are entered from the InPen Start Order.

6. Review the settings and tap **Home** to return to the Home screen.

7. Setup is complete.
CALCULATE A DOSE

Using the Dose Calculator with Blood Glucose Data

1. Launch the App by tapping the icon.
2. Open the dose calculator by tapping the icon.
3. Enter the current blood glucose as measured by BGM or CGM. Note: If a connected BGM or CGM is used and shared through Apple Health, blood glucose will be pre-populated.
4. Enter the number of grams of carbohydrates to be eaten. The dose recommendation is displayed.
5. The math used to calculate the dose may be displayed by tapping the recommendation.
6. Tap Save to Return to the Home screen.
7. Use the InPen to prime and then dial and dispense the recommended dose.
8. The Home Screen is updated with the time since last dose and current IOB.

Low Blood Glucose

If a low Blood Glucose value is entered, regardless of Active Insulin or Carbohydrates entered, a recommendation will be made to eat fast acting carbohydrates.
CALCULATE A DOSE

Logging Doses without Using the Dose Calculator

**Note:** If a fast-acting insulin source other than the InPen is used it must be logged as a manual dose.

1. Launch the App by **tapping the icon.**
2. Open the Logbook by tapping the icon and **tap Log Dose.**
3. Choose rapid-acting or long-acting insulin and enter the time and size of the dose taken.

![Dose Calculation Screen](image)

**Note:** If the patient has traveled across a time zone, adjust and enter the dose time as though it was taken in the current time zone.

4. **Tap Save** to return to the Logbook.
5. **Tap Home** to Return to the Home Screen.
6. The Home Screen is updated with the time since last dose and current IOB.
CALCULATE A DOSE

Using the Dose Calculator without Blood Glucose Data

1. Launch the App by tapping the icon.
2. Open the dose calculator by tapping the icon.
3. Enter the number of grams of carbohydrates to be eaten. The dose recommendation is displayed.
4. Use the InPen to dial and dispense the recommended dose.
5. Tap Save to return to the Home Screen.
6. The Home Screen is updated with the time since last dose and current IOB.

Dose Recommendations Greater than Maximum Calculated Dose
The dose calculator has a maximum calculated dose setting that is set by the healthcare provider. 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. The patient should refer to the instructions given by their healthcare provider.

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

If the patient forgets how much insulin was recommended, they may use the dose calculator again to calculate the remaining dose required.
ADDITIONAL DOSE CALCULATOR SETTINGS

Note: Use these steps to program customized time of day settings and dose reminders.

Time of Day Settings

When enabled, up to four time settings may be programmed for a 24 hour period. Target Blood Glucose, Carbohydrate Factor, and Correction Factor may be customized for each time setting. Each time setting ends when the next one begins.

1. Launch the App and open Insulin Settings.
2. Slide the Time of Day Settings switch
3. Tap each Time of Day to enter settings for that period.
4. Tap Back to return to the Home screen.

Note: Time of Day settings are not affected by time zone changes.

Instruct patients to always consult their healthcare provider about actions they should take when using multiple Time of Day settings and traveling to different time zones.

Only the patient’s healthcare provider can determine if differences due to time zone changes are clinically important so as to require the patient to adjust Time of Day settings while traveling.
ADDITIONAL DOSE CALCULATOR SETTINGS

Missed Dose Reminders

When enabled, up to four rapid-acting dose reminders may be programmed for a 24 hour period. If no dose has been logged by the end of the time period then the App will notify the patient.

1. Launch the App and open Insulin Settings.
2. Tap Reminders
3. To enable a reminder, tap the corresponding cell and customize the start and end times of the period as needed.
4. Tap the green checkmark to save the change, or the red X to cancel.
5. Tap Back to return to the Settings screen.

Note: Time periods cannot overlap, so you may need to adjust another time period start or end time to prevent overlap.
ADDITIONAL DOSE CALCULATOR SETTINGS

Long-Acting Reminders

When enabled, up to two long-acting dose reminders may be programmed for a 24 hour period. If no dose has been logged by the end of the time period then the App will notify the patient.

1. Launch the App and open Insulin Settings.

2. Tap Reminders.

3. Tap Long-Acting Reminder.

4. To enable a reminder, slide the corresponding switch and tap the cell to select the long acting insulin type and the number of doses per day.

5. Tap the cell to enter the usual amount of long acting insulin to take.

6. To adjust the reminder time, tap the cell and select the reminder time.

7. To disable a reminder, slide the switch to the left.

8. Tap Save to return to the Reminders screen.
Now you know.

Why InPen?

InPen automatically tracks insulin therapy, reports last dose and active insulin, and helps people with diabetes calculate mealtime and correction doses. This eases the burden of memorizing doses and improves the reliability of the insulin logbook.

Contact your InPen Representative today!

Notes / Questions:

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