InPen™ System

Healthcare Professional
Instructions for Use
# Table of Contents

3 Introduction  
3 InPen Mobile App  
3 Intended Use  
3 Indications for Use  
4 Contraindications  
5 InPen Prescription/Start Orders  
5 General Notes  
6 Definitions  
8 Dose Calculator Meal Therapy Modes  
9 Dose Calculator Algorithm  
10 Basic Setup  
12 Calculate a Dose  
13 Using the Dose Calculator with Glucose Data  
13 Using the Dose Calculator without Eating  
14 Dose Recommendations Greater Than Maximum Calculated Dose  
14 Prime  
15 Split Doses  
15 Time of Day Settings  
16 Dose Reminders  
18 Insights by InPen Reports  
32 Apple Health Compatibility  
33 Frequently Asked Questions
Introduction

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

To learn more visit: www.companionmedical.com

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, record, trend, and share data to support diabetes management. The app is available for use on iOS and Android mobile devices, and is designed to work with the InPen smart injector pen.

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

The InPen dose calculator, a component of the InPen app, is indicated for the management of diabetes by people with diabetes under the supervision of an adult caregiver, or by a patient age 7 and older for calculating an insulin dose or carbohydrate intake based on user entered data.

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

For an insulin dose based on fixed/variable meal sizes, a healthcare professional must provide patient-specific fixed doses/meal sizes to be programmed into the software prior to use.
Contraindications
The InPen System is not intended for anyone unable or unwilling to:

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

Before Prescribing Verify and/or Review with the Patient:

- Patient cognitive ability
- Patient familiarity with mobile devices
- Importance of range, alerts, and current time
- Importance of logging all Rapid-acting insulin and timing
- Crossing time zones/daylight savings time
- Split doses and doses over 30 Units

Important Pediatric User Information:

The following recommendations are meant to help younger patients and their caregivers manage and care for the InPen system. Younger children may inadvertently play with the pen injector or the app, leading to unintentional logging or delivery of insulin. It is the responsibility of the healthcare provider and the caregiver to determine if the patient is appropriate for treatment with the InPen system.

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

For patients who do not self-manage their disease, the smart device should always be under the supervision of a caregiver. Inadvertent button presses may lead to unintentional dose logging or changes to therapy settings. These changes can potentially lead to hypoglycemic or hyperglycemic events which could result in serious injury or death.
InPen Prescription/Start Orders

InPen is dispensed through most retail pharmacy chains and is also available for order through Cardinal, McKesson, and AmerisourceBergen. InPen comes in three colors, please see the chart for appropriate order numbers. The prescriber should also include a prescription for insulin cartridges and needles.

InPen can also be prescribed using the Start Order Form through our Online Retail Pharmacy Partners by downloading and faxing the Start Order Form:


The patient may enter their settings into the InPen App at home once they pair an InPen.

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| Humalog® U100 Cartridges (NDC 00002751659) |

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| NovoLog® U100 PenFills® (NDC 00169330312) | Fiasp® U100 PenFills® (NDC 00169320515) |

General Notes

Note: Refer to the InPen System User Guide for instructions on how to pair the InPen to the mobile device.

If the InPen is out of range of the mobile device the dose calculator may not have all recent doses logged which could result in unsafe recommendations, 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 mobile device
- Make sure to turn on Bluetooth®
- Turn off the Do Not Disturb feature on the mobile device (if available)
- After the mobile device is restarted, make sure the InPen App is running. (Start the app by touching the InPen App icon)
- Set the volume on the mobile device at a level the patient can hear
- Do not close the app. Keep it running in the background when you move on to other apps.
- Unplug headphones when not in use; Alarms and Alerts from the app cannot be heard through the mobile device if headphones are plugged in

It is recommended to allow the mobile device to 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 mobile device.
Definitions

**Active Insulin**

Active Insulin 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. Users can select whether or not they want Active Insulin to display on the home screen.

**Carb Counting**

Dose recommendations are based on the exact amount of carbohydrates within each meal. Doses are calculated using an insulin-to-carbohydrate ratio.

**Current Glucose**

These are displays of the recent glucose entered into the dose calculator or measured with a connected BGM. If the value is older than 10 minutes, no value will display here.

**Duration of Insulin Action**

This is the amount of time that insulin is actively lowering blood glucose. It is used to calculate Active Insulin.

**Fixed Dose**

Dose recommendations are based on a fixed amount of insulin to take at each meal and snack (i.e., breakfast, lunch, dinner, and snacks). The dose may vary for each meal.

**Insulin Sensitivity Factor**

This is the amount blood glucose is lowered by 1 unit of insulin.

**Insulin-to-Carbohydrate Ratio**

This is the number of grams of carbohydrate covered by 1 unit of insulin.

Get to know the InPen

Injection Button
Dose Knob
Dose Window
InPen Body
Screw
Insulin Cartridge (Not Included)
Cartridge Holder
Insulin Needle Compatible with Single-Use Detachable and Disposable Needles (Not Included)
InPen Cap

InPen has a one-year warranty and does not require charging.
Low Blood Glucose

Hypoglycemia, also called low blood glucose or low blood sugar, occurs when the level of glucose in your blood drops below normal.

Maximum Calculated Dose

This is the largest dose a patient should normally take. When using the dose calculator, the calculator never recommends a dose that is greater than this setting. Further, if the total of dose recommendation plus the doses taken in the last two hours exceeds this, a warning will be displayed.

Meal Estimation

Dose recommendations are based on an estimate of the size of each meal, relative to carbohydrates (i.e., low, medium, high carb meals). The dose can vary based on time of meal and size of meal.

Meal Therapy Mode

Meal therapy modes describe the method for determining how much insulin to take with meals. The InPen system offers three different meal therapy modes designed to meet their diabetes management needs: Fixed Dose, Meal Estimation, and Carb Counting. These therapy settings increase in precision as the individual progresses from Fixed Dose through to Carb Counting.

Target Blood Glucose

This is the blood glucose value the patient is 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.

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.

Time of Day Settings

Found in Insulin Therapy Settings, by default, this is disabled and Target Blood Glucose, Correction Factor and when applicable, insulin-to-carbohydrate ratio are constant throughout the day.
Dose Calculator Meal Therapy Modes

The InPen system has three different Meal Therapy modes – Fixed Dosing, Meal Estimation, and Carb Counting. These therapy settings increase in precision as the mode progresses from Fixed Dose to Meal Estimation to Carb Counting.

In **Fixed Dose mode**, the patient is instructed to take a fixed amount of insulin at each meal or snack. The dose sizes may be different for each meal.

In **Meal Estimation mode**, the patient is instructed to choose the relative size of the meal or snack they are eating (by amount of carbohydrates) based on usual intake and take a corresponding amount of insulin. The dose sizes and meal sizes may be different for each meal.

In **Carb Counting mode**, the patient is instructed to enter the amount of carbohydrates to be consumed at each meal or snack and take a corresponding amount of insulin.

In all three modes, the InPen system will account for Active Insulin to reduce the size of the dose recommendation when needed. Because the InPen system accounts for Active Insulin, using the dose calculator to obtain dose recommendations between meals (correction doses) can be done safely and help prevent insulin stacking.

*Note: A new prescription is required to unlock a more precise Meal Therapy mode for your patient. New Meal Therapy settings should be provided to the patient each time the Meal Therapy mode is changed.*
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.¹

The dose calculator utilizes the current blood glucose (BG), carbohydrates or meal type and/or size, active insulin, insulin-to-carbohydrate ratio (ICR), insulin sensitivity factor (ISF), and target blood glucose (target BG) to calculate the recommended dose.

For an insulin dose based on amount of carbohydrates, the equation is as follows:

\[
\text{Dose Recommendation} = \frac{\text{Carbs}}{\text{ICR}} + \frac{BG - \text{Target BG}}{\text{ISF}} - \text{Active Insulin}
\]

For an insulin dose based on fixed/variable meal sizes, the equation is as follows:

\[
\text{Dose Recommendation} = \text{Meal Dose} + \frac{BG - \text{Target BG}}{\text{ISF}} - \text{Active Insulin}
\]

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

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

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

\[
\text{Dose Recommendation} = \frac{\text{Carbs}}{\text{ICR}}
\]

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

Home Screen

Dose Calculator
Current glucose measurement

Current Active Insulin (if enabled)

Notification icons:

Daily Timeline
Time and size of last entry

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

Calculate Dose

118 mg/dL
Current Glucose
4.0 u
Active Insulin

6 AM 10 AM 2 PM NOW

4 u
Rapid-acting
0 min ago

118
Glucose
1 min ago

20 g
Carbs
1 min ago

5.5 u
Rapid-acting
12:10 PM

125
Glucose
12:10 PM

HOME LOGBOOK REPORTS SETTINGS
Basic Setup

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

   *Note: Insulin Therapy Settings must be accurate and correct. If you are unfamiliar with insulin dosing or how to determine Therapy Settings, then do not prescribe the InPen System. (Refer to the SIP Settings Resource Guide)*

2. Download and install the InPen App from the mobile device app store.

3. Launch the app by tapping the InPen icon.

4. Complete the Setup Wizard to choose the meal therapy mode - Carb Counting, Meal Estimation, or Fixed Dose and complete the dose calculator set up, Long-acting, and Meal Times therapy settings.

   *Note: Once the therapy mode is selected it cannot be advanced (e.g. meal estimation to carbohydrate counting) without a new prescription.*

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

   *Note: Patients should be counseled that meal sizes for both fixed dose and meal estimation modes should reflect only the amount of carbohydrate in the meal.*

6. Finish the Setup Wizard to return to the Home screen.

7. Setup is complete.
Calculate a Dose

Using the Dose Calculator with Glucose Data

1. Launch the app by tapping the InPen icon.
2. Open the dose calculator by tapping the icon.
3. Enter the current glucose into the dose calculator.

*Note: If a connected BGM is used and shared through Apple Health, blood glucose will be pre-populated.*

4. Enter the number of grams of carbohydrates to be eaten or select the meal type and/or size. 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 last dose and current Active Insulin (if setting is enabled to display for the user)

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.
Using the Dose Calculator without 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 or select the meal type and/or size. The dose recommendation is displayed.
4. Tap Save to return to the Home Screen.
5. Use the InPen to prime and then dial and dispense the recommended dose.
6. The Home Screen is updated with time since last dose and Active Insulin (if setting is enabled to display for the user).

Using the Dose Calculator without Eating

1. Launch the App by tapping the icon.
2. Open the dose calculator by tapping the icon.
3. Enter in current glucose value.
4. Do not enter carbohydrates or select “Not Eating” along with meal type.
5. Tap Save to return to the Home Screen.
6. Use the InPen to prime and then dial and dispense the recommended dose.
7. The Home Screen is updated with the last dose Active Insulin (if setting is enabled to display for the user).
Logging doses without using the Dose Calculator

*Note: If a Rapid-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.

*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 Active Insulin.

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, a message will be displayed. The calculator caps the recommendation at the specified value and the calculator warns the user if the sum of the recommendation and the Rapid-acting doses in the last two hours exceeds this value. The patient should refer to the instructions given by their healthcare provider.

Prime

InPen automatically determines if a dose was a Prime or a Therapeutic dose. The user can 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.
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 user forgets how much insulin was recommended, they may use the dose calculator again to calculate the remaining dose required.

*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, Insulin Sensitivity Factor and Insulin-to-Carbohydrate Ratio (when applicable) may be customized for each time setting. Each time setting ends when the next one begins.

1. Launch the app and open Therapy 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.
Dose Reminders

Meal Time Settings

Meal Time windows are programmed to identify the time range that the patient typically eats each meal; breakfast, lunch, dinner.

*Note: Meal times are used with Missed Dose Reminders and Insights by InPen. Adjust and optimize Meal Times as needed to match patient needs.*

1. Launch the app and open Therapy Settings
2. Open Meal Times
3. Set start and end time for each meal window.
4. Tap Back to return to the Settings screen.

*Note: Time periods cannot overlap.*

Missed Dose Reminders

Up to three Rapid-acting dose reminders may be programmed for a 24 hour period. If no dose has been logged by the end of the Meal Time window then the app will notify the patient.

1. Launch the app and open Settings.
2. Open Reminders
3. To enable a reminder, slide the corresponding switch.
4. Tap Back to return to the Settings screen.

*Note: To edit the start and end time of each Meal Time window, see Meal Time 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 then the app will notify the patient at the set reminder time.

1. Launch the app and open Settings.
2. Open Reminders.
3. To enable a reminder, slide the corresponding switch.
4. To disable reminders, slide the switch to the left.
5. Tap Save to return to the Reminders screen.

**Active Insulin Display**

When enabled, Active Insulin will display on the Home Screen.

To adjust the Active Insulin display setting:

1. Launch the app and open Therapy Settings.
2. Find Active Insulin Display.
3. Tap to turn the display ON or OFF.

*Note: Disabling Active Insulin only removes it from the Home Screen Display and will not affect the way Active insulin is calculated.*
**Insights by InPen Reports**

**IMPORTANT:** The Insights by InPen report should be used by healthcare professionals familiar with the management of diabetes. The following 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.

*Note: Reports will indicate when a new prescription is needed for InPen devices with a remaining life of less than 100 days.*
Ellen Richards
DOB: 05/27/1942
Target BG 127 mg/dL
ICR 7 g/U
ISF 60 mg/dL/U
Max Dose: 9 U
Duration of Insulin Action: 4h

Days Included in Assessment
13 of last 14 days
Average Daily Dose Taken 12 U
Bedtime to Fasting (Change)

Lisa R.
DOB: 08/23/1963

Notes:

Sat, Jan 11
Ellen Richards

Notes:

Fri, Jan 10

Notes:

Thu, Jan 09

Notes:

Wed, Jan 08

Notes:

Tue, Jan 07

Notes:

Mon, Jan 06

Notes:

Sun, Jan 05

Notes:

Report generated on 3/9/20 11:58 AM P/N SSC-00412 version 1.3.0

Guide to Using the Insights by InPen Integrated Data Report

1. Glucose Data
2. Modal Day Glucose Graph
3. Missed Doses
4. Insulin Data
5. Long-Acting Assessment
6. Dosing Behavior
7. Meal Assessment
8. Daily Charts
9. Settings

- glucose value
- carbohydrates
- active insulin
- calculator override
✓-dosed as advised (+/- 0.5U)
- long-acting dose

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Guide to Using the Insights by InPen Integrated Data Report

1. Glucose Data
   Observe average glucose, standard deviation; percent time in range, time below range, and time above range. The goal for most PWD is > 70% of time or readings within target range (70-180 mg/dL); < 4% below 70 mg/dL; < 1% below 54 mg/dL; < 25% above 180 mg/dL; less than 5% above 250 mg/dL.

2. Modal Day Glucose Graph
   Check to detect any patterns of hypo/hyperglycemia or variability at certain times of day. The first priority is to resolve any patterns of hypoglycemia.

3. Missed Doses
   Detect if any particular meal time insulin dose or basal insulin dose is regularly missed. Ask the PWD if these doses are forgotten, intentionally omitted, or not taken because meals are skipped.
   - As a first priority resolve any barriers the PWD has to taking insulin doses.
   - Adjust meal time settings and reminders in the InPen app as needed.

4. Insulin Data
   Observe Total Daily Dose (TDD) and distribution between basal and bolus doses. The optimal basal/bolus ratio is a 50/50 split though this may differ based on carbohydrate intake, other medications, fitness level, and degree of insulin resistance.
   - Check to see that the PWD has their basal insulin reminder set in the InPen app and that they consistently record their basal doses.
   - Observe average number of boluses per day. Consider how this corresponds with the PWD’s reported usual routine.

5. Long-Acting Assessment
   Assess the need to optimize the basal insulin dose. The goal is to maintain glycemic stability in the fasting state with no more than 30mg/dL change.

6. Dosing Behavior
   Determine if PWD is using the dose calculator at meals and for corrections. If so, are they following the dosing recommendations? If not, explore the root cause(s) of why not e.g. lack of confidence in their therapy settings or fear of hypo/hyperglycemia.

7. Meal Assessment
   Based on glycemic response to meal doses, assess adequacy of meal doses or insulin settings (Insulin to Carbohydrate Ratio [ICR] or meal-size doses recommended).

8. Daily Charts
   Review the daily charts and consider the following:
   - Is glucose checked before each dose?
   - Is the meal size or grams of carbohydrate consumed recorded with meal doses? Does the PWD need more carbohydrate counting education? Would they benefit from access to a food database or help estimating meal sizes?
   - How many meals does the PWD eat per day? Any missed meals? Explore why.
   - Does timing of insulin dose relative to the meal need adjusting?
   - Evaluate glycemic response when the dose calculator was used versus dosing more or less than recommended. If dosing recommendations are not followed explore why.
   - How often are correction doses taken? Detect missed correction opportunities.
   - Is the PWD stacking bolus doses?

9. Therapy Settings
   Based on observations and discussions with the PWD, determine if therapy settings or meal times need adjusting for any time of day or particular meal.

On an ongoing basis, remember to consider the following basics of insulin therapy:
   - If the PWD is missing doses, identify and address barriers to taking insulin first prior to making adjustments in the insulin regimen.
   - Assure quality of insulin (storage, shipping), proper site rotation (examine for lipohypertrophy), injection technique, timing of dose(s).
   - Always address hypoglycemia first.
   - Titrate (optimize) the basal dose first to create a strong foundation for fine-tuning other insulin therapy settings to optimize the meal time insulin regimen.
   - Fine-tune the ICR. Having the ICR correct as well as accurate carbohydrate counting (or meal estimation) helps decrease the need for correction doses.
   - Fine-tune the Insulin Sensitivity Factor (ISF) along with Duration of Insulin Action (DIA).

References:
Insights - Patient Stats

Glucose Overview
Use this chart to understand:

- Average and standard deviation of glucose over the report period
- Percentage of glucose values in and out of the target glucose range:
  - Very Low (< 54 mg/dL)
  - Low (54 – 69mg/dL)
  - Target (70 – 180mg/dL)
  - High (181 – 250mg/dL)
  - Very High (> 250 mg/dL)

Dose Calculator Usage
Use this chart to understand:

- Percentage of doses in which the dose calculator was used within 10 min prior to the dose
- Percentage of doses taken within ± 0.5 U of the advised dose (as advised).
- Percentage of doses taken 1 U over or under the advised dose

Missed Doses
Use this chart to understand:

- 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.

If a Rapid-acting dose is not logged within the time range configured in Meal Times Settings, then it is considered a missed dose. If dose reminders are not enabled missed doses will still be reported.

If a Long-acting dose is not logged within three hours before or after the long acting reminder time then it is considered a missed dose. Missed Long-acting doses are calculated only when the Long-acting reminder is enabled.

Insulin Overview
Use this chart to understand:

- Average total daily Long-acting and Rapid-acting insulin doses (TDD) over the report period for days with at least one insulin dose
- Units and percentages of Long-acting and Rapid-acting insulin within TDD
General

- Available glucose data is aggregated over each hour or 60-minute period.
- A fixed target range of 70-180 mg/dL is shaded grey with glucose data overlaying.
- The black dotted line is the median value for the period.
- The dark purple shows the interquartile range (middle 50%).
- The light purple shows the range of values from the 10th percentile to the 90th percentile.

Modal Day Glucose

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

CGM data will appear like this:
This chart may help identify:

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

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.
**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.

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<td></td>
</tr>
<tr>
<td>12 AM</td>
<td>120</td>
<td></td>
</tr>
</tbody>
</table>

**Long-acting Assessment**

The fasting window is determined based on a 6-hour period of time with the fewest Rapid-acting doses. Glucose values entered into the dose calculator or imported from a connected BGM or CGM during the fasting window are shown. Days with Rapid-acting doses during the fasting window or in the 2 hours prior to the start of the fasting window are excluded.

This assessment may help identify:

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

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A) Understanding the Glucose Visualizations:

- Chart heights are fixed to show glucose from 0 to 400 mg/dL.
- A fixed target range of 70-180 mg/dL is shaded grey with glucose data overlaying.
- The black dotted line is the median value for the period.
- The median bedtime glucose of days included is displayed along the left axis.
- The median fasting glucose of days included is displayed along the right axis.
- The configured Long-acting dose amount and time is displayed in the top left corner.

CGM Visualization

- Available glucose data is aggregated over 30-minute periods.
- The dark purple shows the interquartile range (middle 50%).
- The light purple shows the range of values from the 10th percentile to the 90th percentile.

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

• BGM values taken on the same day, are the same color and are connected with lines to show the relationship between each point.

• Glucose values recorded between the bedtime and fasting window are plotted as hollow points.

• BGM Visualization only reports Median of days with Bedtime and Fasting pairs along the axis.

Long-acting 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.*

B) Understanding the Long-acting Statistics:

• Number of days with glucose data that matches the Long-acting assessment inclusion criteria.

• Average daily Long-acting dose recorded.

• Median of all fasting glucose values plotted.

• Number of days in the fasting window with glucose values < 70 mg/dL.

• Number of days with bedtime and fasting glucose values available.

• The median bedtime glucose minus the median fasting glucose for days when both a bedtime and fasting glucose is available. Used to help identify a rise or fall in glucose values during a true fasting period.

<table>
<thead>
<tr>
<th>Days Included in Assessment</th>
<th>13 of last 14 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Daily Dose Taken</td>
<td>30 U</td>
</tr>
<tr>
<td>Median of All Fasting Glucose</td>
<td>119 mg/dL</td>
</tr>
<tr>
<td># Days with Glucose &lt; 70 mg/dL</td>
<td>3 ▼</td>
</tr>
<tr>
<td>Days with Bedtime and Fasting Glucose</td>
<td>6 of last 14 days</td>
</tr>
<tr>
<td>Median Bedtime to Fasting (Change)</td>
<td>155 to 101 (-54 mg/dL) ▼</td>
</tr>
</tbody>
</table>

*Note: Days with overnight boluses are excluded.*
**Meal Assessment**

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

This assessment may help identify:

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

**Understanding the Meal Assessment Visualizations**

- Chart heights are fixed to show glucose from 0 to 400 mg/dL.
- A fixed target range of 70-180 mg/dL is shaded grey with glucose data overlaying.
- The black dotted line is the median value for the period.
- The median glucose at the start of the meal is displayed along the left axis.
- The median glucose at the end of the meal window is displayed along the right axis.
- The configured dose amount (for Fixed Meal and Meal Estimation modes only) are displayed in the top left corner.

**CGM Visualization**

- Available glucose data is aggregated over 30-minute periods.
- The dark purple shows the interquartile range (middle 50%).
- The light purple shows the range of values from the 10th percentile to the 90th percentile.

Meal Assessments with CGM data will appear like this:
**BGM Visualization**

- Glucose values taken on the same day, are the same color and are connected with lines to show the relationship between each point.
- Glucose values recorded between the start of the meal and end of the meal window are plotted as hollow points.

*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 Assessments with BGM data will appear like this:

![Meal Assessments](image)

Use these charts to visualize glycemic variability that occurs with each meal type and assess appropriateness of configured insulin therapy settings and behavior.
Glucose from CGM or BGM is shown in purple or with meal/type size shown in green. Rapid-acting insulin doses are shown as blue filled curves and Long-acting insulin doses are shown as blue circles.

Daily charts may help identify:
- Effects of individual dosing decisions
- Causes of individual episodes of hypoglycemia or hyperglycemia

Daily charts may help verify:
- Insulin action time
- Insulin sensitivity factor
- Meal Therapy Settings
How to fax, email, or print Insights by InPen report

In app instructions on how to send the Insight Reports.

**STEP 1: Generating a report**

A. From the home screen; click on ‘Reports’ at the bottom.

B. Select ‘settings’ icon in upper left corner.

C. Select your date range and ‘save’ in upper right.
STEP 2: Sharing a report

A. Click on the ‘send’ icon on the top right of the screen. Select how you would like to send report.

B. Enter information (fax number, email address or select printer) and send.
Apple Health Compatibility

Devices Compatible with Apple Health:
See website for a list of compatible devices.

Cartridge/Pen Fill Compatibility
InPen is compatible with Lilly Humalog®, Novo Nordisk Novolog®, and Novo Nordisk Fiasp® U-100 3.0 mL pre-filled cartridge/PenFills® and single-use detachable and disposable needles (not included).
Frequently Asked Questions

**How does InPen work?**

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

The InPen dose calculator, a component of the InPen app, is indicated for the management of diabetes by people with diabetes under the supervision of an adult caregiver, or by a patient age 7 and older for calculating an insulin dose or carbohydrate intake based on user entered data.

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

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

InPen has a one-year warranty and does not require charging.

**Does InPen integrate with Glucose Monitoring Systems?**

Yes, the InPen App for iOS integrates with CGM through Apple Health. InPen App for Android integrates with Dexcom CGM automatically.

**Can my patients share their InPen app data with me?**

Yes, patients simply print, fax, or email the Insights Report directly from the app to your office.
Is InPen covered by insurance?

Yes, InPen is covered as a pharmacy benefit under most insurance plans. A special co-pay assistance program is available, please inquire for more details.*

To prescribe, submit the prescription request through EMR (search InPen NN for Novolog or Fiasp and InPen EL for Humalog) or fax the Start Order Form to 877-444-2373. Start order forms are available online at www.companionmedical.com.

Can I pair more than one InPen to the app?

Yes, the InPen App can be paired with multiple InPens.

What if I have more questions?

Call our toll-free line at 844.843.7903
Email us at: support@companionmedical.com
Visit us at: www.companionmedical.com
Why InPen?

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

Notes / Questions: