



Tempo Insights™ Frequently Asked Questions

What is TempoSmart™ intended to do?

INTENDED USE

TempoSmart™ is a Software as a Medical Device (SaMD) intended to be used by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. TempoSmart is intended to assist patients in managing their diabetes with guidance from their providers.

INDICATION FOR USE

TempoSmart™ is indicated for use by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. TempoSmart is intended to provide secure capture, storage, and transmission of glucose data as well as information to aid in diabetes self-management. TempoSmart automatically receives insulin doserelated data when connected to a compatible Tempo Smart Button™ device via wireless Bluetooth® technology and has the ability to detect and mark which doses are prime and which are injected insulin. TempoSmart analyzes and reports glucose test results and supports medication adherence. In addition, TempoSmart provides coaching messages (motivational, behavioral, and educational) based on real-time glucose values and trends. It includes software intended for patient use on mobile phones and software intended for healthcare provider use through computer web browsers. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The following TempoSmart features require a prescription:

For bolus insulin users with type 1 and type 2 diabetes, TempoSmart includes an insulin dose calculator to allow patients to use their prescribed regimen to calculate a dose of bolus insulin for a given amount of carbohydrates and/or glucose value from a blood glucose meter (BGM).

When connected to a compatible FDA-cleared integrated continuous glucose monitor (iCGM) and if an insulin-to-carb ratio plus correction factor insulin regimen is prescribed, TempoSmart includes a CGM insulin dose calculator.

The TempoSmart CGM insulin dose calculator is software intended for the management of type 1 or type 2 diabetes in persons aged 18 years and older requiring fast-acting insulin. The TempoSmart CGM insulin dose calculator allows patients to calculate a dose of bolus insulin for a given amount of carbohydrates, the most recent CGM glucose reading and rate of change, activity, and insulin on board (IOB).

For basal insulin users with type 2 diabetes, TempoSmart includes a basal titration feature which calculates appropriate long-acting basal insulin doses for titrating insulin levels



based on configuration by a healthcare provider. The healthcare provider must activate the basal titration feature and configure it for patient-specific parameters.

TempoSmart is not intended to replace the care provided by a licensed healthcare provider, including prescriptions, diagnosis, or treatment.

Tempo Insights™ is the healthcare provider-facing component of TempoSmart. Neither Tempo Insights nor TempoSmart is intended to replace the research, expertise, judgment, or treatment provided to patients by healthcare providers.

What functions are available from Tempo Insights?

Tempo Insights, a web-based management portal, is the health care provider-facing component of the TempoSmart™ app. The primary functions of Tempo Insights include the following:

- Invite patients to use TempoSmart
- Access SMART Visit Report®
- Review patient Logbook data, Medication List, and Health Information
- Activate, Edit or Deactivate the Insulin Calculator (Prescription only)
- Initiate, Edit, Monitor the progress, or Deactivate the Basal Insulin Adjustment Program (IAP) (Prescription only)
- Monitor patient population for engagement and outcomes

For full instructions on the use of Tempo Insights, view the User Guides in the **Help Center**.

How is Tempo Smart Data shared to the Lilly Data Analytics Team?

The Tempo Smart Data which is stored in the Azure SQL Database is ingested into the Databricks platform. The data is then shared with the Lilly Data Analytics team via the Delta Sharing protocol. To ensure all transactional updates are captured in Databricks, CDC is enabled in the source database.

What patient data can I view?


- Glucose, medications, food, activity, sleep, and Notes data
- Glucose and insulin summary graphs
- Use of connected Tempo Smart Button™ and/or connected blood glucose meter or Continuous Glucose Monitoring (CGM)



- Tempo Smart Button battery status
- Basal insulin dose adjustment history (if in an IAP)
- Use of Insulin Calculator (if authorized) and patient notifications related to Insulin Calculator

What is the SMART Visit Report® and how can I access it?

The SMART Visit Report provides a summary of patient data, clinical decision support, logbook, and/or food diary. It can be accessed from Tempo Insights™, or it can be sent by your patients from the TempoSmart™ app.

From Tempo Insights, click the **SMART Visit Report**  icon from the patient list or within the patient's record. The SMART Visit Report will open in a new window.

IMPORTANT: The SMART Visit Report is intended to supplement, not replace, medical expertise, research, judgment, or diabetes treatment provided by the health care providers. The report provides information that can be used by health care providers to identify trends to help inform treatment decisions. Decisions regarding diagnosis or treatment of patients will be made solely by the health care providers.

How do I invite my patient to use TempoSmart (non-Insulin Adjustment Program only)?

From the Patient List screen, select **Add Patient**. Then enter the required patient data. To complete the invitation, select **Add**. The patient will receive an email (and SMS text, if a mobile number was provided) invitation to download TempoSmart and register.

Until the patient registers, you will see them in the **Pending Registration** tab. If you need to edit their information, click on the **Edit** icon next to the patient's name and then save your changes. Once registered, the patient will appear in the **Patient List** tab.

What is an Insulin Adjustment Program (IAP) for basal insulin?

The Insulin Adjustment Program for basal insulin is for prescription use only. The basal program titrates basal insulin doses based on configuration by a prescribing health care provider within the Tempo Insights management portal. The program is only available for patients with type 2 diabetes who use basal insulin and do not take bolus insulin.

Please refer to the Tempo Insights Insulin Management Features User Guide (Prescription only) in the **Help Center** for detailed information about the Insulin Adjustment Program.

How do I initiate an Insulin Adjustment Program for basal insulin?



Only prescribing health care providers may initiate an insulin adjustment program for a new or existing patient.

1. From the Home screen, complete the following steps:
 - For New Patients: Select **Add Patient**. Then enter the required patient data and indicate that the patient will be undergoing an Insulin Adjustment Program for Basal Insulin. Click **Add** to continue with setting up the Insulin Adjustment Program.
 - For Existing Patients: Find and open the patient's record. Click the **Insulin Programs** tab. Select **Set Up Insulin Adjustment Program**.

***Note:** If the patient is still under **Pending Registration**, you may edit their insulin program and the patient will get an email update when the changes are saved.*

2. Follow the onscreen prompts to set up the titration parameters. When setup is complete, your patient will receive an email.
 - If they are not using TempoSmart™ app already, they will download TempoSmart and complete registration.
 - If they are using TempoSmart already, they must enter an access code and pair a Smart Button to start the program.
3. Until your patient registers, you will see them in the **Pending Registration** tab. Once registered, the patient will appear in the **Patient List** tab.

How do I monitor my patient's Insulin Adjustment Program for basal insulin?

Open the patient's record and select the **Insulin Adjustment Program** tab. From there, view the patient's basal insulin dose and fasting blood glucose history.

If the patient's insulin or blood glucose data triggers a safety notification, health care providers will see a notification by the patient's name in the **Action Item** tab. Open the patient's record for more information.

How can I filter the patient list?

Within Tempo Insights, the patient list can be filtered to monitor for engagement and/or outcomes. This may allow for identification of patients who may need outreach from the health care team.

From the Patient List screen, select **Filters** and then select the applicable filters. Tap **Search**. The resulting list will display patients who meet the filter criteria.



How do I discontinue my patient's Insulin Adjustment Program?

At any time, health care providers can discontinue the titration. Patients can continue to use TempoSmart to track blood glucose and insulin doses, but insulin dose recommendations and adjustments will be discontinued.

Complete the steps on the next page:

4. From the **Patient List**, click the individual patient's row to bring up the **Overview** screen.
5. Click on the **Insulin Adjustment Program** tab and then click on **Discontinue Titration**.

Miscellaneous information?

This project delivery was initially started and lead by Smita, Taken over by Chaitanya. Deepa joined the team for delivery. Santosh and Jayashree recently upgraded the Tempo SDK for iOS and Android respectively. This was called as BlueStar 8.0. This was the first project in Welldoc that went with maximum modules with PaaS.

What is the Insulin Calculator for bolus insulin?

The Insulin Calculator for bolus insulin is for prescription use only. The Insulin Calculator helps determine bolus insulin doses based on the prescribed regimen. Authorization by a prescribing health care provider is required via the Tempo Insights™ portal.

Who is eligible for the Insulin Calculator for bolus insulin?

To be eligible for the Insulin Calculator (Prescription only), patients must use a qualifying bolus insulin and insulin dosing regimen. Please refer to the Tempo Insights Insulin Management Features User Guide (Prescription only) under **Help Center** for detailed information about the Insulin Calculator.

How do I authorize the Insulin Calculator for bolus insulin?

If you would like to prescribe the Insulin Calculator (Prescription only) for your patient, you can do so from the Tempo Insights portal.

1. From the Home screen, complete the following steps:



- For New Patients: Select **Add Patient**. Then enter the required patient data and indicate that the patient will be undergoing an Insulin Calculator for Bolus Insulin program. Click **Add** to continue with setting up the Insulin Calculator.
- For Existing Patients: Find and open the patient's record. Click the **Insulin Programs** tab. Select **Set Up Insulin Calculator**.

***Note:** If the patient is still under **Pending Registration**, you may edit their insulin program and the patient will get an email update when the changes are saved.*

2. Follow the onscreen prompts to set up the Insulin Calculator dosing regimen and duration of insulin action. When setup is complete, your patient will receive an email.
 - If they are not using TempoSmart app already, they will download the TempoSmart and complete registration.
 - If they are using TempoSmart™ already, they must enter an access code and pair a Smart Button to start the program.
3. Until your patient registers, you will see them in the **Pending Registration** tab. Once registered, the patient will appear in the **Patient List** tab.

***Note:** Only prescribing health care providers can authorize the Insulin Calculator. Please refer to the Tempo Insights Insulin Management Features User Guide (Prescription only) in the **Help Center** for detailed information about the Insulin Calculator.*

How do I monitor my patient's Insulin Calculator usage?

Open the patient's record to the **Overview** tab and view the patient's historical notifications of Insulin Calculator cautions and deactivations received by the patient. Additionally, in the pie graphs, you view details of Insulin Calculator use and the breakdown of recorded doses vs recommendations.

If the patient's insulin calculator triggers a safety notification, health care providers will also see a notification in the **Insulin Calculator** tab.

Where can I find the User Guides?

To locate the Tempo Insights™ User Guide or the Tempo Insights Insulin Management Features User Guide (Prescription only), select **Help Center** on the home screen.

How are Tempo Insights user roles defined?



There are four types of user roles in Tempo Insights: prescribing health care provider, non-prescribing health care professional, Coach and case manager.

When a new patient is added, all users associated with the clinic or account can view the patient's record.

To view your assigned role, click on the top right of the home screen and select **Settings** from the drop-down menu. Here you can view your profile information and assigned role.

What are administrative privileges and who has them?

If clinicians have administrative privileges enabled, they would be able to manage the users and edit clinic through the **User Management** screen.

How can I add other Tempo Insights™ users to my clinic or account?

Please work with your account representative to add new users. To add a new prescribing health care provider user, the health care provider's NPI number is required.

If you have administrative privileges enabled, you will be able to add users at your clinic through the **User Management** feature. Also, select clinics may allow clinicians to create their own user account and associate themselves to their clinic(s).

How do I view my patients from another clinic?

Click on **Clinics** next to your name/profile icon and select the clinic you would like to view on the Patient list screen.

What is an Access Code used for?

On invitation, each patient will get an Access Code that they can enter within TempoSmart™ and start sharing their data with their clinic.

I forgot my password. How can I reset it?

From the Tempo Insights home screen, select **Forgot Password**. Choose how you want to get your temporary password:

- Email
 - a. Enter your email address.
 - b. Check your email for more information about resetting your password.



- c. Follow the instructions in the password reset email to reset password.
- Text message (only available if your mobile phone number has been entered in Tempo Insights for purposes of authenticating your account)
 - a. Check your mobile device for your temporary password.

I forgot my username. How can I reset it?

From the Tempo Insights home screen, select **Forgot Username**. Choose how you want to get your username:

- Email
- Text message (only available if your mobile phone number has been entered in Tempo Insights for purposes of authenticating your account)
 - a. Check your mobile device for your temporary password.

Which browsers are compatible with Tempo Insights™?

To ensure security, it is recommended that desktop users keep their browser up-to-date and have anti-virus installed. Supported browser versions include:

The default/preferred browser that will be supported for Tempo is Google Chrome™, Mozilla Firefox®, Microsoft Edge® and Safari.

Devices that do not meet the above criteria are not compatible with Tempo Insights.

How do I know when Tempo Insights has been updated?

You can find the latest information about Tempo Insights by looking at the software version number in the Help Center.

How do I revoke Insulin Calculator authorization?

The Insulin Calculator (Prescription only) authorization is valid for 365 days after authorization. To remove access sooner, complete the steps below:

1. From the **Patient List**, click the individual patient's row to bring up the **Overview** screen.
2. Click on the **Insulin Calculator** tab and then click on **Deactivate Calculator**.

Alternatively, you can contact Lilly Tempo Support at 1-846-LillyTempo (1-846-5455983), Monday – Saturday, 7am – 7pm Eastern and Sundays 8am – 5pm Eastern.

