



## Frequently Asked Questions

### 1. What is the Welldoc® App intended to do?

Welldoc is an application offering customized programs for individuals, age 18 or older, based on the selection(s) of one or more health condition(s): prediabetes, diabetes, heart failure, high blood pressure, and/or sleep apnea. Additional programs, such as mental well-being and/or weight management, may also be available for use.

The Welldoc App also offers programs for users with diabetes in pregnancy and who use an insulin pump. Patients who are pregnant or using an insulin pump cannot be enrolled in the Insulin Adjustment Program or use the Insulin Calculator. Please see the Welldoc Management Portal User Guide for more information.

Below is the Intended Use and Indications for Use for Welldoc Diabetes and Welldoc Diabetes Rx:

#### Intended use

The Welldoc® App includes Welldoc Diabetes and Welldoc Diabetes Rx, which is 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. Welldoc Diabetes and Welldoc Diabetes Rx are intended to assist patients in managing their diabetes with guidance from their providers. Welldoc Diabetes Rx requires a prescription.

#### Indication for use

The Welldoc® App combines the FDA cleared medical device functionality of Welldoc Diabetes and Welldoc Diabetes Rx with other non-FDA cleared wellness and educational/self-management products.

Welldoc Diabetes is indicated for use by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. Welldoc Diabetes is intended to provide secure capture, storage, and transmission of glucose data as well as information to aid in diabetes self-management. Welldoc Diabetes analyzes and reports glucose test results and supports medication adherence. In addition, Welldoc Diabetes provides coaching messages (motivational, behavioral, and educational) based on real-time glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

Welldoc Diabetes Rx adds the following prescription use only insulin management features:

- For bolus insulin users with type 1 or type 2 diabetes, Welldoc Diabetes Rx 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.

- For basal insulin users with type 2 diabetes, Welldoc Diabetes Rx includes an Insulin Adjustment Program (IAP) 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 IAP and configure it with patient-specific parameters.

Welldoc Diabetes and Welldoc Diabetes Rx are not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

*\*Insulin Dose Calculator may also be referred to as Insulin Calculator*

Below is the Intended Use/Indications for Use for Welldoc for Diabetes in Pregnancy and Insulin Pump Users:

The Welldoc<sup>®</sup> App for Diabetes in Pregnancy and Insulin Pump Users (the software) is Software as a Medical Device (SaMD) intended to be used by patients – aged 18 years and older – who have type 1, type 2 diabetes, or gestational diabetes - who are also pregnant or use an insulin pump.

The software is intended to help people with diabetes manage their health in their daily environment. The software, running on a mobile phone, collects health data, promotes healthy behavior, and encourages adherence to treatment plans and self-monitoring practices as advised by your healthcare provider. The software also generates electronic reports intended for your healthcare provider.

The software provides secure transfer, storage, and secondary display of data from devices such as continuous glucose monitors (CGM), blood glucose meters, blood pressure monitors, activity trackers, and weight scales as well as self-reported health information. When receiving CGM data, the software also serves as a secondary CGM alarm system, providing alerts to enable your immediate awareness of conditions that may require clinical intervention. The software also performs retrospective analysis of your CGM data which may help you and your healthcare provider when determining therapeutic strategies.

The software provides educational content to encourage behaviors which may help living well with diabetes based on guidance from healthcare professional organizations. This may include promoting healthy lifestyle choices such as getting enough sleep, eating a balanced diet, maintaining a healthy weight, and promoting physical activity.

The software is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment nor is it intended to replace self-monitoring practices as advised by a physician. The software does not provide treatment recommendations.



## 2. What functions are available from the Welldoc Care management portal?

The web-based Welldoc Care management portal is the health care provider-facing component of the Welldoc app. The primary functions of the Welldoc portal include the following:

- Invite patients to use the Welldoc App
- Access Health Report
- Review patient Logbook data, Medication List, and Health Information
- Monitor patient population for engagement and outcomes
- Create and send patient surveys
- Activate, Edit, or Deactivate the Insulin Calculator<sup>1</sup> (Prescription only)
- Initiate, Edit, Monitor the progress, or Discontinue the Basal Insulin Adjustment Program (IAP)<sup>1</sup> (Prescription only)

For full instructions on the use of the Welldoc Care portal, view the User Guides in the **Help** tab.

## 3. What patient data can I view?

- Glucose, medications, food, activity, sleep, and blood pressure data
- Glucose and insulin summary graphs
- Use of insulin calculator (if authorized), and/or connected blood glucose meter or Continuous Glucose Monitoring (CGM)
- Basal insulin dose adjustment history (if in an Insulin Adjustment Program)<sup>1</sup>

## 4. How can I filter the patient list?

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

From the **Patients** screen, choose between searching in **My Patients** or **All Patients** list. Select **Filters** at the top right corner and then select the applicable filters to **Apply Filters**. The resulting list will display patients who meet the filter criteria.

- With **My Patients** selected, the list will be filtered by the user's assigned patients.
- With **All Patients** selected, the list will be filtered by all patients.

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<sup>1</sup> Patients who are pregnant or using an insulin pump cannot be enrolled in the Insulin Adjustment Program or use the Insulin Calculator.



## 5. What is the Health Report and how can I access it?

The Health Report provides a summary of patient data, clinical decision support, logbook, and/or food diary. It can be accessed from the Welldoc management portal or it can be sent by your patients from the Welldoc App.

From the Welldoc management portal, click the **Health Report** icon under Actions column on the patient's row from the **Patients** tab or go to the **Report** tab within the patient's record. Select the type to download and the Health Report will open in a new window.

**IMPORTANT:** The Health 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 to identify trends to help inform health care providers' treatment decisions. Decisions regarding diagnoses or treatment of patients will be made solely by the health care providers.

## 6. From the Action Items screen, I no longer see an Action Item notification for my patient. Where can I check historical events?

Another care team member may have dismissed or addressed the notification(s). Once you find and open the patient's record, go to the **History** tab to view all historical actions.

## 7. As a Supervisor Case Manager, how do I assign or reassign patients to multiple case managers?

You can assign select patients to one or multiple case managers at a time from the **Pending Assignment** tab. Select the patients first then proceed to assign them to a case manager or multiple case managers.

You can reassign the patients to another case manager from the **Reassignments** tab. Select the case manager (Care Team Member) first and then select the patients for assignment.

## 8. For both prescribing and non-prescribing providers, how do I invite my patient to use the Welldoc App (non-Insulin Programs only)?

First, search for the patient from the **Patients** tab. When the patient is not found, select + **Add Patient**. Then enter the required patient data and follow the prompts to complete the invitation.

The patient will receive an email invitation to download the Welldoc App and register. The patient record will indicate "Pending" in gray until they are registered.



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

The IAP for basal insulin is for prescription use only<sup>2</sup>. The basal program titrates basal insulin doses based on configuration by a prescribing health care provider within the Welldoc 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 Welldoc Insulin Management Features User Guide (Prescription only) in the **Help** tab for detailed information about the Insulin Adjustment Program.

## 10. For prescribing providers, how do I initiate an Insulin Adjustment Program for basal insulin?

Only prescribing health care providers may initiate an insulin adjustment program<sup>2</sup> for a new or existing patient.

1. From the Patients tab, 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 (basal). Click **Continue** 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**.
2. Follow the onscreen prompts to set up the titration parameters. When setup is complete, your patient will receive an email invitation to download the Welldoc App and register.
3. The patient record will indicate "IAP Pending" in gray until they are registered.

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

At a glance, you can view the patients' Insulin Adjustment Program<sup>2</sup> status, glucose values, and dosing regimen from the **Patients** tab. Open the patient's record to the **Insulin Adjustment** tab to view the patient's basal insulin dose and fasting blood glucose history.

## 12. From the Action Items screen, why can I not dismiss notifications for titration?

The behavior of the Dismiss button is different for prescribing providers and non-prescribing providers.

From the **Notifications** tab, users are not permitted to dismiss notifications for Titration Suspended<sup>2</sup> and Titration Issue<sup>2</sup>.

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<sup>2</sup> Patients who are pregnant or using an insulin pump cannot be enrolled in the Insulin Adjustment Program or use the Insulin Calculator.



From the patient record:

- Users are not permitted to Dismiss notifications for Titration Suspended. These will be resolved once the issue is resolved.
- Prescribing providers may dismiss notifications for a Titration Issue.
- Non-prescribing providers are not permitted to dismiss notifications for a Titration Issue.

### **13. For prescribing providers, how do I discontinue my patient's Insulin Adjustment Program?**

At any time, health care providers can discontinue the titration<sup>3</sup>. Patients can continue to use the Welldoc App to track blood glucose and insulin doses, but insulin dose recommendations and adjustments will be discontinued.

Complete the following steps:

1. From the **Patients** tab, click the individual patient's row.
2. Click on the **Insulin Adjustment** tab.
3. Click **Discontinue**.

### **14. What is the Insulin Calculator for bolus insulin?**

The Insulin Calculator<sup>3</sup> 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 Welldoc management portal.

### **15. Who is eligible for the Insulin Calculator for bolus insulin?**

To be eligible for the Insulin Calculator<sup>3</sup> (Prescription only), patients must use a qualifying bolus insulin and insulin dosing regimen. Please refer to the Welldoc Insulin Management Features User Guide (Prescription only) under the **Help** tab for detailed information about the Insulin Calculator.

### **16. For prescribing providers, how do I authorize the Insulin Calculator for bolus insulin?**

If you would like to authorize the Insulin Calculator<sup>3</sup> (Prescription only) for your patient, you can do so from the Welldoc management portal.

1. From the **Patients** tab, complete the following steps:

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<sup>3</sup> Patients who are pregnant or using an insulin pump cannot be enrolled in the Insulin Adjustment Program or use the Insulin Calculator.



- 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 **Continue** to set up the Insulin Calculator.
  - For Existing Patients: Find and open the patient's record. Click the **Insulin Programs** tab. Select **Set Up Insulin Calculator**.
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 the Welldoc App already, they will download the Welldoc App and complete registration.
    - If they are using the Welldoc App already, they must complete a tutorial before using the Insulin Calculator.
  3. The patient record will indicate "IC Pending" in gray until they are registered.

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

## 17. For prescribing providers, how do I revoke Insulin Calculator authorization?

The Insulin Calculator<sup>4</sup> (Prescription only) authorization is valid for 365 days after authorization. To remove access sooner, complete the steps below:

1. From the **Patients** tab, click the individual patient's row to open the patient's record.
2. Go to the **Insulin Calculator** tab.
3. Click on **Discontinue Calculator**.

## 18. Where can I find the User Guides?

To locate the Welldoc Management Portal User Guide and the Welldoc Insulin Management Features User Guide<sup>4</sup> (Prescription only), select the **Help** tab.

## 19. How are the Welldoc management portal user roles defined?

There are three types of user roles in the Welldoc management portal: account admin, prescribing health care provider, and non-prescribing health care professional (e.g., case manager, supervisor case manager).

To view your assigned role, look under your profile information at the top right corner of the portal screen.

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<sup>4</sup> Patients who are pregnant or using an insulin pump cannot be enrolled in the Insulin Adjustment Program or use the Insulin Calculator.



## 20. I forgot my password. How can I reset it?

From the Welldoc portal login 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 the Welldoc portal for purposes of authenticating your account)
  - a. Check your mobile device for your temporary password.

## 21. I forgot my username. How can I reset it?

From the Login 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 the Welldoc portal for purposes of authenticating your account)
  - a. Check your mobile device for your temporary password.

## 22. Which browsers are compatible with the Welldoc Management Portal?

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

The default/preferred browsers that will be supported for the management are Google Chrome™, Mozilla Firefox®, Microsoft Edge®, and Internet Explorer.

Devices that do not meet the above criteria are not compatible with the Welldoc portal.

## 23. How do I know when the Welldoc management portal has been updated?

You can find the latest information about the Welldoc portal by looking at the software version number in the **Help** tab.