

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. Please see the Welldoc Management Portal User Guide for more information.

Below is the diabetes description:

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.

- For bolus insulin users with type 2 diabetes, the Welldoc Diabetes Rx IAP calculates appropriate dose adjustments of bolus insulin based on configuration of a healthcare provider. Qualified type 2 diabetes patients are those who are not achieving glycemic targets despite optimization of their basal insulin dose or their current bolus insulin regimen.
- For premixed insulin users with type 2 diabetes, the Welldoc Diabetes Rx IAP calculates appropriate dose adjustments of premixed insulin based on the configuration of a healthcare provider. Qualified type 2 diabetes patients are those who are not achieving glycemic targets and who do not take other types of insulin.

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

2. What functions are available from the Welldoc portal?

The Welldoc portal, a web-based 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
- Initiate Insulin Adjustment Program and monitor progress (Prescription only)
- Monitor patient population for engagement and outcomes
- Create and send patient surveys

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

3. What patient data can I view?

- Blood glucose, medications, food, activity, sleep, and blood pressure data
- Blood glucose and insulin summary graphs
- Use of insulin calculator (if authorized), and/or connected blood glucose meter

^{*}Insulin Dose Calculator may also be referred to as Insulin Calculator



• Basal, Bolus, or Premixed insulin dose adjustment history (if in an Insulin Adjustment Program)

4. How can I filter the patient list?

Within the management portal, 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 to **Apply Filters**. The resulting list will display patients who meet the filter criteria.

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 management portal or it can be sent by your patients from the Welldoc App.

From the management portal, click the **Health Report** icon from the patient list or the icon or tab within the patient's record. 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. How do I invite my patient to use the Welldoc App (non-IAP only)?

From the Patient List screen, select **Add Patient**. Then enter the required patient data and select **Add Patient**. The patient will receive an email invitation to download the Welldoc App and register.

Until the patient registers, you will see them in the **Pending Registration** tab. Once registered, the patient will appear in the **Patient List** tab.

7. What is an Insulin Adjustment Program for basal, bolus, or premixed insulin?

The Insulin Adjustment Program for basal, bolus, or premixed insulin is for prescription use only. 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.

The bolus program titrates bolus 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 are inadequately managed on non-insulin therapies and their current dose of basal insulin.

The premixed program titrates premixed 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 are inadequately managed on noninsulin therapies and their current dose of basal or premixed insulin.

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

8. How do I initiate an Insulin Adjustment Program for basal, bolus, or premixed 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:
 - i. <u>For New Patients:</u> Select **Add Patient**. Then enter the required patient data and indicate that the patient will be undergoing an Insulin Adjustment Program (basal, bolus, or premixed).
 - ii. <u>For Existing Patients:</u> Find and open the patient's record. Click the **Insulin Adjustment Program** tab. Select the appropriate type and click **Continue**.
- 2. Follow the onscreen prompts to set up the titration parameters. When set up is complete, your patient will receive an email invitation to download the Welldoc App and register.
- 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.

9. How do I monitor my patient's Insulin Adjustment Program for basal, bolus or premixed insulin?

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

10. 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 a fax request.

11. 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 Insulin Management Features User Guide (Prescription only) under **Help Center** for detailed information about the Insulin Calculator.

12. How do I authorize the Insulin Calculator for bolus insulin?

If your patient would like to use the Insulin Calculator (Prescription only), a Prescription Request Form can be sent from the Welldoc App to the provider containing the dosing information the patient entered into the Welldoc App.

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

13. How do I revoke Insulin Calculator authorization?

The Insulin Calculator (Prescription only) authorization is valid for 365 days after authorization. To remove access sooner, please call the Welldoc portal Customer Care at 1-888-327-5345, Monday – Friday, 8 AM – 6 PM (EST).

14. Where can I find the User Guides?

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

15. How are the management portal user roles defined?

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

When a new patient is added, all users associated with the account can view the patient's record. Only prescribing health care providers can initiate the Insulin Adjustment Program.



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.

16. 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.

17. I forgot my username. How can I reset it?

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

18. Which browsers are compatible with the Welldoc Management Portal?

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 the management is Google Chrome[™], Mozilla Firefox[®], Microsoft Edge[®], and Internet Explorer.

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

19. 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 Center**.