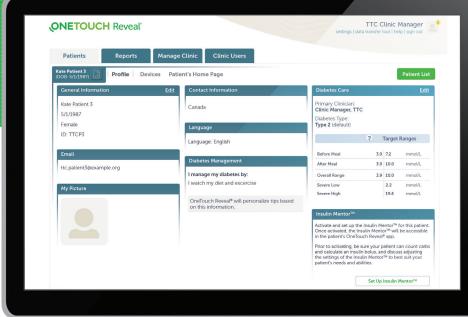
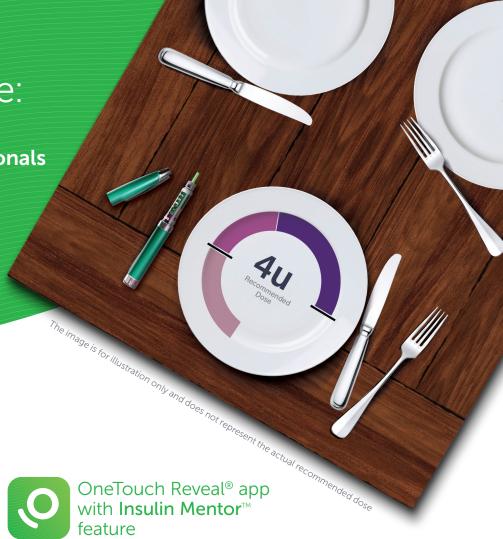
Healthcare Professionals Guide:

Activating and setting up the Insulin Mentor™ feature

OneTouch Reveal® web app for healthcare professionals







The Insulin Mentor™ feature is indicated for people with diabetes requiring bolus insulin, age 18 and older. Before use, a physician or healthcare professional must activate the functionality and program the set-up of patient-specific parameters and patients are required to complete a first-use tutorial. An accurate dose recommendation is dependent upon the data that the patient entered into the functionality as well as the settings their healthcare professional entered inclusive of patient's target blood glucose, insulin-to-carbohydrate ratio, insulin duration and insulin sensitivity.



Contents

Introduction	page 1
Continue 4	
Section 1	
Important Insulin Mentor™ feature settings	page 4
Section 2	
Activation and set up using the OneTouch	
Reveal® web app for healthcare professionals	page 9
Section 3	
Monitoring patients' progress using the OneTouch	
Reveal® web app for healthcare professionals	page 16

Intended Use of the OneTouch Reveal® web application

The OneTouch Reveal® web application is intended for use by individuals or healthcare professionals in the home or healthcare facilities for transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server database to support diabetes management. The device is intended for professional use and over-the-counter sales.

WARNING: Reports are intended to be used by your healthcare professional only. Please review your reports with your healthcare professional prior to making any changes to your diabetes care regimen.

The OneTouch Reveal® web application is intended for use by people with diabetes or healthcare professionals, in the home or healthcare facilities, for viewing data from home monitoring devices such as blood glucose meters to a server database – and to log, view, track and trend blood glucose data as well as other related indicators such as insulin, carbs and activity to support diabetes management.

The OneTouch Reveal® web application can also be used by physicians or healthcare professionals to activate the Insulin Mentor $^{\text{M}}$ functionality of the OneTouch Reveal® mobile application.

WARNING: Reports are intended to help patients track and trend their diabetes management, please share these reports with your healthcare professional prior to making any changes to your diabetes regimen.



Introducing the Insulin Mentor™ feature

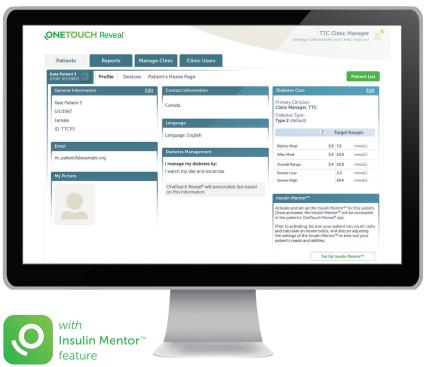
Makes mealtime insulin dose calculations so simple, patients can self-adjust with confidence.*

- Helps patients calculate carb values using the integrated food library.
- Calculates the recommended mealtime insulin dose taking into account recent blood glucose, carb values and insulin that may still be active in their body.



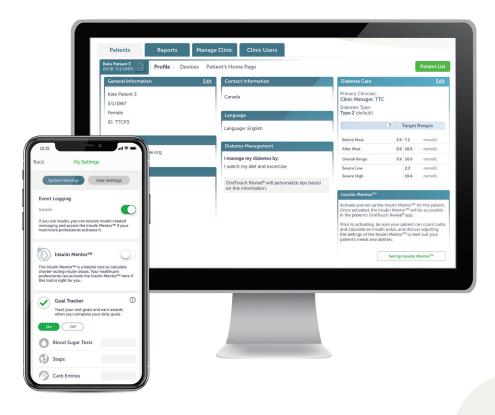








Introducing the Insulin Mentor™ feature



Before use, a healthcare professional must activate and set up the Insulin Mentor[™] feature for their patients. This can be completed in two ways:

1. Using the OneTouch Reveal® web app for healthcare professionals

OR

2. Directly on the patients mobile device using the OneTouch Reveal® mobile app





Includes the required settings for customizing the Insulin Mentor™ feature on the OneTouch Reveal® mobile app for each patient. Ask your LifeScan representative for details.



Bolus Calculation Mathematical Formula

The Insulin Mentor™ feature reflects a widely used and generally accepted bolus calculation that, by automating, may help address paper-based errors. Additionally, providing other features, such as consideration of active insulin and implementation of patient messaging and dose recommendation restrictions, does not present additional risks to the patient.

Fig. 1*

Calculated Dose (t) =
$$\left(\frac{CHO}{ICR}\right) + \left(\frac{Actual BG - Target BG}{CF}\right) - IOB$$
 (t)

For a given calculation, there are two primary outputs from the algorithm and Insulin Mentor™ feature: the **calculated dose** and the **recommended dose**.

The calculated dose at time, t, corresponds to the bolus dose that an individual would calculate by hand and is visible in the Insulin Mentor $^{\text{\tiny M}}$ feature. It is the sum of the insulin needed for carbs (first component, Fig. 1) and the insulin needed to correct a BG (second component, Fig. 1), less any active insulin at time, t (third component, Fig. 1).

The recommended dose is the insulin bolus dose that the algorithm calculates and the Insulin Mentor™ feature suggests on screen based on the patient's settings, as well as the data used in the calculation. If the calculated dose can accommodate the dosage increment selected in the settings, then the recommended dose will equal the calculated dose. If it cannot, the algorithm rounds the calculated dose down to recommend a dose that can be delivered. For example, the calculated dose may be 2.8 u. If the patient's settings indicate that the dosage increment is 1.0 u, the recommended dose will be 2.0 u. If the dosage increment is 0.5 u, the recommended dose will be 2.5 u. When rounding the recommended dose, the algorithm conservatively rounds down for safety.

If the calculated dose is less than zero, the recommended dose will be zero. When the calculated dose is greater than the maximum single dose limit, the recommended dose will always equal the maximum single dose limit.



Section 1

Important Insulin Mentor™ feature settings

Important Insulin Mentor™ feature settings

- Carefully read the "Help" file located in the menu of the OneTouch Reveal® web app for healthcare professionals
- The sequence of patient-specific parameters is different for activation using the OneTouch Reveal® web app for healthcare professionals.

Patient-specific parameters	Format or units	Pre-set range limits
Dosage increment	units	0.5u or 1u
Active insulin duration	hours	2.0 hours to 6.5 hours in half-hour increments
Insulin concentration	units	U100 (Regular)U100 (Rapid-acting)U200 (Rapid-acting)
Maximum single dose limit	Insulin units(u)	1u to 150u
Target Blood Glucose	x mmol/L (+/- y mmol/L) (variable by time of day — user set up to 12 different time periods within a 24-hour day) The +/- cell represents the acceptable deviation from set target.	3.9 to 11.1 mmol/L (+/- 0 to 2.8 mmol/L)
Correction factor	1:x mmol/L (variable by time of day — set up to 12 different time periods within a 24-hour day)	1:1 to 1:11 mmol/L
Insulin to carb ratio	1:x grams (variable by time of day — user set up to 12 different time periods)	1:1g to 1:100g
HCP can grant patients permission to change/edit their settings	_	yes/no



Feature Terminology

Dosage increment

Set the dosage increment (0.5 units or 1.0 units) during the Insulin Mentor™ feature activation.

Active insulin duration

The active insulin duration tells the patient how long the Insulin Mentor^{T} feature will consider a previously logged insulin bolus dose as active in the body. Once that duration is up, the Insulin Mentor^{T} feature will stop including the dose in calculations. This value is initially set by the healthcare professional.

Let's say the active insulin duration is four hours and the patient took a bolus insulin dose three hours ago. The Insulin Mentor™ feature will still consider part of that insulin dose as active in the body. As a result, it will lower the dose recommended to correct the blood glucose.

Now let's say a patient took the last bolus insulin dose five hours ago. The Insulin Mentor™ feature will not consider the insulin from that last dose as active in the body. That insulin will not be included in the calculation, as the active insulin is zero.

The Insulin Mentor[™] feature asks, "Have you recorded your recent insulin?" as a safety reminder to help avoid any insulin stacking.



Feature Terminology

Insulin concentration

Set the insulin concentration during the activation of the Insulin Mentor[™] feature.

The options are:

- U100 (Regular)
- U100 (Rapid-acting)
- U200 (Rapid-acting)

Maximum single dose limit

The maximum single dose limit is set as a safety feature. If the recommended dose is greater than this limit, the patient will be notified. Since taking too much insulin can be dangerous, set a single dose limit to help keep patients safe. If the recommended dose is greater than this limit, patients should do a recheck. Did they enter anything incorrectly? Is their blood glucose higher than expected? They should consider washing their hands and rechecking it. If they find their recommended dose is still greater than their maximum single dose limit, they should contact their healthcare professional for guidance.



Feature Terminology

Target BG (variable by time of day)

The Insulin Mentor[™] feature aims to get blood glucose back to this target and recommends a dose based on that goal. You may also include a buffer zone with the target in the patient's settings. If this is the case, the Insulin Mentor[™] feature will consider this buffer zone when it calculates a recommendation.

Let's say the target is 6.7 mmol/L +/- 1.1 mmol/L. If the blood glucose is greater than 7.8 mmol/L, the Insulin Mentor™ feature will recommend a correction dose.

If the blood glucose is 7.8 mmol/L, no dose will be recommended. Similarly, if a result is below 5.6 mmol/L, the Insulin Mentor[™] feature will take away from the correction dose. If the blood glucose is 5.6 mmol/L, no dose will be recommended.

In both situations, the goal is to get the blood glucose to the target of 6.7 mmol/L.

Correction factor (variable by time of day)

This is also known as an insulin sensitivity factor. It is an estimate made by the healthcare professional of the effect one unit of insulin has on blood glucose.

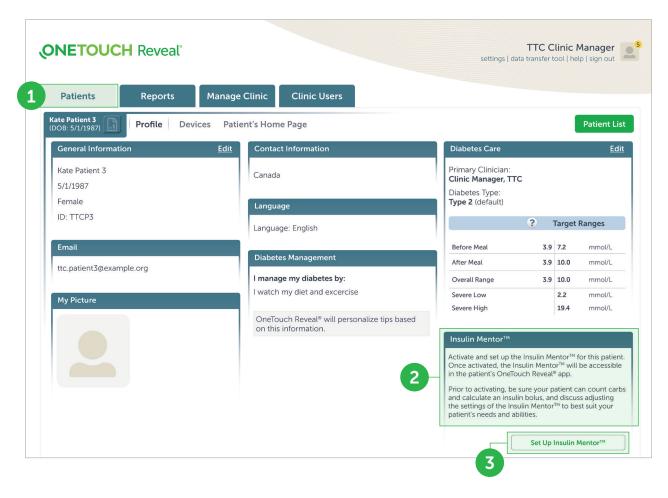
Let's say the correction factor is 1 unit:2.2 mmol/L. The Insulin Mentor™ feature will include one unit of insulin in the recommended dose for every 2.2 mmol/L blood glucose is above the target. It will subtract one unit for every 2.2 mmol/L blood glucose is below the target.

Insulin to carb ratio (variable by time of day)

This ratio tells the patient how many grams of carbs are covered with one unit of mealtime insulin. As an example, if the insulin-to-carb unit ratio is 1:20, this means that one unit of insulin will cover 20 grams of carbs.

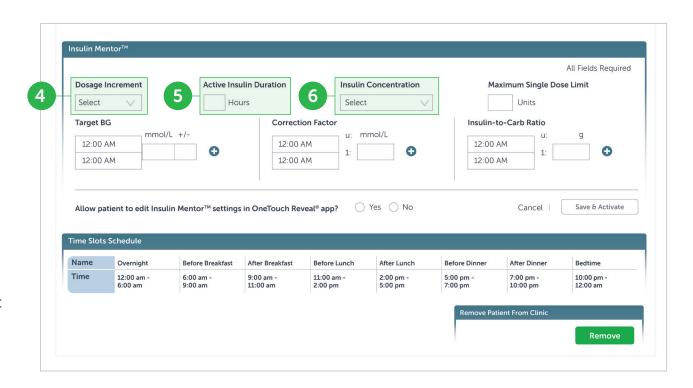


Section 2



- Select a patient from the **Patients** tab.
- When the patient's **Profile** loads, scroll down to **Insulin Mentor**™ on the right side of the screen.
- 3 Click Set Up Insulin Mentor™.

- 4 Select the **Dosage Increment** that the patient's Insulin Mentor™ feature will use: choose half units (**0.5 unit**) or whole units (**1 unit**) from the drop-down menu.
- 5 Input an Active Insulin
 Duration in half-hour
 increments from 2.0 to 6.5.
- 6 Choose one of the following values from the **Insulin**Concentration drop-down menu:
 - U100 (Regular)
 - U100 (Rapid-acting)
 - U200 (Rapid-acting)





7 Select the Maximum Single
Dose Limit. This is the maximum
dosage you want a singular patient
administering at one time.

The minimum value is 1 unit; the maximum value is **150 units**.

8 Set the Target Blood Glucose

This is the blood-glucose level that you want the patient to reach after administering a bolus dose of insulin. The +/- cell represents the acceptable deviation from that target.

If you set the patient's **Target Blood Glucose** to be **6.5 mmol/L** with a deviation (+/-) of **1.0 mmol/L**, then

the Insulin Mentor™ feature will only calculate:

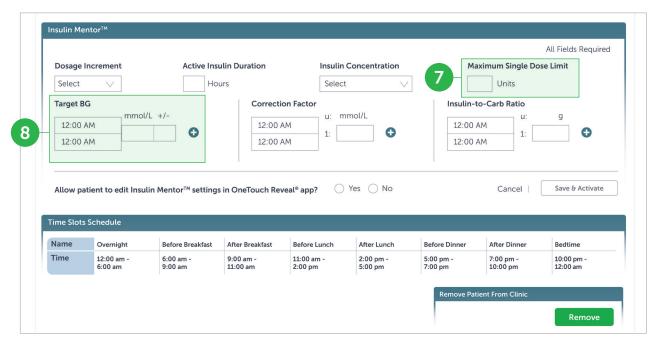
- a positive correction dose if the patient's BG reading will be less than 5.5 mmol/L
- a negative correction dose if the patient's BG reading will be higher than 7.5 mmol/L

after taking into account the patient's last BG reading, any entered Carbs that the patient recently ate or plans to eat, and any Active Insulin.

You can set a single Target BG and deviation for a 24-hour period.

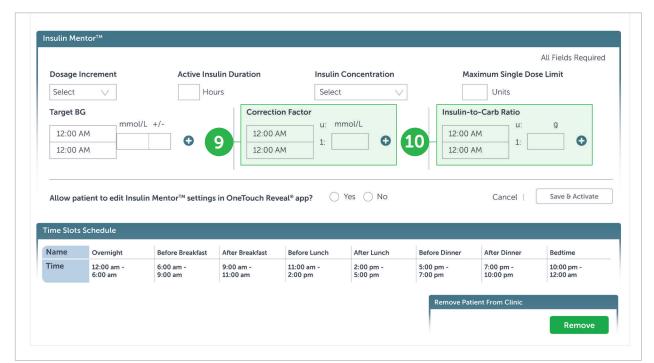
Additional settings

Click the plus (+) icon and set up to 12 different time periods with different Target BGs and deviations for different times throughout the day.

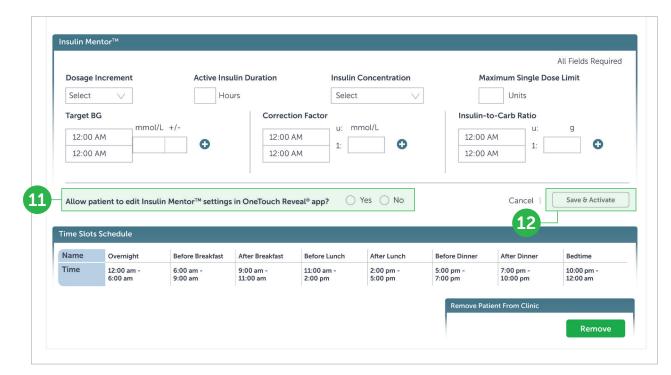




- 9 Choose the Correction Factor that you want the patient to adhere to as 1:x mmol/L. The minimum Correction Factor ratio you can set is 1:1 mmol/L; the maximum ratio is 1:11 mmol/L. You can set a single Correction Factor for a 24-hour period, or you can click the plus icon (+) and set up to 12 different time periods with different Correction Factors for different times throughout the day.
- Set the Insulin-to-Carb Ratio. An Insulin-to-Carb Ratio of 1:10 means that one unit of insulin would cover 10 grams of carbohydrates. The minimum Insulin-to-Carb Ratio is 1:1; the maximum is 1:100. You can set a single Insulin-to-Carb Ratio for a 24-hour period, or you can click the plus (+) icon and set up to 12 different time periods with different Insulin-to-Carb Ratios for different times throughout the day.







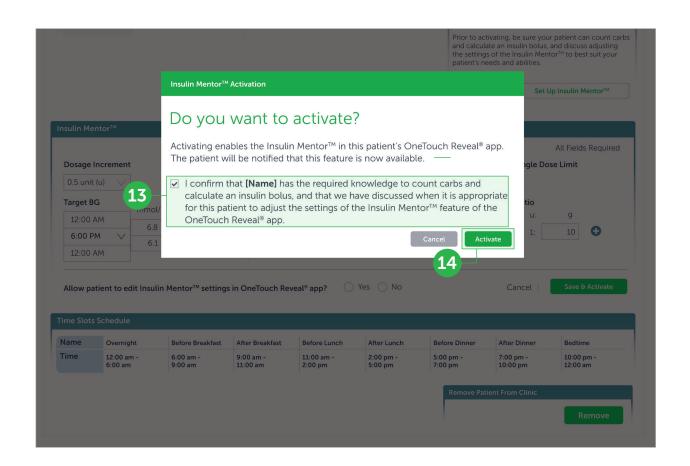
- You can give the patient the ability to change these settings themselves from within the OneTouch Reveal® mobile app. Next to Allow patient to edit Insulin Mentor™ Settings in the OneTouch Reveal® mobile app, click the Yes radio button to grant the patient permission to change their settings, or No to restrict the ability to change settings.
- When you have configured all fields, click **Save & Activate**.



- A Do you want to activate?

 pop up will appear with the text:

 "I confirm that [Name] has the
 required knowledge to count
 carbs and calculate an insulin
 bolus, and that we have discussed
 when it is appropriate for this
 patient to adjust the settings of
 the Insulin Mentor™ feature of
 the OneTouch Reveal® app."
- Check the box confirming that the patient has the required knowledge to use the Insulin Mentor™ feature and click **Activate**.





Section 3

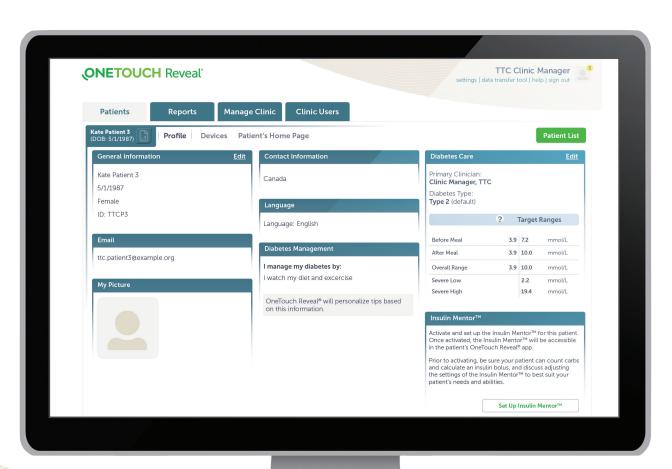
Monitoring patients' progress using the OneTouch Reveal® web app for healthcare professionals

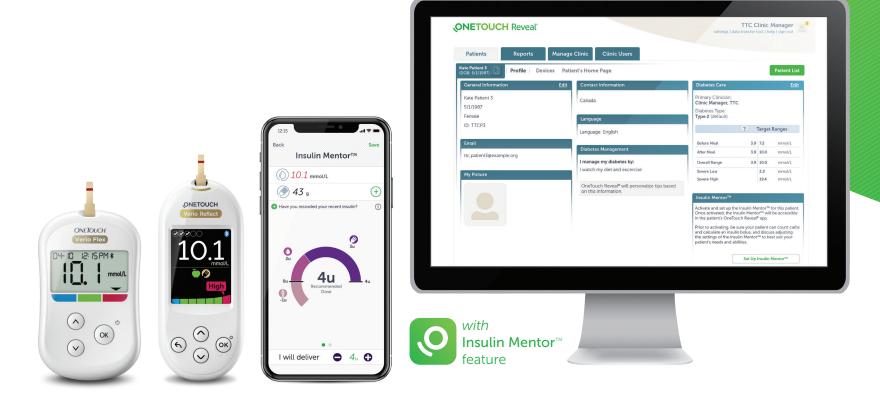
Monitoring patients' progress using the OneTouch Reveal® web app for healthcare professionals

With the OneTouch Reveal® professional web app, healthcare professionals can monitor their patients' progress remotely and make adjustments to their Insulin Mentor™ feature parameters between visits.

Healthcare professionals can see the insulin doses administered in the following reports in the OneTouch Reveal® professional web app:

- Logbook
- Data List
- Integrated Daily View
- Details by Day of Week
- Details by Time of Day





We are here to help. Our Customer Care team contacts all patients who register their OneTouch® meter to offer individualized training and support.





Call OneTouch® Customer Care 1 800 663-5521