MODI Diary

DreaMed Diary App for MODI

User Guide

Exclusively for clinical investigation

MODI WAS DEVELOPED BY –

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In the US: For in-vitro diagnostic use only

NOTE: This user manual is subject to periodic review, update and revision.

MODI algorithm SW ver.: 03.00.XX

2025-XX-XX

℞ Only

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use.

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Table 1 – Symbols and Concepts Used in This Manual

Symbol	What It Means
	Manufacturer
	Manufacturing Date
	Caution: Federal law restricts this device to sale by or on the order of a physician.
	**Note –** A note provides helpful information.
 **Caution**	**Caution –** A caution notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage. The caution includes the precaution that should be taken to avoid the hazard.
 **WARNING**	**WARNING –** A warning is a statement that alerts you to the possibility of injury, death or other serious adverse reactions associated with the use or misuse of DreaMed Diary.
 **Important**	**IMPORTANT –** An important notice provides information or instructions essential for the correct use of DreaMed Diary. Ignoring this information may result in reduced performance, incorrect operation, or unintended outcomes.

1. Preface

The DreaMed Diary for MODI is a mobile app intended for the management of diabetes for people with type 1 and type 2 diabetes mellitus

MODI is designed to provide comprehensive analysis of individual diabetes data based on CGM readings (with or without SMBG), i.e. glucose data, reported insulin injection data and meals information.

The User Guide provides instructions for using the DreaMed Diary app for MODI.

CAUTION

- MODI Dose guidance and the Diary app are not monitored by your healthcare provider. Users are solely responsible for reviewing their recommendations and should consult their HCP if they have concerns.
- Please read the entire User Guide before using the app and always follow the instructions for use. Not following these instructions may result in harm and/or lead to harmful treatment decisions.
- Using MODI requires prior knowledge of diabetes management. Before starting, consult with your physician about using MODI together with the DreaMed Diary app to help manage your diabetes.
- MODI and the DreaMed Diary app use a smartphone. Make sure you are comfortable with this technology before use.

2. Important Safety Information

Indications for Use

MODI is indicated for use by patients for optimizing insulin injections treatment plan for basal therapy with or without bolus therapy (which includes meal, and correction bolus) based on reported continuous glucose monitor (CGM) readings (with or without SMBG) and insulin delivery (i.e. time of dose with or without amount of dose).

MODI integrates into a patient diabetes management mobile application and uses CGM and connected insulin injection device data to recommend insulin treatment plan changes to people with type 1 and type 2 diabetes (T1D & T2D) over the age of 18, who use subcutaneous injections of the following insulin types as their therapy:

Long-acting insulin; with or without

Short acting insulin (rapid acting analogs or regular human insulin, according to manufacturer indications for use).

MODI is intended for single patient use.

MODI is Rx - For Prescription Use Only

Bolus Calculator

The Bolus Calculator, a component of the DreaMed Diary App, is a diabetes management tool for people with type 1 diabetes above the age of 6 and type 2 diabetes above the age of 10, who use subcutaneous insulin injections therapy (not for pump use). This tool can help calculate their rapid acting analogs for insulin bolus doses based on user-entered blood glucose and/or meal information.

The initial setup of the user's account must be performed by the clinical study team.

Contraindications for MODI Algorithm

- DreaMed Diary and MODI algorithm is not intended for use by patients who use insulin(s) other than the types indicated below. Using MODI with other types of insulin may lead to potential harm.
- MODI algorithm is not intended for use with patients treated with insulin pump, intravenous (IV) insulin injections, or a combination of insulin injections and/or IV insulin and insulin pump therapy.

Potential Harms and Residual Risks

Information is recorded in the DreaMed Diary app and may be shared with your healthcare provider during follow-up visits.

The following are the risks associated with the use of MODI:

- Incorrect dosing of insulin (under/overdose) required for maintaining desirable blood glucose levels.
- Risks associated with severe hypoglycemia and hyperglycemia, resulted from false in MODI algorithm, quality of the input data, and cybersecurity issues.

There are potential risks associated if the shared information is inaccurate or misleading. Potential risks may include –

- Hyperglycemia
- Ketosis
- Diabetic Ketoacidosis (DKA)
- Mild hypoglycemia
- Severe hypoglycemia
- Obstetrics complications
- Data confidentiality
- Data availability
- Data integrity

Based on the residual risk evaluation, all risks were reduced as far as possible, to an acceptable level. The harms of these risks are similar to the common risks for diabetes patients during everyday life, using insulin.

This user guide provides information regarding the safety features incorporated into the app to help avoid the risks listed above. Be sure to follow the instructions in this manual to further reduce these risks.

General Information for Safe use

This chapter outlines important safety behaviors and limitations of the DreaMed Diary App for MODI. Please read the entire user manual before using the app and always follow the instructions for use. Not following these instructions may result in harm and/or lead to harmful treatment decisions.

General User Information and Precautions

- **MODI does not replace clinical judgement**
  MODI is designed to support your insulin treatment, but it does not replace clinical judgment or your responsibilities in managing your therapy.
- **Log all your insulin doses before injecting**
  The Bolus Calculator provides recommendations based on the information available. You are responsible for verifying and approving each dose before injection. While you are using the Bolus Calculator, make sure you have correctly logged in all bolus events in the last three hours so that active insulin is correctly calculated.
- **Compatible glucose sensors**
  MODI uses the sensor (CGM) data to adjust your treatment plan. Use your sensor according to the manufacturer's instructions for use.
- **Plan updates require user approval**
  MODI may recommend changes to your insulin plan, but these are never applied automatically. Always review and approve any new plan before using it.

Warnings and Cautions for using MODI

- **Pregnancy**
  MODI is not designed for use during pregnancy. If you are or become pregnant, consult your healthcare provider immediately and stop using MODI Dose Guidance.
- **Medical supervision is still required**
  MODI does not replace your healthcare provider. Always consult your care team before making changes to your therapy.
- **Accurate data entry**

  Ensure that all data entered into the app, including weight, insulin doses, and glucose readings, is correct and up to date. Inaccurate or outdated information may lead to inappropriate insulin recommendations which may result in harm.

- **MODI is not a real-time monitoring system**
  MODI does not monitor your glucose levels in real-time and should not be used as an emergency channel. MODI analyses your data once daily or even every few days.
- **MODI is not monitored by your healthcare provider**

  Your healthcare provider does not actively monitor your data in MODI. In case of emergency contact your healthcare provider or call 911.
- **Keep your information up to date**

  To ensure the MODI provides accurate recommendations, always keep your personal settings current:
    - Update your insulin plan whenever it changes - whether you adjust it yourself or your healthcare provider updates it.
    - If your weight changes by more than 5%, update it in the app as soon as possible.
- **Insulin Plan Updates**

  Any change to the insulin plan made by the user or their HCP must be updated in the app. The app cannot identify changes made outside the app and will continue to operate based on the data provided by the user.
- **Independent Use**

  MODI provides insulin dose guidance based on the data entered but does not replace medical judgment. Users are solely responsible for reviewing their recommendations and should consult their HCP if they have concerns.
- **Traveling Across Time Zones**

  MODI analyses your glucose and insulin data to optimize your insulin plan. When your local time shifts by more than 3 hours (due to travel or daylight saving changes), MODI will delay generating the next plan for a few days to let your body adjust. Frequent travel across time zones with an hour or more difference may limit MODI's ability to adjust your plan effectively. If this applies to you, consider whether using MODI fits your current lifestyle.
- **Internet connection**

  MODI requires a stable internet connection for proper operation. Ensure your device is connected to the internet for several hours each day to enable data syncing and receive important updates.

During set up, the App asks for phone permissions. Please allow these. If your phone is not set up properly, you will not be able to get alerts and use the App adequately. Confirm your settings are as follows:

If you restart your phone, open the App to make sure it's working properly.

Authorized Devices

Table 2 details the devices that are currently authorized to be used with DreaMed Diary for MODI.

Table 2 – Authorized Devices for Use

Device Type	Device Manufacturer	Brand Name
Blood Glucose Meter	All meters with regulatory approval (dependent on location: EU/US/Rest of the World [ROW])	
CGM	Abbott	Libre 2
		Libre 3
		Libre Pro

NOTE: Authorized devices should be used according to manufacturer's labeling.

Authorized Insulins

Table 3 – Approved Insulins for use

Type of Insulin	Insulin Brand Name
Rapid Acting Analogs	Novolog, Apidra, Humalog U-100, Humalog U-200, Admelog, Fiasp, Lyumjev U-100, Lyumjev U-200
Regular Insulin	Humulin-R U-100, Novolin-R, Velosulin
Long Acting Insulin	Levemir, Lantus, Rezvoglar, Semglee, Toujeo, Basaglar, Tresiba U-100, Tresiba U-200, Xultophy, Soliqua

NOTE: Insulin should be used according to manufacturer's labeling.

3. Introduction

About the DreaMed Diary App for MODI

The **DreaMed Diary App** is a mobile application designed to help people with diabetes manage their insulin treatment plan by combining standard diabetes diary functions with automated insulin dose guidance.

In addition to recording insulin doses, glucose values, and other relevant diabetes data, the app uses **DreaMed MODI Dose Guidance** feature to analyze patterns in glucose control and provide optimized insulin treatment plans. These treatment plans are based solely on the data entered by the user into the app and on connected compatible devices, if used.

The app's dose guidance includes:

- **Scheduled Titration** – periodic evaluation of glycemic control, typically on a weekly basis, to recommend adjustments to the insulin treatment plan.
- **Daily Guard** – daily monitoring feature that identifies repeated and/or severe hypoglycemia events and may reduce insulin doses to ensure your insulin plan is safe and aligned with your therapeutic requirements.

The DreaMed Diary App for MODI operates as an independent tool for insulin dose guidance and does not require active involvement or supervision by a healthcare professional after it is prescribed. The healthcare professional cannot view or access the user's data through the app.

The app is intended to be used as a support tool and does not replace the user's judgment in managing diabetes. Users should consult their healthcare professional in case of uncertainty about their treatment plan or if they experience unexpected changes in glucose control.

Important

Log all bolus insulin doses taken **3 hours prior** to using the Bolus Calculator. Missing recent doses may lead to incorrect dose recommendations.

Description of Intended Clinical Benefit

The key aim of diabetes management is to prevent acute complications, such as severe hypoglycemia and Diabetic Ketoacidosis (DKA), enhance overall well-being and mitigate the risk of long-term chronic complications. These goals can be achieved by optimizing the patients' glycemic control.

Results from clinical studies have demonstrated the benefits of normal or near-normal blood glucose levels and the importance of using glucose monitoring devices to achieve this1. Experts recommend that most people with diabetes should try to keep blood glucose levels as close to normal as safely possible2.

In addition, HbA1c reduction will be considered as meaningful clinical benefit, as HbA1c was defined as a marker for diabetes control and future complications, which is used to assess the success of glycemic management.

Intended Audience

- The DreaMed Diary App for MODI is intended for **adults aged 18 years and older** with diabetes who manage their own insulin treatment. It is not intended for children, adolescents, or individuals unable to independently manage their insulin therapy.
- Using MODI requires prior knowledge of diabetes management. Users shall have sufficient understanding of diabetes management and shall be confident in using the associated technology.
- The app is provided under prescription from a healthcare professional (HCP). However, after the initial prescription, the HCP is not involved in reviewing or managing the data in the app. The DreaMed Diary App MODI operates independently.

Connecting to Glucose Sensors

MODI requires a Libre Freestyle Continuous Glucose Monitor (CGM) sensor (see section 2.5 – Authorized devices) in order to monitor your glucose and provide insulin dosing changes. You will be connected by your clinical study team.

NOTE: If at any point you are disconnected….contact your team

[1] ADA Position Statement. Test of glycaemia in diabetes. Diabetes Care 2003;26(Suppl.1): S106-108

2 Diabetes Control and Complications Trial Research Group (DCCT): The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin dependent diabetes mellitus. New Engl J Med, 1993;329:977-86.

iOS or Android

The DreaMed Diary app is suited for both iPhone and Android users. The DreaMed Diary app can integrate with the Apple Health app for Apple users. This feature is not available for Android platforms.

- **For iOS Devices –** Requires iOS 12.4 or later. Compatible with iPhone, iPad and iPod touch.
- **For Android Devices –** Requires device from the following brands – Samsung, LG or Google, from Android 6.0 or later. The app is compatible with most models.

4. First Steps

The onboarding process begins once your healthcare professional (HCP) prescribes the MODI Diary App and sends you an invitation. After this initial step, your HCP will not be involved in your app usage or in reviewing your data.

Receiving Your Invitation

You will receive an invitation by email after your HCP prescribes the DreaMed Diary App for MODI. The invitation includes a link to set up your account.

Setting Up Your Account

1. Open the link included in the invitation email.
2. Follow the on-screen instructions to set your personal password. Your account is now created and automatically linked to your HCP's prescription. You do not need to create an account manually.

Downloading the App

1. Download and install the DreaMedDiary App from the Google Play Store or the Apple App Store.
2. Open the app and log in using the email address that received the invitation and the password you created.

Onboarding Process

The onboarding process starts automatically when you log in for the first time. Follow the on-screen prompts to complete the setup.

Once completed, the **MODI Dose Guidance** feature will become active—no additional steps are required.

Pregnancy Confirmation

- The first screen asks you to confirm that you are **not pregnant**.
- MODI Dose Guidance is not designed for use during pregnancy. If you are or become pregnant, consult your healthcare provider immediately and stop using MODI Dose Guidance. If you are pregnant, it is important that you do not rely on MODI recommendations and instead turn off the MODI Dose Guidance feature. This can be done in the Settings > Dose Guidance menu.

Weight Entry

- Enter your current weight when prompted.
- MODI accepted weight range is 22-250 kg and 50-500lbs.
- Ensure the value is accurate, as it is used to calculate insulin dose recommendations.
- In the future, the app will periodically prompt you to confirm or update your weight.

WARNING

Keep your weight information up to date. Update it in the app if it changes by more than 5% or whenever the app asks you to confirm it. Your weight helps Dose Guidance understand your insulin needs. Please make sure your weight is correct

Setting up Your Insulin Plan

A. Long-acting insulin plan (Basal plan)

1. Select your **long-acting (basal) insulin type** from the list.
2. Enter your daily long-acting insulin dose.
3. If you are unsure of your dose:
   a) Consult your HCP, or
   b) Tap "I don't know my dose" to allow DreaMed Diary to calculate an initial plan for you.

MODI may calculate the initial long-acting insulin dose only for users who do not use rapid-acting (bolus) insulin.
The initial dose will be set to the minimum between 10 units and 0.1 unit/Kg

B. Mealtime insulin (Rapid-acting / Bolus)

4. Indicate whether you also use a mealtime (bolus) insulin.
   - This insulin is different from your long-acting insulin and is usually taken with meals.
   - MODI refers to it as **rapid-acting insulin** or **bolus insulin**.
5. If you do not use mealtime insulin, you may proceed to review your plan.
6. If you do use it, continue to set up your bolus plan:
   - Select your rapid-acting insulin type from the list.
   - Choose the dosing plan you use:
     - **Fixed meal** – For users who take specific insulin doses for **breakfast, lunch, and dinner**.
     - **Meal size** – For users who select a dose based on meal size (e.g., small, normal, large), which may be influenced by the meal's carbohydrate content.
   - Enter the insulin amounts according to your selected plan.

MODI sets and manages your insulin correction plan. The plan updates automatically by MODI and you cannot edit it.
You may view your correction plan as a sliding scale table when tapping edit from your insulin plan screen.

MODI calculates your initial correction plan, based on the following:
Correction target: 110 mg/dL

Correction factor: 1800 / (0.5 unit/Kg)

C. Finalizing Your Plan

1. Review your insulin settings and weight carefully.
2. Confirm the plan to complete setup.

Important

If your insulin plan changes—whether by your own decision or based on instructions from your healthcare provider—you must update it manually in the Diary App.

Completion

- After onboarding is complete, you can immediately begin logging your insulin doses and using the Bolus Calculator for mealtime insulin.
- MODI periodically reviews your logged data in the background and may generate insulin plan suggestions based on usage patterns and glucose trends.

5. Overview of Daily Use

What You Need to Do Each Day

The app is designed to assist you in maintaining your insulin regimen consistently and accurately.

After completing onboarding, the DreaMed Diary App for MODI supports your day-to-day diabetes management by helping you calculate insulin doses and provide you with insulin plan updates to meet your needs.

To use MODI effectively:

1. **Log every basal (long-acting) insulin injection.**
2. **Use the Bolus Calculator** to calculate and log your mealtime (rapid-acting) insulin doses.
3. **Review and approve new plan suggestions** when MODI offers them—these will not apply automatically.
4. **Keep your information up to date**

   To ensure the MODI provides accurate recommendations, always keep your personal settings current:

   - Update your insulin plan whenever it changes - whether you adjust it yourself or your healthcare provider updates it.
   - If your weight changes by more than 5%, update it in the app as soon as possible.

The following sections explain how to complete each of these steps.

WARNING

Logging your basal injections and reporting boluses using the Bolus Calculator are critical for MODI to titrate your insulin plan. Be sure to log them daily.

Logging Basal (Long-Acting) Insulin

To log a basal dose:

1. Open the Diary screen.
2. Tap the **"+" (Add Event)** button.
3. Select your long-acting insulin.
4. Enter the dose and confirm.

Caution

Log all your basal insulin doses. Missing entries or wrong data entry may affect the accuracy of dose suggestions.

Calculating and Logging Rapid-Acting Insulin

This section applies only to users who use rapid-acting (bolus) insulin.

To use the Bolus Calculator:

1. On the **Diary** screen, tap the **Bolus Calculator** button.
2. Enter your current glucose value as shown on your Sensor or glucometer.
3. Based on your plan type, the screen will display one of the following options:
    - **Fixed Meal plan**: You will be asked whether you are about to eat your regular meal (Yes/No).
    - **Meal Size plan**: You will be asked to select the portion size of carbohydrates you are about to eat: No Meal, Small, Normal, or Large.
4. Tap **Calculate** and view your recommended dose. You may edit the dose if you decide to deliver a different amount.
5. Tap **Save** to log the dose.

WARNING

Log all bolus insulin doses taken **3 hours prior** to using the Bolus Calculator. Missing recent doses may lead to incorrect recommendations.

Important

If your insulin plan changes, update it in the app before using the Bolus Calculator.

Reviewing and Approving Plan Updates

When a plan update is available you will be asked if you want to view your new plan, or choose **Later**.

1. Tap "**Yes**" to view the suggested changes.
2. Review the new plan and Tap **"Ok"** to apply it.

3. If you tap **Later,** a banner will appear at the top of the screen to remind you that a new insulin plan is waiting for your review. Tap the banner to view and apply the new plan.

Important

MODI analyzes your glucose data and behavioral patterns and may suggest plan updates from time to time. These updates will never be applied automatically.
You will always be asked to **review and approve** any recommended changes before your insulin plan is updated.

Caution

MODI analyses your recent data to create insulin plan recommendations for future use. If your recent weeks were not typical - such as during illness, temporary lifestyle changes, or if you plan to change your diet or exercise routine - review the new plan carefully. If you are unsure, consult your healthcare provider before applying the changes.

Important

Look for messages at the top of your new insulin plan. It may include important behavioural tips that will help you improve your glycaemic control or even refer you to your healthcare provider.

6. Screens Overview

Navigation Bar

You can move between the main screens of the Diary App using the navigation bar at the bottom of the screen.

The navigation bar includes the following buttons:

- **Diary** – Opens the main Diary screen, where you can view and log your insulin doses, meals, and glucose readings. The **Bolus Calculator** is also accessed from this screen.
- **Insulin Plan** – Opens your current insulin plan, including both basal and rapid-acting insulin settings.
- **Settings** – Opens the settings screen, where you can update personal information, configure app preferences, and access help information.

Tap any of these buttons to switch between screens.

Diary Screen

The Diary screen is your home screen. It displays your insulin and meal logs in a timeline format, and it is also where MODI communicates important updates.

Main Features:

- **Daily Log View**
  Entries are organized by day and time, showing logged insulin doses, meal details, and glucose readings.
- **Add Event Button**
  Tap this button to manually log basal insulin. You may add bolus events to log missed injections.
- **Bolus Calculator**
  For users with rapid-acting insulin plans, the Bolus Calculator button opens the Bolus Calculator interface, helping you calculating your next bolus dose.

NOTE: You can scroll back to previous days to review your past entries, and tap any entry to view its details and edit it when needed.

Insulin Plan Screen

The **Insulin Plan** screen displays the insulin settings currently recommended for your treatment. These include your long-acting (basal) insulin plan and, if applicable, your rapid-acting (bolus) insulin plan.

- The **basal plan** is your long-acting insulin dose. View and inject this dose as scheduled.
- The **bolus plan** includes the meal and correction components and is used by the **Bolus Calculator** to recommend your mealtime (rapid-acting) insulin doses.

Main Features:

- **Basal Plan**
  Shows your selected basal insulin type, time of injection and daily dose.
- **Bolus Plan** *(for users using rapid-acting insulin)*
  Displays your selected bolus insulin type and meal plan. MODI supports two types of bolus treatment plans:
    - **Fixed Meal Plan** – insulin doses are assigned for each main meal.
    - **Meal Size Plan** – insulin doses are assigned for different portion sizes (small, normal, or large) for each meal of the day.

      The Meal Size Plan divides the day into four time periods: Morning, Afternoon, Evening, and Night. The Evening and Night periods share the same settings. Each time period includes the available meal sizes and their corresponding insulin doses.
- **Edit Plan**

  Tap the **Edit Plan** button to update your basal and bolus settings.

  In the basal plan you may edit your insulin type, injection time and dose.
  For users with a bolus plan, this section includes both:

  - The meal component, which can be edited
  - The correction component, based on a sliding scale of glucose values

  The correction plan is used by the Bolus Calculator to adjust your insulin dose when needed. It is view-only and cannot be edited.

Caution

The Bolus Calculator uses both your meal plan and your defaulted correction plan to calculate recommended doses. Always ensure your editable insulin settings are up to date.

NOTE: When MODI suggests a new plan based on your recent data, it will appear in the Diary screen for your review and approval. Once approved, the new plan will be reflected here.

Settings Screen

The **Settings** screen allows you to manage your personal profile, dose Bolus Calculator preferences, and access support materials and app information. It is organized into the following sections:

Profile

- View the name of the app user
- View and update your current weight.
  You may be prompted from time to time to confirm or update your weight.
- Log Out – Tap this option to securely sign out of your DreaMed Diary app account.

WARNING

Keep your weight information up to date. Update it in the app if it changes by more than 5% or whenever the app asks you to confirm it. Your weight helps Dose Guidance understand your insulin needs. Please make sure your weight is correct.

General Settings

These settings are used when generating bolus dose recommendations.

- **Active Insulin Time** – Defines how long the Bolus Calculator considers previous boluses when calculating a new dose. Default 3 hours.
- **Maximum Dose Limit** – Sets an upper safety limit for rapid-acting insulin dose recommendations.

Caution

The values in General Settings affect how bolus doses are calculated. Do not change your settings if you're unsure what they should be. When needed, you may consult your healthcare provider

About

Displays the app version and regulatory information.

Help

Provides access to the user guide.

7. Notifications and Reminders

This chapter describes how the Diary app for MODI uses notifications to help you stay on track with your insulin treatment and app use. Notifications are designed to assist you in maintaining consistent logging, reviewing important updates, and confirming required information like new insulin plans.

Types of Notifications

The Diary app may send the following types of notifications:

- **Reminders to log insulin doses**
  You may receive a reminder to log your insulin injections if no entries have been detected for two consecutive days.
- **Plan Update notification**
  If MODI detects a need to update your insulin plan based on your recent data, you will receive a notification prompting you to review and approve the new plan.
  Open the app, review the suggested plan, and tap **OK** to activate it.
- **Reminders to wear your CGM**
  MODI may periodically check whether CGM readings are being received. If no CGM data is detected, you will receive a reminder to wear your sensor or contact your clinic team.

🔎 **Tip:** For the best use experience, keep notifications enabled so you don't miss reminders or important plan updates.

8. MODI Titration

Preliminary Checks Before Reviewing an endo.digital Report

TBD

Step 3: endo.digital Pulls Data from Various Data Sources

Once a healthcare provider asks for a new recommendation using the **New Recommendation** button, the data is pulled by the endo.digital system from the supported data sources and the DreaMed Diary App.

endo.digital algorithm provides treatment recommendations for patients on MDI-Carbs counting and MDI-Sliding scale treatment plans. For patients who are on MDI-Fixed meal, MDI-Meal estimation, or Generic treatment plans, the endo.digital system will automatically direct you to a manual recommendation where you can create a treatment recommendation for your patient based on your professional knowledge and judgment and not based on endo.digital's algorithm.

endo.digital algorithm requires at least 12 **valid days** for Type 1 diabetes patients (including Type 1 with insulin resistance) and at least 6 **valid days** for Type 2 diabetes patients to produce recommendations (as defined in Table 4), including an insulin injection plan. If the conditions are not met, endo.digital algorithm will not provide recommendations on new insulin treatment plans. If there is not enough insulin data at certain times of the day, endo.digital algorithm will generate a recommendation, but it may not recommend changes for specific times of the day where the data is missing.

Table 4 – Definition of a Valid Day for endo.digital algorithm Analysis

Data source	Requirement
Glucose	**T1DM and Insulin resistant type 1:** **CGM:** At least 67% of the expected sensor measurements per day according to the sensor's sample rate. –OR– **Glucometer:** At least 3 BG measurements a day that are at least 210 minutes apart.
	T2DM: **CGM or Glucometer**: Fasting glucose level. A fasting glucose level is considered as any glucose measurement found between 4AM and 12PM.

Caution

endo.digital uses CGM data from approved devices. As part of this approval process, the accuracy of the sensors was evaluated when the sensor was used according to the manufacturer's instructions. It is recommended that you advise your patient to calibrate the sensor according to the manufacturer's instructions. Otherwise, a less accurate sensor could cause endo.digital to analyze inaccurate sensor data.

NOTE: Data is pulled automatically into endo.digital. All data is analyzed as-is. You cannot edit, change, replace or flag out the data, nor can the patient do so.

Step 4: endo.digital Generates Recommendations

endo.digital Processes and Analyzes the Data

First, endo.digital uses the raw data input to detect patterns and events for analysis. The detection process is based on the following methodologies and assumptions:

- **CGM/SMBG Data Filtration –** endo.digital may ignore some of the CGM/SMBG values in cases where the algorithm considers them non-physiological or in cases where the blood glucose meter value contradicts the CGM value at a given time stamp.
- **High/ Eu / Low Glycemic Patterns –** endo.digital uses adaptive thresholds to detect patterns of low and high glycemic patterns. These thresholds are based on the patient Pre-meal glucose targets, as defined by the HCP in the patient's personal information page as follows:

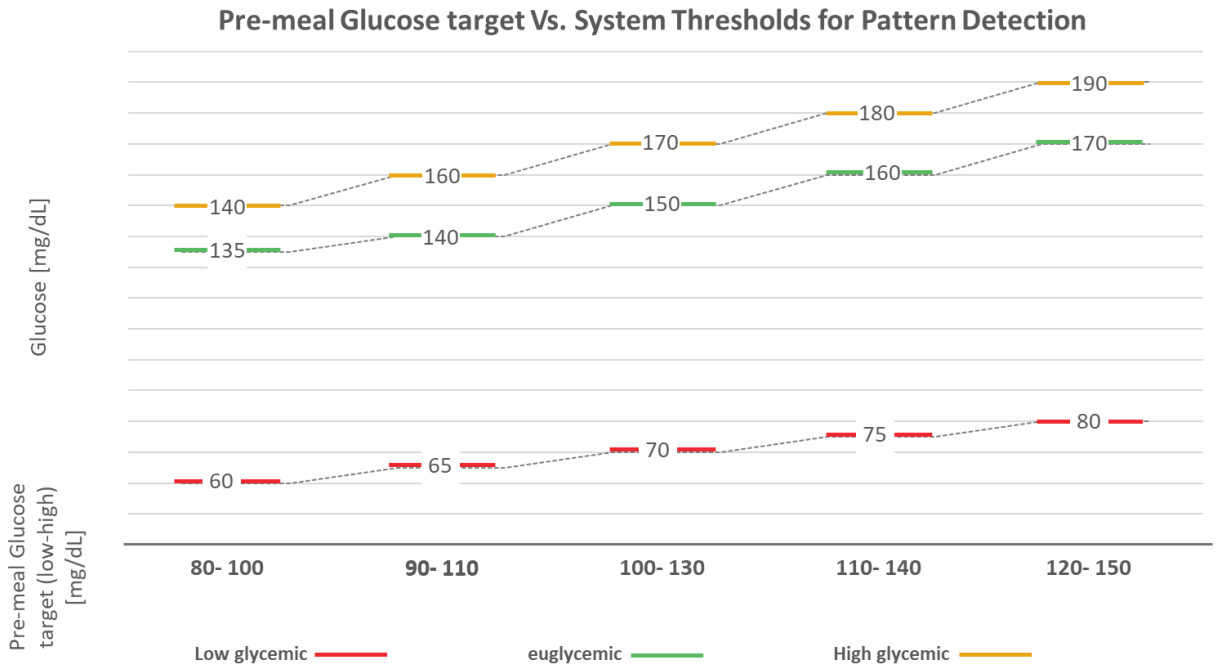


Figure 1 – The adaptive thresholds used by the system to define patterns of low/eu and high glucose patterns as defined by the patient pre-meal glucose targets

- **Insulin Dosing Decisions Events by the Patient –** The algorithm uses the reported insulin, glucose, and meal data and CGM/meter data to characterize each insulin dosing event. In cases where there is no carbohydrate information available for a bolus delivery, endo.digital uses the patient's insulin treatment plan to estimate whether carbohydrates were consumed at the time of a bolus.

endo.digital Analyzes Patterns and Creates Recommendations

endo.digital evaluates the following events:

- Each insulin dosing decision made by the patient
- High and low glycemic patterns.

Potential recommendations may include:

- Changes to the patient's Basal plan
- Changes to the patient's Bolus plan
- Providing a personalized diabetes management tip relating to the way the patient delivers insulin

endo.digital integrates safeguards into its recommendations in order to ensure the patient safety. The information in Table 11 below presents the particular safeguards and limitations used in recommending a change to the patient's insulin treatment plan.

Table 5 – endo.digital Limitations When Recommending Changes to a Patient's MDI treatment plan

Variable Name	Limitation	How is It Used in the endo.digital Analysis Process?
Basal Plan (Long acting insulin)	Limitation on the changes for the daily basal amount	±20% of the current daily basal amount.
	Limitation on the daily basal amount	The recommended basal plan cannot go outside hard boundaries depending on the type of diabetes: • T1DM - below 1 and above 72 units a day • T2DM / insulin resistant T1DM - below 1 and above 250 units a day
	Potential number of basal injections	1 or 2, depending on the input basal plan and/ or the basal plan as identified by the system from the patient basal injection records. *Note that the system will not recommend changing the long acting insulin type*
CR Plan	Limitation on the CR changes that can be recommended by endo.digital	± 30% of the current CR value based on the patient's current CR settings and up to ±1$[\frac{gr}{U}]$
	Limitation on the CR values that can be recommended by endo.digital	The recommended CR plan cannot go outside hard boundaries depending on the type of diabetes: • T1DM - below 3 and above 70 $[\frac{gr}{U}]$ • T2DM / insulin resistant T1DM - below 2 and above 70 $\left[\frac{gr}{U}\right]$ *Note that the limits are reflective of the selected carbs unit (units to 10 or 15 grams exchange)*
	Potential number of CR periods	Always 4: morning, afternoon, evening and night time.
CF Plan	Limitation on the CF changes that can be recommended by endo.digital	± 30% of the current CF value based on the patient's current CF settings and up to ±5$[\frac{mg/dL}{U}]$
	Limitation on the CF values that can be recommended by endo.digital	The recommended CF plan cannot go outside hard boundaries depending on the type of diabetes: • T1DM - below 10 and above 280 $\left[\frac{mg/dL}{U}\right]$ • T2DM/ insulin resistant T1DM - below 5 and above 280 $[\frac{mg/dL}{U}]$
	Potential number of CF periods	Always 4: morning, afternoon, evening and night time.
Other bolus plans:	Limitation on the changes that can be recommended by endo.digital	± 30% of the current plan values based on the patient's current settings ±1$[U]$

- Fixed meal **- Meal Estimation** **- Sliding scale table for correction** **- Sliding scale table for meal + correction**	Limitation on the values that can be recommended by endo.digital	The recommended plan cannot go outside hard boundaries depending on the type of diabetes: • T1DM - below 0 and above 30 $[U]$ • T2DM / insulin resistant T1DM - below 0 and above 99 $[U]$ In case of sliding scale table, the increments between the table scales cannot go above: • T1DM: 5 [U] • T2DM/ insulin resistant T1DM: 10 [U]
	Potential number of day periods	Always 4: morning, afternoon, evening and night time.
Bolus target plan	Limitation on the target changes that can be recommended by the endo.digital	- 20 mg/dL, only if the bolus target plan is above 150 mg/dL *Note that the endo.digital only recommends changes to the bolus target plan if it's above 150 mg/dL.*
	Limitation on the target plan values that can be recommended by endo.digital	The recommended bolus target plan cannot go below 70 or above 180 mg/dL. In addition, the bolus target plan cannot exceed more than ±20 mg/dL of the patient pre-meal target ranges, as defined by the HCP in the patient settings page.
	Potential number of target periods	Always 4: morning, afternoon, evening and night time.

NOTES:

- **Plan threshold values in Table 11 are not configurable.**
- **An insulin pen only enables discrete injection unit values. Some pens only enable whole injection units (such as 1.0, 2.0, 3.0 and so on) and other pens enable half injection units (such as 0.5, 1.0, 1.5 and so on). endo.digital rounds the recommended value for basal plan and sliding scale plans to the closest value that is supported by the pen. For example, for a pen that supports half units, a value of 1.25 is rounded to 1.0 and a value of 1.26 is rounded to 1.5.**
- **The endo.digital system always uses the actual amount of insulin that was delivered (basal and bolus) for its analysis. In case there is no basal delivery data reported, the endo.digital will use the basal plan from the DreaMed Diary App. In addition, if the actual values of CR and CF at the time of each bolus are available, endo.digital will use this data as well. However, the recommended changes to the patient's plan are always calculated as a percentage of the most recent settings that were in the DreaMed Diary App.**
- **endo.digital will not recommend changes to the patient's insulin type.**

endo.digital uses the results of the analysis of each event to create the patient's recommendation. This recommendation aims to treat patterns of high and/or low glucose values that occur throughout the day. The recommendation may include changes to the Basal Plan and Bolus Plan, and diabetes management tips about how to avoid unbalanced glucose levels. The recommendations could include the creation of new injection dosages or modifications of existing ones by changing the values of each. If the patient experienced a glucose imbalance and endo.digital was not able to create a recommendation, endo.digital will indicate it.

Caution

endo.digital requires a certain number of bolus events to conclude a recommendation about a particular time of day. Please note that the recommendation could be generated by a limited number of analyzed events. For example, a patient may have had only a few injections in the morning. endo.digital may change this patient's morning insulin based on a small amount of data.

Add all alerts and behavioral tips

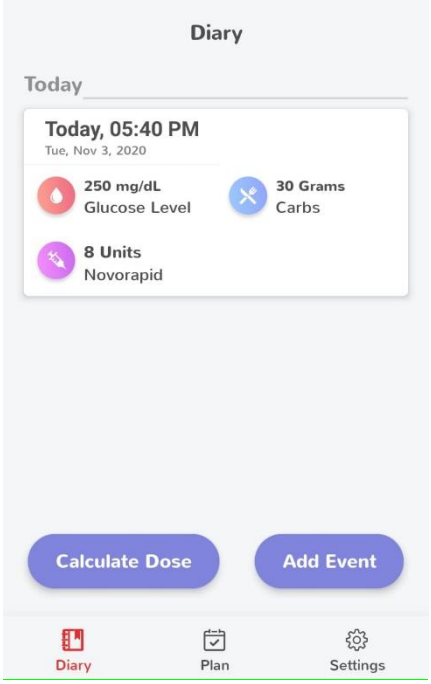
9. Information for Prescribers

WARNING

Please ensure that your patient is an appropriate candidate for MODI. Prior to use, confirm that the patient has sufficient understanding of diabetes management and is comfortable using technology.

10. Using the Bolus Calculator

The Bolus Calculator helps you calculate the amount of insulin you need to inject for your bolus, based on your current bolus plan.



WARNING

Before using the Bolus Calculator, make sure that your bolus plan is correct and up to date. Using an incorrect or an outdated treatment plan may lead to potential harm.

Caution

In order to prevent potential insulin overdose, make sure that all of your bolus injections from the last three hours are logged correctly in the diary.

WARNING

It is highly recommended to configure your smartphone use date and time settings directly from the network, in order to capture your events correctly

- **Android:** In the **Settings** menu ➔ **System** ➔ **Date & Time enable Use network provided time and network provided time zone**.

iOS: In the **Settings** menu ➔ **General** ➔ **Date & Time** ➔ turn on **Set automatically.**

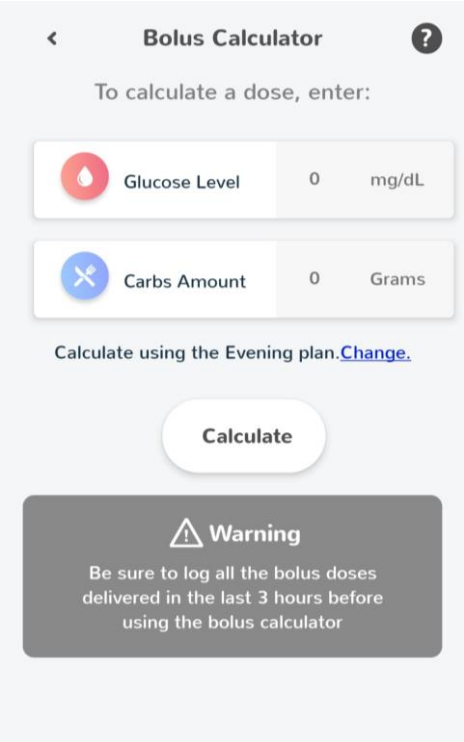
Tap the **Calculate Dose** button and follow the displayed instructions for calculating your bolus. Enter your measured blood glucose level and information about the meal you anticipate eating. You can enter either of these values or both for the calculation.

Caution

Be sure to use your current blood glucose level. Using an incorrect or outdated blood glucose level may lead to potential harm.

You can calculate the bolus using the bolus plan that matches the current time segment (i.e. morning, afternoon, etc.). For example, the screen below shows that the bolus will be calculated based on the Evening plan. Tap **Change** to calculate your dose using the plan of a different segment.

The Diary app does not permit you to change the hours of a plan. Therefore, for example, if you plan to eat your dinner at 4:55 pm instead of after 5:00 pm, you should change the segment to Evening plan.



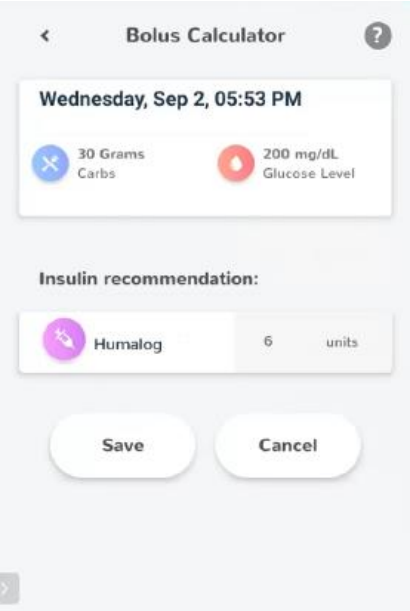
Tap the help button at the top right corner of the screen to view a quick Bolus Calculator guide.

Tap **Calculate** to generate the bolus recommendation.

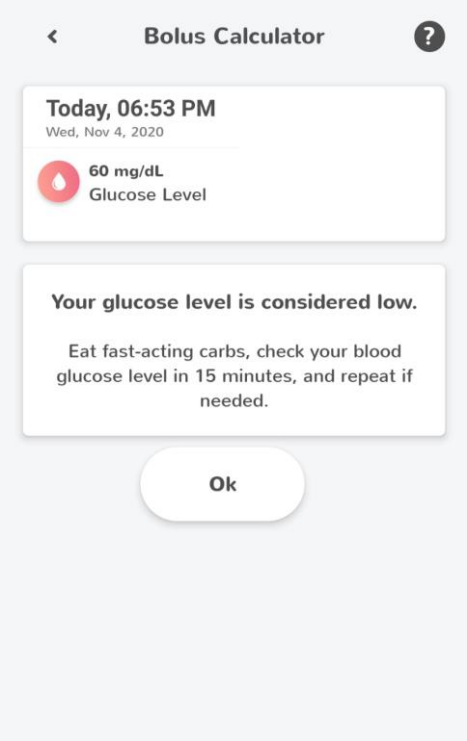
Caution

Be sure to log all your insulin events from the last four hours or at least as specified in the **Active Insulin Time** found in your general settings.

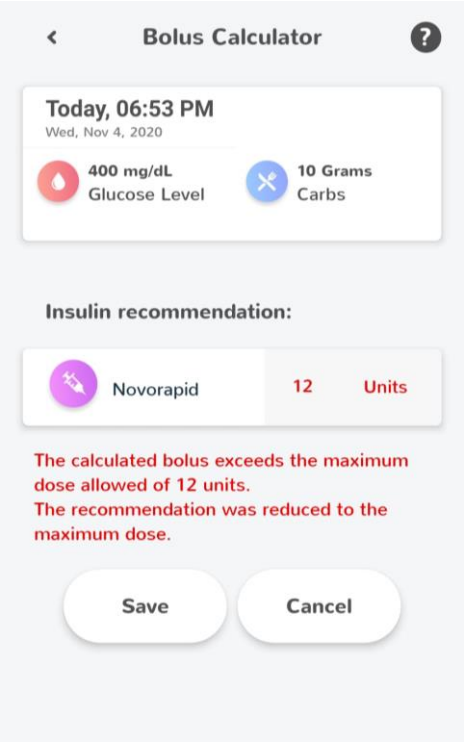
A recommendation is generated for the bolus. Tap **Save** to confirm that you intend to inject the amount of insulin recommended by the Bolus Calculator and to save the event in your diary. If you need to modify the recommended amount, you can do so and then tap **Save** to confirm that you intend to inject that amount of insulin.



If your blood glucose is below 70mg/dl and you have not entered any carbs, a message indicating that you should eat fast-acting carbs in order to raise your blood glucose level, and then recheck your blood glucose in 15 minutes is shown.



The following screen displays when more than the **Maximum Recommended Dose** (see page **Error! Bookmark not defined.**) is recommended for the bolus.



Bolus Calculator algorithm

The Bolus Calculator uses the following equation to calculate the suggested amount of bolus:

$$Bolus = Meal\ Bolus + Correction\ Bolus$$

Note:

- The calculated bolus amount is rounded down to the nearest unit.
- The calculated bolus amount cannot exceed the maximum bolus amount, as defined in the general settings section, or go below 0 Units.

The amount for the meal is taken from your insulin plan for the meal at the time of the bolus.

- **Fixed meal** – For users who take specific insulin doses for **breakfast, lunch, and dinner –** indicate if you are about to eat the relevant meal for the current time of the day, or calculate a correction bolus to lower your high glucose, without eating a meal.
- **Meal size** – For users who select a dose based on meal size (e.g., small, normal, large) – indicate the meal's carbohydrate content size you are about to eat, or select no meal to calculate a correction bolus to lower your high glucose, without eating a meal.

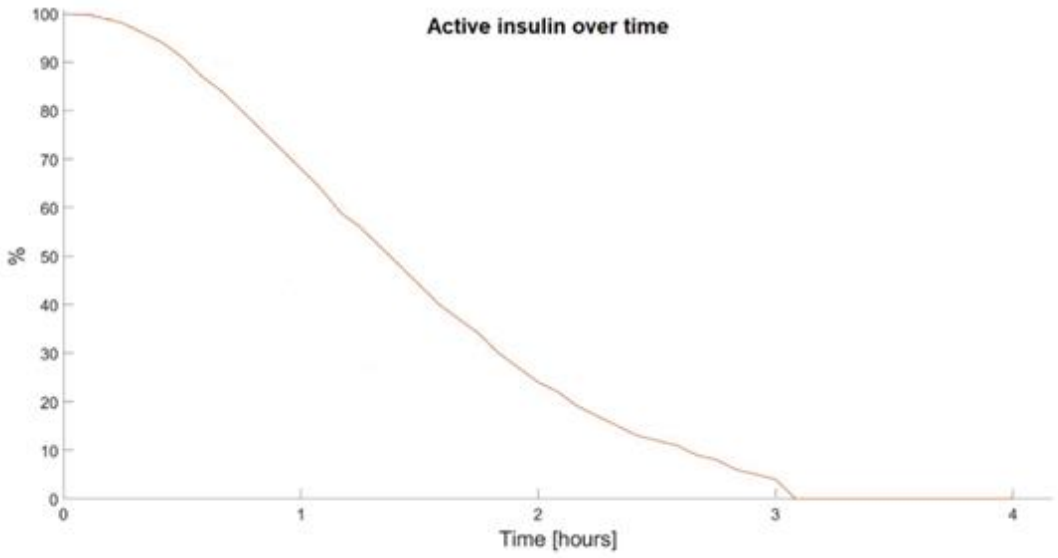
The correction bolus calculation depends on the entered glucose level (BG) and the bolus plan's sliding scale correction table.

The correction bolus will never be reduced below 0.

$$Correction\ Bolus = < Insulin\ value\ for\ the\ current\ BG > - Active\ Insulin$$

Note: In practice, the AI is calculated using the following decays:[3]

[3] Adapted from Mudaliar et al, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501



The total dose is calculated by adding the meal dose and the correction dose, rounded to the nearest insulin unit.

Example I: Eating, BG above target and no AI

Breakfast (units)	4
Correction from sliding scale (units)	2
Active Insulin (AI):	0

$$\text{Correction Bolus} = Correction\ Insulin - AI = 2 - 0 = 2U$$

$$\text{Suggested bolus} = 4 + 2 = 6\ U$$

Example II: Eating, BG above target, with AI that nullifies the correction amount

Small breakfast (units)	5
Correction from sliding scale (units)	2
Active Insulin (AI):	3

$$\text{Correction Bolus} = Correction\ Insulin - AI = 2 - 3 = -1 \xrightarrow{nullify\ value} 0\ U$$

$$\text{Suggested bolus} = 5 + 0 = 5\ \text{U}$$

Example III: Not eating, BG above target, with AI

No Meal (units)	0
Correction from sliding scale (units)	3
Active Insulin (AI):	1

$$\text{Correction Bolus} = Correction\ Insulin - AI = 3 - 1 = 2\ U$$

$$\text{Suggested bolus} = 0\ + 2\ = 2\ \text{U}$$

Example IV: Eating, No current BG, with AI

Small breakfast (units)	4
Current BG (mg/dL):	-
Correction from sliding scale (units)	-
Active Insulin (AI):	1

$$\text{Correction Bolus} = 0\ U$$

$$\text{Suggested bolus} = 4 + 0 = 4\ \text{U}$$


MODI Diary

11. Troubleshooting

12. Appendix A –Diabetes Management Tips

13. Appendix B - Glossary

Table 6 – Glossary

Term	Definition/Description
Active insulin	Amount of insulin that has been delivered and is still having an effect in lowering the blood glucose.
Insulin on board (IOB)	Same as Active Insulin. Amount of insulin that has been delivered and is still having an effect in lowering the blood glucose.
Active insulin time	The time (measured in hours) it will take until the bolus of insulin stops affecting the blood glucose. This time is used by a Bolus Calculator when calculating a bolus.
Basal insulin	A long acting insulin that is used to maintain a baseline amount of insulin throughout the day.
Basal plan	A set of one or more basal injections that covers a full-day period.
Bolus	Amount of insulin that is given to treat high glucose levels and/or carbohydrate intake.
Glucose target	Indicates the value toward which the glucose level is corrected. This target is used for correcting high glucose levels manually or in the Bolus Calculator.
Carbohydrate Ratio (CR)	Indicates the ratio between an amount of carbohydrates and insulin. The ratio is used for covering carbohydrate intake.
CGM / Sensor	A Continuous Glucose Monitoring device, which is the sensor that continuously measures the interstitial glucose levels.
Correction Factor (CF)	Indicates how much one unit of insulin reduces glucose levels. This factor is used for correcting high glucose levels.
DKA	Diabetic Ketoacidosis, which is a life-threatening complication of diabetes mellitus.
Glucometer	Any blood glucose meter.
Pre meal glucose target range	Indicates the desired glucose range before a meal, specifically before breakfast. This glucose target range is used in MODI's insulin plans.
U-100	Type of insulin in which every milliliter (ml) of liquid contains 100 units of insulin.
U-200	Type of insulin in which every milliliter (ml) of liquid contains 200 units of insulin.

THIS PAGE NOT FOR PUBLICATION

AUDIT TRAIL			
Ref. #	**Version**	**Change Description**	**Date**
–-	1.0	Initial version	

Remarks:
N/A

	Name	**Position**	**Signature and Date**
Prepared by	Eran Agmon	VP Product	
Reviewed and approved by	Adi Berkovitch	VP RA & QA	