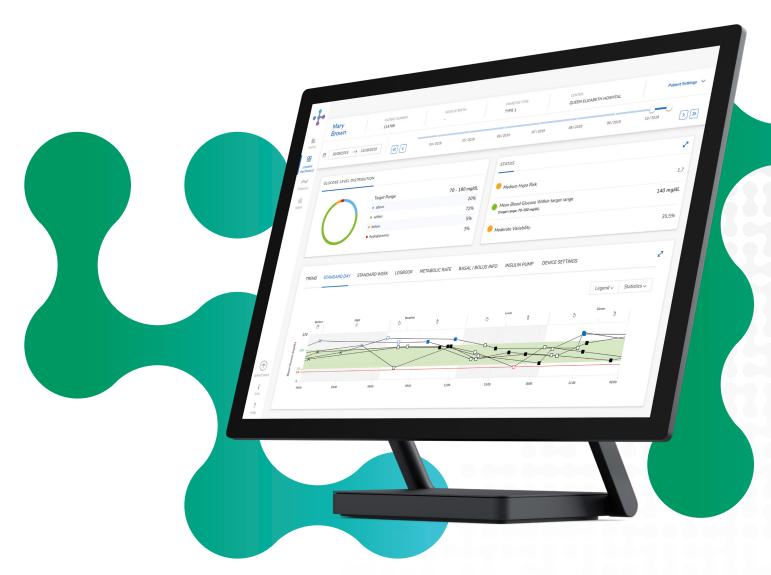


Reports Interpretation Guide

Clinical use of the RocheDiabetes Care Platform reports.



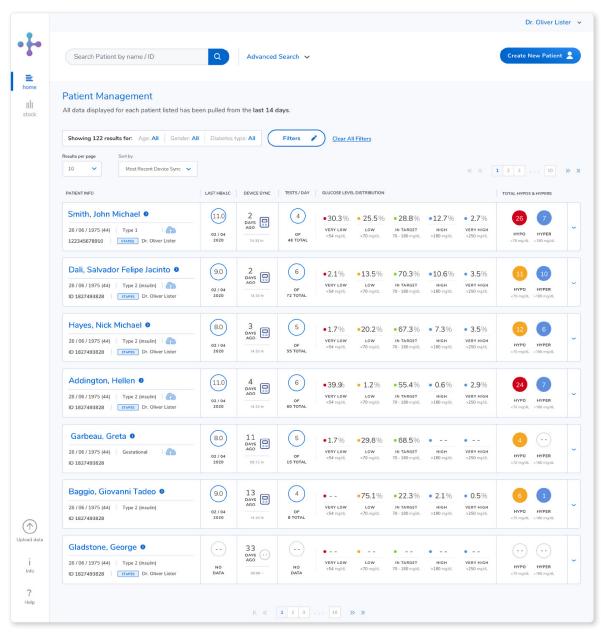
Contents

Patient Management3
Patient Dashboard
Trend Report
Standard Day Report
Standard Week Report8
Logbook Reports9
Metabolic Rate Report10
Insulin Pump Reports11
Patterns
Summary
References14
Additional Support15

The RocheDiabetes Care Platform is a decision support tool designed to help healthcare professionals (HCPs) quickly connect to actionable insights from patient data for a more personalized approach to diabetes care. The digital platform organizes data for easy visualization to help discover patterns and draw attention to areas that need intervention. It enhances collaboration with patients through simple reports that can facilitate diabetes management skills and engagement communication.



Patient Management



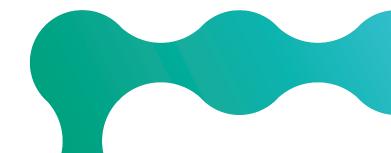
After logging in to the RocheDiabetes Care Platform, HCPs can view high-level information for the last 14 days for multiple patients on the Patient Management dashboard.

By default, the dashboard lists patients alphabetically by last name. Filters and advanced search options allow HCPs to refine the list or search for specific patients using patient ID, diabetes type, average blood glucose, and more.

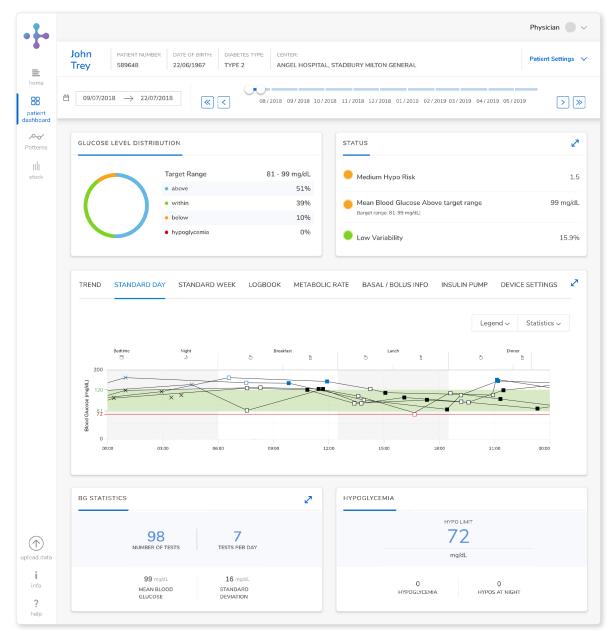
Each row displays information for the patient, including the date and time of last device sync, glucose level distribution, and the number of hypo and hyper events.

Secondary information about hypos and hypers can be viewed by clicking the drop-down arrow beside the HYPO and HYPER values.





Patient Dashboard



The RocheDiabetes Care Platform is designed to enable rapid navigation from a dashboard that supports consistent clinical evaluations and decision-making.

The patient dashboard provides a comprehensive view with the flexibility to change the report from Standard Day to one of the other reports simply by clicking the report name, while maintaining a view of key information "cards" that provide test frequency, glucose distribution and hypoglycemia statistics.

From the patient dashboard, HCPs can choose to go deeper into the information cards, either to access a different view or to expand information.



This symbol indicates expandable cards on the patient dashboard HCPs can click for additional information or details.

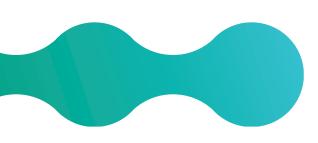


Controls for the time range enable HCPs to adjust the report period by selecting calendar dates or dragging sliders to increase or decrease the range.

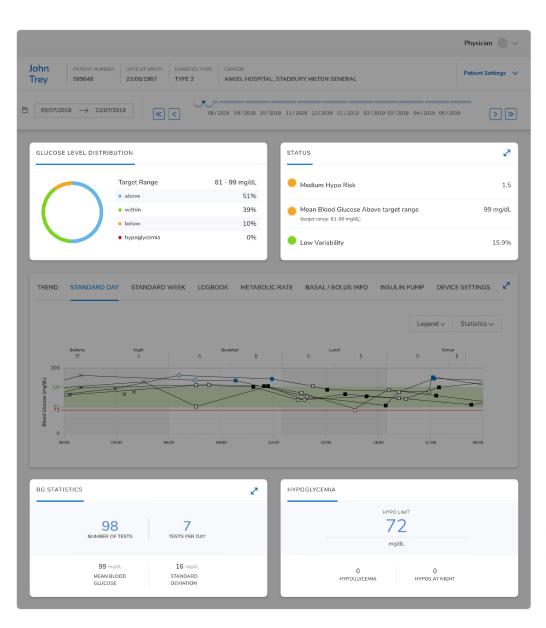
Patient Dashboard: A Closer Look

The information cards on the patient dashboard add specific benefit to a quick data analysis. They provide simple visuals to engage patients on overall goals for diabetes management and to analyze areas of effectiveness from changes since the last visit, such as glucose distribution and testing frequency.

Glucose Level Distribution provides an easy and practical way to work with patients on glycemic targets and to visualize improvements or changes from a previous period.



BG Statistics provides a quick overview of the number of measurements made and indicates if there are a sufficient quantity to support treatment decisions.^{1,2} A lack of sufficient tests can facilitate education about glucose monitoring and its importance in decision-making.



Status provides a rapid view of the risk of hypoglycemia, using the Low Blood Glucose Index,^{3,4} mean blood glucose and variability.⁵

Hypoglycemia provides the number of glucose tests in the hypoglycemic range and if they occurred at night.

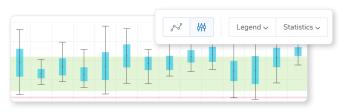
Trend Report

The Trend graph displays the dynamics of glucose results and diabetes data in chronological order, supporting a view of changes in glucose levels over time. It can be used to quickly evaluate glucose control over time with a pattern management process that has been found to support better overall glycemic control when used in collaboration with healthcare providers and their patients.8

The trend graph provides useful information for assessing the following clinical scenarios:

- > Have there been recent changes in glycemic control?
- Did glucose values improve after a therapeutic adjustment, such as a medication change?
- Does the patient experience elevated glucose results the day before changing an infusion set? Do glucose levels return to the target range after changing the infusion set?

On most reports, HCPs can adjust the view using a toggle for a linear graph or box graph view. They can also click to view a drop-down display for the graph Legend or Statistics.

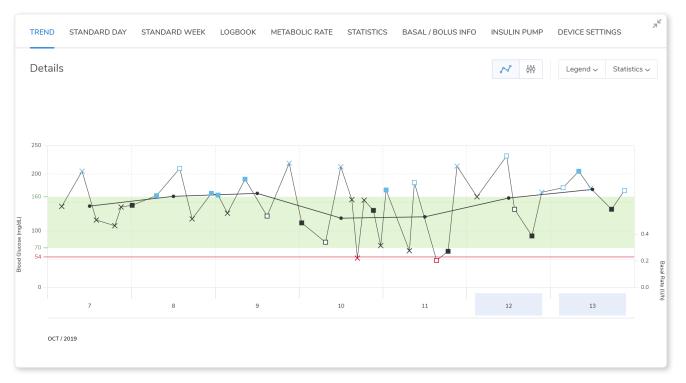


Box graph

Pattern management process

The process is a step-wise analysis with the following four steps:

- 1. Identify the glycemic abnormality in the suggested order:
 - » Hypoglycemia
 - » Fasting hyperglycemia
 - » Postprandial hyperglycemia
- 2. Determine timing and frequency of occurrence
- 3. Investigate potential causes
- 4. Take action

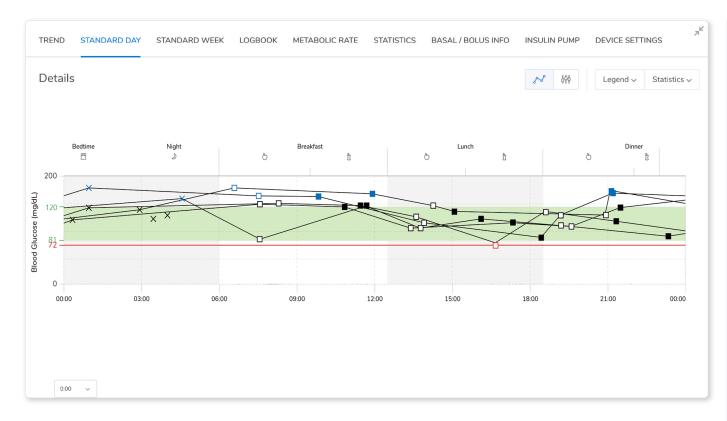


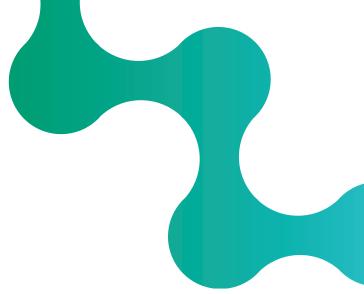
Linear graph

Standard Day Report

Standard Day organizes glucose and contextual data such as insulin therapy and carbohydrate consumption across a 24-hour day by overlaying all the data in pre-defined time-time blocks: pre- and post-meal, bedtime, and night. The Standard Day report is frequently used to assess blood glucose before and after meals to help patients understand the effects of meal and lifestyle choices on glucose levels

and assist HCPs in identifying and tracking postprandial hyperglycemia. Evidence suggests that reducing excessive postprandial excursions may be equally or more important than reducing fasting or preprandial glucose in relation to achieving overall HbA1c goals and in reducing risk of diabetes-related complications.^{6,7}





Standard Day supports an analysis of daily glycemic patterns and facilitates a discussion with patients regarding diabetes self-management. It can help identify daily recurring challenges, for example:

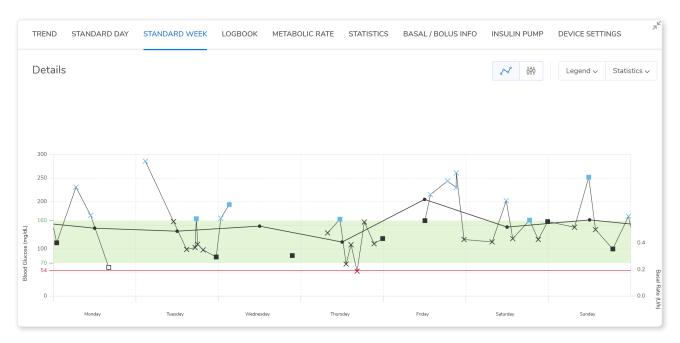
- Does the patient have enough glucose results within a specific time block for meaningful analysis?
- Are results consistently too high or low at a certain time of day?
- Do patterns in glycemic variability occur at certain times of day?
- Do the post-meal excursions or glucose results exceed the target glucose?
- Is the patient experiencing low glucose levels overnight?
- Are there potential challenges with antihyperglycemic medication timing and adherence based on out-of-range glucose results in a specific time block?

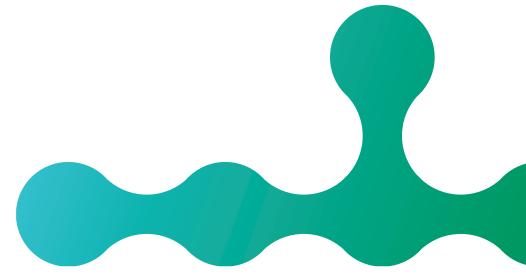
Standard Week Report

While Standard Day is useful for assessing intra-day glucose factors, such as meals or medication, the Standard Week report supports day-to-day pattern analysis for changes in glycemic control on specific days. This report displays the days of the week from Monday to Sunday in an overlay view across the selected time range.

Standard Week is usually a second level report used to investigate causality of a concerning glucose pattern. It can help detect whether the glucose challenge occurs on a particular day of the week; for example, on days when a patient plays sports or on weekends. This assessment can help direct therapy modification to accommodate repeating events throughout the week or lifestyle differences between workdays and non-work days (weekends).

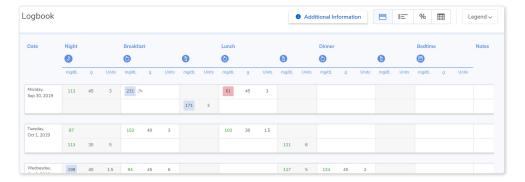
This report may be useful for pump therapy patients who could benefit from a different basal profile to accommodate repeating events that occur on specific days.



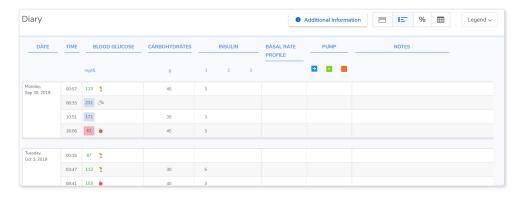


Logbook Reports

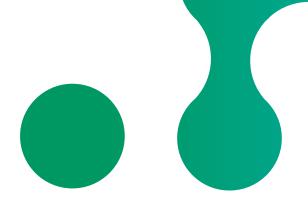
There are four views available for the Logbook by expanding the Patient dashboard view: Diary, Daily Statistics and 24-Hour Logbook. The additional formats and data are designed to accommodate personal clinician preferences and can be used to assess different aspects of the patient's diabetes management.

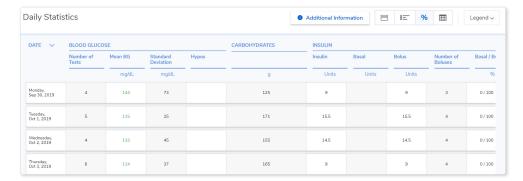


Logbook is useful to explain the cause and effect of insulin and carbohydrates on pre- and post-meal glucose levels to patients with limited ability to understand complex graphs. It can also help to evaluate the effectiveness of insulin-to-carb ratios and bolus doses.



The **Diary** incorporates insulin pump data and can be used to assess the patient's use of pump features, such as different types of boluses, and to determine the efficacy of those choices.





Daily Statistics shows the relationship between the number of glucose tests, boluses, carbs and insulin doses per day. It provides a rapid analysis of days with better outcomes than others, which can be helpful to encourage patient engagement.



The **24-Hour Logbook** provides rapid assessment of diabetes management effectiveness, such as insulin-to-carb parameters and bolus type.

Metabolic Rate Report

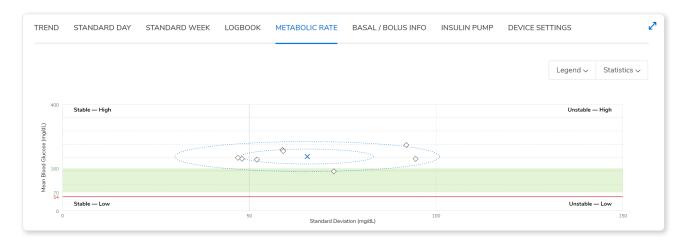
Metabolic Rate calculates the mean blood glucose and the standard deviation (SD/variance of the values) for each day of the analyzed time range. These two results together provide the coordinates for an entry (per day) in the chart.

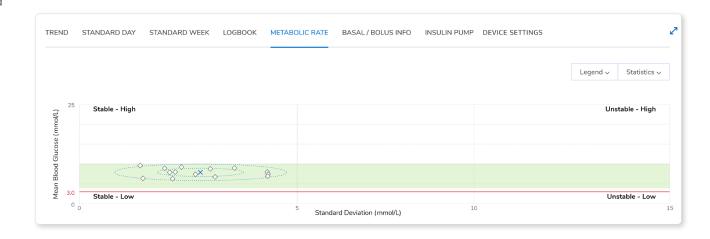
- > The mean blood glucose is plotted along the y-axis
- > The standard deviation is plotted along the x-axis

The chart is split into four quadrants, described by the attributes "stable/unstable" (referring to standard deviation) and "low/high" (referring to mean blood glucose). This gives each quadrant two attributes.

The Metabolic Rate graph provides a fast visualization to overall metabolic control, by providing the extent of glycemic exposure and glycemic variability.

Good metabolic control (example right) can be recognized by the fact that there are as many markers as possible in the "stable-low" quadrant (bottom left), with no cases of hypoglycemia in the respective time range.







Insulin Pump Reports

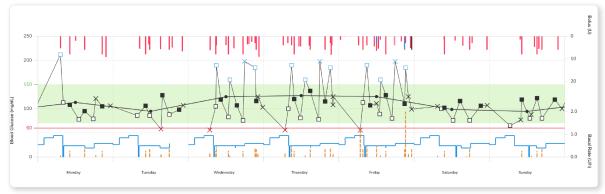
The RocheDiabetes Care Platform includes three reports developed to provide specific information for patients who use pump therapy:

- > Basal/Bolus
- > Insulin Pump
- > Device Settings

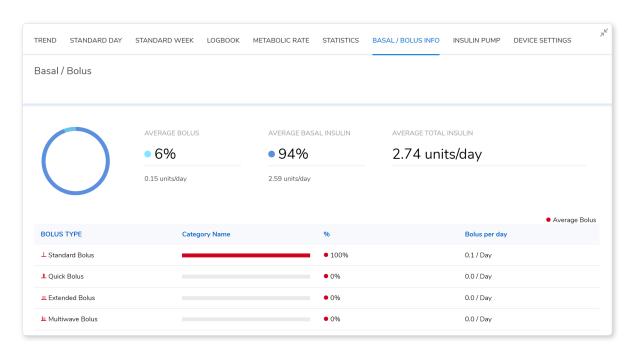
In addition to pump-specific reports, any patient with data synchronized from a supported insulin pump device can view available pump data on: Standard Day, Standard Week and Trend reports.

The **Basal/Bolus report** provides a summary for the report range of the total amount of daily insulin and boluses, and the ratio basal/bolus. This report is useful to assess the total daily dose of insulin, its basal/bolus distribution, and can help assess the following:

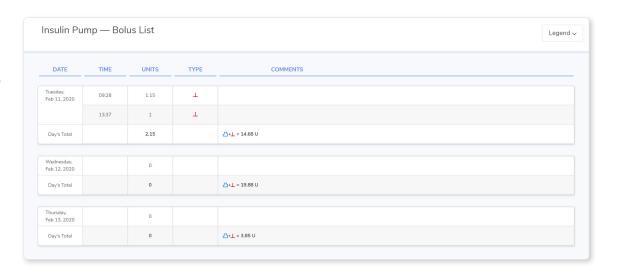
- Patient pump use and intensity of interaction with specific features of the pump
- If the disparity between basal and bolus is too wide, and help facilitate adjustment as appropriate
- Bolus per day to help initiate discussion about appropriate bolus frequency
- Use of different bolus types to manage different food choices, such as extended bolus use with high fat or high carbohydrate meals



In the example shown (above), Bolus (U) and Basal Rate (U/h) information can be viewed along with the available glucose results.



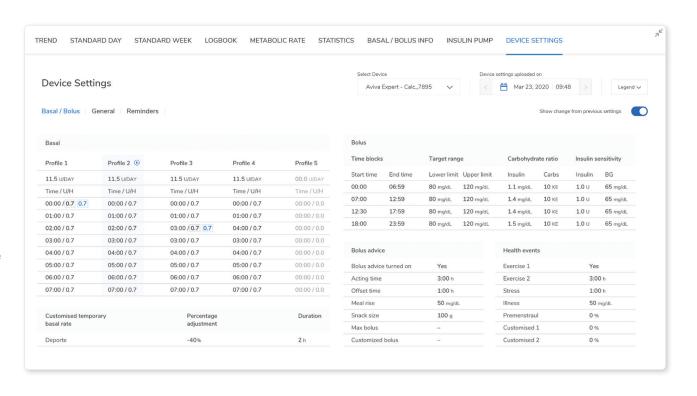
The **Insulin Pump—Bolus List report** provides a tabular view of all daily bolus doses along with the time of dose, amount (U) and bolus type. This report is helpful to see how many boluses have been delivered and assess patient use of the bolus advisor support, if available.



Device Settings shows the settings of the patient's downloaded and connected devices (e.g., pumps, meters) to provide all the relevant device information on one screen without having to access that information on actual devices.

- Basal/Bolus shows all of the basal profiles, with previous settings presented in blue, as well as the predefined temporary basal rate. The bolus device settings provide all of the parameters that are set to enable bolus advice
- General provides additional insulin delivery and meter settings
- Reminders displays a record of all reminders that have been set on the specified device

Quickly compare current and previous device settings by changing the "Device settings uploaded on" date or click to highlight changes from previous settings.



Patterns

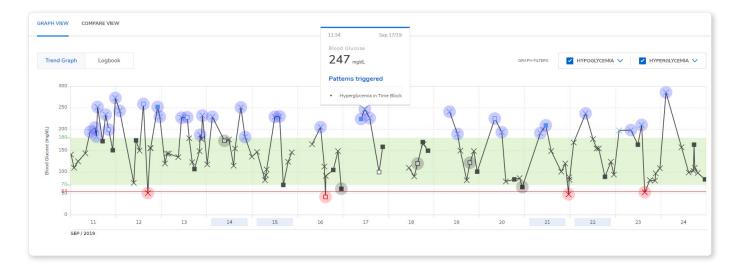
Pattern management in diabetes has been defined as the systematic interpretation of self-monitored blood glucose (SMBG) and other self-management data over time to determine whether changes are needed to optimize blood glucose (BG) control.9

The RocheDiabetes Care Platform recently introduced the pattern management feature, which provides visual indicators for up to 21 different glucose patterns outside of pre-established thresholds, potential causal factors, adherence, or device usage patterns used in clinical routines. Patterns are organized into five different groups:

- > Hypoglycemia
- > Hyperglycemia
- › Blood Glucose Variability
- Use of System
- > Treatment Adherence

The pattern feature provides useful information for quickly detecting glucose control and diabetes self-management patterns and starting a collaborative conversation with the patient. It provides an opportunity to acknowledge positive patterns, such as minimal hypo events for patients on insulin therapy or enough blood glucose test results to support a clinical assessment. After addressing positive

observations, focus on patterns outside desired thresholds. HCPs can engage patients in a discussion on causal factors and potential changes for therapy optimization. The pattern feature provides a longitudinal view of patterns, which shows the different pattern status with color indicators. This view supports comparison of different weekly, monthly, and quarterly intervals.



A visual color indicator applied to each pattern and group signals if a pattern has been triggered.

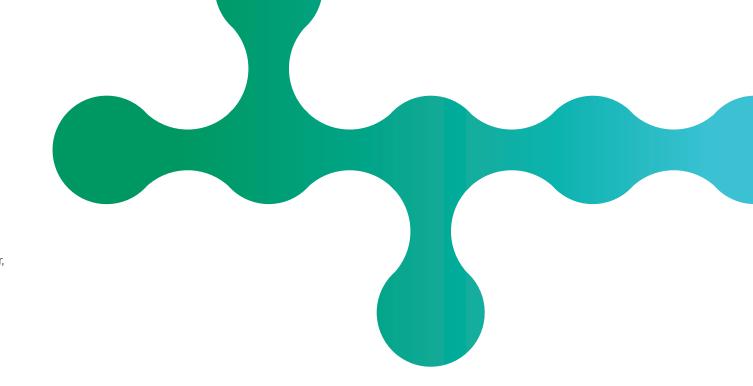
- Green—no pattern triggered
- Red—pattern triggered
- Gray—insufficient data

Patterns can be viewed in a Trend Graph or Logbook format. Checkboxes (upper right) enable the HCPs to filter patterns shown by hypoglycemia or hyperglycemia.



Summary

The RocheDiabetes Care Platform has been thoughtfully designed with easily navigated reports to support consultations and collaboration with patients. HCPs can share reports with patients to provide objective feedback on test frequency, diet, medication and exercise. The reports can help patients visualize the connection between behavior, medication, and glycemic control.



References

- Kan K, Zhu W, Lu F, Shen Y, Gao F, Mo Y, et al. Contribution of Structured Self-Monitoring of Blood Glucose to the Glycemic Control and the Quality of Life in Both Insulin- and Noninsulin-Treated Patients with Poorly Controlled Diabetes. Diabetes Technol Ther. 2017;19(12):707-14.
- Parkin CG, Buskirk A, Hinnen DA, Axel-Schweitzer M. Results that matter: structured vs. unstructured self-monitoring of blood glucose in type 2 diabetes. Diabetes Res Clin Pract. 2012;97(1):6-15.
- Kovatchev BP, Cox DJ, Kumar A, Gonder-Frederick L, Clarke WL.
 Algorithmic evaluation of metabolic control and risk of severe
 hypoglycaemia in type 1 and type 2 diabetes using self-monitoring
 blood glucose data. Diabetes Technol Ther. 2003;5(5):817-28.

- Kovatchev BP, Cox DJ, Gonder-Frederick LA, Young-Hyman D, Schlundt D, Clarke W. Assessment of risk for severe hypoglycaemia among adults with IDDM: validation of the low blood glucose index. Diabetes Care. 1998;21(11):1870-5.
- Hirsch I, Parkins, C. Is A1c the best measure of glycemia. Is A1c the best measure of glycemic control? . US Endocrinology. 2005;1.
- Riddle MC. Erratum. Basal Glucose Can Be Controlled, but the Prandial Problem Persists-It's the Next Target! Diabetes Care 2017;40:291-300. Diabetes Care. 2017;40(8):1133.
- 7. Ceriello A, Genovese S. Atherogenicity of postprandial hyperglycemia and lipotoxicity. Rev Endocr Metab Disord. 2016;17(1):111-6.

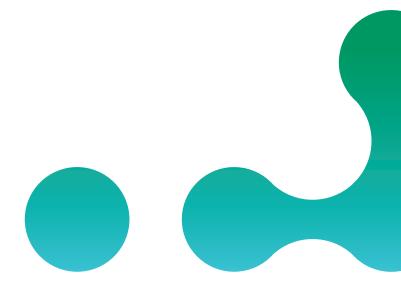
- Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulintreated type 2 diabetes: results from the Structured Testing Program study. Diabetes Care. 2011;34(2):262-7.
- Pearson J, Bergenstal, R. Fine-Tuning Control: Pattern Management Versus Supplementation. Diabetes Spectrum. 2001;Apr;14(2):75-8.

Additional Support

For a full list of Customer Support numbers and contact information, refer to the RocheDiabetes Care Platform Help Guide.

www.diabetescareplatform.com

For support, call 1-800-628-3346.





Roche Diabetes Care, Inc. 9115 Hague Rd, Indianapolis, IN 46256

ROCHE DIABETES CARE and ROCHEDIABETES CARE PLATFORM are trademarks of Roche. All other product names and trademarks are the property of their respective owners. © 2020 Roche Diabetes Care. © 2020 Roche. 348-56685K-1020