CareLink[™] software

Management Software for Diabetes

REPORT REFERENCE GUIDE

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How to use this guide

Each type of CareLink™ report and its components are described in the following sections. Report data used to generate the sample reports was from sample patient data.

If there are fewer than five days of sensor glucose (SG) readings in the selected period, the Therapy Management Dashboard and Episode Summary reports will not be available.

In CareLink™ reports, sensor values at or below the low glucose target value are reported as hypoglycemia and sensor values at or above the high target are reported as hyperglycemia. You can change the high and low target during the report generation process.

Note: CareLink™ reports are intended for use with a healthcare professional only. These reports are provided to patients to enable discussion and assessment of a patient's glucose management history with their healthcare professional. Patients should always consult with their healthcare professional before adjusting pump settings.

The standard for units of glucose measurement varies by country. The illustrative reports shown herein reflect mmol/L values. To convert to mg/dL, multiply by 18.0182. Actual reports may also look different based on device data uploaded, device compatibility and regional approval status. For more information, please refer to CareLink™ FAQ on the Home page.



Page 2 - Therapy Management Dashboard report This report provides a summary of the patient's glucose, carbohydrate, and insulin data for the selected period. It provides an overview of a patient's glycemic control (daily, overnight, and at meal times) and comprehensive statistical data.



Page 5-Adherence report This report presents patient behavior data for a selected period. It provides a review of a patient's adherence according to the indices of glucose measurements, bolus events, and insulin pump activities.



Page 7 - Sensor and Meter Overview report This report summarizes meter glucose (and sensor glucose, if applicable), carbohydrate, and insulin data for a selected period. It provides an overview of a patient's glycemic control (daily, overnight, and at meal times) and comprehensive statistical data.



Page 11 - Logbook report This report presents meter glucose, carbohydrate, and insulin data for each hour of a selected period. It provides a diary of events recorded hourly, as well as daily averages and totals.



Page 13 - Device Settings Snapshot report This report presents the settings of a patient's device at the time of a selected upload. It can be used to help interpret other reports or simply to document a patient's device settings for the report range selected.

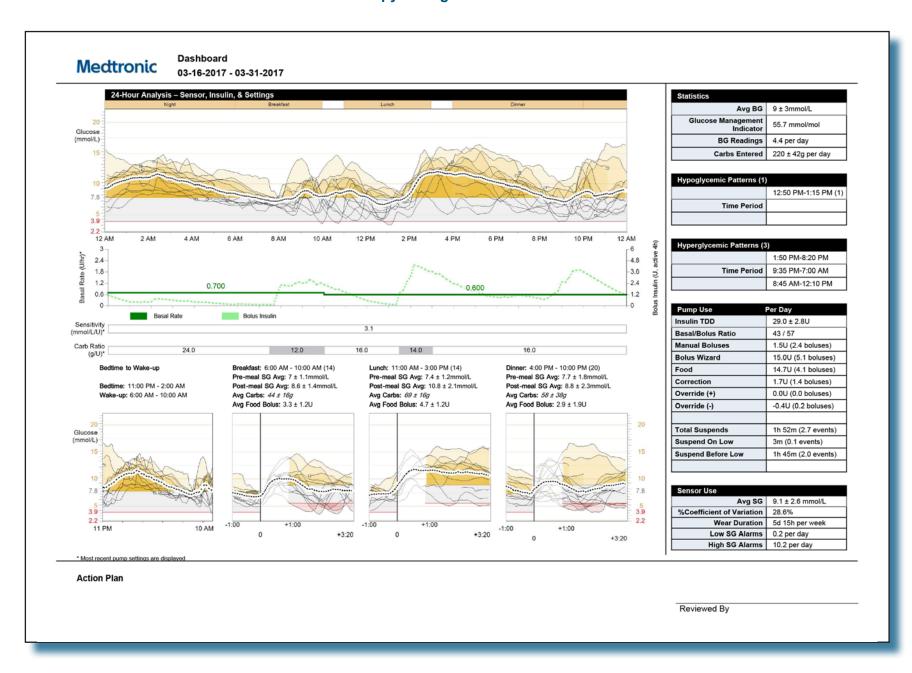


Page 15 - Daily Detail report This report presents glucose, carbohydrate, and insulin data for a selected day. It provides the details of a patient's glycemic control, bolus events, basal activity, and comprehensive statistical data.



Page 17 - Episode Summary report This report provides a summary of hypoglycemic and hyperglycemic patterns that last 30 minutes or more, and details of these episodes, including a description of some events preceding episodes of low and high glucose.

Therapy Management Dashboard



Therapy Management Dashboard

The Therapy Management Dashboard provides a summary of a patient's glucose, carbohydrate, and insulin data for a selected time period. It provides an overview of the patient's glycemic control (daily, overnight, and at meal times) and comprehensive statistical data.

This report is intended to provide a comprehensive summary to help you determine the level and quality of control your patient has achieved. The report provides detailed information of glycemic patterns throughout the day, data related to meals, and basal and bolus insulin delivery.

By viewing the different graphs and tables, you can examine periods of hypoglycemia and hyperglycemia. The report also shows events that may have preceded these excursions.

24-Hour Analysis – Sensor, Insulin & Settings graph

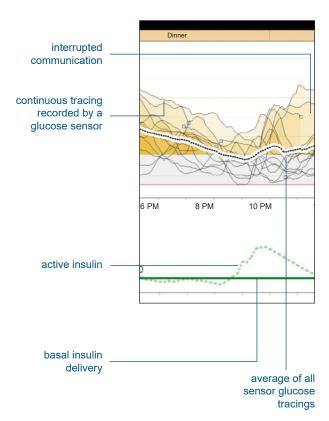
The upper portion of the 24-Hour Analysis – Sensor, Insulin & Settings graph overlays the sensor glucose tracings from each day during which a glucose sensor was worn. The patient's meal periods are shown in gold blocks above the graph. The patient's glucose target range is shaded gray.

The lower portion shows insulin delivery information. The most recently programmed insulin sensitivity factors and carbohydrate ratio profiles are shown below the graph.

Bedtime to Wake-up graph

The Bedtime to Wake-up graph combines the SG tracing recorded between bedtime and wake-up from each day on which a glucose sensor was worn during the reporting period. Bedtimes and wake-up times are based upon the patient's customized settings shown above the graph.

Note: If there are fewer than five days of sensor glucose readings in the selected period, the Therapy Management Dashboard report will not be available. Note that the report may show sensor hypoglycemic or hyperglycemic episodes where there were no corresponding blood glucose meter readings outside of the target range. Conversely, there may be blood glucose meter readings outside of the target range where no sensor hypoglycemic or hyperglycemic episodes are reported.



Glucose Management Indicator (GMI)

GMI provides an approximate value of laboratory-measured A1C based on average glucose measured by continuous glucose monitoring (CGM). GMI along with other data collected from CGM, can be used to create a personalized diabetes management plan. There may be instances where GMI and laboratory-measured A1C are different due to the duration of analyzed data. At least 14 days of information is needed to calculate the GMI.

Each unit of measure displays GMI differently. Separate formulas are used to calculate GMI for the mg/dL and mmol/L units of measure. Each unit of measure displays GMI differently. Separate formulas are used to calculate GMI for the mg/dL and mmol/L units of measure.

The mg/dL unit of measure displays GMI as a percentage using the following formula:

GMI(%) = 3.31 + 0.02392 x [mean glucose in mg/dL]

The mmol/L unit of measure displays GMI as a mmol/mol value using the following formula:

GMI(mmol/mol) = 12.71 + 4.70587 x [mean glucose in mmol/L]

Hypoglycemic and Hyperglycemic Patterns tables

The Hypoglycemic and Hyperglycemic Patterns tables provide the number and time periods during which hypoglycemia and hyperglycemia occurred. An episode must be at least 30 minutes in duration to be reported.

Standard Deviation (SD) and %Coefficient of Variation (%CV)

The most commonly used measurements for glycemic variability are SD and %CV. Glycemic variability is considered when the quality of glycemic control is evaluated. The SD is highly correlated with most other measurements of glycemic variability, which includes interquartile range. The %CV is correlated with risk of hypoglycemia.

Statistics				
Avg BG	9 ± 3mmol/L			
Glucose Management Indicator	55.7 mmol/mol			
BG Readings	4.4 per day			
Carbs Entered	220 ± 42g per day			

Hypoglycemic Patterns (1)				
	12:50 PM-1:15 PM (1)			
Time Period				

Hyperglycemic Patterns (3)				
	1:50 PM-8:20 PM			
Time Period	9:35 PM-7:00 AM			
	8:45 AM-12:10 PM			

Pump Use	Per Day
Insulin TDD	29.0 ± 2.8U
Basal/Bolus Ratio	43 / 57
Manual Boluses	1.5U (2.4 boluses)
Bolus Wizard	15.0U (5.1 boluses)
Food	14.7U (4.1 boluses)
Correction	1.7U (1.4 boluses)
Override (+)	0.0U (0.0 boluses)
Override (-)	-0.4U (0.2 boluses)
Total Suspends	1h 52m (2.7 events)
Suspend On Low	3m (0.1 events)
Suspend Before Low	1h 45m (2.0 events)

Sensor Use	
Avg SG	9.1 ± 2.6 mmol/L
%Coefficient of Variation	28.6%
Wear Duration	5d 15h per week
Low SG Alarms	0.2 per day
High SG Alarms	10.2 per day

Adherence report

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Adherence (1 of 5) 02/03/17 - 15/03/17

		Glucose Measi	urements	Bolus Events				Fill Events					-	
		BG Readings	Sensor Duration (h:mm)	Manual Boluses	Bolus Wizard Events	With Food	With Correction	Overridden	Rewind	Cannula Fills	Cannula Amount (U)	Tubing Fills	Tubing Amount (U)	Suspen Duration (h:mm)
0	Thursday 02/03/17								1					7:09
	Friday 03/03/17	-	-	-	-	-	-	-		-	-	-	-	-
	Saturday 04/03/17	-	-	-	-	-		-		-		-	-	-
	Sunday 05/03/17	-	-	-	-	-	-	-		-	-	-	-	-
•	Monday 06/03/17								4					23:56
•	Tuesday 07/03/17								1					2:18
	Wednesday 08/03/17		-	-		-		-		-	-	-	-	-
	Thursday 09/03/17	-	-	-	-	-	-	-		-	-	-	-	-
	Friday 10/03/17	-	-	-	-	-	-	-		-	-	-	-	-
	Saturday 11/03/17	-	-	-	-	-	-	-	-	-	-	-	-	-
	Sunday 12/03/17		-	-	-	-	-	-		-	-	-	-	-
	Monday 13/03/17	-	-	-	-	-	-	-	-	-	-	-	-	-
•	Tuesday 14/03/17	1												2:25
	Wednesday 15/03/17	4	22:50	2	2	2								5:01
	Summary	4.0/day	22h 50m	2.0/day	2.0/day	100.0%	0.0%	0.0%	6	0	-	0	-	1d 16h 4

Adherence report

The Adherence report presents data from a patient's insulin pump, blood glucose meter, and glucose sensor (if used). It can provide insight into the patient's glucose management behavior. The Adherence report summarizes up to two weeks of data. The sections of the report are described below.

Date column

The Partial day symbol may appear in this column to indicate that only partial data for the day was obtained. This can occur when a time change was made on the device.

Glucose Measurements

The Glucose Measurements section contains columns for the number of meter readings and the duration of glucose sensor use.

Bolus Events

The Bolus Events section consists of five columns that present total numbers for the following:

- · Manual boluses
- Bolus Wizard[™] events
- Bolus Wizard[™] boluses with a food component
- Bolus Wizard[™] boluses with a correction component
- Bolus Wizard[™] calculator overrides
- SmartGuard[™] Auto Mode bolus

Fill Events (priming events)

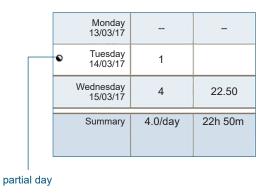
The Fill Events (or priming events) section includes columns for events related to filling or priming the cannula and tubing, including the number of events that occurred, and the volume of insulin used. The terminology in this section of the report differs depending on the pump model.

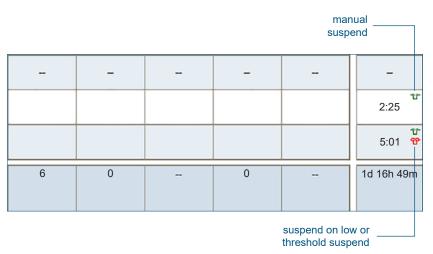
Pump suspends

The last column in the table shows the duration in hours and minutes that the insulin pump was suspended. The Threshold suspend or Suspend on low symbol may appear in this column to indicate at least one suspend was started on a given day.

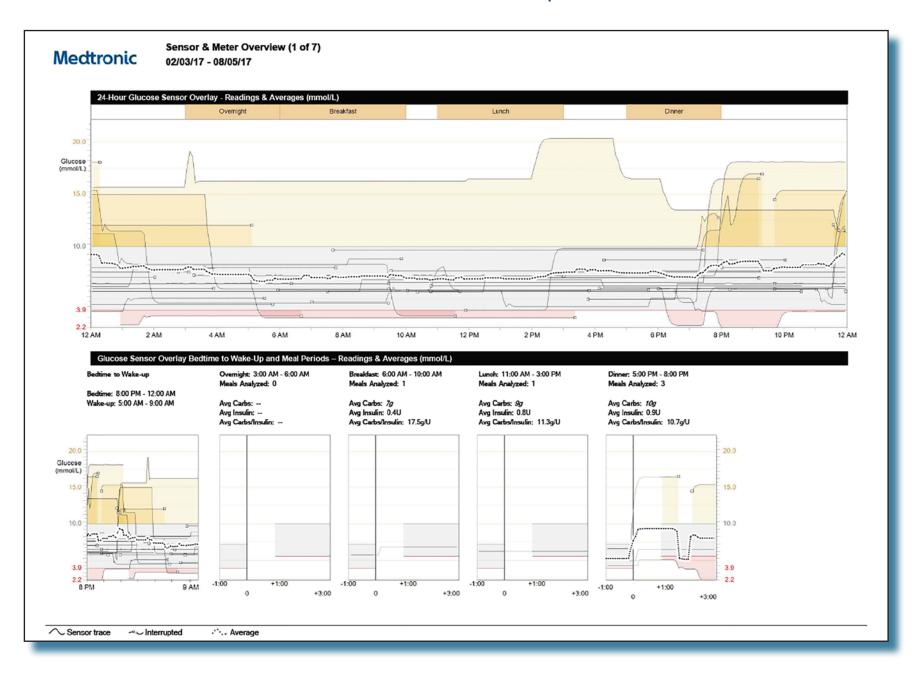
Summary row

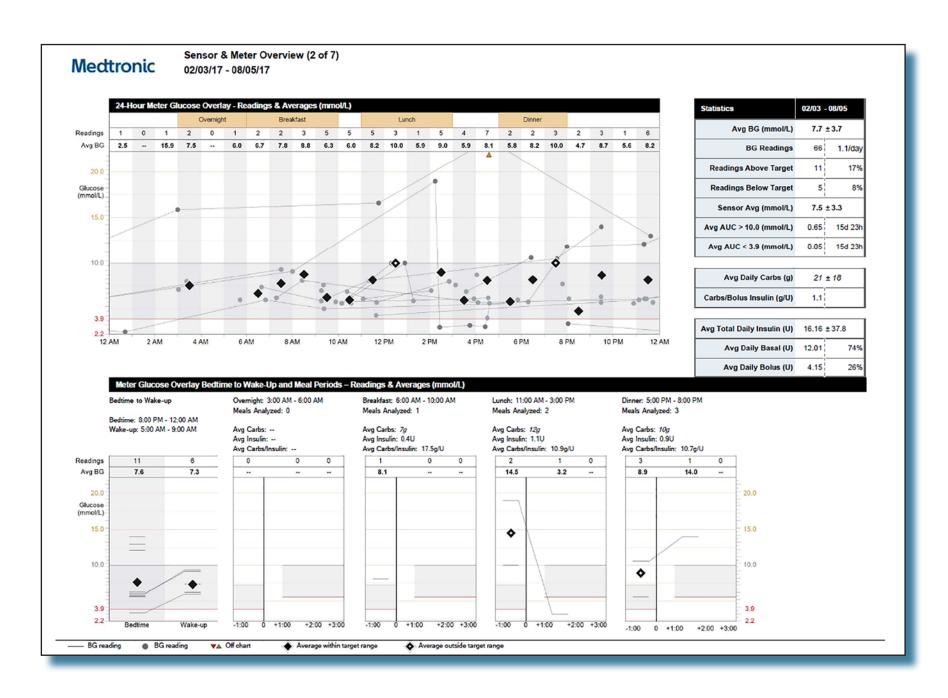
The averages, totals, or percentages are listed at the bottom of each column.

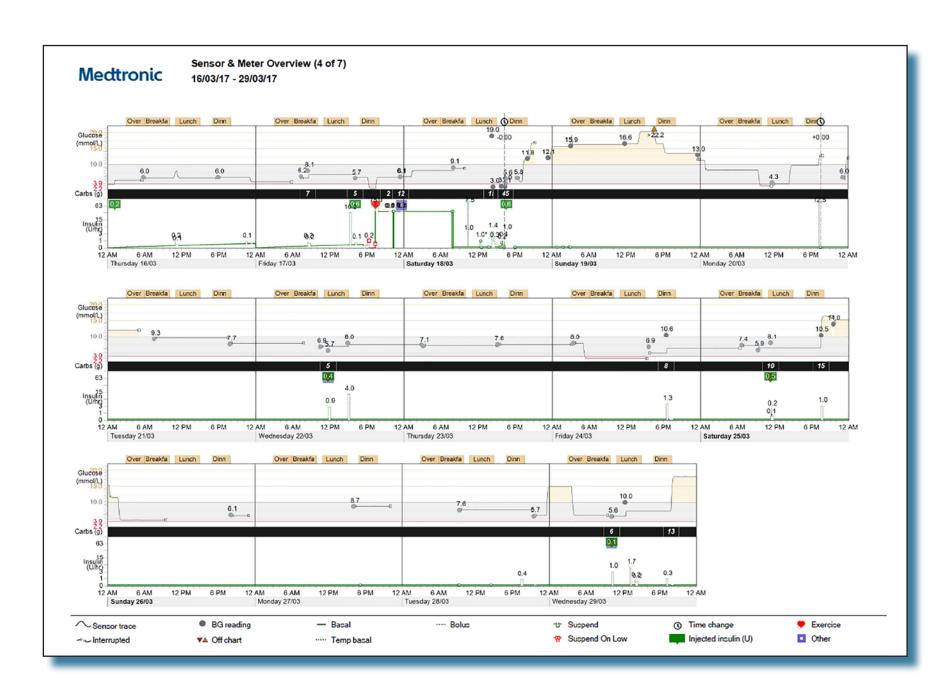




Sensor and Meter Overview report





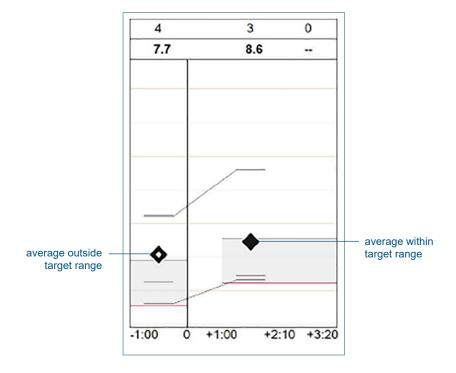


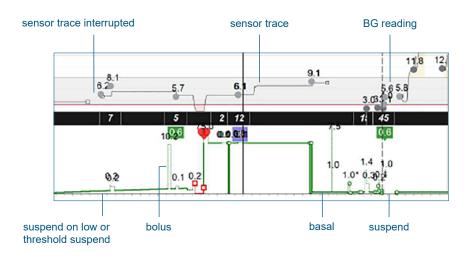
Sensor & Meter Overview report

The Sensor & Meter Overview report presents data from a patient's insulin pump, glucose meter, and glucose sensor. It highlights areas of interest for further investigation. This report can span multiple pages.

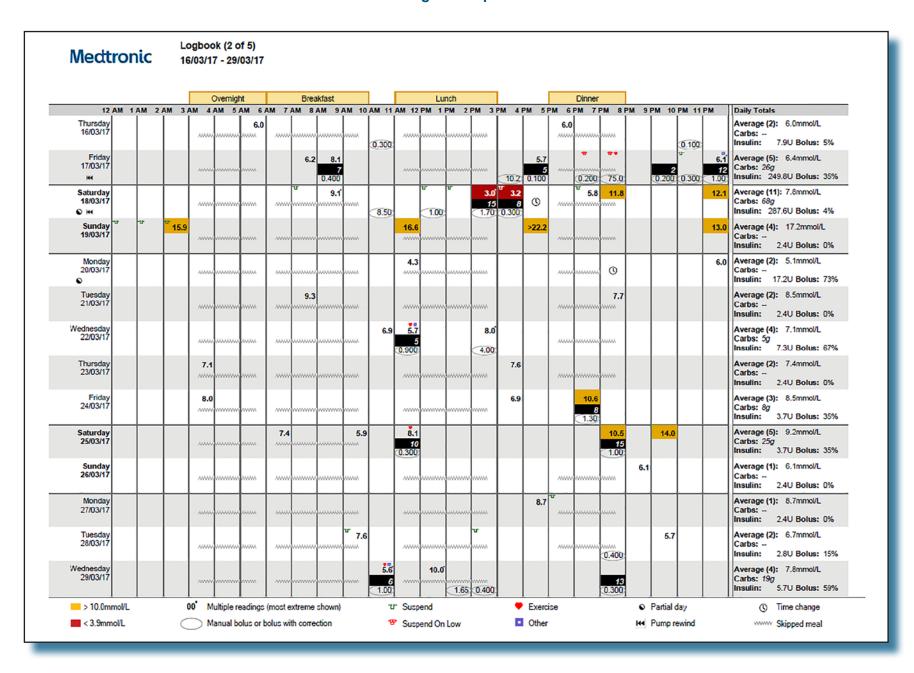
The report provides data to help you determine the level and quality of control your patient has over his or her diabetes. By viewing the different charts and graphs, you can identify where the quality of control varies within a typical day and across the reporting period.

Note: You set the meal periods and target range during the report generation process.





Logbook report



Logbook report

The Logbook report presents two weeks of data from a patient's insulin pump and blood glucose meter in a tabular format. The table shows the reported days in rows and each hour in columns, creating data cells. This report does not provide any sensor data.

Glucose values

Blood glucose (BG) values show in the top portion of a data cell. Glucose values above or below the patient's target range are highlighted. If multiple values were obtained for a single hour, they are indicated with a dot in the upper right corner of the glucose value, and the value considered most extreme is shown based on these priorities:

- The lowest of any values below the patient's target is shown.
- If there are no lows, but there are values above the patient's target, the highest of these is shown.
- If there are no lows or highs, the value farthest from the center of the patient's target range is shown.

Boluses

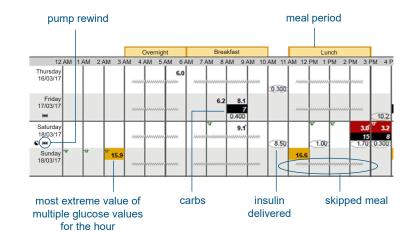
Boluses programmed within an hour are shown in the bottom portion of a data cell. Bolus insulin values are circled if the value is from a manual bolus, Bolus Wizard™ correction, or SmartGuard™ Auto Mode bolus.

Data cells

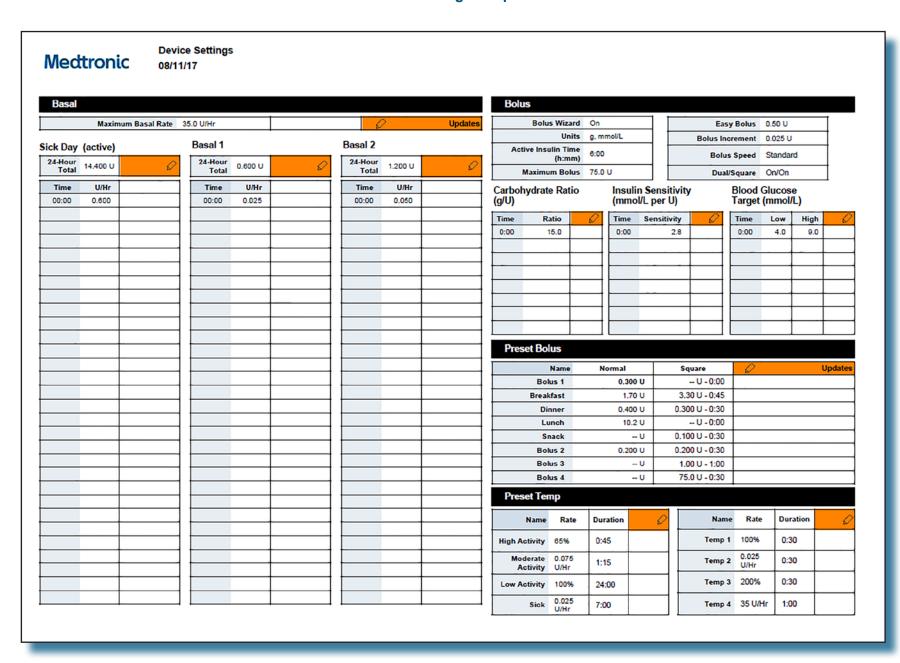
Each data cell in the reporting period corresponds to an hour within a day and can contain up to three values: (1) meter, (2) grams of carbohydrates, and (3) units of insulin delivered as a bolus. Time frames that correspond to meals are highlighted at the top of the report.

Meals

Meal time frames correspond to the patient's specified meal periods and are called out at the top of the report. Carbohydrate values recorded from Bolus Wizard™ calculations are totalled for each hour in a meal period and are shown in a black box in the middle portion of the data cell. If there are no carbohydrate values recorded for an hour within a meal period, the Skipped meal symbol is shown.



Device Settings Snapshot

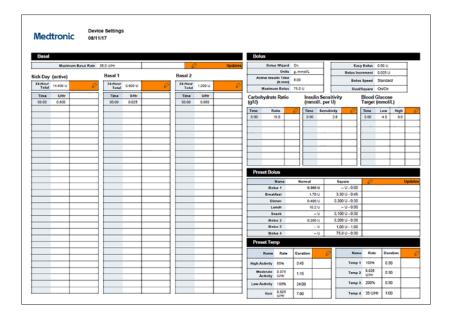


Device Settings Snapshot

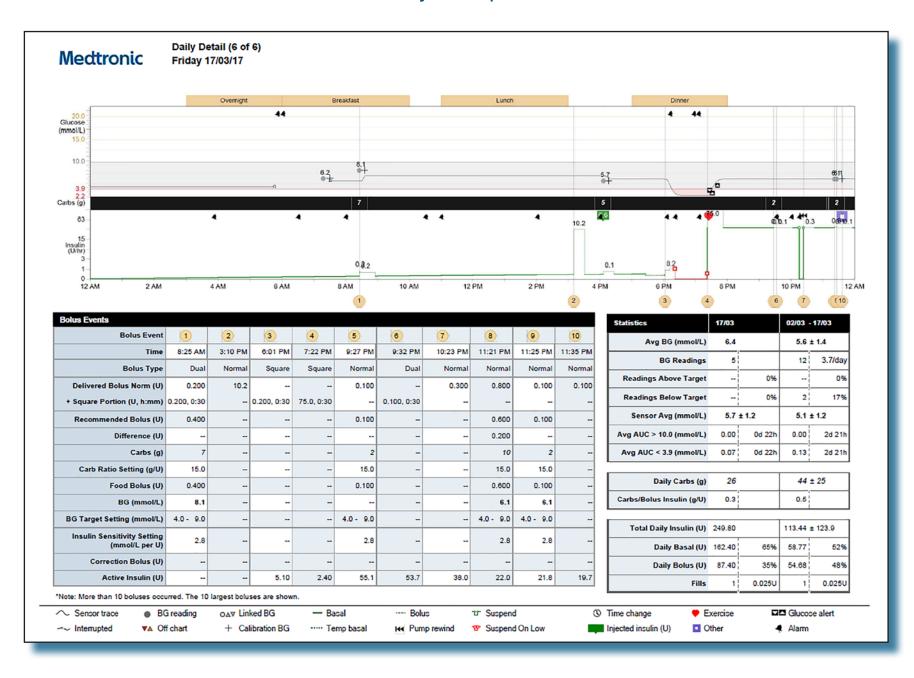
The Device Settings Snapshot report presents the customized settings of a patient's device that were active on the date and time when the patient's device was uploaded.

The report presents tables of active settings for the report period selected.

Note: The Device Setting Snapshot report only shows the settings available for the uploaded device. Please refer to FAQ.

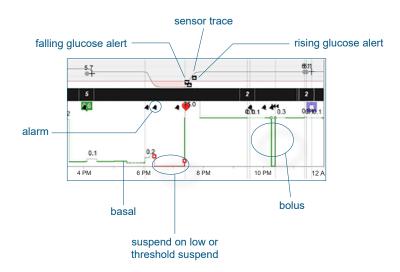


Daily Detail report



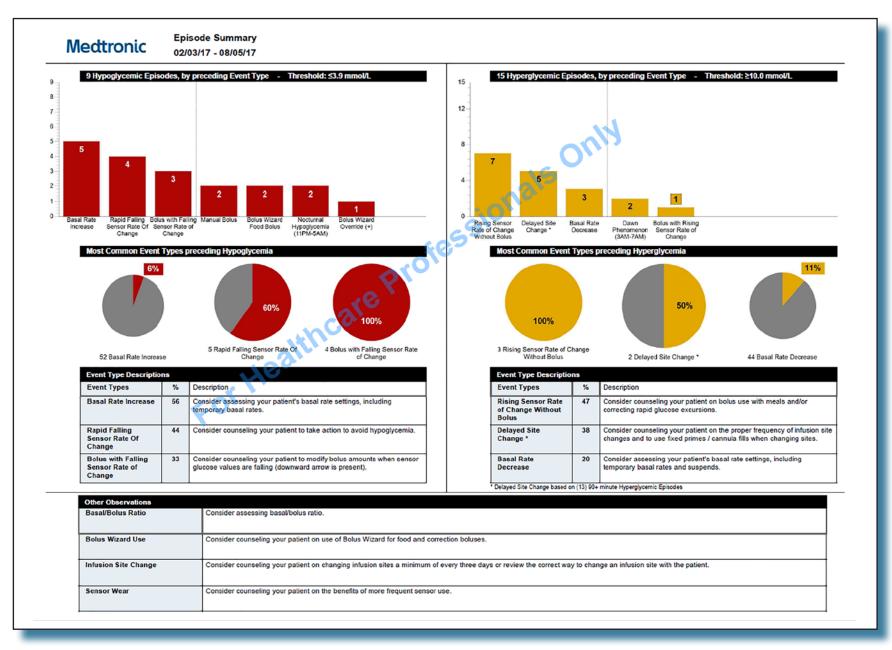
Daily Detail report

The Daily Detail report presents data from a patient's insulin pump, blood glucose meter, and glucose sensor, if used, to provide insight into a patient's control, including response to carbohydrate intake and insulin use. This report covers one day of data.



Symbol	Meaning
~	Interrupted: Interrupted communication between the sensor transmitter and the insulin pump
▼▲	Off chart: Meter glucose value
ΟΔΨ	Linked BG: Meter BG values automatically sent to the insulin pump from a wireless link meter
+	Calibration BG: Meter glucose value used to calibrate a sensor
****	Temp basal: Temporary change in the rate of basal insulin delivery
-13-	Suspend: User-initiated suspension of all insulin delivery from the insulin pump, or pump-initiated suspension of all insulin delivery that is not based on SG values
0	Time change: A time change occurred on the device clock; a time change is considered a partial day
-	Injected insulin (U): A user-entered event marker, indicating an insulin injection
•	Exercise: A user-entered event marker, indicating physical activity
	Other: A user-defined event marker, indicating such things as taking medications, feeling ill, stress, and so on

Episode Summary



Episode Summaries are for healthcare professional use only.

Episode Summary

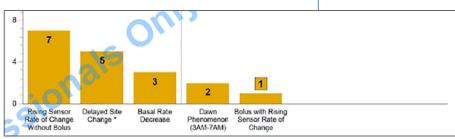
The Episode Summary provides a summary of a patient's glucose, carbohydrate, and insulin data for a selected time period. It provides an overview of the patient's glycemic control (daily, overnight, and at meal times) and comprehensive statistical data.

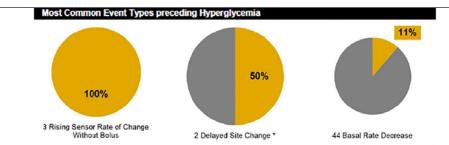
The Episode Summary describes events that preceded hypoglycemia and hyperglycemia and provides a section called Other Observations that may contain important factors in achieving optimal glucose control. The list of considerations is not meant to capture all possible issues that could affect glucose control. As always, clinical judgment is required.

For more information about the Event Types, Observations, and Patient and Healthcare Professional discussion points that CareLink™ identifies for individual components of the Episode Summary, see the Appendix.

Note: If there are fewer than five days of SG readings in the selected period, the Episode Summary report will not be available. Note that the report may show sensor hypoglycemic or hyperglycemic episodes where there were no corresponding blood glucose meter readings outside of the target range. Conversely, there may be blood glucose meter readings outside of the target range where no sensor hypoglycemic or hyperglycemic episodes are reported.

you set the glucose target range during the report generation process.





Appendix

CareLink™ reports are intended for use with a healthcare professional only. These reports are provided to patients to enable discussion and assessment of patients' glucose management history with their healthcare professional. Patients should always consult with their healthcare professional before adjusting pump settings.

The tables in the Appendix list the definitions for all the Event Types and Observations that CareLink™ identifies. Not all factors that could precede high or low glucose are covered, and therefore CareLink™ does not replace standard clinical assessment of patients.

In CareLink™ reports, sensor values at or below the low glucose target value are reported as hypoglycemia and sensor values at or above the high target are reported as hyperglycemia. You can change the range during the report generation process.

Note: For any time period referenced, such as 3 a.m. – 4 p.m, in the tables under the Patient & Healthcare Professional Discussion Points column, the time period is based on a patient's personalized data. The time period may vary for a patient's reports.

Hypoglycemic Episode Event Types						
Event	Observation	Patient & Healthcare Professional Discussion Points				
Basal Rate Increase	Reported when it correlates with hypoglycemic episodes that start within three hours following the rate change.	Consider assessing your patient's basal rate settings, including temporary basal rates.				
Bolus with Falling Sensor Rate of Change	Reported when it correlates with hypoglycemic episodes that start within three hours following the bolus.	Consider counseling your patient to modify bolus amounts when SG values are falling (downward arrow is present).				
Bolus Wizard Food Bolus	Reported when it correlates with hypoglycemic episodes that start within three hours following the bolus.	Consider assessing the Bolus Wizard™ settings, counseling your patient on accurate carbohydrate counting, and the timing of insulin delivery with respect to carbohydrate intake.				
Bolus Wizard Override (+)	Reported when it correlates with hypoglycemic episodes that start within three hours following the bolus.	Consider counseling your patient to use the Bolus Wizard™ feature recommendations.				
Carbohydrate Entry (> 80 g)/ Carbohydrate Entry (> 5.3 ex)	Reported when it correlates with hypoglycemic episodes that start within three hours following the carbohydrate entry.	Consider counseling your patient on the effect of high carbohydrate intake.				
Correction Bolus with Falling Sensor Rate of Change	Reported when it correlates with hypoglycemic episodes that start within three hours following the bolus.	Consider counseling your patient to modify correction bolus amounts when sensor glucose values are falling (downward arrow is present).				
Hyperglycemia Preceding Hypoglycemia	Reported when it correlates with hypoglycemic episodes that start within three hours following the bolus.	Consider assessing your patient's insulin sensitivity factors. Consider counseling your patient on the management of hyperglycemia.				
Manual Bolus	Reported when it correlates with hypoglycemic episodes that start between the second bolus and up to three hours after the last bolus.	Consider counseling your patient to use the Bolus Wizard™ feature.				
Multiple Correction Boluses	Reported when it correlates with hypoglycemic episodes that start between the second bolus and up to three hours after the last bolus.	Consider counseling your patient about the additive effect of multiple correction boluses and the time profile of insulin action.				
Multiple Manual Boluses	Reported when it correlates with hypoglycemic episodes that start between the second bolus and up to three hours after the last bolus.	Consider counseling your patient to use the Bolus Wizard™ feature. Consider counseling your patient on the additive effect of multiple boluses and the time profile of insulin action.				
Nocturnal Hypoglycemia (11PM-5AM)	Reported when it correlates with hypoglycemic episodes that start between 11 p.m. and 5 a.m.	Consider assessing overnight basal rates and counseling your patient on evening boluses.				
Rapid Falling Sensor Rate Of Change	Reported when it correlates with hypoglycemic episodes that start within three hours of the end of the period.	Consider counseling your patient to take action to avoid hypoglycemia.				

Hyperglycemic Episode Event Types							
Event	Observation	Patient & Healthcare Professional Discussion Points					
Basal Rate Decrease	Reported when it correlates with hyperglycemic episodes within three hours following the rate change.	Consider assessing your patient's basal rate settings, including temporary basal rates and suspends.					
Bolus with Rising Sensor Rate of Change	Reported when it correlates with hyperglycemic episodes that are still above the target range two hours after the bolus.	Consider counseling your patient to modify bolus amounts when sensor glucose values are rising (upward arrow is present).					
Bolus Wizard Food Bolus	Reported when it correlates with hyperglycemic episodes that are still above the target range two hours following the bolus.	Consider assessing the Bolus Wizard™ settings, counseling your patient on accurate carbohydrate counting, and the timing of insulin delivery with respect to carbohydrate intake.					
Bolus Wizard Override (-)	Reported when it correlates with hyperglycemic episodes that are still above the target range two hours following the bolus.	Consider counseling your patient to use the Bolus Wizard™ feature recommendations.					
Carbohydrate Entry (> 80 g)/ Carbohydrate Entry (> 5.3 ex)	Reported when it correlates with hyperglycemic episodes that start within three hours following the carbohydrate entry.	Consider counseling your patient on the effect of high carbohydrate intake.					
Dawn Phenomenon (3AM–7AM)	Reported when it correlates with hyperglycemic episodes that start between 3 a.m. and 7 a.m.	Consider assessing the overnight basal rates.					
Delayed Site Change	Reported when it correlates with hyperglycemic episodes that start more than 3.5 days after the most recent fixed prime (cannula fill). Only reported for episodes that are at least 90 minutes long.	Consider counseling your patient on the proper frequency of infusion site changes and to use fixed primes and cannula fills when changing sites.					
Overcorrection of Hypoglycemia	Reported when it correlates with hyperglycemic episodes that start within three hours following a low sensor reading.	Consider counseling your patient on the management of hypoglycemia.					
Pump Suspends (> 60 minutes)*	Reported when it correlates with hyperglycemic episodes that start within three hours of the suspend.	Consider counseling your patient on the use of pump suspends. Consider counseling your patient on bolus use with meals and correcting rapid glucose excursions.					
Rising Sensor Rate of Change Without Bolus	Reported when it correlates with hyperglycemic episodes that start within three hours of the event.	Consider counseling your patient on bolus use with meals and correcting rapid glucose excursions.					

^{*} Evaluate whether hyperglycemic episodes were preceded by user-initiated suspend events or suspend by sensor events (such as Threshold suspend or Suspend on low). In cases where hyperglycemic episodes are preceded by suspend by sensor events, evaluate whether the suspend by sensor limit(s) on the pump are set appropriately for the patient.

If there are repeated suspend by sensor events lasting > 60 minutes, consider assessing and optimizing the treatment regimen to prevent hypoglycemia (pump settings, alerts, dietary regimen) and patient response to alarms (fingerstick confirmation and recommended treatments).

	Other Observations							
Priority	Event	Observation	Patient & Healthcare Professional Discussion Points					
1	Basal to Bolus Ratio	Message is displayed when the basal portion of the basal to bolus ratio is 55% or greater.	Consider assessing basal to bolus ratio.					
2	Bolus Wizard Use	Message is displayed when the Bolus Wizard™ feature is used for boluses less than 67% of the time.	Consider counseling your patient on use of Bolus Wizard™ feature for food and correction boluses.					
3	Correction Bolus Insulin	Message is displayed when more than 50% of all the insulin recommended by the Bolus Wizard™ feature is correction insulin.	Consider assessing the basal rates, Bolus Wizard™ settings, and carbohydrate counting to deliver more accurate food boluses to prevent the frequent need for correction boluses.					
4	Infusion Site Change	Message is displayed when there is an average of more than 3.5 days between fixed prime (cannula fill) events.	Consider counseling your patient on changing infusion sites a minimum of every three days or review the correct way to change an infusion site with the patient.					
5	Sensor Wear	Message is displayed when there are fewer than five days of sensor readings per week on average.	Consider counseling your patient on the benefits of more frequent sensor use.					
6	BG Entry Frequency	Message is displayed when there are fewer than four BG readings per day on average.	Discuss the frequency of fingerstick glucose testing with your patient.					

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