

## User Acceptability and Perceived Benefits of New Reports in CareLink Pro 3.0 Therapy Management Software for Diabetes

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CareLink® Therapy Management Software for Diabetes (Medtronic MiniMed, Inc., Northridge, CA) allows information stored in insulin pumps, continuous glucose monitoring (CGM) devices, and blood glucose meters to be uploaded and analyzed retrospectively. Patients typically use CareLink Personal to upload and review CGM and pump data; health care professionals can retrieve this data through CareLink Pro, which allows them to interpret reports and suggest therapy adjustments. Use of the CareLink system has been associated with improved glycemic control in children with type 1 diabetes on insulin pump therapy.<sup>1</sup>

CareLink Pro 3.0 includes two new reports: (1) Therapy Management Dashboard (**Figure 1**) and (2) Episode Summary. The Therapy Management Dashboard provides an overview of glycemic control, insulin delivery, and key pump settings. Pattern tables identify repeated episodes of hypoglycemia and hyperglycemia. Sensor use data include average sensor glucose values and the average number of high/low threshold and predictive alarms per day. The Episode Summary (not shown) presents 12 types of events that precede glycemic excursions.

In a 2010 study funded by Medtronic, a survey was created to evaluate these new reports to verify that they meet acceptability criteria and to assess their value with respect to managing patients on sensor-augmented insulin pumps.

Physicians received laptop computers with CareLink Pro 3.0, and were trained on its use. Data from patients' insulin pumps (Medtronic Paradigm 522 or 722 models) were uploaded into the CareLink database; reports for patient data that included at least 5 days of sensor wear were then generated in CareLink Pro 3.0 and reviewed by the physicians. Physicians completed identical questionnaires after 30 and 120 days. Questions regarding acceptability were rated with a 7-point Likert Scale, and perceived value and benefits were evaluated by whether or not physicians agreed with certain statements.

Responses to the Product Acceptability Questionnaire were favorable. The predefined criteria for product acceptability at 30 and 120 days were exceeded, with all investigators agreeing that the CareLink Pro 3.0 reports were acceptable, consistent with earlier versions of CareLink Pro, and consistent with therapy recommendations that they might consider in their own practices. Responses to the Perceived Product Benefits Questionnaire were also favorable. Eight of the 9 physicians agreed that the new reports would help them more easily identify the root causes of hypoglycemic and hyperglycemic events and more easily determine appropriate therapy adjustments. All physicians agreed that the reports would help them gain additional value from CGM data, and would recommend CareLink Pro 3.0 to their peers.

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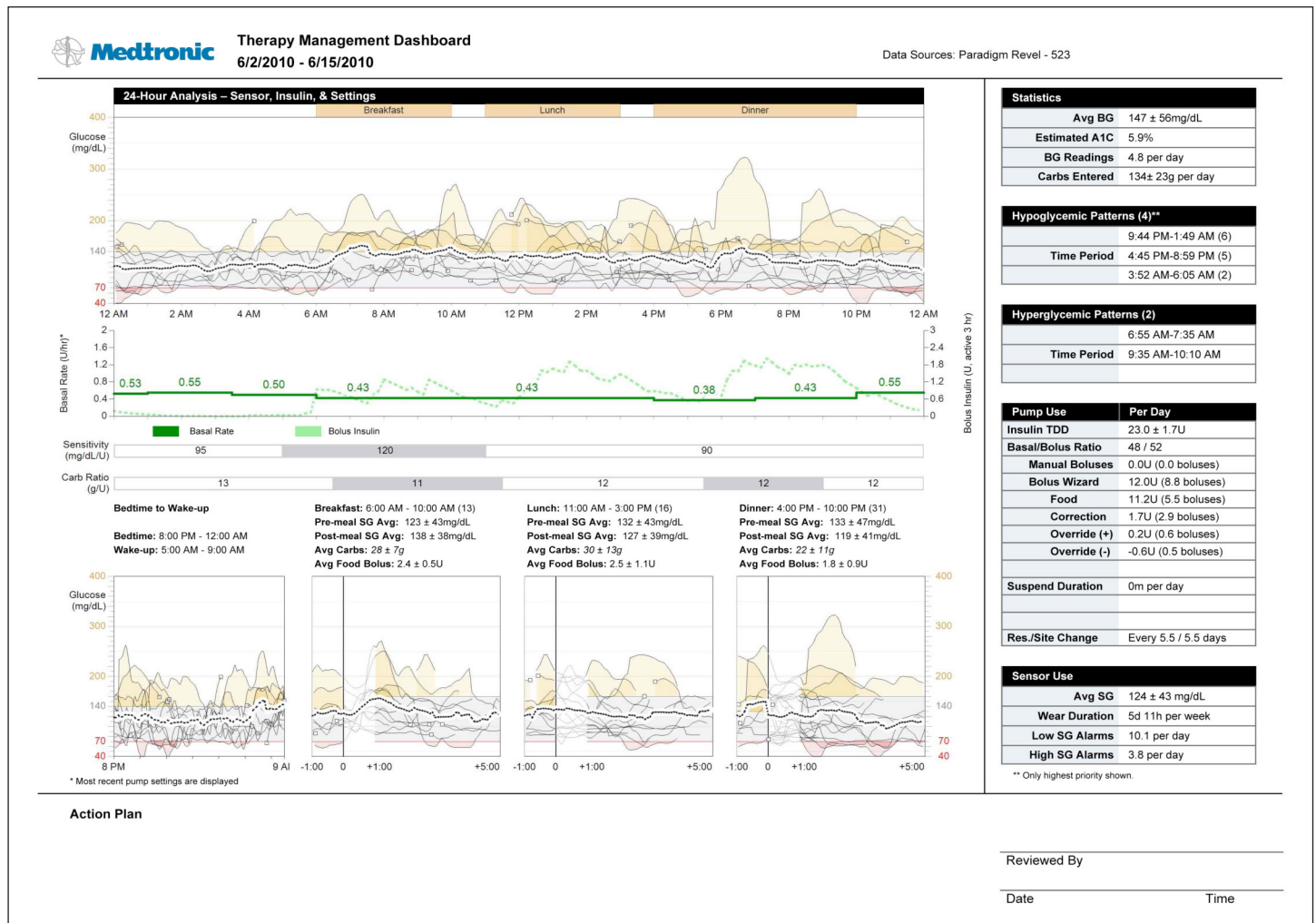


Figure 1. Therapy Management Dashboard Display.

Sensor-augmented insulin pumps play a central role in diabetes management by housing data on insulin delivery and glucose readings, and assisting in bolus estimation. Remote data storage and analysis capabilities, such as those provided by CareLink, provide additional opportunities for exploratory data analysis among individuals and large populations.<sup>2</sup> Two new reports in CareLink Pro 3.0 were designed to efficiently summarize and present data from sensor-augmented insulin pump systems in order to facilitate patient interactions and inform management decisions. Questionnaire responses described here suggest that the Therapy Management Dashboard and the Episode Summary meet these goals.

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All authors are employees of Medtronic, Inc.

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