

PathFinder™

*Data Management
Software*



User Guide

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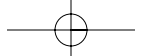
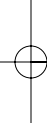
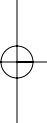
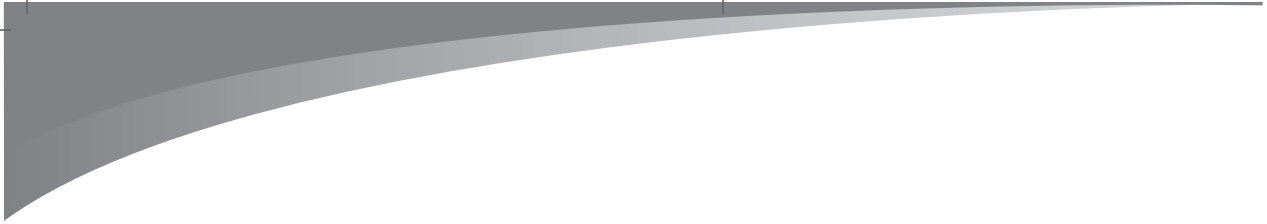
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Introduction

The OmniPod PathFinder 1.0 Data Management Software enables OmniPod Insulin Management System users and their healthcare providers to view recent blood glucose and insulin delivery records.

The Software downloads diabetes management records from the OmniPod Personal Diabetes Manager (PDM) to a personal computer, including up to 30 days of blood glucose statistics, 7 and 14 day blood glucose graphs, and up to 4 days of insulin delivery and carbohydrate records. Downloaded information includes basal insulin delivery, mealtime and correction boluses, carbohydrate intake, alarms and alerts, and other details of daily insulin treatment. The software then presents the information in charts and graphs that users can review, save, and print from their computer.

This user guide explains how to:

- Install the OmniPod PathFinder Data Management Software and accompanying hardware
- Download data from the OmniPod Personal Diabetes Manager (PDM)
- Interpret charts and graphs

1 Installing PathFinder Software and Hardware

■ Components & Accessories

The PathFinder kit contains:

- This PathFinder User Guide
- PathFinder installation software CD

You will also need:

- An infrared cable (IR Dongle)
- USB to RS-232 serial adapter (optional)

■ Computer Requirements

- Computer with a Microsoft Windows XP and a CD-ROM drive
- Microsoft Excel 2003

■ Installing the PathFinder Software

To install the PathFinder software:

1. Place the PathFinder CD into your computer's CD-ROM drive.
2. Open the **Start** menu.
3. Click **Run**.
4. Enter D:\setup.exe, where D is the CD-ROM drive letter. Or, browse to the CD and double-click **setup.exe**.
5. Press **OK**.
6. Follow the on-screen instructions.

When you have completed the installation, remove the CD from the drive and store it in a safe place.

Installing PathFinder Software and Hardware 1

■ Installing the IR Dongle

To install the IR dongle:

1. Plug the IR dongle cable into an available serial port on your computer.



If you prefer a USB connection, the IR dongle can be used with a USB to RS-232 serial adapter. To use a USB adapter, install the USB to RS-232 serial adapter and plug the IR dongle cable into the adapter. For technical support on installing the adapter, contact the manufacturer.

2 Using the PathFinder Software

To use the PathFinder software, run the PathFinder program and follow the on-screen instructions. Once the data has finished downloading, you can review, save, and print the results.



If your OmniPod is active, you must suspend insulin delivery before you begin downloading data.

To run the PathFinder program:

1. Double-click the PathFinder desktop icon. Or open the **Start** menu, click **All Programs**, choose **OmniPod PathFinder 1.0**, and then click **OmniPod PathFinder**.

2. Progress through the on-screen instructions by clicking **Next** or **Start**. To back out of the program, click **Exit** at any screen.



If you do not enter any patient or clinician information, none will appear on the PathFinder reports. You cannot enter them on the reports later, except by hand.

3. When the download is complete, click **Finish** to close the program.

Microsoft® Excel opens automatically, showing the results of the PathFinder download.



If your OmniPod is active, remember to resume insulin delivery once you complete the data download.

Interpreting the Results 3

■ Overview

Once you have downloaded information from the PDM, Microsoft® Excel will automatically open and display your data.

The Pathfinder spreadsheet includes 6 different pages (worksheets) of data:

- Pages 1 through 4 show Daily Results (and second Event Log pages, if needed)
- Page 5 shows Blood Glucose Graphs and Blood Glucose Statistics
- Page 6 shows Notes and Legends

NOTE: The download program may load more than 6 worksheets of data, depending on the amount of downloaded information.

The top line of every page shows the patient and clinician information (if entered during the download), plus today's date and the PDM serial number. You cannot change this line after the download.

Information shown on the rest of the pages is described in detail in the rest of this section.

3 Interpreting the Results

■ Daily Results

Each Daily Results page in PathFinder displays the information for one day's history downloaded from the PDM. Refer to the example of a Daily Results page on page 6. Each lettered item is discussed in detail in the sections that follow.

Each report contains the Daily Results for four days—usually in four pages.



If the user changed the date or time of the PDM within the last 4 days, then the results for the day that the date/time change occurred are split into two pages. You will see a note in the Event Log at the time that the change occurred.



If a day's Event Log is too long for a single page the remaining data will be extend onto a second page. So it is possible that the Daily Results may cover more than 4 pages.

Each Daily Results page shows:

- Total insulin delivered, date, and number of BG readings for the day (A on page 6, top)
- Graph of BG readings for the day (B)
- Chart of BG readings for the day (C)
- Chart of basal insulin delivered that day (D)
- Chart of boluses delivered that day, with details (E)
- A detailed log of the events of the day (F)

Interpreting the Results 3

Total Daily Delivery and Readings

Refer to A in the example on page 6, top.

The second line of the report shows the total amount of insulin that was delivered during the day. The daily delivery is shown in three parts, each in units and as a percent of the total:

- **TOTAL Bolus:** Shows the volume of all boluses delivered (18.65 U and 56% in the example)
- **TOTAL Basal:** Shows the volume of all basal insulin delivered (14.50 U and 44% in the example)
- **TOTAL Daily:** Shows the volume of total boluses plus total basal (33.15 U and 100% in the example)

The third line shows the date for this Daily Results page, taken from the PDM, followed by the number of BG readings taken that day. For example, N=6 means the user took six BG readings.



If the user changed the date or time, then the Total Daily Delivery results are not displayed. Instead "DATE/TIME CHANGE. SEE EVENT LOG" is shown.



If a Daily Results page contains basal or bolus data that is Lost, then the Total Daily Delivery results are not displayed. Instead "LOST DATA EXISTS. SEE EVENT LOG" is shown.

3 Interpreting the Results

Blood Glucose Graph

Refer to *B* in the example on page 6, top.

The Blood Glucose Graph occupies the top half of the Daily Results page. BG readings are shown in mg/dL, from 20 to 500. The time scale goes from midnight to midnight. The exact time of each reading is shown in the Event Log, with detailed notes.

The dotted lines across the graph represent the range of the BG goal, as the user has set it in the PDM. In the example, the BG goal is 80 to 140 mg/dL.

BG readings that fall between 20 and 500 mg/dL are displayed as solid blue squares at the time of day the readings occurred. In the example, these readings can be seen at 6A, 8A, 12P, 5P, and 9P.

Any reading of HIGH appears as a pink dot at the 500 level. Any reading of LOW appears as a pink dot at the 20 level. In the example, a LOW reading appears in the graph at 7P.



BG readings that the user tagged as Control tests, or readings when the meter temperature was out of range, do not appear in the BG graph.

Blood Glucose Chart

Refer to *C* in the example on page 6, middle.

The chart is in the center of the Daily Results page, and the first row is labeled "BG mg/dL." The row is divided into one-hour cells showing BG readings.

Each cell displays the first valid BG reading of the hour (meter errors, readings when the temperature was out of range, and control tests are not considered valid BG readings.) If the first reading of the hour is a HIGH or LOW, then "HIGH" or "LOW" is displayed in the corresponding cell.

If there is additional information in the Event Log relating to a cell, then an asterisk (*) will be displayed in the cell. Look in the Event Log for more information on these readings.

Interpreting the Results 3

Reasons for an asterisk (*) include:

- Multiple BG readings in an hour
- BG readings with BG tags
- Meter errors
- BG readings when the temperature was out of range
- Manually entered BG readings

For example, in the 12P cell, the BG Chart shows 78*. The Event Log shows:

12:03p BG meter err 3

12:06p BG 78 mg/dL

This means that at 12:03p a meter error occurred (see "Notes and Legends" later in the chapter for definitions of meter errors.) Then, at 12:06, a valid BG reading of 78 mg/dL was taken by the PDM.

Another example is in the 9P cell. The BG Chart shows 130*, and the Event Log shows:

9:13p BG 130 mg/dL **M**

This means that at 9:13p the user manually entered a BG reading of 130 mg/dL.



If the only reading during the hour was tagged as a control test, a meter error, or a reading when the temperature was out of range, then the BG Chart shows only a single asterisk (*).

Basal Chart

Refer to D in the example on page 6, middle..

Below the Blood Glucose Chart is the Basal Chart. It contains two rows of cells, each denoting a half-hour time period.

The first row in the Basal Chart shows a half-hour time period that starts at the top of the hour and lasts for 30 minutes. For example, the first 3 cells in the first row denote 12:00AM-12:30AM, 1:00AM-1:30AM, and 2:00AM-2:30AM.

3 Interpreting the Results

The second row in the Basal Chart shows a half-hour time period that starts in the middle of the hour and lasts for 30 minutes. For example, the first 3 cells in the second row denote 12:30AM-1:00AM, 1:30AM-2:00AM, and 2:30AM-3:00AM.

Each cell displays the basal rate that was active when the user entered the half-hour time period. (If there was no active basal rate during the half-hour, the cell is blank.)

If the basal rate remains unchanged from the previous half-hour, then three dash marks are displayed (---). These dash marks (---) indicate that the user's basal rate at the beginning of that half-hour was the same as the rate at the beginning of the previous half-hour.

If the basal rate at the beginning of the half-hour is not the same as the rate at the beginning of the previous half-hour, the new rate is shown in the cell.

For example, in the 12A cell (in the upper row), the Basal Chart shows 0.75. In the 3A cell (upper row), the chart shows 1.10. The Event Log shows:

12:00a basal 0.75 U/hr

3:00a basal 1.10 U/hr

This tells us that the user had a starting basal rate of 0.75 U/hr at midnight. This basal rate remained unchanged all the way until 3:00 AM, when the rate was changed to 1.10 U/hr.

If the user's basal rate changes during a half-hour time period, the corresponding cell displays an asterisk (*). The asterisk indicates that there is more information in the Event Log.

Reasons for an asterisk include:

- User manually changes the basal program
- Start or stop of a suspension
- Start or stop of a temporary basal program
- An OmniPod is activated or deactivated
- Basal rate is considered "Lost"

Interpreting the Results 3

For example, in the 11A cell (in the first row), the Basal Chart shows “---*.” In the 11A cell (in the second row), the chart shows “1.35*.”

The Event Log shows:

11:15a basal 1.35 U/hr temp

11:45a basal 0.90 U/hr

This tells us that the user programmed a temporary basal rate of 1.35 U/hr at 11:15 AM. This temporary basal rate ran until 11:45 AM, when the rate was changed to back to 0.90 U/hr.

Blank cells indicate that an OmniPod was not active during that time period, or there was a date/time change.

Bolus Chart

Refer to *E* in the example on page 6, middle.

Below the Basal Chart is the Bolus Chart. It contains 6 rows of information, divided into hour-long blocks:

- Bolus U—total bolus delivered now (immediate only)
- Suggest U—total bolus suggested by the PDM (if suggested bolus calculations are turned ON)
- Carb—grams of carbohydrate eaten, as entered by the user
- IC Ratio—insulin-to-carbohydrate ratio currently in effect; for example, 15 means a ratio of 1:15
- Target BG—target blood glucose currently in effect, in mg/dL
- CF—correction factor currently in effect; for example, 50 means a factor of 1:50

NOTE: If a bolus is completely extended, then the Bolus U row will show 0.00

3 Interpreting the Results

The details of the first bolus dosage of the hour is displayed in these cells.

In the example, during the 7A hour, the Bolus Chart shows:

Bolus U	3.00
Suggest U	3.00
Carb	45
IC Ratio	15
Target BG	
CF	

The Event Log shows:

7:14a bolus 3.00 U
suggested 3.00 U
meal 3.00 U; carb 45 g; IC 15

This tells us that at 7:14 AM the user entered 45 carbs into the PDM. The PDM suggested a bolus dosage of 3.00 units, which the user delivered immediately.



The Target BG and CF lines are left blank because the user did not take a correction dosage.

An asterisk (*) in the Bolus U line of the Bolus Chart indicates more information is shown in the Event Log.

Reasons for an asterisk (*) include:

- Multiple bolus dosages during the hour
- Extended bolus dosages
- Lost bolus
- Delivery spans midnight

Bolus dosages are displayed in the Event Log in the following format:

5:07p bolus 4.50 U
bolus 2.00 U 1:00 e
suggested 6.50 U
meal 4.00 U; carb 60 g; IC 15
correct. 2.50 U; BG 225 mg/dL;
target 100 mg/dL; CF 50; IOB 0.00 U

Interpreting the Results 3

The first line tells us how much insulin was delivered immediately. For example: 5:07p bolus 4.50 U. This means that at 5:07 PM, 4.50 units of insulin were delivered.

The second line tells us how much insulin was extended, and for how long. For example: bolus 2.00 U 1:00 e. This means that 2.00 units of a bolus were extended over 1 hour.

NOTE: If the bolus dosage does not contain an extended portion, this line is not shown.

The next line shows us how much insulin was suggested by the PDM. For example: suggested 6.50 U. This means the PDM suggested that 6.50 units of insulin be delivered.

NOTE: If suggested bolus calculation is not turned On, this line is not shown.

NOTE: The suggested dosage is calculated by adding the meal bolus to the correction bolus, and subtracting insulin on board. If this number does not equal the dosage delivered, then the user manually adjusted the dosage before delivery.

The next line shows details of the meal portion of the bolus. For example: meal 4.00 U; carb 60 g; IC 15. This means that the insulin-to-carb (IC) ratio was 1 to 15, the patient entered 60 grams of carbs, and 4.00 units of the bolus were intended to cover the meal.

NOTE: If a bolus dosage does not contain a meal portion, this line is not shown.

The next two lines show details of the correction dosage. For example: correct 2.50 U; BG 225 mg/dL; target 100 mg/dL; CF 50; IOB 0.00 U. This means that insulin on board (IOB) was 0.00 units, the current correction factor was 1 to 50, the target BG was 100 mg/dL, the patient's BG was 225 mg/dL, and the suggested correction dosage was 2.50 units.

3 Interpreting the Results

In the example, during the 5P hour, the Bolus Chart shows:

Bolus U	4.50*
Suggest U	6.50
Carb	60
IC Ratio	15
Target BG	100
CF	50

The Event Log shows:

5:07p bolus 4.50 U
 bolus 2.00 U 1:00 e
 suggested 6.50 U
 meal 4.00 U; carb 60 g; IC 15
 correct. 2.50 U; BG 225 mg/dL;
 target 100 mg/dL; CF 50; IOB 0.00 U

This tells us that at 5:07 PM the user entered a blood glucose (BG) of 225 mg/dL and 60 carbs. A correction dosage of 2.50 units was suggested, because the target BG value is 100 mg/dL, the correction factor

was 1 to 50, and insulin-on-board (IOB) was 0.00 units. The PDM also suggested a meal bolus dosage of 4.00, because the user entered 60 carbs and the active insulin-to-carb ratio was 1 to 15. The total suggested dosage was 6.50 units. The user delivered 4.50 units immediately, with 2.00 units as an extended bolus over the next hour.



If the amount of the bolus delivered (immediate plus extended) and the suggested bolus are not equal, then the user manually changed the bolus dosage before delivery.



If insulin-on-board (IOB) is greater than the meal bolus and the correction bolus, then the suggested bolus will be 0.00.

Interpreting the Results 3

Event Log

Refer to *F* in the example on page 6, bottom.

The Event Log is a detailed list of all the events of each day, including BG, basal and bolus deliveries, and alarm history. The log shows events in the order they occur during the day.

The Event Log also displays special symbols that can offer more information about the events of the day. These symbols are “**M**”, “**S**,” and “**L**”.

The “**M**” symbol next to a BG reading indicates that the value was manually entered by the user. In the example on page 6, at 9:13 PM a BG value of 130 mg/dL was manually entered by the user.

The “**S**” symbol indicates that delivery of an extended bolus spans midnight. The “**L**” symbol indicates that the record has been “lost” by the PDM. For more information see the *OmniPod User Guide*.



Each Event Log contains room for 48 records. If more space is required, PathFinder will add a second Excel worksheet that displays the remaining Event Log entries of the day.



If an extended bolus dosage both spans midnight and is considered lost, the next line of the Event Log will read “Note: Preceding record lost.”



If the PDM detects that the temperature was out of range on a BG reading, the Event Log will show “Note: Meter temperature out of range” in the line after the BG reading.

■ Blood Glucose Summary

The Blood Glucose Summary is the next-to-last page of the PathFinder report. It shows graphs of the user’s BG readings for the previous 7 and 14 days, plus statistics for the 7-day, 14-day, and 30-day periods. The summary occupies one page.

3 Interpreting the Results

7-Day and 14-Day Graphs

Refer to G and H in the example on page 7.

At the top of each graph is the title, "7 Day" or "14 Day," followed by a number. This is the number of valid BG readings recorded during that time period.



Any BG reading that has been tagged as a control test, or a reading where the temperature was out of range, is not considered a valid reading. It will not be shown in the graphs or included in the statistics charts.

In the example, in the 7-Day Graph, N=54 means the user recorded 54 valid BG readings during the previous 7 days.



If multiple BG readings are similar in time and value they may not appear because they overlap with other BG readings.

Each graph uses the same BG and time scales as the Daily Results BG Graph and shows the same BG goal lines.

7-Day, 14-day, and 30-Day Charts

Refer to I in the example on page 7.

At the bottom of the page are three charts of BG statistics, one each for the preceding 7 days, 14 days, and 30 days. The statistics include:

- Avg BG—the average of BG readings recorded or entered for the period
- Min BG—the minimum BG for the period
- Max BG—the maximum BG for the period
- BG goal—the range of the BG goal for the period
- Within goal—the percentage of BG readings within the BG goal
- Above goal—the percentage of BG readings above the BG goal
- Below goal—the percentage of BG readings below the BG goal



HIGH and LOW values that appear on the graphs as pink dots are not included in the BG statistics.

Interpreting the Results 3

■ Notes and Legends

The final page of the PathFinder report is the Notes and Legends page.

Below the patient and clinician information is a section for you to write notes (on the printed report). At the bottom of the page are legends describing the BG tags, meter errors, and other symbols that may appear in the Event Log.

BG Tag Legend

The BG Tag Legend describes the numbers, from 1 to 18, that may be displayed in the Event Log to the right side of a BG reading. If the user has “tagged” a blood glucose reading, the Event Log will show the associated tag number, which may help explain a particular BG reading.

The BG Tag numbers are:

1	Control	10	Exercise (moderate)
2	Pre-meal	11	Exercise (strenuous)
3	Post-meal	12	Fasting
4	Missed bolus	13	Sick day
5	Carb guess	14	Ketones (neg)
6	Basal evaluation (start)	15	Ketones (trace)
7	Basal evaluation (stop)	16	Ketones (small)
8	Skipped meal	17	Ketones (moderate)
9	Exercise (light)	18	Ketones (large)

In the Event Log , the entry at 5:07p includes a “2” at the right of the entry, meaning the user tagged this reading as “Pre-meal.”

3 Interpreting the Results

Meter Error Legend

The Meter Error Legend describes examples of what may have caused the PDM to display a meter error. They are:

1	Very low BG (<20 mg/dL)
2	Very high BG (>500 mg/dL)
3	Incorrect test procedure
4	Problem with strip or meter
6	Blood sample applied while code number was being changed

In the Event Log, the entry at 12:03p is for a meter error 3, meaning the user may have performed an incorrect test procedure.

There are actually several reasons why meter errors may occur. For more information on meter errors and their causes, the the OmniPod *User Guide*.

Symbol Legend

The Symbol Legend describes the symbols you may see in the Daily Results pages. These are:

*	See event log for more information
M	Manual BG entry
L	"Lost" history record
S	"Delivery Spans Midnight" history record
•	LOW or HIGH BG value
---	Basal delivery remains unchanged

In the Event Log, the entry at 9:13 PM show a BG value of 130 mg/dL with an "**M**" next to it. This tells us that the user manually entered the BG value.

PathFinder Error Messages and Resolution 4

If you cannot get the PathFinder program to work properly, or if you receive error messages during the download process, see the instructions below to resolve the issue.

■ PDM & PathFinder Cannot Establish Communication

As the PDM is attempting to download data to the PathFinder program, if the infrared cable does not detect the PDM in 2 minutes, this error message appears:



1. Click **OK**. The program returns to the Align IR Ports screen. Realign the infrared ports on the PDM and the IR dongle cable. Follow the instructions on the screen to retry data download.

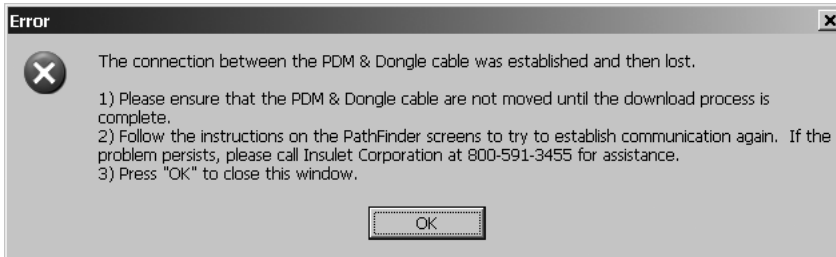
2. If you retry and see the same error message, call Insulet Corporation at 800.591.3455.

4 PathFinder Error Messages and Resolution

■ Connection Lost

Once the PDM begins to download data, if the infrared connection is broken, this error message appears:

1. Click **OK**. The program returns to the Align IR Ports screen. Realign the infrared ports on the PDM and IR dongle. Follow the instructions on the screen to retry data download.

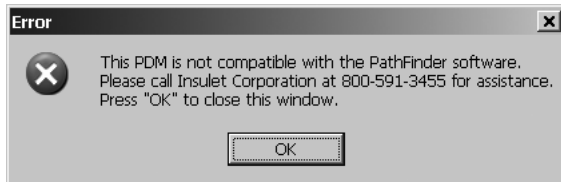


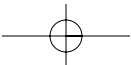
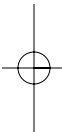
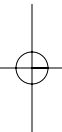
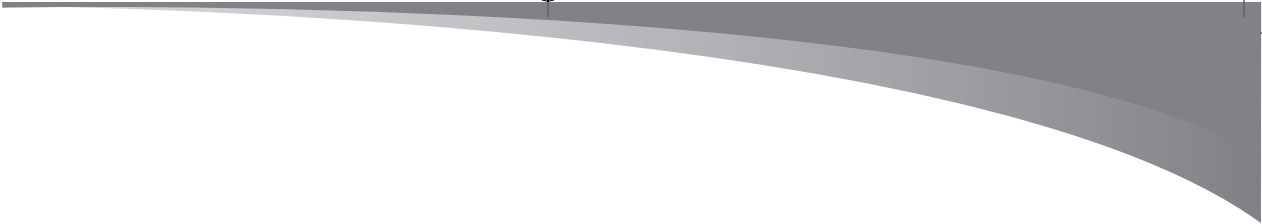
2. If you retry and see the same error message, call Insulet Corporation at 800.591.3455.

■ Not Compatible with PDM

If the PathFinder program is not compatible with the PDM, this error message appears:

1. Call Insulet Corporation at 800.591.3455.





PathFinder™

*Data Management
Software*

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