FreeStyle *Libre*

Software Version 1.0

User's Manual

Abbott

Contents

Intended Use

FreeStyle Libre software is intended for use by individuals and health care professionals to aid in the review, analysis, and evaluation of information such as Sensor glucose readings, blood glucose test results, blood ketone test results, and other data uploaded from the FreeStyle Libre or FreeStyle Libre 2 Flash Glucose Monitoring System, in support of an effective diabetes health management program.

FreeStyle Libre software is not intended for the diagnosis of or screening for diabetes mellitus. Users should be aware that the FreeStyle Libre software is merely an information management tool and it is therefore not intended to substitute for the support of a health care professional. Individuals should always consult their health care professional if they have any queries or concerns about diabetes management.

Note: Not all products may be available in all countries.

System Requirements

At minimum, a computer with a USB 2.0 compliant hub with a dual-core processor (1.6 GHz for Mac computer, 2.53 GHz for PC computer) and 2 GB RAM.

Customer Service

Customer Service is available to answer any questions you may have about FreeStyle Libre software. Go to www.FreeStyleLibre.com or the Reader Kit User's Manual for your Customer Service phone number. Printed User's Manuals are available upon request.

The FreeStyle Libre software Home Screen allows you to access the different features of the application for creating reports and changing Reader settings.

Before you start using the application:

- Connect your Reader to the computer using the USB cable in your Reader Kit. Plug one end into the USB port on the Reader and the other end into the USB port on the computer. Use only the USB cable included with the System.

- Add a Reader Profile if you want to create reports.
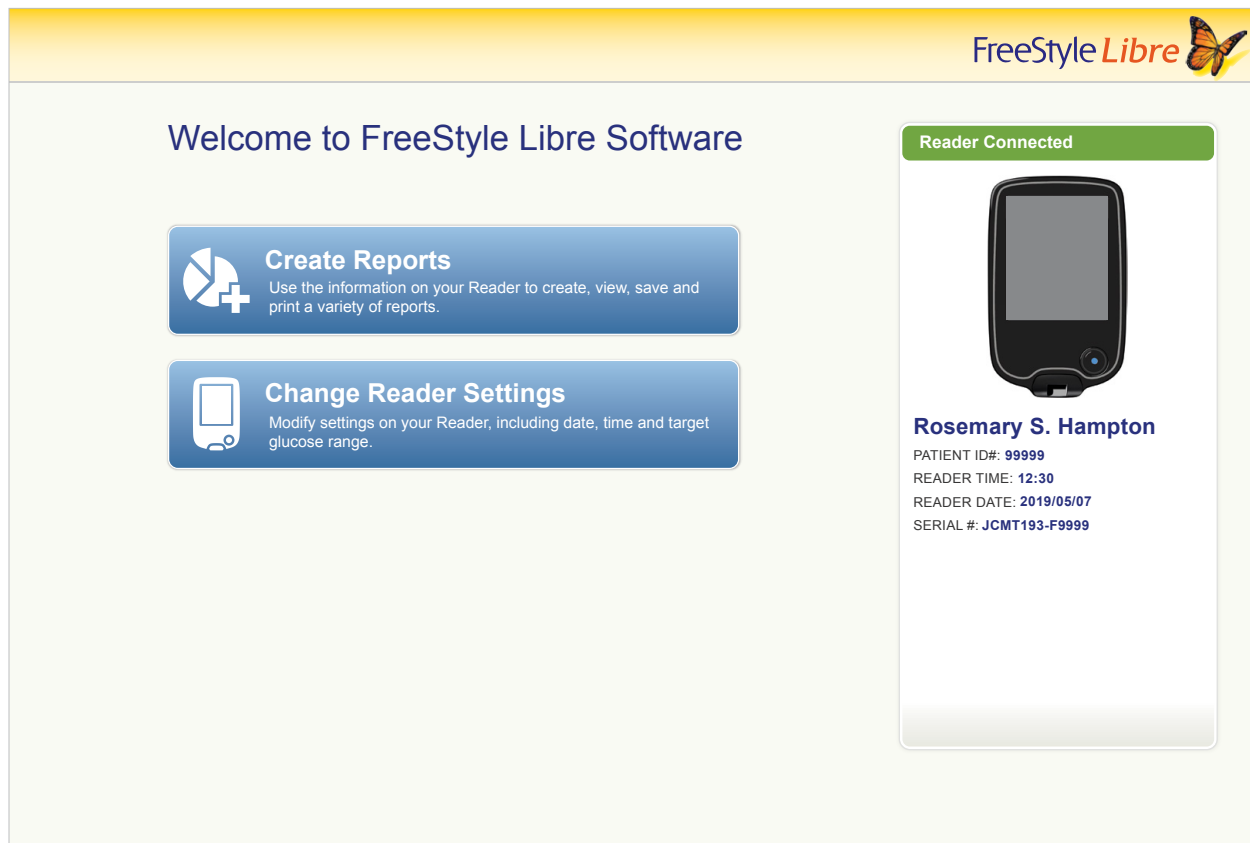
If you have connected the Reader but the application does not recognise it, try these troubleshooting tips:

- Connect only one Reader to the computer at a time – The application may not work when multiple Readers are connected.

- Secure the connection – Double-check that the USB cable is securely connected to both the Reader and the computer.

WARNING: DO NOT use the Reader's built-in meter while the Reader is connected to an electrical outlet or a computer.

The Create Reports screen lets you select reports and set report parameters. Selected reports can be viewed, printed, and saved as a PDF.

Selecting Reports

Select one or more of the following reports that you would like to view or print.

Snapshot
The Snapshot report shows a summary of the glucose, Sensor usage, carbohydrate and insulin data within the selected timeframe. It also includes comments about the data.

Daily Patterns
The Daily Patterns report shows glucose, carbohydrate and insulin data over the "typical" day based on all days within the selected timeframe. It includes the Ambulatory Glucose Profile, a graph of the 10th, 25th, 50th (median), 75th and 90th percentiles of glucose readings. The second page includes individual Sensor glucose readings.

Glucose Pattern Insights
The Glucose Pattern Insights report shows glucose over the "typical" day based on all days within the selected timeframe. It includes an assessment of Glucose Control Measures and the Ambulatory Glucose Profile, a graph of the 10th, 25th, 50th (median), 75th and 90th percentiles of glucose readings. The second page includes individual Sensor glucose readings. See *Glucose Pattern Insights* section for more information.

Mealtime Patterns
The Mealtime Patterns report shows glucose, carbohydrate and insulin data for "typical" meals based on all food notes within the selected timeframe.

Monthly Summary
The Monthly Summary report shows glucose and Sensor usage data in a calendar format for each month within the selected timeframe.

Weekly Summary
The Weekly Summary report shows daily glucose, carbohydrate, insulin and other data in a weekly format for each week within the selected timeframe.

Daily Log
The Daily Log report shows the detailed glucose, carbohydrate, insulin and other data for each day within the selected timeframe. This report is the only one that includes strip test results.

Reader Details
The Reader Details report shows the current settings on the Reader and any changes to the settings over the last 30 days.

Setting Report Parameters

> **IMPORTANT:** Work with your health care professional to set your report parameters.

These two parameters are used in all reports. They are set within the Set Report Parameters window and are used to generate reports. They do not change any settings on your Reader.

Timeframe	The Timeframe selects the date range that will be used for all reports. You can select the last 1 to 4 weeks, or you can select a custom start and end date within the last 90 days.
Target Glucose Range	The Target Glucose Range is displayed on some glucose graphs and used to calculate your Time in Target. You can select a range within 70 to 180 mg/dL (3.9 to 10.0 mmol/L). **Note:** The range must be at least 30 mg/dL (1.7 mmol/L) wide (e.g. 90 to 120 mg/dL (5.0 to 6.7 mmol/L)) in order to generate reports.

These additional parameters are used *only* by the Glucose Pattern Insights report and are saved to the Reader. They are set using the **Edit** button within the Set Report Parameters window.

Daily Events	Daily Events define the periods during the day used to analyse the Glucose Control Measures. You can set the typical times of your Breakfast, Lunch, Dinner and Bedtime.
Median Goal	The Median Goal parameter sets the glucose level for which Median Glucose is reported as Low, Moderate or High when compared with this goal. You can select one of the values below:

Goal	A1c equivalent
126 mg/dL (7.0 mmol/L)	6.0%, or 42 mmol/mol
140 mg/dL (7.8 mmol/L)	6.5%, or 48 mmol/mol
154 mg/dL (8.6 mmol/L)	7.0%, or 53 mmol/mol
169 mg/dL (9.4 mmol/L)	7.5%, or 58 mmol/mol
183 mg/dL (10.2 mmol/L)	8.0%, or 64 mmol/mol
197 mg/dL (10.9 mmol/L)	8.5%, or 69 mmol/mol

Low-Glucose Allowance

The Low-Glucose Allowance parameter sets the threshold for which Likelihood of Low Glucose is reported as Low, Moderate or High. You can set this allowance to Small, Medium or Large.

Increasing this parameter allows more glucose readings below 70 mg/dL (3.9 mmol/L) before causing the Likelihood of Low Glucose to go from Low to Moderate to High. The allowance is based on both the frequency and value of low readings. These settings translate approximately to:

Small	2% of readings at 50 mg/dL (2.8 mmol/L), or 4% of readings at 60 mg/dL (3.3 mmol/L)
Medium	4% of readings at 50 mg/dL (2.8 mmol/L), or 8% of readings at 60 mg/dL (3.3 mmol/L)
Large	10% of readings at 50 mg/dL (2.8 mmol/L), or 20% of readings at 60 mg/dL (3.3 mmol/L)

Printing, Viewing and Saving Reports

When the report parameters are set, you can choose to **Print Reports** or **View Reports** while the Reader is connected.

Click **Print Reports** to print reports without viewing. The software will then display a print window. You should confirm your printer settings and select Print. Reports can be printed in colour or black and white.

Click **View Reports** to view, save and then print reports. The software will display the selected reports. You can navigate through these reports to view them on screen either by selecting the report name from the dropdown menu, or by clicking through the pages (e.g. 1/6).

- The ⬈ , ⊖ and ⊕ buttons can be used to fit the report within the window, zoom out and zoom in to the report on the screen.

- The **Back** button goes back to the Create Reports screen, where you can change report selections or parameters.

- The **Save** button prompts you to save all selected reports to your computer as a PDF document.

- The **Print All** button opens the standard print window to allow printing of all selected reports.

> **IMPORTANT:** Work with your health care professional to understand your reports.

Use the report labels and legends to understand your reports. Additional information is provided below:

- **Estimated A1c** in the reports uses your Sensor glucose data. This may not match your A1c measured in a laboratory. The formula is based on the published reference[1], which compared average Sensor glucose and laboratory-measured A1c:

$$A1c_\% = (\text{Avg SG}_{mg/dL} + 46.7)/28.7$$
$$A1c_\% = (\text{Avg SG}_{mmol/L} + 2.59)/1.59$$

- Out-of-range Sensor glucose and blood glucose values are displayed as follows:

Out-of-range value	Displayed in reports
Sensor glucose above 500 mg/dL (27.8 mmol/L)	500 mg/dL (27.8 mmol/L)
Blood glucose above 500 mg/dL (27.8 mmol/L)	500 mg/dL (27.8 mmol/L)
Sensor glucose below 40 mg/dL (2.2 mmol/L)	40 mg/dL (2.2 mmol/L)
Blood glucose below 20 mg/dL (1.1 mmol/L)	20 mg/dL (1.1 mmol/L)
Blood ketone above 8.0 mmol/L	8.0 mmol/L

- Glucose values are labeled as **high** when higher than 240 mg/dL (13.3 mmol/L) and **low** when lower than 70 mg/dL (3.9 mmol/L). A low-glucose event uses the same low threshold.

- **Sensor data captured** is the percentage of possible Sensor data the Reader recorded from scanning your Sensor. To maximise this percentage, wear your Sensor for the entire timeframe and scan at least once every 8 hours.

Sometimes information may appear to be missing from reports, if:

- You did not wear the Sensor for the entire timeframe.
- You did not scan at least once every 8 hours.
- You did not enter food and/or insulin information in the Reader.
- You changed the time on the Reader.
- There was an excess of information to include in the report.

Glucose Pattern Insights

The Glucose Pattern Insights report includes an assessment of the following three Glucose Control Measures for each of the 5 time periods (there are 2 periods between Bedtime and Breakfast) in the "typical" day.

- **Likelihood of Low Glucose** is the probability that low-glucose values have exceeded an allowable, user-defined threshold.
- **Median Glucose** is an indication of when the median glucose has exceeded a user defined goal. Median glucose is strongly correlated to A1c.
- **Variability Below Median** is a measure of the spread of glucose data below the median. It is calculated as the difference between the 50th and 10th percentile glucose readings for the time period.

Important! When *variability below median* is high, it is difficult to achieve the median goal without increasing the *likelihood of low glucose*. Factors that could contribute to variability below median include erratic diet, incorrect or missed medication, alcohol consumption, variations in activity level or illness.

Note: The Glucose Pattern Insights report assesses Glucose Control Measures as Low, Moderate or High based on these criteria:

Glucose Control Measure	Assessment		
	OK Low	**Moderate**	**High**
Likelihood of Low Glucose	Less than 10% likelihood of exceeding the low-glucose allowance*	Between 10% and 50% likelihood of exceeding the low-glucose allowance*	Greater than 50% likelihood of exceeding the low-glucose allowance*
Median Glucose (compared to goal)	Less than goal	Greater than goal	Greater than goal AND More than 20% and 40 mg/dL (2.2 mmol/L) greater than the whole-day median
Variability Below Median (Median to 10th percentile)	Less than 35 mg/dL (1.9 mmol/L)	Between Low and High	Greater than a level that would support achieving the Median Goal without potentially causing low glucose

* See *Setting Report Parameters* section for information about the Low-Glucose Allowance setting.

Changing Reader Settings

The Reader Settings section lets you make changes to General Reader settings, Target Glucose Range, Reader Profile, Notes and Reminders. Remember to click the **Save To Reader** button after you make changes.

Note: Do not disconnect the Reader while you are making changes to the Reader settings. Your settings may not be saved if you disconnect the Reader during the saving process.

Home

FreeStyle *Libre*

Reader Settings

General

Target Glucose Range

Reader Profile

Notes

Reminders

General

Time and Date

Reader Time and Date
Thursday, 24 October 2019 11:28

Computer Time and Date
Thursday, 24 October 2019 11:31

Update   Pressing Update will adjust the time and date on the Reader to match your computer's time and date. This will not affect the data recorded prior to the update.

Clock Style

○ 12-hour (am/pm)

○ 24-hour

Language   English ▼

Discard Changes   Save To Reader

Time and Date	You can change the Reader time and date to match the Computer time and date by clicking the **Update** button. You can also change the Clock Style to either 12-hour or 24-hour. **CAUTION:** It is very important to set the time and date correctly. These values affect the Reader data and settings.
Language	You can change the language on the Reader. (This option is only available on Readers with multiple languages.)
Target Glucose Range	You can set the target glucose range for the Reader. Work with your health care professional to determine your Target Glucose Range. The Target Glucose Range can be set within 70 to 180 mg/dL (3.9 to 10.0 mmol/L). **Note:** • On the Reader, the Target Glucose Range is displayed on glucose graphs and used to calculate your Time in Target. • If you have a FreeStyle Libre 2 Reader, remember that the Target Glucose Range setting will not set your glucose alarm levels.
Reader Profile	You can change the name/and or ID that will be printed on the reports. The name and ID will be saved to the Reader but will not be visible on the Reader itself.
Notes	You can add notes to glucose readings and strip results on the Reader. There are five standard notes available, and you can add up to six custom notes. • Add notes to the list by clicking the **Add Note** button and typing in the desired note text. • Change the order that notes are displayed on the Reader by using the up and down arrows. • Delete a note by clicking the "**X**" symbol.
Reminders	You can change reminders set on the Reader. • Select **Reminder Type** (Check Glucose, Take Insulin, Other, or Custom) by using the dropdown menu. • Select **Reminder Frequency** (Once, Daily or Timer) by using the dropdown menu. • Set **Reminder Time** by using the up and down arrows or by typing in the desired time. • Turn Reminder **On** or **Off**. **Note:** Use the **Add Reminder** button to create up to 12 reminders.

Additional Features

Software Update	If a software update is available, a message will be shown on the FreeStyle Libre software Home Screen. Follow the on-screen instructions to perform the update.
Uninstall	You can uninstall the application using the normal uninstall procedure on the computer's operating system. Uninstalling the application will erase the installation files. Any reports that were saved on the computer can still be viewed as a PDF even if the software is uninstalled.
Auto-Launch	Auto-Launch is accessible through the File menu on the top menu bar. If Auto-Launch is enabled, the software will launch when a Reader is connected.
Auto-Save	Auto-Save is accessible through the File menu on the top menu bar. If Auto-Save is enabled, the software will automatically save your reports whenever you print or view them. You can choose the file name format and save location.
Export Data	Export Data is accessible through the File menu on the top menu bar. This allows you to export data from your Reader to a file that can be archived.

References

IFCC: Jeppsson JO, Kobold U, Barr J, et al.; International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Approved IFCC reference method for the measurement of HbA1c in human blood. Clin Chem Lab Med 2002; 40:78–89

NGSP: Little RR, Rohlfing CL, Wiedmeyer HM, Myers GL, Sacks DB, Goldstein DE; NGSP Steering Committee. The national glycohemoglobin standardization program: a five-year progress report. Clin Chem 2001; 47: 1985–1992

[1]Nathan DM, Kuenen J, Borg R, Zheng H, Schoenfeld D, Heine RJ for the A1c-Derived Average Glucose (ADAG) Study Group: Translating the hemoglobin A1c assay into estimated average glucose values. Diabetes Care 2008, 31:1473-8.

Sacks DB. Measurement of Hemoglobin A1c: A new twist on the path to harmony. Diabetes Care 2012, 35: 2674–2680.

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Labelling Symbols:

⩀	Manufacturer	📖i	Consult instructions for use
CE	CE Mark	REF	Catalogue number

Patent: https://www.abbott.com/patents

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