User's Guide

FreeStyle Auto-Assist™ Neo

Diabetes Management Software

For use with FreeStyle Optium Neo and FreeStyle Precision Neo

Abbott

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Important Information about the FreeStyle Auto-Assist Neo Software

Purpose

FreeStyle Auto-Assist Neo software is designed to help you get the most out of the FreeStyle Optium Neo and FreeStyle Precision Neo Blood Glucose and Ketone Monitoring Systems.

- **Patients** can generate, view and print reports and change their meter settings.
- **Healthcare professionals** can generate, view and print reports and configure the insulin settings that the patient will see on the meter.

This user's guide will explain how to perform these tasks on the software. Additional information is available in the software when you see this symbol: 

IMPORTANT: Patients should always consult their healthcare professional if they have any questions or concerns about their diabetes management or results.

CAUTION: Do not use FreeStyle Auto-Assist Neo software to upload data from any device that has stored data for more than one person. FreeStyle Auto-Assist Neo software assumes that the data on the device is from one individual.

Intended Use

FreeStyle Auto-Assist Neo Diabetes Management software is a qualitative, automated, stand-alone in vitro medical device software.

It is intended for use by patients and healthcare professionals to aid in the review, analysis and evaluation of information such as blood glucose test results, blood ketone test results and other data uploaded from a meter of patients with diabetes mellitus and ketosis including diabetic ketoacidosis (DKA).

- The software, when used with the FreeStyle Optium Neo or FreeStyle Precision Neo meters, is intended to be used by patients to generate, view and print reports and change settings. The software can also be used to configure the meter to set recommendations to insulin doses based on data entered by the healthcare professional.
- The software, when used with FreeStyle Optium Neo H or FreeStyle Precision Neo H meters, is intended to be used in a healthcare professional setting. Healthcare professionals can generate, view and print reports and configure the settings for the meter.

The software is not intended for the diagnosis of or screening for diabetes mellitus or diabetes ketoacidosis (DKA).

System Requirements

A computer running one of the following operating systems:

- Microsoft® Windows 7 (32 or 64 bit)
- Microsoft® Windows 8 (32 or 64 bit)
- Microsoft® Windows XP (Service Pack 3)

At a minimum, a computer with a USB 2.0-compliant hub with a dual-core 2.4 GHz processor and 2 GB RAM is required. Adobe® Reader is recommended to view PDF-formatted reports.

Connecting the Meter

In order to create reports or change meter settings, the meter must be connected to the computer. A USB cable is provided in the system kit. Plug one end into the USB port on the meter and the other end into the USB port on the computer. Use only the USB cable included with the system kit.
If you have connected the meter but the software does not recognise it, go to the Troubleshooting section of this user's guide.

WARNING: To avoid the possibility of electric shock, never perform a blood glucose test while the meter is connected to the computer.

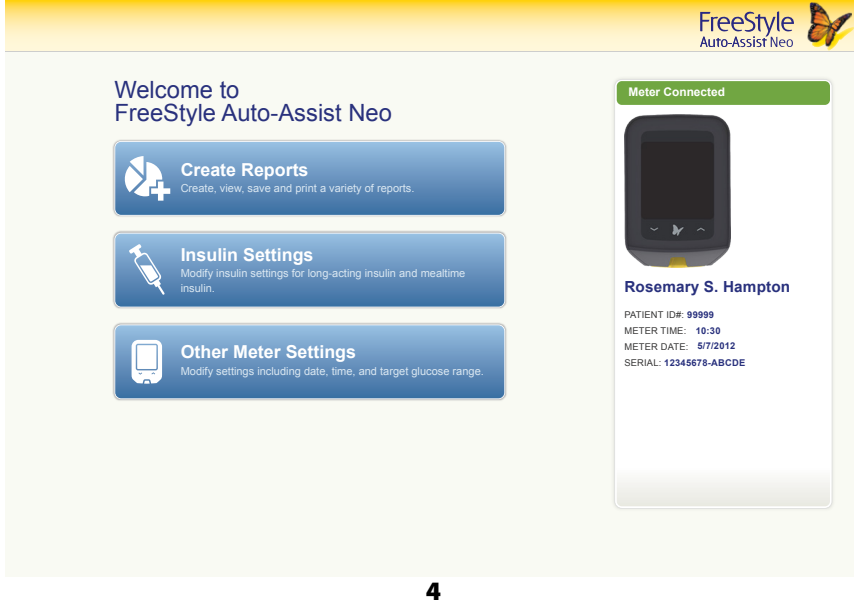
Setting Time and Date

The correct time and date are required on the meter, as this affects the data in reports.

You may be asked to update the time on the meter when it is connected to FreeStyle Auto-Assist Neo software. When you click **Update**, the meter time will change to match the current time on the computer.

Getting to Know the FreeStyle Auto-Assist Neo Software

The Home Screen allows you to access the different features of the software for generating reports and changing meter settings. Once the meter is connected and recognised by the software, the following buttons will appear on the Home Screen:



Create Reports

Patients and their healthcare professionals go here to create and print a variety of blood glucose reports. Reports may also be saved to the computer as a PDF.

> **IMPORTANT:** Work with your healthcare professional to understand your report data.

Insulin Settings

Healthcare professionals may set up this section using an access code. Patients may view and print but not edit insulin settings if they were previously configured on the meter.

Once the correct code is entered, the insulin settings may be edited and then saved to the meter. Insulin settings may include one or more of the following:

- Long-acting insulin base doses
- Meal insulin base doses
- Mealtime insulin adjustments
- Basal titration feature

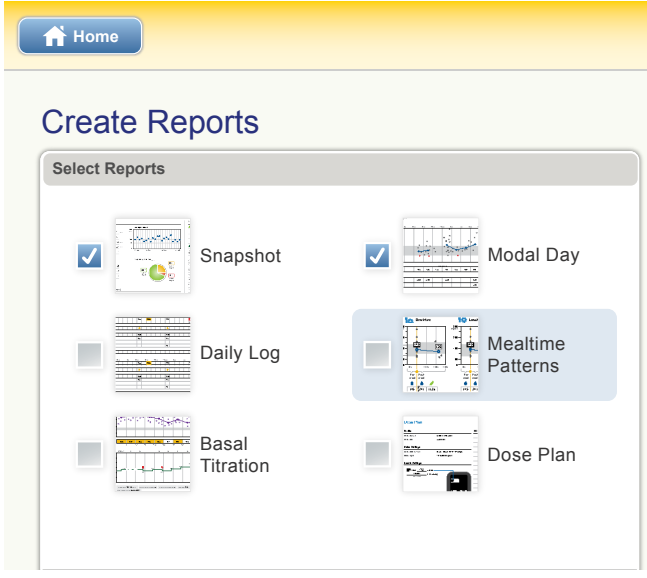
Other Meter Settings

This is the place to edit the following:

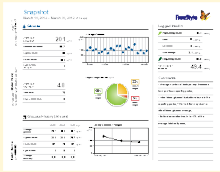
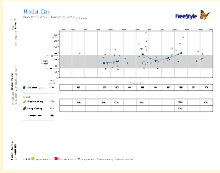
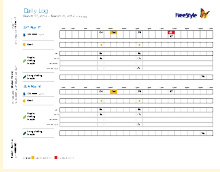
- Name or patient ID
- Time and date
- Hyper | hypoglycaemic trend indicators

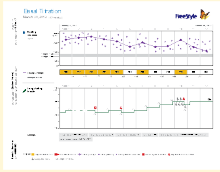
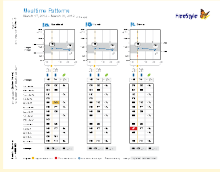
Creating Reports

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



Types of Reports

Report	What It Does
	The **Snapshot** report is a general summary of data for the specified date range. It also includes notes to inform patients and their healthcare professionals about important trends in blood glucose data by putting the data into words. Up to 6 notes are displayed at one time.
	The **Modal Day** report shows the daily pattern of blood glucose results over the specified date range.
	The **Daily Log** report is a table of blood glucose results and other values, such as ketone test results and insulin doses, for each day in the specified date range. **NOTE:** Insulin doses are only available if logged in the meter.

Report	What It Does
	The **Basal Titration** report compares fasting blood glucose levels with long-acting insulin doses over a 12-week period. The report also shows when long-acting insulin doses have been adjusted based on fasting blood glucose trends.
	The **Mealtime Patterns** report compares the before-meal and after-meal blood glucose levels for breakfast, lunch and dinner, over the specified date range. This report also shows before- and after-meal averages and logged insulin.
	The **Dose Plan** report shows all current insulin settings on the meter.

Setting Report Parameters

These parameters are used in the software reports and are not saved on the meter. They are set within the **Set Report Parameters** window.

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. The timeframe defaults to the one previously used to generate a report, unless it was previously selected using a custom start and end date.
Target Glucose Range	The target glucose range is displayed on some glucose graphs and is used to calculate your time in target. You can select a range within 70 to 200 mg/dL (3.9 to 11.1 mmol/L). **NOTE:** Your blood glucose target range and hyperglycaemic or hypoglycaemia threshold preferences will only be used in the reports and will not change any meter settings.

Low Glucose Threshold	Blood glucose levels that are below the low glucose threshold will be specifically marked on the reports by either a red down arrow, or the glucose value will be outlined in red.
Pre-Meal Target	This is the target blood glucose level for readings immediately before a meal. The mealtime patterns report uses this for comparing readings with the desired range.
Post-Meal Target	This is the target blood glucose level for readings 1, 2 or 3 hours after a meal. The mealtime patterns report uses this for comparing readings with the desired range.

Print, View and Save Reports

When the report parameters are set, you can choose to **Print** or **View** the reports.

NOTE: A name or patient ID must be added to the **User Profile** in order to **Print** or **View** reports.

The software will display a print window. Confirm the printer settings, then select **Print**.

The software will display the selected reports. Navigate through these reports to view them on screen either by selecting the report name from the drop-down menu or by clicking through the pages (for example, 1/6).

- The  ,  and  buttons can be used to fit the report within the window, zoom out and zoom into the report on the screen.
- The **Back** button goes back to the Create Reports screen. Report parameters can then be changed and the reports can be viewed again.
- The **Save** button prompts you to save the reports to the computer as a PDF.
- The **Print All** button opens the standard print window to allow printing.

Insulin Settings (for Healthcare Professionals Only)

To use the insulin features, healthcare professionals must first set up **Insulin Settings** with an access code.

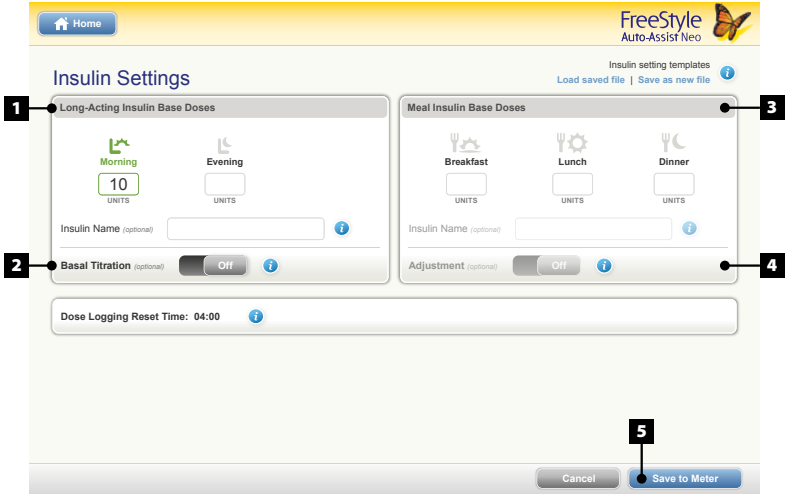
CAUTION: Abbott Diabetes Care provides the access code to healthcare professionals only. The set up of this feature is intended for healthcare professionals only who have an understanding of insulin use. Misuse or misunderstanding of this feature may lead to inappropriate insulin dosing.

To set up the insulin settings feature, follow these steps:

Step	Action
1	Click **Insulin Settings** on the Home Screen.
2	Click **Set Up Insulin**. If insulin settings have already been configured on the meter, the button will say **Edit Insulin**.
3	Enter the access code when prompted.

Overview

Once the access code has been entered, a healthcare professional may begin to configure **Insulin Settings**. When complete, click **Save to Meter**.



1 **Long-Acting Insulin Base Doses**

Long-acting insulin may also be called 'basal' or 'background' insulin. It refers to insulin that works throughout the day and night to provide a steady level of insulin in the body.

2 **Basal Titration**

Click **Basal Titration On**. Once **On**, you will be able to set parameters for how the patient should titrate to the optimal dose, based on the patient's fasting blood glucose readings.

This feature will only work if:

- One long-acting insulin base dose is entered (morning *or* evening) *and*
- No meal insulin doses are entered

3 **Meal Insulin Base Doses**

Meal insulin may also be called 'rapid-acting', 'short-acting' or 'bolus' insulin. It refers to the insulin taken at meal times to cover food the patient eats and this feature is only associated with meals not different times of day.

4 **Mealtime Insulin Adjustments**

When **Adjustment** is **On**, the meter will be able to make recommended mealtime insulin adjustments for the patient after a healthcare professional has entered an adjustment (correction) table or a correction factor.

This feature will only work if:

- **Basal Titration** is turned Off and
- One or more meal doses are entered

WARNING: This feature can only be used with rapid-acting or short-acting insulin (NOT pre-mixed insulin).

5 **Save to Meter**

Click to save your insulin settings to the meter. (Once settings are saved, you will have the option to print them.)

IMPORTANT: Click **Save to Meter** and wait until the software confirms that the meter settings have been saved before unplugging the meter from the computer, or your changes will be lost.

Setting Up Long-Acting Insulin Base Doses

'Long-acting insulin base doses' refers to doses that the patient takes each day, not including any adjustments made for basal titration (those will be entered separately).

Step	Action
1	Enter the number of long-acting insulin units the patient takes in the appropriate field(s).
2	When all units are entered, click **Save to Meter**.

Setting Up Meal Insulin Base Doses

'Meal insulin base doses' refers to doses that the patient takes specifically for breakfast, lunch or dinner, not including any adjustments made for mealtime insulin adjustments (those will be entered separately).

Step	Action
1	Enter the number of meal insulin units the patient takes in the appropriate box(es). • If the patient does not take a base dose, but does adjust at mealtime, enter a '0' (zero) for base dose. • If the patient does not take any insulin for a particular meal, leave the base dose field(s) blank.
2	When all units are entered, click **Save to Meter**.

What about pre-mixed insulin?
If the patient takes pre-mixed insulin (a mix of intermediate-acting and rapid-acting or short-acting insulin combined in one dose), the pre-mixed doses may be entered under **Meal Insulin Base Doses**. However, the basal titration and mealtime insulin adjustments feature **cannot** be used with pre-mixed insulin.

Setting Up Basal Titration

The meter includes the capability to increase or decrease a patient's base dose of long-acting insulin based on fasting glucose trends.

Step	Action
1	Enter the number of long-acting insulin units the patient takes in either the Morning or the Evening entry field.
2	Click the **Basal Titration On**.  This feature can only be turned **On** when • One long-acting insulin base dose is entered (morning or evening) *and* • No meal insulin doses are entered

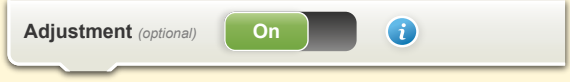
Step	Action
3	Enter a blood glucose target range. If the patient's average fasting blood glucose is within this target range, the dose will not change. • If the average is above the target range, the dose will titrate up by the number of units you enter in Step 5. • If the average is below the target range, the dose will titrate down by the number of units you enter in Step 5. • To enter a single target (instead of a range), set the 'low' and 'high' fields to the same number.
4	Enter the number of days to average for titration. *Example: If you enter a '3', the dose will titrate to the next increment after three fasting blood glucose have been logged by the patient and the average fasting blood glucose is above or below the target range in Step 3.*

Step	Action
5	Enter the units of insulin to add or subtract when titration occurs. *Example: If you enter '2' here, the next scheduled long-acting dose will be adjusted up or down by two units when titration occurs.*
6	Enter the maximum titrated dose. This is the maximum dose the meter will suggest for long-acting insulin.
7	Set **Auto Shut-off**. If left in the default position **On**, titration will stop once the average fasting glucose is within range for three consecutive titration periods. If the toggle is switched to **Off**, the meter will continue to monitor for results above or below the blood glucose target and adjust the base dose on an ongoing basis.

Step	Action
8	Set **Night-time hypoglycaemia check**. The default position is **Off**. When **On**, the patient will be required to perform a blood glucose test within the three hours preceding the **Dose Logging Reset Time**. *Example: If **Dose Logging Reset Time** is set for 04:00, the **Night-time hypoglycaemia check** test window would be 01:00 to 04:00.* Step 8a. If **Night-time hypoglycaemia check** is **On**, you must enter a **Night-time hypoglycaemia limit**. The patient will be required to perform one overnight blood glucose test during each titration period before a new long-acting dose will be given. If the patient's blood glucose is below the Night-time hypoglycaemia limit, then the next scheduled long-acting dose will automatically titrate down by the number of units you entered in Step 5.
9	Click **Save to Meter**.

Having trouble turning the Basal Titration feature On?
Make sure that one long-acting insulin base dose is entered. Make sure **Adjustment** is **Off** and no values are entered in the **Rapid-Acting Base Doses**. Basal titration will not work if there are any rapid-acting doses entered or if the patient is on a split long-acting dose.

Setting Up Mealtime Adjustment (Using a Table)

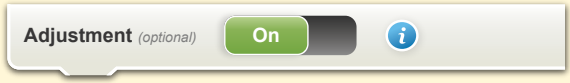
Step	Action
1	Enter the number of rapid-acting or short-acting insulin units the patient takes at each meal.
2	Click **Adjustment On**. 

Step	Action
3	When setting up the meter for the first time, an adjustment (correction) table will appear at the bottom of the page. (You may need to scroll down.) Fill in the table with the desired values for blood glucose ranges and their corresponding insulin adjustment values. **NOTE:** If the meter has been configured previously for a correction factor, click **By Table** to complete this step. 
4	When the table is complete, click **Save to Meter**.

Adjustment (Correction) Table: Helpful Tips

- Click **Different adjustment for each meal On** if you would like to enter unique adjustment values for each meal. (If left **Off**, the single adjustment will apply to all meals for which there is a base dose entered.)
- Click **Add Range** at the bottom of the table to add new rows. (The table can have between 3 and 20 rows.)
- Place the cursor anywhere over a row and click on that appears on the left to delete that row.
- To enter a negative adjustment, enter a - (minus) and a number in the insulin unit field.

Setting Up Mealtime Insulin Adjustment (Using a Correction Factor)

Step	Action
1	Enter the number of rapid-acting or short-acting insulin units the patient takes at each meal.
2	Click **Adjustment On**. 

Step	Action
3	An adjustment (correction) table will appear at the bottom of the page. (You may need to scroll down.) Click **By Factor**.  **NOTE:** If the meter has been configured previously for a correction factor, the screen will automatically show the **By Factor** view.
4	Enter the patient's target blood glucose range. If the patient's blood glucose is within this range, the meter will not suggest an adjustment dose.
5	Enter a correction factor. A correction factor may also be referred to as an 'insulin correction factor' (ICF) or 'sensitivity factor'. It determines how many points the patient's blood sugar will drop with one unit of rapid-acting or short-acting insulin. Example: A correction factor of 50 means one unit of insulin drops the blood glucose by 50 mg/dL. A correction factor of 2.8 means one unit of insulin drops the blood glucose by 2.8 mmol/L.
6	Click **Save to Meter**.

Printing and Saving Insulin Settings

There are two times when you will have the option to print your insulin settings. In both cases, the meter must still be connected to the software.

- After configuring insulin settings and clicking **Save to Meter**, you will see the option to **Print** or **Save as PDF**.
- When re-connecting a meter that has already been set up, you should see a button on the lower left of the **Insulin Settings** page that says **Print**. You may print the settings or save them as a PDF, even if you do not have an access code.

Creating Insulin Settings Templates (for Healthcare Professionals Only)

An **Insulin Settings Template** is a group of settings that you create and then save as a document on the computer. Later, you may import that group of insulin settings back into the software when setting up a new meter.

Healthcare professionals who frequently set up meters can use these templates to save time. For example, if you use the same adjustment (correction) table for certain types of patients, you may save those settings as a template. When setting up a new meter for the same type of patient, you can import or load a saved template instead of re-entering the table. Settings can be edited before saving them to each meter.

Saving a New Template

Step	Action
1	Fill in the insulin settings form in the software.
2	Prior to saving the insulin settings to the meter, click the **Save as a new file** link in the upper right corner of the screen. **NOTE:** To save the insulin settings to the meter, click **Save to Meter**.
3	Follow the on-screen instructions for saving your document to the computer. Make sure to give the file a name that will be easy to recognise later, especially if you plan to save different templates for different types of patients. *Examples: 'Male Type2' or 'New Basal Patient'*

Using an Existing Template

Step	Action
1	Connect your patient's meter and go to **Insulin Settings**.
2	Click the **Load saved file** link in the upper right corner of the screen.
3	Follow the on-screen instructions for selecting your saved file and importing it into the software.
4	You will see your previously saved values on the **Insulin Settings** page.
5	Make any needed changes to the settings on the screen. These changes will only be applied to the meter that is connected, not the template.
6	When the settings on your screen are complete, click **Save to Meter**.

Setting Time and Date

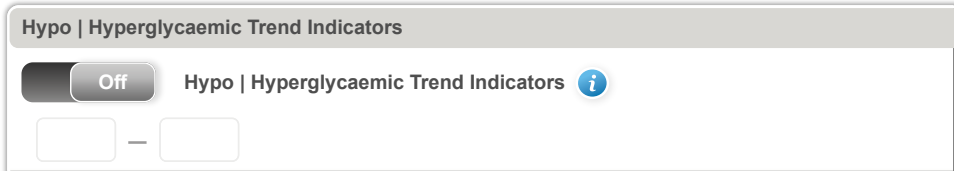
It's important that the time and date are accurate. If you would like to update, go to the Home Screen, click on **Other Meter Settings** and go to the meter time and date area. Click **Update** to sync the meter time and date to the computer.

User Profile

The patient's name and ID can be saved to the connected meter but are not visible anywhere on the meter itself. The profile information is only visible within the software when the meter is connected.

Step	Action
1	Click **Other Meter Settings**.
2	Enter the patient's name and/or ID number (optional).
3	Click **Save to Meter**.

Hypo | Hyperglycaemic Trend Indicators



When the **Hypo** | **Hyperglycaemic Trend Indicators** is **On**, the meter will notify the patient with a ↓ if the patient's blood glucose is below the set low glucose threshold or a ↑ if the patient's blood glucose is above the set high glucose threshold. The meter will also use these ranges to determine patterns. Click **Save to Meter**.

Additional Features

Software Update	If a software update is available, a message will appear on the Home Screen. Follow the on-screen instructions to perform the update.
Uninstall	Uninstall the software using the uninstall procedure on the computer's operating system. Uninstalling the software 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	From the menu bar at the top of the screen, click **File**. From the drop-down, click on **Auto-Launch** to tick and untick. When **Auto-Launch** is ticked, FreeStyle Auto-Assist Neo software will automatically start and upload data when a compatible meter is connected to your computer. When **Auto-Launch** is unticked, FreeStyle Auto-Assist Neo software must be started manually. Once started, data will upload automatically when a meter is connected. **NOTE:** If you are using any other software program or application that communicates with Abbott Diabetes Care meters, the **Auto-Launch** feature must be unticked and the FreeStyle Auto-Assist Neo software closed before the other application can communicate with the connected meter.
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.

Troubleshooting

If the computer does not recognise the meter, check the following:

- **Using a supported meter?**
  The software only supports the FreeStyle Optium Neo and FreeStyle Precision Neo meters.
- **Only one meter connected?**
  The software may not work when multiple meters are connected. Make sure only one meter is connected to the computer at any given time.
- **Secure connection?**
  Ensure that the cable is securely connected to both the meter and the computer.
- **Exit and restart the software**
  If the meter is still not recognised, exit the software and try again.

If you continue to have difficulty, contact Customer Care.

Getting More Help

Additional information is available within the software when you see:

Symbol	What It Does
	Gives general help information about specific features or functionality.
	Describes specific errors that must be corrected before saving settings to the meter.
	Highlights settings in the adjustment (correction) table that may have been created in error.

Customer Care

For a printed copy of this User's Guide, contact Customer Care.
Contact the Abbott Diabetes Care Customer Care for your country (**www.AbbottDiabetesCare.com**).

Reporting of Serious Incidents

If a serious incident has occurred in relation to this device, it should be reported to Abbott Diabetes Care. Please go to www.MyFreeStyle.com or refer to the manual in your Meter Kit for your Customer Service phone number. In European Union Member States, serious incidents should also be reported to the competent authority, (the government department responsible for medical devices) in your country. Please refer to your government website for details of how to contact your competent authority.

A 'serious incident' means any incident that directly or indirectly led, might have led or might lead to:

- The death of a patient, user or other person.
- The temporary or permanent serious deterioration of a patient's, user's or other person's state of health.

Disclaimers and Limitations of Liability

The information contained in this Guide, including, but not limited to, any product specifications, is subject to change without notice. For the most up-to-date information, please visit our website, www.AbbottDiabetesCare.com.

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Description of Symbols	
	Manufacturer
CE	CE Mark
EC REP	Authorised Representative in the European Community
IVD	*In vitro* diagnostic medical device
REF	Catalogue Number
	Date of Manufacture
UDI	Unique Device Identifier
UK CA	UKCA Marking

India Voluntary registration number: M/sAb-GBR/I/MD/002518

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