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IVD

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User's Manual



11/17/10 2:40 PM



Definition of Symbols

These symbols are associated with your meter.

LOT	Batch code		The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The
REF	Catalogue number		batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.
\triangle	Caution		This packaging is capable of being recycled
[]i	Consult instructions for use		Manufacturer
\sim	Date of manufacture	STERILE R	Sterilised using irradiation (lancets only)
	Do not drink	1	Temperature limitation
2	Do not reuse		Use by
IVD	<i>In vitro</i> diagnostic medical device	SN	Serial number

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Intended Use

Use outside the body only (in vitro diagnostic use) for self testing or professional use in the management of diabetes

Use for measuring blood glucose from samples taken from the forearm, upper arm, base of the thumb, or fingers.

- Test blood glucose in fresh whole blood samples
- Test blood β -Ketone (β -hydroxybutyrate) in fresh whole blood samples from fingers only

IMPORTANT: Use only FreeStyle Optium blood glucose test strips and $FreeStyle\ Optium\ blood\ \beta$ -Ketone test strips. Other test strips may produce inaccurate results. **IMPORTANT:** See test strip instructions for use for more information about sample types.

Potential infection risk: Healthcare professionals performing blood tests with this system on multiple patients must always wear gloves and should follow the infection control policies and procedures approved by their facility.

Read the instructions in this user's manual. Failure to follow instructions will cause incorrect results. Practise the testing procedures before using the meter. Follow your healthcare professional's advice when testing blood glucose levels and blood

Observe caution when using around children. Small parts may constitute a choking hazard.

How Your FreeStyle Optium Blood Glucose Monitoring System Works

When you insert a test strip into your meter, the Apply Sample message shows on your meter's display window. When a blood sample or control solution sample is applied to the test strip, the glucose or $\beta\text{-Ketone reacts with the chemicals on the test strip. This reaction produces a small electrical current}$ that is measured. The result shows on your meter's display window.

> IMPORTANT: Avoid getting dust, dirt, blood, control solution, water or any other substance in the meter's test strip port.

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Monitoring System Kit Contents Monitoring System Kit contains: • Meter • Logbook • User's Manual • Warranty Card • Carrying Case Your Kit may also contain: • Blood Glucose Test Strips • Lancets • Lancing Device Items not included:

Data Management System

Setting Up the Meter **Enter Setup Mode** • Press ① to move between setup displays Start with the meter off (no test strip inserted). • Press > to move forward • Press **◀** to go back • Press 🔆 to turn display light On and Off √ □ Press and hold ① until $\sqrt{}$ and $\sqrt{}$ appear. This indicates the beeper is turned on. X and Π indicate the beeper is turned off. ХЛ Beeper

The beeper sounds when: • The test countdown starts

Press **●** or **▶** to change the beeper setting. Press **()** to save the beeper setting and move • The test countdown ends to set time.

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• Blood β-Ketone Test Strips

• Control Solutions

(



Time

15:00**

The hour flashes. Press \P or ightharpoonup until the correct hour appears. Press 1 to save the hour and to move to set minutes.

The minutes flash. Press ¶ or № until the correct minutes appear. Press ① to save the minutes and to move to set date.

Date

(

20 10 Year

10-1

Month - Day

The year flashes. Press \P or \blacksquare until the correct year appears. Press \P to save the year and to move to set month.

The month flashes. Press ◀ or ▶ until the correct month appears. Press ① to save the month and to move to set day.

The day flashes. Press \P or \P until the correct day appears. Press \P to save the day and to move to set time format.

Time Format



Note: If using the 12-hour time format, AM and PM appear.

The time format flashes. Press \P or \blacktriangleright to change the time format. Press \P to save the time format and to move to set date format.

Date Format

|**[]-** |**5** Month – Day The date format flashes. Press \blacktriangleleft or \blacktriangleright to change the date format. Press 1 to save the date format and to move to the measurement units.

15. 10 Day.Month

IMPORTANT: Please check that the correct time and date is set before you use the meter for the first time. This will help you keep records of when you monitor and will help you and your healthcare professional make informed decisions about your care. **You must set the time and date to review averages**.

Measurement Units

mmol/L mg/dL The unit of measurement set by the factory appears. You cannot change this setting. Contact Customer Service for more information.

Press 1 to return to set beeper, or press and hold 1 to turn off the meter.

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Testing Your Blood Glucose

Important Testing Notes



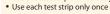
This display always appears when the meter is turned on. You should check that your meter matches the example you see here exactly every time your meter turns on.

Do not use the meter if the display check screen does not exactly match the example.

If the screen does not match, the meter may show an incorrect result. Please contact Customer Service.



- Use the meter within the test strip operating range
- Use the test strip immediately after removing it from its foil packet





Do not use expired test strips; they may produce inaccurate results. The expiry date is the last day of the month if only the month and year are shown.

Do not use a wet, bent, scratched or damaged test strip. **Do not** use the test strip if its foil packet has a puncture or tear in it.

Note: See test strip instructions for use for operating range and more information on limitations of use.

Test Site



IMPORTANT: Wash your hands and the test site with warm soapy water to ensure accurate results. Thoroughly dry your hands and the test site. To warm the site, apply a warm dry pad or rub vigorously for a

Note: Avoid areas near bones, areas with lots of hair, and squeezing the puncture site. Bruising may occur at alternate sites, but will disappear quickly. If bruising occurs, consider selecting another site.

Finger tip testing is different to alternative site testing. (Adjust the lancing device accordingly for testing site. See lancing device instructions for use for more information.)

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Alternative Sites





Upper arm

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Obtaining a blood sample from alternative sites – forearm, upper arm, and base of the thumb – is subject to limitation. Contact your healthcare professional before beginning alternative site testing.

- Alternative site results may differ from fingertip results when blood glucose levels change rapidly (e.g. after eating a meal or taking insulin, or during or after exercise)
- Use alternative sites before, or more than two hours after, you eat a meal, take insulin, or exercise

Do not use blood samples from alternative sites when:

- You think your blood glucose is low or changing rapidly
- You have been diagnosed with hypoglycaemic unawareness
- $\bullet\,$ Alternative site results do not match the way you feel
- You are within two hours of eating a meal, taking insulin, or exercising

Performing a Blood Glucose Test





Open the foil test strip packet at the notch and tear down to remove the test strip.



Insert the Test Strip

With the contact bars (3 black lines) facing up, insert the test strip into the meter until it stops. This turns on the meter.

Note: The meter turns off after 3 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.



This display always appears when the meter is turned on.

Do not use the meter if the display check screen does not exactly match the example. Contact Customer Service.

See "Testing Your Blood Glucose" section for more information.

10:30^{AM} 12-5 Time and date (if set) appear next.





The Apply Sample symbols \spadesuit and \square appear next, indicating the meter is ready for you to apply a sample to the test strip.



Obtain a Blood Sample

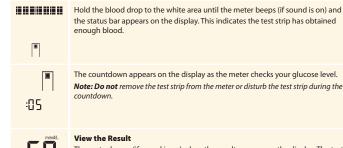
Select a test site. Use the lancing device to obtain a blood sample. (See lancing device instructions for use for more information.)



Apply Blood to the Test Strip

Bring the blood drop to the white area at the end of the test strip. The blood is drawn into the test strip.

IMPORTANT: If the countdown does not start, you may not have applied enough blood to the test strip. See test strip instructions for use for re-application instructions. If the countdown still does not start, remove the used strip and discard it correctly. Start a new test with a new test strip.



View the Result

The meter beeps (if sound is on) when the result appears on the display. The test is complete (example shown). The result is stored in memory or you can write it in a



Turn Off the Meter

Use the opened foil packet to remove the used test strip. This turns off the meter. Discard the used test strip correctly.

Note: You can also press and hold 1 for at least 2 seconds to turn off the meter. The meter also turns off after 60 seconds of inactivity.

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Understanding Blood Glucose Test Results

Low and High Blood Glucose Results

The meter displays results in mmol/L or mg/dL. The unit of measurement is preset. You cannot change this setting.

IMPORTANT: The meter displays results from 1.1–27.8 mmol/L (20–500 mg/dL). Low or high blood glucose results can indicate a potentially serious medical condition.

General:

Result	What It Means	What To Do
Lower than 2.8 mmol/L (Lower than 50 mg/dL)	Low (hypoglycaemic)	Repeat the test with a new test strip, even if you do not feel that you have low blood glucose.
Higher than 16.7 mmol/L (Higher than 300 mg/dL)	High (hyperglycaemic)	Repeat the test with a new test strip, even if you do not feel that you have high blood glucose.

Meter:

meter:		
Display	What It Means	What To Do
Appears when result is: Lower than 1.1 mmol/L (Lower than 20 mg/dL))	Severe low blood glucose or There may be a problem with the test strip	Repeat the test with a new test strip. If the result is LO, contact your healthcare professional immediately .
KETONES? Appears with result which is: Higher than or equal to 16.7 mmol/L (Higher than or equal to 300 mg/dL)	Blood glucose level is high	Check blood β-Ketone, if checking ketones is part of your diabetes management programme.

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Testing Your Blood β-Ketone

Important Testing Notes



- Use the meter within the test strip operating range
- Use the test strip immediately after removing it from the foil packet
- Use each test strip only once

Do not use expired test strips; they may produce inaccurate results. The expiry date is the last day of the month if only the month and year are shown.

Do not put urine on the test strip.

Do not use a wet, bent, scratched or damaged test strip.

Do not use the test strip if its foil packet has a puncture or tear in it.

Note: See test strip instructions for use for operating range and more information on limitations of use.

Check your ketones:

- When you have an illness
- When your blood glucose is above 16.7 mmol/L (300 mg/dL)
- When you are experiencing unusual blood glucose results
 When you and your healthcare professional feel it is necessary

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Test Site



IMPORTANT: Wash your hands with warm soapy water to ensure accurate results. Thoroughly dry your hands. To warm the site, apply a warm dry pad or rub vigorously for a few seconds.

Note: Avoid squeezing the puncture site.

Use only fingertip blood samples for blood β -Ketone testing.

Performing a Blood β-Ketone Test



Open the foil test strip packet at the notch and tear down to remove



Insert the Test Strip

With the contact bars (3 black lines) facing up, insert the test strip into the meter until it stops. This turns on the meter.

Note: The meter turns off after 3 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.



This display always appears when the meter is turned on.

Do not use the meter if the display check screen does not exactly match the example. Contact Customer Service.

See "Testing Your Blood Glucose" section for more information.

10:30^ 12-5

Time and date (if set) appear next.

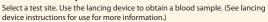
KETONE

KETCHE and the Apply Sample symbols $\stackrel{\bullet}{\blacktriangle}$ appear, indicating the meter is ready for you to apply a sample to the test strip.





Obtain a Blood Sample





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Apply Blood to the Test Strip

Bring the blood drop to the white area at the end of the test strip. The blood is drawn into the test strip.

> **IMPORTANT:** If the countdown does not start, you may not have applied enough blood to the test strip. See test strip instructions for use for re-application instructions. If the countdown still does not start, remove the used strip and discard it correctly. Start a new test with a new test strip.



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Hold the blood drop to the white area until the meter beeps (if sound is on) and the status bar appears on the display. This indicates the test strip obtained enough blood.

KETONE

The countdown appears on the display as the meter checks your β -Ketone level. **Note: Do not** remove the test strip from the meter or disturb the test strip during the

: 10

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View the Result

The meter beeps (if sound is on) when the result and KETOHE appears on the display. The test is complete (example shown). The result is stored in memory or you can write it in a logbook.

Turn Off the Meter

Use the opened foil packet to remove the used test strip. This turns off the meter. Discard the used test strip correctly.

Note: You can also press and hold $\widehat{\mathbf{Q}}$ for at least 2 seconds to turn off the meter. The meter also turns off after 60 seconds of inactivity.





Understanding Blood β-Ketone Test Results

High Blood β-Ketone Results

The meter displays results in mmol/L. The unit of measurement is preset. You cannot change this setting.

IMPORTANT: The meter displays results from 0.0 - 8.0 mmol/L. Consult your healthcare professional before changing your diabetes medication programme.

Blood β -Ketone is expected to be below 0.6 mmol/L. 2 High blood β -Ketone may be caused by illness, fasting, vigorous exercise, or uncontrolled blood glucose levels. 13

Repeat a blood $\beta\textsc{-Ketone}$ test using a new blood $\beta\textsc{-Ketone}$ test strip when:

- HI appears on the display
- Your result is unusually high
- You question your result
- Your blood β-Ketone result is 0.0 mmol/L, but your blood glucose is higher than 16.7 mmol/L (300 mg/dL)

Meter

Display	What It Means	What To Do
Result is between: 0.6 – 1.5 mmol/L and your blood glucose result is: Higher than 16.7 mmol/L (Higher than 300 mg/dL)	High blood β-Ketone A problem requiring medical assistance may be occurring	Contact your healthcare professional for sick-day management instructions.
Result remains: 0.6 – 1.5 mmol/L or becomes: Higher than 1.5 mmol/L	You may be at risk of developing diabetic ketoacidosis (DKA) ²⁻⁶	Contact your healthcare professional immediately.
H Appears when result is: Higher than 8.0 mmol/L	Very high blood β-Ketone or There may be a problem with the test strip	Repeat the test with a new test strip. If the result is HI, contact your healthcare professional immediately .

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MediSense or Optium Glucose and Ketone Control Solutions



IMPORTANT: When you open a control solution bottle for the first time, count forward 90 days and write this date on the control solution bottle using a pen that won't smear or wipe off. Throw away any remaining solution after this date.

Control solutions may be used with either glucose or β -Ketone test strips. Use control solution:

- To practise testing without using your own blood
- To confirm that the meter and test strips work together correctly
- When you are unsure of your blood glucose or blood β -Ketone test results Contact Customer Service for information on how to obtain control solutions.

Important Control Solution Testing Notes

- Use only MediSense or Optium Glucose and Ketone control solutions with the meter
- Replace the cap securely on the bottle immediately after use

Do not use control solution past the expiry date.

Do not add water or other liquid to control solution.

Do not swallow or inject the control solution.

Do not use the control solution as eye drops.

IMPORTANT: Control solution results should fall within the control solution range printed on the test strip instructions for use. Check that the lot number printed on the test strip packet and instructions for use match.

- Repeat the test if control solution results are outside this range
- Stop using the meter if control solution results are continually outside the range printed on the test strip instructions for use. Contact Customer Service

 $\label{eq:mportant:control} \begin{tabular}{ll} \textbf{IMPORTANT:} Control solution results do not reflect your blood glucose or blood β-Ketone level. \end{tabular}$

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Performing a Control Solution Test



Open the foil test strip packet at the notch and tear down to remove the test strip.



Insert the Test Strip

Time and date (if set) appear next.

With the contact bars (3 black lines) facing up, insert the test strip into the meter until it stops. This turns on the meter.

Note: The meter turns off after 3 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.



This display always appears when the meter is turned on.

Do not use the meter if the display check screen does not exactly match the example. Contact Customer Service.

See "Testing Your Blood Glucose" section for more information.

10:30*** 12-5

The Apply Sample symbols and and also appear.

Note: ΚΕΤΩΝΕ and will appear if performing a β-Ketone control solution test.

Press () to mark the test as a control solution test.

The appears. The meter is now ready for you to apply control solution to the test strip.

IMPORTANT: The test result will be saved to memory as a blood glucose or blood β-Ketone result if not marked as a control solution test. This may affect your blood glucose averages.

Apply Control Solution to the Test Strip

Shake the control solution bottle to mix the solution. Apply a drop of control solution to the white area at the end of the test strip in the area shown. The control solution is drawn into the test strip.

Hold the control solution drop to the white area until the meter beeps (if sound is on) and the status bar appears on the display. This indicates the test strip has obtained enough control solution.



Compare the control solution result to the range printed on the blood glucose or blood β -Ketone test strip instructions for use. The result should fall within the range. Causes of out-of-range results include:

 \bullet The meter and test strips may not be working correctly

Repeat the test with a new test strip. Follow the testing instructions carefully. Contact Customer Service if the result is still outside the printed range.

Turn Off the Meter

Note: You can also press and hold 1 for at least 2 seconds to turn off the meter. The meter also turns off after 60 seconds of inactivity.



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Managing Your Results

Meter memory stores up to 450 events – control solution, blood glucose, and blood β -Ketone results, and other meter information. The most recent events appear first.

Viewing Test Results in Memory



Start with the meter off (no test strip inserted).

Press 1 to turn the meter on.



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This display always appears when the meter is turned on.

Do not use the meter if the display check screen does not exactly match the example. Contact Customer Service.

See "Testing Your Blood Glucose" section for more information.



Your most recent result, with time and date (if set) it was obtained, appears next. The following symbols indicate the type of result:

MEM = Blood glucose result



KET $MEM = Blood \beta$ -Ketone result

| Glucose control solution result





Press d to review the previous result. Repeat this for each result you wish to review

o review.

Note: To exit meter memory at any time, press and hold \bigcirc .



Appear on the display when there are no previous results to view.



Press to return to a previously reviewed result. Repeat this for each result you

Note: To exit meter memory at any time, press and hold ①.

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Viewing Blood Glucose Averages

IMPORTANT:

- Set the date and time before testing to be able to review averages
- Averages do not include glucose and β -Ketone control solution results, blood β -Ketone results, and results that do not show time and date
- Control solution results not marked as control solution tests may cause averages to be inaccurate
- appear on the display when there are no current averages to view
 blood glucose test results appear in averages as 1.1 mmol/L (20 mg/dL)
- H | blood glucose test results appear in averages as 27.8 mmol/L (500 mg/dL)





While in memory, press ①. Your 7-day average appears.

Note: n = number of results included in your 7-, 14-, or 30-day average.



Press ◀ to view the 14-day average.



Press ◀ to view the 30-day average.

Press ◀ to return to the 7-day average, or Press 1 to return to the memory screen.



Press and hold $\ensuremath{\textcircled{1}}$ to turn off the meter. The meter turns off after 30 seconds of inactivity.

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Transferring Results to a Computer

Transferring test results to a computer requires a compatible data management system. For more information, please go to our website or contact Customer Service.

Error Messages

	Message	What It Means	What To Do
	E-1	The temperature is too hot or too cold for the meter to work correctly	 Move the meter and test strips to a location where the temperature is within the test strip operating range. (See test strip instructions for use for the appropriate range.) Wait for the meter and test strips to adjust to the new temperature. Repeat the test using a new test strip. If the error reappears, contact Customer Service.
3	E-2	Meter error	Turn off the meter. Repeat the previous testing steps. If the error reappears, contact Customer Service.

Message	What It Means	What To Do
E-3	The blood glucose level may be too low to be read by the system or There may be a problem with the test strip	Review the testing instructions. Repeat the test using a new test strip. If the error reappears, contact your healthcare professional immediately.
E-4	The blood glucose level may be too high to be read by the system or There may be a problem with the test strip	Repeat the test using a new test strip. If the error reappears, contact your healthcare professional immediately.
E-5	Blood was applied to the test strip too soon	Review the testing instructions. Repeat the test using a new test strip. If the error reappears, contact Customer Service.

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Message	What It Means	What To Do
E-6	Meter error	Check that you are using the correct strip for this meter. (See test strip instructions for use to verify your strip is compatible with this meter.) Repeat the test using a test strip for use with your meter. If the error reappears, contact Customer Service.
[-]	No coding required or Test strip may be damaged, used, or the meter does not recognise it	Check that you are using the correct test strip for this meter. (See test strip instructions for use to verify your strip is compatible with this meter.) Repeat the test using a test strip for use with your meter.
E-B or E-9	Meter error	Turn off the meter. Repeat the previous testing steps. If the error reappears, contact Customer Service.
;		

Troubleshoo	oting	
	What It Means	What To Do
The meter does not enter test mode after inserting a test strip.	Test strip is not inserted correctly or fully into the meter	With the contact bars (3 black lines) facing up, insert the test strip into the meter until it stops. This turns on the meter. If the meter still does not enter test mode, contact Customer Service.
	No battery is installed Battery is installed incorrectly	1. Install battery with (+) facing up.
	Dead battery	Replace battery. Reset date and time, if necessary.

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	What It Means	What To Do
The test does not start after applying the blood sample.	Blood sample is too small	See test strip instructions for use for re-application instructions. If the countdown still does not start, remove the used strip and discard it correctly. Repeat the test using a new test strip. If the test still does not start, contact Customer Service.
7	Sample applied after meter turns off	 Remove the used strip and discard it correctly. Review the testing instructions. Repeat the test using a new test strip. If the test still does not start, contact Customer Service.
7		

The test does not start after applying the blood sample. Defective meter or test strip 1. Remove the used strip and discard it correctly. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact Customer Service.		What It Means	What To Do
	not start after applying the	Defective meter or test strip	correctly. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact

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Replacing the Battery

The meter comes with a CR 2032 lithium (coin cell) battery installed. It provides power for about 1,000 tests.



• Appears on the display when the battery is low.

Causes the display light to fail to turn on.

When () appears, you may still use the meter and the results will be accurate. The display light will not work. Replace the battery immediately.



When () appears alone, the meter is not usable. The meter turns off automatically. Replace the battery immediately.



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1. Gently push the battery cover in and up to remove it.



If the meter includes a plastic tab, pull on the tab to remove the battery.
 If the meter does not include a plastic tab, push the battery upward to remove it.



3. Insert a new CR 2032, lithium (coin cell) battery: (+) facing up.



4. Slide the battery cover into place until it clicks.

Note: Dispose of used batteries correctly.





5. Press and hold ① to turn the meter on. If the meter does not turn on, check to see that the battery was installed correctly.

If meter turns on, the meter may prompt you to reset the time and date. (See 'Setting Up the Meter' in this user's manual.)

Note: Test results will be not be lost even if the meter loses its time and date settings.

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Cleaning the Meter

 $\label{prop:control} \mbox{Avoid getting dirt, dust, blood, control solution, or liquid in the meter test strip port.}$ Clean the outside of the meter using a damp cloth and mild soap.

Healthcare Professionals:

Acceptable cleaning solutions include:
• 70% isopropyl alcohol, or

- A mixture of 1 part ammonia, 9 parts water, or
- A mixture of 1 part household bleach, 9 parts water

IMPORTANT:

Do not try to clean the test strip port.

Do not pour liquid into the test strip port or onto the buttons. **Do not** immerse the meter in water or other liquid.



Storing the Meter

Store the meter in the carrying case provided.

Specifications		
Size		
Length	7.47 cm	
Width	Top 5.33 cm	
	Bottom 4.32 cm	
	Depth 1.63 cm	
Weight	40 to 46 grams	
Power Source	1 CR 2032 Lithium (coin cell) battery	
Battery Life	Approximately 1,000 tests	
Memory	Up to 450 events, including control solution, blood glucose and blood $\beta\textsc{-Ketone}$ results, and other meter information.	
Storage Temperature		
Meter	-25 ° to 55 °C (–13 ° to 131 °F)	

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Test strips	See test strip instructions for use.
Control solution	See control solution instructions for use.
Assay Method	Amperometric electrochemistry
Assay Range	
Blood glucose	See blood glucose test strip instructions for use.
Blood β-Ketone	See blood β -Ketone test strip instructions for use.
Control Solution Range	
Blood glucose	See blood glucose test strip instructions for use.
Blood β-Ketone	See blood β -Ketone test strip instructions for use.
Functions	
Blood glucose testing	
Blood β-Ketone testing	
Memory	450 events
Glucose averaging	7-, 14-, and 30-day
Control solution marking and testing	

Beeper	On: When countdown starts and ends.
Display Light	On: Stays on during countdown; turns off 30 seconds after results appear. Stays on while transferring results to a computer.
Data Port	Yes
Operating Range	
Meter temperature	10 ° to 50 °C (50 ° to 122 °F)
System temperature	See operating range of the test strip you are using.
	See test strip instructions for use.
Meter relative humidity	10% to 90%, non-condensing
System relative humidity	10% to 90%, non-condensing
System altitude	Clinical testing demonstrates that altitudes up to 2,195 metres (7,200 feet) above sea level do not affect results

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