



Owner's Booklet



FreeStyle

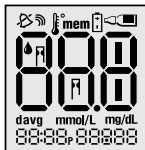
Freedom Lite

Blood Glucose Monitoring System



 **Abbott**

The FreeStyle Freedom Lite Meter and How It Works



System Check Screen

This display always appears when the meter is turned on. You should check that your meter matches the example 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 Care.

Display Screen

Displays your test results and other important information.

m (Mode) Button

- Moves to different mode settings
- Scrolls backward
- Silences a reminder alarm

Sample Areas (dark-colored half-circles on test strip)

Apply blood or control solution to one sample area only. Insert strip into the meter printed side up (see image to the right).



Data Port

Downloads test results. Requires a compatible data management system. *For more information, please go to our website or contact Customer Care.*

c (Configure) Button

- Marks a control solution test
- Scrolls forward
- Silences a reminder alarm
- Changes the date, time, alarm settings, sound options and reviews stored readings

Test Strip Port

Insert the **Top** end of a new FreeStyle Lite test strip here. The meter powers on when you insert the test strip.

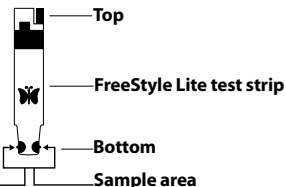
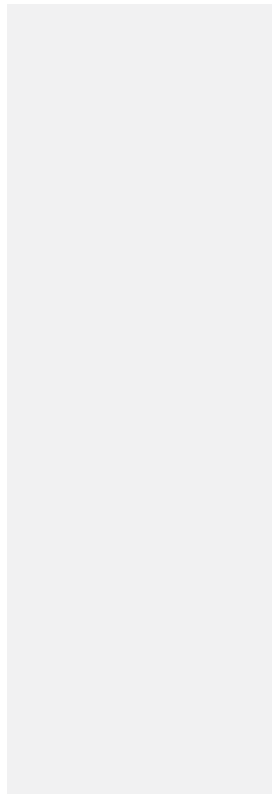


Table of Contents

The FreeStyle Freedom Lite Meter and How It Works	i
Important Information About Your Blood Glucose Monitoring System	1
Intended Use	1
Setting Up the Meter	2
Purpose	2
Set Sound Volume	3
Set Time	4
Set Date	5
Testing Your Blood Glucose	7
Purpose	7
Prepare to Test	7
Important Test Strip Information	9
Performing a Blood Glucose Test	10
Understanding Blood Glucose Test Results	12
Low and High Blood Glucose Results	13
Error Codes	16
Troubleshooting	19

FreeStyle Control Solution	21
Purpose	21
Control Solution Information	21
Out of Range Control Solution Results	22
Performing a Control Solution Test	23
Using Your Meter Memory	26
Purpose	26
Viewing Blood Glucose Averages in Memory	26
Viewing Test Results in Memory	27
Setting Reminder Alarms (optional)	28
Purpose	28
Transferring Test Results To a Computer	29
Maintaining the Meter	30
Replacing the Battery	30
Cleaning the Meter	32
Specifications	33
Definition of Symbols	35



Important Information About Your Blood Glucose Monitoring System

Intended Use

Use outside the body only (*in vitro* diagnostic use).

The FreeStyle Freedom Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the forearm, upper arm, thigh, calf, fingers and hand and venous whole blood. It is intended for self testing and for use by healthcare professionals for people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control programme. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates or arterial blood.

IMPORTANT: Use only FreeStyle Lite test strips and FreeStyle control solution with this meter. Other products can produce inaccurate results.

Warning:

- Test on your fingers if you are testing for low blood glucose (hypoglycaemia) or if you suffer from hypoglycaemia unawareness.
- This system contains small parts that may be dangerous if swallowed.

Caution: Please read all the instructions provided in this owner's booklet and practise the testing procedures before using the FreeStyle Freedom Lite system. Blood glucose monitoring should be done with the guidance of a healthcare professional.

Setting Up the Meter

Purpose

The purpose of this section is to set the meter sound volume, time and date.



1. With the meter off, press and **hold** (m) for **3** seconds until SET appears.

2. Press (m) to bypass setting the optional reminder alarms. You may choose to set these later (see Setting Reminder Alarms section).

Set Sound Volume



With the sound volume on, your meter will beep when:

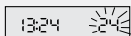
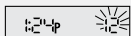
- The test strip is full of blood
- The test result appears on the display
- An error occurs

You may also choose to silence your meter.

3. Set sound volume

If you prefer:	Press C until you see:	Then
No sound		• Press m to save
A low beep		
A louder beep		

Set Time



Time Format

Note: Your meter can display either the 12-hour (12:24P) or the 24-hour (13:24) time formats. If you prefer the 12-hour format, there is no “A” for AM. If setting a PM time, continue to press **(C)** until you see the “P” displayed for PM.



Hour

4. Set hour

- Press **(C)** to display correct hour
- Press **(m)** to save



Minutes

5. Set minutes

- Press **(C)** to display correct minutes
- Press **(m)** to save



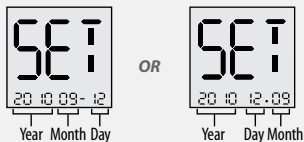
Time Format

6. Set time format

- Press **(m)** to accept time format or
- Press **(C)** to change
- Press **(m)** to save

Set Date

Note: The date format can display either:



Month

The month will flash first

7. Set month

- Press **C** to display correct month
- Press **m** to save



Day

8. Set day

- Press **C** to display correct day
- Press **m** to save



Date Format

9. Set date format

- Press **(m)** to accept date format or
- Press **(c)** to change
- Press **(m)** to save



Year

10. Set year

- Press **(m)** to accept year or
- Press **(c)** to change
- Press **(m)** to save

- 11.** Press and **hold** **(m)** for **3** seconds until meter turns off. Meter set up is complete.

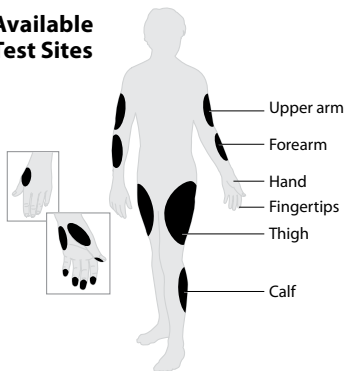
Testing Your Blood Glucose

Purpose

The purpose of this section is to produce an accurate blood glucose test result.

Prepare to Test

Available Test Sites



1. Select your test site.

Note: Avoid moles, veins, bones and tendons. Bruising may occur at the test site. If bruising occurs, consider selecting another site.

There are differences in testing on fingers versus alternative sites.

Warning:

Test on your fingers if you are testing for low blood glucose (hypoglycaemia) or if you suffer from hypoglycaemia unawareness.

Check for low blood glucose when:

- You feel symptoms such as weakness, sweating, shakiness, headache or confusion
- You eat a delayed meal after taking insulin
- You are following your healthcare professional's advice



IMPORTANT:

- 2.** Wash your hands and the test site with warm soapy water to ensure accurate results.
- Thoroughly dry your hands and the test site.
 - Do *not* use lotion or cream on the test site.



- 3.** Check test strip expiry date.

Do *not* use expired test strips; they may produce inaccurate results.

IMPORTANT: Use only FreeStyle Lite test strips. Other test strips can produce inaccurate results. The test strips are for single use only.

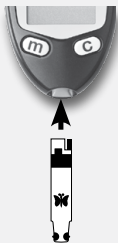
Important Test Strip Information

Please read the FreeStyle Lite test strip package insert for more information.

- Use the test strips within the meter's operating range: 40° – 104° F (4° – 40° C).
- Store test strips in a cool, dry place between 40° – 86° F (4° – 30° C).
- Store test strips away from direct sunlight and heat.
- Store test strips in their original vial only.
- Clean and dry your hands before removing a strip from the vial.
- Close the vial cap tightly immediately after removing a test strip.
- Do *not* transfer test strips to another container.
- Do *not* store test strips outside the vial.
- Do *not* bend, cut or alter test strips.
- Do *not* apply blood to both sides of the test strip.
- Do *not* press the test strip against the test site.
- Do *not* scrape the blood onto the test strip.
- Do *not* apply blood to the flat side of the test strip.
- Do *not* apply blood to the test strip when the test strip is out of the meter.
- Do *not* put blood or foreign objects into the meter.

Warning: Drying agents in the test strip vial or cap may be harmful if inhaled or swallowed and may irritate skin and eyes.

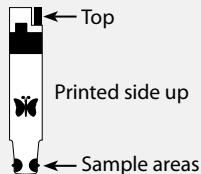
Performing a Blood Glucose Test



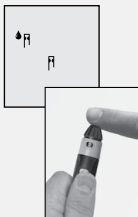
1. Remove test strip from vial.
2. Insert test strip to turn meter on.

Note: The meter turns off after 2 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.



If the meter does not turn on, go to Troubleshooting section.



3. Confirm System Check Screen.
 - This display appears when you turn on the meter. **Do not use the meter if the display check screen does not exactly match the example. Contact Customer Care.**
 - See The FreeStyle Freedom Lite Meter and How It Works section for more information.
 - If the system check screen does not appear, go to Troubleshooting section.



4. Obtain a blood drop.

When the  and  appears, use the lancing device to obtain a blood drop. (See FreeStyle lancing device insert for instructions.)

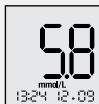
The test strip requires only a 0.3 microliter of blood for accurate results.



5. Apply and **hold** blood to 1 sample area of the test strip until:

- You see short lines moving clockwise on the display or
- You hear a beep

This indicates the test strip obtained enough blood and the meter is checking your glucose level. If a short line does not appear after 5 seconds, the sample may be too small. You can add blood to the same side only for up to 60 seconds. If the test does not start after applying blood drop, go to Troubleshooting section.



(Example only)

6. View result

The result appears on the display when the test is complete. The time that the meter takes to display a result depends on your blood glucose level. Higher glucose levels require more time.

Note: If you see an “Er1, Er2, Er3 or Er4” on the display, it is an error code. Go to Error Codes section.

7. Remove test strip to turn meter off.

Dispose of used lancet and test strip correctly.

Understanding Blood Glucose Test 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 1.1 – 27.8 mmol/L. Low or high blood glucose results can indicate a potentially serious medical condition.


- The expected normal fasting blood glucose level for an adult without diabetes is less than 6.1 mmol/L.¹
- Two hours after meals, the blood glucose level for an adult without diabetes should be less than 7.8 mmol/L.¹
- Consult your healthcare professional to determine the range that is appropriate for you.

Reference:

¹Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. World Health Organization, Geneva, Switzerland 2006.

Low and High Blood Glucose Results

Result	What It Means	What To Do
lower than 3.3 mmol/L	Low (hypoglycaemic)	<p>Repeat the test with a new test strip, even if you do <i>not</i> feel that you have low blood glucose.</p> <p>If your blood glucose result is still not consistent with your symptoms, contact your healthcare professional and follow his or her treatment advice.</p>
higher than 13.3 mmol/L	High (hyperglycaemic)	<p>Repeat the test with a new test strip, even if you do <i>not</i> feel that you have high blood glucose.</p> <p>If your blood glucose result is still not consistent with your symptoms, contact your healthcare professional and follow his or her treatment advice.</p>

Display	What It Means	Symptoms	What To Do
 Appears when result is: lower than 1.1 mmol/L	Severe low blood glucose	Weakness Sweating Shakiness Headache Confusion	Follow your healthcare professional's advice to treat low blood glucose. If your blood glucose result does not match how you feel, perform a control solution test to confirm that your meter and strips are working properly.


IMPORTANT:






- Severe dehydration may cause false low results. If you believe you are suffering from severe dehydration, contact your healthcare professional immediately.
- Contact your healthcare professional if you have symptoms that do *not* match your test result, and you have followed the instructions in this owner's booklet.

Display	What It Means	Symptoms	What To Do
<p data-bbox="175 107 235 159">HI</p> <p data-bbox="124 184 299 311">Appears when result is: higher than 27.8 mmol/L</p>	<p data-bbox="351 104 570 163">Severe high blood glucose</p>	<p data-bbox="625 104 714 125">Fatigue</p> <p data-bbox="625 135 694 156">Thirst</p> <p data-bbox="625 166 820 187">Excess Urination</p> <p data-bbox="625 197 773 218">Blurry Vision</p>	<p data-bbox="865 104 1300 163">Follow your healthcare professional's advice to treat high blood glucose.</p> <p data-bbox="865 174 1291 339">If your blood glucose result does not match how you feel, perform a control solution test to confirm that your meter and strips are working properly.</p>

Error Codes




Message	What It Means	What To Do
Er 1	<ul style="list-style-type: none">• The sample is too small• There may be a problem with the test strip• Meter error• Very low blood glucose lower than 1.1 mmol/L	<ol style="list-style-type: none">1. Follow your healthcare professional's advice to treat low blood glucose if you have symptoms such as:<ul style="list-style-type: none">• Weakness• Sweating• Confusion• Shakiness• Headache2. Perform a control solution test using a new test strip. If the test results are within the range printed on the test strip vial, retest using blood and a new test strip.3. If the control solution result is out of range or the error reappears, contact Customer Care.

Message	What It Means	What To Do
	<ul style="list-style-type: none">• There may be a problem with the test strip• Meter error• Very high blood glucose higher than 27.8 mmol/L• HIGH control solution was applied when the temperature was too cold. (Applies only to control solution labeled as HIGH).	<ol style="list-style-type: none">1. Follow your healthcare professional's advice to treat high blood glucose if you have symptoms such as:<ul style="list-style-type: none">• Fatigue• Excess urination• Thirst• Blurry vision2. Perform a control solution test using a new test strip. If the test results are within the range printed on the test strip vial, retest using blood and a new test strip.3. If the control solution result is out of range or the error reappears, contact Customer Care.

Message	What It Means	What To Do
Er3	<ul style="list-style-type: none"> • Incorrect test procedure. For example, putting blood on the test strip before inserting it into the meter or applying blood before  and  appear • There may be a problem with the test strip • Meter error 	<ol style="list-style-type: none"> 1. Wait for   and  to appear before applying blood or control solution. 2. Perform a control solution test using a new test strip. If the test results are within the range printed on the test strip vial, retest using blood and a new test strip. 3. If the control solution result is out of range or the error reappears, contact Customer Care.
Er4	<ul style="list-style-type: none"> • There may be a problem with the test strip • Meter error 	<ol style="list-style-type: none"> 1. Perform a control solution test using a new test strip. If the test results are within the range printed on the test strip vial, retest using blood and a new test strip. 2. If the control solution result is out of range or the error reappears, contact Customer Care.

Troubleshooting

	What It Means	What To Do
1. The meter does not enter test mode after inserting a test strip.	<ul style="list-style-type: none">• Test strip is inserted upside down, or bottom end in, or not fully inserted into the meter	<ol style="list-style-type: none">1. Insert test strip print side up, top end in.
	<ul style="list-style-type: none">• No battery is installed• Battery is installed incorrectly	<ol style="list-style-type: none">1. Install battery with (+) facing up.
	<ul style="list-style-type: none">• Dead battery	<ol style="list-style-type: none">1. Replace battery. Reset date and time, if necessary.2. If meter still does <i>not</i> enter test mode, contact Customer Care.
	<ul style="list-style-type: none">• Defective test strip or meter• Blood or foreign objects put in the test strip port	<ol style="list-style-type: none">1. Contact Customer Care.

	What It Means	What To Do
2. The test does not start after applying the blood drop.	<ul style="list-style-type: none"> • Blood drop is too small 	<ol style="list-style-type: none"> 1. Add blood to the same sample area within 60 seconds, or repeat the test using a new test strip and a larger blood drop.
	<ul style="list-style-type: none"> • Defective test strip • Sample applied after meter turns off 	<ol style="list-style-type: none"> 1. Repeat the test using a new test strip. Wait for   and  to appear before applying blood or control solution. 2. If problem persists, contact Customer Care.
	<ul style="list-style-type: none"> • Defective meter 	<ol style="list-style-type: none"> 1. Contact Customer Care.

FreeStyle Control Solution

Purpose

FreeStyle control solution is a red liquid that contains a fixed amount of glucose.

The purpose of doing a control solution test is:

- To practise testing *without* using your own blood
- To confirm that the meter and test strips work together properly
- When you are unsure of your blood glucose test results

Contact Customer Care for information on how to obtain control solution.

Control Solution Information

- Use only FreeStyle control solution with the meter.
- Replace the cap securely on the bottle immediately after use.
- Control solution results are accurate only between 59° – 104° F (15° – 40° C).
- Do *not* add water or other liquid to control solution.
- There are three levels of control solution available (Low, Normal, High).

For information on how to obtain control solution, contact Customer Care.



IMPORTANT: Control solution results should fall within the control solution range printed on the test strip vial. Do *not* use this range when testing blood glucose.

Out of Range Control Solution Results

- Repeat the test if control solution results are outside the range printed on the test strip vial.
- Stop using the meter if control solution results are consistently outside the range printed on the test strip vial. Contact Customer Care.

Causes of out-of-range results include:

- Expired or bad control solution
- Expired or bad test strip
- Testing error
- Watered-down control solution
- Meter malfunction
- Test strip deterioration
- Control solution test done outside 59° – 104° F (15° – 40° C)

Performing a Control Solution Test



1. Check control solution expiry date.

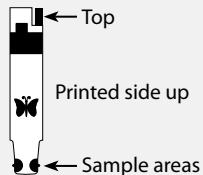
IMPORTANT: Do *not* use control solution past expiry date. Discard control solution 3 months after opening or on the expiry date printed on the bottle whichever comes first. (Example: open April 15, discard July 15; write the discard date on the side of the bottle.)



2. Remove test strip from vial.
3. Insert test strip to turn meter on.

Note: The meter turns off after 2 minutes of inactivity. Remove and reinsert the unused test strip to restart the meter.

If the meter does not turn on go to Troubleshooting section.





4. Confirm System Check Screen.

- This display appears when you turn on the meter. **Do not use the meter if the display check screen does not exactly match the example. Contact Customer Care.**
- See The FreeStyle Freedom Lite Meter and How It Works section for more information.
- If the system check screen does not appear, go to Troubleshooting section.



5. Apply and **hold** control solution to 1 sample area of the test strip until:

- You see short lines moving clockwise on the display or
- You hear a beep

This indicates the test strip obtained enough control solution and the meter is processing. If the test does not start after applying the control solution, go to Troubleshooting section.

IMPORTANT: If a short line does *not* appear after 5 seconds, the sample may be too small. Do *not* add control solution to both sides of the strip. The test strips are for single use only. Do *not* reuse test strips. Dispose of used test strips.



(Example only)

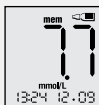
6. View result.

The result appears on the display when the test is complete.





7. Compare the control solution result to the range printed on the test strip vial. The result should fall within the range.

Note: If you see an “Er1, Er2, Er3 or Er4” on the display, it is an error code. Go to Error Codes section.



(Example only)

8. Press and **hold** **C** for 2 seconds until  appears on the display to mark the result as a control solution result. To unmark a control solution test result, press and **hold** **C** for 2 seconds. A value with the  indicates you have marked this reading as a control solution test.

9. Remove the test strip to turn meter off.

Using Your Meter Memory

Purpose

The purpose of this section is to review your stored test results and 7-, 14- and 30-day averages.

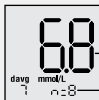
Viewing Blood Glucose Averages in Memory

Start with the meter off (no test strip inserted). Press **(m)**. Your 7-day average appears (control solution, LO and HI readings *not* included).

Note: To exit meter memory at any time, press and hold **(m)**.

Example:

Memory Display






your average

n= number of results included in your average

- Press **(C)** to scroll through 14- and 30-day averages and all stored test results. The most recent result appears first.
- Press **(m)** to scroll backward.

Viewing Test Results in Memory

Meter memory stores the last 400 test results with time and date. Press  to scroll through the results. The most recent result appears first.

mem	on the display indicates that you are viewing stored test results.
davg	shows the average value of glucose readings from the last 7-, 14- or 30-days.
	on the display indicates that the test result occurred when it was too hot or too cold to use the meter and may <i>not</i> be accurate. This result is included in 7-, 14- and 30-day averages.
LO	a test result of under 1.1 mmol/L is included in memory as LO.
HI	a test result of over 27.8 mmol/L is included in memory as HI.
mem 	indicates a control solution test result.

Setting Reminder Alarms (optional)

Purpose

The purpose of this section is to set up to four reminder alarms to prompt you to test throughout the day.



Reminder Alarm

1. With the meter off, press and **hold** **(m)** for **3** seconds until **SET** appears and **0** is flashing.
2. Press **(C)**. Reminder alarm **1** flashes.



Hour

Note: You are setting time for Reminder Alarm not clock time.




3. Set hour
 - Press **(m)** to set hour
 - Press **(C)** to display correct hour
 - Press **(m)** to save



Minutes

4. Set minutes
 - Press **(C)** to display correct minutes
 - Press **(m)** to save

5. Set alarm sound volume

If you prefer:	Press C until you see:	Then
No sound		• Press m to save
A low beep		
A louder beep		

6. Press **C** and repeat 2, 3, 4 and 5 to set remaining reminder alarms or

7. Press and **hold m** for 3 seconds until meter turns off.

Transferring Test Results To a Computer

PC



appears on the display when you insert a data cable in the data port. The computer must have a compatible data management system to complete the transfer. Remove this cable before performing a test.


Contact Customer Care to learn more about the data management system.



Maintaining the Meter

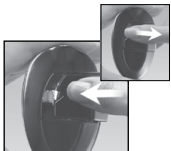
Replacing the Battery

The meter comes with a #2032, 3-volt, lithium battery installed. It provides power for about 1000 tests.

- When  appears on the display, the battery is low.
- When  appears, the meter may fail to turn on.

IMPORTANT: When  appears, replace the battery immediately.

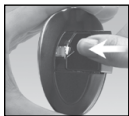
- When you are ready to install a new battery, remove the old battery and install the new battery within 60 seconds to avoid losing time and date settings.
- If time and date settings are lost, both time  and date  will flash until reset. Reset time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, you may still perform an accurate blood glucose test.
- Memory log and previously stored user settings, such as date and time format, are not affected by removing the battery.



1. Slide the battery door to the right to open.
2. To remove the battery, pull the plastic tab up to release the battery.



3. Insert a new battery: (+) facing up.



4. To close, slide the battery door in until it snaps into place.



Note: *The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The batteries in this product should be removed and disposed of in accordance with local regulations for separate collection of spent batteries.*

Cleaning the Meter

Avoid getting dirt, dust, blood, control solution or liquid in the meter test strip and data ports.

Clean the outside of the meter using a damp cloth and:

- Mild detergent/soap and water, or
- 70% isopropyl alcohol, or
- A mixture of 1 part household bleach, 9 parts water

IMPORTANT:














Do *not* immerse the meter in water or other liquid.

Specifications

Assay method	Coulometric electrochemical sensor
Automatic shutoff	2 minutes of inactivity
Battery life	1000 tests
Calibration	Plasma equivalent
Haematocrit	15% to 65%
Measurement units	mmol/L
Meter storage temperature	- 4° to 140° F (-20° to 60° C)
Memory	400 blood glucose and control solution tests with date and time

Operating relative humidity	5% to 90% (non-condensing)
Operating temperature	40° to 104° F (4° to 40° C)
Power source	One CR 2032, 3V lithium battery, replaceable
Result range	1.1 to 27.8 mmol/L
Sample	Fresh capillary and venous whole blood samples
Sample size	0.3 microliter (300 nanoliters)
Size	2.0 in (w) x 3.3 in (l) x 0.63 in (d) 5.1 cm (w) x 8.4 cm (l) x 1.6 cm (d)
Weight	1.4 to 1.6 oz. (39.7 to 45.4 g) including battery

Definition of Symbols

	Consult instructions for use		Use by
	Temperature limitation		For <i>in vitro</i> diagnostic medical device
	Manufacturer		Catalogue number
	CE Mark		Recycle
	Authorised representative in the European Community		Serial number
	Batch code		Do not reuse
	The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment. The batteries in this product should be removed and disposed of in accordance with local regulations for separate collection of spent batteries.		

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This product(s) and/or its use are protected by one or more of the following patents: US6,071,391; US6,120,676; US6,143,164; US6,156,173; US6,299,757; US6,338,790; US6,503,381; US6,591,125; US6,616,819; US6,618,934; US6,676,816; US6,749,740; US6,893,545; US6,942,518; US7,058,437; US7,615,637; US7,713,406; US7,740,581; US7,802,467; US7,866,026; US7,895,740; US7,901,554; USD611,8545; USD613,1905; USD615,8845; EP1119637; EP1145000; EP0958495, CA2346415; CA2358993; CA2351796; CA2423837; CA121137. Additional patents may be issued and/or pending.



 **Abbott**

IVD

CE **0086**

EC REP

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ART22311-101 Rev. B 08/14