



U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER: (ixg)

FOLDER: K092602 - 590 pages (FOI:10004587)

COMPANY: ABBOTT DIABETES CARE INC. (ABBODIABCAREA)

PRODUCT: SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER (NBW)

SUMMARY: Product: FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS,
MODELS 100 COUNT: 70827-22,

DATE REQUESTED: Oct 25, 2011

DATE PRINTED: Oct 25, 2011

Note: Releasable Version



K092602

MAY 14 2010

510(k) Summary

According to the requirements Per 21 CFR §807.92, the following information is provides sufficient detail to understand the basis for a determination of substantial equivalence.

Company:	Abbott Laboratories
Division:	Abbott Diabetes Care, Inc.
Street Address:	1360 South Loop Road
City, State Zip:	Alameda, CA 94502
Telephone No:	510-749-5400
Fax No:	510-864-4791
Contact Person:	Arul Sterlin; Tel No. 510-864-4310; Fax No. 510-864-4791; arul.sterlin@abbott.com
Proprietary Name:	FreeStyle Lite Blood Glucose Test Strips
Common Name:	Reagent Test Strips
Classification Name:	Glucose Dehydrogenase, Glucose, Class II (21 CFR§ 862.1345) Product codes: NBW, LFR; Single Analyte Control Solution, Class I (21 CFR§ 862.1660) Product code: JJX
Predicate Device:	FreeStyle Lite Blood Glucose Monitoring System (K070850)
Manufacturing Site:	Establishment: Abbott Diabetes Care Inc. 1360 South Loop Rd. Alameda, CA 94502 Registration Number: 2954323 Establishment: Abbott Ireland Diabetes Care Donegal Town, Co. Donegal Donegal Town, IRELAND Donegal Registration Number: 3007031103

Description of the Device:

A chemistry change has been made to the FreeStyle Lite Blood Glucose Test Strip. The modified strip is to be marketed under the brand name, FreeStyle Lite, and is intended for use with the following Blood Glucose Monitoring Systems:

- FreeStyle Lite Blood Glucose Monitoring System
- FreeStyle Freedom Lite Blood Glucose Monitoring System

The meters and other system components contained within these systems have not been modified. Each of the aforementioned blood glucose monitoring systems are comprised of a handheld glucose meter, glucose reagent test strips, a quality control solution, a lancing device, lancets, lancing cap, and labeling for performing a blood glucose test. The intended uses and principles of operation for each of the systems remains the same as previously submitted and cleared for market entry. The systems utilize coulometric biosensor technology to quantitatively measure glucose concentration in whole blood samples. The systems are intended for self-monitoring of glucose in capillary and venous whole blood. The primary users are persons with diabetes. The systems are meant to aid in diabetes management and for healthcare professionals to aid in monitoring the effectiveness of diabetes control program. The FreeStyle Lite Blood Glucose Test Strip is an electrochemical biosensor that fits into a handheld meter. The blood sample volume is approximately 0.3 microliters (300 nanoliters), which can be obtained from the finger, upper arm, or palm. Test results display in accordance with the blood glucose meter's software algorithm (approximately 5 seconds). The internal volume of the test strip is precisely controlled, and a blood glucose result will not be displayed on the meter unless the internal sample chamber is filled. Once the measurement begins, the glucose is rapidly oxidized by the reagents that are present in the inside of the sample chamber. The electrochemical signal that results from this process depends only on the total amount of glucose present. The reagent chemistry enables electrolysis of glucose in the blood sample. A mediator molecule shuttles electrons rapidly between a glucose-oxidizing enzyme and the working electrode on the strip. The mediator is capable of reacting rapidly with both the electrode and the enzyme, resulting in a rapid reaction time and minimizing the total amount of mediator required. The small mediator load results in high accuracy at the low end of the glucose measurement range.

Description of Modifications:

The modifications to the system are comprised of changes to the blood glucose test strip which include chemistry, materials, appearance, and modification of the meter turn-on bar.

Chemistry:

The FreeStyle Lite Blood Glucose Test Strip chemistry for the new enzyme test strip is changed from GDH-PQQ with nPBI mediator (Osmium complex with n-pentyl benzimidazole ligand), to GDH-FAD with MAP mediator (ligand of mediator has changed to n-methyl pyridine). GDH-FAD does not show interference in the presence of carbohydrates such as maltose, lactose and galactose as compared with assays performed with GDH-PQQ. The n-pentyl benzimidazole

ligand of the mediator has changed to n-methyl pyridine and a new source of carbon ink is used to make the new enzyme chemistry compatible with on-market meters.

Materials:

The modified FreeStyle Lite Blood Glucose Test Strip will utilize the same materials as the current FreeStyle Lite Blood Glucose Test Strip, with the exception of the spacer tape and source of carbon. A new adhesive system is utilized as the spacer tape. The new spacer tape uses the exact same base polymer resin as the current FreeStyle Lite adhesive coupled with a different crosslinking agent. Screen printed carbon electrodes are made using DuPont carbon ink instead of Ercon carbon. All other materials in the modified FreeStyle Lite Blood Glucose Test Strip, (that is, the melinex and the silver/silver chloride ink) are exactly the same as those used in the FreeStyle Lite Test Strip, currently being marketed.

Appearance:

The physical appearance of the test strip has been changed to aid customers to distinguish visually between the new enzyme version of the product from the current on-market product.

Meter Turn On Bar:

Blood Glucose Test Strips that are branded as FreeStyle Lite will have a modified turn-on bar but will continue to require the same user interface no coding activities as those currently available in the market.



Abbott Diabetes Care Inc.
c/o Arul Sterlin
Regulatory Affairs Associate
1360 South Loop Road
Alameda, CA 94502

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

MAY 14 2010

Re: k092602
Trade Name: Freestyle Lite Blood Glucose Monitoring System and
Freestyle Freedom Life Blood Glucose Monitoring System.
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, LFR
Dated: May 08, 2010
Received: May 10, 2010

Dear Arul Sterlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K092602

Device Name: FreeStyle Lite Blood Glucose Monitoring System

Indication For Use:

The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm; and venous blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.

Prescription Use
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092602

page 1 of 2

Indication for Use

510(k) Number (if known): K092602

Device Name: FreeStyle Freedom Lite Blood Glucose Monitoring System

Indication For Use:

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page 2 of 2



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10903 New Hampshire Avenue
Silver Spring, MD 20993

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c/o Arul Sterlin
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FEB - 1 2011

Re: k092602
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Regulatory Class: Class II
Product Codes: NBW, LFR
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Dear Arul Sterlin:

This letter corrects our substantially equivalent letter of May 14, 2010.

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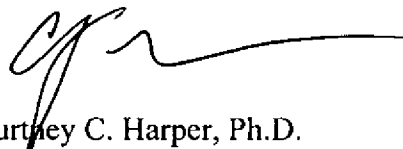
Page 2

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Courtney C. Harper, Ph.D.
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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092602

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Evaluation and Safety

510(k) K092602

page 2 of 2

(b)(4)

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Truth and Accuracy Statement

(b)(4)

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Sincerely,

(b)(4)

[Redacted signature]

(b)(4)

*Department of Health and Human Services
Food and Drug Administration*

CDRH PreMarket Review Submission Cover Sheet

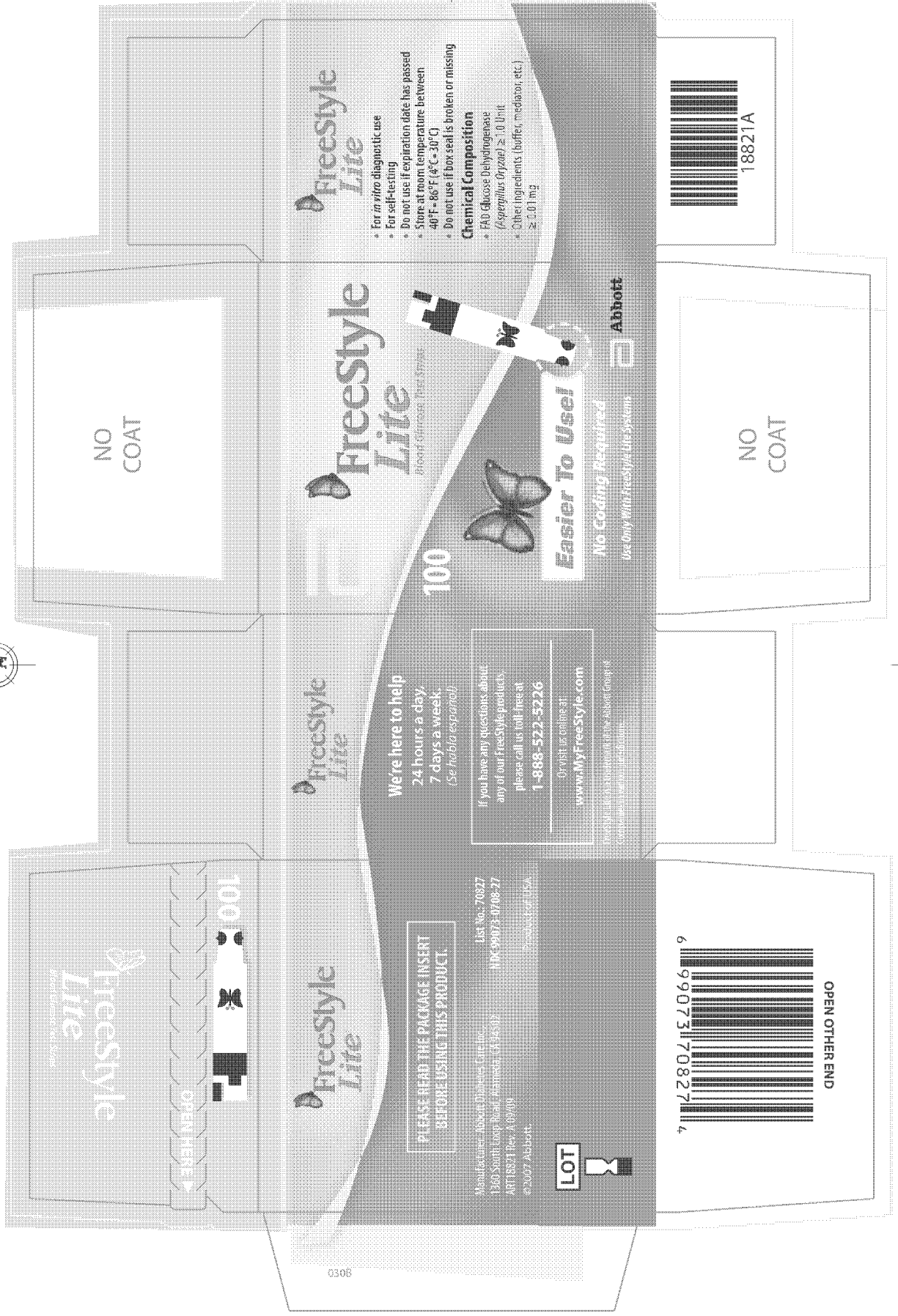
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OMB No. 0910-0120*

(b)(4)

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Last Modified Date: 03 Sep 09 By: DLM;
Software/Version: InDesign CS3
Dieline: 0308

Bar Code: UPC: 128:
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Fonts: MyriadPro-

ABBOTT DIABETES CARE, DIELINE 0308
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The dimensions are inner dimensions from center score to center score.
Tolerance is +/- 0.03 inches
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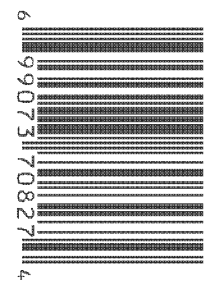


- For *in vitro* diagnostic use
 - For self-testing
 - Do not use if expiration date has passed
 - Store at room temperature between 40°F - 86°F (4°C - 30°C)
 - Do not use if box seal is broken or missing
- Chemical Composition**
- FAD Glucose Dehydrogenase (*Aspergillus oryzae*) ≥ 0 Unit
 - Other ingredients (buffer, mediator, etc.) ≥ 0.01 mg

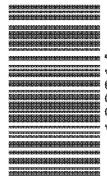
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24 hours a day
7 days a week
(See *habla.español*)

If you have any questions about any of our FreeStyle products, please call us toll-free at 1-888-522-5226. Or visit us online at www.MyFreeStyle.com

Manufacturer: Abbott Diabetes Care, Inc.
1360 Smith Lane, Alameda, CA 94501
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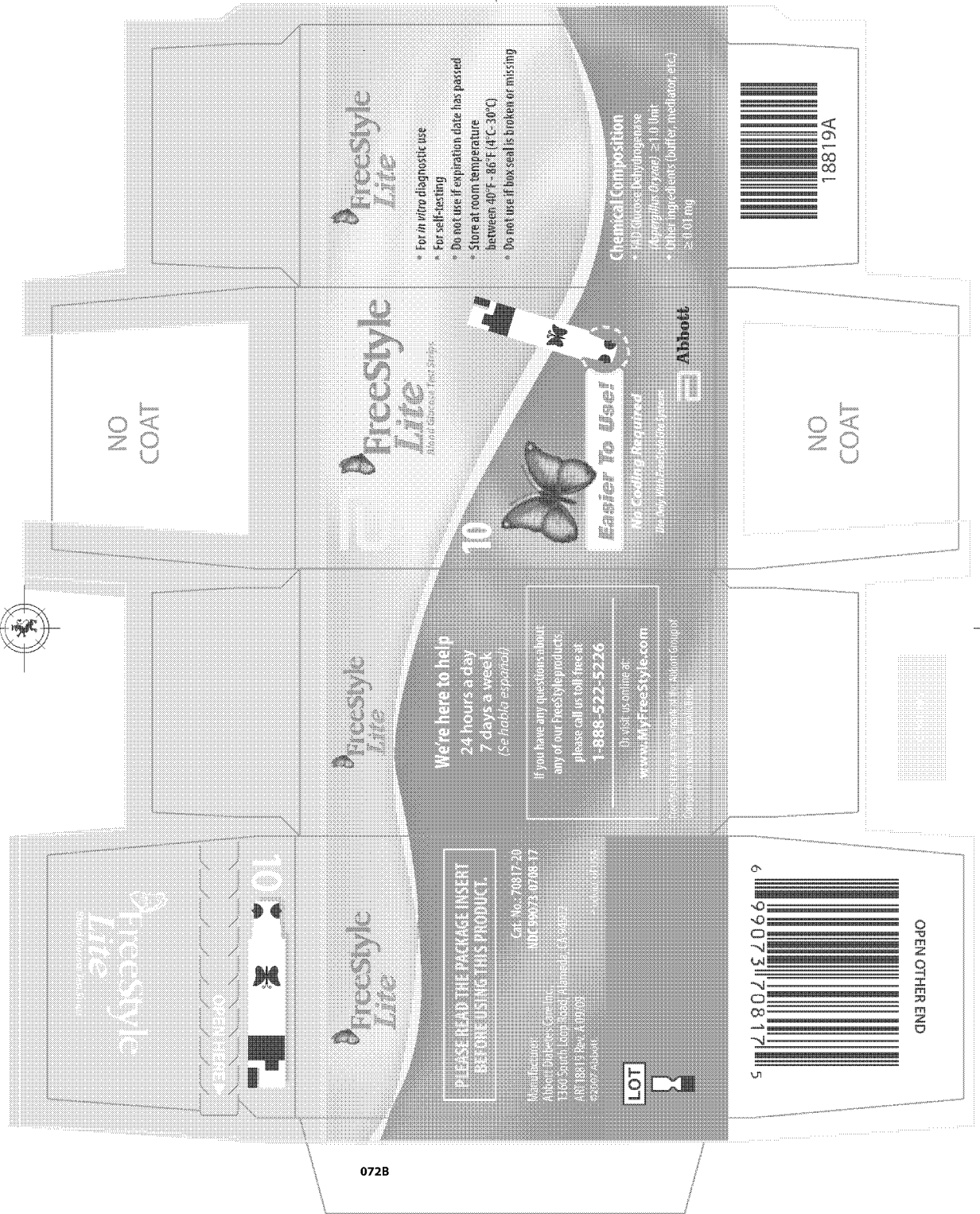
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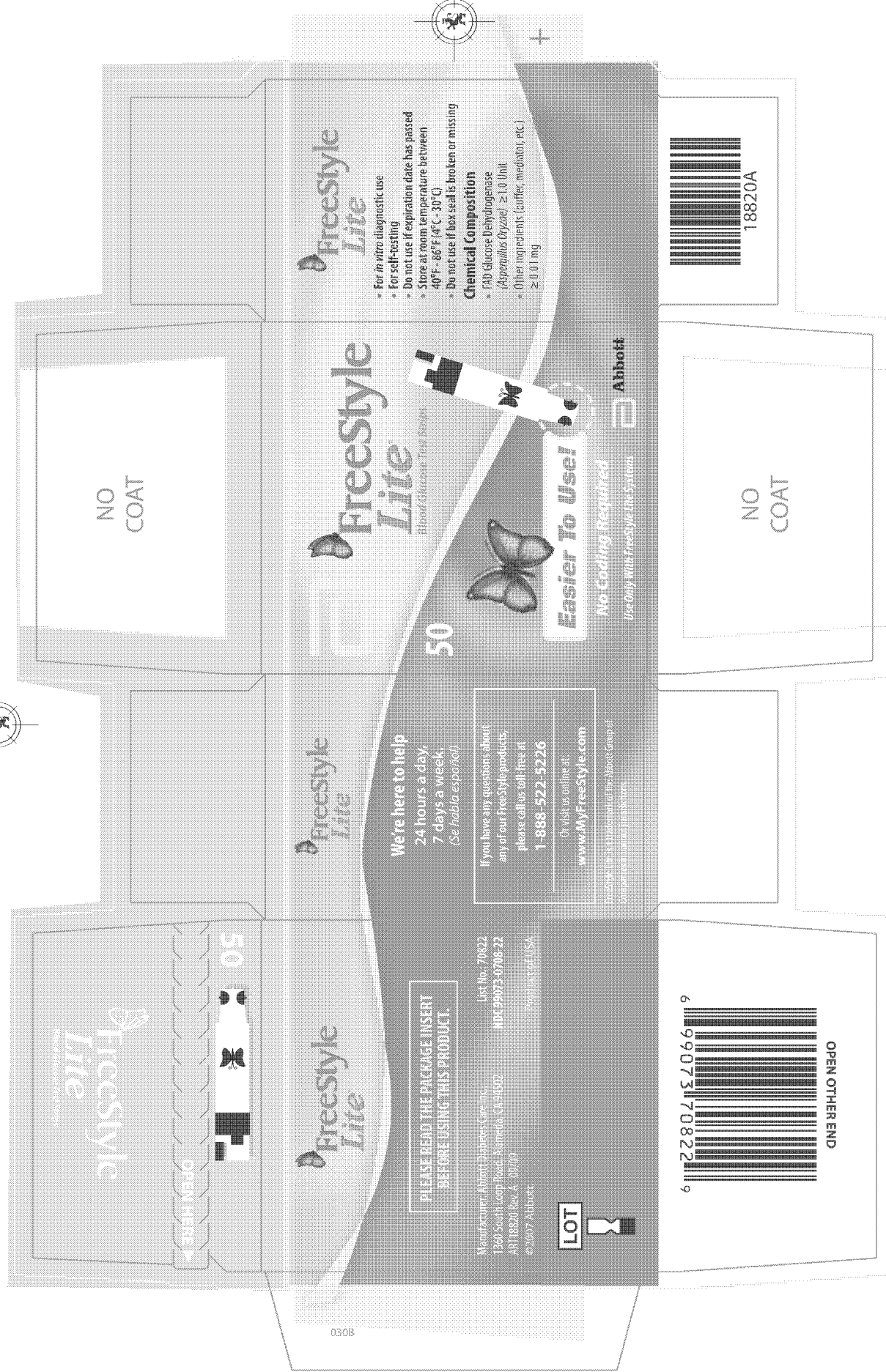
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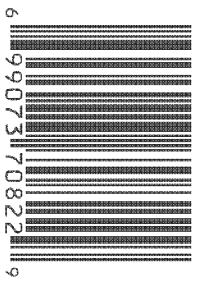
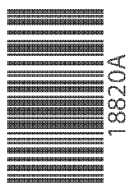
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030B

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24 hours a day,
7 days a week.
(See table opposite)

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any of our FreeStyle products,
please call us toll free at
1-888-522-5226

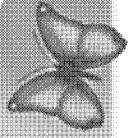
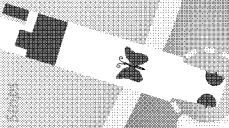
Or visit us online at:
www.MyFreeStyle.com

FreeStyle is the registered trademark of the Abbott Group of
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Manufacturer: Abbott Diabetes Care, Inc.
1385 South Loop Road, Alameda, CA 94501
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List No: 70822
NDC 29073-0708-22

Printed in the USA



freestyle
Lite

freestyle
Lite
Blood Glucose Test Strips

freestyle
Lite

- For in vitro diagnostic use
 - For self-testing
 - Do not use if expiration date has passed
 - Store at room temperature between 40°F - 86°F (4°C - 30°C)
 - Do not use if box seal is broken or missing
- Chemical Composition**
- FAB Glucose Dehydrogenase (Aspergillus Oryzae) ≥ 1.0 Unit
 - Other ingredients (buffer, mediator, etc.) ≥ 0.01 mg

Easier To Use!
No Coding Required
Use Only With FreeStyle Lite Systems

Abbott

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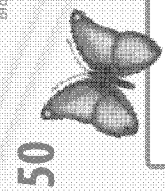
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Abbott Diabetes Care logo and Freestyle Life logo

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Freestyle Life
Broad Glucose Test Strips



Easier To Use!

No Coding Required
Use Only With FreeStyle Life Systems

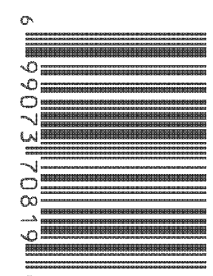
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Freestyle Life

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ART1818 Rev A 09/09
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Product of USA

LOT



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NOT FOR RETAIL SALE

NOT FOR RETAIL SALE

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24 hours a day,
7 days a week.
(Se habla español)

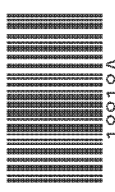
If you have any questions about
any of our FreeStyle products,
please call us toll-free at
1-888-522-5226

Or visit us online at
www.MyFreeStyle.com

FreeStyle Life is a trademark of the Abbott Group of
Companies in various jurisdictions.

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EPPO

Summary of system accuracy for finger samples with YSI glucose results of 75 mg/dL (4.2 mmol/L) or higher.

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
68% (117/168)	95% (160/168)	99% (166/168)	99% (167/168)
73% (8/11)	100% (11/11)		100% (11/11)

Summary of system accuracy for alternate site samples.

	Hand	Calf	Forearm	Palm	Thigh	Upper Arm
Percentage of results within ± 15 mg/dL (0.8 mmol/L) for results less than 75 mg/dL (4.2 mmol/L) or ± 20% for results of 75 mg/dL (4.2 mmol/L) or higher	97% (58/60)	95% (57/59)	97% (58/60)	98% (59/60)	88% (52/59)	98% (59/60)

The regression statistics are derived from a plot of the lay user finger data versus YSI capillary data.

Slope	0.95
y-intercept	7.3 mg/dL (0.41 mmol/L)
Correlation coefficient (R)	0.99
Number of samples tested in duplicate	179
Range tested	38.375 mg/dL (2.1208 mmol/L)

Precision
 Within-in and within-visit precision of these test strips was measured with venous blood samples in the laboratory.

Within-Lot Precision		mg/dL		mmol/L		mg/dL		mmol/L	
Average Glucose Concentration	43.3 (7.4)	43.3 (7.4)	94.2 (5.2)	140.7 (7.8)	238.3 (13.2)	345.0 (19.2)	238.3 (7.8)	140.7 (7.8)	94.2 (5.2)
SD	1.5 (0.1)	1.5 (0.1)	2.3 (0.1)	2.9 (0.2)	4.8 (0.3)	6.8 (0.4)	4.8 (0.3)	2.9 (0.2)	2.3 (0.1)
CV	% 3.3	% 3.3	% 2.4	% 2.4	% 2.2	% 2.3	% 2.3	% 1.9	% 2.1

Within-Visit Precision		mg/dL		mmol/L		mg/dL		mmol/L	
Average Glucose Concentration	43.3 (7.4)	43.3 (7.4)	94.2 (5.2)	140.7 (7.8)	238.3 (13.2)	345.0 (19.2)	238.3 (7.8)	140.7 (7.8)	94.2 (5.2)
SD	1.5 (0.1)	1.5 (0.1)	2.0 (0.1)	2.4 (0.1)	3.9 (0.2)	6.0 (0.3)	3.9 (0.2)	2.4 (0.1)	2.1 (0.1)
CV	% 2.9	% 2.9	% 2.2	% 1.8	% 1.9	% 2.1	% 1.9	% 1.9	% 2.1

Variability in blood tests from strip to strip was 3.3% or less.

Chemical Composition
 FAD Glucose Dehydrogenase (*Agarwalia Oryzae*)
 Other ingredients (buffer, mediator, etc.)

Reference
 ≥ 1.0 Unit
 ≥ 0.01 mg

- ROBERT FOR US ONLY:**
- Diagnosis and management of diabetes mellitus and intermediate hyperglycemic report of a WHO/IDF consultation. *World Health Organization, Geneva, Switzerland 2006.*
 - American Diabetes Association Clinical Practice Recommendations: Diagnosis and classification of diabetes mellitus. *Diabetes Care 2005;28(Suppl 1):S37-S42.*
 - Atkins SH, Dasmanpattana A, Jaker WA, Chromat RH, Reddy S: Fingerstick glucose determination in shock. *Ann Int Med 194; 10:20-1024, 1991.*
 - Sandler AL, Low Boer T: Misleading capillary glucose measurements. *Practical Diabetes 7:210, 1990.*
 - Whickham WHB, Akbar RN: Core BH: Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes 3; 190, 1986.*

Description of Symbols

	Consult instructions for use		Batch code
	Temperature limitation		Use by
	Manufacturer		Do not reuse
	CE Mark		<i>in vitro</i> diagnostic medical device
	Authorized Representative in the European Community		Calibration number

in testing.
 in FreeStyle Lite blood glucose test results without the consent and advice of a
 us or for use with neonatal samples or arterial blood.
 The FreeStyle systems are suitable for self-testing only.
 al is not recommended.
 as that might be considered a choking hazard.
 nts to protect the test strips. Drying agents may be harmful if inhaled or swallowed
 n.
 n test results that fall outside the range printed on the test strip, repeat the
 st result is still outside the range printed on the test strip, the system may not
 be system to test your blood until you get a control solution test result within the
 label.
 the left and right sample areas during a single test. This may cause inaccurate test
 spiration date printed on the package since this may cause inaccurate results.
 lation between the finger, and other test sites like the forearm, upper arm, thigh,
 enies in blood glucose measurements from the other test sites and your finger.
 urements between the other test sites and your finger may be observed after
 Changes in blood glucose may be observed in finger blood samples sooner than
 and other alternate sites. Vigorous rubbing of the alternate test sites before lancing
 ream between finger and alternate site test results. If you are testing for hypoglycemia
 from hypoglycemia unawareness, we recommend that you test on your fingers.

ent is displayed with each result. See Owner's Booklet for further details.
 is may cause false low results. If you believe you are suffering from severe dehydration, consult
 ould be disposed of properly.

piration date printed on the vial.
 eparate the vial cap immediately and close it tightly. Use each strip immediately after removing
 only. The cap or vial contains drying agents to protect the test strips. Do not transfer test strips to
 to 86°F (4°C to 30°C). Use test strips only within the system operating temperature range as
 ureatures.
 test strip in any way.
 uth the test strip anywhere when removing it from the vial or inserting it into the meter.

at strip, the glucose in the blood reacts with the chemicals on the test strip, producing a small
 urrent over time, calculates the electrical change, and converts it to a glucose value.

See Owner's Booklet for a step-by-step guide on how to do the test.
 on your finger, hand, forearm, upper arm, calf, and thigh.
 ct. Use warm, soapy water. Rinse and thoroughly dry. To bring fresh blood to the surface, rub the
 a few seconds until you feel it getting warm.
 n automatically.

appears on the screen, use your lancing device to obtain a blood sample.
 n of the test strip to the blood sample. If the strip does not fill, reapply the sample to the same
 sample to both edges of the strip. Do not put the sample on top of the sample application area.
 'p' or you will see the moving lines on the display.

7.
 n adult without diabetes is less than 110 mg/dL (6.1 mmol/L).
 range for an adult without diabetes is less than 240 mg/dL (13.3 mmol/L).
 etic, non-pregnant feeding adult is under 100 mg/dL (5.5 mmol/L).
 ss than 40 mg/dL (2.2 mmol/L).
 etermine the range that is appropriate for you.
 ndicate a potentially serious medical condition. If your blood glucose reading is unusually low or
 eading indicates, repeat the test with a new test strip. If your reading is not consistent with your
 is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L), you should contact
 is or their treatment advice.

ive accurate results when the following limitations are observed:
 not reuse test strips.
 e site you have selected to test.
 ad dry thoroughly before testing.
 000 feet (3,048 meters) above sea level.

Professionals:
 e used. Use venous blood within 20 minutes after drawing. Common anticoagulants (heparin,
) or triglycerides up to 3,000 mg/dL (34 mmol/L) do not significantly affect test results. However,
 e levels should be interpreted with caution.
 od flow, capillary blood testing may not be appropriate as it may not represent the true
 ode but are not limited to: severe dehydration caused by diabetic ketoacidosis or the
 ision, shock, or peripheral vascular disease.³⁻⁵ Critically ill patients should not be tested with

formance of the meters, test strips, and your testing technique. The system is performing
 is within the specific control solution range listed on your FreeStyle Lite test strip vial.
 ed get results within the expected range printed on the test strip vial. If control solution test



FPO

FPO

Manufacturer/Manufacturer:
Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502 USA

Customer Care is available 24 hours a day, 7 days a week.
Customer Care is available 24 hours a day, 7 days a week.

www.MyFreeStyle.com
Call Customer Care
Toll Free at 1-888-522-5226

www.MyFreeStyle.com
Call Customer Care
Toll Free at 1-888-522-5226

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6,071,391; 6,120,676; 6,143,164; 6,299,757; 6,338,790; 6,503,381; 6,591,125; 6,607,658; 6,616,819;
6,618,934; 6,676,816; 6,749,618; 6,749,740; 6,893,545; 6,942,518; 7,058,437; 7,074,308; Des444,557;
Des447,566; Des450,854; EP1119637; EP1145000; EP0958495; CA2346415; CA2358993; CA2423837.
Additional patents may be issued and/or pending.

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DOC18313 Rev. B 09/09

FOI - Page 25 of 590

DOC18313_Rev-B-Cvr.indd 1-2

The advertisement features a central image of a Freestyle Lite blood glucose meter. The meter's screen displays a reading of 105 mg/dL. To the left of the meter, the text reads 'Freestyle Lite Blood Glucose Monitoring System' and 'Blood Glucose Monitoring System'. Below the meter, it states 'No Coding Required' twice. To the right of the meter, it says 'Owner's Booklet' twice. The Abbott logo is in the bottom right corner.

For Artwork and Packaging Department Use Only
Slug 06 2006

Artwork File Name: DOC18313_Rev-B-Cvr
Orig. Creation Date: 15/May/06
Last Modified Date: 15/Jan/07
By: WRA; 09/Jan/07
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By: LG; 05 Jun 09
By: LG; 10 Jun 09
By: LG; 15 Jun 09
By: LG; 15 Jun 09
By: DM; 18 Jun 09
By: JC; 19 Jun 09
By: VT; 03 Aug 09
By: DLM; 04 Aug 09
By: LG; 04 Aug 09
By: DM; 12 Aug 09
By: VT; 3 Sept 09
By: LG; 04 Aug 09
Software/Version: Adobe CS
Deline: N/A
Bar Code: N/A
Colors: CMYK + PMS286 + PMS7461

9/3/09 11:34:05 AM

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LANGUAGE1

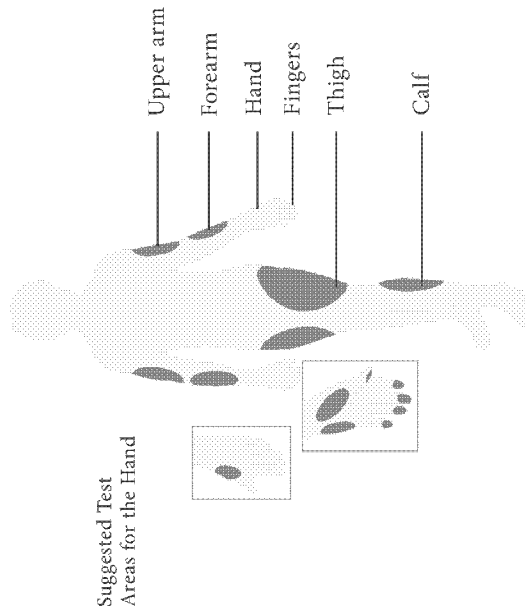
LANGUAGE2

The FreeStyle Lite® System Uses a Tiny Sample of 0.3µl So You Can Test on a Variety of Locations

Important Information About Your FreeStyle Lite® Blood Glucose Monitoring System

How the FreeStyle Lite System Should Be Used

Many Test Sites Available



- The FreeStyle Lite system is intended for use outside the body (in other words, *in vitro* diagnostic use only).
- The FreeStyle Lite system is used for measuring blood glucose (also known as blood sugar) from samples taken from the forearm, upper arm, hand, thigh, calf, or fingers.
- The FreeStyle Lite meter should only be used with FreeStyle Lite test strips and FreeStyle control solution. Using other test strips and control solution with this meter can produce inaccurate results.

Do use the FreeStyle Lite system for:

- Testing blood glucose.
- Testing glucose in fresh capillary whole blood samples.

Do not use the FreeStyle Lite system for:

- The diagnosis of or screening for diabetes mellitus.
- Testing on newborns.
- Testing of arterial blood.

The human figure above shows the areas where you can test with the FreeStyle Lite system. Avoid moles, veins, bones, and tendons.

WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Important Information About Your FreeStyle Lite®
Blood Glucose Monitoring System (continued)

WARNING:

- The FreeStyle Lite System contains small parts that may be dangerous if swallowed.

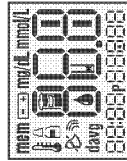
Caution: Please read all the instructions provided in this *Owner's Booklet* and practice the testing procedures before using the FreeStyle Lite system. Blood glucose monitoring should be done with the guidance of a healthcare professional.

Important Health-Related Information

- Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L) you should contact your healthcare professional and follow his or her treatment advice.
- For additional information, consult your test strip product information.

The FreeStyle Lite® Meter and How It Works

System Check Screen
 This screen always appears when the meter is turned on so that you can make sure the display is working properly. Do not use the meter if the system check screen does not match the example here. Please call Customer Care.



Display Screen

Displays your test results and other important information.

Mode Button

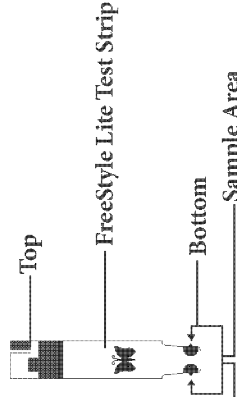
- Move to different mode settings.
- Scrolls backward.
- Silence a reminder alarm.

Light Button

Controls the display backlight and test light.

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).



Top

FreeStyle Lite Test Strip

Bottom

Sample Area

Data Port

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

Configure Button

- Marks a control solution test.
- Scrolls forward.
- Displays clock.
- Silence a reminder alarm.

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.

The FreeStyle Lite[®] Meter Display

Memory Mode Symbol

Shows you test results stored in the meter memory.

Control Solution Test Result Symbol

Shows that you have marked a test result as a control solution test.

Battery Symbol

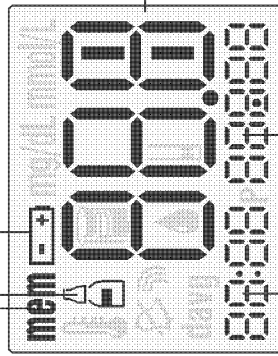
Appears when you should replace your meter battery.

Test Result Area

Displays test results.

Message Area

Displays date, time, and number of tests.



Thermometer Symbol

Appears if your meter is out of operating temperature range.

Sound Level Symbols

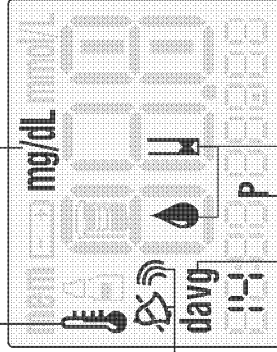
Indicates high, low, or off sound volume.

Day Average Symbol

Shows the average value of glucose readings from the last 7-, 14- or 30-days.

mg/dL (U.S. Standard)

Indicates unit of measurement.



Blood Drop and Test Strip Symbols

These symbols work together in an animation to tell you when the meter is ready for you to apply blood or control solution.

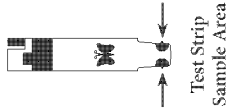
P Symbol

Indicates PM in 12-hour format only (for example 4:00 p.m.)

The FreeStyle Lite® Test Strip

Apply blood or control solution to only **one Test Strip Sample Area** per test.

Important: Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Lite® meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

Important Test Strip Information

- The FreeStyle Lite System has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight and heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.

- Do not use test strips beyond the expiration date. This may cause inaccurate results.
 - Do not bend, cut, or alter FreeStyle Lite® test strips.
- Note:** For further information, refer to the FreeStyle Lite test strip package insert.

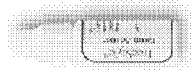
The FreeStyle® Control Solution

Each FreeStyle control solution vial contains a red liquid with a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.

A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

For information on how to obtain control solution, call Customer Care at 1-888-522-5226.



Control Solution Information

FreeStyle® control solution is good for three months after opening the bottle or until the expiration date printed on the label, whichever comes first.

Important: Count forward three months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle.

Example: You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.

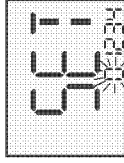
- Use only FreeStyle control solution with your FreeStyle Lite system.
- Replace the cap on the control solution bottle immediately after using.
- Do not use control solution past the expiration date.
- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when used between 59° to 104° F (15° to 40° C).
- Control solution test results should fall within the range printed on the test strip vial label.

Important: The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.

- If control solution results are out of this range, repeat the test.
- If your control solution test results continue to fall outside the range printed on the test strip vial, do not use the FreeStyle Lite system to test your blood glucose. Contact Customer Care.

Caution: Results from FreeStyle control solution tests do not reflect your blood glucose level.

Meter Setup



- **To Enter Setup Mode**
Start with the meter off (no test strip inserted). Press and firmly hold the “m” button until the SE I display screen appears.

To Exit at Any Time

Press and hold the “m” button until the meter turns off.

To Move Through the Screens

Press the “m” button to move through all the setup screens such as reminder alarms, sound level, time, date, and so on.

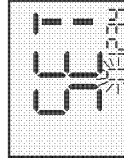
To Change Settings Within the Screen

Press the “c” (configure) button.

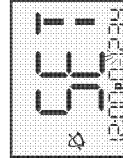
Setting the Reminder Alarms

You may set up any or all of the reminder alarms (1-4). Note: A reminder alarm will never sound during a test.

To set a reminder alarm or multiple reminder alarms, please follow these steps.

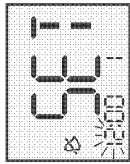


1. Start with the meter off. Press the “m” button and hold until the SE I display appears with 01234. You are now in the reminder alarm setting mode and the “0” is blinking.

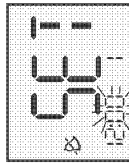


2. To move to the first reminder alarm press the “c” button once. You are now ready to set reminder alarm 1 (“1” is blinking).

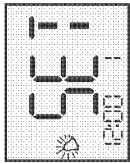
Select reminder alarm



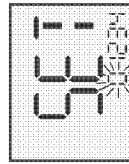
Select hour



Select minute



Select reminder alarm volume



Select reminder alarm

3. Press the “m” button to move to the hour setting. With the hour blinking, press the “c” button until the correct hour appears.

4. Press the “m” button to move to the minute setting. With the minute blinking, press the “c” button until the correct minute appears.

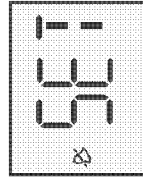
5. Press the “m” button to move to the reminder alarm volume setting. Default setting is off. Press the “c” button to select the desired volume setting: low, high, or off.

6. Press the “m” button to finalize your alarm setting. This will bring you back to the reminder alarm setting 5 E T mode. If you wish to set multiple reminder alarms press “c” to move to reminder alarm 2. Repeat.

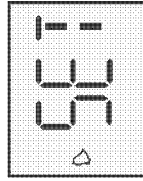
Note: To save your reminder alarm settings and exit setup mode, press and hold the “m” button until the meter turns off. Press the “m” button when “0” is blinking to move to the next setup screen without setting any reminder alarms.

Setting the Sound

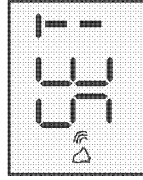
There are three (3) sound volume options:



Off



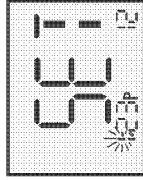
Low



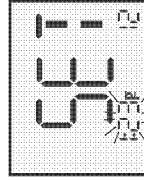
High

There are three sound volume options to let you know when the test strip is full, when the reading is done, and when an error occurs:

1. Press the “c” button until the desired sound level appears
2. Press the “m” button to move to “Setting the Time.”



Hour



Minute

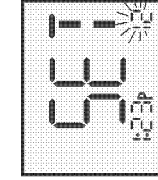
Setting the Time

1. With the hour blinking, press the “c” button until the correct hour appears. The default for the meter is the 12-hour time format. The “p” displays for “PM” times.

2. Press the “m” button to move to minute setting.

3. With the minute blinking, press the “c” button until the correct minute appears.

4. Press the “m” button to move to “Setting the Time Format.”



Time Format

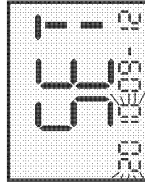
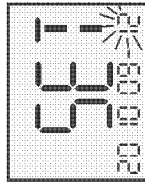
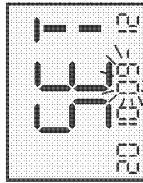
Setting the Time Format

1. With the hour mode blinking, press the “c” button to move between 12-hour and 24-hour format. The time automatically updates to the format selected.

2. Press the “m” button to move to “Setting the Date.”

Setting the Date and Date Format

1. With the month blinking, press the “c” button until the correct month appears.
2. Press the “m” button to move to the day setting.
3. With the day blinking, press the “c” button until the correct day appears.
4. Press the “m” button to move to “Date Format.”
5. With the date blinking, press the “c” button to select month-day or day-month format. The date automatically updates to the format selected.
6. Press the “m” button to move to the year setting.
7. With the year blinking, press the “c” button until the correct year appears.

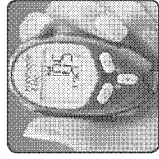


You have completed Meter Setup.

- To move to “Setting the User Reminder Alarms” press the “m” button.
- To exit press and hold the “m” button.

Using Your Meter's Lights

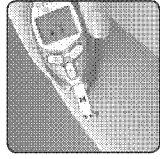
Depending on what mode your meter is in, pressing the light button (☀) turns on either the display backlight or the test light.



Using the Display Backlight

Pressing the light button powers on the display backlight in all modes except when applying a sample. When applying a sample, the light button turns the test light on.

The display backlight goes out when you press the light button (☀) again or when the meter is inactive for 10 seconds.



Using the Test Light

Pressing the light button while the Blood Drop and Test Strip symbols appear on the display screen powers on the test light

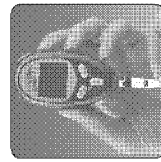
The test light goes out:

- When you press the light button again.
- When the meter receives the correct amount of blood for a test (the FreeStyle Lite test strip is filled).
- After 60 seconds of no activity.
- When a FreeStyle Lite test strip is removed from the meter.

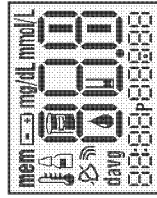
If you use either the backlight or the test light during the test mode, the backlight lights again to show you the test results after the measurement is complete.

Performing a Control Solution Test

1



Insert the top of the test strip into your meter until it stops. This will power on the meter.

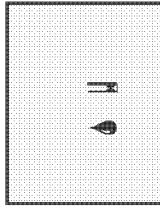


System Check Screen

When the meter powers on, this screen will appear so that you can make sure the display is working properly.

System Check

2



Wait for the meter to display the Blood Drop and Test Strip symbols.

3



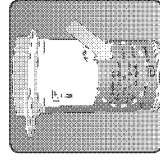
Gently touch only *the Sample Area* of the test strip to the control solution.

Important: Do not apply control solution to both Test Strip Sample Areas.

If the sound prompt is on, your meter will beep when the test strip is full. A short line then moves clockwise around the display screen while the sample is processing.

The result will appear on the display screen and if the sound is on, your meter will beep twice. To mark the result as a control solution result, press and hold the “c” button for two seconds until the control solution symbol (c) appears at the top left of the display screen.

If you have marked a blood glucose test as a control solution test by mistake, you can unmark it by pressing and holding the “c” button again for two seconds.

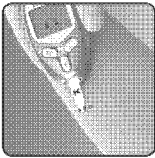


Compare your control solution test result to the range printed on your test strip vial label. Your control solution results should fall within the range printed on the side of your test strip vial.

Out of range test results may be caused by:

- Error in performing the test.
- Expired or contaminated control solution.
- Test strip deterioration.
- Meter malfunction.

Testing Your Blood Glucose



Important: To ensure accurate results, wash your hands and test site (for example, your forearm) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

- With the FreeStyle Lite® meter, you can test your blood glucose on your forearm, upper arm, hand, thigh, calf, or fingers.
- Testing with the FreeStyle Lite meter requires a very small sample size, 0.3 microliters of blood; about the size of pinhead (example: ••).

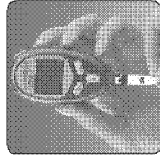
WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Times when you may be checking for low blood glucose include:

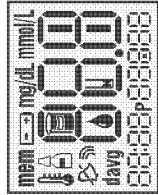
- When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.
- When you have delayed a meal after taking insulin.
- When your healthcare professional advises you to do so.

Performing a Blood Glucose Test



Prepare Your Meter
Insert a FreeStyle Lite test strip into the meter until it stops. The meter will power on.

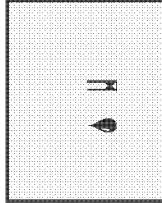
Note: If you do not start the test within two minutes, the meter will turn off. To restart your meter, take out the unused FreeStyle Lite test strip and reinsert it into the meter.



System Check Screen

When the meter powers on, this screen will appear so that you can make sure the display is working properly.

System Check



The Blood Drop and Test Strip symbols will appear on the display screen. Your meter is now ready to apply blood sample.

Blood Drop and Test Strip Symbols

Potential Bruising

It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another test site.

2 Obtain a Blood Sample

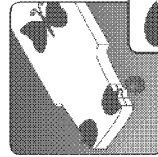
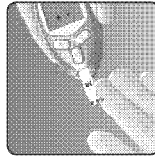
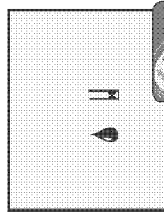
Select a test site. There are differences in testing on fingers versus other alternative sites. Use your lancing device to obtain a blood sample. Refer to the lancing device insert for detailed instructions on how to use the FreeStyle lancing device.

WARNING: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.

3

Filling the FreeStyle Lite Test Strip with Blood

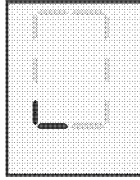
- a. Make sure that the FreeStyle Lite test strip is in the meter and the meter is powered on. You are now ready to apply the blood sample.
- b. Bring the FreeStyle Lite test strip to the blood sample at a slight angle.
- c. The FreeStyle Lite test strip pulls the blood into the strip through the sample area.



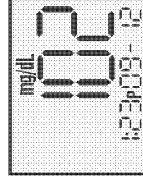
Important Test Strip Information

- Do not press the FreeStyle Lite test strip against the test site.
- Do not scrape the blood onto the FreeStyle Lite test strip.
- Do not apply blood to the flat side of the FreeStyle Lite test strip.
- Do not apply blood to the FreeStyle Lite test strip when the FreeStyle Lite test strip is out of the meter.
- Do not put blood or foreign objects into the FreeStyle Lite test strip port.

4 Waiting for Result



- Do not pull the FreeStyle Lite test strip away from the sample until you hear one beep or see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.
- If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same sample area of the test strip from which you started for up to 60 seconds from the time of the first application.



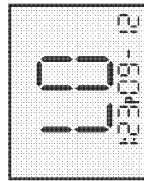
- The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps.
- The time that the meter takes to display a reading depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

LANGUAGE1

LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle Lite™ meter displays results from 20 to 500 mg/dL (1.1 to 27.8 mmol/L).

If your test result is lower than 20 mg/dL (1.1 mmol/L), LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).

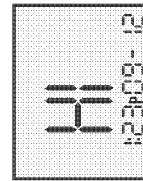


LO Reading

LO Reading without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, follow your doctor's recommendation to treat hypoglycemia.

If your test is above 500 mg/dL (27.8 mmol/L), HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).



HI Reading

HI Reading without Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip. If you still get a HI reading, follow your doctor's recommendation to treat hyperglycemia.

LANGUAGE1

Meter Results
Meter Memory

- To Enter

Start with the meter off (no test strip inserted). Press the “m” button and release; the first memory screen to appear will be your 7-day average.

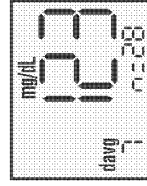
- To Exit

Press and hold the “m” button until the meter turns off.

7-, 14-, 30- Day Average

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)

Example:



7 day avg = your 7-day average
n = indicates the number of results included in your average

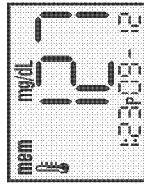
The “c” button allows you to scroll forward to 14- and 30-day averages. Continue to press the “c” button to view stored test results. Your most recent result will display first.

The “m” button allows you to scroll backward.

LANGUAGE1

Test Results

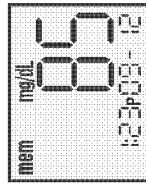
The meter stores the last 400 test readings with time and date. You may scroll through all of the readings by pressing and holding the “c” button. The first reading you see is the most recent result.



Temperature: A result with a thermometer symbol indicates that the reading was taken outside of the meter’s specified operating temperature range and may not be accurate. This value is included in your 7-, 14- and 30-day averages.

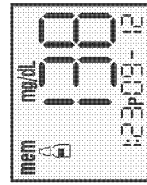
LO Reading: A LO reading (under 20 mg/dL or 1.1 mmol/L) is included in the memory as LO.

HI Reading: A HI reading (over 500 mg/dL or 27.8 mmol/L) is included in the memory as HI.



Blood Glucose Test

A result without a control solution symbol (A) indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.

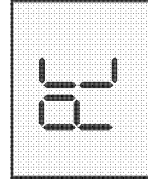


Control Solution Test

A value with (A) indicates that you have marked this reading as a control solution test. The date and time of the control solution reading will appear on the bottom of the screen.

LANGUAGE1

Data Download



The “PC” symbol displays when a data cable is inserted in the meter data port. You cannot perform a test while the data cable is in the meter data port.


The meter will display “PC” until the data cable is removed from the data port.

(Requires a compatible data management system.)

For more information, please go to our website or call Customer Care.

LANGUAGE2

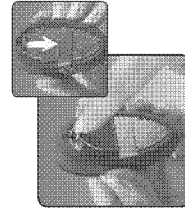
Meter Maintenance
Battery

Your FreeStyle Lite® meter comes with one preinstalled, #2032, 3 volt, lithium battery. The battery provides enough power for the meter to perform about 500 tests. If your battery runs low, the battery symbol () appears on every display screen until you change the battery. When the battery runs low, the display backlight and test light may not power on.

Important: *When this symbol appears, or when the backlight and test light begin to dim, you should replace the battery immediately.*

- To avoid losing the time and date settings, replace the battery within one minute of removing the old battery.
- If you take more than one minute to replace the battery, you may need to reset the time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, the time and date displays flash 12:00 and 00-00 until they are reset.
- Removing the battery does not affect the meter's memory log or previously-stored user settings (such as date and time format).
- Even if you lose your time and date settings – you can perform a blood glucose test, and results will not be affected.

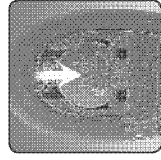
Replacing the Battery



Turn the meter over. Press in the battery door clip to open. Swing the battery door up to open and then off the meter.

To remove the battery, push the battery downward to release the battery.

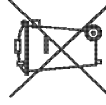
Replacing the Battery (continued)



2 Install the battery with the positive (+) sign up toward you.



3 To close, angle the battery door back onto the meter and swing down until it snaps into place.



Note: The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

Caring for Your Meter

Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip and data ports.

Clean the outside of the meter using a cloth dampened with one of the following:

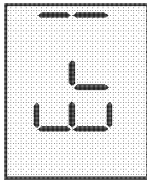
- Mild detergent/mild soap and water.
- 70% isopropyl alcohol.
- A mix of one part household bleach, nine parts water.

Important: *Never immerse the meter in water or any other liquid.*

System Troubleshooting

Error Messages

Error 1



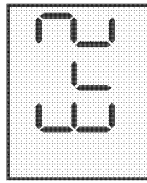
Possible Causes

- Sample is too small.
- Problem with the FreeStyle Lite® test strip.
- Problem with the meter.
- Very low blood glucose (less than 20 mg/dL or 1.1 mmol/L).

What You Should Do

1. If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your doctor's recommendation for treating hypoglycemia.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 2



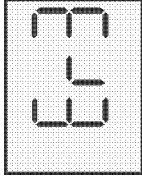
Possible Causes

- Problem with the FreeStyle Lite test strip.
- Problem with the meter.
- Very high glucose (above 500 mg/dL or 27.8 mmol/L).
- HIGH control solution applied when temperature is too cold. (This applies only to control solution that is labeled as HIGH.)

What You Should Do

1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your doctor's recommendation for treating hyperglycemia.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite Test Strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 3



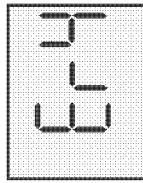
Possible Causes

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter or applying blood before the Blood Drop and Test Strip symbols display.
- Problem with the FreeStyle Lite test strip.
- Problem with the meter.

What You Should Do

1. Be sure you see the Blood Drop and Test Strip symbols on the display screen before you apply blood or control solution.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 4



Possible Causes

- Problem with FreeStyle Lite® test strip.
- Problem with the meter.

What You Should Do

1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite® Test Strip.
2. If the retest using control solution does not work or the error persists, call Customer Care.

Troubleshooting

Meter does not enter the test mode after inserting a test strip.

Probable Cause	What to Do
The battery is dead.	Replace the battery (and reset the date and time, if necessary.)
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the FreeStyle Lite test strip with the printed side up and the top of the strip in the meter.
Defective meter or test strips.	Call Customer Care.
Blood or foreign objects put into the test strip port.	Call Customer Care.

Test does not start after applying the blood sample.

Probable Cause	What to Do
Blood sample too small.	You may add blood to the same sample area of the FreeStyle Lite test strip from which you started for up to 60 seconds from the time of the first application. If necessary, repeat the test using a new FreeStyle Lite test strip and a larger blood sample.
Defective test strip.	Repeat the test with a new FreeStyle Lite test strip.
Sample applied after meter times out (two minutes) and turns off.	Repeat the test using a new test strip. Wait until you see the Blood and Test Strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Call Customer Care.

FreeStyle Lite System Specifications

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	500 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	mg/dL
Meter Storage Temp.	-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 #2032, 3 volt, lithium battery, replaceable
Result Range	20 to 500 mg/dL (1.1 to 27.8 mmol/L)
Sample	Fresh capillary whole blood samples
Sample Size	0.3 microliter (300 nanoliters)
Size	Width 1.57" x Length 2.9" x Depth 0.65"
Weight	1.0 to 1.1 ounces (28.3 to 31.2 grams) including battery

LANGUAGE1

LANGUAGE2





Abbott Diabetes Care Inc.
c/o Arul Sterlin
Regulatory Affairs Associate
1360 South Loop Road
Alameda, CA 94502

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

MAY 14 2010

Re: k092602
Trade Name: Freestyle Lite Blood Glucose Monitoring System and
Freestyle Freedom Life Blood Glucose Monitoring System.
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, LFR
Dated: May 08, 2010
Received: May 10, 2010

Dear Arul Sterlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K092602

Device Name: FreeStyle Lite Blood Glucose Monitoring System

Indication For Use:

The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm; and venous blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.

Prescription Use
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092602

Page 1 of 2

Indication for Use

510(k) Number (if known): K092602

Device Name: FreeStyle Freedom Lite Blood Glucose Monitoring System

Indication For 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 finger, upper arm and palm; and venous blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.

Prescription Use
 (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
 (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



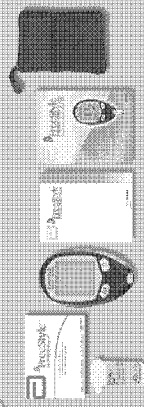
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092602

Page 2 of 2

Do not use if seal is broken or missing.

**FreeStyle
FREEDOM[®] Lite**
Blood Glucose Monitoring System



REVISED DATE : Dec/08	Size:
Die Owner:	5-1/8" x 2-3/16" x 6-1/16"
ADC, A&P	

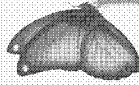
ALL SALES MANAGED CARE

**Use Only With FreeStyle Lite
Test Strips**

En español

NOT FOR RETAIL SALE MANAGED CARE

**FreeStyle
FREEDOM[®] Lite**
Blood Glucose Monitoring System



**FreeStyle
FREEDOM[®] Lite**
Blood Glucose Monitoring System

**¡No requiere
codificación!**

- La muestra más pequeña del mundo
- Amplia pantalla
- Resultados rápidos en un promedio de 5 segundos
- Instrucciones incluidas

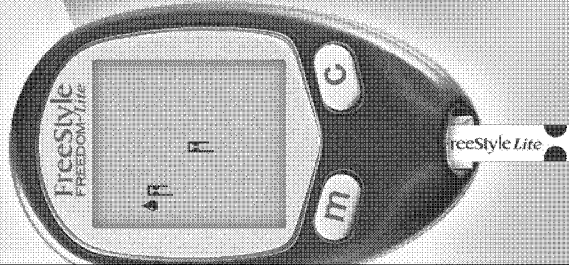
The Friends for Life Commitment
At Abbott Diabetes Care, our first priority is you. Join our Friends for Life Program*. Membership is FREE. Details inside.

Customer Care
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Or visit us online at:
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90-Day Money Back Guarantee*

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- Multiple test sites so your fingers can get a rest
- 4 reminder alarms
- Stores up to 400 results with date and time
- Provides results in 7-, 14- and 30-day averages



**No Coding
Required!**

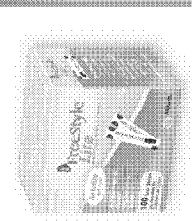
World's Smallest Sample Size

Large Display

Comfortable, Easy-to-Hold

FreeStyle Lite Test Strips

When enough blood is applied to 60 seconds, the strip has enough blood



**Use Only With FreeStyle Lite
Test Strips**

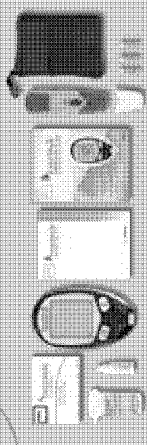


Abbott

DO NOT use if seal is broken or missing.

FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System



REVISED DATE: Dec/08	Die Owner:
ADC, A&P	5-1/8" x 2-3/16" x 6-1/16"

Use Only With **FreeStyle Lite** Test Strips

En español

NOT FOR RETAIL SALE

NOT FOR RETAIL SALE



FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System

FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System

¡No requiere codificación!

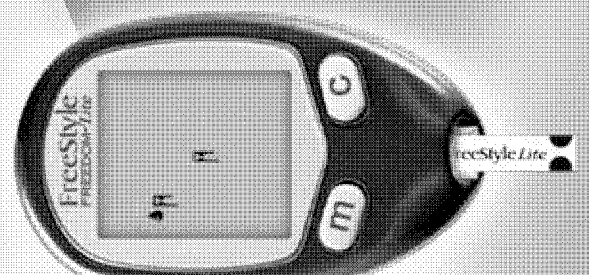
- La muestra más pequeña del mundo
- Amplia pantalla
- Resultados rápidos en un promedio de 5 segundos
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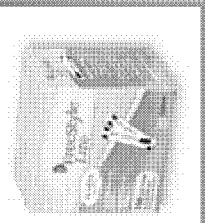
*Abbott may modify or discontinue this program at any time without notice. Offer subject to limitation. See insert for details.

- Multiple test sites so your fingers can get a rest
- 4 reminder alarms
- Stores up to 400 results with date and time
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No Coding Required!

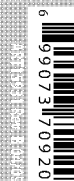
World's Smallest Sample Size
Large Display
Comfortable, Easy-to-Hold



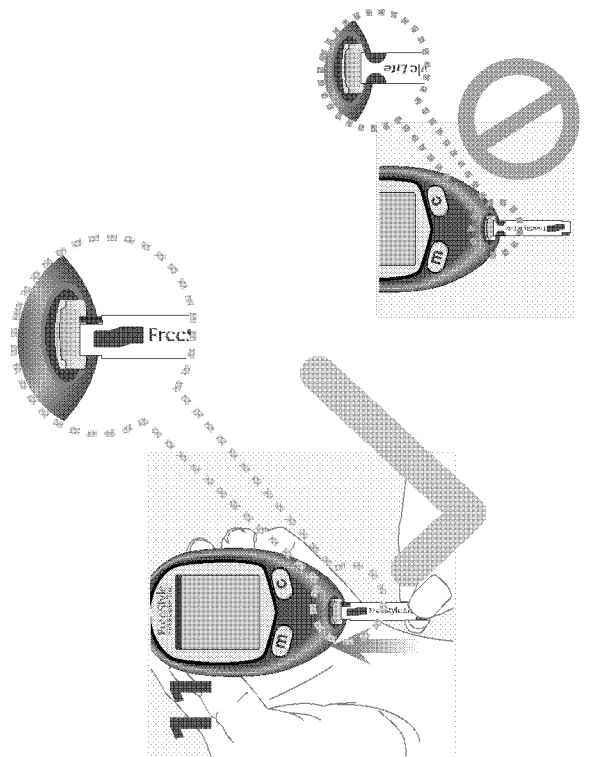
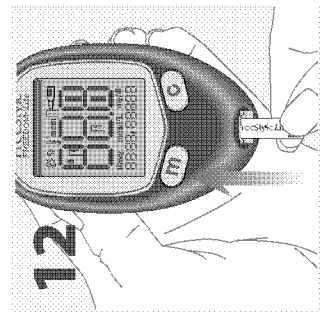
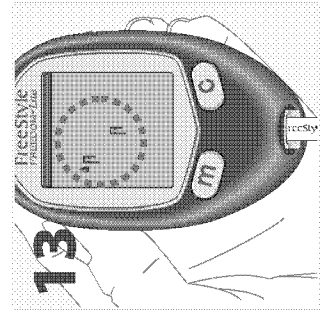
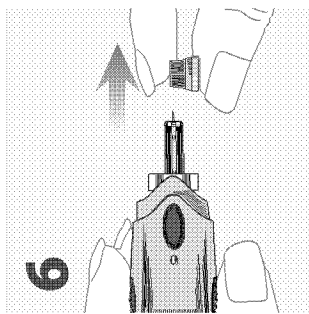
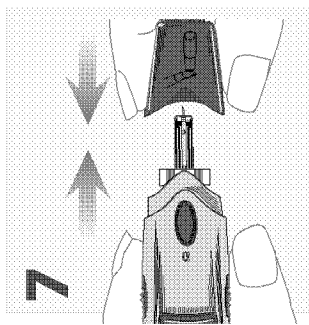
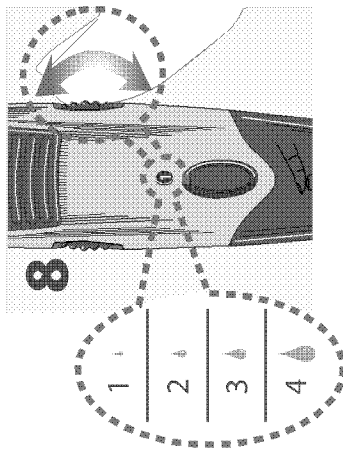
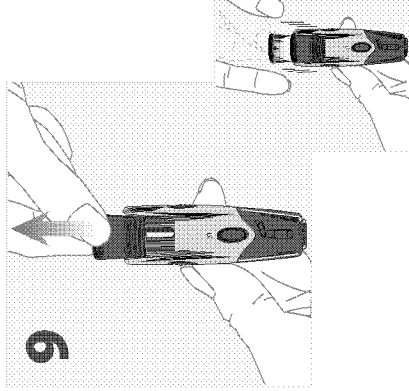
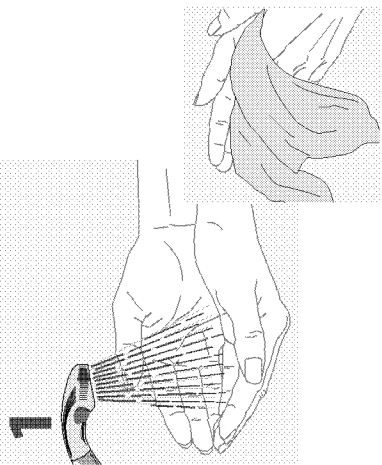
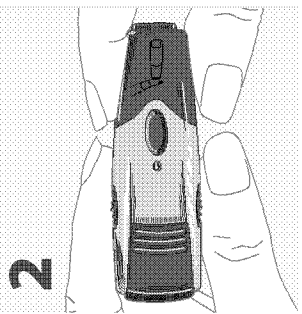
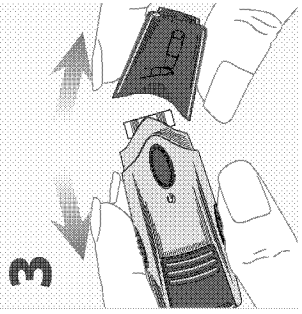
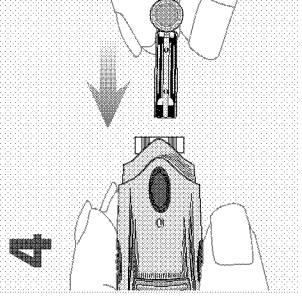
FreeStyle Lite Test Strips
enough blood is applied to 60 seconds
strip has enough blood

Use Only With **FreeStyle Lite** Test Strips

Abbott



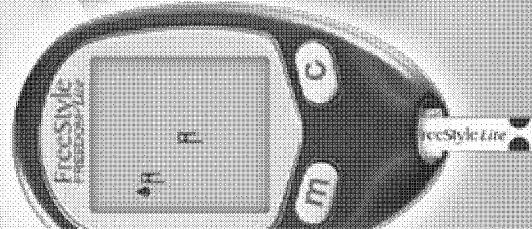
026071E40669
0.3 micro FreeStyle Freedom
We prick fingers (low blood hypoglycemia) For in vitro Use test operation your Own
Catalog Number: 769251-1 | 100's 59175-0735-20
Main Facility: Abbott Diabetes Care, Inc., 1350 South Loop West, Alameda, CA 94502, USA
© 2007 Abbott. All rights reserved. FreeStyle Lite is a registered trademark of Abbott Diabetes Care, Inc.
Seal and tag may be included in package. This product's serial tag use are protected by one or more of the following patents:



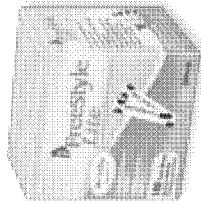
REVISED DATE : June/08	
Die Supplier:	Size:
ADC, A&P	5" x 2.812" x 7.125"

FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System



- Multiple test sites so your fingers can get a rest
- 4 reminder alarms
- Stores up to 400 results with date and time
- Provides results in 7-, 14- and 30-day averages

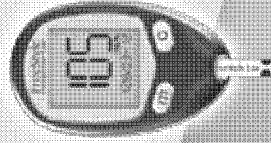


FreeStyle Freedom Lite Test Strips

Enough blood is applied to 60 seconds. The strip has enough blood

FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System



¡No requiere codificación!

- La muestra más pequeña del mundo
- Amplia pantalla
- Resultados rápidos en un promedio de 5 segundos
- Instrucciones incluidas

The FreeStyle Promise[™] Program

At Abbott Diabetes Care, our first priority is you. Join our FreeStyle Promise Program[™] by calling 1-888-246-2693. Membership is FREE. Details inside!

Customer Care
1-888-522-5226

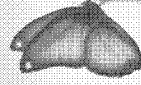
24 hours a day / 7 days a week / Habla mi idioma español
Or visit us online at
www.MyFreeStyle.com

90-Day Money Back Guarantee*

*Abbott may modify or discontinue this program at any time without notice. Offer subject to limitation. See insert for details.

- Test Strips sold separately
- Control Solution available through Customer Care: 1-888-522-5226

En español



FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System



No Coding Required!

World's Smallest Sample Size
Large Display
Comfortable, Easy-to-Hold

Use Only With FreeStyle Lite Test Strips

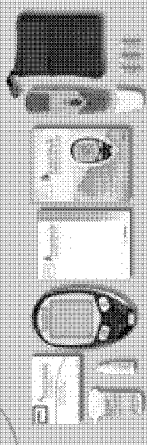
Use Only With FreeStyle Lite Test Strips

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DO NOT use if seal is broken or missing.

FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System



REVISED DATE: Dec/08
Die Owner: ADC, A&P
Size: 5-1/8" x 2-3/16" x 6-1/16"

Use Only With **FreeStyle Lite**
Test Strips

En español

NOT FOR RETAIL SALE

NOT FOR RETAIL SALE



FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System

FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System

¡No requiere
codificación!

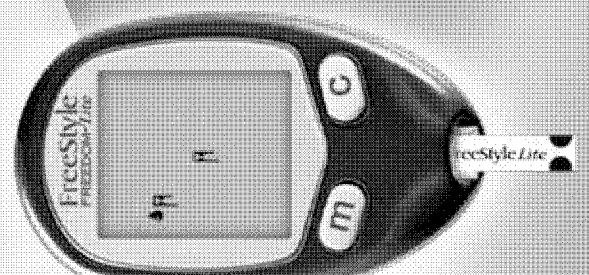
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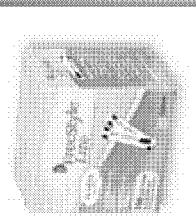
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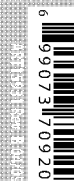
World's Smallest Sample Size
Large Display
Comfortable, Easy-to-Hold



FreeStyle Lite Test Strips
enough blood is applied
to 60 seconds
strip has enough blood

Use Only With **FreeStyle Lite**
Test Strips

Abbott



026071E40669
30408 B and LEGALISE
Catalog Number: 769792-11 | 100% 59973-0735-20
Manufacturer: Abbott Diabetes Care, Inc., 1350 South Loop West, Alameda, CA 94502, USA
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*Seal and tag may be included in package. This product's barcode use are protected by one or more of the following patents:

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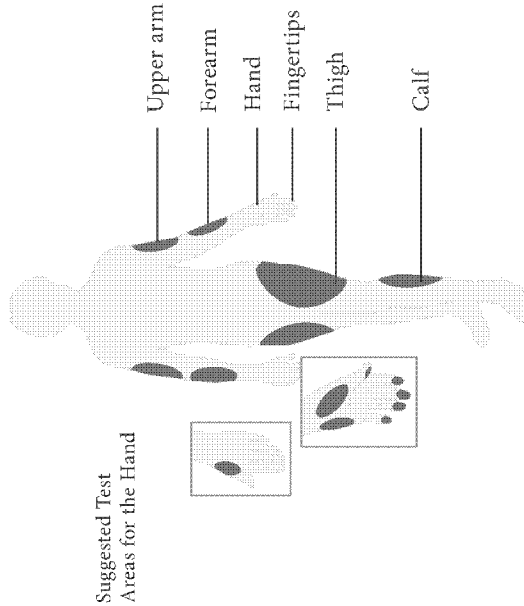
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The FreeStyle Freedom[®] Lite System Uses the World's Smallest Sample So You Can Test on a Variety of Locations

Most Test Sites Available



Suggested Test Areas for the Hand

Important Information About Your FreeStyle Freedom[®] Lite Blood Glucose Monitoring System
How the FreeStyle Freedom Lite System Should Be Used

- The FreeStyle Freedom Lite system is intended for use outside the body (in other words, *in vitro* diagnostic use only).
- The FreeStyle Freedom Lite system is used for measuring blood glucose (also known as blood sugar) from samples taken from the forearm, upper arm, hand, thigh, calf, or fingers.

Important: The FreeStyle Freedom Lite meter should only be used with FreeStyle[®] Lite test strips and FreeStyle control solution. Using other test strips and control solution with this meter can produce inaccurate results.

Do use the FreeStyle Freedom Lite system for:

- Testing blood glucose.
- Testing only with fresh capillary whole blood samples.

Do not use the FreeStyle Freedom Lite system for:

- The diagnosis of diabetes.
- Testing on newborns.
- Testing of arterial blood.

The human figure above shows the areas where you can test with the FreeStyle Freedom Lite system. Avoid moles, veins, bones, and tendons.

WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Important Information About Your FreeStyle Freedom[®] Lite Blood Glucose Monitoring System (cont.)

WARNING:

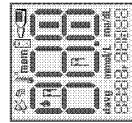
- The FreeStyle Freedom Lite system contains small parts that may be dangerous if swallowed.
- Patients receiving peritoneal dialysis using solutions containing icodextrin or receiving intravenous immunoglobulin preparations containing maltose should not use these test strips.
- Blood concentrations of galactose \geq 13 mg/dL, maltose \geq 20 mg/dL, or lactose \geq 10 mg/dL, causes overestimation of blood glucose results.

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

Important Health-Related Information

- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
- Test results below 60 mg/dL mean low blood glucose (hypoglycemia).
- Test results greater than 240 mg/dL mean high blood glucose (hyperglycemia).
- If you get results below 60 mg/dL or above 240 mg/dL and do not have symptoms of hypoglycemia or hyperglycemia, repeat the test. If you have symptoms or continue to get results that fall below 60 mg/dL or above 240 mg/dL, follow the treatment advice of your healthcare professional.
- If you are experiencing symptoms that are not consistent with your blood glucose test and you have followed all instructions described in the FreeStyle Freedom[®] Lite owner's booklet, call your healthcare professional.

The FreeStyle Freedom® Lite Meter and How It Works

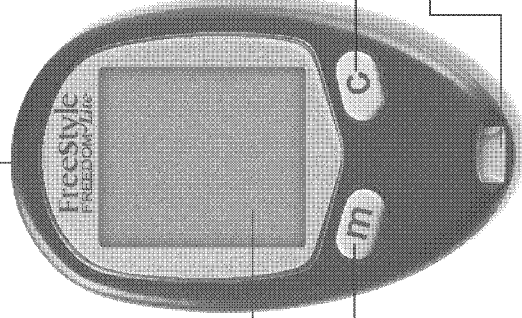


System Check Screen

This screen briefly appears each time the meter is turned on so that you can make sure the display is working properly. Do not use the meter if the system check screen does not match the example here. Please call Customer Care.

Data Port

Download test results. Requires a compatible data management system. For more information, please go to our website or call 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.

Display Screen

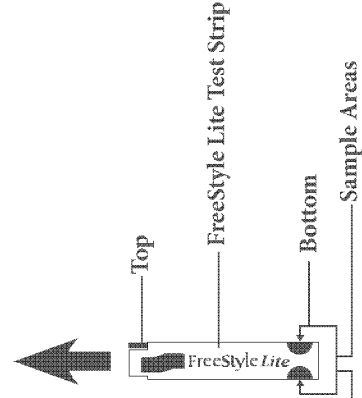
Displays your test results and other important information.

m (Mode) Button

- Move to different mode settings.
- Scrolls backward.
- Silences a reminder alarm.

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

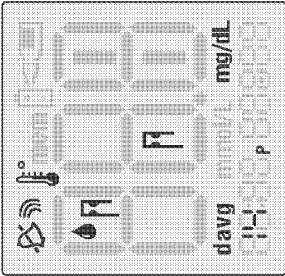
Apply blood or control solution to one sample area only. Insert strip into the meter printed side up (see image to the right.)



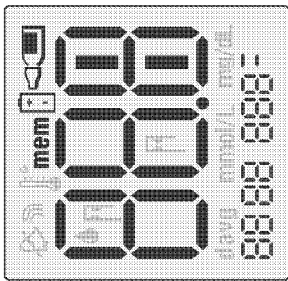
Sample Areas

5 Call Customer Care Toll Free at 1-888-522-5226 www.AbbottDiabetesCare.com

ENGLISH



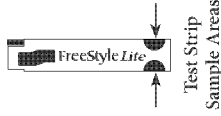
ENGLISH



The FreeStyle® Lite Test Strip

Apply blood or control solution to only **one test strip sample area** per test.

Important: Use only one sample area of the test strip per test. Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Freedom® Lite meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

Important Test Strip Information

- The FreeStyle Freedom Lite system has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight or heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.

9

Call Customer Care Toll Free at 1-888-522-5226 www.AbbottDiabetesCare.com

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ART12214_Rev-B-MAN.indd 9-10

- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter FreeStyle® Lite test strips.

Note: For further information, refer to the FreeStyle Lite test strip package insert.

The FreeStyle® Control Solution

FreeStyle control solution is a red liquid that contains a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.



A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

For information on how to obtain control solution, call Customer Care at 1-888-522-5226.

10

10/22/07 3:49:09 PM

Important Control Solution Information

FreeStyle® control solution is good for three months after opening the bottle or until the expiration date printed on the label, whichever comes first.

Important: Count forward three months from the date you open a new bottle of control solution. Write this date on the side of your control solution bottle. This is your discard date, unless the expiration date printed on the bottle comes first.

Example: You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.

- Use only FreeStyle control solution with your FreeStyle Freedom® Lite system.
- Replace the cap on the control solution bottle immediately after using.
- Do not use control solution past the expiration date.
- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when used between 59° to 104° F (15° to 40° C).
- Control solution test results should fall within the range printed on the test strip vial label.

Important: The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.

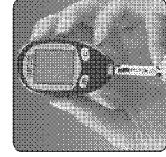
- If control solution results are out of this range, repeat the test.
- If your control solution test results continue to fall outside the range printed on the test strip vial, do not use the FreeStyle Freedom Lite system to test your blood glucose. Contact Customer Care.

Caution: Results from FreeStyle control solution tests do not reflect your blood glucose level.

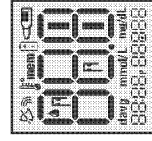
11 Call Customer Care Toll Free at 1-888-522-5226 www.AbbottDiabetesCare.com

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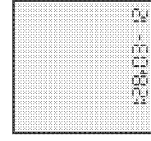
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Performing a Control Solution Test

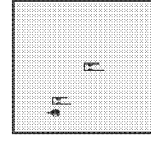
1 Insert the top of the test strip into your meter until it stops. This will power on the meter.

**System Check Screen**

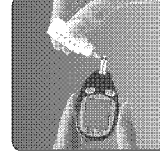
Each time the meter powers on, this screen briefly appears so that you can make sure the display is working properly.

System Check

The date and time will briefly appear after the system check screen so that you can make sure your meter is set to the correct time and date.



2 Wait for the meter to display the blood drop and test strip symbols.



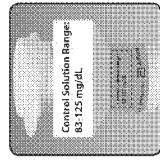
3 Gently touch only one of the sample areas on the test strip to the control solution.

Important: Do not apply control solution to both test strip sample areas.

If the sound is on, your meter will beep when the test strip is full. A short line then moves clockwise around the display screen while the sample is processing.

The result will appear on the display screen and if the sound is on, your meter will beep twice. To mark the result as a control solution result, press and hold the “c” button for two seconds until the control solution symbol (☐) appears at the top right of the display screen.

If you have marked a blood glucose test as a control solution test by mistake, you can unmark it by pressing and holding the “c” button again for two seconds.



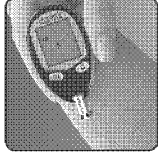
Compare your control solution test result to the range printed on your test strip vial label. Your control solution results should fall within the range printed on the side of your test strip vial.

Out of range test results may be caused by:

- Expired or bad control solution.
- Expired or bad test strip.
- Error in performing test.
- Watered-down control solution.
- Meter malfunction.
- Control solution test done outside 59° to 104° F.

To turn the meter off, remove the test strip.

Testing Your Blood Glucose



Important: To ensure accurate results, wash your hands and test site (for example, your forearm) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

- With the FreeStyle Freedom® Lite meter, you can test your blood glucose on your forearm, fingers, upper arm, hand, thigh, or calf.
- Testing with the FreeStyle Freedom Lite meter requires a very small sample size, 0.3 microliters of blood; about the size of pinhead (example: • •).

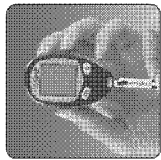
WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Times when you may be checking for low blood glucose include:

- When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.
- When you have delayed a meal after taking insulin.
- When your healthcare professional advises you to do so.

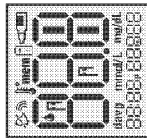
Performing a Blood Glucose Test



Prepare Your Meter

Insert a FreeStyle® Lite test strip into the meter until it stops. The meter will power on.

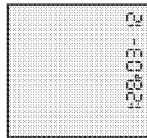
Note: If you do not start the test within two minutes, the meter will turn off. To restart your meter, take out the unused FreeStyle Lite test strip and reinsert it into the meter.



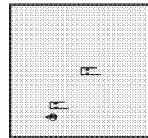
System Check

System Check Screen

Each time the meter powers on, this screen briefly appears so that you can make sure the display is working properly.



The date and time will briefly appear after the system check screen so that you can make sure your meter is set to the correct time and date.



Blood Drop and Test Strip Symbols

The blood drop and test strip symbols will appear on the display screen. Your meter is now ready to apply blood sample.

Important: The FreeStyle Freedom® Lite meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

15 Call Customer Care Toll Free at 1-888-522-5226 www.AbbottDiabetesCare.com

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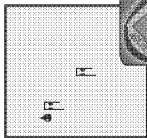
ART12214_Rev-B-MAN.indd 15-16

2 Obtain a Blood Sample

Select a test site. There are differences in testing on fingers versus other alternative sites.

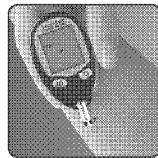
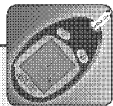
Use your lancing device to obtain a blood sample. Refer to the lancing device insert for detailed instructions on how to use the FreeStyle lancing device.

WARNING: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.



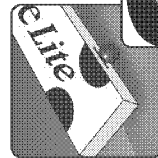
3 Filling the FreeStyle® Lite Test Strip with Blood

a. Make sure that the FreeStyle Lite test strip is in the meter, the meter is powered on and the blood drop and test strip symbols are displayed. (If the meter is off, take out the test strip and reinsert it into the meter.) You are now ready to apply the blood sample.



b. Bring the FreeStyle Lite test strip to the blood sample at a slight angle.

Important: Use only one test strip sample area per test. Do not apply blood to both edges, or you may get an inaccurate result. Test strips may be used only once. Discard used test strips.



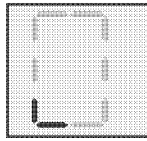
c. The FreeStyle Lite test strip acts like a sponge and pulls the blood into the strip through the sample area.





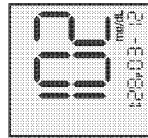
- Do not press the FreeStyle® Lite test strip against the test site.
- Do not scrape the blood onto the FreeStyle Lite test strip.
- Do not apply blood to the flat side of the FreeStyle Lite test strip.
- Do not apply blood to the FreeStyle Lite test strip when the FreeStyle Lite test strip is out of the meter.
- Do not put blood or foreign objects into the FreeStyle Freedom® Lite test strip port.

4 Waiting for Result



- Do not pull the FreeStyle Lite test strip away until you hear one beep or see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.

- If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same sample area of the test strip from which you started for up to 60 seconds from the time of the first application.



- The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps if the sound is on.
- On average, your reading will display in 5 seconds. The time that the meter takes depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

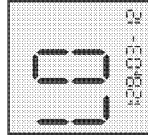
Potential Bruising

It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another test site.

LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle Freedom® Lite meter displays results from 20 to 500 mg/dL.

If your test result is lower than 20 mg/dL, LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).



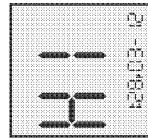
LO Reading with Symptoms

If you have a LO reading and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.

LO Reading

LO Reading without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, follow your doctor's recommendation to treat hypoglycemia. If your test is above 500 mg/dL, HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).



HI Reading

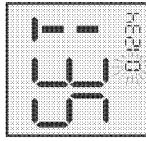
HI Reading with Symptoms

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.

HI Reading without Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip. If you still get a HI reading, follow your doctor's recommendation to treat hyperglycemia.

Meter Set-Up
Setting Up Your Meter



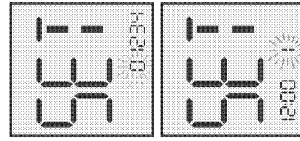
- **To Enter Setup Mode**
Start with the meter off (no test strip inserted). Press and hold the “m” button for two seconds until the 5E 1 display screen appears.

- **To Exit at Any Time**
Press and hold the “m” button for two seconds until the meter turns off.
- **To Move Through the Screens**
Press the “m” button to move through all the setup screens such as reminder alarms, sound level, time, date, and so on.
- **To Change Settings Within the Screen**
Press the “c” button.

Setting the Reminder Alarms

You may set up any or all of the reminder alarms (1-4). Note: A reminder alarm will never sound during a test.

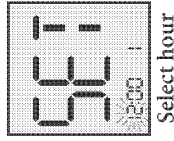
To set a reminder alarm or multiple reminder alarms, please follow these steps.



Select reminder alarm

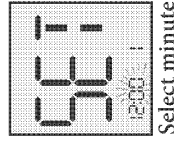
1. Start with the meter off. Press the “m” button and hold until the 5E 1 display appears with 01234. You are now in the reminder alarm setting mode and the “0” is blinking.
2. To move to the first reminder alarm press the “c” button once. You are now ready to set reminder alarm 1 (“1” is blinking).

3. Press the “m” button to move to the hour setting. With the hour blinking, press the “c” button until the correct hour appears.



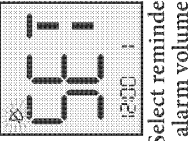
Select hour

4. Press the “m” button to move to the minute setting. With the minute blinking, press the “c” button until the correct minute appears.



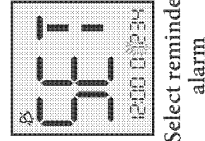
Select minute

5. Press the “m” button to move to the reminder alarm volume setting. Default setting is off. Press the “c” button to select the desired volume setting: low, high, or off.



Select reminder alarm volume

6. Press the “m” button to finalize your alarm setting. This will bring you back to the reminder alarm setting 5E 1 mode. If you wish to set multiple reminder alarms press “c” to move to reminder alarm 2. Repeat.

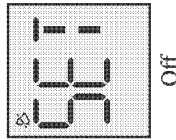


Select reminder alarm

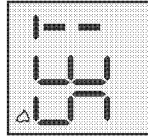
Note: To save your reminder alarm settings and exit set up mode, press and hold the “m” button for two seconds until the meter turns off. Press the “m” button when “0” is blinking to move to the next set-up screen without setting any reminder alarms.

Setting the Sound

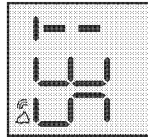
There are three (3) sound volume options:



Off



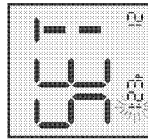
Low



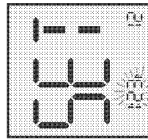
High

There are three sound volume options to let you know when the test strip is full, when the reading is done, and when an error occurs:

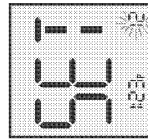
1. Press the “c” button until the desired sound level appears.
2. Press the “m” button to move to “Setting the Time.”



Hour



Minute



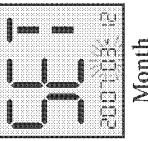
Time Format

Setting the Time

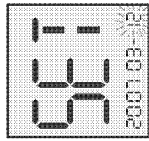
1. With the hour blinking, press the “c” button until the correct hour appears. The “p” displays for “PM” times.
2. Press the “m” button to move to minute setting. With the minute blinking, press the “c” button until the correct minute appears.
3. Press the “m” button to move to “Setting the Time Format.”

Setting the Time Format

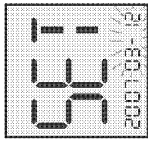
1. With the hour mode blinking, press the “c” button to move between 12-hour and 24-hour format. The time automatically updates to the format selected.
2. Press the “m” button to move to “Setting the Date and Date Format.”



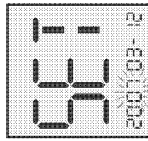
Month



Day



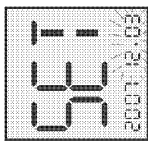
Year-Month-Day



Year

Setting the Date and Date Format

1. With the month blinking, press the “c” button until the correct month appears.
2. Press the “m” button to move to the day setting. With the day blinking, press the “c” button until the correct day appears.
3. Press the “m” button to move to “Date Format.” With the date blinking, press the “c” button to select month-day or day-month format. The date automatically updates to the format selected.
4. Press the “m” button to move to the year setting. With the year blinking, press the “c” button until the correct year appears.



Year-Day-Month

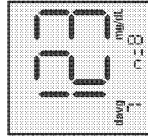
- You have completed Meter Set-Up.
- To move to “Setting the User Reminder Alarms” press the “m” button.
 - To exit press and hold the “m” button for two seconds.

Meter Results
Meter Memory

- **To Enter**
Start with the meter off (no test strip inserted). Press and release the “m” button; the first memory screen to appear will be your 7-day average.
- **To Exit**
Press and hold the “m” button for two seconds until the meter turns off.

7-, 14-, 30- Day Average

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)



7davg: Example:

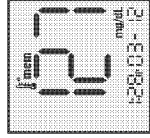
7davg=your 7-day average

n = indicates the number of results included in your average

The “c” button allows you to scroll forward to 14- and 30-day averages. Continue to press the “c” button to view stored test results. Your most recent result will display first.

Test Results

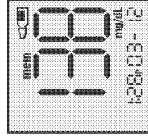
The meter stores the last 400 test readings with time and date. You may scroll forward through all of the readings by pressing the “c” button. The “m” button allows you to scroll backward. The first reading you see is the most recent result.



Temperature: A result with a thermometer symbol (🌡️) indicates that the reading was taken outside of the meter’s specified operating temperature range and may not be accurate. This value is included in your 7-, 14- and 30-day averages.

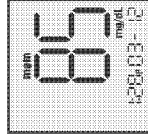
LO Reading: A LO reading (under 20 mg/dL) is included in the memory as LO; it is not included in your 7-, 14- and 30-day averages.

HI Reading: A HI reading (over 500 mg/dL) is included in the memory as HI; it is not included in your 7-, 14- and 30-day averages.



Control Solution Test

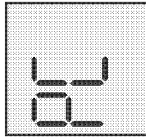
A value with (CS) indicates that you have marked this reading as a control solution test. The date and time of the control solution reading will appear on the bottom of the screen.



Blood Glucose Test

A result without a control solution symbol indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.

Data Download



The "PC" symbol displays when a data cable is inserted in the meter data port. You cannot perform a test while the data cable is in the meter data port.

The meter will display "PC" until the data cable is removed from the data port.

Requires a compatible data management system. For more information, please go to our website or call Customer Care.

Meter Maintenance

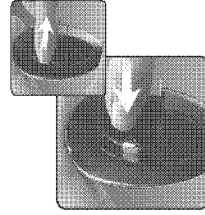
Battery

Your FreeStyle Freedom® Lite meter comes with one preinstalled, #2032, 3 volt, lithium battery. The battery provides enough power for the meter to perform about 1000 tests. If your battery runs low, the battery symbol (🔋) appears on every display screen until you change the battery.

Important: *When this symbol appears, you should replace the battery immediately.*

- **To avoid losing the time and date settings, replace the battery within one minute of removing the old battery.**
- If you take more than one minute to replace the battery, you may need to reset the time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, the time and date displays flash 12:00 and 00-00 until they are reset.
- Removing the battery does not affect the meter's memory log or previously-stored user settings (such as date and time formats).
- If the time and date settings are not reset, test results will be stored in memory with a time of 12:00 and a date of 00-00.
- Even if you lose your time and date settings – you can perform a blood glucose test, and results will not be affected.

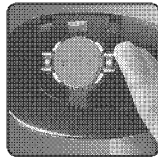
Replacing the Battery



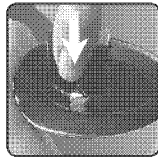
1 Turn the meter over. Slide the battery door to the right to open.

To remove the battery, pull the plastic tab up to release the battery.

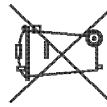
Replacing the Battery (*cont.*)



2 Install the battery with the positive (+) sign up toward you.



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



Note: Batteries need to be properly disposed of. Contact your local government for disposal or recycling practices in your area.

Caring for Your Meter

Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip and data ports.

Important: *Never immerse the meter in water or any other liquid. This may cause inaccurate reading or meter malfunction.*

Do not try to clean the strip or data ports.

Do not pour liquid into the strip port, data port or buttons.

Do not place your meter in water or any other bath.

Clean the **outside** of the meter using a cloth dampened with one of the following:

- Mild detergent/mild soap and water.
- 70% isopropyl alcohol.
- A mix of one part household bleach, nine parts water.

27 Call Customer Care Toll Free at 1-888-522-5226 www.AbbottDiabetesCare.com

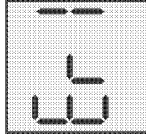
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System Troubleshooting

Error Messages

Error 1



Possible Causes

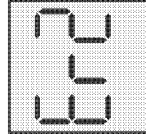
- Sample is too small.
- Problem with the FreeStyle® Lite test strip.
- Problem with the meter.
- Very low blood glucose (less than 20 mg/dL).

What You Should Do

1. If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your doctor's recommendation for treating hypoglycemia.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.

3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 2

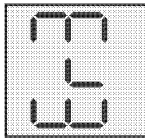


Possible Causes

- Problem with the FreeStyle Lite test strip.
- Problem with the meter.
- Very high glucose (above 500 mg/dL).
- HIGH control solution applied when temperature is too cold. (This applies only to control solution that is labeled as HIGH.)

What You Should Do

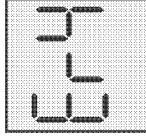
1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your doctor's recommendation for treating hyperglycemia.
2. Conduct a control solution test using a new FreeStyle® Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 3**Possible Causes**

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter or applying blood before the blood drop and test strip symbols display.
- Problem with the FreeStyle Lite test strip.
- Problem with the meter.

What You Should Do

1. Be sure you see the blood drop and test strip symbols on the display screen before you apply blood or control solution.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 4**Possible Causes**

- Problem with FreeStyle Lite test strip.
- Problem with the meter.

What You Should Do

1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle® Lite test strip.
2. If the retest using control solution does not work or the error persists, call Customer Care.

Meter does not enter the test mode after inserting a test strip.

Probable Cause	What to Do
The battery is dead.	Replace the battery (and reset the date and time, if necessary.)
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the FreeStyle Lite test strip with the printed side up and the top of the strip in the meter.
Defective meter or test strips.	Call Customer Care.
Blood or foreign objects put into the test strip port.	Call Customer Care.

Test does not start after applying the blood sample.

Probable Cause	What to Do
Blood sample too small.	You may add blood to the same sample area of the FreeStyle® Lite test strip from which you started for up to 60 seconds from the time of the first application. If necessary, repeat the test using a new FreeStyle Lite test strip and a larger blood sample.
Defective test strip.	Repeat the test with a new FreeStyle Lite test strip
Sample applied after meter times out (two minutes) and turns off.	Repeat the test using a new test strip. Wait until you see the blood and test strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Call Customer Care.

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	1000 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	mg/dL
Meter Storage Temp.	-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 #2032, 3 volt, lithium battery, replaceable
Result Range	20 to 500 mg/dL
Sample	Whole blood, capillary
Sample Size	0.3 microliter (300 nanoliters)
Size	Width 2.00" x Length 3.30" x Thickness 0.63" (at thickest point)
Test Time	Average of 5 seconds
Weight	1.50 oz. including battery

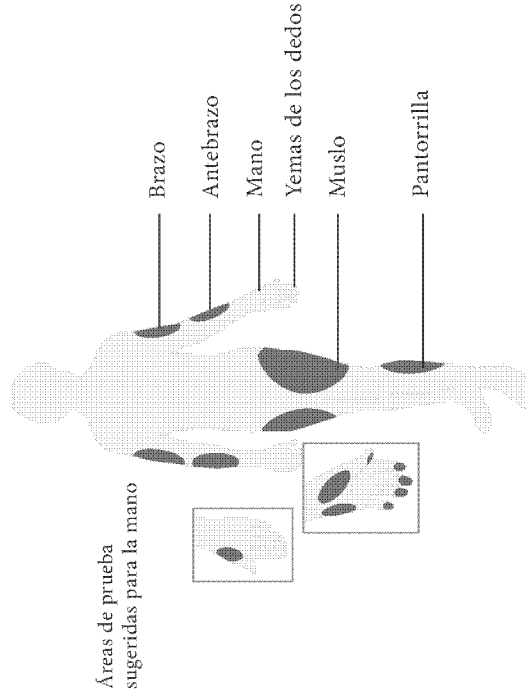
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ESPAÑOL

El Sistema FreeStyle Freedom Lite utiliza la muestra más pequeña del mundo para que pueda realizar pruebas en varios lugares

La mayoría de las zonas de prueba disponibles



ESPAÑOL

Información importante acerca de su sistema de prueba para glucosa en sangre FreeStyle Freedom Lite

Cómo se debe usar el Sistema FreeStyle Freedom Lite

- El Sistema FreeStyle Freedom Lite está destinado a utilizarse fuera del organismo (es decir, sólo para uso diagnóstico *in vitro*).
- El Sistema FreeStyle Freedom Lite se utiliza para medir la glucosa en sangre (también conocida como azúcar en sangre) de muestras extraídas del antebrazo, brazo, mano, muslo, pantorrilla o dedos.

Importante: El medidor FreeStyle Freedom Lite sólo debe utilizarse con tiras de prueba FreeStyle Lite y solución de control FreeStyle. El uso de otras tiras de prueba y solución de control con este medidor puede producir resultados inexactos.

Utilice el Sistema FreeStyle Freedom Lite para:

- realizar pruebas de glucosa en sangre;
- realizar pruebas sólo con muestras de sangre entera capilar reciente.

No utilice el Sistema FreeStyle Freedom Lite para:

- obtener un diagnóstico de diabetes;
- realizar pruebas a recién nacidos;
- realizar pruebas de sangre arterial.

ESPAÑOL

La figura humana que aparece arriba muestra las zonas donde puede realizar pruebas con el sistema FreeStyle Freedom Lite. Evite lunares, venas, huesos y tendones.

ADVERTENCIA:

Le recomendamos que realice las pruebas en los dedos de la mano si está haciendo una prueba de hipoglucemia (bajo nivel de glucosa en sangre) o si sufre de hipoglucemia asintomática.

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Información importante acerca de su sistema de prueba para glucosa en sangre FreeStyle Freedom® Lite (cont.)

ADVERTENCIA:

- El sistema FreeStyle Freedom Lite contiene piezas pequeñas que pueden ser peligrosas si se ingieren.
- Los pacientes que estén recibiendo diálisis peritoneal con una solución que contenga icodextrina o que reciban preparaciones con inmunoglobulina intravenosa que contengan maltosa no deben usar estas tiras de prueba.
- Las concentraciones de galactosa en sangre ≥ 13 mg/dL, maltosa ≥ 20 mg/dL o lactosa ≥ 10 mg/dL, provocan una sobrevaloración de los resultados de prueba de glucosa en sangre.

Precaución: Lea todas las instrucciones detalladas en este *Manual del propietario* y practique los procedimientos de prueba antes de utilizar el Sistema FreeStyle Freedom Lite. El control de glucosa en sangre debe realizarse con la orientación de un profesional de la salud.

ESPAÑOL

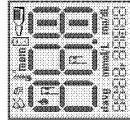
Información sanitaria de importancia

- Es posible que la deshidratación grave y la pérdida de agua en exceso provoquen resultados bajos incorrectos. Si cree que está sufriendo de deshidratación grave, consulte a su médico inmediatamente.
- Los resultados de pruebas por debajo de 60 mg/dL muestran un bajo nivel de glucosa en sangre (hipoglucemia).
- Los resultados de prueba superiores a 240 mg/dL muestran un alto nivel de glucosa en sangre (hiperglucemia).
- Si obtiene resultados inferiores a 60 mg/dL o superiores a 240 mg/dL y no presenta síntomas de hipoglucemia ni de hiperglucemia, repita la prueba. Si tiene síntomas o continúa obteniendo resultados inferiores a 60 mg/dL o superiores a 240 mg/dL, siga el tratamiento sugerido por su médico.
- Si tiene síntomas que no coinciden con su prueba de glucosa en sangre y ha seguido todas las instrucciones descritas en el manual del propietario de FreeStyle Freedom® Lite, consulte a su médico.

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El medidor FreeStyle Freedom[®] Lite y cómo funciona



Pantalla de comprobación del sistema

Esta pantalla aparece brevemente cada vez que el medidor se enciende para que pueda asegurarse de que la pantalla funciona correctamente. No use el medidor si la pantalla de comprobación del sistema no coincide con este ejemplo. Comuníquese con el Departamento de Atención al Cliente.

Pantalla

Muestra los resultados de sus pruebas y otra información importante.

Botón M (Modo)

- Cambia a distintas configuraciones de modo.
- Retrocede.
- Silencia una alarma de recordatorio.

Puerto de datos

Descarga de los resultados de prueba. Requiere un sistema de control de datos compatible.

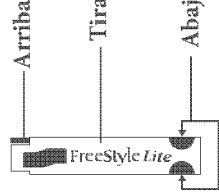
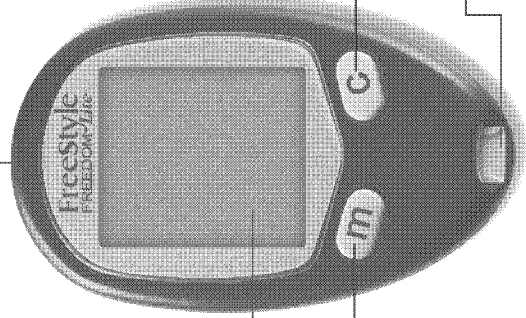
Para obtener más información, visite nuestro sitio web o comuníquese con el Departamento de Atención al Cliente.

Botón C (Configurar)

- Señala una prueba de solución de control.
- Adelanta.
- Silencia una alarma de recordatorio.
- Cambia la fecha, hora, configuraciones de alarma, opciones de sonido y lecturas de revisiones almacenadas.

Puerto de la tira de prueba

Introduzca aquí el extremo de arriba de una nueva tira de prueba FreeStyle Lite. El medidor se enciende cuando introduce la tira de prueba.



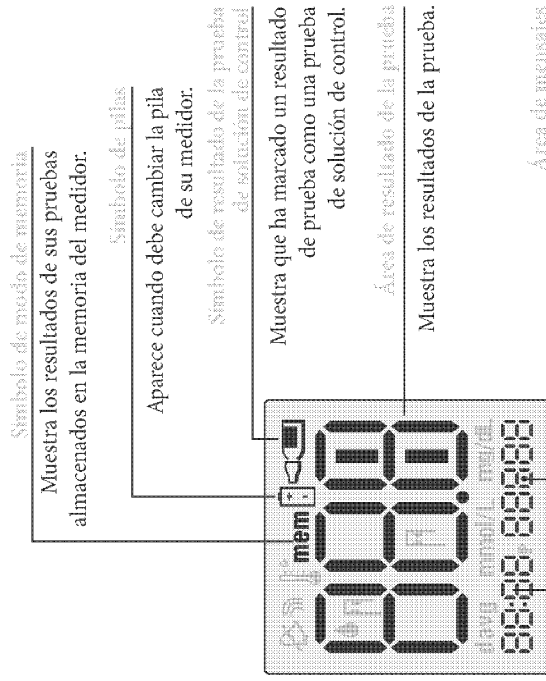
Áreas de muestra (señaladores de color oscuro en la tira de prueba)

Aplique sangre o solución de control a una sola área de muestra. Introduzca la tira en el medidor con el lado impreso hacia arriba (ver imagen a la derecha).

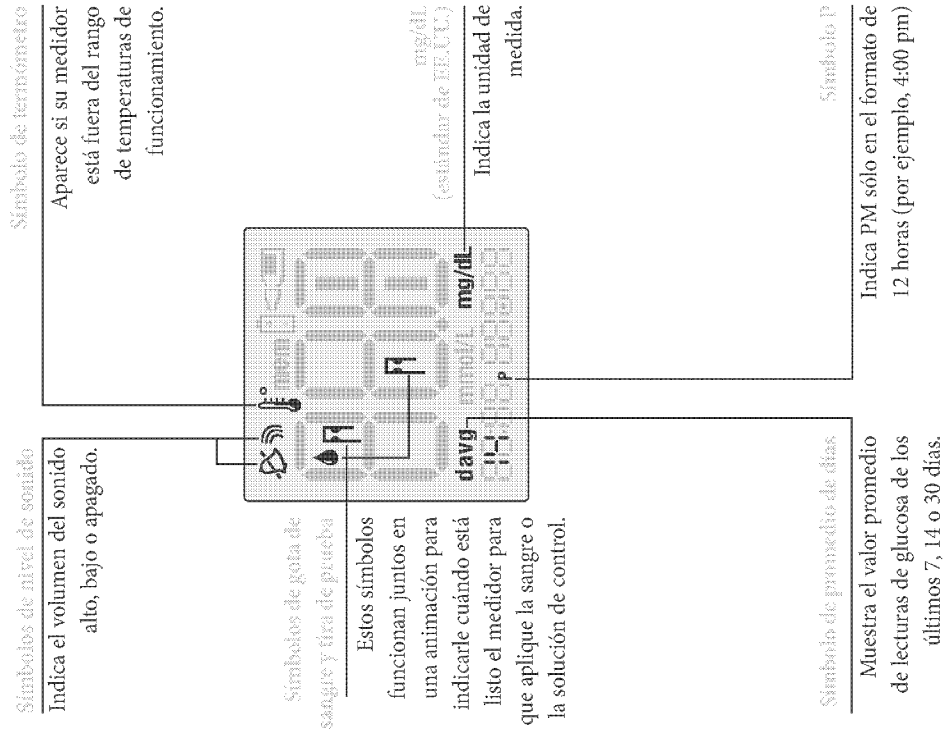
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La pantalla del medidor FreeStyle Freedom[®] Lite

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La tira de prueba FreeStyle® Lite

Aplique sangre o solución de control en **una sola área de muestra de la tira de prueba** por prueba.

Importante: Use solamente un área de muestra de la tira de prueba por prueba. No aplique sangre en ambas áreas de muestra. Las tiras de prueba se podrán usar una sola vez. Deseche las tiras de prueba usadas. Puede continuar llenando la tira de prueba durante 60 segundos como máximo. Asegúrese de volver a aplicar la muestra en la misma área de muestra.



ADVERTENCIA:

El tapón o el vial contienen secantes que pueden ser nocivos si son inhalados o ingeridos y pueden causar irritación en los ojos o en la piel.

Importante: El medidor FreeStyle Freedom® Lite sólo se debe usar con tiras de prueba FreeStyle Lite. El uso de otras de tiras de prueba con este medidor puede dar lugar a resultados inexactos.

Información importante de las tiras de prueba

- El sistema FreeStyle Freedom Lite tiene un rango de funcionamiento de 40 °F a 104 °F (4 °C a 40 °C)
- Almacene el paquete de tiras de prueba en un lugar fresco y seco, a una temperatura de 40 °F a 86 °F (4 °C a 30 °C)
- Utilice las tiras de prueba sólo dentro del rango de temperaturas de funcionamiento del sistema.
- Manténgalas alejadas de la luz solar directa o del calor.
- Almacene sus tiras de prueba solamente en su vial original; nunca las transfiera a otro vial u otro recipiente.
- Nunca almacene tiras de prueba individuales fuera del vial.

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- Después de extraer una tira de prueba FreeStyle Lite del vial, cierre bien el tapón del vial inmediatamente.
- Con las manos limpias y secas, puede tocar la tira de prueba en cualquier lado, al extraerla del vial o introducirla dentro del medidor.
- No utilice tiras de prueba después de su fecha de caducidad. Esto puede dar lugar a resultados inexactos.
- No doble, corte ni altere las tiras de prueba FreeStyle® Lite.

Nota: Para obtener más información, consulte el prospecto de las tiras de prueba FreeStyle Lite.

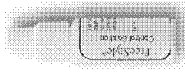
La solución de control FreeStyle®

La solución de control FreeStyle es un líquido rojo que contiene una cantidad fija de glucosa que se utiliza para:

- realizar pruebas de práctica sin tener que usar su propia sangre;
- asegurarse de que su medidor y tiras de prueba estén funcionando en conjunto de manera adecuada;

Cuando dude de sus resultados y desee confirmar que su monitor y tiras de prueba están funcionando de manera adecuada, se deberá realizar una prueba de solución de control.

Para obtener información sobre cómo obtener soluciones de control, comuníquese con el Departamento de Atención al Cliente llamando al 1-888-522-5226.



Información importante acerca de la solución de control

La solución de control FreeStyle® dura hasta tres meses una vez abierta la botella o hasta la fecha de caducidad impresa en la etiqueta, lo que ocurra primero.

Importante: Cuenten tres meses hacia adelante a partir de la fecha en que abre una nueva botella de solución de control. Escriba esta fecha en el lado de la botella de su solución de control. Ésta es su fecha de desecho, a menos que la fecha de vencimiento impresa en la botella sea anterior.

Ejemplo: Abra la solución de control el 15 de enero. Cuenten tres meses hacia adelante hasta el 15 de abril. Ésta es la fecha de desecho que figura en la botella.

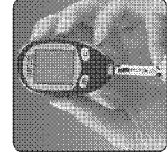
- Use solamente la solución de control FreeStyle con su sistema FreeStyle Freedom® Lite.
 - Vuelva a colocar el tapón en la botella de la solución de control inmediatamente después de usarla.
 - No utilice la solución de control después de la fecha de caducidad.
 - No agregue agua ni ningún otro líquido a la solución de control.
 - Las pruebas de la solución de control están especificadas para ser precisas sólo cuando se usan entre 59 °F y 104 °F (15 °C y 40 °C)
 - Los resultados de las pruebas de la solución de control deberían estar dentro del rango impreso en la etiqueta del vial de la tira de prueba.
- Importante:** El rango de la solución de control es un rango deseado sólo para la solución de control. No es un rango deseado para su nivel de glucosa en sangre.

- Si los resultados de la solución de control están fuera de este rango, repita la prueba.
- Si los resultados de su prueba de solución de control continúan estando fuera del rango impreso del vial de la tira de prueba, no utilice el sistema FreeStyle Freedom Lite para medir su glucosa en sangre. Póngase en contacto con el Departamento de Atención al Cliente.

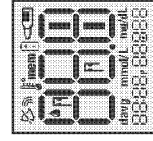
Precaución: Los resultados obtenidos en las pruebas de soluciones de control FreeStyle no reflejan sus niveles de glucosa en sangre.

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Cómo realizar una prueba de solución de control



Introduzca la parte de arriba de la tira de prueba en el medidor hasta que se detenga. Esto encenderá el medidor.

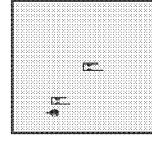


Pantalla de comprobación del sistema

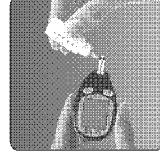
Cada vez que el medidor se enciende, aparecerá brevemente esta pantalla para que se asegure de que esté funcionando correctamente.

Comprobación del sistema

La fecha y hora aparecerán brevemente después de la pantalla de comprobación del sistema para que se asegure de que el medidor esté programado con la hora y fecha correctas.



Espera a que el medidor muestre los símbolos de gota de sangre y tira de prueba.



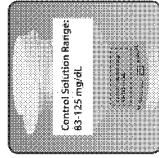
Toque suavemente sólo **las áreas de la muestra** de la tira de prueba con la solución de control.

Importante: No aplique solución de control a las áreas de muestra de la tira de prueba.

Si el sonido está activo, su medidor emitirá un sonido cuando la tira de prueba esté llena. Luego, una línea corta se mueve alrededor de la pantalla en el sentido de las agujas del reloj mientras la muestra se está procesando.

El resultado aparecerá en la pantalla y si el sonido está activado, su medidor emitirá un sonido dos veces. Para marcar el resultado como un resultado de la solución de control, mantenga presionado el botón "c" durante 2 segundos hasta que el símbolo de solución de control (☐) aparezca en la parte superior derecha de la pantalla.

Si ha marcado una prueba de glucosa en sangre como prueba de solución de control por error, puede desmarcarlo manteniendo presionado el botón "c" nuevamente durante dos segundos.



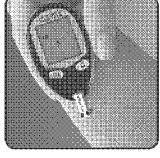
Compare el resultado de su prueba de solución de control con el rango impreso en la etiqueta del vial de su tira de prueba. Los resultados de la solución de control deberían estar dentro del rango impreso en el lado del vial de su tira de prueba.

Los resultados de las pruebas fuera de rango pueden ser causados por:

- solución de control vencida o en mal estado;
- tira de prueba vencida o en mal estado;
- error al realizar la prueba;
- solución de control debilitada;
- mal funcionamiento del medidor;
- la prueba de la solución de control se realizó fuera del rango de 59 °F a 104 °F.

Para apagar el medidor, retire la tira de prueba.

Prueba de su glucosa en sangre



Importante: Para garantizar resultados exactos, lave sus manos y la zona de prueba (por ejemplo, su antebrazo) con agua y jabón. Cerciórese de que no haya loción ni crema en la zona de prueba. Seque completamente sus manos y la zona de prueba.

- Con el medidor FreeStyle Freedom® Lite, puede medir la glucosa en sangre en el antebrazo, dedos, brazo, mano, muslo o pantorrilla.
- Las pruebas con el medidor FreeStyle Freedom Lite requieren una muestra de tamaño muy pequeño, 0.3 microlitros de sangre; aproximadamente el tamaño de una cabeza de alfiler (ejemplo: ••).

ADVERTENCIA:

Le recomendamos que realice las pruebas en los dedos de la mano si está haciendo una prueba de hipoglucemia (bajo nivel de glucosa en sangre) o si sufre de hipoglucemia asintomática.

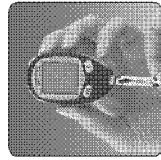
Los momentos en los que puede controlar si su glucosa en sangre está baja son:

- cuando tiene síntomas como debilidad, sudores, nerviosismo, dolor de cabeza o confusión;
- cuando ha demorado una comida después de tomar insulina;
- cuando se lo recomienda su médico.

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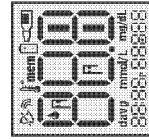
Cómo realizar una prueba de glucosa en sangre



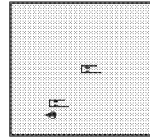
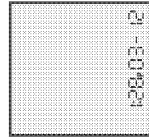
Prepare su medidor

Introduzca una tira de prueba FreeStyle® Lite en el medidor hasta que se detenga. El medidor se encenderá.

Nota: Si no comienza la prueba en dos minutos, el medidor se apagará. Para reiniciar el medidor, saque la tira de prueba FreeStyle Lite sin usar y vuelva a introducirla en el medidor.



Comprobación del sistema



Símbolos de gota de sangre y tira de prueba

Importante: El medidor FreeStyle Freedom® Lite sólo se debe usar con tiras de prueba FreeStyle Lite. El uso de otras tiras de prueba con este medidor puede dar lugar a resultados inexactos.

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2 Cómo obtener una muestra de sangre

Seleccione una zona de prueba. Existen diferencias entre realizar una prueba en los dedos de la mano o en otras zonas alternativas. Use su dispositivo para lancetas para obtener la muestra de sangre. Consulte el prospecto del dispositivo para lancetas para obtener instrucciones detalladas sobre cómo usar el dispositivo para lancetas FreeStyle.

ADVERTENCIA: Le recomendamos que realice las pruebas en los dedos de la mano, si está haciendo una prueba de hipoglucemia (bajo nivel de glucosa en sangre) o si sufre de hipoglucemia asintomática.

3

Llene la tira de prueba FreeStyle® Lite con sangre

- Asegúrese que la tira de prueba FreeStyle Lite esté en el medidor, que el medidor esté encendido y que los símbolos de gota de sangre y tira de prueba aparezcan en pantalla. (Si el medidor está apagado, retire la tira de prueba y vuelva a introducirla.) Ahora está listo para aplicar la muestra de sangre.

- Acerque la tira de prueba FreeStyle Lite a la muestra de sangre levemente en ángulo.

Importante: Use solamente un área de muestra de la tira de prueba por cada prueba. No aplique sangre en ambos bordes, o podrá obtener un resultado inexacto. Las tiras de prueba se podrán usar una sola vez. Deseche las tiras de prueba usadas.

- La tira de prueba FreeStyle Lite actúa como una esponja y absorbe la sangre en la tira a través del área de la muestra.



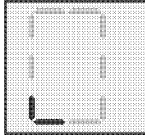
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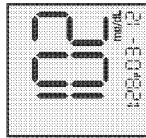
- No presione la tira de prueba FreeStyle® Lite contra la zona de prueba.
- No frote la sangre contra la tira de prueba FreeStyle Lite.
- No aplique sangre al lado plano de la tira de prueba FreeStyle Lite.
- No aplique sangre a la tira de prueba FreeStyle Lite cuando la tira de prueba FreeStyle Lite se encuentra fuera del medidor.
- No coloque sangre ni objetos extraños en el puerto de la tira de prueba FreeStyle Freedom® Lite.

4 A la espera del resultado



- No jale la tira de prueba FreeStyle Lite hasta que escuche un sonido o vea la línea corta moviéndose en el sentido de las agujas del reloj en la pantalla de su medidor. Esto significa que tiene suficiente sangre y que el medidor está leyendo su glucosa.

- Si después de cinco segundos, su medidor no muestra una línea corta moviéndose alrededor de la pantalla, es posible que la muestra sea demasiado pequeña. Puede agregar sangre a la misma área de la muestra de la tira de prueba con la cual comenzó, durante 60 segundos como máximo a partir del momento de la primera aplicación.



- El resultado de la prueba está completo cuando aparece en la pantalla el resultado de su prueba de glucosa en sangre y escuchará dos sonidos si el sonido está encendido.
- En promedio, su lectura se mostrará en 5 segundos. El tiempo que tome el medidor depende de su nivel de glucosa en sangre. Cuanto más alto sea el nivel de glucosa, más tiempo lleva obtener un resultado.

Posibles hematomas

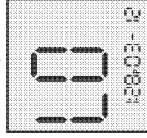
Es posible que aparezcan hematomas en la zona de prueba. Si esto ocurre, puede oprimir por pinchar en otra zona de prueba.

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Lecturas LO (BAJO) y HI (ALTO)

Importante: Las lecturas de glucosa en sangre altas o bajas pueden indicar una condición médica potencialmente grave. El medidor FreeStyle Freedom® Lite muestra resultados de 20 a 500 mg/dL.

Si el resultado de su prueba es inferior a 20 mg/dL, aparecerá LO (BAJO) en la pantalla del medidor. Esta lectura indica hipoglucemia grave (bajo nivel de glucosa en sangre).



Lectura BAJO

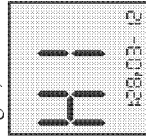
Lectura LO (BAJO) con síntomas

Si obtiene LO (BAJO) en la lectura y presenta síntomas como debilidad, sudores, nerviosismo, dolor de cabeza o confusión, **entonces** siga las recomendaciones de su médico para tratar la hipoglucemia.

Lectura LO (BAJO) sin síntomas

Si obtiene LO (BAJO) en la lectura, pero no tiene síntomas de bajo nivel de glucosa en sangre, **entonces** vuelva a realizar la prueba con una nueva tira de prueba en sus dedos. Si aún obtiene LO (BAJO) en la lectura, siga las recomendaciones de su médico para tratar la hipoglucemia.

Si su prueba es superior a 500 mg/dL, aparecerá HI (ALTO) en la pantalla. Esto indica hiperglucemia grave (alto nivel de glucosa en sangre).



Lectura ALTO

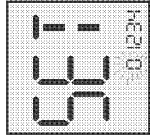
Lectura HI (ALTO) con síntomas

Si presenta síntomas como fatiga, sed, orina en exceso o visión borrosa, **entonces** siga las recomendaciones de su médico para tratar la hiperglucemia.

Lectura HI (ALTO) sin síntomas

Si obtiene una lectura HI (ALTO), pero no tiene síntomas de alto nivel de glucosa en sangre, **entonces** vuelva a realizar la prueba con una nueva tira de prueba. Si aún obtiene HI (ALTO) en la lectura, siga las recomendaciones de su médico para tratar la hiperglucemia.

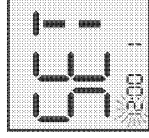
Configuración del medidor Cómo configurar su medidor



- **Para ingresar en el modo configurar**
Comience con el medidor apagado (sin haber introducido una tira de prueba). Presione y sujete con firmeza el botón “m” hasta que aparezca la pantalla de configuración.

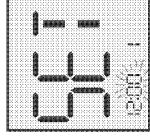
- **Para salir en cualquier momento**
Presione y sujete el botón “m” durante dos segundos hasta que el medidor se apague.
- **Para desplazarse de una pantalla a otra**
Presione el botón “m” para desplazarse por todas las pantallas de configuración como alarmas de recordatorio, nivel de sonido, hora, fecha, etc.
- **Para cambiar la configuración dentro de la pantalla**
Presione el botón “c”.

ESPAÑOL



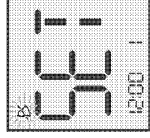
Seleccione la hora

3. Presione el botón “m” para ir a la configuración de la hora. Con la hora intermitente, presione el botón “c” hasta que aparezca la hora correcta.



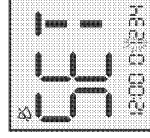
Seleccione los minutos

4. Presione el botón “m” para ir a la configuración de minutos. Con los minutos intermitentes, presione el botón “c” hasta que aparezca el minuto correcto.



Seleccione el volumen de la alarma de recordatorio

5. Presione el botón “m” para ir a la configuración de volumen de la alarma de recordatorio. La configuración predeterminada está apagada. Presione el botón “c” para seleccionar la configuración de volumen deseada: bajo, alto o apagado.



Seleccione la alarma de recordatorio

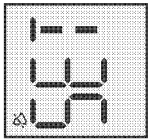
6. Presione el botón “m” para finalizar la configuración de su alarma. Esto lo llevará nuevamente al modo de configuración de alarma de recordatorio.
Si desea configurar varias alarmas de recordatorio, presione el botón “c” para ir a la alarma de recordatorio 2. Repita.

Nota: Para guardar sus configuraciones de alarma de recordatorio y salir del modo configurar, mantenga presionado el botón “m” durante dos segundos hasta que el medidor se apague. Presione el botón “m” cuando aparece el “0” intermitentemente para ir a la siguiente pantalla de configuración sin configurar ninguna alarma de recordatorio.

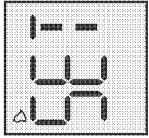
ESPAÑOL

Configuración del sonido

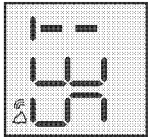
Hay tres (3) opciones de volumen de sonido:



Apagado



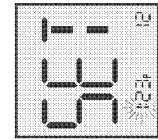
Bajo



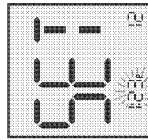
Alto

Hay tres opciones de volumen de sonido que le permiten saber cuando la tira de prueba está llena, cuando se realiza la lectura y cuando se produce un error:

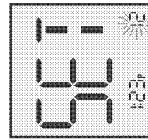
1. Presione el botón “c” hasta que aparezca el nivel de sonido deseado.
2. Presione el botón “m” para ir a “Cómo configurar la hora”.



Hora



Minuto



Formato de hora

Cómo configurar la hora

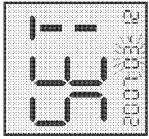
1. Con la hora intermitente, presione el botón “c” hasta que aparezca la hora correcta. Aparece la “P” para las horas “PM”.
2. Presione el botón “m” para ir a la configuración de minutos. Con los minutos intermitentes, presione el botón “c” hasta que aparezca el minuto correcto.
3. Presione el botón “m” para ir a “Cómo configurar el formato de hora”.

Cómo configurar el formato de hora

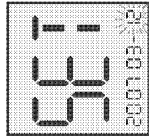
1. Con el modo hora intermitente, presione el botón “c” para desplazarse entre el formato de 12 y 24 horas. La hora se actualiza automáticamente al formato seleccionado.
2. Presione el botón “m” para ir a “Cómo configurar la fecha y formato de fecha”.

Cómo configurar la fecha y el formato de fecha

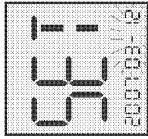
1. Con el mes intermitente, presione el botón “c” hasta que aparezca el mes correcto.



Mes



Día



Año-mes-día

2. Presiones el botón “m” para ir a la configuración del día. Con el día intermitente, presione el botón “c” hasta que aparezca el día correcto.

ESPAÑOL

3. Presione el botón “m” para ir al “Formato de fecha”. Con la fecha intermitente, presione el botón “c” para seleccionar el formato mes-día o día-mes. La fecha se actualiza automáticamente al formato seleccionado.

4. Presiones el botón “m” para ir a la configuración del año. Con el año intermitente, presione el botón “c” hasta que aparezca el año correcto.

Ha completado la configuración del medidor.

- Para ir a “Configuración de alarmas de recordatorio del usuario”, presione el botón “m”.
- Para salir, mantenga presionado el botón “m” durante dos segundos.

Resultados del medidor Memoria del medidor

- **Para ingresar**

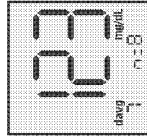
Comience con el medidor apagado (sin haber introducido una tira de prueba). Presione el botón “m” y suéltelo; la primera pantalla de memoria que aparece será su promedio de 7 días.

- **Para salir**

Presione y sujete el “m” botón durante dos segundos hasta que el medidor se apague.

Promedio de 7, 14 y 30 días

La primera pantalla de memoria que ve es su promedio de 7 días. Esto incluye todas las lecturas desde los últimos 7 días, comenzando desde la fecha y la hora actuales que se muestran en el medidor. (Las lecturas de solución de control, BAJO y ALTO no están incluidas en el promedio).



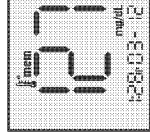
Promedio de 7 días: Ejemplo:

Promedio de 7 días = su promedio de 7 días
n = indica la cantidad de resultados
incluidos en su promedio

El botón “c” le permite adelantar los promedios de 14 y 30 días. Continúe presionando el botón “c” para ver los resultados de prueba almacenados. Su resultado más reciente se mostrará primero.

Resultados de pruebas

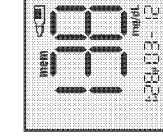
El medidor almacena lecturas de las últimas 400 pruebas con fecha y hora. Puede avanzar todas las lecturas manteniendo presionado el botón “c”. El botón “m” le permite retroceder. La primera lectura que ve es el resultado más reciente.



Temperatura: Un resultado con un símbolo de termómetro (°F) indica que la lectura fue tomada fuera del rango de temperaturas de funcionamiento especificado para el medidor y puede no ser preciso. Este valor se incluye en su promedio de 7, 14 y 30 días.

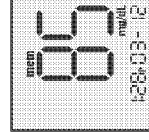
Lectura LO (BAJO): Una lectura BAJO (inferior a 20 mg/dL) se incluye en la memoria como BAJO; no se incluye en los promedios de 7, 14 y 30 días.

Lectura HI (ALTO): Una lectura ALTO (superior a 500 mg/dL) se incluye en la memoria como ALTO; no se incluye en los promedios de 7, 14 y 30 días.



Prueba de solución de control

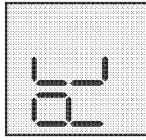
Un valor con (c) indica que ha marcado esta lectura como una prueba de solución de control. La fecha y hora de la lectura con solución de control aparecerán en la parte inferior de la pantalla.



Prueba de glucosa en sangre

Un resultado sin un símbolo de solución de control indica que es una lectura de glucosa en sangre. La fecha y hora de la prueba aparecerán en la parte inferior de la pantalla.

Cómo descargar datos



El símbolo "PC" muestra cuando se introdujo un cable de datos en el puerto de datos del medidor. No puede realizar una prueba mientras el cable de datos está en el puerto de datos del medidor.

El medidor mostrará "PC" hasta que el cable de datos se extraiga del puerto de datos.

Requiere un sistema de control de datos compatible. Para obtener más información, visite nuestro sitio web o llame a Atención al Cliente.

ESPAÑOL

Mantenimiento del medidor

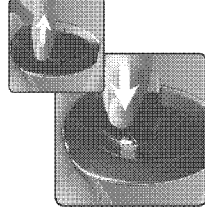
Pila

Su medidor FreeStyle Freedom® Lite viene con una pila de litio ya instalada Nº 2032 de 3 voltios. La pila le brinda suficiente energía para que el medidor realice 1000 pruebas. Si se queda sin pila, el símbolo de pila (🔋) aparece en todas las pantallas hasta que cambie la pila.

Importante: Cuando aparece este símbolo, debe cambiar la pila de inmediato.

- Para evitar perder las configuraciones de la hora y la fecha, cambie la pila antes de que pase un minuto desde que extrajo la pila vieja.
- Si toma más de un minuto cambiar la pila, es posible que deba reiniciar la fecha y la hora para obtener el promedio de 7, 14 y 30 días correcto. Si se pierden la fecha y la hora, las pantallas de hora y fecha muestran 12:00 y 00-00 en forma intermitente hasta que se reinicie.
- El hecho de extraer la pila no afecta el registro de memoria del medidor ni las configuraciones del usuario previamente almacenadas (como los formatos de hora y de fecha).
- Si no reinicia las configuraciones de hora y de fecha, los resultados de las pruebas serán almacenados en la memoria con hora 12:00 y fecha 00-00.
- Aun si pierde sus configuraciones de fecha y hora – puede realizar una prueba de glucosa en sangre, y los resultados no se verán afectados.

Cómo cambiar la pila



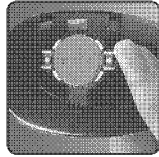
Voltee el medidor. Deslice la puerta del compartimento de las pilas hacia la derecha para abrirla.

Para retirar la pila, tire de la lengüeta plástica para liberar la pila.

ESPAÑOL

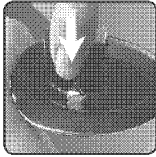
Cómo cambiar la pila (continuación)

2

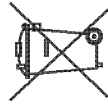


Instale la pila con el polo positivo (+) hacia arriba y hacia usted.

3



Para cerrar, deslice la puerta del compartimento de pilas hasta que se traben en su lugar haciendo un clic.



Nota: Es necesario desechar las pilas de forma adecuada. Comuníquese con su gobierno local para conocer las prácticas de desecho y reciclaje en su área.

Cuidado de su medidor

Evite que entre suciedad, polvo, sangre, solución de control, agua o cualquier otro líquido en los puertos de la tira de prueba y de datos del medidor.

Importante: No sumerja el medidor en agua ni en ningún otro líquido. Esto podría ocasionar la lectura inexacta o el mal funcionamiento del medidor.

No intente limpiar el puerto de la tira o el puerto de datos.

No vierta líquido en el puerto de la tira, puerto de datos, ni sobre los botones.

No sumerja el medidor en agua ni en ningún otro líquido.

Limpie la parte exterior del medidor usando un paño humedecido en algunos de estos líquidos:

- Detergente/jabón suave y agua.
- Alcohol isopropílico 70%.
- Una mezcla de una parte de blanqueador doméstico y nueve partes de agua.

Llame al número gratuito de Atención al Cliente al 1-888-522-5226

www.AbbottDiabetesCare.com

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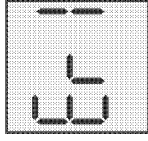
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Resolución de problemas del sistema

Mensajes de error

Error 1



Causas posibles

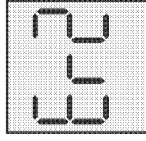
- La muestra es demasiado pequeña.
- Problema con la tira de prueba FreeStyle® Lite.
- Problema con el medidor.
- Glucosa en sangre muy baja (inferior a 20 mg/dL).

Qué debe hacer

1. Si tiene síntomas como debilidad, sudores, nerviosismo, dolor de cabeza o confusión, siga las recomendaciones de su médico para tratar la hipoglucemia.
2. Realice una prueba de solución de control con una nueva tira de prueba FreeStyle Lite. Si los resultados de la prueba de solución de control están dentro del rango impreso en el lado del vial de su tira de prueba, vuelva a realizar la prueba usando sangre y una nueva tira de prueba FreeStyle Lite.

3. Si la segunda prueba usando solución de control no funciona o si el error persiste, comuníquese con el Departamento de Atención al Cliente.

Error 2



Causas posibles

- Problema con la tira de prueba FreeStyle Lite.
- Problema con el medidor.
- Glucosa muy alta (superior a 500 mg/dL).
- Solución de control ALTA aplicada cuando la temperatura es demasiado fría. (Esto se aplica solamente a una solución de control etiquetada como ALTA).

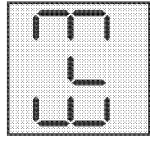
28

10/22/07 3:49:35 PM

Qué debe hacer

1. Si tiene síntomas como sed, fatiga, orina en exceso o visión borrosa, siga las recomendaciones de su médico para tratar la hiperglucemia.
2. Realice una prueba de solución de control con una nueva tira de prueba FreeStyle® Lite. Si los resultados de la prueba de solución de control están dentro del rango impreso en el lado del vial de su tira de prueba, vuelva a realizar la prueba usando sangre y una nueva tira de prueba FreeStyle Lite.
3. Si la segunda prueba usando solución de control no funciona o si el error persiste, comuníquese con el Departamento de Atención al Cliente.

Error 3



Causas posibles

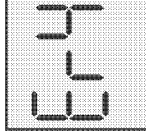
- Procedimiento de prueba incorrecto. Por ejemplo, colocar sangre en la tira de prueba antes de introducir la tira de prueba en el medidor o aplicar sangre antes de que aparezcan los símbolos gota de sangre y tira de prueba.
- Problema con la tira de prueba FreeStyle Lite.
- Problema con el medidor.

Qué debe hacer

1. Asegúrese de ver los símbolos gota de sangre y tira de prueba en la pantalla antes de aplicar la sangre o la solución de control.
2. Realice una prueba de solución de control con una nueva tira de prueba FreeStyle Lite. Si los resultados de la prueba de solución de control están dentro del rango impreso en el lado del vial de su tira de prueba, vuelva a realizar la prueba usando sangre y una nueva tira de prueba FreeStyle Lite.
3. Si la segunda prueba usando solución de control no funciona o si el error persiste, comuníquese con el Departamento de Atención al Cliente.

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Error 4



Causas posibles

- Problema con una tira de prueba FreeStyle Lite.
- Problema con el medidor.

Qué debe hacer

1. Realice una prueba de solución de control con una nueva tira de prueba. Si los resultados de la prueba de solución de control están dentro del rango impreso en el lado del vial de su tira de prueba, vuelva a realizar la prueba usando sangre y una nueva tira de prueba FreeStyle® Lite.
2. Si la segunda prueba usando solución de control no funciona o si el error persiste, comuníquese con el Departamento de Atención al Cliente.

ESPAÑOL

El medidor no ingresa en el modo de prueba después de introducir una tira de prueba.

Causa probable	Qué hacer:
La pila está descargada.	Cambie la pila (y vuelva a configurar la fecha y la hora, si es necesario).
La pila se instaló incorrectamente o no hay pila en el medidor.	Compruebe que la pila esté instalada correctamente con el polo positivo (+) hacia arriba y hacia usted.
La tira de prueba se introdujo al revés, se introdujo el extremo incorrecto o no se introdujo por completo en el medidor.	Introduzca la tira de prueba FreeStyle Lite con el lado impreso hacia arriba y la parte superior de la tira en el medidor.
Medidor o tiras de prueba defectuosos.	Comuníquese con el Departamento de Atención al Cliente.
Sangre u objetos extraños en el puerto de la tira de prueba.	Comuníquese con el Departamento de Atención al Cliente.

La prueba no comienza después de aplicar la muestra de sangre.

Causa probable	Qué hacer:
La muestra es demasiado pequeña.	Puede agregar sangre al área de la muestra de la tira de prueba FreeStyle Lite con la cual comenzó, durante 60 segundos como máximo después del momento de la primera aplicación. Si es necesario, repita la prueba con una nueva tira de prueba FreeStyle Lite y una muestra de sangre más grande.
Tira de prueba defectuosa.	Repita la prueba con una nueva tira de prueba FreeStyle Lite
Se aplicó la muestra después del tiempo de espera del medidor (dos minutos) y éste se apaga.	Repita la prueba con una tira de prueba nueva. Espere hasta ver los símbolos gota de sangre y la tira de prueba en la pantalla antes de aplicar la sangre.
Medidor o tiras de prueba defectuosos.	Comuníquese con el Departamento de Atención al Cliente.

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Método de ensayo	Sensor electromecánico coulométrico
Apagado automático	Dos minutos después de la última acción del usuario
Duración de la pila	1000 pruebas
Calibración	Equivalente en plasma
Hematocrito	De 15% a 65%
Unidades de medida	mg/dL
Temperatura para almacenamiento del medidor.	-4 °F a 140 °F (-20 °C a 60 °C)
Memoria	400 pruebas de glucosa en sangre y solución de control con fecha y hora
Humedad relativa de funcionamiento	de 5% a 90% (sin condensación)
Temperatura de funcionamiento	40 °F a 104 °F (4 °C a 40 °C)
Fuente de alimentación	Una pila de litio N° 2032 de 3 voltios reemplazable
Rango de resultados	De 20 a 500 mg/dL
Muestra	Sangre entera, capilar
Tamaño de la muestra	0.3 microlitros (300 nanolitros)
Tamaño	Ancho 2.00" x Largo 3.30" x Grosor 0.63" (en el punto más grueso)
Duración de la prueba	Promedio de 5 segundos
Peso	1.50 oz. incluye la pila



Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502

Customer Care is available 24 hours a day, 7 days a week.
El Departamento de Atención al Cliente atiende las 24 horas del día, los 7 días de la semana.

www.AbbottDiabetesCare.com
Call Customer Care
Toll Free at 1-888-522-5226

www.AbbottDiabetesCare.com
Comuníquese con el Departamento de
Atención al Cliente
de forma gratuita llamando al 1-888-522-5226

Covered by one or more of the following U.S. Patents:

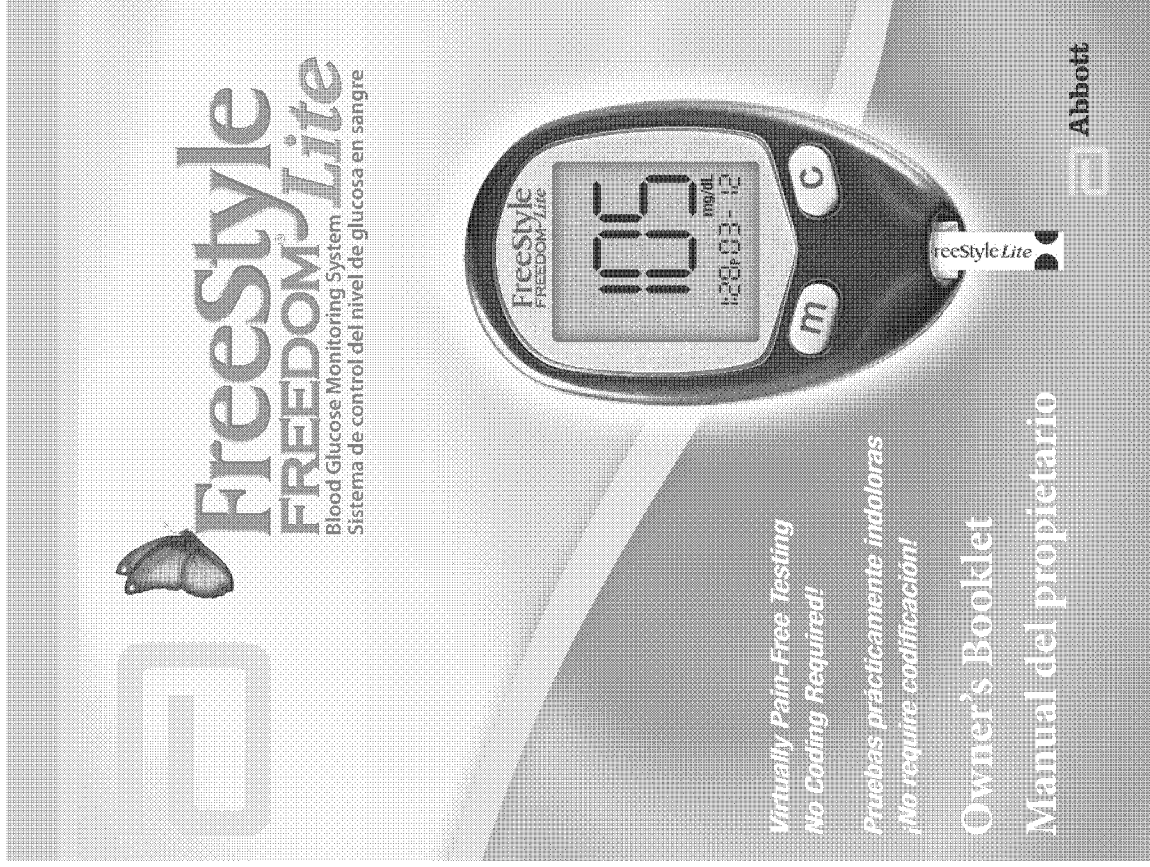
Cubierto por una o más de las siguientes patentes de los Estados Unidos:

D424,696 and D426,638 and 6,071,391 and 6,120,676 and 6,143,164 and 6,338,790 and 6,299,757 and 6,461,496 and 6,503,381 and 6,591,125 and 6,592,745 and 6,616,819 and 6,618,934 and 6,676,816 and 6,749,740 and 6,893,545.
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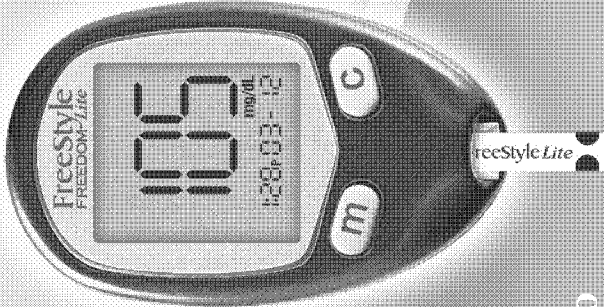
ART12214 Rev. B 10/07

FOI - Page 180 of 590

ART12214_Rev-B-CVR.indd 1-2



**Freestyle
FREEDOM-Lite**
Blood Glucose Monitoring System
Sistema de control del nivel de glucosa en sangre



*Virtually Pain-Free Testing
No Coding Required!*

*Pruebas prácticamente indoloras
¡No requiere codificación!*

**Owner's Booklet
Manual del propietario**

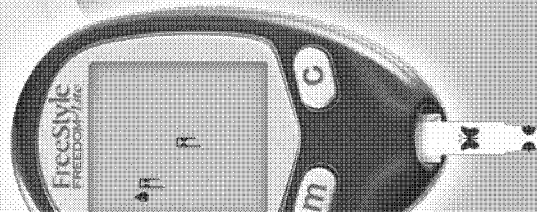
Abbott

10/22/07 4:23:52 PM

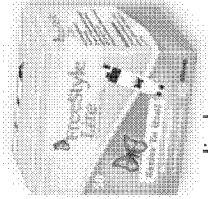
REVISED DATE : June/08	Size:
Die Supplier:	5" x 2.812" x 7.125"
ADC, A&P	

FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System



- Multiple test sites so your fingers can get a rest
- 4 reminder alarms
- Stores up to 400 results with date and time
- Provides results in 7-, 14- and 30-day averages



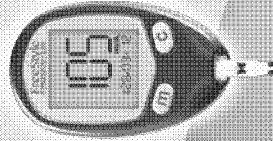
FreeStyle Lite Test Strips

60 seconds
when enough blood is applied



FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System



**No Coding
Required!**

The FreeStyle Promise[™] Program
At Abbott Diabetes Care, our first priority is you. Join our FreeStyle Promise Program[™] by calling 1-866-246-2683. Membership is **FREE**. Details inside.

Customer Care
1-888-522-5226

24 hours a day, 7 days a week. Se habla español.

Or visit us online at

www.MyFreeStyle.com

90-Day Money Back Guarantee[™]

*Abbott may modify or discontinue this program at any time without notice. Offer subject to limitation. See insert for details.

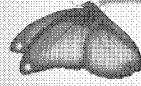
• Test Strips sold separately

• Control Solution available through

Customer Care: 1-888-522-5226

Instrucciones incluidas

Use Only With FreeStyle Lite
Test Strips



FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System



**No Coding
Required!**

World's Smallest
Sample Size

Large Display

Comfortable,
Easy-to-Hold

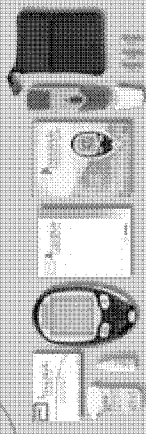
Use Only With FreeStyle Lite
Test Strips



DO NOT use if seal is broken or missing.

FreeStyle FREEDOM^{Lite}

Blood Glucose Monitoring System



REVISED DATE:	Dec/08
Die Owner:	Size:
ADC, A&P	5-1/8" x 2-3/16" x 6-1/16"

NOT FOR RETAIL SALE

NOT FOR RETAIL SALE

**Use Only With FreeStyle Lite
Test Strips**

Instrucciones incluidas

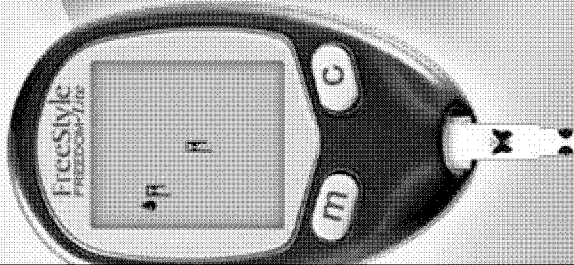
FreeStyle FREEDOM^{Lite}

Blood Glucose Monitoring System

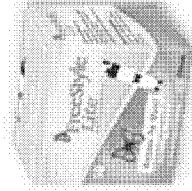


**No Coding
Required!**

- Multiple test sites so your fingers can get a rest
- 4 reminder alarms
- Stores up to 400 results with date and time
- Provides results in 7-, 14- and 30-day averages



FreeStyle Lite Test Strips



to 60 seconds
only when enough blood is applied

FreeStyle FREEDOM^{Lite}

Blood Glucose Monitoring System

**No Coding
Required!**

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World's Smallest Sample Size

Large Display

Comfortable, Easy-to-Hold

**Use Only With FreeStyle Lite
Test Strips**

Abbott

026071E2066

9 026071E2066

026071E2066

026071E2066

no coat area

DO NOT use if seal is broken or missing.

Crat. # number: 0495-25 100-99035-019970
Manufacturer: Abbott Diabetes Care Inc., 130 South Loop West, Alameda, CA 94501 USA
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Some packaging may be included in package. This product's and/or its use are protected by one or more pending patents.

Life record
If you are
glucose)
unaware
For it will
40° F - 86°
within the
range as
FreeStyle F
are trade
are tradem
jurisdiction

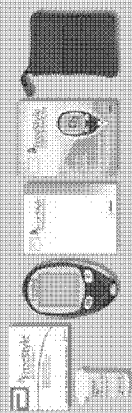
0.3 micro
FreeStyle
Freedom

No
Re

NOT

Do not use if seal is broken or missing.

FreeStyle FREEDOM[®] Lite



REVISED DATE : Dec/08	Size:
Die Owner:	5-1/8" x 2-3/16" x 6-1/16"
ADC, A&P	

Use Only With FreeStyle Lite
Test Strips

Instrucciones incluidas

ALL SALES MANAGED CARE

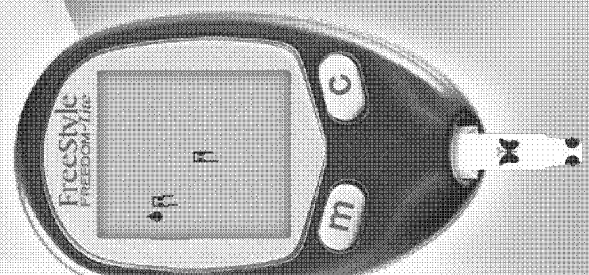
NOT FOR RETAIL SALE MANAGED CARE

FreeStyle FREEDOM[®] Lite

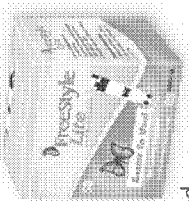


FreeStyle FREEDOM[®] Lite

Blood Glucose Monitoring System



- Multiple test sites so your fingers can get a rest
- 4 reminder alarms
- Stores up to 400 results with date and time
- Provides results in 7, 14- and 30-day averages



FreeStyle Lite[®] Test Strips

60 seconds only when enough blood is applied

No Coding Required!

No Coding Required!

The FreeStyle Promise[™] Program
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World's Smallest Sample Size
Large Display
Comfortable, Easy-to-Hold

Use Only With FreeStyle Lite
Test Strips

Abbott

Call toll free: 1-866-246-2483 • MFG 99075-07 (4/07)
Manufacturer: Abbott Diabetes Care Inc., 1300 South Loop West, Alhambra, CA 91801-1195
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60 seconds only when enough blood is applied

Manufacturer/Fabricante:
Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502, USA

Customer Care is available 24 hours a day, 7 days a week.
El departamento de Atención al cliente está disponible
las 24 horas del día, los 7 días de la semana.

www.MyFreeStyle.com
Call Customer Care
Toll Free at 1-888-522-5226

www.MyFreeStyle.com
Llame sin cargo al departamento de
Atención al cliente al 1-888-522-5226

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6,071,391; 6,120,676; 6,143,164; 6,299,757; 6,338,790; 6,503,381; 6,591,125; 6,607,658; 6,616,819;
6,618,934; 6,676,816; 6,749,740; 6,893,545; 6,942,518; 7,058,437; 7,074,308; Des.444,557;
Des.447,566; Des.450,854; EP1119637; EP1145000; EP0958495; CA2346415; CA2358993; CA2423837.
Additional patents may be issued and/or pending.

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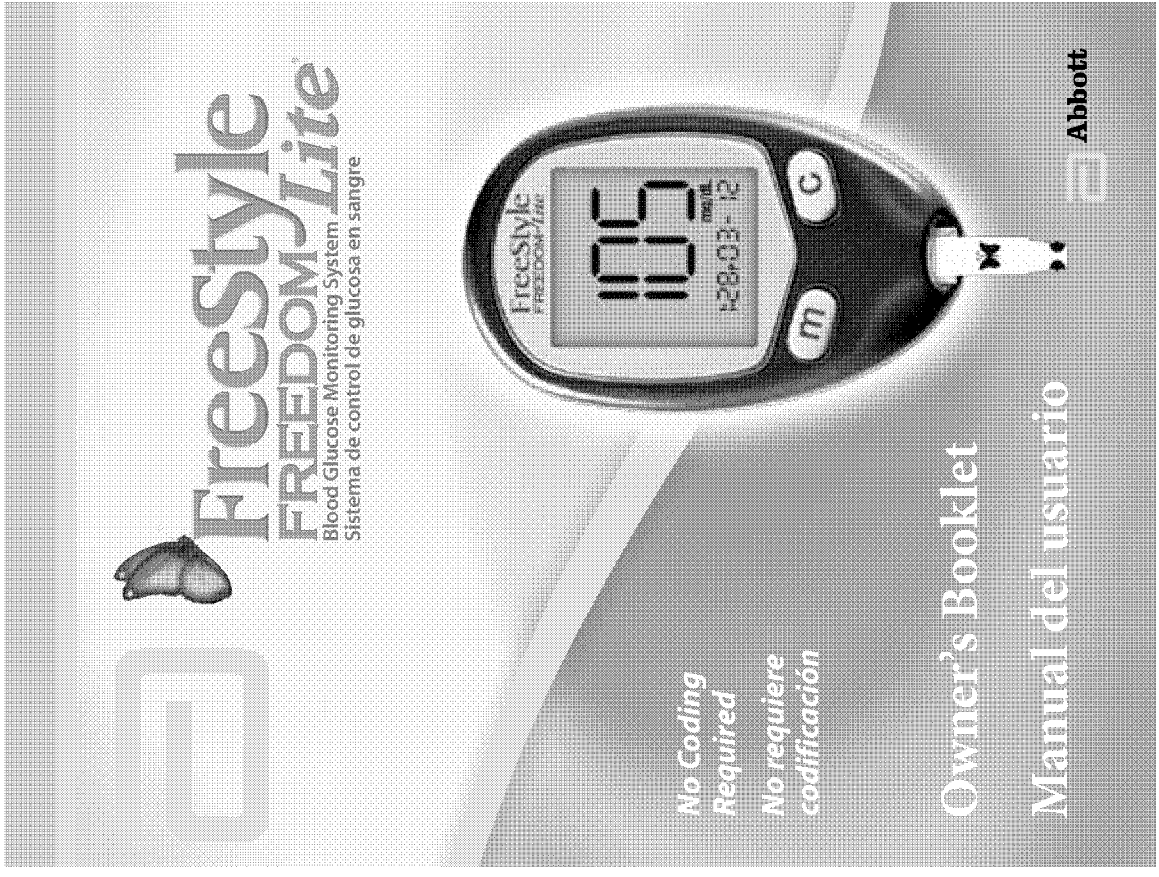
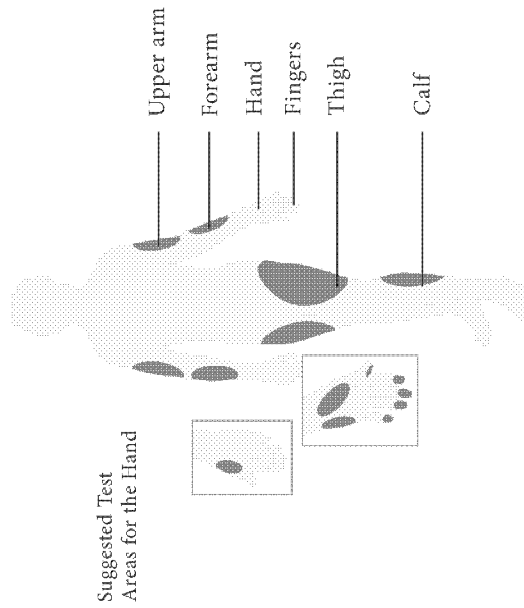


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The FreeStyle Freedom Lite® System Uses a Tiny Sample of 0.3µl So You Can Test on a Variety of Locations

Many Test Sites Available



The human figure above shows the areas where you can test with the FreeStyle Freedom Lite system. Avoid moles, veins, bones, and tendons.

WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Important Information About Your FreeStyle Freedom Lite® Blood Glucose Monitoring System

How the FreeStyle Freedom Lite System Should Be Used

- The FreeStyle Freedom Lite system is intended for use outside the body (in other words, *in vitro* diagnostic use only).
- The FreeStyle Freedom Lite system is used for measuring blood glucose (also known as blood sugar) from samples taken from the forearm, upper arm, hand, thigh, calf, or fingers.
- The FreeStyle Freedom Lite meter should only be used with FreeStyle Lite® test strips and FreeStyle control solution. Using other test strips and control solution with this meter can produce inaccurate results.

Do use the FreeStyle Freedom Lite system for:

- Testing blood glucose.
- Testing glucose in fresh capillary whole blood samples.

Do not use the FreeStyle Freedom Lite system for:

- The diagnosis of diabetes.
- Testing on newborns.
- Testing of arterial blood.

Important Information About Your FreeStyle
Freedom Lite® Blood Glucose Monitoring System
(continued)

WARNING:

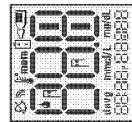
- The FreeStyle Freedom Lite system contains small parts that may be dangerous if swallowed.

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

Important Health-Related Information

- Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L) you should contact your healthcare professional and follow his or her treatment advice.
- For additional information, consult your test strip product information.

The FreeStyle Freedom Lite® Meter and How It Works



System Check Screen

This screen briefly appears each time the meter is turned on so that you can make sure the display is working properly. Do not use the meter if the system check screen does not match the example here. Please call Customer Care.

Display Screen

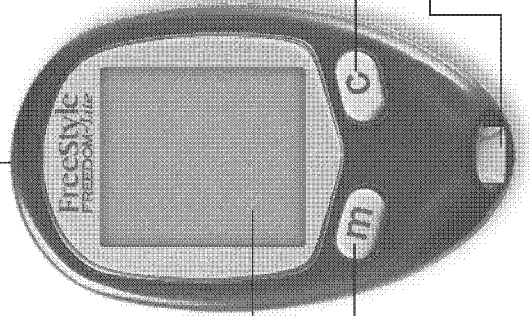
Displays your test results and other important information.

m (Mode) Button

- Move to different mode settings.
- Scrolls backward.
- Silences a reminder alarm.

Data Port

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

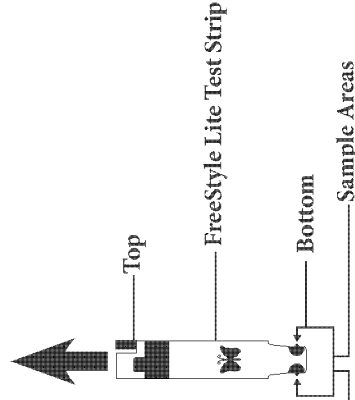


c (Configure) Button

- 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

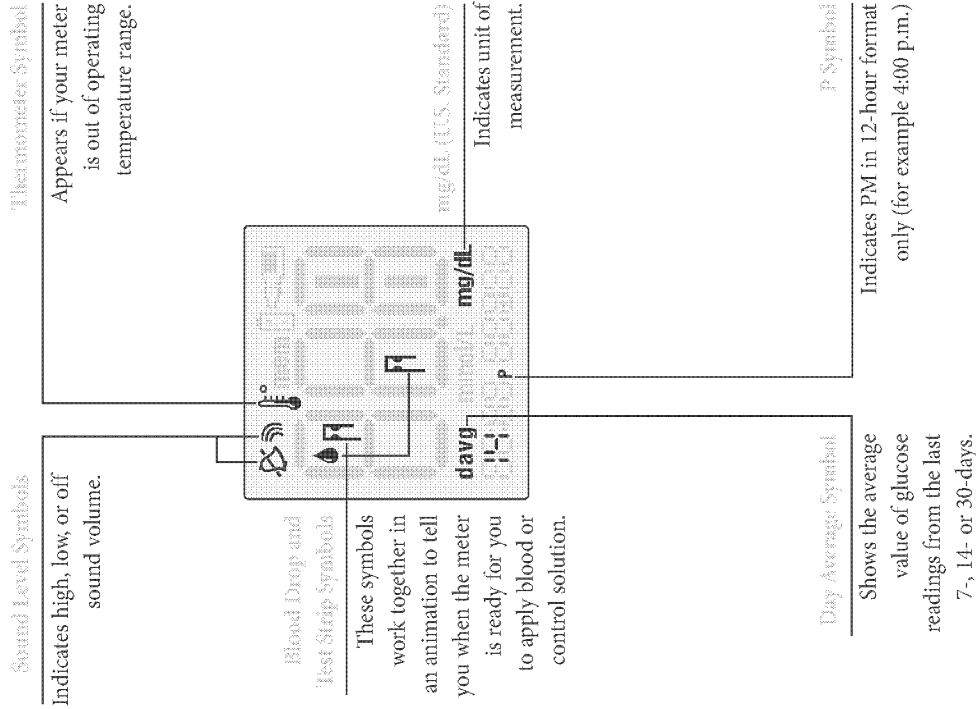
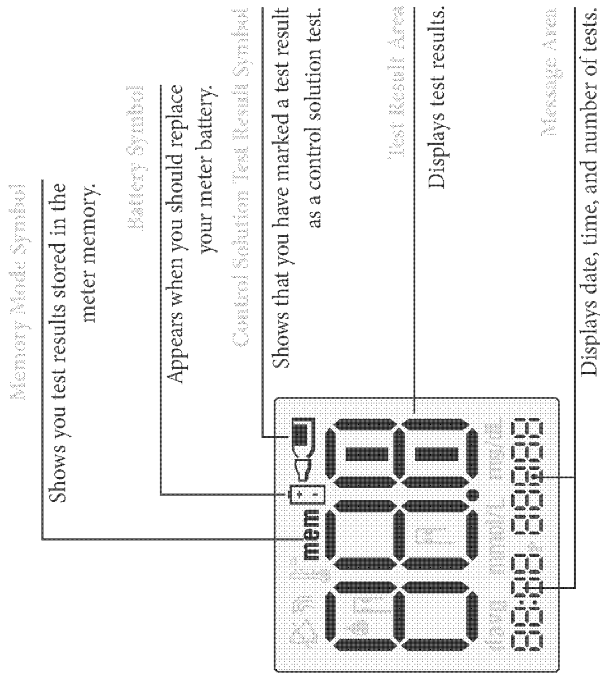
Insert the Top end of a new FreeStyle Lite® test strip here. The meter powers on when you insert the test strip.



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).

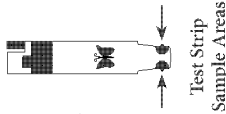
The FreeStyle Freedom Lite™ Meter Display



The FreeStyle Lite® Test Strip

Apply blood or control solution to only **one test strip sample area** per test.

Important: Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Freedom Lite® meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

Important Test Strip Information

- The FreeStyle Freedom Lite system has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight or heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.

9

Call Customer Care Toll Free at 1-888-522-5226 www.MyFreeStyle.com

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ART18402_Rev-A-Man.indd 9-10

- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter FreeStyle Lite® test strips.

Note: For further information, refer to the FreeStyle Lite test strip package insert.

The FreeStyle® Control Solution

Each FreeStyle control solution vial contains a red liquid with a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.



A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

For information on how to obtain control solution, call Customer Care at 1-888-522-5226.

10

8/12/09 1:24:12 PM

Control Solution Information

FreeStyle® control solution is good for three months after opening the bottle or until the expiration date printed on the label, whichever comes first.

Important: Count forward three months from the date you open a new bottle of control solution. Write this date on the side of your control solution bottle. This is your discard date, unless the expiration date printed on the bottle comes first.

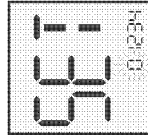
Example: You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.

- Use only FreeStyle control solution with your FreeStyle Freedom Lite® system.
- Replace the cap on the control solution bottle immediately after using.
- Do not use control solution past the expiration date.
- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when used between 59° to 104° F (15° to 40° C).
- Control solution test results should fall within the range printed on the test strip vial label.
- **Important:** The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.
- If control solution results are out of this range, repeat the test.
- If your control solution test results continue to fall outside the range printed on the test strip vial, do not use the FreeStyle Freedom Lite system to test your blood glucose. Contact Customer Care.

Caution: Results from FreeStyle control solution tests do not reflect your blood glucose level.

11 Call Customer Care Toll Free at 1-888-522-5226 www.MyFreeStyle.com

Meter Setup Setting Up Your Meter

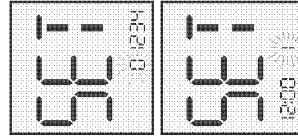


- **To Enter Setup Mode**
Start with the meter off (no test strip inserted). Press and hold the “m” button for two seconds until the 5E1 display screen appears.
- **To Exit at Any Time**
Press and hold the “m” button for two seconds until the meter turns off.
- **To Move Through the Screens**
Press the “m” button to move through all the setup screens such as reminder alarms, sound level, time, date, and so on.
- **To Change Settings Within the Screen**
Press the “c” button.

Setting the Reminder Alarms

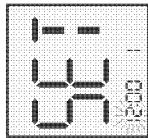
You may set up any or all of the reminder alarms (1-4). Note: A reminder alarm will never sound during a test.

To set a reminder alarm or multiple reminder alarms, please follow these steps.

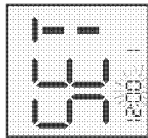


Select reminder alarm

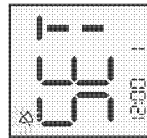
1. Start with the meter off. Press the “m” button and hold until the 5E1 display appears with 01:23:4. You are now in the reminder alarm setting mode and the “0” is blinking.
2. To move to the first reminder alarm press the “c” button once. You are now ready to set reminder alarm 1 (“1” is blinking).



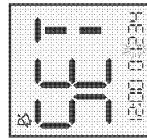
Select hour



Select minute



Select reminder alarm volume



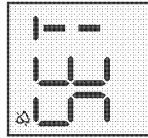
Select reminder alarm

3. Press the “m” button to move to the hour setting. With the hour blinking, press the “c” button until the correct hour appears.
4. Press the “m” button to move to the minute setting. With the minute blinking, press the “c” button until the correct minute appears.
5. Press the “m” button to move to the reminder alarm volume setting. Default setting is off. Press the “c” button to select the desired volume setting: low, high, or off.
6. Press the “m” button to finalize your alarm setting. This will bring you back to the reminder alarm setting 5E 1 mode. If you wish to set multiple reminder alarms press “c” to move to reminder alarm 2. Repeat.

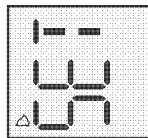
Note: To save your reminder alarm settings and exit setup mode, press and hold the “m” button for two seconds until the meter turns off. Press the “m” button when “0” is blinking to move to the next setup screen without setting any reminder alarms.

Setting the Sound

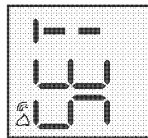
There are three (3) sound volume options:



Off



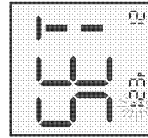
Low



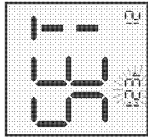
High

There are three sound volume options to let you know when the test strip is full, when the reading is done, and when an error occurs:

1. Press the “c” button until the desired sound level appears.
2. Press the “m” button to move to “Setting the Time.”



Hour



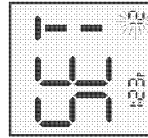
Minute

Setting the Time

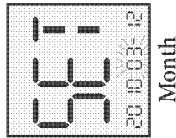
1. With the hour blinking, press the “c” button until the correct hour appears. The “p” displays for “PM” times.
2. Press the “m” button to move to minute setting. With the minute blinking, press the “c” button until the correct minute appears.
3. Press the “m” button to move to “Setting the Time Format.”

Setting the Time Format

1. With the hour mode blinking, press the “c” button to move between 12-hour and 24-hour format. The time automatically updates to the format selected.
2. Press the “m” button to move to “Setting the Date and Date Format.”

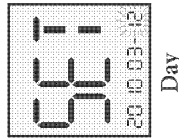


Time Format

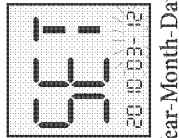


Setting the Date and Date Format

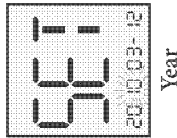
1. With the month blinking, press the “c” button until the correct month appears.



2. Press the “m” button to move to the day setting. With the day blinking, press the “c” button until the correct day appears.



3. Press the “m” button to move to “Date Format.” With the date blinking, press the “c” button to select month-day or day-month format. The date automatically updates to the format selected.

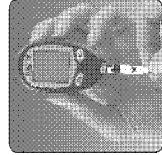


4. Press the “m” button to move to the year setting. With the year blinking, press the “c” button until the correct year appears.

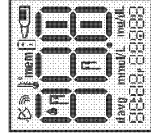
You have completed Meter Setup.

- To move to “Setting the User Reminder Alarms” press the “m” button.
- To exit press and hold the “m” button for two seconds.

Performing a Control Solution Test



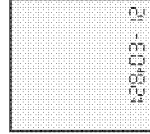
1 Insert the top of the test strip into your meter until it stops. This will power on the meter.



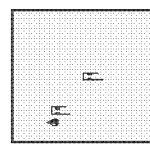
System Check Screen

Each time the meter powers on, this screen briefly appears so that you can make sure the display is working properly.

System Check



The date and time will briefly appear after the system check screen so that you can make sure your meter is set to the correct time and date.



2 Wait for the meter to display the blood drop and test strip symbols.



3 Gently touch only one of the sample areas on the test strip to the control solution.

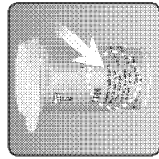
Important: Do not apply control solution to both test strip sample areas.

If the sound is on, your meter will beep when the test strip is full. A short line then moves clockwise around the display screen while the sample is processing.

The result will appear on the display screen and if the sound is on, your meter will beep twice. To mark the result as a control solution result, press and hold the “c” button for two seconds until the control solution symbol (☐) appears at the top right of the display screen.

If you have marked a blood glucose test as a control solution test by mistake, you can unmark it by pressing and holding the “c” button again for two seconds.

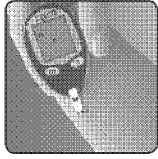
4



Compare your control solution test result to the range printed on your test strip vial label. Your control solution results should fall within the range printed on the side of your test strip vial.

- Out of range test results may be caused by:
- Error in performing the test
 - Expired or contaminated control solution
 - Test strip deterioration
 - Meter malfunction

Testing Your Blood Glucose



Important: To ensure accurate results, wash your hands and test site (for example, your forearm) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

- With the FreeStyle Freedom Lite® meter, you can test your blood glucose on your forearm, upper arm, hand, thigh, calf, or fingers.
- Testing with the FreeStyle Freedom Lite meter requires a very small sample size, 0.3 microliters of blood; about the size of pinhead (example: ••).

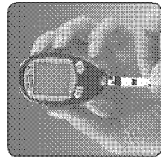
WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Times when you may be checking for low blood glucose include:

- When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.
- When you have delayed a meal after taking insulin.
- When your healthcare professional advises you to do so.

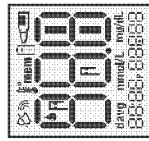
Performing a Blood Glucose Test



1 Prepare Your Meter

Insert a FreeStyle Lite® test strip into the meter until it stops. The meter will power on.

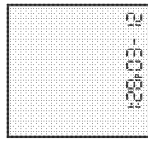
Note: If you do not start the test within two minutes, the meter will turn off. To restart your meter, take out the unused FreeStyle Lite test strip and reinsert it into the meter.



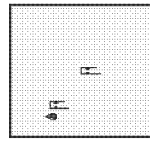
2 System Check Screen

Each time the meter powers on, this screen briefly appears so that you can make sure the display is working properly.

System Check



The date and time will briefly appear after the system check screen so that you can make sure your meter is set to the correct time and date.



Blood Drop and Test Strip Symbols

The blood drop and test strip symbols will appear on the display screen. Your meter is now ready to apply blood sample.

Potential Bruising

It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another test site.

2 Obtain a Blood Sample

Select a test site. There are differences in testing on fingers versus other alternative sites.

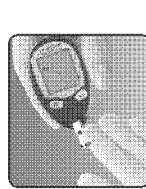
Use your lancing device to obtain a blood sample. Refer to the lancing device insert for detailed instructions on how to use the FreeStyle lancing device.

WARNING: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.

3

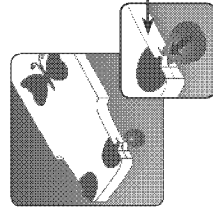


a. Make sure that the FreeStyle Lite test strip is in the meter, the meter is powered on and the blood drop and test strip symbols are displayed. You are now ready to apply the blood sample.



b. Bring the FreeStyle Lite test strip to the blood sample at a slight angle.

Important: Use only one test strip sample area per test. Do not apply blood to both edges, or you may get an inaccurate result. Test strips may be used only once. Discard used test strips.



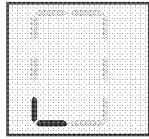
c. The FreeStyle Lite test strip pulls the blood into the strip through the sample area.

Test Strip Sample Area

Important Test Strip Information:

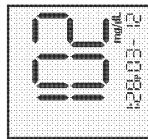
- Do not press the FreeStyle Lite® test strip against the test site.
- Do not scrape the blood onto the FreeStyle Lite test strip.
- Do not apply blood to the flat side of the FreeStyle Lite test strip.
- Do not apply blood to the FreeStyle Lite test strip when the FreeStyle Lite test strip is out of the meter.
- Do not put blood or foreign objects into the FreeStyle Freedom Lite® test strip port.

4 Waiting for Result



- Do not pull the FreeStyle Lite test strip away from the sample until you hear one beep or see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.

- If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same sample area of the test strip from which you started for up to 60 seconds from the time of the first application.

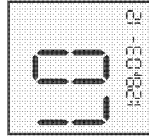


- The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps if the sound is on.
- The time that the meter takes to display a reading depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle Freedom Lite® meter displays results from 20 to 500 mg/dL (1.1 to 27.8 mmol/L).

If your test result is lower than 20 mg/dL (1.1 mmol/L), LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).



LO Reading with Symptoms

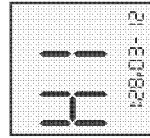
If you have a LO reading and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.

LO Reading

LO Reading without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, follow your doctor's recommendation to treat hypoglycemia.

If your test is above 500 mg/dL (27.8 mmol/L), HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).



HI Reading with Symptoms

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.

HI Reading

HI Reading without Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip. If you still get a HI reading, follow your doctor's recommendation to treat hyperglycemia.

Meter Results
Meter Memory

- **To Enter**

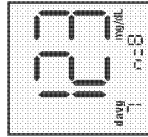
Start with the meter off (no test strip inserted). Press and release the “m” button; the first memory screen to appear will be your 7-day average.

- **To Exit**

Press and hold the “m” button for two seconds until the meter turns off.

7-, 14-, 30-Day Average

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)



Example:

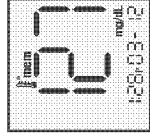
7avg = your 7-day average

n = indicates the number of results included in your average

The “c” button allows you to scroll forward to 14- and 30-day averages. Continue to press the “c” button to view stored test results. Your most recent result will display first.

Test Results

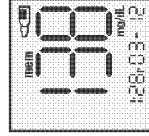
The meter stores the last 400 test readings with time and date. You may scroll forward through all of the readings by pressing the “c” button. The “m” button allows you to scroll backward. The first reading you see is the most recent result.



Temperature: A result with a thermometer symbol (°F) indicates that the reading was taken outside of the meter’s specified operating temperature range and may not be accurate. This value is included in your 7-, 14- and 30-day averages.

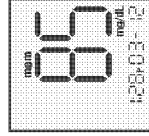
LO Reading: A LO reading (under 20 mg/dL or 1.1 mmol/L) is included in the memory as LO; it is not included in your 7-, 14- and 30-day averages.

HI Reading: A HI reading (over 500 mg/dL or 27.8 mmol/L) is included in the memory as HI; it is not included in your 7-, 14- and 30-day averages.



Control Solution Test

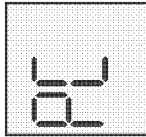
A value with (c) indicates that you have marked this reading as a control solution test. The date and time of the control solution reading will appear on the bottom of the screen.



Blood Glucose Test

A result without a control solution symbol indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.

Data Download




The “PC” symbol displays when a data cable is inserted in the meter data port. You cannot perform a test while the data cable is in the meter data port.

The meter will display “PC” until the data cable is removed from the data port.

Requires a compatible data management system. For more information, please go to our website or call Customer Care.

Meter Maintenance

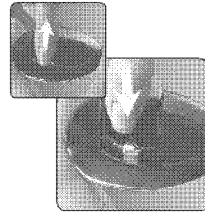
Battery

Your FreeStyle Freedom Lite® meter comes with one preinstalled, #2032, 3 volt, lithium battery. The battery provides enough power for the meter to perform about 1000 tests. If your battery runs low, the battery symbol () appears on every display screen until you change the battery.

Important: *When this symbol appears, you should replace the battery immediately.*

- **To avoid losing the time and date settings, replace the battery within one minute of removing the old battery.**
- If you take more than one minute to replace the battery, you may need to reset the time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, the time and date displays flash 12:00 and 00-00 until they are reset.
- Removing the battery does not affect the meter’s memory log or previously-stored user settings (such as date and time formats).
- If the time and date settings are not reset, test results will be stored in memory with a time of 12:00 and a date of 00-00.
- Even if you lose your time and date settings – you can perform a blood glucose test, and results will not be affected.

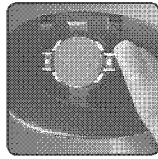
Replacing the Battery



I Turn the meter over. Slide the battery door to the right to open.

To remove the battery, pull the plastic tab up to release the battery.

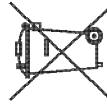
Replacing the Battery (*continued*)



2 Install the battery with the positive (+) sign up toward you.



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



Note: The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

Caring for Your Meter

Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip and data ports.

Important: Never immerse the meter in water or any other liquid. This may cause inaccurate reading or meter malfunction.

Do not try to clean the strip or data ports.

Do not pour liquid into the strip port, data port or buttons.

Do not place your meter in water or any other bath.

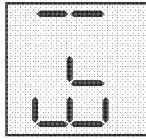
Clean the **outside** of the meter using a cloth dampened with one of the following:

- Mild detergent/mild soap and water.
- 70% isopropyl alcohol.
- A mix of one part household bleach, nine parts water.

System Troubleshooting

Error Messages

Error 1



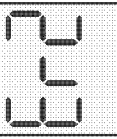
Possible Causes

- Sample is too small.
- Problem with the FreeStyle Lite® test strip.
- Problem with the meter.
- Very low blood glucose (less than 20 mg/dL or 1.1 mmol/L).

What You Should Do

1. If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your doctor's recommendation for treating hypoglycemia.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 2

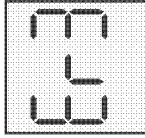


Possible Causes

- Problem with the FreeStyle Lite test strip.
- Problem with the meter.
- Very high glucose (above 500 mg/dL or 27.8 mmol/L).
- HIGH control solution applied when temperature is too cold. (This applies only to control solution that is labeled as HIGH.)

What You Should Do

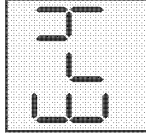
1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your doctor's recommendation for treating hyperglycemia.
2. Conduct a control solution test using a new FreeStyle Lite® test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 3**Possible Causes**

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter or applying blood before the blood drop and test strip symbols display.
- Problem with the FreeStyle Lite test strip.
- Problem with the meter.

What You Should Do

1. Be sure you see the blood drop and test strip symbols on the display screen before you apply blood or control solution.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 4**Possible Causes**

- Problem with FreeStyle Lite® test strip.
- Problem with the meter.

What You Should Do

1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
2. If the retest using control solution does not work or the error persists, call Customer Care.

Troubleshooting

Meter does not enter the test mode after inserting a test strip.	
Probable Cause	What to Do
The battery is dead.	Replace the battery (and reset the date and time, if necessary).
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the FreeStyle Lite test strip with the printed side up and the top of the strip in the meter.
Defective meter or test strips.	Call Customer Care.
Blood or foreign objects put into the test strip port.	Call Customer Care.
Test does not start after applying the blood sample.	
Probable Cause	What to Do
Blood sample too small.	You may add blood to the same sample area of the FreeStyle Lite® test strip from which you started for up to 60 seconds from the time of the first application. If necessary, repeat the test using a new FreeStyle Lite test strip and a larger blood sample.
Defective test strip.	Repeat the test with a new FreeStyle Lite test strip.
Sample applied after meter times out (two minutes) and turns off.	Repeat the test using a new test strip. Wait until you see the blood and test strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Call Customer Care.

FreeStyle Freedom Lite® System Specifications

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	1000 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	mg/dL
Meter Storage Temp.	-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 #2032, 3 volt, lithium battery, replaceable
Result Range	20 to 500 mg/dL (1.1 to 27.8 mmol/L)
Sample	Fresh capillary whole blood samples
Sample Size	0.3 microliter (300 nanoliters)
Size	Width 2.00" x Length 3.30" x Thickness 0.50" (at thickest point)
Weight	1.4 to 1.6 ounces (39.7 to 45.4 grams) including battery

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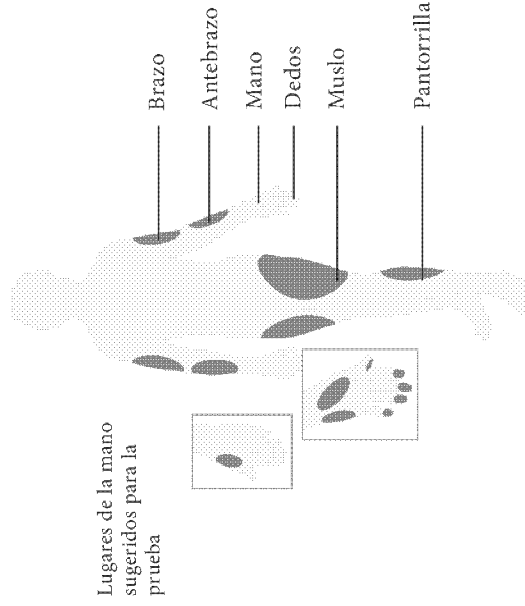
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ESPAÑOL

El sistema FreeStyle Freedom Lite® emplea una pequeña muestra de 0.3 µl para que usted pueda realizar las pruebas en diversos lugares

Información importante sobre el sistema de control de glucosa en sangre FreeStyle Freedom Lite®
Cómo debe usarse el sistema FreeStyle Freedom Lite

Posibilidad de realizar la prueba en muchos sitios



ESPAÑOL

ESPAÑOL

- El sistema FreeStyle Freedom Lite está diseñado para uso externo (es decir, únicamente para uso diagnóstico *in vitro*).
- El sistema FreeStyle Freedom Lite se usa para medir la glucosa en sangre (también llamada “azúcar en sangre”) a partir de muestras tomadas en el antebrazo, el brazo, la mano, el muslo, la pantorrilla o los dedos.
- El medidor FreeStyle Freedom Lite debe usarse únicamente con las tiras de prueba FreeStyle Lite® y la solución de control FreeStyle. El uso de otras tiras de prueba y solución de control con este medidor puede dar lugar a resultados inexactos.

Use el sistema FreeStyle Freedom Lite para:

- Pruebas de glucosa en sangre.
- Pruebas de glucosa en muestras de sangre entera capilar reciente.

No use el sistema FreeStyle Freedom Lite para:

- Diagnóstico de diabetes.
- Pruebas en recién nacidos.
- Pruebas con sangre arterial.

En la figura humana se muestran las zonas donde puede realizar las pruebas con el sistema FreeStyle Freedom Lite. Evite los lunares, las venas, los huesos y los tendones.

ADVERTENCIA:

Se recomienda realizar la prueba con sangre del dedo si va a controlar si tiene hipoglucemia (bajo nivel de glucosa en sangre) o si sufre de hipoglucemia asintomática.

Llame sin cargo al departamento de Atención al cliente al 1-888-522-5226
www.MyFreeStyle.com

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ART18402_Rev-A-Man.indd 1-2

Información importante sobre el sistema de control de glucosa en sangre FreeStyle Freedom Lite® (continuación)

ADVERTENCIA:

- El sistema FreeStyle Freedom Lite contiene piezas pequeñas que pueden ser peligrosas si se ingieren.

Precaución: Lea todas las instrucciones provistas en este *Manual del usuario* y practique el procedimiento para realizar la prueba antes de usar el sistema FreeStyle Freedom Lite. El control de la glucosa en sangre debe llevarse a cabo con la orientación de un profesional de la salud.

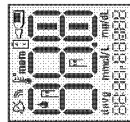
ESPAÑOL

Información importante relacionada con la salud

- Las lecturas de glucosa en sangre bajas o altas pueden indicar un estado de salud posiblemente grave. Si su lectura de glucosa en sangre es excepcionalmente baja o alta, o si la lectura no refleja el modo en que usted se siente, repita la prueba con una tira de prueba nueva. Si la lectura no concuerda con sus síntomas o si su resultado de glucosa en sangre es inferior a 60 mg/dL (3.3 mmol/L) o superior a 240 mg/dL (13.3 mmol/L), comuníquese con su profesional de la salud y siga el tratamiento que le aconseje.
- Consulte la información sobre el producto de las tiras de prueba para obtener más información.

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El medidor FreeStyle Freedom Lite® y su funcionamiento



Pantalla de verificación del sistema

Esta pantalla aparece brevemente cada vez que se enciende el medidor para que usted pueda comprobar que la pantalla funciona correctamente. No use el medidor si la pantalla de verificación del sistema no coincide con el ejemplo que se muestra aquí. Llame al departamento de Atención al cliente.

Pantalla

Muestra los resultados de sus pruebas y otra información importante.

Botón m (modo)

- Cambia a distintas configuraciones de modo.
- Retrocede.
- Silencia una alarma de recordatorio.

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Puerto de datos

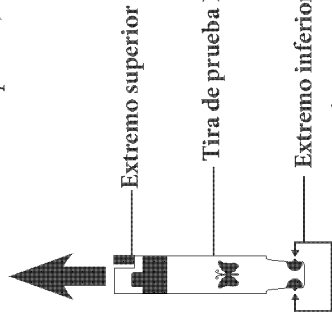
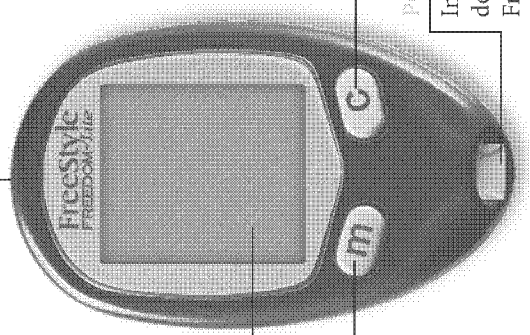
Descarga los resultados de las pruebas. Requiere un sistema de administración de datos compatible. Si desea más información, visite nuestro sitio en Internet o llame al departamento de Atención al cliente.

Botón c (configuración)

- Marca una prueba de solución de control.
- Avanza.
- Silencia una alarma de recordatorio.
- Cambia la fecha, la hora, las opciones de sonido, y revisa las lecturas almacenadas.

Puerto de la tira de prueba

Introduzca aquí el extremo superior de una nueva tira de prueba FreeStyle Lite®. Al introducir la tira de prueba, se enciende el medidor.



Extremo superior

Tira de prueba FreeStyle Lite

Extremo inferior

Áreas de la muestra

Áreas de la muestra (semicírculos de color oscuro en la tira de prueba)

Aplique sangre o solución de control en una sola área de la muestra. Introduzca la tira en el medidor con el lado impreso hacia arriba (vea la imagen a la derecha).

Llame sin cargo al departamento de Atención al cliente al 1-888-522-5226 www.MyFreeStyle.com

La pantalla del medidor FreeStyle Freedom Life®

Símbolo del modo de memoria

Muestra los resultados de pruebas almacenados en la memoria del medidor.

Símbolo de la pila

Aparece cuando se debe cambiar la pila del medidor.

Símbolo de resultado de la prueba de la solución de control

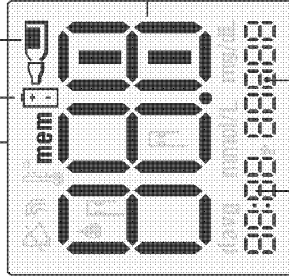
Muestra que se marcó un resultado de prueba como una prueba de la solución de control.

Área de resultado de la prueba

Muestra los resultados de la prueba.

Área de mensaje

Muestra la fecha, la hora y la cantidad de pruebas.



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Símbolos de niveles de sonido

Indican el volumen de sonido alto, bajo o apagado.

Símbolos de la gota de sangre y la tira de prueba

Estos símbolos se presentan juntos en una animación para indicarle cuando está listo el medidor para que le aplique sangre o solución de control.

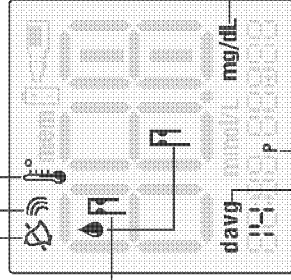
Símbolo de promedio de días

Muestra el valor promedio de las lecturas de glucosa de los últimos 7, 14 o 30 días.

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Símbolo del termómetro

Aparece si el medidor se encuentra fuera del rango de temperatura de funcionamiento.



mg/dL (estándar estadounidense)

Indica la unidad de medida.

Símbolo P

Indica "PM" en el formato de 12 horas únicamente (por ejemplo, 4:00 p.m.).

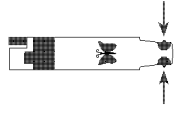
La tira de prueba FreeStyle Lite®

Aplique sangre o solución de control en **una sola área de la muestra de la tira de prueba** por prueba.

Importante: No aplique sangre en ambas áreas de la muestra. Las tiras de prueba son para un solo uso.

Deseche las tiras de prueba usadas. Puede continuar llenando la tira de prueba durante 60 segundos.

Asegúrese de volver a aplicar la muestra en la misma área de la muestra.



Áreas de la muestra de la tira de prueba

ADVERTENCIA:

El tapón o el vial contienen agentes secantes que pueden ser nocivos si se inhalan o ingieren y pueden causar irritación en la piel o los ojos.

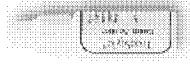
Importante: El medidor FreeStyle Freedom Lite® debe usarse solamente con las tiras de prueba FreeStyle Lite. El uso de otras tiras de prueba con este medidor puede dar lugar a resultados inexactos.

Información importante sobre la tira de prueba

- El sistema FreeStyle Freedom Lite tiene un rango de funcionamiento de 40 °F a 104 °F (4 °C a 40 °C).
- Conserve el paquete de las tiras de prueba en un lugar fresco y seco, a una temperatura de entre 40 °F y 86 °F (4 °C y 30 °C).
- Use las tiras de prueba solamente dentro del rango de temperatura de funcionamiento del sistema.
- Mantenga las tiras de prueba lejos de la luz directa del sol y el calor.
- Conserve las tiras de prueba únicamente en su vial original; no las traspase a otro vial ni a ningún otro envase.
- No conserve tiras de prueba individuales fuera del vial.
- Después de extraer una tira de prueba FreeStyle Lite del vial, cierre herméticamente el tapón del vial de inmediato.
- Con las manos limpias y secas puede tocar con cuidado cualquier parte de la tira de prueba al extraerla del vial o introducirla en el medidor.

9 Llame sin cargo al departamento de Atención al cliente al 1-888-522-5226
www.MyFreeStyle.com

ESPAÑOL



La solución de control FreeStyle®

Cada vial de solución de control FreeStyle contiene un líquido de color rojo con una cantidad determinada de glucosa que se usa para:

- Practicar la prueba sin tener que usar sangre.
- Asegurarse de que el medidor y las tiras de prueba funcionen correctamente juntos.

Es aconsejable que realice una prueba de la solución de control cuando dude de los resultados que obtenga y desee corroborar que su medidor y las tiras de prueba funcionan correctamente.

Si desea información sobre cómo conseguir una solución de control, llame al departamento de Atención al cliente al 1-888-522-5226.

Información sobre la solución de control

La solución de control FreeStyle® tiene validez durante tres meses a partir de la fecha en que se abre el frasco o hasta la fecha de caducidad impresa en la etiqueta, lo que tenga lugar primero.

Importante: *Cuente tres meses a partir de la fecha en que abre un frasco nuevo de solución de control y escriba esa fecha en la parte lateral del frasco de solución de control. Esa es la fecha en que debe desechar el frasco, salvo que la fecha de caducidad impresa en el frasco sea anterior.*

Ejemplo: Usted abre la solución de control el 15 de enero. Cuento tres meses hacia delante: 15 de abril. Esa es la fecha que debe anotar y en la que debe desechar el frasco.

- Use solamente solución de control FreeStyle con su sistema FreeStyle Freedom Lite®.
- Vuelva a colocar el tapón en el frasco de la solución de control inmediatamente después de usarla.
- No use la solución de control después de su fecha de caducidad.
- No agregue agua ni ningún otro líquido a la solución de control.
- Está especificado que las pruebas de la solución de control son exactas únicamente cuando se las realiza a una temperatura de entre 59 °F y 104 °F (15 °C y 40 °C).
- Los resultados de la prueba de la solución de control deben encontrarse dentro del rango impreso en la etiqueta del vial de las tiras de prueba.

Importante: El rango de la solución de control es un rango deseado únicamente para la solución de control. No es un rango deseado para el nivel de glucosa en sangre.

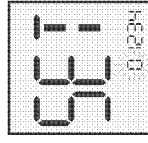
- Si los resultados de la solución de control se encuentran fuera de ese rango, repita la prueba.
- Si los resultados de la prueba de la solución de control siguen estando fuera del rango impreso en el vial de las tiras de prueba, no use el sistema FreeStyle Freedom Lite para controlar su glucosa en sangre. Comuníquese con el departamento de Atención al cliente.

Precaución: Los resultados de las pruebas de la solución de control FreeStyle no reflejan su nivel de glucosa en sangre.

Lláme sin cargo al departamento de Atención al cliente al 1-888-522-5226
www.MyFreeStyle.com

Configuración del medidor

Configuración del medidor



- **Para entrar en el modo de configuración** Comience con el medidor apagado (sin introducir una tira de prueba). Oprima sin soltar el botón “m” durante dos segundos hasta que aparezca la pantalla 5E1.

Para salir en cualquier momento

Oprima sin soltar el botón “m” durante dos segundos hasta que se apague el medidor.

Para cambiar de pantallas

Oprima el botón “m” para pasar por todas las pantallas de configuración, por ejemplo, de alarmas de recordatorio, niveles de sonido, hora, fecha, etc.

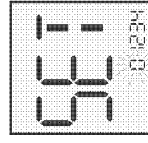
Para cambiar la configuración en una misma pantalla

Oprima el botón “c”.

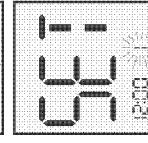
Configuración de las alarmas de recordatorio

Puede configurar cualquiera de las alarmas de recordatorio o todas ellas (1-4). Nota: Las alarmas de recordatorio no suenan mientras se realiza una prueba.

Para configurar una alarma de recordatorio o varias, siga estos pasos.

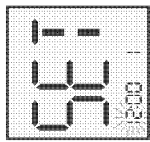


1. Comience con el medidor apagado. Oprima sin soltar el botón “m” hasta que aparezca la pantalla 5E1 con 01234. Ya se encuentra en el modo de configuración de alarma de recordatorio y el “0” parpadea.



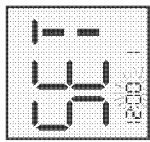
2. Para ir a la primera alarma de recordatorio, oprima una vez el botón “c”. Ya puede configurar la alarma de recordatorio 1 (el “1” parpadea).

Seleccione la alarma de recordatorio



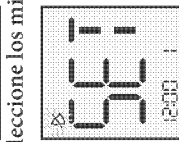
Seleccione la hora

3. Oprima el botón “m” para pasar a configurar la hora. Mientras la hora parpadea, oprima el botón “c” hasta que aparezca la hora correcta.



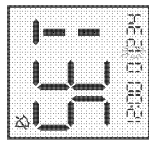
Seleccione los minutos

4. Oprima el botón “m” para pasar a configurar los minutos. Mientras los minutos parpadean, oprima el botón “c” hasta que aparezcan los minutos correctos.



Seleccione el volumen de la alarma de recordatorio

5. Oprima el botón “m” para pasar a configurar el volumen de la alarma de recordatorio. La configuración predeterminada es “apagado”. Oprima el botón “c” para seleccionar la configuración de volumen que desee: alto, bajo o apagado.



Seleccione la alarma de recordatorio

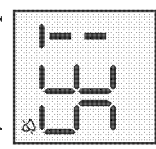
6. Oprima el botón “m” para finalizar la configuración de la alarma. Este paso lo llevará nuevamente al modo 5 5 1 de configuración de la alarma de recordatorio. Si desea configurar varias alarmas de recordatorio, oprima el botón “c” para pasar a la alarma de recordatorio 2. Repita los pasos.

Nota: Para guardar las configuraciones de alarma de recordatorio y salir del modo de configuración, oprima sin soltar el botón “m” durante dos segundos hasta que se apague el medidor. Oprima el botón “m” cuando el “0” esté parpadeando para pasar a la siguiente pantalla de configuración sin configurar ninguna alarma de recordatorio.

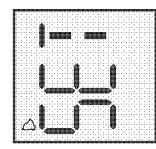
13 Llame sin cargo al departamento de Atención al cliente al 1-888-522-5226
www.MyFreeStyle.com

Configuración del sonido

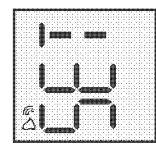
Hay tres (3) opciones de volumen de sonido:



Apagado



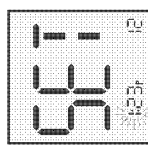
Bajo



Alto

Hay tres opciones de volumen de sonido para indicar cuando la tira de prueba está llena, cuando se completa la lectura y cuando se produce un error.

- 1. Oprima el botón “c” hasta encontrar el nivel de sonido que desee.
- 2. Oprima el botón “m” para ir a “Configuración de la hora”.



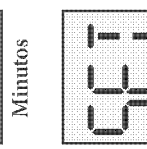
Hora

Configuración de la hora

1. Mientras la hora parpadea, oprima el botón “c” hasta que aparezca la hora correcta. Se muestra la “P” para las horas “PM”.

2. Oprima el botón “m” para ir a la configuración de los minutos. Mientras los minutos parpadean, oprima el botón “c” hasta que aparezcan los minutos correctos.

3. Oprima el botón “m” para ir a la “Configuración del formato de la hora”.



Minutos

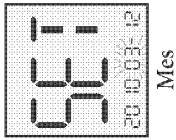
Configuración del formato de la hora

1. Mientras parpadea el modo de la hora, oprima el botón “c” para cambiar entre el formato de 12 horas y el de 24 horas. La hora se pasa automáticamente al formato seleccionado.

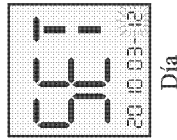
2. Oprima el botón “m” para ir a la “Configuración de la fecha y el formato de la fecha”.

Configuración de la fecha y el formato de la fecha

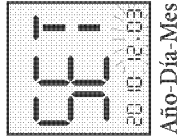
1. Mientras parpadea el mes, oprima el botón “c” hasta que aparezca el mes correcto.



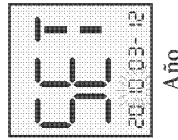
2. Oprima el botón “m” para ir a la configuración del día. Mientras parpadea el día, oprima el botón “c” hasta que aparezca el día correcto.



3. Oprima el botón “m” para ir al “Formato de la fecha”. Mientras parpadea la fecha, oprima el botón “c” para seleccionar el formato de mes-día o día-mes. La fecha pasará automáticamente al formato seleccionado.



4. Oprima el botón “m” para ir a la configuración del año. Mientras parpadea el año, oprima el botón “c” hasta que aparezca el año correcto.

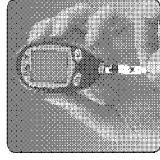


Se completó la configuración del medidor.

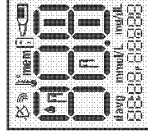
- Para ir a la “Configuración de las alarmas de recordatorio para el usuario”, oprima el botón “m”.
- Para salir, oprima sin soltar el botón “m” durante dos segundos.

Cómo realizar una prueba de la solución de control

Introduzca el extremo superior de la tira de prueba en el medidor hasta el tope. Esto hace que se encienda el medidor.

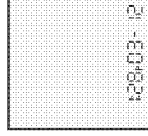


Pantalla de verificación del sistema
Cada vez que se enciende el medidor, aparece brevemente esta pantalla para que usted pueda comprobar que la pantalla funcione correctamente.

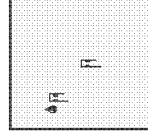


Verificación del sistema

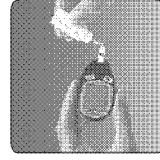
Después de la pantalla de verificación del sistema, aparecen brevemente la fecha y la hora para que usted pueda confirmar que el medidor está configurado con la fecha y hora correctas.



Espera a que el medidor muestre los símbolos de la gota de sangre y la tira de prueba.



Toque suavemente la solución de control con una sola de **las áreas de la muestra de la tira de prueba**.



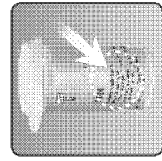
Importante: No aplique solución de control en ambas áreas de la muestra de la tira de prueba.

Si el sonido está encendido, el medidor emite un pitido cuando la tira de prueba está llena. Mientras se procesa la muestra, una línea corta se mueve alrededor de la pantalla en sentido horario.

El resultado aparece en la pantalla y, si el sonido está encendido, el medidor emite dos pitidos. Para marcar el resultado como un resultado de solución de control, oprima sin soltar el botón "c" durante dos segundos hasta que se vea el símbolo de la solución de control (☒) en el ángulo superior derecho de la pantalla.

Si por equivocación marcó una prueba de glucosa en sangre como una prueba de solución de control, puede desmarcarla volviendo a oprimir sin soltar el botón "c" durante dos segundos.

4

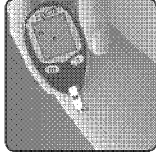


Compare el resultado de la prueba de la solución de control con el rango impreso en la etiqueta del vial de las tiras de prueba. Los resultados de la solución de control deben encontrarse dentro del rango impreso en la parte lateral del vial de las tiras de prueba.

Los resultados fuera de rango pueden deberse a:

- Un error en la realización de la prueba.
- La solución de control caducada o contaminada.
- El deterioro de la tira de prueba.
- El mal funcionamiento del medidor.

Realización de pruebas de glucosa en sangre



Importante: Para asegurarse de que los resultados sean exactos, lávese las manos y la zona de prueba (por ejemplo, el antebrazo) con agua y jabón. Asegúrese de no tener crema o loción en la zona de prueba. Séquese bien las manos y la zona de prueba.

- Con el medidor FreeStyle Freedom Lite®, puede hacer pruebas de glucosa en sangre con sangre del antebrazo, el brazo, la mano, el muslo, la pantorrilla o los dedos.
- Para realizar la prueba con el medidor FreeStyle Freedom Lite se necesita una muestra muy pequeña, de 0.3 microlitros de sangre, del tamaño aproximado de una cabeza de alfiler (**ejemplo: •**).

ADVERTENCIA:

Se recomienda realizar la prueba con sangre del dedo si va a controlar si tiene hipoglucemia (bajo nivel de glucosa en sangre) o si sufre de hipoglucemia asintomática.

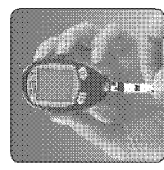
Entre las ocasiones en las que puede controlar si su glucosa en sangre es baja se incluyen:

- Cuando tenga síntomas tales como debilidad, transpiración, nerviosismo, dolor de cabeza o confusión.
- Cuando demore una comida después de administrarse insulina.
- Cuando su profesional de la salud le aconseje que lo haga.

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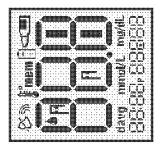
ESPAÑOL

Cómo realizar una prueba de glucosa en sangre



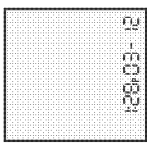
1 **Prepare su medidor**
Introduzca una tira de prueba FreeStyle Lite® en el medidor hasta el tope. El medidor se enciende.

Nota: Si no comienza la prueba en un lapso de dos minutos, el medidor se apaga. Para volver a encender el medidor, retire la tira de prueba FreeStyle Lite sin usar y vuelva a introducirla en el medidor.

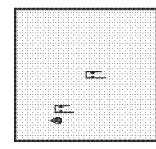


2 **Pantalla de verificación del sistema**
Cada vez que se enciende el medidor, aparece brevemente esta pantalla para que usted pueda comprobar que la pantalla funcione correctamente.

Verificación del sistema



Después de la pantalla de verificación del sistema, aparecen brevemente la fecha y la hora para que usted pueda confirmar que el medidor está configurado con la fecha y hora correctas.



Símbolos de la gota de sangre y la tira de prueba

En la pantalla aparecen los símbolos de una gota de sangre y una tira de prueba. El medidor ya está listo para aplicarle la muestra de sangre.

Posibles hematomas

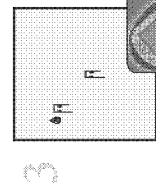
Es posible que sufra un hematoma en la zona de prueba. Si se le produce un hematoma, puede optar por realizar la punción en otra zona de prueba.

2 **Obtenga una muestra de sangre**

Elija una zona de prueba. Existen diferencias en la realización de la prueba con sangre de los dedos en comparación con otros sitios alternativos.

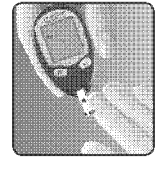
Use el dispositivo de punción para obtener una muestra de sangre. Consulte las instrucciones detalladas sobre cómo usar el dispositivo de punción FreeStyle en el prospecto del dispositivo de punción.

ADVERTENCIA: Si va a realizar una prueba de hipoglucemia (glucosa en sangre baja), o si sufre de hipoglucemia asintomática, se recomienda hacer la prueba con sangre del dedo.



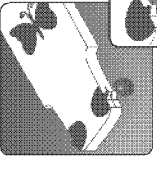
3 **Llene la tira de prueba FreeStyle Lite® con sangre**

a. Asegúrese de que la tira de prueba FreeStyle Lite esté en el medidor, el medidor esté encendido y se muestren los símbolos de la gota de sangre y la tira de prueba. Ya puede aplicar la muestra de sangre.



b. Acerque la tira de prueba FreeStyle Lite, levemente inclinada, a la muestra de sangre.

Importante: Use una sola área de la muestra de la tira de prueba por prueba. No aplique sangre en ambos bordes; si lo hace, puede obtener un resultado inexacto. Las tiras de prueba son para un solo uso. Deseche las tiras de prueba usadas.



c. La tira de prueba FreeStyle Lite absorbe la sangre a través del área de la muestra.

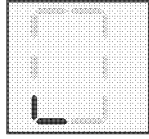


Área de la muestra de la tira de prueba

Información importante sobre la tira de prueba

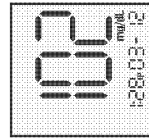
- No presione la tira de prueba FreeStyle Lite® contra el sitio de prueba.
- No frote la sangre sobre la tira de prueba FreeStyle Lite.
- No aplique sangre en el lado plano de la tira de prueba FreeStyle Lite.
- No aplique sangre en la tira de prueba FreeStyle Lite cuando la tira esté fuera del medidor.
- No ponga sangre ni objetos extraños en el puerto de la tira de prueba FreeStyle Freedom Lite®.

4 Espere el resultado



- No aparte la tira de prueba FreeStyle Lite de la muestra hasta que oiga un pitido o vea la línea corta que se mueve en sentido horario alrededor de la pantalla del medidor. Eso significa que aplicó suficiente sangre y el medidor está leyendo su glucosa.

- Si al cabo de cinco segundos el medidor no muestra una línea corta que se mueve alrededor de la pantalla, es posible que la muestra sea demasiado pequeña. Puede agregar sangre en la misma área de la muestra de la tira de prueba con la que comenzó antes de que transcurran 60 segundos desde el momento de la primera aplicación.

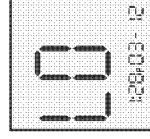


- La prueba de glucosa en sangre se completa cuando el resultado se muestra en la pantalla y se oyen dos pitidos, si el sonido está encendido.
- El tiempo que el medidor tarda en mostrar una lectura depende de su nivel de glucosa en sangre. Cuanto más alto sea su nivel de glucosa, más tiempo tarda en obtenerse el resultado.

Lecturas alta (LO) y baja (HI)

Importante: Las lecturas de glucosa en sangre bajas o altas pueden indicar un estado de salud posiblemente grave. El medidor FreeStyle Freedom Lite® muestra resultados comprendidos entre 20 y 500 mg/dL (1.1 y 27.8 mmol/L).

Si el resultado de su prueba es inferior a 20 mg/dL (1.1 mmol/L), la pantalla del medidor muestra "LO" (bajo). Esa lectura indica hipoglucemia severa (nivel bajo de glucosa en sangre).



Lectura LO (baja) con síntomas

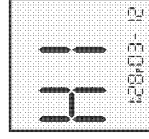
Si tiene una lectura LO (baja) y síntomas tales como debilidad, transpiración, nerviosismo, dolor de cabeza o confusión, **siga** la recomendación de su médico para tratar la hipoglucemia.

Lectura LO (baja)

Lectura LO (baja) sin síntomas

Si tiene una lectura LO (baja) pero no tiene síntomas de nivel bajo de glucosa en sangre, **repita** la prueba con una tira de prueba nueva con sangre del dedo. Si aun así obtiene una lectura LO (baja), siga la recomendación de su médico para tratar la hipoglucemia.

Si el resultado de su prueba es superior a 500 mg/dL (27.8 mmol/L), la pantalla muestra "HI" (alto). Esa lectura indica hiperglucemia severa (nivel alto de glucosa en sangre).



Lectura HI (alta) con síntomas

Si tiene síntomas tales como fatiga, sed, micción excesiva o visión borrosa, **siga** la recomendación de su médico para tratar la hiperglucemia.

Lectura HI (alta)

Lectura HI (alta) sin síntomas

Si tiene una lectura HI (alta) pero no tiene síntomas de nivel alto de glucosa en sangre, **repita** la prueba con una tira de prueba nueva. Si aun así obtiene una lectura HI (alta), siga la recomendación de su médico para tratar la hiperglucemia.

Resultados del medidor Memoria del medidor

- **Para entrar**

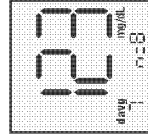
Comience con el medidor apagado (sin introducir una tira de prueba). Oprima y suelte el botón “m”; la primera pantalla de memoria que aparece es la del promedio de 7 días.

- **Para salir**

Oprima sin soltar el botón “m” durante dos segundos hasta que el medidor se apague.

Promedio de 7, 14 y 30 días

La primera pantalla de la memoria que se ve es el promedio de 7 días. Incluye todas las lecturas de los últimos 7 días desde la fecha y hora actuales que se muestran en el medidor. (Las lecturas de la solución de control y de glucosa alta y baja no se incluyen en el promedio.)



Ejemplo:

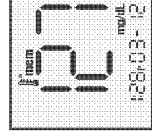
7 davg = promedio de 7 días

n = indica la cantidad de resultados incluidos en el promedio

El botón “c” le permite avanzar a los promedios de 14 y 30 días. Si continúa oprimiendo el botón “c”, puede ver los resultados de pruebas almacenados. En primer lugar se muestra su resultado más reciente.

Resultados de la prueba

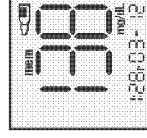
El medidor almacena las últimas 400 lecturas de pruebas con fecha y hora. Para avanzar por todas las lecturas, oprima el botón “c”. Con el botón “m” puede retroceder. La primera lectura que se ve es el resultado más reciente.



Temperatura: Un resultado con el símbolo de un termómetro (°F) indica que la lectura se tomó fuera del rango de temperatura de funcionamiento especificado para el medidor y es posible que no sea exacto. Ese valor se incluye en los promedios de 7, 14 y 30 días.

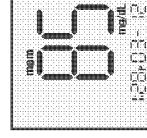
Lectura LO (baja): Una lectura LO (baja) (inferior a 20 mg/dL o 1.1 mmol/L) se incluye en la memoria como baja; no se incluye en los promedios de 7, 14 y 30 días.

Lectura HI (alta): Una lectura HI (alta) (superior a 500 mg/dL o 27.8 mmol/L) se incluye en la memoria como alta; no se incluye en los promedios de 7, 14 y 30 días.



Prueba de la solución de control

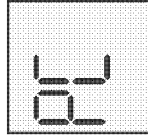
Un valor con (TEST) indica que esa lectura se marcó como prueba de la solución de control. La fecha y hora de la lectura de la solución de control aparecen en la parte inferior de la pantalla.



Prueba de glucosa en sangre

Un resultado sin el símbolo de la solución de control indica que se trata de una lectura de glucosa en sangre. La fecha y hora de la prueba aparecen en la parte inferior de la pantalla.

Descarga de datos



El símbolo "PC" se muestra cuando se introduce un cable de datos en el puerto de datos del medidor. No se pueden realizar pruebas mientras el cable de datos está en el puerto de datos del medidor.

El medidor muestra "PC" hasta que se retira el cable de datos del puerto de datos.

Requiere un sistema de administración de datos compatible. Si desea más información, visite nuestro sitio en Internet o llame al departamento de Atención al cliente.

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Mantenimiento del medidor

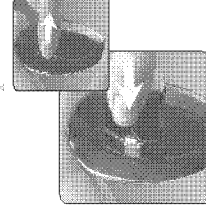
Pila

El medidor FreeStyle Freedom Lite® viene con una pila de litio N.º 2032, de 3 voltios, previamente instalada. La pila suministra suficiente energía para que el medidor realice alrededor de 1000 pruebas. Si la pila se está agotando, aparece el símbolo de una pila (🔋) en cada pantalla hasta que se cambia la pila.

Importante: Cuando aparece este símbolo, es preciso cambiar la pila de inmediato.

- Para no perder las configuraciones de la fecha y la hora, cambie la pila antes de que transcurra un minuto después de retirar la pila vieja.
- Si tarda más de un minuto en cambiar la pila, es posible que deba volver a configurar la fecha y la hora para obtener los promedios correctos de 7, 14 y 30 días. Si se pierde la configuración de la fecha y la hora, éstas se muestran intermitentemente como 12:00 y 00-00 hasta que se las vuelve a configurar.
- La extracción de la pila no afecta el registro de la memoria del medidor ni las configuraciones guardadas previamente por el usuario (como los formatos de la fecha y la hora).
- Si no se vuelven a configurar la fecha y la hora, los resultados de pruebas se almacenarán en la memoria con una hora de 12:00 y una fecha de 00-00.
- Aunque pierda la configuración de la fecha y la hora, puede realizar una prueba de glucosa en sangre y los resultados no se verán afectados.

Cambio de la pila

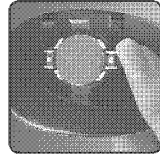


Dé vuelta el medidor. Deslice la tapa de la pila hacia la derecha para abrirla.

Para retirar la pila, tire de la lengüeta de plástico hacia arriba para que se libere la pila.

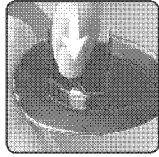
Cambio de la pila (continuación)

2

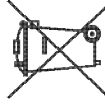


Instale la pila con el signo positivo (+) hacia arriba, mirando hacia usted.

3



Para cerrar la tapa de la pila, deslícela hacia adentro hasta que se trabaje con un clic.



Nota: Las pilas de este producto deben retirarse y desecharse de acuerdo con la normativa local para la recolección separada de pilas agotadas.

Cuidado de su medidor

Evite que entre polvo, suciedad, sangre, solución de control, agua o cualquier otro líquido en el puerto de la tira de prueba y el puerto de datos del medidor.

Importante: No sumerja el medidor en agua ni en ningún otro líquido, ya que puede dar lugar a una lectura inexacta o al mal funcionamiento del medidor.

No intente limpiar el puerto de datos ni el puerto de la tira de prueba.

No vierta líquido en el puerto de la tira de prueba, el puerto de datos o los botones.

No sumerja el medidor en agua ni en ningún otro líquido.

Limpie el exterior del medidor con un paño humedecido con uno de los siguientes productos:

- Detergente o jabón suave y agua.
- Alcohol isopropílico al 70%.
- Una mezcla de una parte de blanqueador de uso doméstico y nueve partes de agua.

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Lláme sin cargo al departamento de Atención al cliente al 1-888-522-5226
www.MyFreeStyle.com

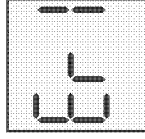
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Resolución de problemas del sistema

Mensajes de error

Error 1



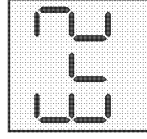
Causas posibles

- La muestra es demasiado pequeña.
- Problema con la tira de prueba FreeStyle Lite®.
- Problema con el medidor.
- Nivel muy bajo de glucosa en sangre (inferior a 20 mg/dL o 1.1 mmol/L).

Qué debe hacer

1. Si tiene síntomas tales como debilidad, transpiración, nerviosismo, dolor de cabeza o confusión, siga la recomendación de su médico para tratar la hipoglucemia.
2. Realice una prueba de la solución de control con una tira de prueba FreeStyle Lite nueva. Si los resultados de la prueba de la solución de control se encuentran dentro del rango impreso en la parte lateral del vial de la tira de prueba, repita la prueba con sangre y una tira de prueba FreeStyle Lite nueva.
3. Si la nueva prueba con la solución de control no funciona o el error persiste, llame al departamento de Atención al cliente.

Error 2



Causas posibles

- Problema con la tira de prueba FreeStyle Lite.
- Problema con el medidor.
- Nivel muy alto de glucosa (superior a 500 mg/dL o 27.8 mmol/L).
- Se aplicó solución de control ALTA cuando la temperatura está demasiado baja. (Corresponde solamente a la solución de control etiquetada como "ALTA".)

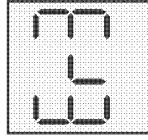
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Qué debe hacer

1. Si tiene síntomas tales como sed, fatiga, micción excesiva o visión borrosa, siga la recomendación de su médico para tratar la hiperglucemia.
2. Realice una prueba de la solución de control con una tira de prueba FreeStyle Lite® nueva. Si los resultados de la prueba de la solución de control se encuentran dentro del rango impreso en la parte lateral del vial de la tira de prueba, repita la prueba con sangre y una tira de prueba FreeStyle Lite nueva.
3. Si la nueva prueba con la solución de control no funciona o el error persiste, llame al departamento de Atención al cliente.

Error 3



Causas posibles

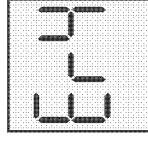
- Procedimiento de prueba incorrecto. Por ejemplo, se aplicó sangre en la tira de prueba antes de introducirla en el medidor o se aplicó sangre antes de que se mostraran los símbolos de la gota de sangre y la tira de prueba.
- Problema con la tira de prueba FreeStyle Lite.
- Problema con el medidor.

Qué debe hacer

1. Asegúrese de ver los símbolos de la gota de sangre y la tira de prueba en la pantalla antes de aplicar sangre o solución de control.
2. Realice una prueba de la solución de control con una tira de prueba FreeStyle Lite nueva. Si los resultados de la prueba de la solución de control se encuentran dentro del rango impreso en la parte lateral del vial de la tira de prueba, repita la prueba con sangre y una tira de prueba FreeStyle Lite nueva.
3. Si la nueva prueba con la solución de control no funciona o el error persiste, llame al departamento de Atención al cliente.

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Error 4



Causas posibles

- Problema con la tira de prueba FreeStyle Lite®.
- Problema con el medidor.

Qué debe hacer

1. Realice una prueba de la solución de control con una tira de prueba nueva. Si los resultados de la prueba de la solución de control se encuentran dentro del rango impreso en la parte lateral del vial de la tira de prueba, repita la prueba con sangre y una tira de prueba FreeStyle Lite nueva.
2. Si la nueva prueba con la solución de control no funciona o el error persiste, llame al departamento de Atención al cliente.

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Resolución de problemas

El medidor no ingresa en el modo de prueba después de que se introduce una tira de prueba.

Causa probable	Qué hacer
La pila se agotó.	Cambie la pila (y vuelva a configurar la fecha y la hora, si es necesario).
La pila no está bien instalada o el medidor no tiene pila.	Verifique que la pila esté instalada correctamente con el signo positivo (+) hacia arriba, mirando hacia usted.
La tira de prueba se introdujo al revés, por la punta equivocada, o no se introdujo completamente en el medidor.	Introduzca la tira de prueba FreeStyle Lite con el lado impreso hacia arriba y el extremo superior en el medidor.
El medidor o las tiras de prueba presentan fallas.	Llame al departamento de Atención al cliente.
Se introdujo sangre o un objeto extraño en el puerto de la tira de prueba.	Llame al departamento de Atención al cliente.

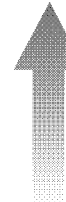
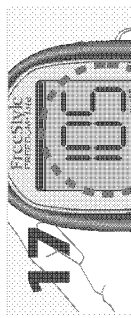
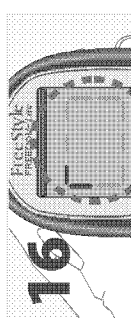
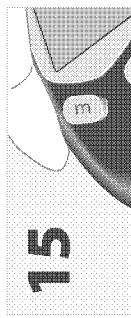
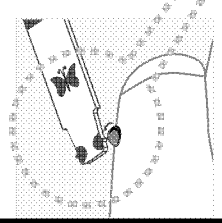
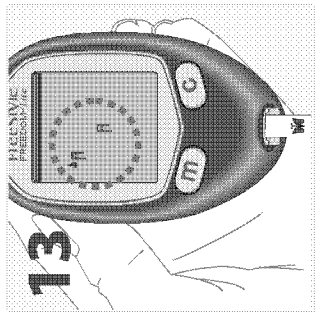
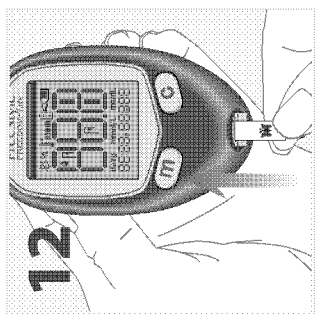
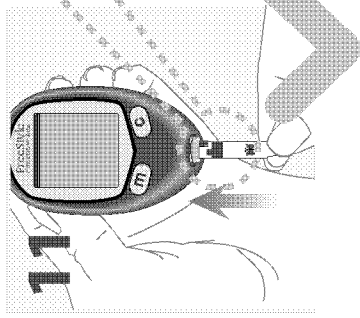
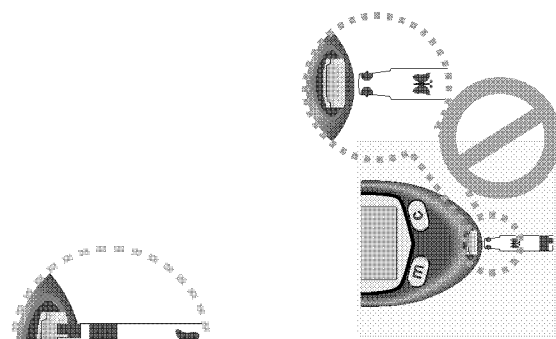
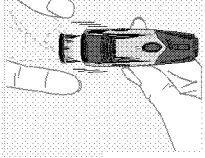
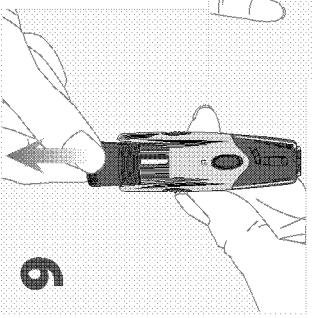
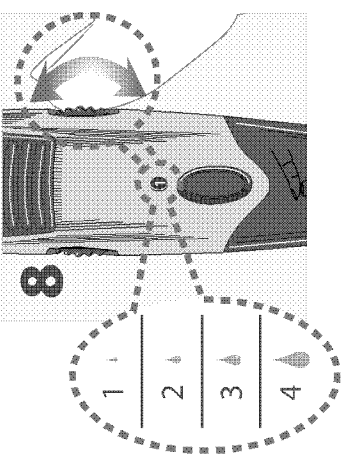
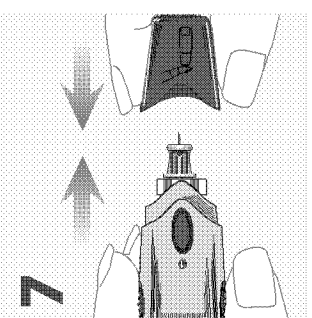
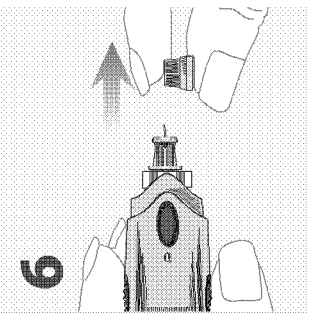
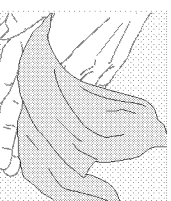
La prueba no comienza después de que se aplica la muestra de sangre.

Causa probable	Qué hacer
La muestra de sangre es demasiado pequeña.	Puede agregar sangre en la misma área de la muestra de la tira de prueba FreeStyle Lite® con la que comenzó antes de que transcurran 60 segundos desde el momento de la primera aplicación. Si es necesario, repita la prueba con una tira de prueba FreeStyle Lite nueva y una muestra de sangre más grande.
La tira de prueba presenta fallas.	Repita la prueba con una tira de prueba FreeStyle Lite nueva.
La muestra se aplicó después de que transcurrió el tiempo de espera (dos minutos) y se apagó el medidor.	Repita la prueba con una tira de prueba nueva. Espere a ver los símbolos de la gota de sangre y la tira de prueba en la pantalla antes de aplicar la muestra de sangre.
El medidor o las tiras de prueba presentan fallas.	Llame al departamento de Atención al cliente.

Especificaciones del sistema FreeStyle Freedom Lite®

Método de ensayo	Sensor electroquímico coulométrico
Apagado automático	Dos minutos después de la última acción del usuario
Duración de la pila	1000 pruebas
Calibración	Equivalente a plasma
Hematocrito	Del 15% al 65%
Unidades de medida	mg/dL
Temperatura de conservación del medidor	Entre -4 °F y 140 °F (-20 °C y 60 °C)
Memoria	400 pruebas de glucosa en sangre y solución de control con fecha y hora
Humedad relativa de funcionamiento	Del 5% al 90% (sin condensación)
Temperatura de funcionamiento	Entre 40 °F y 104 °F (4 °C y 40 °C)
Fuente de energía	Una pila de litio N.º 2032, de 3 voltios, que se puede cambiar
Rango de resultados	Entre 20 y 500 mg/dL (1.1 y 27.8 mmol/L)
Muestra	Muestras de sangre entera capilar reciente
Tamaño de la muestra	0.3 microlitros (300 nanolitros)
Dimensiones	2.00 pulgadas de ancho x 3.30 pulgadas de largo x 0.50 pulgada de espesor (en el punto de mayor espesor)
Peso	Entre 1.4 y 1.6 onzas (39.7 y 45.4 gramos) con la pila incluida

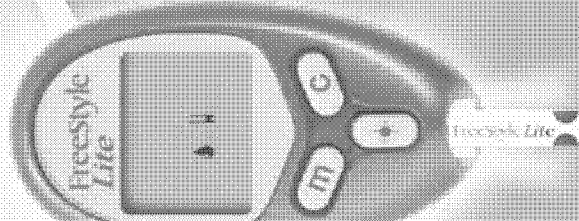




REVISED DATE: June/08	
Die Supplier:	Size:
ADC, A&P	5" x 2.812" x 7.125"

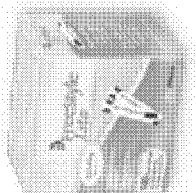
FreeStyle

Blood Glucose Monitoring System



- Multiple test sites so your fingers can get a rest
- 4 reminder alarms to maintain your testing schedule
- Stores up to 400 results with date and time
- Provides results in 7-, 14- and 30-day averages

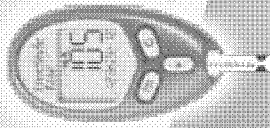
FreeStyle Lite Test Strips



Enough blood is applied to the strip so you can get a reading in 60 seconds

FreeStyle Lite

Blood Glucose Monitoring System



¡No requiere codificación!

- La muestra más pequeña del mundo
- Medidor pequeño y discreto
- Resultados rápidos en un promedio de 5 segundos
- Instrucciones incluidas

The FreeStyle Promise™ Program

At Abbott Diabetes Care, our first priority is you. Join our FreeStyle Promise Program* by calling 1-866-246-2683. Membership is **FREE**. Details inside!

Customer Care

1-888-522-5226

24 hours a day/7 days a week/se habla español

Or visit us online at

www.MyFreeStyle.com

90-Day Money Back Guarantee*

*Abbott may modify or discontinue this program at any time without notice. Offer subject to limitation. See insert for details.

Blood Glucose Monitoring System

- Test Strips sold separately
- Control Solution available through Customer Care: 1-888-522-5226

En español

Use Only With FreeStyle Lite Test Strips



FreeStyle Lite

Blood Glucose Monitoring System

No Coding Required!

World's Smallest Sample Size

Small And Discreet Meter

Fast, 5-Second Average Test Time

Use Only With FreeStyle Lite Test Strips



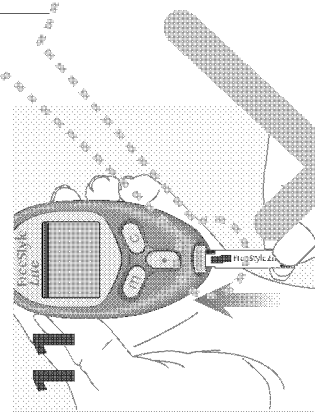
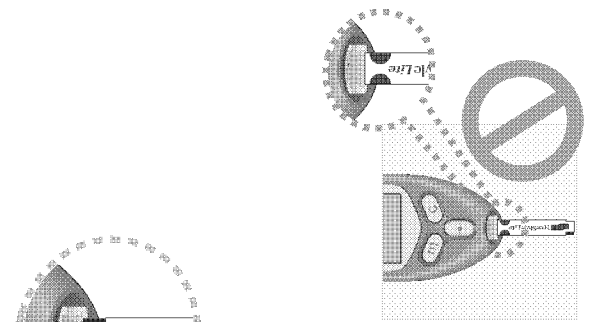
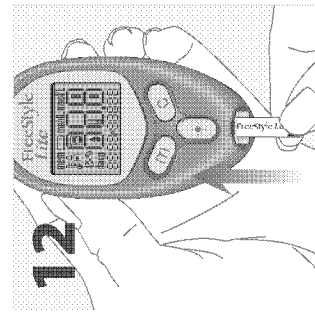
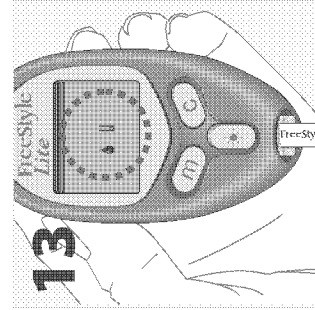
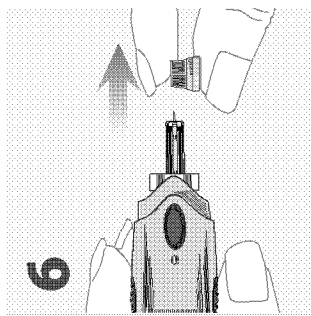
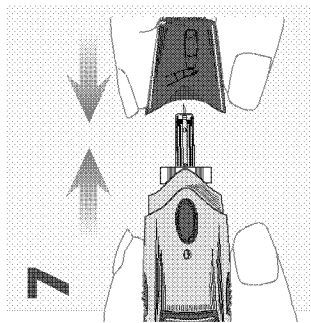
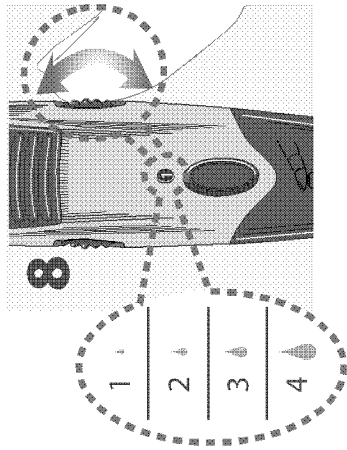
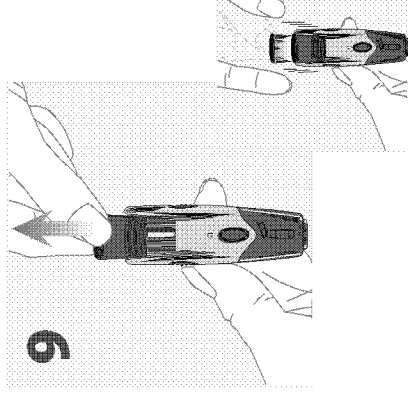
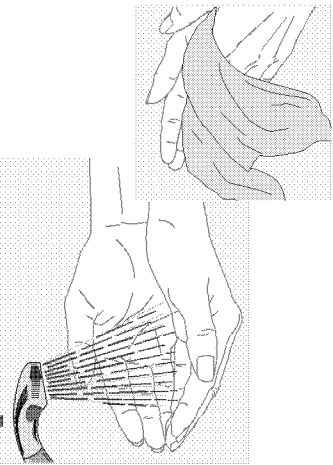
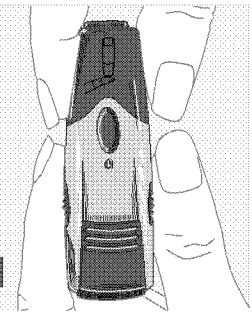
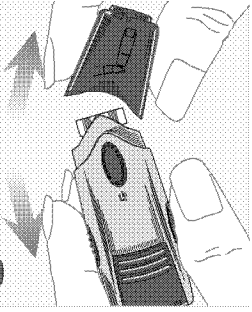
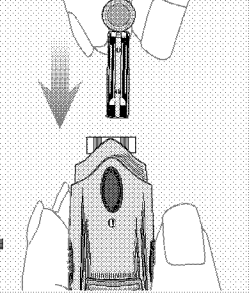


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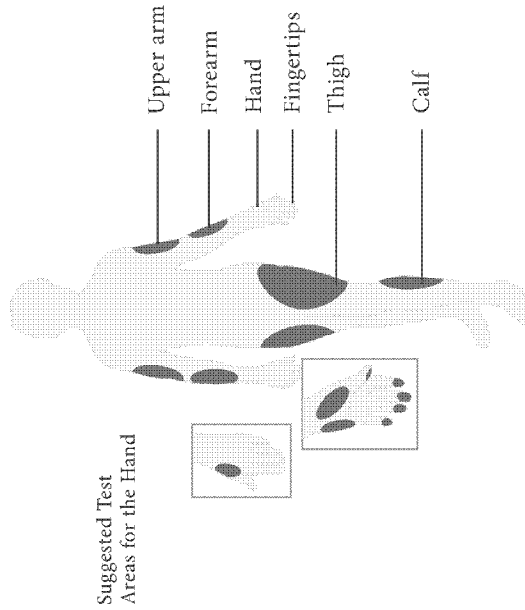
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The FreeStyle Lite System Uses the World's Smallest Sample So You Can Test on a Variety of Locations

Most Test Sites Available



The human figure above shows the areas where you can test with the FreeStyle Lite System. Avoid moles, veins, bones, and tendons.

WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Important Information About Your FreeStyle® Lite Blood Glucose Monitoring System

How the FreeStyle Lite System Should Be Used

- The FreeStyle Lite System is intended for use outside the body (in other words, *in vitro* diagnostic use only).
- The FreeStyle Lite System is used for measuring blood glucose (also known as blood sugar) from samples taken from the forearm, upper arm, hand, thigh, calf, or fingers.

Important: The FreeStyle Lite Meter should only be used with FreeStyle Lite Test Strips and FreeStyle Control Solution. Using other test strips and control solution with this meter can produce inaccurate results.

Do use the FreeStyle Lite System for:

- Testing blood glucose.
- Testing only with fresh capillary whole blood samples.

Do not use the FreeStyle Lite System for:

- The diagnosis of diabetes.
- Testing on newborns.
- Testing of arterial blood.

Important Information About Your FreeStyle® Lite Blood Glucose Monitoring System (cont)

WARNING:

- The FreeStyle Lite System contains small parts that may be dangerous if swallowed.
- Peritoneal dialysis solutions containing Icodextrin or compounds of Galactose ≥ 13 mg/dL, Maltose ≥ 20 mg/dL or Lactose ≥ 10 mg/dL cause the FreeStyle Lite Blood Glucose Monitoring System to overestimate blood glucose test results.

Caution: Please read all the instructions provided in this *Owner's Booklet* and practice the testing procedures before using the FreeStyle Lite System. Blood glucose monitoring should be done with the guidance of a healthcare professional.

Important Health-Related Information

- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
- Test results below 60 mg/dL mean low blood glucose (hypoglycemia).
- Test results greater than 240 mg/dL mean high blood glucose (hyperglycemia).
- If you get results below 60 mg/dL or above 240 mg/dL and do not have symptoms of hypoglycemia or hyperglycemia, repeat the test. If you have symptoms or continue to get results that fall below 60 mg/dL or above 240 mg/dL, follow the treatment advice of your healthcare professional.
- If you are experiencing symptoms that are not consistent with your blood glucose test and you have followed all instructions described in the FreeStyle® Lite Owner's Booklet, call your healthcare professional.

The FreeStyle® Lite Meter and How It Works

System Check Screen

This screen always appears when the meter is turned on so that you can make sure the display is working properly. Do not use the meter if the system check screen does not match the example here. Please call Customer Care.

Display Screen

Displays your test results and other important information.

M (Mode) Button

- Move to different mode settings.
- Scrolls backward.
- Silence a reminder alarm.

Light Button

Controls the display backlight and test light.

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

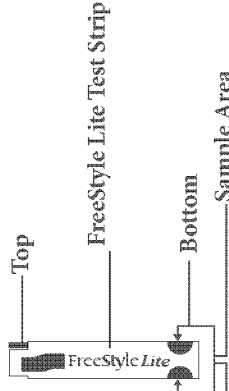
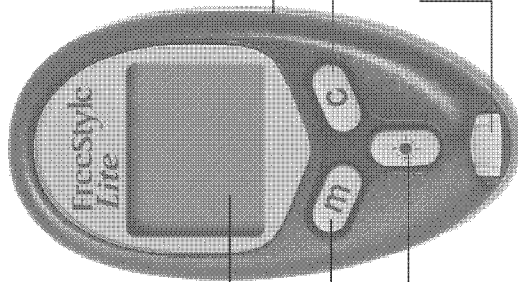
Download test results. Requires a compatible data management system. *For more information, please go to our website or call Customer Care.*

C (Configure) Button

- Marks a control solution test.
- Scrolls forward.
- Displays clock.
- Silence a reminder alarm.

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.



The FreeStyle® Lite Meter Display

Memory Mode Symbol

Shows you test results stored in the meter memory.

Control Solution Test Result Symbol

Shows that you have marked a test result as a control solution test.

Battery Symbol

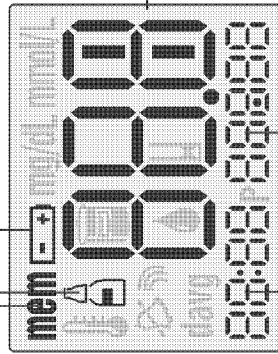
Appears when you should replace your meter battery.

Test Result Area

Displays test results.

Message Area

Displays date, time, and number of tests.



Thermometer Symbol

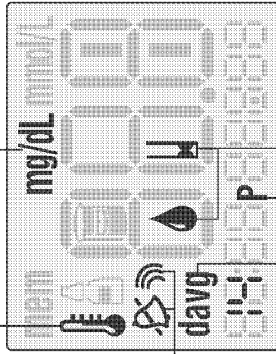
Appears if your meter is out of operating temperature range.

Sound Level Symbols

Indicates high, low, or off sound volume.

Day Average Symbol

Shows the average value of glucose readings from the last 7-, 14- or 30-days.



mg/dL (U.S. Standard)

Indicates unit of measurement.

Blood Drop and Test Strip Symbols

These symbols work together in an animation to tell you when the meter is ready for you to apply blood or control solution.

P Symbol

Indicates PM in 12-hour format only (for example 4:00 p.m.)

The FreeStyle Lite Test Strip

Apply blood or control solution to only **one Test Strip Sample Area** per test.

Important: Use only one sample area of the test strip per test. Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Lite Meter should only be used with FreeStyle Lite Test Strips. Using other test strips with this meter can produce inaccurate results.

Important Test Strip Information

- The FreeStyle Lite System has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight and heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite Test Strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.

9 Call Customer Care Toll Free at 1-888-522-5226 www.AbbottDiabetesCare.com

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- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter FreeStyle Lite Test Strips.

Note: For further information, refer to the FreeStyle Lite Test Strip package insert.

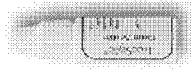
The FreeStyle® Control Solution

FreeStyle Control Solution is a red liquid that contains a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.

A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

For information on how to obtain Control Solution, call Customer Care at 1-888-522-5226.



Important Control Solution Information

FreeStyle® Control Solution is good for three months after opening the bottle or until the expiration date printed on the label, whichever comes first.

Important: Count forward three months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle.

Example: You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.

- Use only FreeStyle Control Solution with your FreeStyle Lite System.
- Replace the cap on the control solution bottle immediately after using.
- Do not use control solution past the expiration date.
- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when used between 59° to 104° F (15° to 40° C).
- Control solution test results should fall within the range printed on the test strip vial label.

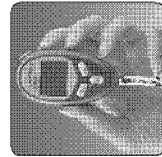
Important: The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.

- If control solution results are out of this range, repeat the test.
- If your control solution test results continue to fall outside the range printed on the test strip vial, do not use the FreeStyle Lite System to test your blood glucose. Contact Customer Care.

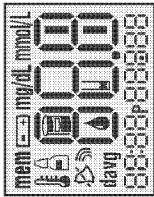
Caution: Results from FreeStyle Control Solution tests do not reflect your blood glucose level.

Performing a Control Solution Test

1



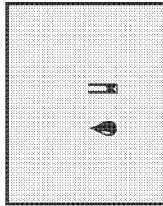
Insert the top of the test strip into your meter until it stops. This will power on the meter.

**System Check Screen**

When the meter powers on, this screen will appear so that you can make sure the display is working properly.

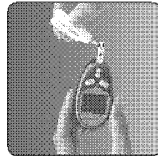
System Check

2



Wait for the meter to display the Blood Drop and Test Strip symbols.

3



Gently touch only *the Sample Area* of the test strip to the control solution.

Important: Do not apply control solution to both Test Strip Sample Areas.

If the sound prompt is on, your meter will beep when the test strip is full. A short line then moves clockwise around the display screen while the sample is processing.

The result will appear on the display screen and if the sound is on, your meter will beep twice. To mark the result as a control solution result, press and hold the “c” button for two seconds until the control solution symbol (ⓐ) appears at the top left of the display screen.

If you have marked a blood glucose test as a control solution test by mistake, you can unmark it by pressing and holding the “c” button again for two seconds.



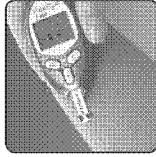
Compare your control solution test result to the range printed on your test strip vial label. Your control solution results should fall within the range printed on the side of your test strip vial.

Out of range test results may be caused by:

- Expired or bad control solution.
- Expired or bad test strip.
- Error in performing test.
- Watered-down control solution.
- Meter malfunction.
- Control solution test done outside 59° to 104° F.

To turn the meter off, remove the test strip.

Testing Your Blood Glucose



Important: To ensure accurate results, wash your hands and test site (for example, your forearm) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

- With the FreeStyle® Lite Meter, you can test your blood glucose on your forearm, fingers, upper arm, hand, thigh, or calf.
- Testing with the FreeStyle Lite Meter requires a very small sample size, 0.3 microliters of blood; about the size of pinhead (example: •).

WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Times when you may be checking for low blood glucose include:

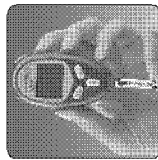
- When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.
- When you have delayed a meal after taking insulin.
- When your healthcare professional advises you to do so.

Performing a Blood Glucose Test

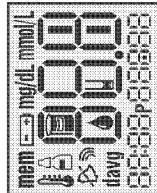
1

Prepare Your Meter

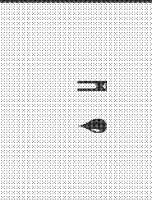
Insert a FreeStyle Lite Test Strip into the meter until it stops. The meter will power on.



Note: If you do not start the test within two minutes, the meter will turn off. To restart your meter, take out the unused FreeStyle Lite Test Strip and reinsert it into the meter.



System Check



Blood Drop and Test Strip Symbols

Important: The FreeStyle Lite Meter should only be used with FreeStyle Lite Test Strips. Using other test strips with this meter can produce inaccurate results.

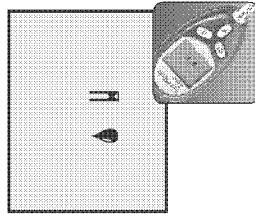
2 Obtain a Blood Sample

Select a test site. There are differences in testing on fingers versus other alternative sites.

Use your lancing device to obtain a blood sample. Refer to the Lancing Device insert for detailed instructions on how to use the FreeStyle Lancing Device.

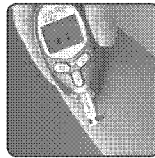
WARNING: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.

3

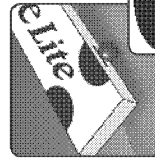


Filling the FreeStyle Lite Test Strip with Blood

a. Make sure that the FreeStyle Lite Test Strip is in the meter and the meter is powered on. (If the meter is off, take out the test strip and reinsert it into the meter.) You are now ready to apply the blood sample.



b. Bring the FreeStyle Lite Test Strip to the blood sample at a slight angle.



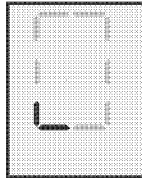
c. The FreeStyle Lite Test Strip acts like a sponge and pulls the blood into the strip through the sample area.

Test Strip Sample Area

- Do not press the FreeStyle Lite Test Strip against the test site.
- Do not scrape the blood onto the FreeStyle Lite Test Strip.
- Do not apply blood to the flat side of the FreeStyle Lite Test Strip.
- Do not apply blood to the FreeStyle Lite Test Strip when the FreeStyle Lite Test Strip is out of the meter.
- Do not put blood or foreign objects into the FreeStyle Lite Test Strip port.

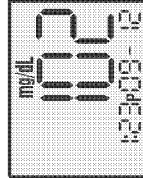


4 Waiting for Result



- Do not pull the FreeStyle Lite Test Strip away until you hear one beep or see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.

If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same sample area of the test strip from which you started for up to 60 seconds from the time of the first application.



- The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps.
- On average, your reading will display in 5 seconds. The time that the meter takes depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

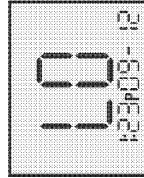
Potential Bruising

It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another test site.

LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle® Lite Meter displays results from 20 to 500 mg/dL.

If your test result is lower than 20 mg/dL, LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).



LO Reading with Symptoms

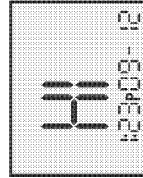
If you have a LO reading and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.

LO Reading

LO Reading without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, follow your doctor's recommendation to treat hypoglycemia.

If your test is above 500 mg/dL, HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).



HI Reading with Symptoms


If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.

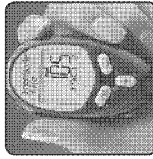
HI Reading

HI Reading without Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip. If you still get a HI reading, follow your doctor's recommendation to treat hyperglycemia.


Using Your Meter's Lights

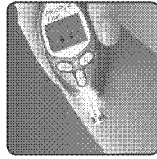
Depending on what mode your meter is in, pressing the light button () turns on either the display backlight or the test light.



Using the Display Backlight

Pressing the light button powers on the display backlight in all modes except when applying a sample. When applying a sample, the light button turns the test light on.

The display backlight goes out when you press the light button () again or when the meter is inactive for 10 seconds.



Using the Test Light

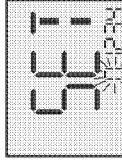
Pressing the light button while the Blood Drop and Test Strip symbols appear on the display screen powers on the test light

The test light goes out:

- When you press the light button again.
- When the meter receives the correct amount of blood for a test (the FreeStyle Lite Test Strip is filled).
- After 60 seconds of no activity.
- When a FreeStyle Lite Test Strip is removed from the meter.

If you use either the backlight or the test light during the test mode, the backlight lights again to show you the test results after the measurement is complete.

Meter Set-Up

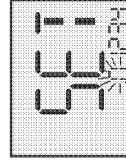


- **To Enter Setup Mode**
Start with the meter off (no test strip inserted). Press and firmly hold the “m” button until the 5E I display screen appears.
- **To Exit at Any Time**
Press and hold the “m” button until the meter turns off.
- **To Move Through the Screens**
Press the “m” button to move through all the setup screens such as reminder alarms, sound level, time, date, and so on.
- **To Change Settings Within the Screen**
Press the “c” (configure) button.

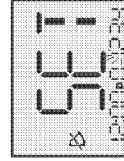
Setting the Reminder Alarms

You may set up any or all of the reminder alarms (1-4). Note: A reminder alarm will never sound during a test.

To set a reminder alarm or multiple reminder alarms, please follow these steps.

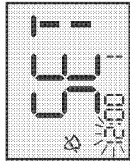


1. Start with the meter off. Press the “m” button and hold until the 5E I display appears with 01234. You are now in the reminder alarm setting mode and the “0” is blinking.



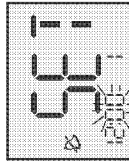
2. To move to the first reminder alarm press the “c” button once. You are now ready to set reminder alarm 1 (“1” is blinking).

Select reminder alarm



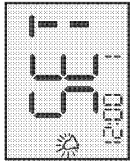
Select hour

- Press the “m” button to move to the hour setting. With the hour blinking, press the “c” button until the correct hour appears.



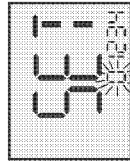
Select minute

- Press the “m” button to move to the minute setting. With the minute blinking, press the “c” button until the correct minute appears.



Select reminder alarm volume

- Press the “m” button to move to the reminder alarm volume setting. Default setting is off. Press the “c” button to select the desired volume setting: low, high, or off.



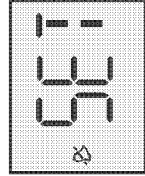
Select reminder alarm

- Press the “m” button to finalize your alarm setting. This will bring you back to the reminder alarm setting 5 E 1 mode. If you wish to set multiple reminder alarms press “c” to move to reminder alarm 2. Repeat.

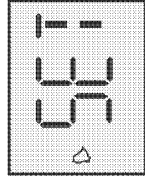
Note: To save your reminder alarm settings and exit set up mode, press and hold the “m” button until the meter turns off. Press the “m” button when “0” is blinking to move to the next set-up screen without setting any reminder alarms.

Setting the Sound

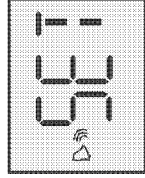
There are three (3) sound volume options:



Off



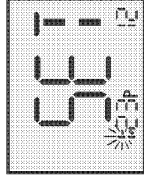
Low



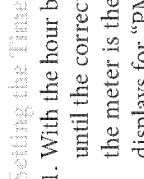
High

There are three sound volume options to let you know when the test strip is full, when the reading is done, and when an error occurs:

- Press the “c” button until the desired sound level appears
- Press the “m” button to move to “Setting the Time.”

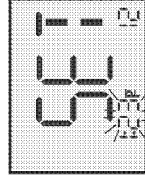


Hour



Setting the Time

- With the hour blinking, press the “c” button until the correct hour appears. The default for the meter is the 12-hour time format. The “p” displays for “PM” times.



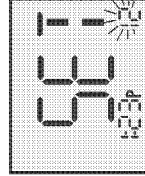
Minute

- Press the “m” button to move to minute setting.

- With the minute blinking, press the “c” button until the correct minute appears.

- Press the “m” button to move to “Setting the Time Format.”

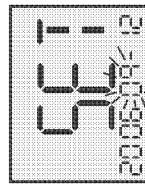
Setting the Time Format



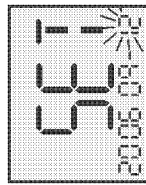
Time Format

- With the hour mode blinking, press the “c” button to move between 12-hour and 24-hour format. The time automatically updates to the format selected.

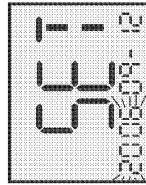
- Press the “m” button to move to “Setting the Date.”



Month



Day



Year

You have completed Meter Set-Up.

- To move to "Setting the User Reminder Alarms" press the "m" button.
- To exit press and hold the "m" button.

Meter Results Meter Memory

- **To Enter**

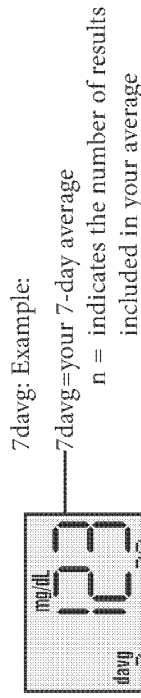
Start with the meter off (no test strip inserted). Press the "m" button and release; the first memory screen to appear will be your 7-day average.

- **To Exit**

Press and hold the "m" button until the meter turns off.

7-, 14-, 30- Day Average

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)

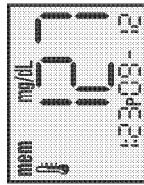


The "c" button allows you to scroll forward to 14- and 30-day averages. Continue to press the "c" button to view stored test results. Your most recent result will display first.

The "m" button allows you to scroll backward.

Test Results

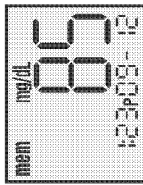
The meter stores the last 400 test readings with time and date. You may scroll through all of the readings by pressing and holding the “c” button. The first reading you see is the most recent result.



Temperature: A result with a thermometer symbol indicates that the reading was taken outside of the meter’s specified operating temperature range and may not be accurate. This value is included in your 7-, 14- and 30-day averages.

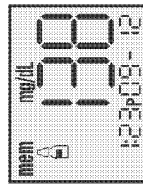
LO Reading: A LO reading (under 20 mg/dL) is included in the memory as LO.

HI Reading: A HI reading (over 500 mg/dL) is included in the memory as HI.



Blood Glucose Test

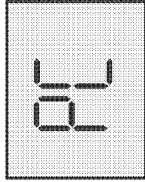
A result without a control solution symbol (Ⓜ) indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.



Control Solution Test

A value with (Ⓜ) indicates that you have marked this reading as a control solution test. The date and time of the control solution reading will appear on the bottom of the screen.

Data Download




The “PC” symbol displays when a data cable is inserted in the meter data port. You cannot perform a test while the data cable is in the meter data port.

The meter will display “PC” until the data cable is removed from the data port.

(Requires a compatible data management system.)

For more information, please go to our website or call Customer Care.

Meter Maintenance Battery

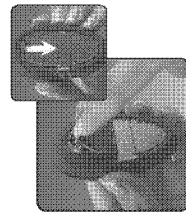
Your FreeStyle® Lite Meter comes with one preinstalled, #2032, 3 volt, lithium battery. The battery provides enough power for the meter to perform about 500 tests. If your battery runs low, the battery symbol () appears on every display screen until you change the battery. When the battery runs low, the display backlight and test light may not power on.

Important: When this symbol appears, or when the backlight and test light begin to dim, you should replace the battery immediately.

- To avoid losing the time and date settings, replace the battery within one minute of removing the old battery.
- If you take more than one minute to replace the battery, you may need to reset the time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, the time and date displays flash 12:00 and 00-00 until they are reset.
- Removing the battery does not affect the meter's memory log or previously-stored user settings (such as date and time format).
- Even if you lose your time and date settings – you can perform a blood glucose test, and results will not be affected.

Replacing the Battery

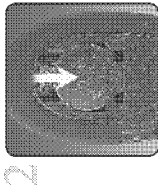
1



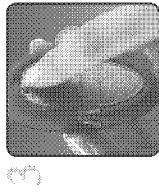
Turn the meter over. Press in the battery door clip to open. Swing the battery door up to open and then off the meter.

To remove the battery, push the battery downward to release the battery.

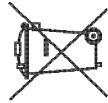
Replacing the Battery (cont)



Install the battery with the positive (+) sign up toward you.



To close, angle the battery door back onto the meter and swing down until it snaps into place.



Note: Batteries need to be properly disposed of. For this purpose, all shops selling batteries provide battery collection boxes on their premises.

Caring for Your Meter

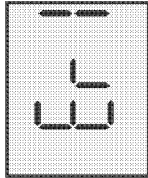
Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip and data ports.

Clean the outside of the meter using a cloth dampened with one of the following:

- Mild detergent/mild soap and water.
- 70% isopropyl alcohol.
- A mix of one part household bleach, nine parts water.

Important: Never immerse the meter in water or any other liquid.

Error 1



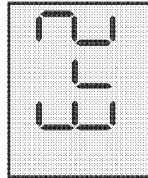
Possible Causes

- Sample is too small.
- Problem with the FreeStyle Lite Test Strip.
- Problem with the meter.
- Very low blood glucose (less than 20 mg/dL).

What You Should Do

1. If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your doctor's recommendation for treating hypoglycemia.
2. Conduct a control solution test using a new FreeStyle Lite Test Strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite Test Strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 2



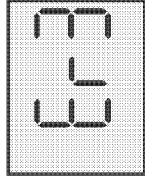
Possible Causes

- Problem with the FreeStyle Lite Test Strip.
- Problem with the meter.
- Very high glucose (above 500 mg/dL).
- HIGH control solution applied when temperature is too cold. (This applies only to control solution that is labeled as HIGH.)

What You Should Do

1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your doctor's recommendation for treating hyperglycemia.
2. Conduct a control solution test using a new FreeStyle Lite Test Strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite Test Strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 3

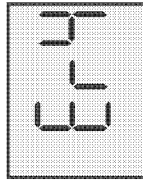


Possible Causes

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter or applying blood before the Blood Drop and Test Strip symbols display.
- Problem with the FreeStyle Lite Test Strip.
- Problem with the meter.

What You Should Do

1. Be sure you see the Blood Drop and Test Strip symbols on the display screen before you apply blood or control solution.
2. Conduct a control solution test using a new FreeStyle Lite Test Strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite Test Strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.



Possible Causes

- Problem with FreeStyle Lite Test Strip.
- Problem with the meter.

What You Should Do

1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite Test Strip.
2. If the retest using control solution does not work or the error persists, call Customer Care.

Troubleshooting

Meter does not enter the test mode after inserting a test strip.

Probable Cause	What to Do
The battery is dead.	Replace the battery (and reset the date and time, if necessary.)
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the FreeStyle Lite Test Strip with the printed side up and the top of the strip in the meter.
Defective meter or test strips.	Call Customer Care.
Blood or foreign objects put into the test strip port.	Call Customer Care.

Test does not start after applying the blood sample.

Probable Cause	What to Do
Blood sample too small.	You may add blood to the same sample area of the FreeStyle Lite Test Strip from which you started for up to 60 seconds from the time of the first application. If necessary, repeat the test using a new FreeStyle Lite Test Strip and a larger blood sample.
Defective test strip.	Repeat the test with a new FreeStyle Lite Test Strip
Sample applied after meter times out (two minutes) and turns off.	Repeat the test using a new test strip. Wait until you see the Blood and Test Strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Call Customer Care.

FreeStyle Lite System Specifications

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	500 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	mg/dL
Meter Storage Temp.	-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 #2032, 3 volt, lithium battery, replaceable
Result Range	20 to 500 mg/dL
Sample	Whole blood, capillary
Sample Size	0.3 microliter (300 nanoliters)
Size	Width 1.57" x Length 2.9" x Depth 0.65"
Test Time	Average of 5 seconds
Weight	1.4 oz. including battery

ENGLISH

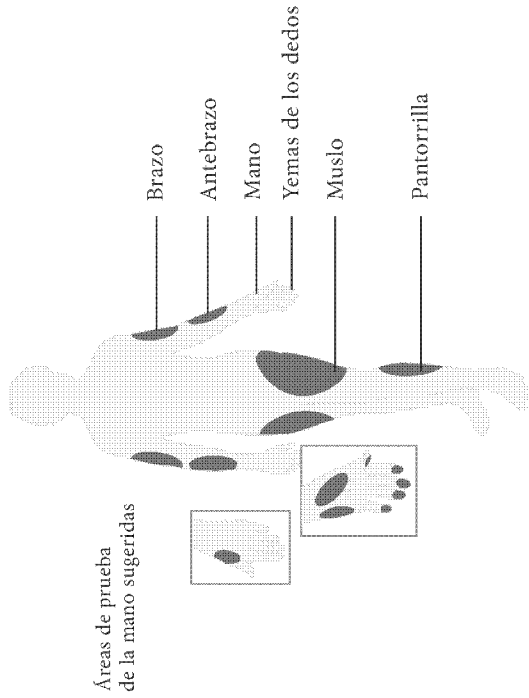
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ESPAÑOL

El sistema FreeStyle Lite utiliza la muestra más pequeña del mundo para que pueda realizar pruebas en varios lugares

La mayoría de las zonas de prueba disponibles



ESPAÑOL

Información importante acerca de su sistema de prueba para glucosa en sangre FreeStyle® Lite

Cómo se debe usar el sistema FreeStyle Lite

- El sistema FreeStyle Lite está destinado a utilizarse fuera del organismo (es decir, sólo para uso diagnóstico *in vitro*).
- El sistema FreeStyle Lite se utiliza para medir la glucosa en sangre (también conocida como azúcar en sangre) de muestras extraídas del antebrazo, brazo, mano, muslo, pantorrilla o dedos.

Importante: El medidor FreeStyle Lite sólo debe utilizarse con tiras de prueba FreeStyle Lite y solución de control FreeStyle. El uso de otras tiras de prueba y solución de control con este medidor puede producir resultados inexactos.

Utilice el sistema FreeStyle Lite para:

- realizar pruebas de glucosa en sangre;
- realizar pruebas sólo con muestras de sangre entera capilar reciente.

No utilice el sistema FreeStyle Lite para:

- obtener un diagnóstico de diabetes;
- realizar pruebas a recién nacidos;
- realizar pruebas de sangre arterial.

ESPAÑOL

La figura humana que aparece más arriba muestra las zonas donde puede realizar pruebas con el sistema FreeStyle Lite. Evite lunares, venas, huesos y tendones.

ADVERTENCIA:

Le recomendamos que realice las pruebas en los dedos de la mano si está haciendo una prueba de hipoglucemia (bajo nivel de glucosa en sangre) o si sufre de hipoglucemia asintomática.

Comuníquese con el Departamento de Atención al Cliente de forma gratuita llamando al 1-888-522-5226 o visítenos en www.AbbottDiabetesCare.com.

Información importante sobre su sistema para prueba de glucosa en sangre FreeStyle® Lite (*continuación*)

ADVERTENCIA:

- El sistema FreeStyle Lite contiene piezas pequeñas que pueden ser peligrosas si se ingieren.
- Las soluciones para diálisis peritoneal que contienen Icodextrina o compuestos de Galactosa ≥ 13 mg/dL, Maltosa ≥ 20 mg/dL, o Lactosa ≥ 10 mg/dL hacen que el sistema de prueba para glucosa en sangre FreeStyle Lite sobrevalore los resultados correspondientes.

Precaución: Lea todas las instrucciones detalladas en este *manual del propietario* y practique los procedimientos de prueba antes de utilizar el sistema FreeStyle Lite. El control de glucosa en sangre debe realizarse con la orientación de un profesional de la salud.

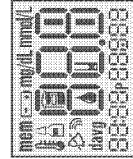
ESPAÑOL

Información sanitaria de importancia

- Es posible que la deshidratación grave y la pérdida de agua en exceso provoquen resultados bajos incorrectos. Si cree que está sufriendo de deshidratación grave, consulte a su médico inmediatamente.
- Los resultados de pruebas por debajo de 60 mg/dL muestran un bajo nivel de glucosa en sangre (hipoglucemia).
- Los resultados de prueba superiores a 240 mg/dL muestran un alto nivel de glucosa en sangre (hiperglucemia).
- Si obtiene resultados inferiores a 60 mg/dL o superiores a 240 mg/dL y no presenta síntomas de hipoglucemia ni de hiperglucemia, repita la prueba. Si tiene síntomas o continúa obteniendo resultados inferiores a 60 mg/dL o superiores a 240 mg/dL, siga el tratamiento sugerido por su profesional de la salud.
- Si tiene síntomas que no coincidan con su prueba de glucosa en sangre y ha seguido todas las instrucciones descritas en el manual del propietario de FreeStyle® Lite, consulte a su profesional de la salud.

ESPAÑOL

El medidor FreeStyle® Lite y cómo funciona



Pantalla de comprobación del sistema
Esta pantalla siempre aparece cuando el medidor se enciende para que pueda asegurarse de que la pantalla funciona correctamente. No use el medidor si la pantalla de comprobación del sistema no coincide con este ejemplo. Comuníquese con el Departamento de Atención al Cliente.

Pantalla

Muestra los resultados de sus pruebas y otra información importante.

Botón principal

- Cambia a distintas configuraciones de modo.
- Retrocede.
- Silencia una alarma de recordatorio.

Botón de luz

Controla la retroiluminación de la pantalla y la luz de prueba.

Áreas de muestra (semitrazos de color oscuro en la tira de prueba)

Aplice sangre o solución de control a una sola área de muestra. Introduzca la tira en el medidor con el lado impreso hacia arriba (ver imagen a la derecha).

ESPAÑOL

Puerto de datos

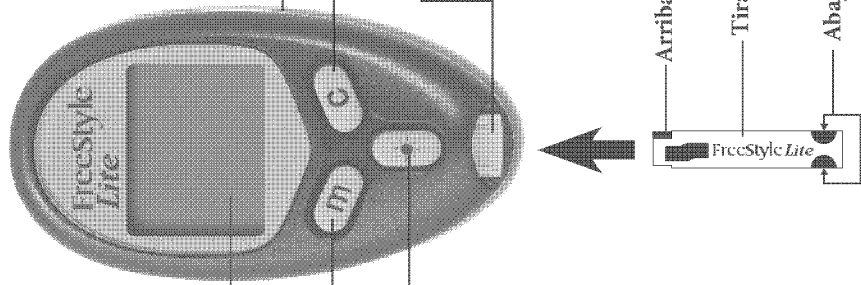
Descarga de los resultados de prueba. Requiere un sistema de control de datos compatible. Para obtener más información, visite nuestro sitio web o comuníquese con el Departamento de Atención al Cliente.

Botón c (Configurar)

- Señala una prueba de solución de control.
- Adelanta.
- Muestra el reloj.
- Silencia una alarma de recordatorio.

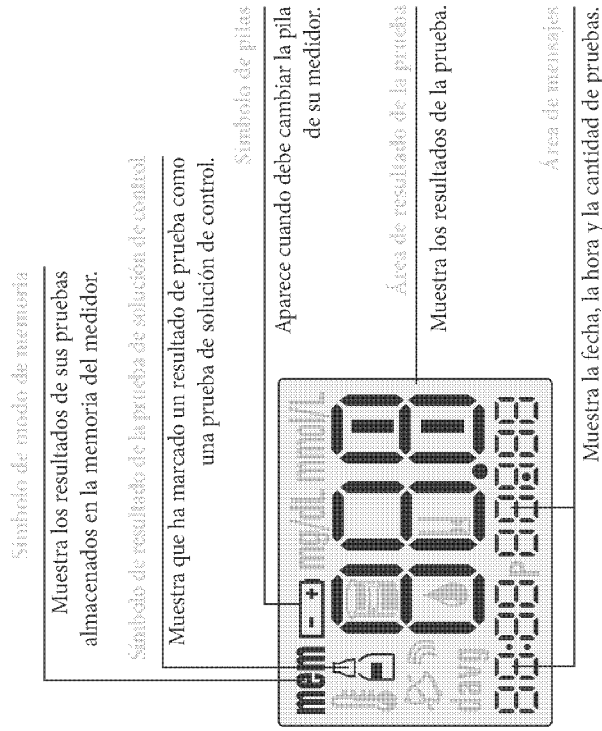
Puerto de la tira de prueba

Introduzca aquí el extremo de arriba de una nueva tira de prueba FreeStyle Lite. El medidor se enciende cuando introduce la tira de prueba.

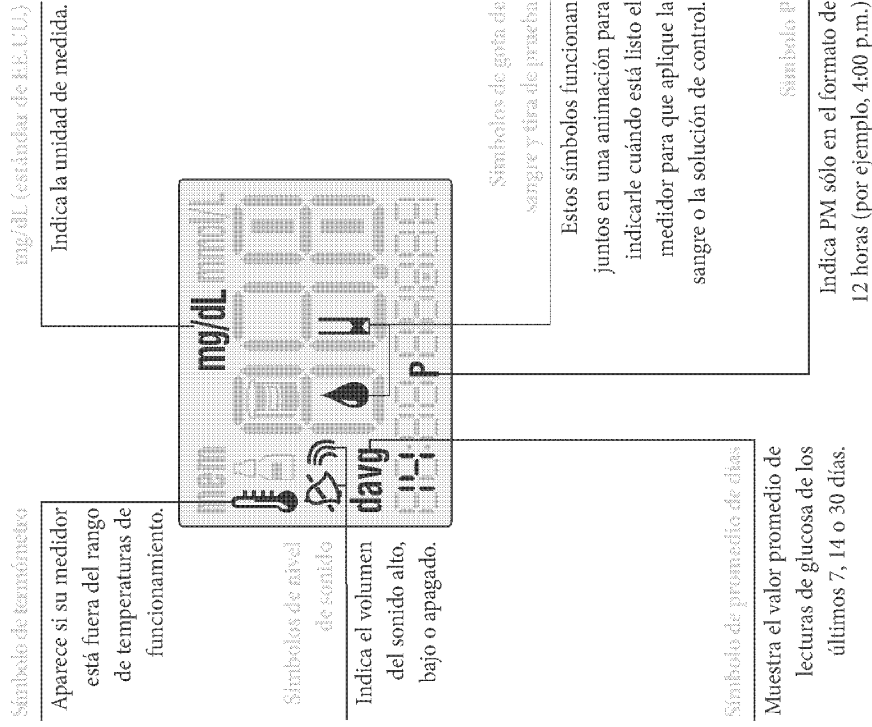


Comuníquese con el Departamento de Atención al Cliente de forma gratuita llamando al 1-888-522-5226 o visitenos en www.AbbottDiabetesCare.com.

La pantalla del medidor FreeStyle® Lite



ESPAÑOL



ESPAÑOL

Comuníquese con el Departamento de Atención al Cliente de forma gratuita llamando al 1-888-522-5226 o visítenos en www.AbbottDiabetesCare.com.

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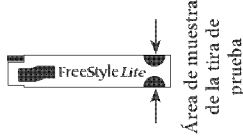
8

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La tira de prueba FreeStyle Lite

Aplique sangre o solución de control en una sola **área de muestra de la tira de prueba** por prueba.

Importante: Use solamente un **área de muestra de la tira de prueba** por prueba. No aplique sangre a ambas áreas de muestra. Las tiras de prueba se podrán usar una sola vez. Deseche las tiras de prueba usadas. Puede continuar llenando la tira de prueba durante 60 segundos como máximo. Asegúrese de volver a aplicar la muestra a la misma área de muestra.



ESPAÑOL

ADVERTENCIA:

El tapón o el vial contienen secantes que pueden ser nocivos si son inhalados o ingeridos y pueden causar irritación en los ojos o en la piel.

Importante: El medidor FreeStyle Lite sólo se debe usar con tiras de prueba FreeStyle Lite. El uso de otras tiras de prueba con este medidor puede producir resultados inexactos.

Información importante de las tiras de prueba

- El sistema FreeStyle Lite tiene un rango de funcionamiento de 40° a 104°F (4° a 40° C).
- Almacene el paquete de tiras de prueba en un lugar fresco y seco, a una temperatura de entre 40° y 86° F (4° a 30° C).
- Utilice las tiras de prueba sólo dentro del rango de temperaturas de funcionamiento del sistema.
- Manténgalas alejadas de la luz directa del sol y del calor.
- Almacene sus tiras de prueba solamente en su vial original; nunca las transfiera a otro vial u otro recipiente.
- Nunca almacene tiras de prueba individuales fuera del vial.
- Después de extraer una tira de prueba FreeStyle Lite del vial, cierre bien el tapón del vial inmediatamente.
- Con las manos limpias y secas, puede tocar la tira de prueba en cualquier lado, al extraerla del vial o introducirla dentro del medidor.

Comuníquese con el Departamento de Atención al Cliente de forma gratuita llamando al 1-888-522-5226 o visítenos en www.AbbottDiabetesCare.com.

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ESPAÑOL

- No utilice tiras de prueba después de su fecha de caducidad. Esto puede dar lugar a resultados inexactos.
- No doble, corte ni altere las tiras de prueba FreeStyle Lite.

Nota: Para obtener más información, consulte el tríptico del paquete de las tiras de prueba FreeStyle Lite.

La solución de control FreeStyle®

La solución de control FreeStyle es un líquido rojo que contiene una cantidad fija de glucosa que se utiliza para:

- realizar pruebas de práctica sin tener que usar su propia sangre;
- asegurarse de que su medidor y tiras de prueba estén funcionando en conjunto de manera adecuada;



Cuando dude de sus resultados y desee confirmar que su monitor y tiras de prueba están funcionando de manera adecuada, se deberá realizar una prueba de solución de control.

Para obtener información sobre cómo obtener soluciones de control, comuníquese con el Departamento de Atención al Cliente llamando al 1-888-522-5226.

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Información importante acerca de la solución de control

La solución de control FreeStyle® dura hasta tres meses una vez abierta la botella o hasta la fecha de caducidad impresa en la etiqueta, lo que ocurra primero.

Importante: Cuenté tres meses hacia adelante a partir de la fecha en que abre una nueva botella de solución de control. Ésta es la fecha de desecho. Escriba esta fecha en el lado de la botella de la solución de control.

Ejemplo: Abra la solución de control el 15 de enero. Cuenté tres meses hacia adelante hasta el 15 de abril. Ésta es la fecha de desecho que registrará en la botella.

- Use solamente la solución de control FreeStyle con su sistema FreeStyle Lite.
- Vuelva a colocar el tapón en la botella de la solución de control inmediatamente después de usarla.
- No utilice la solución de control después de la fecha de caducidad.
- No agregue agua ni algún otro líquido a la solución de control.
- Las pruebas de la solución de control están especificadas para ser precisas sólo cuando se usan entre 59° y 104° F (15° y 40° C).
- Los resultados de las pruebas de la solución de control deberían estar dentro del rango impreso en la etiqueta del vial de la tira de prueba.

Importante: El rango de la solución de control es un rango deseado sólo para la solución de control. No es un rango deseado para su nivel de glucosa en sangre.

- Si los resultados de la solución de control están fuera de este rango, repita la prueba.
- Si los resultados de su prueba de solución de control continúan estando fuera del rango impreso del vial de la tira de prueba, no utilice el sistema FreeStyle Lite para medir su glucosa en sangre. Póngase en contacto con el Departamento de Atención al Cliente.

Precaución: Los resultados obtenidos en las pruebas de soluciones de control FreeStyle no reflejan sus niveles de glucosa en sangre.

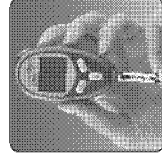
Comuníquese con el Departamento de Atención al Cliente de forma gratuita llamando al 1-888-522-5226 o visítenos en www.AbbottDiabetesCare.com.

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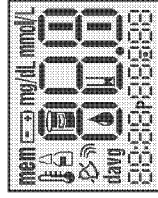
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Cómo realizar una prueba de solución de control



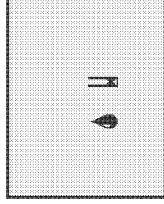
Introduzca la parte de arriba de la tira de prueba en el medidor hasta que se detenga. Esto encenderá el medidor.



Pantalla de comprobación del sistema

Cuando el medidor se enciende, aparecerá esta pantalla para que se asegure de que está funcionando correctamente.

Comprobación del sistema



2

Espere a que el medidor muestre los símbolos de gota de sangre y tira de prueba.



3

Toque suavemente sólo el área de la muestra de la tira de prueba con la solución de control.

Importante: No aplique solución de control a las dos áreas de muestra de la tira de prueba.

Si el aviso de sonido está activo, su medidor emitirá un sonido cuando la tira de prueba esté llena. Luego, una línea corta se mueve alrededor de la pantalla en el sentido de las agujas del reloj mientras la muestra se está procesando.

ESPAÑOL

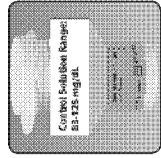
ESPAÑOL

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El resultado aparecerá en la pantalla y si el sonido está activado, su medidor emitirá un sonido dos veces. Para marcar el resultado como un resultado de la solución de control, mantenga presionado el botón "c" durante 2 segundos hasta que el símbolo de solución de control (A) aparezca en la parte superior izquierda de la pantalla.

Si ha marcado una prueba de glucosa en sangre como prueba de solución de control por error, puede desmarcarlo manteniendo presionado el botón "c" nuevamente durante dos segundos.



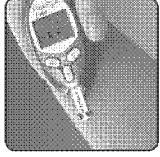
Compare el resultado de su prueba de solución de control con el rango impreso en la etiqueta del vial de su tira de prueba. Los resultados de la solución de control deberían estar dentro del rango impreso en el lado del vial de su tira de prueba.

Los resultados de las pruebas fuera de rango pueden ser causados por:

- solución de control vencida o en mal estado;
- tira de prueba vencida o en mal estado;
- error al realizar la prueba;
- solución de control debilitada;
- mal funcionamiento del medidor;
- la prueba de la solución de control se realizó fuera del rango de 59° a 104°F.

Para apagar el medidor, retire la tira de prueba.

Prueba de su glucosa en sangre



Importante: Para garantizar resultados exactos, lave sus manos y la zona de prueba (por ejemplo, su antebrazo) con agua y jabón. Cerciórese de que no haya loción ni crema en la zona de prueba. Seque completamente sus manos y la zona de prueba.

- Con el medidor FreeStyle® Lite, puede medir la glucosa en sangre en el antebrazo, dedos, brazo, mano, muslo o pantorrilla.
- Las pruebas con el medidor FreeStyle Lite requieren una muestra de tamaño muy pequeño, 0,3 microlitros de sangre; aproximadamente el tamaño de una cabeza de alfiler (ejemplo: •).

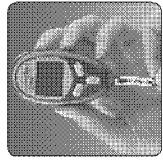
ADVERTENCIA:

Le recomendamos que realice las pruebas en los dedos de la mano si está haciendo una prueba de hipoglucemia (bajo nivel de glucosa en sangre) o si sufre de hipoglucemia asintomática.

Los momentos en los que puede controlar si su glucosa en sangre está baja son:

- cuando tiene síntomas como debilidad, sudores, nerviosismo, dolor de cabeza o confusión;
- cuando ha demorado una comida después de tomar insulina;
- cuando se lo recomienda su profesional de la salud.

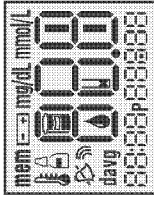
Cómo realizar una prueba de glucosa en sangre



Cómo preparar su medidor

Introduzca una tira de prueba FreeStyle Lite en el medidor hasta que se detenga. El medidor se encenderá.

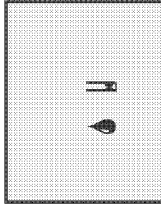
Nota: Si no comienza la prueba en dos minutos, el medidor se apagará. Para reiniciar su medidor, retire la tira de prueba FreeStyle Lite sin usar y vuelva a introducirla en el medidor.



Pantalla de comprobación del sistema

Cuando el medidor se enciende, aparecerá esta pantalla para que se asegure de que está funcionando correctamente.

Comprobación del sistema



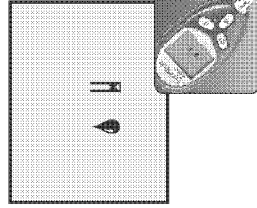
Símbolos de gota de sangre y tira de prueba

Importante: El medidor FreeStyle Lite sólo se debe usar con tiras de prueba FreeStyle Lite. El uso de otras tiras de prueba con este medidor puede dar lugar a resultados inexactos.

2 Cómo obtener una muestra de sangre

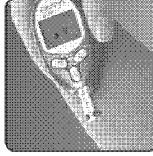
Seleccione una zona de prueba. Existen diferencias entre realizar una prueba en los dedos de la mano o en otras zonas alternativas. Use su dispositivo para lancetas para obtener una muestra de sangre. Consulte el tríptico del dispositivo para lancetas para obtener instrucciones detalladas sobre cómo usar el dispositivo para lancetas FreeStyle.

ADVERTENCIA: Le recomendamos que realice las pruebas en los dedos de la mano, si está haciendo una prueba de hipoglucemia (bajo nivel de glucosa en sangre) o si sufre de hipoglucemia asintomática.

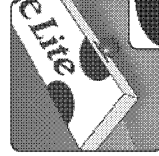


3

a. Asegúrese de que la tira de prueba FreeStyle Lite esté en el medidor y que el medidor esté encendido. (Si el medidor está apagado, retire la tira de prueba y vuelva a introducirla.) Ahora está listo para aplicar la muestra de sangre.



b. Acerque la tira de prueba FreeStyle Lite a la muestra de sangre en ángulo.



c. La tira de prueba FreeStyle Lite actúa como una esponja y absorbe la sangre en la tira a través del área de la muestra.

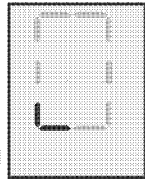
Área de muestra de la tira de prueba



- No presione la tira de prueba FreeStyle Lite contra la zona de prueba.
- No frote la sangre contra la tira de prueba FreeStyle Lite.
- No aplique sangre al lado plano de la tira de prueba FreeStyle Lite.

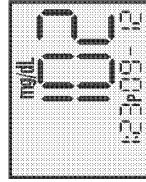
- No aplique sangre a la tira de prueba FreeStyle Lite cuando la tira de prueba FreeStyle Lite se encuentra fuera del medidor.
- No coloque sangre ni objetos extraños en el puerto de la tira de prueba FreeStyle Lite.

4. A la espera del resultado



- No jale la tira de prueba FreeStyle Lite hasta que escuche un sonido o vea la línea corta moviéndose en el sentido de las agujas del reloj en la pantalla de su medidor. Esto significa que tiene suficiente sangre y que el medidor está leyendo su glucosa.

- Si después de cinco segundos, su medidor no muestra una línea corta moviéndose alrededor de la pantalla, es posible que la muestra sea demasiado pequeña. Puede agregar sangre a la misma área de la muestra de la tira de prueba con la cual comenzó durante 60 segundos como máximo a partir del momento de la primera aplicación.



- El resultado de la prueba está completo cuando aparece en la pantalla el resultado de su prueba de glucosa en sangre y escuchará dos sonidos.
- En promedio, su lectura se mostrará en 5 segundos. El tiempo que tome el medidor depende de su nivel de glucosa en sangre. Cuanto más alto sea el nivel de glucosa, más tiempo lleva obtener un resultado.

Posibles hematomas

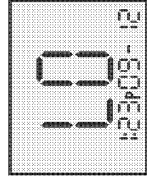
Es posible que aparezcan hematomas en la zona de prueba. Si esto ocurre, puede optar por pinchar en otra zona de prueba.

Comuníquese con el Departamento de Atención al Cliente de forma gratuita llamando al 1-888-522-5226 o visítenos en www.AbbottDiabetesCare.com.

Lecturas LO (BAJO) y HI (ALTO)

Importante: Las lecturas de glucosa en sangre altas o bajas pueden indicar una enfermedad potencialmente grave. El medidor FreeStyle Lite muestra resultados de 20 a 500 mg/dL.

Si el resultado de su prueba es inferior a 20 mg/dL, aparecerá LO (BAJO) en la pantalla del medidor. Esta lectura indica hipoglucemia grave (bajo nivel de glucosa en sangre).



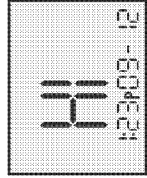
Lectura LO (BAJO) con síntomas

Si obtiene LO (BAJO) en la lectura y presenta síntomas como debilidad, sudores, nerviosismo, dolor de cabeza o confusión, entonces siga las recomendaciones de su médico para tratar la hipoglucemia.

Lectura LO (BAJO) sin síntomas

Si obtiene LO (BAJO) en la lectura, pero no tiene síntomas de bajo nivel de glucosa en sangre, entonces vuelva a realizar la prueba con una nueva tira de prueba en sus dedos. Si aún obtiene LO (BAJO) en la lectura, siga las recomendaciones de su médico para tratar la hipoglucemia.

Si su prueba es superior a 500 mg/dL, aparecerá HI (ALTO) en la pantalla. Esto indica hiperglucemia grave (alto nivel de glucosa en sangre).



Lectura HI (ALTO) con síntomas

Si presenta síntomas como fatiga, sed, orina en exceso o visión borrosa, entonces siga las recomendaciones de su médico para tratar la hiperglucemia.

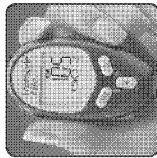
Lectura HI (ALTO)

Lectura HI (ALTO) sin síntomas

Si obtiene una lectura HI (ALTO), pero no tiene síntomas de alto nivel de glucosa en sangre, entonces vuelva a realizar la prueba con una nueva tira de prueba. Si aún obtiene HI (ALTO) en la lectura, siga las recomendaciones de su médico para tratar la hiperglucemia.

Cómo usar las luces de su medidor

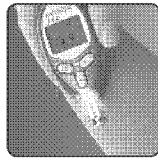
Según el modo en que esté su medidor, al presionar el botón de luz (☀) se enciende la retroiluminación de la pantalla o bien la luz de prueba.



Cómo usar la retroiluminación de la pantalla

Al presionar el botón de luz, se enciende la retroiluminación de la pantalla en todos los modos excepto cuando aplica una muestra. Cuando aplica una muestra, el botón de luz enciende la luz de prueba.

La retroiluminación de la pantalla se apaga cuando presiona el botón de luz (☀) nuevamente o cuando el medidor está inactivo durante 10 segundos.



Cómo usar la luz de prueba

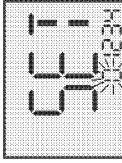
Al presionar el botón de luz mientras aparecen en la pantalla los símbolos gota de sangre y tira de prueba, se enciende la luz de prueba

La luz de prueba se apaga:

- cuando presiona el botón de luz nuevamente;
- cuando el medidor recibe la cantidad correcta de sangre para una prueba (la tira de prueba FreeStyle Lite está llena);
- después de 60 segundos de inactividad;
- cuando se extrae una tira de prueba FreeStyle Lite del medidor.

Si utiliza ya sea la retroiluminación o la luz de prueba durante el modo de prueba, la retroiluminación se enciende nuevamente para mostrarle los resultados de la prueba después de que se completó la medición.

Cómo configurar su medidor



- **Para ingresar en el modo configurar**
Comience con el medidor apagado (sin haber introducido una tira de prueba). Presione y sostenga con firmeza el botón "m" hasta que 5E1 aparezca en la pantalla.

- **Para salir en cualquier momento**

Mantenga presionado el botón "m" hasta que el medidor se apague.

- **Para desplazarse de una pantalla a otra**

Presione el botón "m" para desplazarse por todas las pantallas de configuración tales como alarmas de recordatorio, nivel de sonido, hora, fecha, etc.

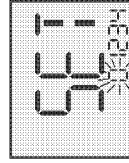
- **Para cambiar la configuración dentro de la pantalla**

Presione el botón "c" (configurar).

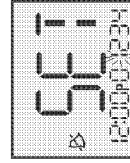
Cómo configurar las alarmas de recordatorio

Puede configurar todas las alarmas de recordatorio (de 1 a 4) o ninguna. Nota: Una alarma de recordatorio nunca sonará durante una prueba.

Para configurar una alarma de recordatorio o varias alarmas de recordatorio, siga estos pasos.

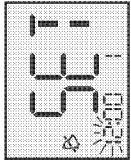


1. Comience con el medidor apagado. Presione el botón "m" y sosténgalo hasta que aparezca 5E1 y 01234 en la pantalla. Ahora está en el modo de configuración de alarma de recordatorio y aparece el "0" intermitentemente.



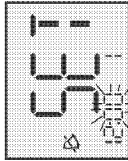
Seleccione
alarma de
recordatorio

2. Para ir a la primera alarma de recordatorio presione el botón "c" una vez. Ahora está listo para configurar la alarma de recordatorio 1 ("1" aparece intermitentemente).



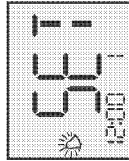
Seleccione la hora

3. Presione el botón “m” para ir a la configuración de la hora. Con la hora intermitente, presione el botón “c” hasta que aparezca la hora correcta.



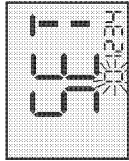
Seleccione los minutos

4. Presione el botón “m” para ir a la configuración de los minutos. Con los minutos intermitentes, presione el botón “c” hasta que aparezca el minuto correcto.



Seleccione el volumen de la alarma de recordatorio

5. Presione el botón “m” para ir a la configuración de volumen de la alarma de recordatorio. La configuración predeterminada está apagada. Presione el botón “c” para seleccionar la configuración de volumen deseada: bajo, alto o apagado.



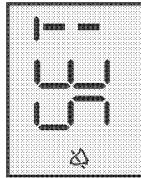
Seleccione la alarma de recordatorio

6. Presione el botón “m” para finalizar la configuración de su alarma. Esto lo llevará nuevamente al modo de configuración de alarma 5E1 de recordatorio. Si desea configurar varias alarmas de recordatorio, presione el botón “c” para ir a la alarma de recordatorio 2. Repita.

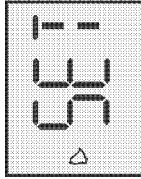
Nota: Para guardar sus configuraciones de alarma de recordatorio y salir del modo configurar, mantenga presionado el botón “m” hasta que el medidor se apague. Presione el botón “m” cuando aparece el “0” intermitentemente para ir a la siguiente pantalla de configuración sin configurar ninguna alarma de recordatorio.

Configuración del sonido

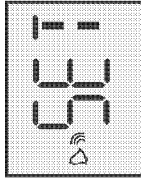
Hay tres (3) opciones de volumen de sonido:



Apagado



Bajo

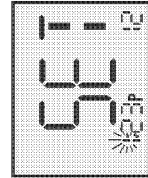


Alto

Hay tres opciones de volumen de sonido que le permiten saber cuando la tira de prueba está llena, cuando se realiza la lectura y cuando se produce un error:

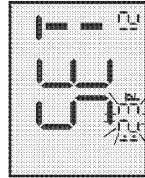
1. Presione el botón “c” hasta que aparezca el nivel de sonido deseado
2. Presione el botón “m” para ir a “Cómo configurar la hora”.

Cómo configurar la hora



Hora

1. Con la hora intermitente, presione el botón “c” hasta que aparezca la hora correcta. El medidor está predeterminado en formato de 12 horas. Aparece la “P” para las horas “PM”.

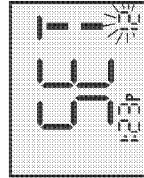


Minuto

2. Presione el botón “m” para ir a la configuración de minutos.
3. Con los minutos intermitentes, presione el botón “c” hasta que aparezcan los minutos correctos.

4. Presione el botón “m” para ir a “Cómo configurar el formato de hora”.

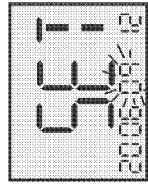
Cómo configurar el formato de hora



Formato de hora

1. Con el modo hora intermitente, presione el botón “c” para desplazarse entre el formato de 12 y 24 horas. La hora se actualiza automáticamente al formato seleccionado.
2. Presione el botón “m” para ir a “Cómo configurar la fecha”.

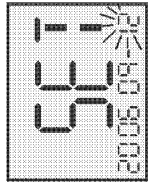
Cómo configurar la fecha y el formato de fecha



1. Con el mes intermitente, presione el botón “c” hasta que aparezca el mes correcto.

2. Presione el botón “m” para ir a la configuración del día.

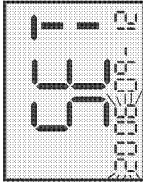
3. Con el día intermitente, presione el botón “c” hasta que aparezca el día correcto.



4. Presione el botón “m” para ir a “Formato de fecha”.

5. Con la fecha intermitente, presione el botón “c” para seleccionar el formato mes-día o día-mes.

La fecha se actualiza automáticamente al formato seleccionado.



6. Presione el botón “m” para ir a la configuración del año.

7. Con el año intermitente, presione el botón “c” hasta que aparezca el año correcto.

Ha completado la configuración del medidor.

- Para ir a “Configuración de alarmas de recordatorio del usuario”, presione el botón “m”.
- Para salir, mantenga presionado el botón “m”.

Resultados del medidor

Memoria del medidor

- **Para ingresar**

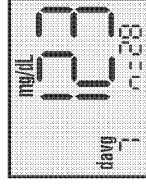
Comience con el medidor apagado (sin haber introducido una tira de prueba). Presione el botón “m” y suéltelo; la primera pantalla de memoria que aparece será su promedio de 7 días.

- **Para salir**

Mantenga presionado el botón “m” hasta que el medidor se apague.

Promedio de 7, 14 y 30 días

La primera pantalla de memoria que ve es su promedio de 7 días. Esto incluye todas las lecturas desde los últimos 7 días, comenzando desde la fecha y la hora actuales que se muestran en el medidor. (Las lecturas de solución de control, BAJO y ALTO no están incluidas en el promedio).



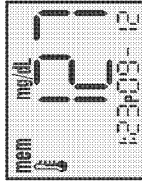
Promedio de 7 días: Ejemplo:

Promedio de 7 días = su promedio de 7 días
n = indica la cantidad de resultados incluidos en su promedio

El botón “c” le permite adelantar los promedios de 14 y 30 días. Continúe presionando el botón “c” para ver los resultados de prueba almacenados. Su resultado más reciente se mostrará primero. El botón “m” le permite retroceder.

Resultados de pruebas

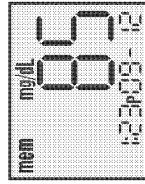
El medidor almacena lecturas de las últimas 400 pruebas con fecha y hora. Puede recorrer todas las lecturas manteniendo presionado el botón “c”. La primera lectura que ve es el resultado más reciente.



Temperatura: Un resultado con el símbolo de termómetro indica que la lectura fue tomada fuera del rango de temperaturas de funcionamiento especificado para el medidor y puede no ser preciso. Este valor se incluye en su promedio de 7, 14 y 30 días.

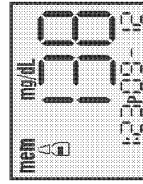
Lectura LO (BAJO): Una lectura LO (BAJO) (inferior a 20 mg/dL) se incluye en la memoria como LO (BAJO).

Lectura HI (ALTO): Una lectura HI (ALTO) (superior a 500 mg/dL) se incluye en la memoria como HI (ALTO).



Prueba de glucosa en sangre

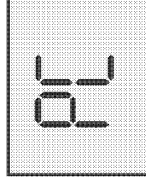
Un resultado sin un símbolo de solución de control (☺) indica que es una lectura de glucosa en sangre. La fecha y hora de la prueba aparecerán en la parte inferior de la pantalla.



Prueba de solución de control

Un valor con (☺) indica que ha marcado esta lectura como una prueba de solución de control. La fecha y hora de la lectura de solución de control aparecerán en la parte inferior de la pantalla.

Cómo descargar datos



El símbolo “PC” muestra cuándo se introdujo un cable de datos en el puerto de datos del medidor. No puede realizar una prueba mientras el cable de datos está en el puerto de datos del medidor.

El medidor mostrará “PC” hasta que el cable de datos se extraiga del puerto de datos.

(Requiere un sistema de control de datos compatible.)

Para obtener más información, visite nuestro sitio web o comuníquese con el Departamento de Atención al Cliente.

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Mantenimiento del medidor

Pila

Su medidor FreeStyle® Lite viene con una pila de litio ya instalada N° 2032 de 3 voltios. La pila le brinda suficiente energía para que el medidor realice 500 pruebas. Si la pila está baja, el símbolo de pila (☐+☐) aparece en todas las pantallas hasta que cambie la pila.

Cuando la pila está baja no se encenderán la retroiluminación de la pantalla y la luz de prueba.

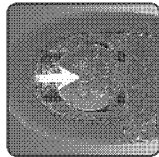
Importante: Cuando aparece este símbolo o cuando la retroiluminación y la luz de prueba comienzan a quedar más tenues, debe cambiar la pila inmediatamente.

- Para evitar perder las configuraciones de la hora y la fecha, cambie la pila antes de que pase un minuto desde que extrajo la pila vieja.
- Si toma más de un minuto cambiar la pila, es posible que deba reiniciar la fecha y la hora para obtener el promedio de 7, 14 y 30 días correcto. Si se pierden la fecha y la hora, las pantallas de hora y fecha muestran 12:00 y 00:00 en forma intermitente hasta que se reinicie.
- El hecho de extraer la pila no afecta el registro de memoria del medidor ni las configuraciones del usuario previamente almacenadas (como formato de hora y de fecha).
- Aún si pierde sus configuraciones de fecha y hora, puede realizar una prueba de glucosa en sangre y los resultados no se verán afectados.

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Cómo cambiar la pila (continuación)

2

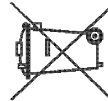


Instale la pila con el polo positivo (+) hacia arriba y hacia usted.

3



Para cerrar, coloque la tapa del compartimiento de las pilas en ángulo dentro del medidor y mueva hacia abajo hasta que quede en su lugar.



Nota: Es necesario desechar las pilas de forma adecuada. Por ello, todas las tiendas que venden pilas cuentan con cajas para la recolección de pilas.

Cuidado de su medidor

Evite que entre suciedad, polvo, sangre, solución de control, agua o cualquier otro líquido en los puertos de la tira de prueba y de datos del medidor.

Limpie la parte exterior del medidor usando un paño humedecido en algunos de estos líquidos:

- Detergente/agua y jabón suave.
- Alcohol isopropílico 70%.
- Una mezcla de una parte de blanqueador doméstico y nueve partes de agua.

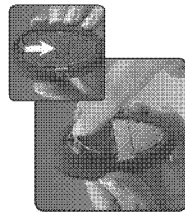
Importante: No sumerja el medidor en agua ni en ningún otro líquido.

Cómo cambiar la pila

Voltee el medidor. Presione el clip de la tapa del compartimiento de las pilas para abrir.

Mueva la tapa del compartimiento de las pilas para abrir y luego apague el medidor.

Para extraer la pila, empuje la pila hacia abajo para liberarla.



Comuníquese con el Departamento de Atención al Cliente de forma gratuita llamando al 1-888-522-5226 o visítenos en www.AbbottDiabetesCare.com.

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ART10792-Rev-B-MAN.indd 27-28

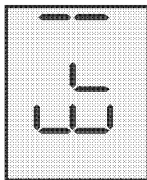
ESPAÑOL

28

1/19/07 4:36:13 PM

Resolución de problemas del sistema Mensajes de error

Error 1



Causas posibles

- La muestra es demasiado pequeña.
- Problema con la tira de prueba FreeStyle Lite.
- Problema con el medidor.
- Glucosa en sangre muy baja (inferior a 20 mg/dL).

Qué debe hacer

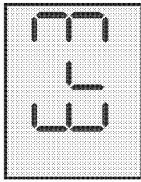
1. Si tiene síntomas como debilidad, sudores, nerviosismo, dolor de cabeza o confusión, siga las recomendaciones de su médico para tratar la hipoglucemia.
2. Realice una prueba de solución de control con una nueva tira de prueba FreeStyle Lite. Si los resultados de la prueba de solución de control están dentro del rango impreso en el lado del vial de su tira de prueba, vuelva a realizar la prueba usando sangre y una nueva tira de prueba FreeStyle Lite.
3. Si la segunda prueba usando solución de control no funciona o si el error persiste, comuníquese con el Departamento de Atención al Cliente.

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Qué debe hacer

1. Si tiene síntomas como sed, fatiga, orina en exceso o visión borrosa, siga las recomendaciones de su médico para tratar la hiperglucemia.
2. Realice una prueba de solución de control con una nueva tira de prueba FreeStyle Lite. Si los resultados de la prueba de solución de control están dentro del rango impreso en el lado del vial de su tira de prueba, vuelva a realizar la prueba usando sangre y una nueva tira de prueba FreeStyle Lite.
3. Si la segunda prueba usando solución de control no funciona o si el error persiste, comuníquese con el Departamento de Atención al Cliente.

Error 3



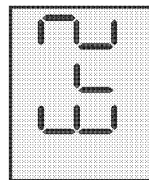
Causas posibles

- Procedimiento de prueba incorrecto. Por ejemplo, colocar sangre en la tira de prueba antes de introducir la tira de prueba en el medidor o aplicar sangre antes de que aparezcan los símbolos gota de sangre y tira de prueba.
- Problema con la tira de prueba FreeStyle Lite.
- Problema con el medidor.

Qué debe hacer

1. Asegúrese de ver los símbolos gota de sangre y tira de prueba en la pantalla antes de aplicar la sangre o la solución de control.
2. Realice una prueba de solución de control con una nueva tira de prueba FreeStyle Lite. Si los resultados de la prueba de solución de control están dentro del rango impreso en el lado del vial de su tira de prueba, vuelva a realizar la prueba usando sangre y una nueva tira de prueba FreeStyle Lite.
3. Si la segunda prueba usando solución de control no funciona o si el error persiste, comuníquese con el Departamento de Atención al Cliente.

Error 2

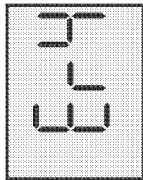


Causas posibles

- Problema con la tira de prueba FreeStyle Lite.
- Problema con el medidor.
- Glucosa muy alta (superior a 500 mg/dL).
- Solución de control ALTA aplicada cuando la temperatura es demasiado fría. (Esto se aplica solamente a una solución de control etiquetada como ALTA).

Comuníquese con el Departamento de Atención al Cliente de forma gratuita llamando al 1-888-522-5226 o visítenos en www.AbbottDiabetesCare.com.

Error 4



Causas posibles

- Problema con una tira de prueba FreeStyle Lite.
- Problema con el medidor.

Qué debe hacer

1. Realice una prueba de solución de control con una nueva tira de prueba. Si los resultados de la prueba de solución de control están dentro del rango impreso en el lado del vial de su tira de prueba, vuelva a realizar la prueba usando sangre y una nueva tira de prueba FreeStyle Lite.
2. Si la segunda prueba usando solución de control no funciona o si el error persiste, comuníquese con el Departamento de Atención al Cliente.

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Resolución de problemas

El medidor no ingresa en el modo de prueba después de introducir una tira de prueba.

Causa probable	Qué hacer
La pila está descargada.	Cambie la pila (y vuelva a configurar la fecha y la hora, si es necesario).
La pila se instaló incorrectamente o no hay pila en el medidor.	Compruebe que la pila esté instalada correctamente con el polo positivo (+) hacia arriba y hacia usted.
La tira de prueba se introdujo al revés, se introdujo el extremo incorrecto o no se introdujo por completo en el medidor.	Introduzca la tira de prueba FreeStyle Lite con el lado impreso hacia arriba y la parte superior de la tira en el medidor.
Medidor o tiras de prueba defectuosos.	Comuníquese con el Departamento de Atención al Cliente.
Sangre u objetos extraños en el puerto de la tira de prueba.	Comuníquese con el Departamento de Atención al Cliente.

La prueba no comienza después de aplicar la muestra de sangre.

Causa probable	Qué hacer
La muestra es demasiado pequeña.	Puede agregar sangre al área de la muestra de la tira de prueba FreeStyle Lite con la cual comenzó durante 60 segundos como máximo después del momento de la primera aplicación. Si es necesario, repita la prueba con una nueva tira de prueba FreeStyle Lite y una muestra de sangre más grande.
Tira de prueba defectuosa.	Repita la prueba con una nueva tira de prueba FreeStyle Lite
Se aplicó la muestra después del tiempo de espera del medidor (dos minutos) y éste se apaga.	Repita la prueba con una tira de prueba nueva. Espere hasta ver los símbolos gota de sangre y tira de prueba en la pantalla antes de aplicar la muestra de sangre.
Medidor o tiras de prueba defectuosos.	Comuníquese con el Departamento de Atención al Cliente.

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Comuníquese con el Departamento de Atención al Cliente de forma gratuita llamando al 1-888-522-5226 o visitenos en www.AbbottDiabetesCare.com.

Especificaciones del sistema FreeStyle Lite

Método de ensayo	Sensor electromecánico coulométrico
Apagado automático	Dos minutos después de la última acción del usuario
Duración de la pila	500 pruebas
Calibración	Equivalente en plasma
Hematocrito	15% a 65%
Unidades de medida	mg/dL
Temperatura para almacenamiento del medidor	-4° a 140° F (-20° a 60° C)
Memoria	400 pruebas de glucosa en sangre y solución de control con fecha y hora
Humedad relativa de funcionamiento	de 5% a 90% (sin condensación)
Temperatura de funcionamiento	40° a 104° F (4° a 40° C)
Fuente de alimentación	Una pila de litio N° 2032 de 3 voltios reemplazable
Rango de resultados	20 a 500 mg/dL
Muestra	Sangre entera, capilar
Tamaño de la muestra	0,3 microlitros (300 nanolitros)
Tamaño	1,57" de ancho x 2,9" de largo x 0,65" de profundidad
Duración de la prueba	Promedio de 5 segundos
Peso	1,4 oz., y esto incluye la pila

Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502

Customer Care is available 24 hours a day, 7 days a week.
El Departamento de Atención al Cliente atiende
las 24 horas del día, los 7 días de la semana.

www.AbbottDiabetesCare.com
Call Customer Care
Toll Free at 1-888-522-5226

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Comuníquese con el Departamento de
Atención al Cliente de forma gratuita
llamando al 1-888-522-5226

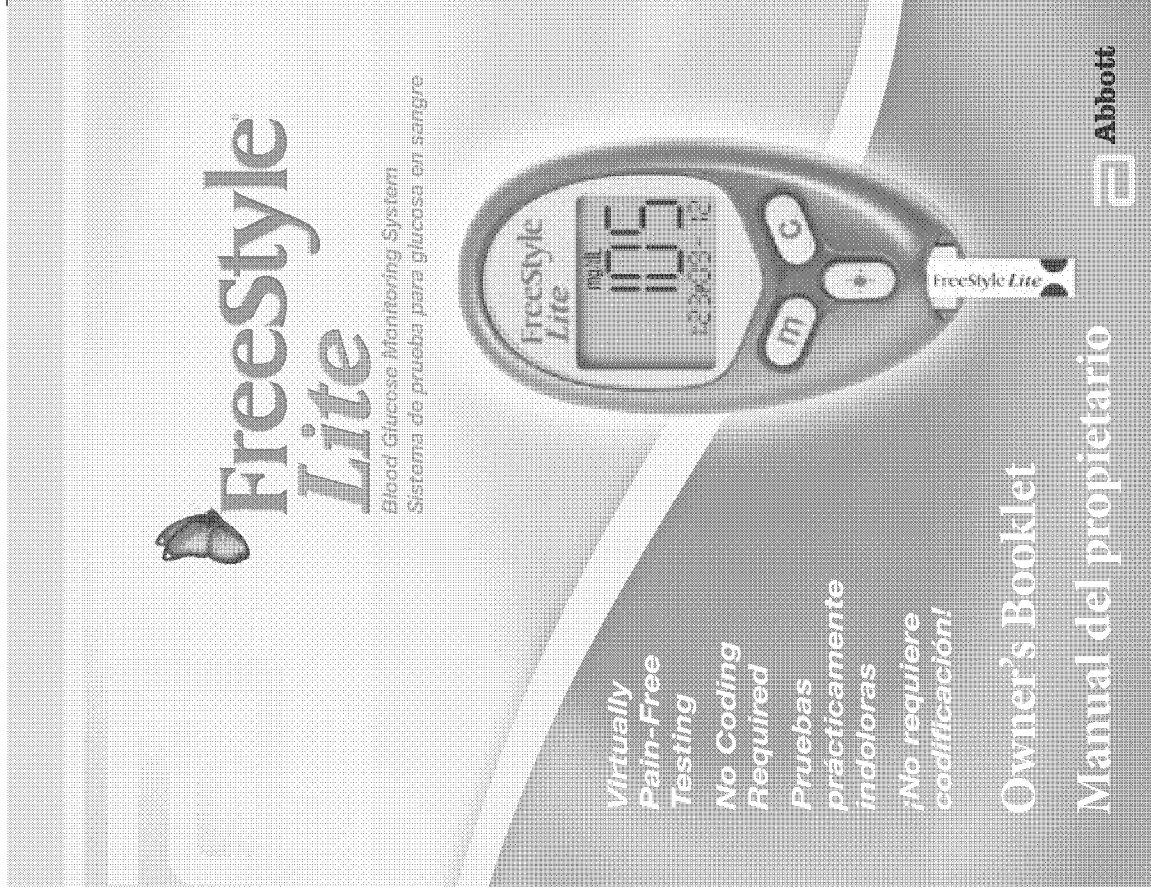
Covered by one or more of the following U.S. Patents:
Cubierto por una o más de las siguientes patentes de los Estados Unidos:
D424,696 and D426,638 and 6,071,391 and 6,120,676 and 6,143,164 and
6,338,790 and 6,299,757 and 6,461,496 and 6,503,381 and 6,591,125 and
6,592,745 and 6,616,819 and 6,618,934 and 6,676,816 and 6,749,740 and 6,893,545.

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Freestyle Lite
Blood Glucose Monitoring System
Sistema de prueba para glucosa en sangre

*Virtually
Pain-Free
Testing
No Coding
Required
Pruebas
practicamente
indoloras
¡No requiere
codificación!*

Owner's Booklet
Manual del propietario

Abbott

The advertisement features a central image of the Freestyle Lite glucometer. The device's screen displays a reading of 105 mg/dL, with a target range of 72-144 mg/dL. The glucometer is shown with a white test strip inserted into its top. The background is a light, textured surface with a white swoosh graphic.

For Artwork and Packaging Department Use Only
Slug 062006

Artwork File Name: ART10792-Rev-B

Orig. Creation Date: 15/May/06

By: WRA

Last Modified Date: 15/Jan/07

Software/Version: Adobe CS2

Dieline:

Bar Code:

Colors: CMYK + PMS286 + PMS7461

Inside: PMS 289 & PMS 124

Fonts: Refer to collection report.

12/Jan/07 By: WRA

19/Jan/07 By: WRA

1/19/07 4:29:50 PM

Do not use if seal is broken or missing.

Freestyle Lite

Blood Glucose Monitoring System

REVISED DATE :	Dec/08
Die Owner:	Size:
ADC, A&P	5-1/8" x 2-3/16" x 6-1/16"

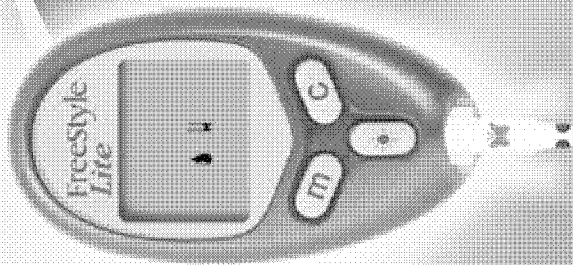
NOT FOR RETAIL SALE

NOT FOR RETAIL SALE

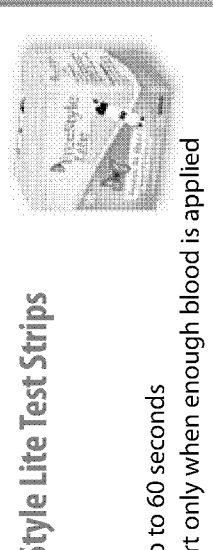
NOT FOR RETAIL SALE

Freestyle Lite

Blood Glucose Monitoring System



- Multiple test sites so your fingers can get a rest
- 4 reminder alarms
- Stores up to 400 results with date and time
- Provides results in 7-, 14- and 30-day averages

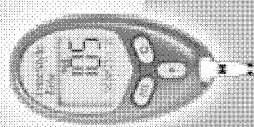


Freestyle Lite Test Strips

...to 60 seconds
...t only when enough blood is applied

Freestyle Lite

Blood Glucose Monitoring System



No Coding Required!

The Freestyle Promise™ Program
At Abbott Diabetes Care, our first priority is you. Join our Freestyle Promise Program* by calling 1-866-246-2683. Membership is FREE. Details inside!

Customer Care
1-888-522-5226
24 hours a day / 7 days a week / Se habla español
Or visit us online at
www.AbbottDiabetesCare.com
90-Day Money Back Guarantee*

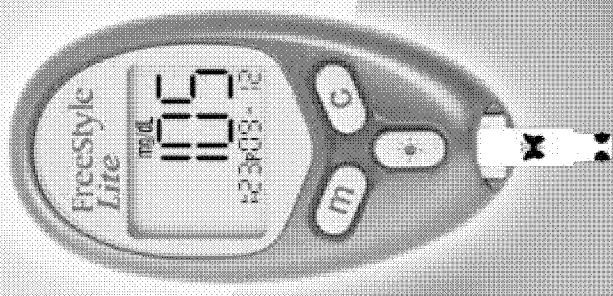
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Freestyle Lite

Blood Glucose Monitoring System

No Coding Required!

World's Smallest Sample Size
Small and Discreet Meter
Results, as Fast as 4 Seconds

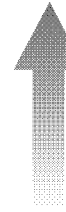
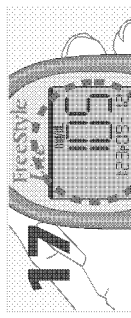
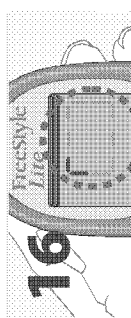
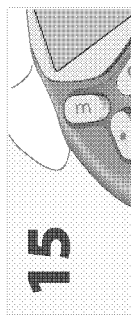
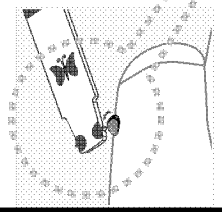
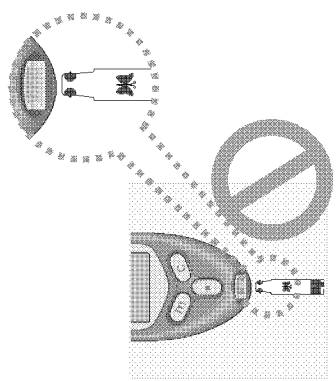
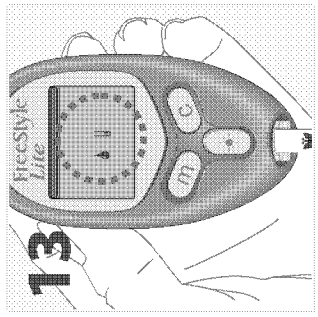
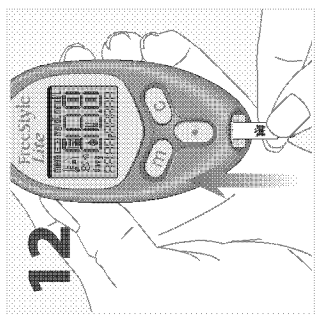
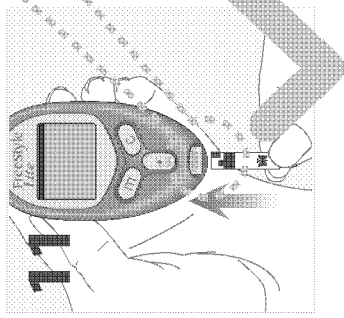
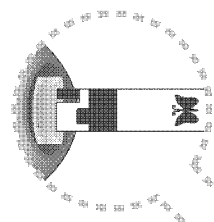
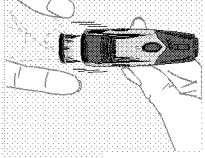
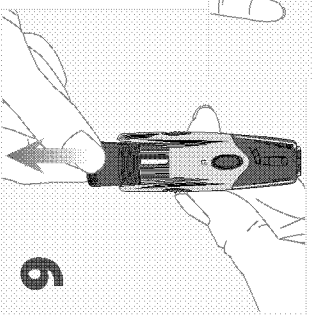
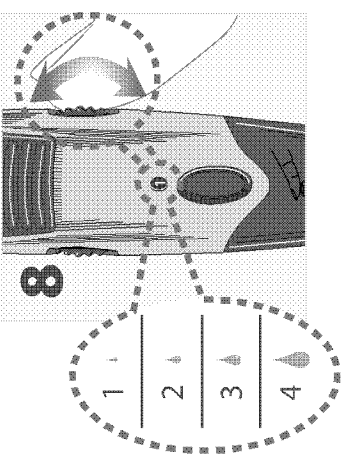
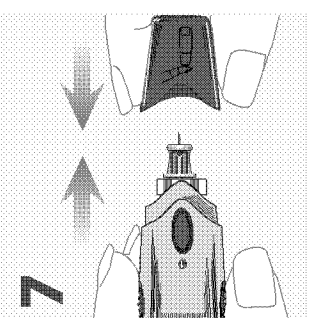
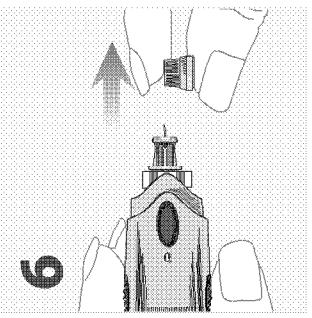
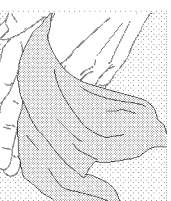


Use Only With Freestyle Lite Test Strips

Use Only With Freestyle Lite Test Strips

Instrucciones incluidas

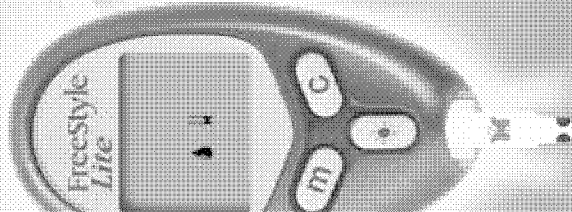
Abbott



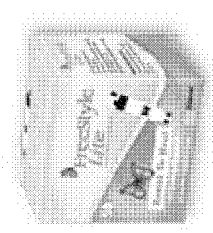
REVISED DATE: June/08	
Die Supplier:	Size:
ADC, A&P	5" x 2.812" x 7.125"

FreeStyle

Blood Glucose Monitoring System



- Multiple test sites so your fingers can get a rest
- 4 reminder alarms
- Stores up to 400 results with date and time
- Provides results in 7, 14- and 30-day averages

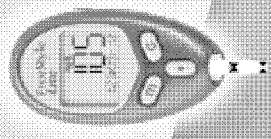


FreeStyle Lite Test Strips

...to 60 seconds
...only when enough blood is applied

FreeStyle

Blood Glucose Monitoring System



No Coding Required!

The FreeStyle Promise™ Program
At Abbott Diabetes Care, our first priority is you. Join our FreeStyle Promise Program* by calling **1-866-246-2683**. Membership is **FREE**. Details inside!

Customer Care
1-888-522-5226

24 hours a day / 7 days a week / Se habla español

Or visit us online at:
www.MyFreeStyle.com
90-Day Money Back Guarantee*

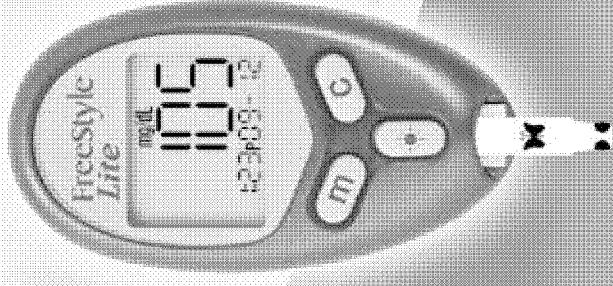
* Abbott may modify or discontinue this program at any time without notice. Offer subject to limitation. See insert for details.

- Test Strips sold separately
- Control Solution available through Customer Care: 1-888-522-5226

Instrucciones incluidas

FreeStyle

Blood Glucose Monitoring System



No Coding Required!

World's smallest sample size

Small and discreet meter

Results, as fast as 4 seconds

Use Only With FreeStyle Lite Test Strips



Use Only With FreeStyle Lite Test Strips



Manufacturer/Manufacturer:
Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502 USA

Customer Care is available 24 hours a day, 7 days a week.
Customer Care is available 24 hours a day, 7 days a week.

www.AbbottDiabetesCare.com
Call Customer Care
Toll Free at 1-888-522-5226

www.AbbottDiabetesCare.com
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6,071,391; 6,120,676; 6,143,164; 6,299,757; 6,338,790; 6,503,381; 6,591,125; 6,607,658; 6,616,819;
6,618,934; 6,676,816; 6,749,618; 6,749,740; 6,893,545; 6,942,518; 7,058,437; 7,074,308; Des444,557;
Des447,566; Des450,854; EPI119637; EP1145000; EP0958495; CA2346415; CA2358993; CA2423837.
Additional patents may be issued and/or pending.

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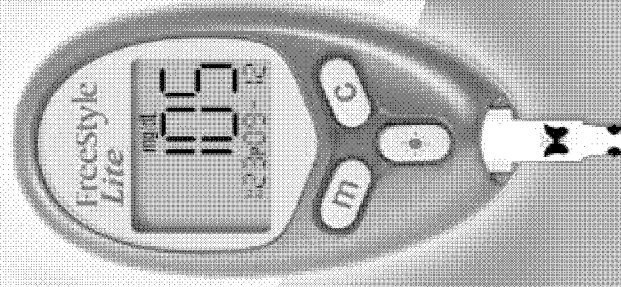
DOC18313 Rev. A 06/09

FOI - Page 264 of 590

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FreeStyle Lite

Blood Glucose Monitoring System
Blood Glucose Monitoring System



No Coding
Required

No Coding
Required

Owner's Booklet
Owner's Booklet



6/22/09 9:00:36 AM

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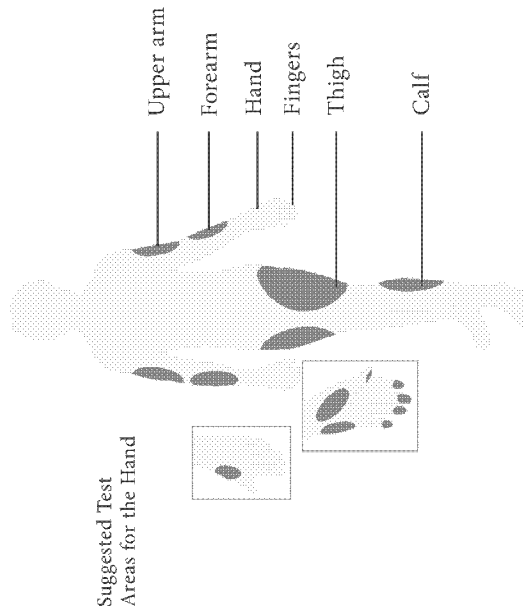
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LANGUAGE1

LANGUAGE2

The FreeStyle Lite® System Uses a Tiny Sample of 0.3µl So You Can Test on a Variety of Locations

Many Test Sites Available



The human figure above shows the areas where you can test with the FreeStyle Lite system. Avoid moles, veins, bones, and tendons.

WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Important Information About Your FreeStyle Lite® Blood Glucose Monitoring System

How the FreeStyle Lite System Should Be Used

- The FreeStyle Lite system is intended for use outside the body (in other words, *in vitro* diagnostic use only).
- The FreeStyle Lite system is used for measuring blood glucose (also known as blood sugar) from samples taken from the forearm, upper arm, hand, thigh, calf, or fingers.
- The FreeStyle Lite meter should only be used with FreeStyle Lite test strips and FreeStyle control solution. Using other test strips and control solution with this meter can produce inaccurate results.

Do use the FreeStyle Lite system for:

- Testing blood glucose.
- Testing glucose in fresh capillary whole blood samples.

Do not use the FreeStyle Lite system for:

- The diagnosis of diabetes.
- Testing on newborns.
- Testing of arterial blood.

LANGUAGE1

Important Information About Your FreeStyle Lite® Blood Glucose Monitoring System (continued)

WARNING:

- The FreeStyle Lite System contains small parts that may be dangerous if swallowed.

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

LANGUAGE2

LANGUAGE1

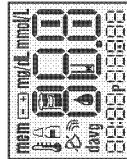
Important Health-Related Information

- Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L) you should contact your healthcare professional and follow his or her treatment advice.
- For additional information, consult your test strip product information.

LANGUAGE2

The FreeStyle Lite® Meter and How It Works

System Check Screen
 This screen always appears when the meter is turned on so that you can make sure the display is working properly. Do not use the meter if the system check screen does not match the example here. Please call Customer Care.



Display Screen

Displays your test results and other important information.

m (Mode) Button

- Move to different mode settings.
- Scrolls backward.
- Silence a reminder alarm.

Light Button

Controls the display backlight and test light.

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

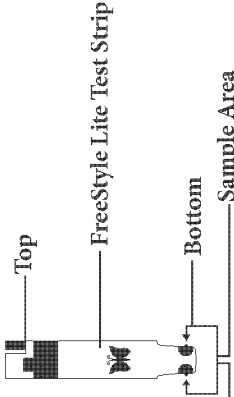
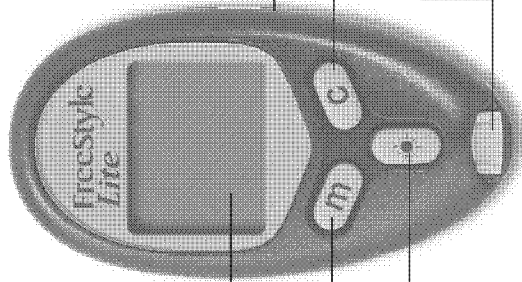
Download test results. Requires a compatible data management system. *For more information, please go to our website or call Customer Care.*

c (Configure) Button

- Marks a control solution test.
- Scrolls forward.
- Displays clock.
- Silence a reminder alarm.

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.



Sample Area

The FreeStyle Lite[®] Meter Display

Memory Mode Symbol

Shows you test results stored in the meter memory.

Control Solution Test Result Symbol

Shows that you have marked a test result as a control solution test.

Battery Symbol

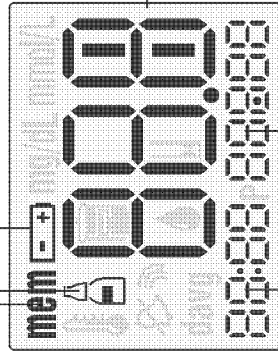
Appears when you should replace your meter battery.

Test Result Area

Displays test results.

Message Area

Displays date, time, and number of tests.



Thermometer Symbol

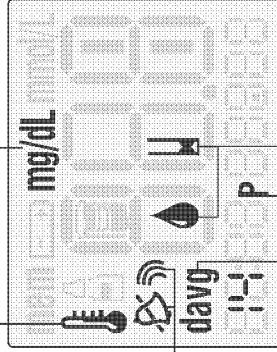
Appears if your meter is out of operating temperature range.

Sound Level Symbols

Indicates high, low, or off sound volume.

Day Average Symbol

Shows the average value of glucose readings from the last 7-, 14- or 30-days.



mg/dL (U.S. Standard)

Indicates unit of measurement.

Blood Drop and Test Strip Symbols

These symbols work together in an animation to tell you when the meter is ready for you to apply blood or control solution.

P Symbol

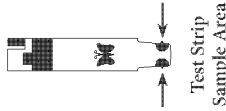
Indicates PM in 12-hour format only (for example 4:00 p.m.)

LANGUAGE1

The FreeStyle Lite® Test Strip

Apply blood or control solution to only **one** Test Strip Sample Area per test.

Important: Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



LANGUAGE2

WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Lite® meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

Important Test Strip Information

- The FreeStyle Lite System has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight and heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.

LANGUAGE1

• Do not use test strips beyond the expiration date. This may cause inaccurate results.

• Do not bend, cut, or alter FreeStyle Lite® test strips.

Note: For further information, refer to the FreeStyle Lite test strip package insert.

The FreeStyle® Control Solution

Each FreeStyle control solution vial contains a red liquid with a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.

A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

For information on how to obtain control solution, call Customer Care at 1-888-522-5226.

Control Solution Information

FreeStyle® control solution is good for three months after opening the bottle or until the expiration date printed on the label, whichever comes first.

Important: Count forward three months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle.

Example: You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.

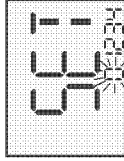
- Use only FreeStyle control solution with your FreeStyle Lite system.
- Replace the cap on the control solution bottle immediately after using.
- Do not use control solution past the expiration date.
- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when used between 59° to 104° F (15° to 40° C).
- Control solution test results should fall within the range printed on the test strip vial label.

Important: The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.

- If control solution results are out of this range, repeat the test.
- If your control solution test results continue to fall outside the range printed on the test strip vial, do not use the FreeStyle Lite system to test your blood glucose. Contact Customer Care.

Caution: Results from FreeStyle control solution tests do not reflect your blood glucose level.

Meter Setup



- **To Enter Setup Mode**
Start with the meter off (no test strip inserted). Press and firmly hold the “m” button until the 5 E 1 display screen appears.

- **To Exit at Any Time**

Press and hold the “m” button until the meter turns off.

- **To Move Through the Screens**

Press the “m” button to move through all the setup screens such as reminder alarms, sound level, time, date, and so on.

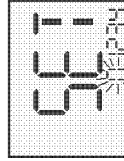
- **To Change Settings Within the Screen**

Press the “c” (configure) button.

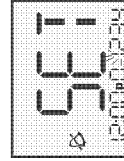
Setting the Reminder Alarms

You may set up any or all of the reminder alarms (1-4). Note: A reminder alarm will never sound during a test.

To set a reminder alarm or multiple reminder alarms, please follow these steps.

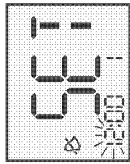


1. Start with the meter off. Press the “m” button and hold until the 5 E 1 display appears with 01234. You are now in the reminder alarm setting mode and the “0” is blinking.

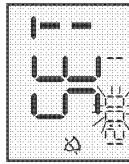


2. To move to the first reminder alarm press the “c” button once. You are now ready to set reminder alarm 1 (“1” is blinking).

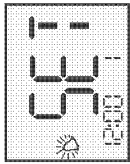
Select reminder alarm



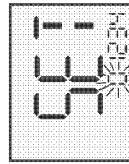
Select hour



Select minute



Select reminder alarm volume



Select reminder alarm

3. Press the “m” button to move to the hour setting. With the hour blinking, press the “c” button until the correct hour appears.

4. Press the “m” button to move to the minute setting. With the minute blinking, press the “c” button until the correct minute appears.

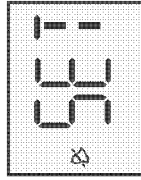
5. Press the “m” button to move to the reminder alarm volume setting. Default setting is off. Press the “c” button to select the desired volume setting: low, high, or off.

6. Press the “m” button to finalize your alarm setting. This will bring you back to the reminder alarm setting 5:00 mode. If you wish to set multiple reminder alarms press “c” to move to reminder alarm 2. Repeat.

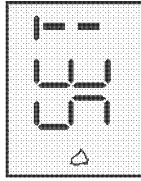
Note: To save your reminder alarm settings and exit setup mode, press and hold the “m” button until the meter turns off. Press the “m” button when “0” is blinking to move to the next setup screen without setting any reminder alarms.

Setting the Sound

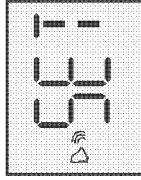
There are three (3) sound volume options:



Off



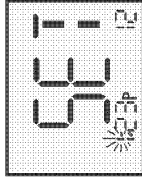
Low



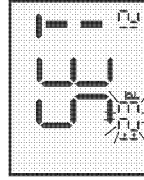
High

There are three sound volume options to let you know when the test strip is full, when the reading is done, and when an error occurs:

1. Press the “c” button until the desired sound level appears
2. Press the “m” button to move to “Setting the Time.”



Hour



Minute

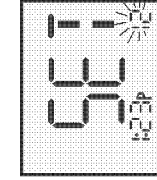
Setting the Time

1. With the hour blinking, press the “c” button until the correct hour appears. The default for the meter is the 12-hour time format. The “p” displays for “PM” times.

2. Press the “m” button to move to minute setting.

3. With the minute blinking, press the “c” button until the correct minute appears.

4. Press the “m” button to move to “Setting the Time Format.”



Time Format

Setting the Time Format

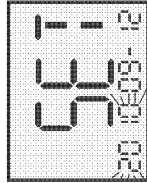
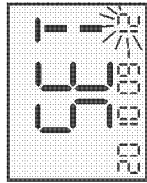
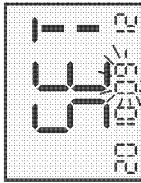
1. With the hour mode blinking, press the “c” button to move between 12-hour and 24-hour format. The time automatically updates to the format selected.

2. Press the “m” button to move to “Setting the Date.”



Setting the Date and Date Format

1. With the month blinking, press the “c” button until the correct month appears.
2. Press the “m” button to move to the day setting.
3. With the day blinking, press the “c” button until the correct day appears.
4. Press the “m” button to move to “Date Format.”
5. With the date blinking, press the “c” button to select month-day or day-month format. The date automatically updates to the format selected.
6. Press the “m” button to move to the year setting.
7. With the year blinking, press the “c” button until the correct year appears.

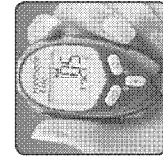


You have completed Meter Setup.

- To move to “Setting the User Reminder Alarms” press the “m” button.
- To exit press and hold the “m” button.

Using Your Meter's Lights

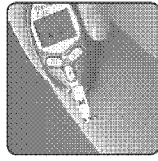
Depending on what mode your meter is in, pressing the light button (☀) turns on either the display backlight or the test light.



Using the Display Backlight

Pressing the light button powers on the display backlight in all modes except when applying a sample. When applying a sample, the light button turns the test light on.

The display backlight goes out when you press the light button (☀) again or when the meter is inactive for 10 seconds.



Using the Test Light

Pressing the light button while the Blood Drop and Test Strip symbols appear on the display screen powers on the test light

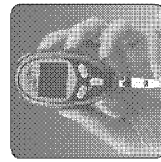
The test light goes out:

- When you press the light button again.
- When the meter receives the correct amount of blood for a test (the FreeStyle Lite test strip is filled).
- After 60 seconds of no activity.
- When a FreeStyle Lite test strip is removed from the meter.

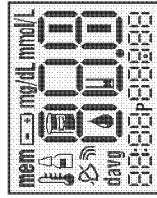
If you use either the backlight or the test light during the test mode, the backlight lights again to show you the test results after the measurement is complete.

Performing a Control Solution Test

1



Insert the top of the test strip into your meter until it stops. This will power on the meter.

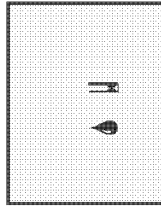


System Check Screen

When the meter powers on, this screen will appear so that you can make sure the display is working properly.

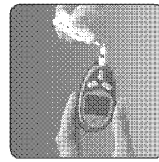
System Check

2



Wait for the meter to display the Blood Drop and Test Strip symbols.

3



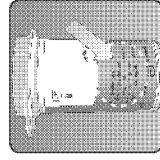
Gently touch only *the Sample Area* of the test strip to the control solution.

Important: Do not apply control solution to both Test Strip Sample Areas.

If the sound prompt is on, your meter will beep when the test strip is full. A short line then moves clockwise around the display screen while the sample is processing.

The result will appear on the display screen and if the sound is on, your meter will beep twice. To mark the result as a control solution result, press and hold the “c” button for two seconds until the control solution symbol (c) appears at the top left of the display screen.

If you have marked a blood glucose test as a control solution test by mistake, you can unmark it by pressing and holding the “c” button again for two seconds.

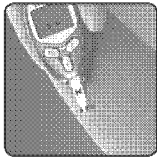


Compare your control solution test result to the range printed on your test strip vial label. Your control solution results should fall within the range printed on the side of your test strip vial.

Out of range test results may be caused by:

- Error in performing the test.
- Expired or contaminated control solution.
- Improper coding of the meter.
- Test strip deterioration.
- Meter malfunction.

Testing Your Blood Glucose



Important: To ensure accurate results, wash your hands and test site (for example, your forearm) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

- With the FreeStyle Lite® meter, you can test your blood glucose on your forearm, upper arm, hand, thigh, calf, or fingers.
- Testing with the FreeStyle Lite meter requires a very small sample size, 0.3 microliters of blood; about the size of pinhead (example: ••).

WARNING:

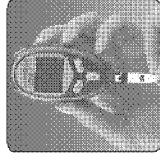
We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Times when you may be checking for low blood glucose include:

- When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.
- When you have delayed a meal after taking insulin.
- When your healthcare professional advises you to do so.

LANGUAGE1

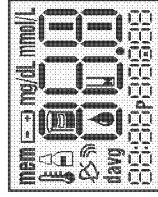
Performing a Blood Glucose Test



Prepare Your Meter

Insert a FreeStyle Lite test strip into the meter until it stops. The meter will power on.

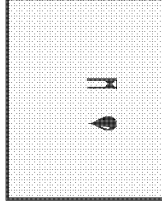
Note: If you do not start the test within two minutes, the meter will turn off. To restart your meter, take out the unused FreeStyle Lite test strip and reinsert it into the meter.



System Check Screen

When the meter powers on, this screen will appear so that you can make sure the display is working properly.

System Check



Blood Drop and Test Strip Symbols

The Blood Drop and Test Strip symbols will appear on the display screen. Your meter is now ready to apply blood sample.

Potential Bruising

It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another test site.

LANGUAGE1

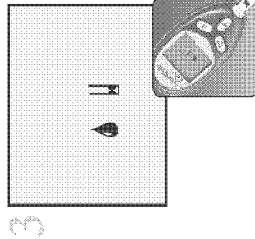
LANGUAGE2

LANGUAGE1

2 Obtain a Blood Sample

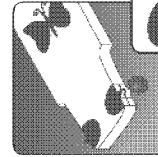
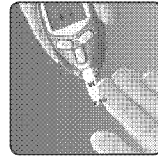
Select a test site. There are differences in testing on fingers versus other alternative sites. Use your lancing device to obtain a blood sample. Refer to the lancing device insert for detailed instructions on how to use the FreeStyle lancing device.

WARNING: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.



3 Filling the FreeStyle Lite Test Strip with Blood

- a. Make sure that the FreeStyle Lite test strip is in the meter and the meter is powered on. You are now ready to apply the blood sample.
- b. Bring the FreeStyle Lite test strip to the blood sample at a slight angle.
- c. The FreeStyle Lite test strip pulls the blood into the strip through the sample area.



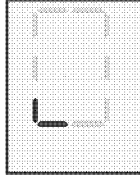
Test Strip Sample Area

LANGUAGE1

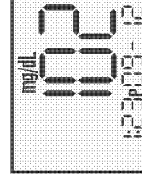
Important Test Strip Information

- Do not press the FreeStyle Lite test strip against the test site.
- Do not scrape the blood onto the FreeStyle Lite test strip.
- Do not apply blood to the flat side of the FreeStyle Lite test strip.
- Do not apply blood to the FreeStyle Lite test strip when the FreeStyle Lite test strip is out of the meter.
- Do not put blood or foreign objects into the FreeStyle Lite test strip port.

4 Waiting for Result



- Do not pull the FreeStyle Lite test strip away from the sample until you hear one beep or see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.
- If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same sample area of the test strip from which you started for up to 60 seconds from the time of the first application.



- The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps.
- The time that the meter takes to display a reading depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

LANGUAGE2

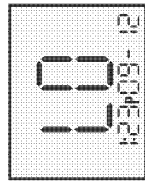
LANGUAGE2

LANGUAGE1

LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle Lite™ meter displays results from 20 to 500 mg/dL (1.1 to 27.8 mmol/L).

If your test result is lower than 20 mg/dL (1.1 mmol/L), LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).

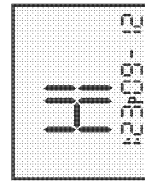


LO Reading

LO Reading without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, follow your doctor's recommendation to treat hypoglycemia.

If your test is above 500 mg/dL (27.8 mmol/L), HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).



HI Reading

HI Reading without Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip. If you still get a HI reading, follow your doctor's recommendation to treat hyperglycemia.

LANGUAGE1

Meter Results
Meter Memory

- To Enter

Start with the meter off (no test strip inserted). Press the “m” button and release; the first memory screen to appear will be your 7-day average.

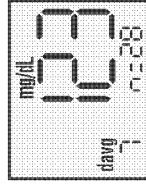
- To Exit

Press and hold the “m” button until the meter turns off.

7-, 14-, 30- Day Average

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)

Example:



7 day = your 7-day average
n = indicates the number of results included in your average

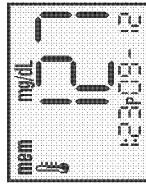
The “c” button allows you to scroll forward to 14- and 30-day averages. Continue to press the “c” button to view stored test results. Your most recent result will display first.

The “m” button allows you to scroll backward.

LANGUAGE1

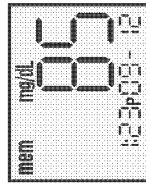
Test Results

The meter stores the last 400 test readings with time and date. You may scroll through all of the readings by pressing and holding the “c” button. The first reading you see is the most recent result.



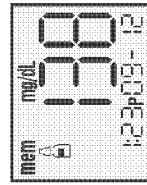
LO Reading: A LO reading (under 20 mg/dL or 1.1 mmol/L) is included in the memory as LO.

HI Reading: A HI reading (over 500 mg/dL or 27.8 mmol/L) is included in the memory as HI.



Blood Glucose Test

A result without a control solution symbol (A) indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.

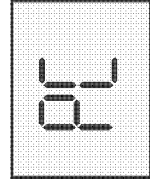


Control Solution Test

A value with (A) indicates that you have marked this reading as a control solution test. The date and time of the control solution reading will appear on the bottom of the screen.

LANGUAGE1

Data Download



The “PC” symbol displays when a data cable is inserted in the meter data port. You cannot perform a test while the data cable is in the meter data port.


The meter will display “PC” until the data cable is removed from the data port.

(Requires a compatible data management system.)

For more information, please go to our website or call Customer Care.

LANGUAGE2

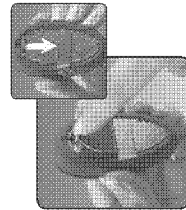
Meter Maintenance
Battery

Your FreeStyle Lite® meter comes with one preinstalled, #2032, 3 volt, lithium battery. The battery provides enough power for the meter to perform about 500 tests. If your battery runs low, the battery symbol () appears on every display screen until you change the battery. When the battery runs low, the display backlight and test light may not power on.

Important: *When this symbol appears, or when the backlight and test light begin to dim, you should replace the battery immediately.*

- To avoid losing the time and date settings, replace the battery within one minute of removing the old battery.
- If you take more than one minute to replace the battery, you may need to reset the time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, the time and date displays flash 12:00 and 00:00 until they are reset.
- Removing the battery does not affect the meter's memory log or previously-stored user settings (such as date and time format).
- Even if you lose your time and date settings – you can perform a blood glucose test, and results will not be affected.

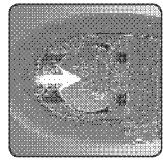
Replacing the Battery



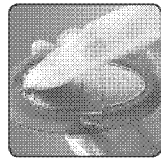
Turn the meter over. Press in the battery door clip to open. Swing the battery door up to open and then off the meter.

To remove the battery, push the battery downward to release the battery.

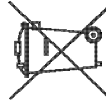
Replacing the Battery (continued)



2 Install the battery with the positive (+) sign up toward you.



3 To close, angle the battery door back onto the meter and swing down until it snaps into place.



Note: The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

Caring for Your Meter

Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip and data ports.

Clean the outside of the meter using a cloth dampened with one of the following:

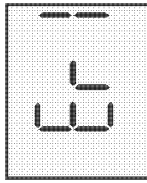
- Mild detergent/mild soap and water.
- 70% isopropyl alcohol.
- A mix of one part household bleach, nine parts water.

Important: *Never immerse the meter in water or any other liquid.*

System Troubleshooting

Error Messages

Error 1

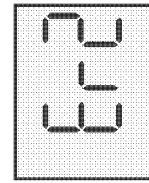


Possible Causes

- Sample is too small.
- Problem with the FreeStyle Lite® test strip.
- Problem with the meter.
- Very low blood glucose (less than 20 mg/dL or 1.1 mmol/L).

What You Should Do

1. If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your doctor's recommendation for treating hypoglycemia.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.



Error 2

Possible Causes

- Problem with the FreeStyle Lite test strip.
- Problem with the meter.
- Very high glucose (above 500 mg/dL or 27.8 mmol/L).
- HIGH control solution applied when temperature is too cold. (This applies only to control solution that is labeled as HIGH.)

29 Call Customer Care Toll Free at 1-888-522-5226 www.AbbottDiabetesCare.com

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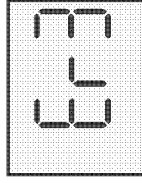
DOC18313_Rev-A-Man.indd 29-30

LANGUAGE1

What You Should Do

1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your doctor's recommendation for treating hyperglycemia.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite Test Strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 3



Possible Causes

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter or applying blood before the Blood Drop and Test Strip symbols display.
- Problem with the FreeStyle Lite test strip.
- Problem with the meter.

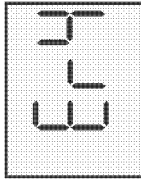
What You Should Do

1. Be sure you see the Blood Drop and Test Strip symbols on the display screen before you apply blood or control solution.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

30

6/22/09 9:16:52 AM

Error 4



Possible Causes

- Problem with FreeStyle Lite® test strip.
- Problem with the meter.

What You Should Do

1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite® Test Strip.
2. If the retest using control solution does not work or the error persists, call Customer Care.

Troubleshooting

Meter does not enter the test mode after inserting a test strip.

Probable Cause	What to Do
The battery is dead.	Replace the battery (and reset the date and time, if necessary.)
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the FreeStyle Lite test strip with the printed side up and the top of the strip in the meter.
Defective meter or test strips.	Call Customer Care.
Blood or foreign objects put into the test strip port.	Call Customer Care.

Test does not start after applying the blood sample.

Probable Cause	What to Do
Blood sample too small.	You may add blood to the same sample area of the FreeStyle Lite test strip from which you started for up to 60 seconds from the time of the first application. If necessary, repeat the test using a new FreeStyle Lite test strip and a larger blood sample.
Defective test strip.	Repeat the test with a new FreeStyle Lite test strip.
Sample applied after meter times out (two minutes) and turns off.	Repeat the test using a new test strip. Wait until you see the Blood and Test Strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Call Customer Care.

FreeStyle Lite System Specifications

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	500 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	mg/dL
Meter Storage Temp.	-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 #2032, 3 volt, lithium battery, replaceable
Result Range	20 to 500 mg/dL (1.1 to 27.8 mmol/L)
Sample	Fresh capillary whole blood samples
Sample Size	0.3 microliter (300 nanoliters)
Size	Width 1.57" x Length 2.9" x Depth 0.65"
Weight	1.4 oz. (40 grams) including battery

LANGUAGE1

LANGUAGE2



Shelf-Life

(b)(4)

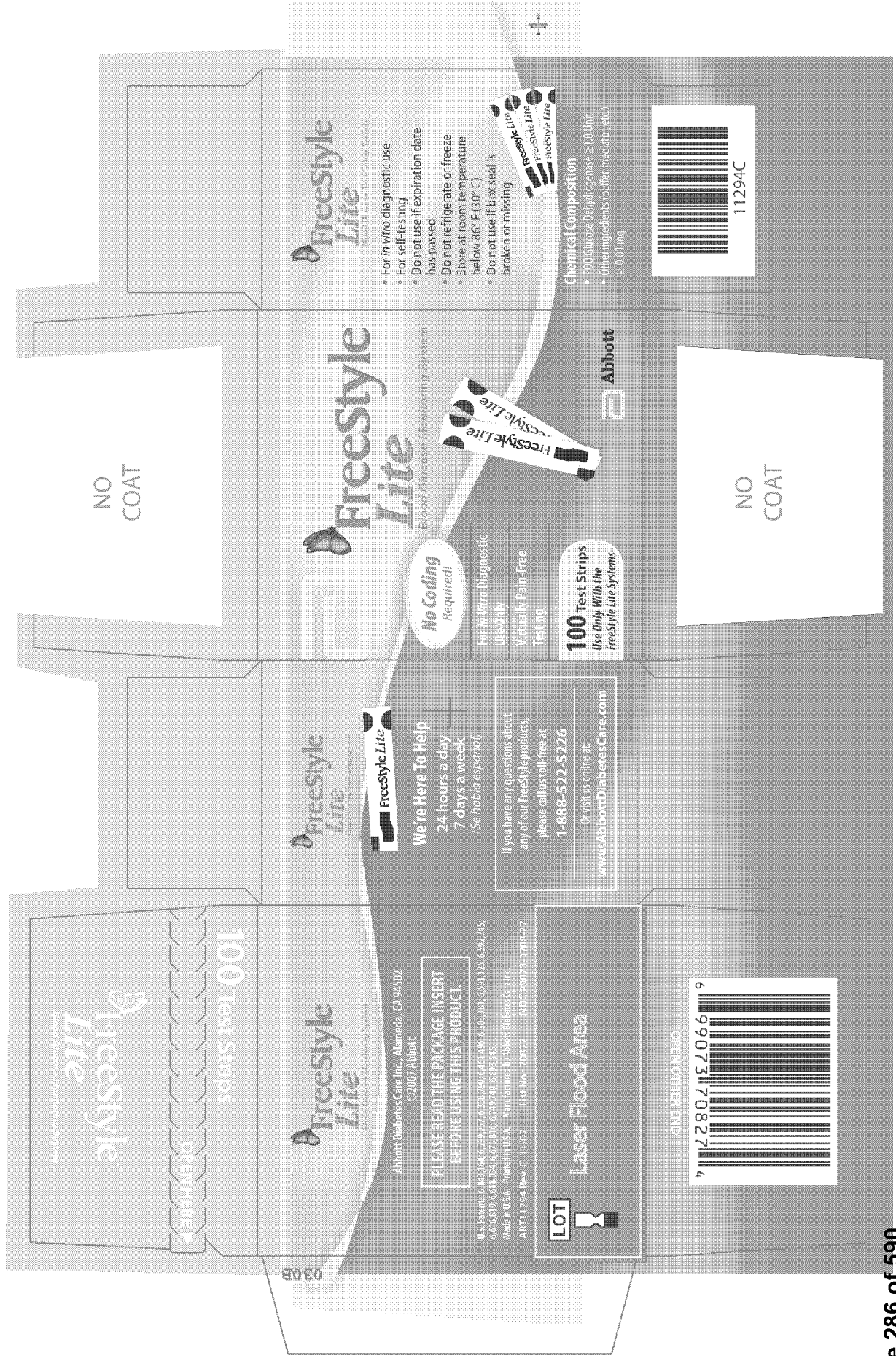


(b)(4)



VERSION 030B
2-1/2 x 1-3/4 x 2-11/16

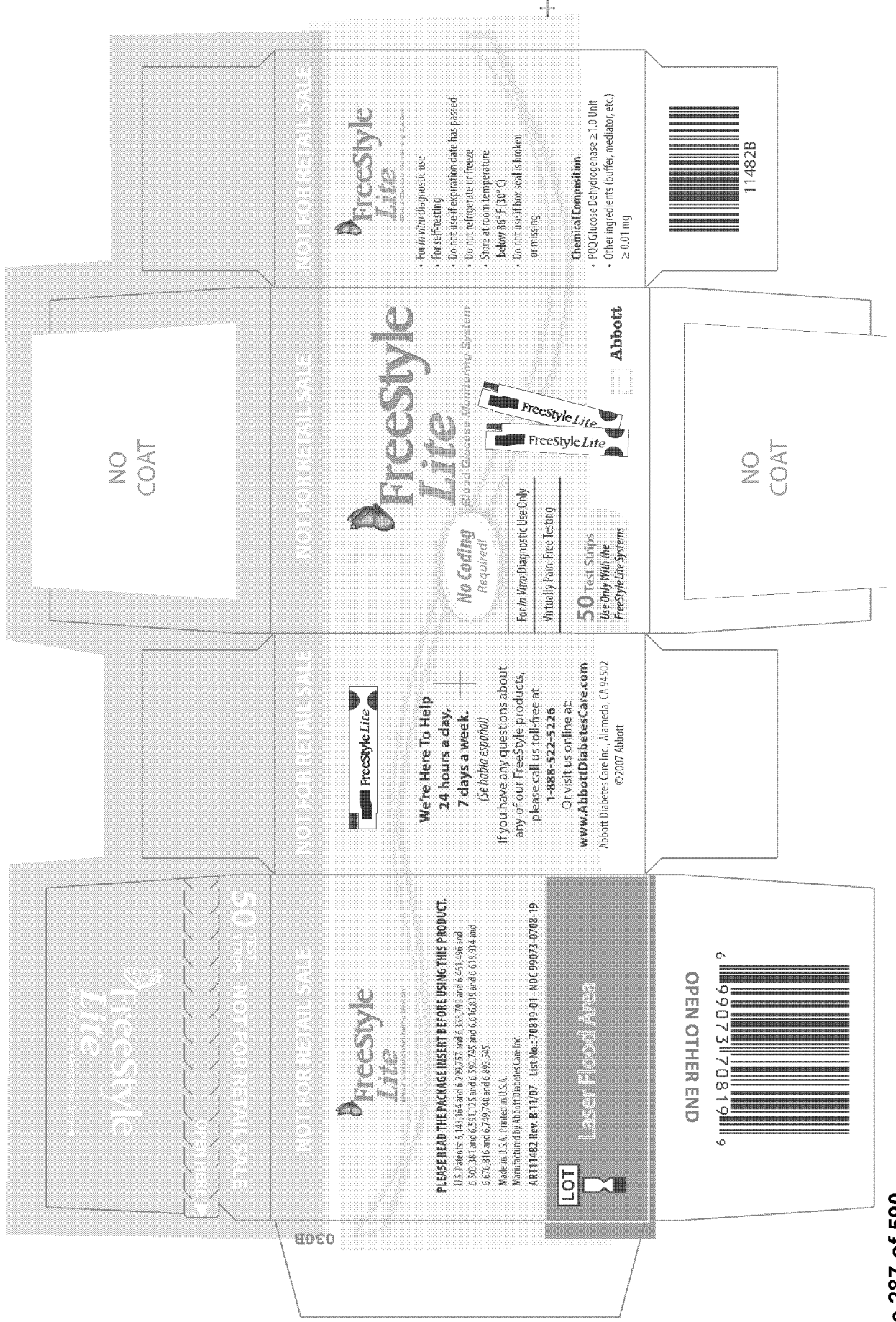
PRINT SIDE



VERSION 030B

2-1/2 x 1-3/4 x 2-11/16

PRINT SIDE



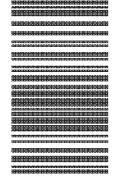
NOT FOR RETAIL SALE



- For *in vitro* diagnostic use
- For self-testing
- Do not use if expiration date has passed
- Do not refrigerate or freeze
- Store at room temperature below 86° F (30° C)
- Do not use if box seal is broken or missing

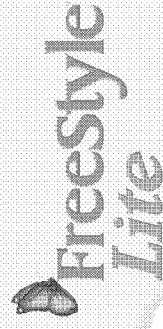
Chemical Composition

- PQQ Glucose Dehydrogenase ≥ 1.0 Unit
- Other ingredients (buffer, mediator, etc.) ≥ 0.01 mg



11482B

NOT FOR RETAIL SALE



Blood Glucose Monitoring Systems

No Coding Required!

For *In Vitro* Diagnostic Use Only

Virtually Pain-Free Testing

50 Test Strips

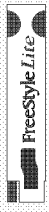
Use Only With the Freestyle Lite Systems

Abbott



NO COAT

NOT FOR RETAIL SALE



We're Here To Help
24 hours a day,
7 days a week.
(Se habla español)

If you have any questions about any of our Freestyle products, please call us toll-free at **1-888-522-5226**

Or visit us online at:

www.AbbottDiabetesCare.com

Abbott Diabetes Care Inc., Alameda, CA 94502 ©2007 Abbott

NOT FOR RETAIL SALE



PLEASE READ THE PACKAGE INSERT BEFORE USING THIS PRODUCT.

U.S. Patents 6,143,764 and 6,299,757 and 6,338,790 and 6,461,496 and 6,503,383 and 6,591,125 and 6,592,745 and 6,616,819 and 6,618,914 and 6,626,816 and 6,749,740 and 6,893,245

Made in U.S.A. Printed in U.S.A.

Manufactured by Abbott Diabetes Care, Inc.

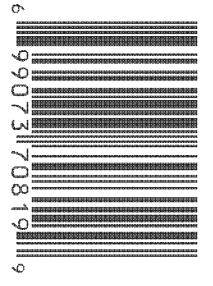
ART11482 Rev. B 11/07 List No.: 70819-01 NDC 99073-0708-19

LOT



Laser Flood Area

OPEN OTHER END



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030B

VERSION 030B

2-1/2 x 1-3/4 x 2-11/16

PRINT SIDE

Freestyle Life
 50 Test Strips
 OPEN HERE ▶

Freestyle Life
 We're Here To Help
 24 hours a day
 7 days a week
 (See table elsewhere)

Freestyle Life
 No Coding Required!

Freestyle Life
 For in vitro diagnostic use
 For self-testing
 Do not use if expiration date has passed
 Do not refrigerate or freeze
 Store at room temperature below 86° F (30° C)
 Do not use if box seal is broken or missing

Freestyle Life
 Abbott Diabetes Care Inc., Alameda, CA 94402
 ©2007 Abbott
 PLEASE READ THE PACKAGE INSERT BEFORE USING THIS PRODUCT.
 U.S. Patents 5,744,639; 5,797,523; 5,749,240; 5,801,516; 5,806,381; 5,931,125; 6,492,745; 6,676,816; 6,816,948; 6,976,116; 6,997,240; 6,997,585
 Made in U.S.A. - Product of U.S.A. - Patent licensed by Abbott Diabetes Care Inc.
 ART11162 Rev. C 11/97 LEK06670827 NDC 59073-0716-22

LOT

Laser Flood Area

Freestyle Life
 For in vitro diagnostic use only
 Virtually Pain-Free Testing
 50 Test Strips Use Only With the Freestyle Life Systems

Freestyle Life
 Abbott

Freestyle Life
 Chemical Composition
 - 100 Glucose Dehydrogenase ≥ 1.0 Unit
 - Other ingredients (buffer, protein, etc.) ≤ 0.1 mg

6 22807 2066 6
 22807 208222 6
 OPEN OTHER END

NO COAT

NO COAT

11162C

FreeStyle Lite Blood Glucose Test Strips-Product Information
 Only for use with FreeStyle Lite Blood Glucose Meters
 to Test for Glucose in Whole Blood

**PLEASE READ THIS INFORMATION AND YOUR OWNER'S BOOKLET
 USING THE FREESTYLE LITE STRIPS TO TEST YOUR BLOOD SUGAR
 Customer Care at 1-888-522-5226, 24 hours a day, 365 days a year.**

FreeStyle Lite blood glucose meters to measure glucose (sugar) in whole blood. FreeStyle Lite test strips are used for testing outside the body
 monitoring systems are intended for use in the home and in professional settings to monitor blood glucose levels.

Essary part of the treatment plan of people with diabetes mellitus¹. The Diabetes Control and Complications Trial (DCCT)² has confirmed the
 art of a larger intensive strategy to tightly control blood glucose concentrations. The DCCT showed that tight control can actually reduce the risk
 kidney disease, nerve damage, and heart and circulatory system problems by about 60%.

FreeStyle Lite blood glucose meters, will accurately measure your blood glucose value. When the **sample area** of the FreeStyle Lite strip is
 blood into the sample chamber and your glucose reading is displayed on the meter. The test measures glucose from 20 mg/dL to 500 mg/dL.
 the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

Owner's Booklet. If you have any questions about your FreeStyle Lite meter or test strips, call Customer Care at 1-888-522-5226.

Test results without the consent and advice of a physician or health care professional is not recommended.

Blood glucose levels at the fingertips are not always the same as those at other test sites. This is a normal physiological difference and does not reflect the accuracy of the system.

and:

Drying agents may be harmful if inhaled or swallowed and may cause skin or eye irritation.

If the range printed on the test strip vial, repeat the test with a new test strip. If the test result is still outside the range printed on the test strip vial, the FreeStyle Lite system may not be

you get a control solution test result within the range printed on the test strip vial label.

er during a single test. This may cause inaccurate test results.

package since this may cause inaccurate results.

id other test sites like the forearm, upper arm, thigh, calf and hand, may result in differences in blood glucose measurements from the other test sites and your finger. Differences in

your finger may be observed after eating, insulin medication or exercise. Changes in blood glucose may be observed in finger blood samples sooner than blood samples from the forearm

sites before lancing will help to minimize the difference between finger and alternate site test results. If you are testing for hypoglycemia (low blood glucose), or if you suffer from

ingers.

potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates,
 is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL or higher than 240 mg/dL, you should contact your
 ent advice.

use false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.

osed of properly.

osed of properly.

C). Use test strips only within the system operating temperature range as outlined in your Owner's Booklet.

m the vial.

ne cap or vial contains drying agents to protect the test strips. Do not transfer test strips to a new vial or any other container.

the vial cap immediately and close it tightly.

ip in any way.

test strip anywhere when removing it from the vial or inserting it into the meter.

e warm, soapy water. Rinse and thoroughly dry. Warm water helps to get the blood flowing to the site you want to lance.

right size blood drop.

your finger, hand, forearm, upper arm, calf, and thigh. To bring fresh blood to the surface, rub the test site (except the finger) vigorously for a few

on the screen, lance the site you have chosen, and obtain a blood sample about the size of a pinhead.

strips to the blood sample. You may fill the test strip from either side, but not both sides. When the strip is full, the meter will "beep" or you will

st the test site. Do not put the sample on top of the sample area.

er to your Owner's Booklet for the average test time.

Lite Blood Glucose Meter Owner's Booklet for a step-by-step guide on how to do the test.

with FreeStyle Lite test strips.

o for any one glucose test.

piration date. Check the test strip vial for the expiration date.

atures.

arly using FreeStyle control solution.

500 mg/dL. The expected glucose range for a non-diabetic, non-pregnant fasting adult is under 100 mg/dL. Two hours after meals, levels should

professional to determine the range that is appropriate for you.

will appear on the meter display. This indicates severe low blood sugar (hypoglycemia). **You should immediately treat low blood sugar as recommended by**

will appear on the meter display screen. This indicates severe high blood sugar (hyperglycemia). **You should immediately treat high blood sugar as**

potentially serious medical condition. If your blood sugar is unusually low or high, or if you do not feel the way your results indicate, repeat the
 istent with your symptoms or if your blood glucose result is less than 60 mg/dL or higher than 240 mg/dL, you should contact your healthcare

trate results when the following limitations are observed:

use test strips.

you have selected to test.

thoroughly before testing.

set above sea level.

3. Do not use control solution up to 500 mg/dL or triglycerides up to 3,000 mg/dL or not significantly direct test results. However, glucose values in speci...

4. Do not use during peritoneal absorption testing.

5. Patients receiving peritoneal dialysis using solutions containing icodextrin or receiving intravenous immunoglobulin preparations contain...

6. In situations of decreased peripheral blood flow, capillary blood testing on finger and other sites may not be appropriate as it may not rep...

include but are not limited to: severe dehydration caused by diabetic ketoacidosis or the hyperosmolar non-ketotic state, hypotension, sh...

patients should not be tested with home use blood glucose meters.

Checking the System

The control solution is used to check the performance of FreeStyle Lite meters, test strips, and your testing technique. The system is performing...
 the specific control solution range listed on your FreeStyle Lite test strip vial.

When a control solution test is done, you should get results within the expected range printed on the test strip vial. If control solution test results
 fall outside the range may be caused by:

- error in performing the test
- expired or contaminated control solution
- test strip deterioration
- meter malfunction

NOTE: A control solution test should be performed when you suspect that the meter or test strips are not working properly. To obtain control sol...

Performance Characteristics

The performance of these test strips has been tested both in laboratory and clinical studies. The testing range is 20 mg/dL to 500 mg/dL.

Accuracy

The accuracy of these test strips was tested by comparing blood glucose results obtained by study subjects with those obtained using a YSI M...
 obtained from subjects with Type 1 or 2 diabetes. The regression statistics are derived from a plot of the arm data versus YSI capillary data.

Slope	0.931
y-intercept	+ 8.1 mg/dL
Correlation coefficient (R)	0.969
Number of samples tested in duplicate	197
Range tested	51 to 487 mg/dL

**WARNING: If you continue to get FreeStyle Control Solution test results that fall outside the range printed on the test strip vial, the FreeStyle Lite System may not be...
 your blood until you get a control solution test result within the range printed on the test strip vial label. Contact Customer Care at 1-888-522-5226 for assistance.**

Precision

Within-lot and within-vial precision of these test strips was measured with venous blood samples in the laboratory. The pooled precision data...
 tables below:

Within-Lot Precision

Average Glucose Concentration (mg/dL)	43
SD (mg/dL)	2.4
CV (%)	5.6

Within-Vial Precision

Average Glucose Concentration (mg/dL)	43
SD (mg/dL)	1.8
CV (%)	4.1

Variability in blood tests from strip to strip was 5.6% or less.

Chemical Composition

PQQ Glucose Dehydrogenase	≥ 1.0 Unit
Other ingredients (buffer, mediator, etc.)	≥ 0.01 mg

Reference

1. American Diabetes Association: Consensus statement on self-monitoring of blood glucose. Diabetes Care 1995; 18: 47-52.
2. The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long...
 mellitus. N Eng J Med 1993; 329: 977-986.
3. American Diabetes Association Clinical Practice Recommendations: Diagnosis and classification of diabetes mellitus. Diabetes Care 2005;28 (suppl.1):S37-S4...
4. Atkins SH, Dasmahapatra A, Jaker MA, Chorost M, Reddy S: Fingertstick glucose determination in shock. Ann Int Med 114: 1020-1024. 1991.
5. Sandler M, Low-Beer T: Misleading capillary glucose measurements. Practical Diabetes 7: 210. 1990.
6. Wickham NWR, Achar KN, Cove DH: Unreliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes 3: 100. 1986.

Description of Symbols

	Consult instructions for use
	Temperature limitation
	Manufactured by

	Batch code
	Use by
	Do not reuse
	in vitro diagnostic medical o...

para utilizar con medidores de glucosa en sangre FreeStyle Lite para realizar pruebas de glucosa en sangre entera

LECTURA Y SU MANUAL DEL PROPIETARIO ANTES DE UTILIZAR LAS TIRAS FREESTYLE LITE PARA REALIZAR UNA PRUEBA DE AZÚCAR EN SANGRE.

Comuníquese con el Departamento de Atención al Cliente llamando al 1-888-522-5226, las 24 horas del día, los 365 días del año.

Las tiras de prueba de glucosa en sangre FreeStyle Lite están destinadas a utilizarse con medidores de glucosa en sangre FreeStyle Lite para medir la glucosa (azúcar) en sangre entera. Las tiras de prueba de glucosa en sangre FreeStyle Lite están destinadas a utilizarse con medidores de glucosa en sangre FreeStyle Lite que están destinados a utilizarse en el hogar para medir la glucosa en sangre.

Este estudio (en inglés) es una parte necesaria en el plan de tratamiento de personas que padecen diabetes mellitus¹. El estudio sobre el control y las pruebas de glucosa en sangre (en inglés)² ha confirmado los beneficios significativos del SMBG cuando se practica como parte de una estrategia intensiva más amplia para el control de la glucosa en sangre. El DCCCT demostró que el control riguroso puede, por cierto, reducir en alrededor del 60% el riesgo de complicaciones a largo plazo, como las enfermedades en los riñones, daño nervioso y problemas circulatorios y cardíacos.

Este sistema de prueba de glucosa en sangre FreeStyle Lite, utilizada con medidores de glucosa en sangre FreeStyle Lite, medirá con precisión sus valores de glucosa en sangre. Cuando el área de prueba de glucosa en sangre FreeStyle Lite se coloca en una gota de sangre, la tira de prueba conduce la sangre a una cámara de muestra y la lectura de la glucosa se visualiza en el medidor. La lectura de glucosa en sangre FreeStyle Lite se calibra para mostrar los valores de glucosa equivalentes en plasma para compararlos sencillamente con los valores de glucosa en plasma.

Si tiene alguna pregunta sobre el medidor o las tiras de prueba FreeStyle Lite, comuníquese con el Departamento de Atención al Cliente llamando al 1-888-522-5226.

Los resultados de la prueba de glucosa en sangre FreeStyle Lite sin el consentimiento y consejo de un médico o profesional de la salud.

Los resultados de los dedos no es siempre la misma. Los niveles de glucosa en sangre en las yemas de los dedos no siempre son los mismos que en otras zonas de prueba. Esta es una de las razones por las que el sistema FreeStyle Lite puede dar lugar a resultados de prueba inexactos.

Los dedos pueden estar secos o agrietados.

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Limitaciones

Las tiras de prueba de glucosa en sangre FreeStyle Lite proporcionan resultados exactos cuando se tienen en cuenta las siguientes limitaciones:

1. Las tiras de prueba sirven para un solo uso. No vuelva a usar las tiras de prueba.
2. Use sangre entera capilar reciente de la zona que ha seleccionado para la prueba.
3. Limpie la zona con agua tibia y jabón y séquela por completo antes de realizar la prueba.
4. No existen efectos por altitud hasta 10,000 pies sobre el nivel del mar.
5. Rango de hematocritos: de 15% a 65%.

Información adicional para los profesionales de la salud:

1. También puede usarse una muestra de sangre entera venosa. Use sangre venosa dentro de los 30 minutos posteriores a la extracción. Puede ser necesario el uso de un anticoagulante como el EDTA, heparina, etc.
2. Las tiras de prueba FreeStyle Lite no están validadas para realizar pruebas en muestras de sangre neonatal y no deben usarse con este fin.
3. El colesterol hasta 500 mg/dL o los triglicéridos hasta 3,000 mg/dL no afectan significativamente los resultados de la prueba. Sin embargo, niveles elevados de colesterol o triglicéridos pueden afectar los resultados de la prueba. Sin embargo, niveles elevados de colesterol o triglicéridos pueden afectar los resultados de la prueba. Sin embargo, niveles elevados de colesterol o triglicéridos pueden afectar los resultados de la prueba.
4. No utilice el producto durante una prueba de absorción de xilosa.
5. Los pacientes sometidos a diálisis peritoneal que utilizan soluciones con bicodextrina o a quienes se administran preparaciones intravenosas de glucosa pueden experimentar niveles elevados de glucosa en sangre cuando se utilizan estas tiras de prueba. Las concentraciones en sangre de galactosa ≥ 13 mg/dL, maltosa ≥ 20 mg/dL o lactosa ≥ 10 mg/dL causan una sobrelectura de glucosa en sangre. Si se sospecha de una sobrelectura de glucosa en sangre, se debe realizar una prueba de glucosa capilar en una zona fisiológica. Se incluyen, entre otros, los siguientes ejemplos: deshidratación grave causada por cetoacidosis diabética o estado hiperosmolar hiperosmolar. Los pacientes en estado crítico no deben realizarse pruebas con medidores de glucosa en sangre para uso en el hogar.

Comprobación del sistema

La solución de control se usa para verificar su técnica de análisis, el rendimiento de las tiras de prueba y de los medidores FreeStyle Lite. El sistema de prueba de glucosa en sangre FreeStyle Lite está diseñado para utilizarse con medidores de glucosa en sangre FreeStyle Lite que están dentro del rango específico de solución de control que se muestra en el vial de las tiras de prueba FreeStyle Lite.

Cuando se realiza una prueba con la solución de control, debe obtener resultados dentro del rango esperado impreso en el vial de las tiras de prueba. Si los resultados de la prueba de control están fuera de este rango, repita la prueba. Las causas de los resultados fuera de este rango pueden ser:

- error al realizar la prueba
- solución de control vencida o contaminada
- deterioro de la tira de prueba
- mal funcionamiento del medidor

NOTA: Se debe realizar una prueba de solución de control cuando sospeche que el medidor o las tiras de prueba no están funcionando de manera adecuada. Para obtener más información, comuníquese con el Departamento de Atención al Cliente.

Características de rendimiento

El rendimiento de estas tiras de prueba ha sido probado en estudios clínicos y de laboratorio. El rango de prueba de estas tiras de prueba de glucosa en sangre FreeStyle Lite es de 40 mg/dL a 400 mg/dL.

Exactitud

La exactitud de estas tiras de prueba se probó comparando los resultados de glucosa de glucosa en sangre obtenidos por individuos participantes en un estudio de precisión con un analizador de glucosa YSI modelo 2300. Los resultados que figuran a continuación se obtuvieron de personas con diabetes tipo 2. El estudio de precisión se realizó con un grupo de personas con diabetes tipo 2 que utilizaron un analizador de glucosa YSI modelo 2300. Los resultados que figuran a continuación se obtuvieron de personas con diabetes tipo 2 que utilizaron un analizador de glucosa YSI modelo 2300. Los resultados que figuran a continuación se obtuvieron de personas con diabetes tipo 2 que utilizaron un analizador de glucosa YSI modelo 2300.

Pendiente	0,931
Intersección y	+ 8.1 mg/dL
Coefficiente de correlación (R)	0,969
Número de muestras probadas en duplicado	197
Rango probado	51 a 487 mg/dL

ADVERTENCIA: Si sigue obteniendo resultados de prueba de solución de control FreeStyle Lite fuera del rango impreso en el vial de las tiras de prueba, es posible que el sistema de prueba de glucosa en sangre FreeStyle Lite no esté funcionando de manera adecuada. Para obtener más información, comuníquese con el Departamento de Atención al Cliente para solicitar asistencia llamando al 1-888-522-5226.

Precisión

Se midió la precisión dentro del lote y dentro del vial de estas tiras de prueba con muestras de sangre venosa en el laboratorio. En las tablas de precisión combinados de cincuenta y cuatro lotes de tiras de prueba (n=5,184):

Concentración de glucosa promedio (mg/dL)	43
DE (mg/dL)	2.4
CV (%)	5.6

Precisión dentro del vial

Concentración de glucosa promedio (mg/dL)	43
DE (mg/dL)	1.8
CV (%)	4.1

La variabilidad de las pruebas de sangre de una tira a otra fue de 5.6% o menos.

Composición química

Glucosa dehidrogenasa PQQ \geq unidad 1.0
Otros ingredientes (tampón, mediador, etc.) \geq 0.01 mg

Referencia

1. American Diabetes Association: Consensus statement on self-monitoring of blood glucose. Diabetes Care 1995; 18: 47-52.
2. The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Eng J Med 1993; 329: 977-986.
3. American Diabetes Association Clinical Practice Recommendations: Diagnosis and classification of diabetes mellitus. Diabetes Care 2005; 28 (suppl.1): S37-S42.
4. Atkins SH, Dasmahapatra A, Jaker MA, Chorost MI, Reddy S: Fingerstick glucose determination in shock. Ann Int Med 114: 1020-1024. 1991.
5. Sandler M, Low-Beer T: Misleading capillary glucose measurements. Practical Diabetes 7: 210. 1990.
6. Wickham NWR, Achar KN, Cove DH: Unreliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes 3: 100. 1986.

Descripción de los símbolos

	Consulte las instrucciones de uso
	Limitación de temperatura
	Fabricado por

	Código de lote
	Fecha de vencimiento
	No reutilizar
	Dispositivo médico de diagnóstico

Las tiras de prueba de glucosa en sangre FreeStyle Lite exclusivamente.

para realizar cualquier prueba de glucosa.

Compruebe la fecha de vencimiento indicada en el vial de tiras de prueba.

Extremas.

Las tiras de prueba de forma regular usando la solución de control FreeStyle.

Los niveles de glucosa esperados para una persona adulta no diabética y no embarazada en ayunas deben ser menores a 100 mg/dL. Los niveles de glucosa esperados para una persona adulta no diabética y no embarazada en ayunas deben ser inferiores a 140 mg/dL.³

Los niveles de glucosa esperados para una persona adulta no diabética y no embarazada en ayunas deben ser inferiores a 140 mg/dL.³

Los niveles de glucosa esperados para una persona adulta no diabética y no embarazada en ayunas deben ser inferiores a 140 mg/dL.³

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ABBOTT DIABETES CARE, DIELINE 0308

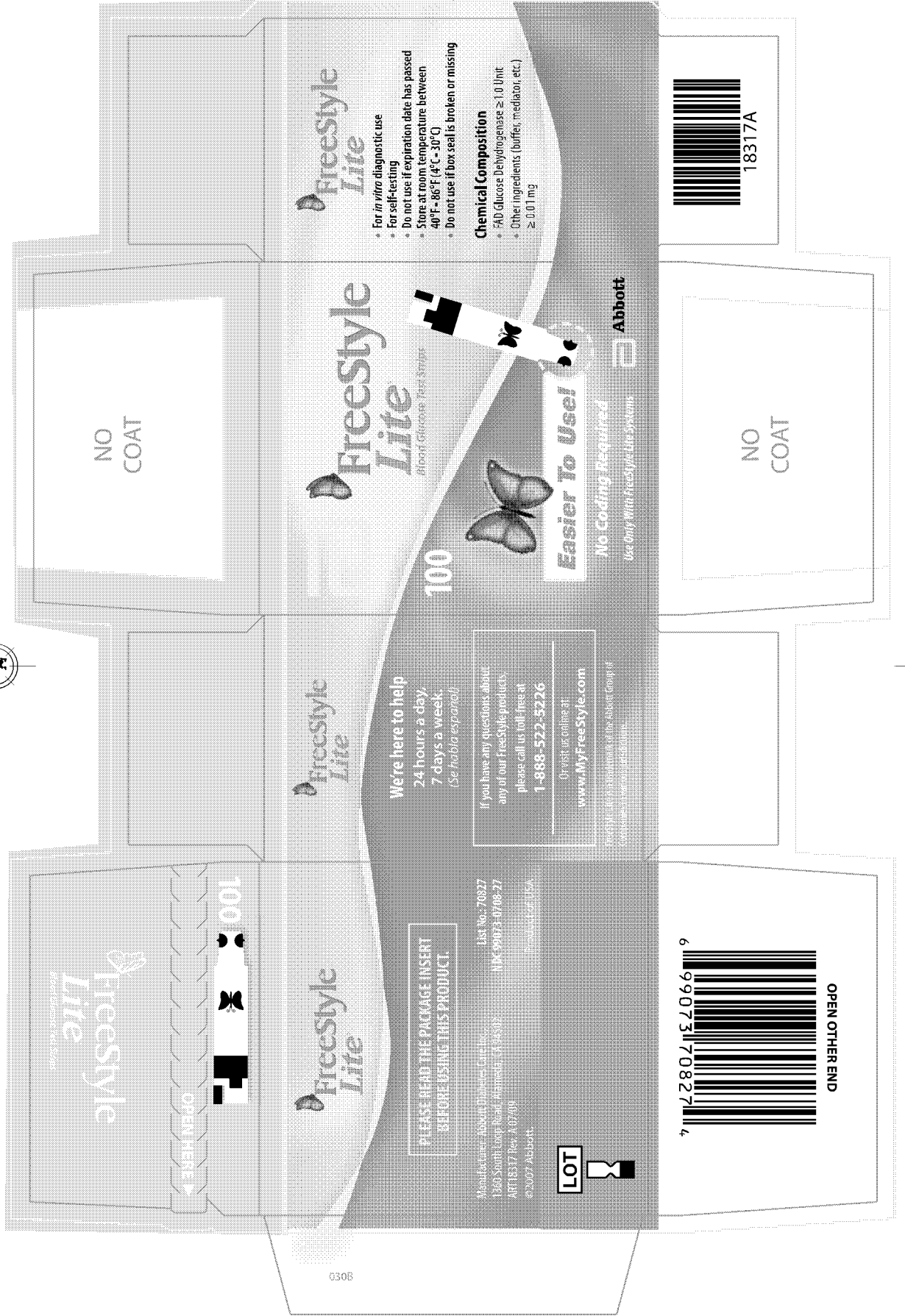
2.5 x 1.75 x 2.69 inches

All dimensions are in inches.

The dimensions are inner dimensions from center score to center score.

Tolerance is +/- 0.03 inches

Print side - QC dimensions are indicated by *



0308

We're here to help
24 hours a day
7 days a week
(See *frabla.espanol*)

If you have any questions about any of our Freestyle products, please call us toll-free at 1-888-522-5226. Or visit us online at www.MyFreeStyle.com

Model 6800e - Abbott Diabetes Care, Inc.
1360 South Loop West, Alameda, CA 94501
ART18317 Rev. A 07/09
©2007 Abbott
Product of USA

LOT
[Hourglass icon]

Freestyle Libre is a trademark of the Abbott Group of companies. ©2007 Abbott Diabetes Care, Inc.

- Freestyle Life**
- For *in vitro* diagnostic use
 - For self-testing
 - Do not use if expiration date has passed
 - Store at room temperature between 40°F - 86°F (4°C - 30°C)
 - Do not use if box seal is broken or missing
- Chemical Composition**
- FAD Glucose Dehydrogenase ≥ 10 Unit
 - Other ingredients (buffer, mediator, etc.) ≥ 0.01 mg

6 990731 708227 4
OPEN OTHER END

18317A

WARNING: If you continue to get FreeStyle control solution test results that fall outside the range printed on the test strip vial, the system may not be functioning properly. DO NOT use the system to test your blood until you get a control solution test result within the range printed on the test strip vial label. Contact Customer Care.

**AD THIS INFORMATION AND YOUR OWNER'S BOOKLET BEFORE
 STYLE LITE TEST STRIPS TO TEST YOUR BLOOD SUGAR.**
 er Care at 1-888-522-5220, 24 hours a day, 7 days a week.

with FreeStyle Lite blood glucose meters to measure glucose (sugar) in whole blood.
 de the body (*in vitro* diagnostic use) and are for self-testing or care giver use. FreeStyle Lite
 or use in the home and in professional settings. This product is not intended for use with

ing.
 eStyle Lite blood glucose test results without the consent and advice of a
 not recommended.
 at might be considered a choking hazard.
 o protect the test strips. Drying agents may be harmful if inhaled or swallowed

it results that fall outside the range printed on the test strip vial, repeat the
 ult is still outside the range printed on the test strip vial, the system may not
 stem to test your blood until you get a control solution test result within the

ft and right sample areas during a single test. This may cause inaccurate test
 ation date printed on the package since this may cause inaccurate results.
 n between the finger, and other test sites like the forearm, upper arm, thigh,
 in blood glucose measurements from the other test sites and your finger.
 ents between the other test sites and your finger may be observed after
 changes in blood glucose may be observed in finger blood samples sooner than
 her alternate sites. Vigorous rubbing of the alternate test sites before lancing
 tween finger and alternate site test results. If you are testing for hypoglycemia
 m hypoglycemia unawareness, we recommend that you test on your fingers.

displayed with each result. See Owner's Booklet for further details.
 cause false low results. If you believe you are suffering from severe dehydration, consult
 disposed of properly.

on date printed on the vial.
 e the vial cap immediately and dose it tightly. Use each strip immediately after removing
 The cap or vial contains drying agents to protect the test strips. Do not transfer test strips to
 °F (4°C to 30°C). Use test strips only within the system operating temperature range as
 ures.
 trip in any way.
 e test strip anywhere when removing it from the vial or inserting it into the meter.

o, the glucose in the blood reacts with the chemicals on the test strip, producing a small
 over time, calculates the electrical charge, and converts it to a glucose value.

eter Owner's Booklet for a step-by-step guide on how to do the test.

our finger, hand, forearm, upper arm, calf, and thigh.
 : warm, soapy water. Rinse and thoroughly dry. To bring fresh blood to the surface, rub the
 y seconds until you feel it getting warm.
 omatically.

on the screen, use your lancing device to obtain a blood sample.
 e test strip to the blood sample. If the strip does not fill, reapply the sample to the same
 le to both edges of the strip. Do not put the sample on top of the sample application area.
 you will see the moving lines on the display.

on-pregnant fasting adult is under 100 mg/dL (5.6 mmol/L).¹
 an 140 mg/dL (7.8 mmol/L).¹
 ine the range that is appropriate for you.
 e a potentially serious medical condition. If your blood glucose reading is unusually low or
 indicates, repeat the test with a new test strip. If your reading is not consistent with your
 : than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L) you should contact
 er treatment advice.

curate results when the following limitations are observed:
 euse test strips.
 you have selected to test.
 thoroughly before testing.
 et (3,048 meters) above sea level.

essionals:
 ed. Use venous blood within 30 minutes after drawing. Common anticoagulants (heparin,
 riglycerides up to 3,000 mg/dL (34 mmol/L) do not significantly affect test results. However,
 ls, should be interpreted with caution.
 w, capillary blood testing may not be appropriate as it may not represent the true
 ut are not limited to: severe dehydration caused by diabetic ketoacidosis or the
 shock, or peripheral vascular disease.^{2,3} Critically ill patients should not be tested with

ance of the meters, test strips, and your testing technique. The system is performing
 in the specific control solution range listed on your FreeStyle Lite test strip vial.
 get results within the expected range printed on the test strip vial. If control solution test
 ults that fall outside the range may be caused by:

Performance Characteristics

The performance of these test strips has been tested both in laboratory and clinical studies. The testing range is 20 mg/dL to 500 mg/dL (1.1 mmol/L to 27.8 mmol/L). The FreeStyle Lite test strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

Accuracy

Capillary blood glucose results obtained by lay users were compared with those obtained using the YSI Glucose Analyzer. For samples with YSI glucose results lower than 75 mg/dL (4.2 mmol/L), 11 of 11 (100%) were within ±15 mg/dL (0.83 mmol/L) of the YSI result. For samples with YSI glucose results of 75 mg/dL (4.2 mmol/L) or higher, 167 of 168 (99%) were within ±20% of the YSI result. In total, 178 of 179 (99%) were within ±15 mg/dL (0.83 mmol/L) or ±20% of the YSI result.

The regression statistics are derived from a plot of the lay user finger data versus YSI capillary data.

Slope	0.95	0.95
y-intercept	7.3 mg/dL	0.41 mmol/L
Correlation coefficient (R)	0.99	0.99
Number of samples tested in duplicate	179	179
Range tested	38-375 mg/dL	2.1-20.8 mmol/L

Precision

Within-lot and within-vial precision of these test strips was measured with venous blood samples in the laboratory.

Within-Lot Precision

Average Glucose Concentration	mg/dL (mmol/L)	43.3 (2.4)	94.2 (5.2)	140.7 (7.8)	238.3 (13.2)	345.0 (19.2)
SD	mg/dL (mmol/L)	1.5 (0.1)	2.3 (0.1)	2.9 (0.2)	4.8 (0.3)	6.8 (0.4)
CV	%	3.3	2.4	2.2	2.3	2.4

Within-Vial Precision

Average Glucose Concentration	mg/dL (mmol/L)	43.3 (2.4)	94.2 (5.2)	140.7 (7.8)	238.3 (13.2)	345.0 (19.2)
SD	mg/dL (mmol/L)	1.3 (0.1)	2.0 (0.1)	2.4 (0.1)	3.9 (0.2)	6.0 (0.3)
CV	%	2.9	2.2	1.8	1.9	2.1

Variability in blood tests from strip to strip was 3.3% or less.








Chemical Composition

FAD Glucose Dehydrogenase ≥ 1.0 Unit
 Other ingredients (buffer, mediator, etc.) ≥ 0.01 mg

Reference

- American Diabetes Association Clinical Practice Recommendations: Diagnosis and classification of diabetes mellitus. Diabetes Care 2005;28 (Suppl.1):S37-S42.
- Atkins SH, Dasmahapatra A, Jaker MA, Chorost MI, Reddy S: Fingerstick glucose determination in shock. Ann Int Med 114: 1020-1024. 1991.
- Sandler M, Low-Beer T: Misleading capillary glucose measurements. Practical Diabetes 7: 210. 1990.
- Wickham HWR, Adhar KM, Cove DH: Unreliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes 3: 100. 1986.

Description of Symbols

	Consult instructions for use		Batch code
	Temperature limitation		Use by
	Manufacturer		Do not reuse
			<i>in vitro</i> diagnostic medical device

de glucosa en sangre FreeStyle Lite: información sobre el producto

temas de prueba para glucosa en sangre FreeStyle Lite y FreeStyle Freedom Lite

a realizar pruebas de glucosa en sangre entera

de glucosa en sangre con tecnología coulométrica)

LEA Y SU MANUAL DEL USUARIO ANTES DE USAR LAS TIRAS DE PRUEBA PARA REALIZAR LA PRUEBA DE AZÚCAR EN SANGRE.
Se al departamento de Atención al cliente al 1-888-522-5220,
24 horas del día, los 7 días de la semana.

FreeStyle Lite son para utilizar con los medidores de glucosa en sangre FreeStyle Lite a fin de medir la prueba FreeStyle Lite se utilizan para realizar pruebas fuera del organismo (uso diagnóstico persona que atiende al paciente. Los sistemas de prueba para glucosa en sangre FreeStyle Lite profesionales. Este producto no está destinado al uso con muestras de sangre neonatal.

de xilosa.
no en el uso de medicamentos en función de los resultados de la prueba de lo sugiera y permita un médico o profesional de la salud.
que podrían representar un riesgo de atragantamiento.
secantes para proteger las tiras de prueba. Los agentes secantes pueden ser den causar irritación cutánea u ocular.
de la solución de control FreeStyle se encuentran fuera del rango repita la prueba con otra tira de prueba. Si el resultado de la prueba sigue vial de la tira de prueba, es posible que el sistema no esté funcionando ara realizar la prueba de sangre hasta que el resultado de la prueba de la o del rango impreso en la etiqueta del vial de la tira de prueba.

de la muestra izquierda y derecha en la misma prueba, ya que los xactos.
ha de caducidad impresa en el paquete ya que podrían obtenerse resultados elación entre el dedo y otras zonas de prueba, como el antebrazo, el no, pueden dar lugar a distintas mediciones de glucosa en sangre entre ichas diferencias en las mediciones pueden observarse después de las a o el ejercicio. Los cambios en la glucosa en sangre pueden observarse en mayor rapidez que en las muestras de sangre del antebrazo y otras zonas a prueba de prueba alternativas antes de realizar la punción para minimizar a prueba del dedo y de las zonas alternativas. Si va a realizar una prueba (ajaja), o si sufre de hipoglucemia asintomática, se recomienda hacer la prueba

correcta con cada resultado. Consulte más detalles al respecto en el manual del usuario. agua pueden generar resultados bajos falsos. Si cree que sufre de deshidratación grave, e deben desecharse como corresponde.
de la fecha de caducidad impresa en el vial.
vuelva a colocar el tapón del vial enseguida y ciérrelo firmemente. Use cada tira únicamente. El tapón o el vial contienen agentes secantes para proteger las tiras de prueba. u otro recipiente.
únicamente. El tapón o el vial contienen agentes secantes para proteger las tiras de prueba. 86 °F (4 °C y 30 °C). Use las tiras de prueba únicamente dentro del rango de temperatura anual del usuario.
extremas.
eStyle Lite de ningún modo.
cuidado cualquier parte de la tira de prueba al extraerla del vial o colocarla en el medidor.

re
prueba, la glucosa en la sangre reacciona con las sustancias químicas de la tira de prueba y dor mide la corriente con respecto al tiempo, calcula la carga eléctrica y la convierte en un
del medidor de glucosa en sangre, donde encontrará una guía detallada sobre cómo realizar la prueba.

realizar pruebas con sangre del dedo, mano, antebrazo, brazo, pantorrilla y muslo. ua jabonosa tibia. Enjuáguela y séquela por completo. Para llevar sangre reciente a la eba (salvo el dedo) durante algunos segundos hasta que sienta que se entibia. encenderá automáticamente.
muestra, use el dispositivo de punción para obtener una muestra de sangre.
na de las zonas de aplicación de la muestra de la tira de prueba. Si la tira no se llena, vuelva que transcurran 60 segundos. No aplique la muestra en ambos extremos de la tira ni

sonido o se verán las líneas que se mueven en la pantalla.
del medidor.
a adulta no embarazada ni diabética en ayunas es inferior a 100 mg/dL (5.6 mmol/L).¹ eben ser inferiores a 140 mg/dL (7.8 mmol/L).¹
minar cuál es el rango apropiado para usted.
pueden indicar un estado de salud posiblemente grave. Si su lectura de glucosa en sangre no refleja el modo en que usted se siente, repita la prueba con otra tira de prueba. Si la resultado de glucosa en sangre es inferior a 60 mg/dL (3.3 mmol/L) o superior a 240 mg/dL al de la salud y siga el tratamiento que le sugiera.

FreeStyle Lite proporcionan resultados exactos cuando se observan las siguientes limitaciones: ueva a utilizarlas.
ue eligió para realizar la prueba.
ela completamente antes de realizar la prueba.
s) sobre el nivel del mar no afecta la prueba.

s de la salud:
entera venosa. La sangre venosa debe usarse en los 30 minutos posteriores a su extracción.arina, EDTA).
13 mmol/L) o triglicéridos de hasta 3,000 mg/dL (34 mmol/L) no afectan significativamente alores de glucosa en muestras con niveles superiores a los indicados se deben interpretar
smunido, puede no ser apropiado realizar la prueba con sangre capilar, dado que es posible tado fisiológico. Los ejemplos incluyen, entre otros, los siguientes: deshidratación grave osmolar sin cetosis, hipotensión, shock o enfermedad vascular periférica.^{2,3,4} Los medidores ben utilizarse para realizar pruebas en pacientes con un estado de salud grave.
el funcionamiento del medidor, las tiras de prueba y la técnica que usted emplea para ente si el resultado de la prueba de la solución de control se encuentra dentro del rango de las tiras de prueba FreeStyle Lite.
ontrol, los resultados obtenidos deben encontrarse dentro del rango esperado impreso en el uecuentran dentro de ese rango, repita la prueba. Los resultados obtenidos fuera del rango

de Atención al cliente.

ADVERTENCIA: Si los resultados de la prueba de la solución de control FreeStyle continúan estando fuera del rango impreso en el vial de la tira de prueba, es posible que el sistema no esté funcionando correctamente. NO utilice el sistema para realizar la prueba de sangre hasta que el resultado de la prueba de la solución de control se encuentre dentro del rango impreso en la etiqueta del vial de la tira de prueba. Comuníquese con el departamento de Atención al cliente.

Características de rendimiento
El rendimiento de estas tiras de prueba ha sido evaluado en estudios clínicos y de laboratorio. El rango de prueba es de 20 mg/dL a 500 mg/dL (de 1.1 mmol/L a 27.8 mmol/L). La tira de prueba FreeStyle Lite está calibrada para mostrar el equivalente de valores de glucosa en plasma a fin de facilitar la comparación de los resultados con métodos de laboratorio.

Exactitud
Se compararon los resultados de glucosa en sangre capilar obtenidos por usuarios no profesionales con aquellos obtenidos usando un analizador de glucosa YSI. En el caso de las muestras con resultados de glucosa inferiores a 75 mg/dL (4.2 mmol/L) según el analizador YSI, los resultados de los usuarios no profesionales en 11 de las 11 muestras (el 100%) se encontraron dentro de los ±15 mg/dL (0.83 mmol/L) con respecto a los resultados obtenidos con el analizador YSI. En el caso de las muestras con resultados de glucosa iguales o superiores a 75 mg/dL (4.2 mmol/L) según el analizador YSI, los resultados de los usuarios no profesionales en 167 de las 168 muestras (el 99%) se encontraron dentro del ±20% con respecto a los resultados obtenidos con el analizador YSI. En total, 178 de las 179 muestras (el 99%) se encontraron dentro de los ±15 mg/dL (0.83 mmol/L) o el ±20% con respecto a los resultados obtenidos con el analizador YSI.

Las estadísticas de regresión se derivan de la representación gráfica de los datos correspondientes a las muestras del dedo obtenidos por usuarios no profesionales en contraposición a los datos correspondientes a las muestras de sangre capilar obtenidos con el analizador YSI.

Pendiente	0.95	0.95
Intersección con el eje y	7.3 mg/dL	0.41 mmol/L
Coefficiente de correlación (R)	0.99	0.99
Número de muestras analizadas por duplicado	179	179
Rango de análisis	38-375 mg/dL	2.1-20.8 mmol/L

Precisión
La precisión intra-lote e intra-vial de estas tiras de prueba se evaluó con muestras de sangre venosa en el laboratorio.

Precisión intra-lote

Concentración promedio de glucosa	mg/dL (mmol/L)	43.3 (2.4)	94.2 (5.2)	140.7 (7.8)	238.3 (13.2)	345.0 (19.2)
SD	mg/dL (mmol/L)	1.5 (0.1)	2.3 (0.1)	2.9 (0.2)	4.8 (0.3)	6.8 (0.4)
CV	%	3.3	2.4	2.2	2.3	2.4

Precisión intra-vial








Concentración promedio de glucosa	mg/dL (mmol/L)	43.3 (2.4)	94.2 (5.2)	140.7 (7.8)	238.3 (13.2)	345.0 (19.2)
SD	mg/dL (mmol/L)	1.3 (0.1)	2.0 (0.1)	2.4 (0.1)	3.9 (0.2)	6.0 (0.3)
CV	%	2.9	2.2	1.8	1.9	2.1

La variabilidad en las pruebas de sangre entre tiras fue del 3.3% o menos.

Composición química
Glucosa deshidrogenasa FAD ≥ 1.0 unidad
Otros ingredientes (solución amortiguadora, mediador, etc.) ≥ 0.01 mg

- Referencias**
- American Diabetes Association Clinical Practice Recommendations: Diagnosis and classification of diabetes mellitus. Diabetes Care 2005;28 (Suppl.1):S37-S42.
 - Atkins SH, Dasmahapatra A, Jaker MA, Chorost MI, Reddy S: Fingerstick glucose determination in shock. Ann Int Med 114: 1020-1024. 1991.
 - Sandler M, Low-Beer T: Misleading capillary glucose measurements. Practical Diabetes 7: 210. 1990.
 - Wickham NWR, Achar KN, Cove DH: Unreliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes 3: 100. 1986.

Descripción de símbolos

	Consultar las instrucciones de uso		Código de lote
	Limitación de temperatura		Fecha de caducidad
	Fabricante		No volver a utilizar
			Dispositivo médico para diagnóstico <i>in vitro</i>

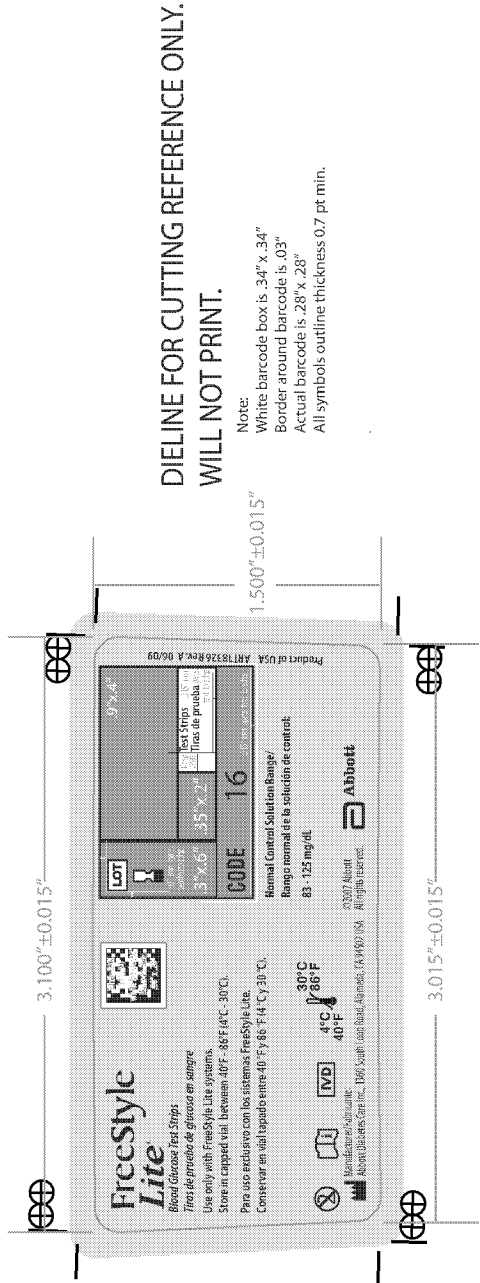
This product(s) and/or following patents: 6,016,338; 6,338,790; 6,503,381; 6,676,816; 6,749,618; 7,074,308; Des444,553; EP1145000; EP0958499. Additional patents may be issued. FreeStyle, FreeStyle Lite and the Abbott Group of Co

Manufacturer/Fabricante:

For Artwork and Packaging Department Use Only Slug06 2006

Artwork File Name: ART18326_Rev.A
 Orig. Creation Date: dd/mm/09 By xx
 Last Modified date: 02/jun/09 By LG; 03/jun/09 By LG; 18/jun/09 By VT;
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 Dieline: FS_Lite_Omni_Vial_Label_Temp.ai
 Bar Code: 20:
 Colors: Black + PMS130 ■ Dieline Does not Print ■
 Fonts: MyriadPro

Generic Name: VIAL LABEL	Revised Date: Feb/2009
ADC DIELINE NAME:	Supplier:
FS_Lite_Omni_Vial_Label_Temp.ai	GSI



**DIELINE FOR CUTTING REFERENCE ONLY.
 WILL NOT PRINT.**

Note:
 White barcode box is .34" x .34"
 Border around barcode is .03"
 Actual barcode is .28" x .28"
 All symbols outline thickness 0.7 pt min.



NO
COAT

NO
COAT

**freestyle
Lite**
Blood Glucose Test Strips

**freestyle
Lite**
Blood Glucose Test Strips

**freestyle
Lite**
Blood Glucose Test Strips

**freestyle
Lite**
Blood Glucose Test Strips

- For *in vitro* diagnostic use
- For self-testing
- Do not use if expiration date has passed
- Do not refrigerate or freeze
- Store at room temperature below 86° F (30° C)
- Do not use if box seal is broken or missing

**No Coding
Required!**

**10 In Vitro Diagnostic
Use Only**

**10 Test Strips
Use Only With the
Freestyle Lite Systems**

Chemical Composition

- Potassium Hydrogenoxalate ≥ 0.01mM
- Other ingredients (buffer, mediator, etc.) ≥ 0.01 mg

**10 Test Strips
Use Only With the
Freestyle Lite Systems**

We're Here To Help
24 hours a day
7 days a week
(See *tabla.espanol*)

If you have any questions about
any of our Freestyle products,
please call us toll-free at
1-888-522-5226

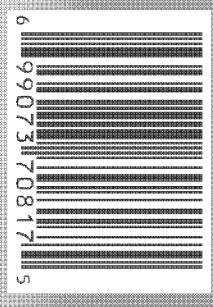
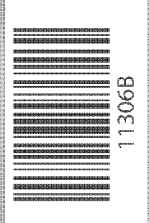
Or visit us online at:
www.AbbottDiabetesCare.com

**PLEASE READ THE PACKAGE INSERT
BEFORE USING THIS PRODUCT.**

U.S. Patent Nos. 6,821,645; 6,821,646; 6,821,647; 6,821,648; 6,821,649;
6,821,650; 6,821,651; 6,821,652; 6,821,653; 6,821,654; 6,821,655;
6,821,656; 6,821,657; 6,821,658; 6,821,659; 6,821,660;
Made in U.S.A. Printed in U.S.A.
Manufactured by Abbott Diabetes Care Inc., Bldg 150, 7805 172nd
Ave, Bldg 1507, NDC 994033-0700-17

LOT

**Laser Flood
Area**



077B

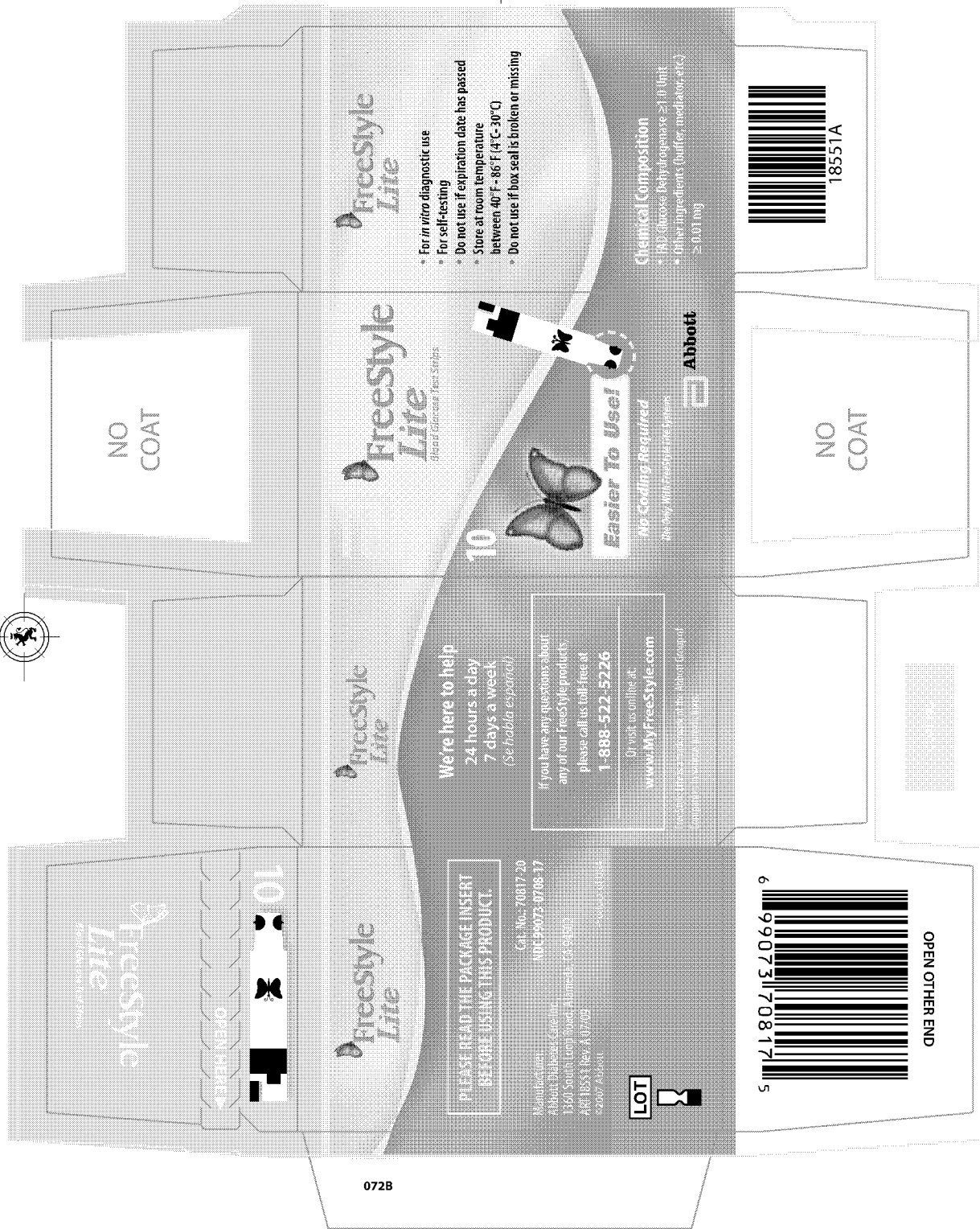
1.85 x 1.75 x 2.69 inches

All dimensions are in inches.

The dimensions are inner dimensions from center score to center score.

Tolerance is +/- 0.03 inches

Print side - QC dimensions are indicated by *



072B

ABBOTT DIABETES CARE, DIELINE 030B

2.5 x 1.75 x 2.69 inches

All dimensions are in inches.

The dimensions are inner dimensions from center score to center score.

Tolerance is +/- 0.03 inches

Print side - QC dimensions are indicated by *



ABBOTT DIABETES CARE, DIELINE 030B

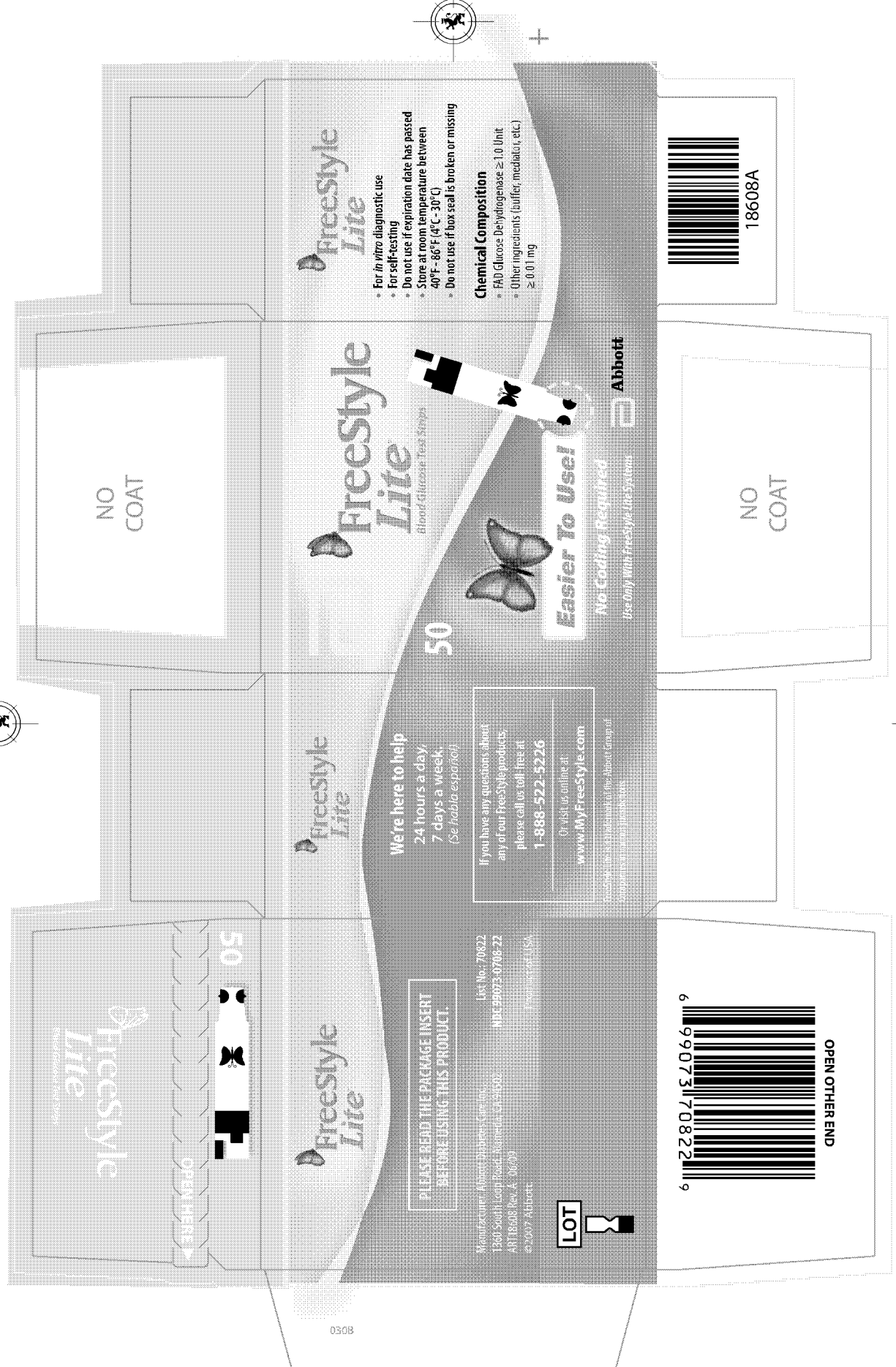
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All dimensions are in inches.

The dimensions are inner dimensions from center score to center score.

Tolerance is +/- 0.03 inches

Print side - QC dimensions are indicated by *

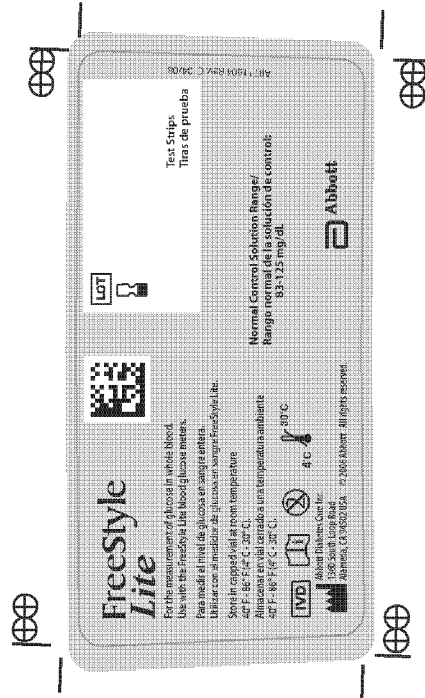


030B

For Artwork and Packaging Department Use Only **Slug06 2006**

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 Last Modified date: 20/Sept/06 By: WRA
 04/Oct/06 By: WRA 27/Sept/06 By: WRA 29/Sept/06 By: WRA
 04/Oct/07 By: LG 03/Nov/06 By: WRA 13/Nov/06 By: WRA
 01 May 08 By: VT 03 Mar/08 By: CRM_BP 04 Apr 08 By: LG
 02 May 08 By: VT

Software/Version: Illustrator CS3
 Dieline: FS_Lite_Strip_Label_Temp.ai
 Bar Code: 2D
 Colors: Black+ PMS292 Dieline does not print
 Fonts: MyriadPro



**DIELINE FOR CUTTING REFERENCE
 ONLY WILL NOT PRINT**

Note:
 White barcode box is .34 x .34"
 Actual barcode is .28" x .28"
 All symbols outline thickness 0.7 pt min.

Indication for Use

510(k) Number (if known): _____

Device Name: FreeStyle Lite Blood Glucose Monitoring System

Indication For Use:

The FreeStyle Lite Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf and hand.

The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.

Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

ABBOTT DIABETES CARE, DIELINE 030B

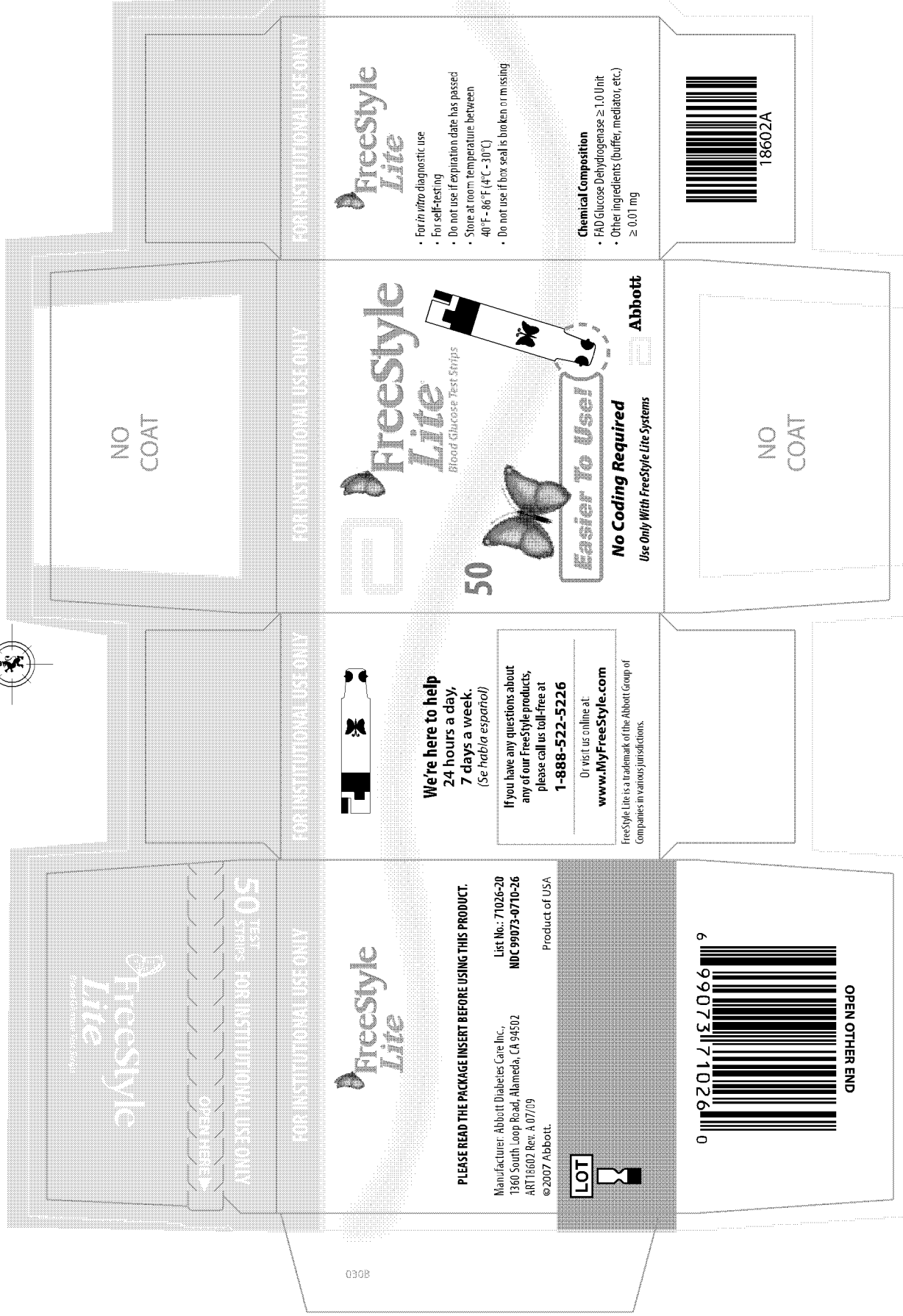
2.5 x 1.75 x 2.69 inches

All dimensions are in inches.

The dimensions are inner dimensions from center score to center score.

Tolerance is +/- 0.03 inches

Print side - QC dimensions are indicated by *



FOR INSTITUTIONAL USE ONLY

FOR INSTITUTIONAL USE ONLY

FOR INSTITUTIONAL USE ONLY

**Freestyle
Life**

**Freestyle
Life**
Blood Glucose Test Strips

**Freestyle
Life**

We're here to help
24 hours a day,
7 days a week.
(Se habla español)

If you have any questions about
any of our Freestyle products,
please call us toll-free at
1-888-522-5226

Or visit us online at:
www.MyFreeStyle.com

Freestyle Life is a trademark of the Abbott Group of
Companies in various jurisdictions.

PLEASE READ THE PACKAGE INSERT BEFORE USING THIS PRODUCT.

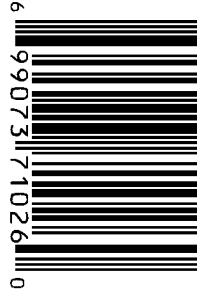
Manufacturer: Abbott Diabetes Care Inc.,
1360 South Loop Road, Alameda, CA 94502
ART18602 Rev. A 07/09
©2007 Abbott.

List No.: 71026-20

NDC 99073-0710-26

Product of USA

LOT



OPEN OTHER END



+



+



+



18602A



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

(b)(4)

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

(b)(4)

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

(b)(4)

Form Approved OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

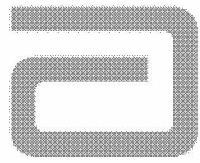
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ABBOTT LABORATORIES 1380 SOUTH LOOP ROAD ALAMEDA CA 94502 US		2. CONTACT NAME Tammy Wharton 2.1 E-MAIL ADDRESS tammy.wharton@abbott.com 2.2 TELEPHONE NUMBER (include Area code) 510-749-5273 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma)			
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)), except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)			

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

20-Jul-2009

(b)(4)



Abbott
Diabetes Care

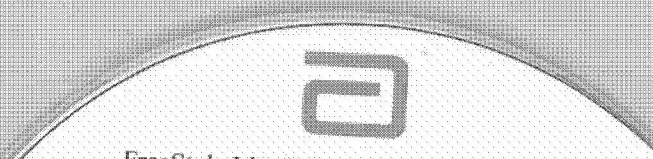
Clinical Report

(b)(4)

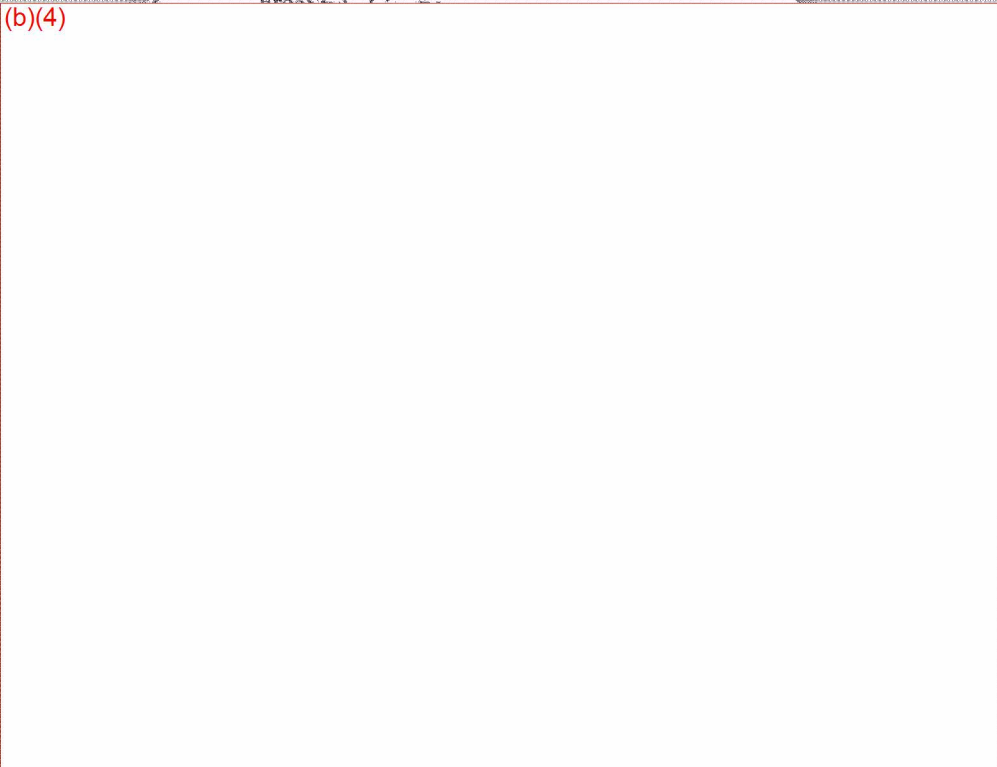
Clinical Evaluation

(b)(4)

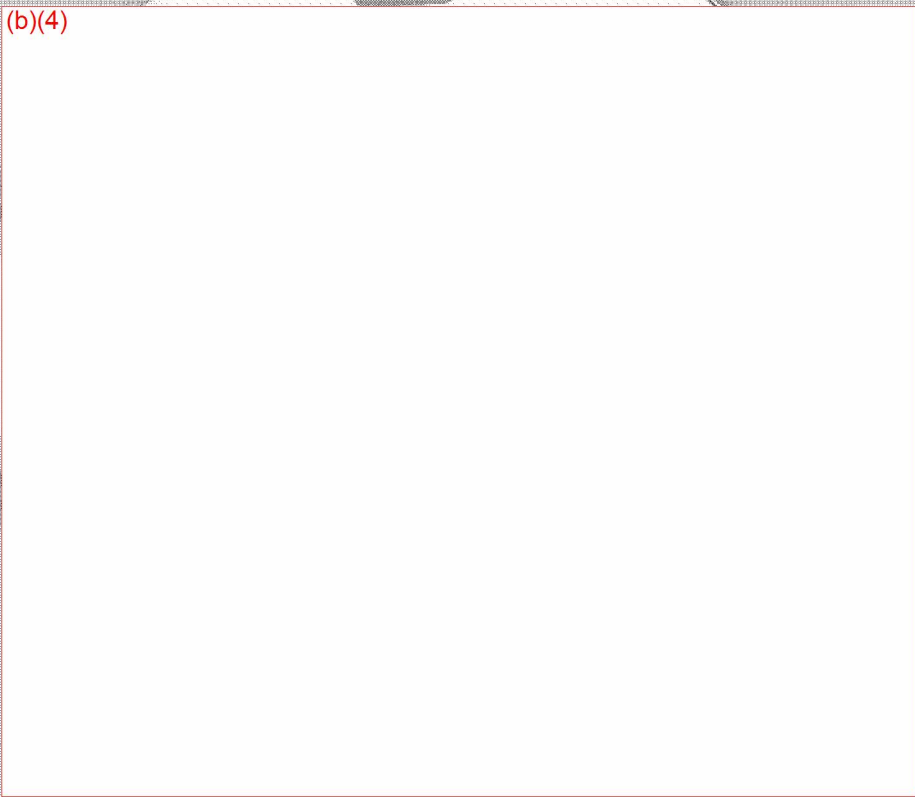
(b)(4)



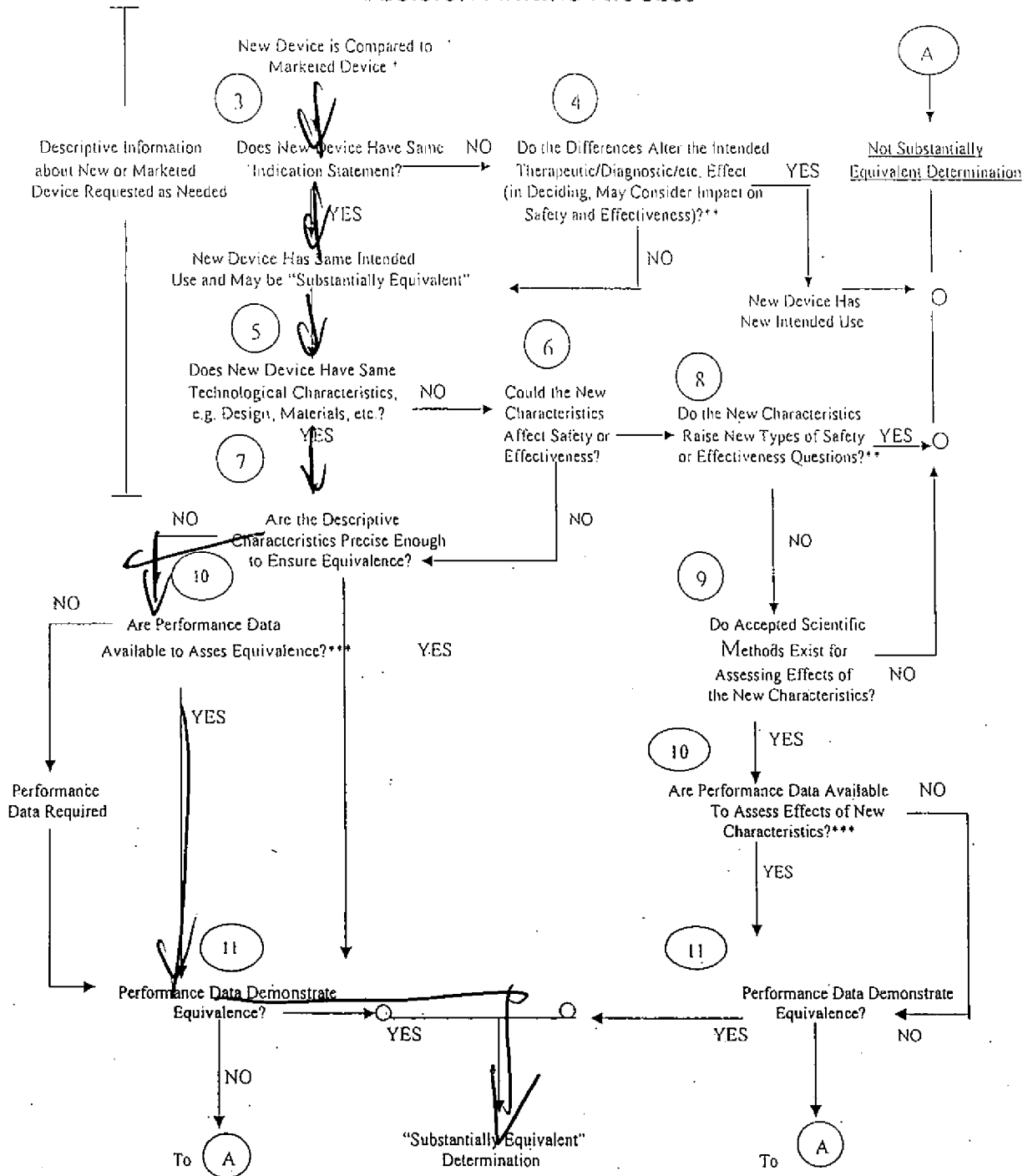
(b)(4)



(b)(4)



510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Indication for Use

510(k) Number (if known): _____

Device Name: FreeStyle Freedom Lite Blood Glucose Monitoring System

Indication For Use:

The FreeStyle Freedom Lite Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm, upper arm, and hand.

The FreeStyle Freedom Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary and venous whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.

Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

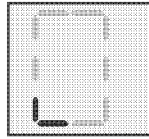
510(k) _____

LANGUAGE1

Important Test Strip Information:

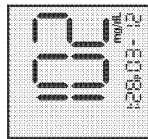
- Do not press the FreeStyle Lite® test strip against the test site.
- Do not scrape the blood onto the FreeStyle Lite test strip.
- Do not apply blood to the flat side of the FreeStyle Lite test strip.
- Do not apply blood to the FreeStyle Lite test strip when the FreeStyle Lite test strip is out of the meter.
- Do not put blood or foreign objects into the FreeStyle Freedom Lite® test strip port.

4 Waiting for Result



- Do not pull the FreeStyle Lite test strip away from the sample until you hear one beep or see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.

- If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same sample area of the test strip from which you started for up to 60 seconds from the time of the first application.

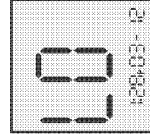


- The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps if the sound is on.
- The time that the meter takes to display a reading depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle Freedom Lite® meter displays results from 20 to 500 mg/dL (1.1 to 27.8 mmol/L).

If your test result is lower than 20 mg/dL (1.1 mmol/L), LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).



LO Reading with Symptoms

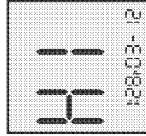
If you have a LO reading and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.

LO Reading

LO Reading without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hypoglycemia.

If your test is above 500 mg/dL (27.8 mmol/L), HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).



HI Reading

HI Reading with Symptoms

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.

LANGUAGE1

LANGUAGE2

LANGUAGE1

LANGUAGE2

HI Reading without Symptoms

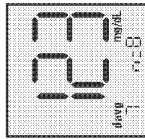
If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip on your fingers. If you still get a HI reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hyperglycemia.

**Meter Results
Meter Memory**

- **To Enter**
Start with the meter off (no test strip inserted). Press and release the "m" button; the first memory screen to appear will be your 7-day average.
- **To Exit**
Press and hold the "m" button for two seconds until the meter turns off.

7-, 14-, 30- Day Average

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)



Example:

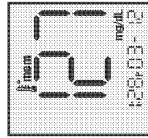
7davg = your 7-day average
n = indicates the number of results included in your average

The "c" button allows you to scroll forward to 14- and 30-day averages. Continue to press the "c" button to view stored test results. Your most recent result will display first.



Test Results

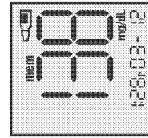
The meter stores the last 400 test readings with time and date. You may scroll forward through all of the readings by pressing the "c" button. The "m" button allows you to scroll backward. The first reading you see is the most recent result.



Temperature: A result with a thermometer symbol (°F) indicates that the reading was taken outside of the meter's specified operating temperature range and may not be accurate. This value is included in your 7-, 14- and 30-day averages.

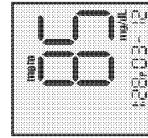
LO Reading: A LO reading (under 20 mg/dL or 1.1 mmol/L) is included in the memory as LO; it is not included in your 7-, 14- and 30-day averages.

HI Reading: A HI reading (over 500 mg/dL or 27.8 mmol/L) is included in the memory as HI; it is not included in your 7-, 14- and 30-day averages.



Control Solution Test

A value with (CS) indicates that you have marked this reading as a control solution test. The date and time of the control solution reading will appear on the bottom of the screen.

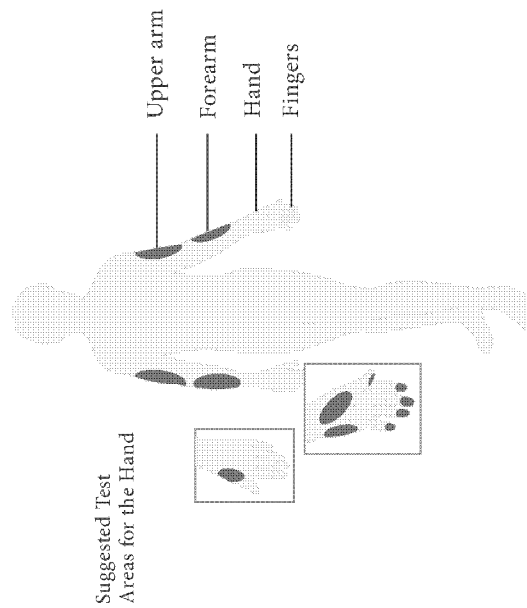


Blood Glucose Test

A result without a control solution symbol indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.

The FreeStyle Freedom Lite® System Uses a Tiny Sample of 0.3µl So You Can Test on a Variety of Locations

Available Test Sites



The human figure above shows the areas where you can test with the FreeStyle Freedom Lite system. Avoid moles, veins, bones, and tendons.

WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Important Information About Your FreeStyle Freedom Lite® Blood Glucose Monitoring System

How the FreeStyle Freedom Lite System Should Be Used

- The FreeStyle Freedom Lite system is intended for use outside the body (in other words, *in vitro* diagnostic use only).
- The FreeStyle Freedom Lite system is used for measuring blood glucose (also known as blood sugar) from samples taken from the forearm, upper arm, hand, or fingers.
- The FreeStyle Freedom Lite meter should only be used with FreeStyle Lite® test strips and FreeStyle control solution. Using other test strips and control solution with this meter can produce inaccurate results.

Do use the FreeStyle Freedom Lite system for:

- Testing blood glucose.
- Testing glucose in fresh capillary whole blood samples.

Do not use the FreeStyle Freedom Lite system for:

- The diagnosis of or screening for diabetes mellitus.
- Testing on newborns.
- Testing of arterial blood.

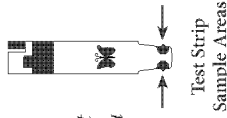
LANGUAGE1

LANGUAGE2

The FreeStyle Lite® Test Strip

Apply blood or control solution to only one test strip sample area per test.

Important: Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Freedom Lite® meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

Important Test Strip Information

- The FreeStyle Freedom Lite system has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight or heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.

LANGUAGE1

- Do not use test strips beyond the expiration date. This may cause inaccurate results.
 - Do not bend, cut, or alter FreeStyle Lite® test strips.
- Note:** For further information, refer to the FreeStyle Lite test strip package insert.

The FreeStyle® Control Solution

Each FreeStyle control solution vial contains a red liquid with a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.

A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

There are three levels of control solution available (Low, Normal, High). For information on how to obtain control solution, call Customer Care at 1-888-522-5226.



LANGUAGE1

LANGUAGE2

510(k) Summary

Per 21 CFR §807.92, the following information is provided for the FreeStyle Lite Blood Glucose Monitoring Systems specifically related to the FreeStyle Lite Blood Glucose Test Strip portion of the system. During the product development, this product was referred to as “Omni” or “Omni-FAD” for project documentation purposes. Supporting documentation included in this submission may make reference to the aforementioned names.

Company:	Abbott Laboratories
Division:	Abbott Diabetes Care, Inc.
Street Address:	1360 South Loop Road
City, State Zip:	Alameda, CA 94502
Telephone No:	510-749-5400
Fax No:	510-864-4791
Contact Person:	Arul Sterlin; Tel No. 510-864-4310; Fax No. 510-864-4791; E-mail. arul.sterlin@abbott.com
Proprietary Name:	FreeStyle Lite Blood Glucose Test Strips
Common Name:	Reagent Test Strips
Classification Name:	Glucose Dehydrogenase, Glucose, Class II (21 CFR§ 862.1345) Product codes: NBW, LFR; Single Analyte Control Solution, Class I (21 CFR§ 862.1660) Product code: JJX
Predicate Device:	FreeStyle Lite Blood Glucose Monitoring System (K070850)
Manufacturing Site:	Establishment: Abbott Diabetes Care Inc. 1360 South Loop Rd. Alameda, CA 94502 Registration Number: 2954323 Establishment: Abbott Ireland Diabetes Care Donegal Town, Co. Donegal Donegal Town, IRELAND Donegal Registration Number: 3007031103

Description of the Device:

A chemistry change has been made to the FreeStyle Lite Blood Glucose Test Strip. The modified strip is to be marketed under the brand name, FreeStyle Lite, and is intended for use with the following Blood Glucose Monitoring Systems:

- FreeStyle Lite Blood Glucose Monitoring System cleared under K070850
- FreeStyle Freedom Lite Blood Glucose Monitoring System filed under a letter to file

The meters and other system components contained within these systems have not been modified. Each of the fore mentioned blood glucose monitoring systems are comprised of a handheld glucose meter, glucose reagent test strips, a quality control solution, a lancing device, lancets, lancing cap, and labeling for performing a blood glucose test. The intended uses and principles of operation for each of the systems remains the same as previously submitted and

cleared for market entry. The systems utilize coulometric biosensor technology to quantitatively measure glucose concentration in whole blood samples. The systems are intended for self-monitoring of glucose in capillary and venous whole blood. The primary users are persons with diabetes. The systems are meant to aid in diabetes management and for healthcare professionals to aid in monitoring the effectiveness of diabetes treatment. The FreeStyle Lite Blood Glucose Test Strip is an electrochemical biosensor that fits into a handheld meter. When the strip is touched to a blood drop, the sample chamber on the strip fills by capillary action. The blood sample volume is approximately 0.3 microliters (300 nanoliters), which can be obtained from the finger, forearm, upper arm, and hand. Test results display in accordance with the blood glucose meter's software algorithm (approximately 5 seconds). The internal volume of the test strip is precisely controlled, and a blood glucose result will not be displayed on the LCD unless the internal sample chamber is filled. Once the measurement begins, the glucose is rapidly oxidized by the reagents that are present in the inside of the sample chamber. The electrochemical signal that results from this process depends only on the total amount of glucose present. The reagent chemistry enables electrolysis of glucose in the blood sample. A mediator molecule shuttles electrons rapidly between a glucose-oxidizing enzyme and the working electrode on the strip. The mediator is capable of reacting rapidly with both the electrode and the enzyme, resulting in a rapid reaction time and minimizing the total amount of mediator required. The small mediator load results in high accuracy at the low end of the glucose measurement range.

Description of Modifications:

The modifications to the system are comprised of changes to the blood glucose test strip which include chemistry, materials, appearance, and modification of the meter turn on bar to the strip.

Chemistry:

The FreeStyle Lite Blood Glucose Test Strip chemistry for the new enzyme test strip is changed from GDH-PQQ with nPBI mediator (Osmium complex with n-pentyl benzimidazole ligand), to GDH-FAD with MAP mediator (ligand of mediator has changed to n-methyl pyridine). GDH-FAD does not show interference in the presence of carbohydrates such as maltose, lactose and galactose as compared with assays performed with GDH-PQQ. The n-pentyl benzimidazole ligand of the mediator has changed to n-methyl pyridine and a new source of carbon ink is used to make the new enzyme chemistry compatible with on-market meters.

Materials:

The modified FreeStyle Lite Blood Glucose Test Strip will utilize the same materials as the current FreeStyle Lite Blood Glucose Test Strip, with the exception of the spacer tape and source of carbon. A new adhesive system is utilized as the spacer tape. The new spacer tape uses the exact same base polymer resin as the current FreeStyle Lite adhesive coupled with a different crosslinking agent. Screen printed carbon active electrodes is made using DuPont carbon ink instead of Ercon carbon. All other materials used for the modified FreeStyle Lite Blood Glucose Test Strip, the melinex and the silver/silver chloride ink used are exactly the same as those used for current FreeStyle Lite production.

Appearance:

The physical appearance of the test strip has been changed to aid customers to distinguish visually between the new enzyme version of the product from the current on-market product. Attachment below contains the image of current and new strip.

Meter Turn On Bar:

Blood Glucose Test Strips that are branded, FreeStyle Lite, will have a modified turn on bar but will continue to require the same user interface no coding activities as those currently employed by users in the market.



Clinical Summary Report

(b)(4)

(b)(4)

Indication for Use

510(k) Number (if known): _____

Device Name: FreeStyle Lite Blood Glucose Monitoring System

Indication For Use:

The FreeStyle Lite Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm, upper arm, and hand.

The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary and venous whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.

Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

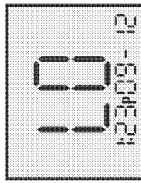
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle Lite® meter displays results from 20 to 500 mg/dL (1.1 to 27.8 mmol/L).

If your test result is lower than 20 mg/dL (1.1 mmol/L), LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).



LO Reading with Symptoms

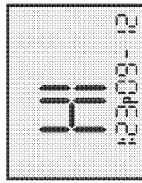
If you have a LO reading and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.

LO Reading

LO Reading without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hypoglycemia.

If your test is above 500 mg/dL (27.8 mmol/L), HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).



HI Reading

HI Reading with Symptoms

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.

HI Reading without Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip on your fingers. If you still get a HI reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hyperglycemia.

Meter Results

Meter Memory

To Enter

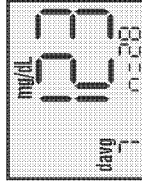
Start with the meter off (no test strip inserted). Press the "m" button and release; the first memory screen to appear will be your 7-day average.

To Exit

Press and hold the "m" button until the meter turns off.

7-, 14-, 30- Day Average

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)



Example:

7 day avg = your 7-day average
n = indicates the number of results included in your average

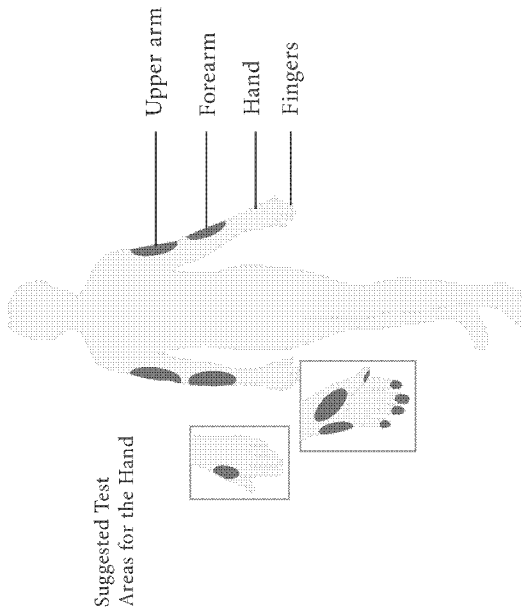
The "c" button allows you to scroll forward to 14- and 30-day averages. Continue to press the "c" button to view stored test results. Your most recent result will display first.

The "m" button allows you to scroll backward.



The FreeStyle Lite[®] System Uses a Tiny Sample of 0.3µl So You Can Test on a Variety of Locations

Available Test Sites



Suggested Test Areas for the Hand

The human figure above shows the areas where you can test with the FreeStyle Lite system. Avoid moles, veins, bones, and tendons.

WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Important Information About Your FreeStyle Lite[®] Blood Glucose Monitoring System

How the FreeStyle Lite System Should Be Used

- The FreeStyle Lite system is intended for use outside the body (in other words, *in vitro* diagnostic use only).
- The FreeStyle Lite system is used for measuring blood glucose (also known as blood sugar) from samples taken from the forearm, upper arm, hand, or fingers.
- The FreeStyle Lite meter should only be used with FreeStyle Lite test strips and FreeStyle control solution. Using other test strips and control solution with this meter can produce inaccurate results.

Do use the FreeStyle Lite system for:

- Testing blood glucose.
- Testing glucose in fresh capillary whole blood samples.

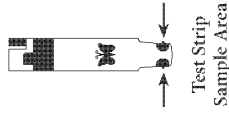
Do not use the FreeStyle Lite system for:

- The diagnosis of or screening for diabetes mellitus.
- Testing on newborns.
- Testing of arterial blood.

The FreeStyle Lite® Test Strip

Apply blood or control solution to only **one Test Strip Sample Area** per test.

Important: Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Lite® meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

Important Test Strip Information

- The FreeStyle Lite System has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight and heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.



• Do not use test strips beyond the expiration date. This may cause inaccurate results.

• Do not bend, cut, or alter FreeStyle Lite® test strips.

Note: For further information, refer to the FreeStyle Lite test strip package insert.

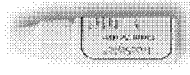
The FreeStyle® Control Solution

Each FreeStyle control solution vial contains a red liquid with a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.

A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

There are three levels of control solution available (Low, Normal, High). For information on how to obtain control solution, call Customer Care at 1-888-522-5226.



Appendix 1

Indication for Use

510(k) Number (if known): _____

Device Name: FreeStyle Lite Blood Glucose Monitoring System

Indication For Use:

The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm; and venous blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.

Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

Indication for Use

510(k) Number (if known): _____

Device Name: FreeStyle Freedom Lite Blood Glucose Monitoring System

Indication For 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 finger, upper arm and palm; and venous blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.

Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

Appendix 2

FREESTYLE LITE[®] BLOOD GLUCOSE TEST STRIPS

Freestyle Lite Blood Glucose Test Strips - Product Information

Only for use with Freestyle Lite and Freestyle Freedom Lite Blood Glucose Systems for Test for Glucose in Whole Blood (Blood Glucose Test Strip with Customized Technology)

IMPORTANT: PLEASE READ THIS INFORMATION AND YOUR OWNER'S BOOKLET BEFORE USING THE FREESTYLE LITE TEST STRIPS TO TEST YOUR BLOOD SUGAR.
For daily self-management care at 7:00am-9:30am, 30 hours a day, 7 days a week.

and the Freestyle Lite Blood Glucose Test Strip is intended for use in the quantitative measurement of glucose in capillary whole blood from the upper arm and palm and refers whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home and in monitoring the effectiveness of a diabetes control program. 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.

Do not use during extreme absorption testing.

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Do not use during extreme absorption testing.

When a control solution test is done, you should get results within the expected range printed on the test strip. If a control solution test result falls outside that range, repeat the test. Results that fall outside the range may be caused by:

- error in performing the test
- expired or contaminated control solution
- test strip deterioration
- water contamination

WARNING: If you continue to get Freestyle control solution test results that fall outside the range printed on the test strip, the system may not be functioning properly. Do NOT use the system to test your blood until you get a control solution test result within the range printed on the test strip label. Contact Customer Care.

Performance Characteristics

The performance of these test strips has been tested both in laboratory and clinical studies. The testing range is 20 mg/dL to 500 mg/dL. The Freestyle Lite test strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

Accuracy

Capillary blood glucose results obtained by lay users were compared with those obtained using the YSI Glucose Analyzer.

Consistency of system accuracy for finger samples with YSI glucose results lower than 75 mg/dL:

Within ± 5 mg/dL	Within ± 10 %	Within ± 15 mg/dL	Within ± 15 %
73% (6/7)	100% (11/11)	100% (11/11)	100% (11/11)

Consistency of system accuracy for finger samples with YSI glucose results of 75 mg/dL or higher:

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
99% (166/168)	99% (166/168)	99% (166/168)	99% (167/168)

Consistency of system accuracy for alternate site samples with YSI glucose results lower than 75 mg/dL:

Test Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Thigh	1/5 (20%)	1/5 (20%)	1/5 (20%)
Upper Arm	0/1 (0%)	0/1 (00%)	0/1 (00%)

Consistency of system accuracy for alternate site samples with YSI glucose results of 75 mg/dL or higher:

Test Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Thigh	1/5 (20%)	1/5 (20%)	1/5 (20%)	1/5 (20%)
Upper Arm	0/1 (0%)	0/1 (00%)	0/1 (00%)	0/1 (00%)

The regression statistics are derived from a plot of the lay user finger data versus YSI capillary data.

Slope	0.95
y-intercept	7.3 mg/dL
Correlation coefficient (R)	0.99
Number of samples tested	179
Range tested	38-375 mg/dL

Precision

Within-run and within-lot precision of these test strips was measured with venous blood samples in the laboratory.

Within-Lot Precision

Average Glucose Concentration	mg/dL	63.3	94.2	140.7	238.5	345.0
SD	mg/dL	1.8	2.1	2.9	4.4	6.6
CV	%	3.3	2.4	2.3	2.1	2.4

Within-Vial Precision

Average Glucose Concentration	mg/dL	63.3	94.2	140.7	238.5	345.0
SD	mg/dL	1.1	1.6	2.4	3.9	6.0
CV	%	2.5	2.7	1.8	1.9	2.1

Variability in blood tests from strip to strip was 3.3% or less.

Chemical Composition

YSI Glucose Dehydrogenase (Aerobic/Oxidase) ≥ 1.0 Unit
Other ingredients (Iles, reagents, etc.) ≥ 0.01 mg

References

1. American Diabetes Association. Clinical Practice Recommendations. Diagnosis and classification of diabetes mellitus. Diabetes Care 2003;26 (Suppl 1):S11-S12.
2. Hodge GE, Baumgartner A, Baker AM, Chovick M, Rinsky L. Fingerprint glucose determination in blood. Analyt Med 114: 1020-1024, 1981.
3. Sautter M, Law-New T. Measuring capillary glucose measurements. Practical Diabetes 7: 210, 1990.
4. Williams RW, Archer RL. Low test unreliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes 3: 100, 1986.

Description of Symbols

	Consult instructions for use		Batch code
	Temperature limitation		Use by
	Manufacturer		Do not touch
			Diabetic drug with medical device

FPO

20059E

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FPO

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Manufacturer / Manufacture:
Abbott Diabetes Care Inc.
1885 South Long Road
Alameda, CA 94502 USA

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Appendix 3

FREESTYLE LITE™ BLOOD GLUCOSE TEST STRIPS

Freestyle Lite Blood Glucose Test Strips Product Information

Only for use with Freestyle Lite and Freestyle Freedom Lite Blood Glucose Systems to Test Urine Glucose in Urine-Blood Glucose Test Strip with CodeMeter™ Technology.

IMPORTANT: PLEASE READ THE INFORMATION AND YOUR OWNERS' BOOKLET BEFORE USING THE FREESTYLE LITE TEST STRIPS TO TEST YOUR BLOOD GLUCOSE.

For help call Customer Care at 1-800-622-5234, 24 hours a day, 7 days a week.

Read the
Freestyle Lite Blood Glucose Test Strip is intended for use in the quantitative measurement of glucose in capillary whole blood from the upper arm, and palm, and venous whole blood. It is intended for use by health care professionals and people with diabetes mellitus of any age and in monitoring the effectiveness of a diabetes control regimen. It is not intended for the diagnosis of or screening for diabetes mellitus, and its use is not intended for use in neonates or pregnant women.

Do not use
Do not use during a glucose absorption testing.
Do not use if you are using a glucose absorption testing.

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Do not use
Do not use if you are using a glucose absorption testing.

When a control solution test is done, you should get results within the expected range printed on the test strip vial. If control solution test results fall outside this range, repeat the test. Results that fall outside the range may be caused by:
- error in performing the test
- expired or contaminated control solution
- test strip deterioration
- meter malfunction

WARNING: If you continue to get Freestyle Lite control solution test results that fall outside the range printed on the test strip vial, the system may not be functioning properly. DO NOT use the system to test your blood until you get a control solution test result within the range printed on the test strip vial label. Contact Customer Care.

Performance Characteristics
The performance of these test strips has been tested both in laboratory and clinical studies. The testing range is 20 mg/dL to 500 mg/dL. The Freestyle Lite test strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

Accuracy
Laboratory blood glucose results obtained by users were compared with those obtained using the YU-100 glucose analyzer.
Summary of system accuracy for finger samples with TG glucose results lower than 75 mg/dL:

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
73% (14/19)	100% (11/11)	100% (11/11)

Summary of system accuracy for finger samples with TG glucose results of 75 mg/dL or higher:

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
69% (115/166)	87% (115/132)	90% (114/126)	96% (113/118)

Summary of system accuracy for alternate site samples with TG glucose results lower than 75 mg/dL:

Test Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Palm	1.0 (20%)	1.0 (20%)	1.0 (20%)
Upper Arm	0.1 (2%)	1.0 (20%)	1.0 (20%)

Summary of system accuracy for alternate site samples with TG glucose results of 75 mg/dL or higher:

Test Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Palm	1.0 (14%)	1.0 (14%)	1.0 (14%)	1.0 (14%)
Upper Arm	1.0 (14%)	1.0 (14%)	1.0 (14%)	1.0 (14%)

The regression statistics are derived from a pool of the try over time data versus YU-100 laboratory data.

Parameter	Value
Slope	0.95
Y-intercept	1.3 mg/dL
Correlation coefficient (R)	0.99
Number of samples tested	179
Range tested	18-175 mg/dL

Precision
Within lot and within lot precision of these test strips was measured with venous blood samples in the laboratory.

Within Lot Precision

Average Glucose Concentration	mg/dL	43.3	94.2	140.7	238.3	345.0
SD	mg/dL	1.5	2.1	2.8	4.8	6.8
CV	%	3.3	2.4	2.0	2.0	1.9

Within Vial Precision

Average Glucose Concentration	mg/dL	43.1	94.2	140.7	238.3	345.0
SD	mg/dL	1.3	2.3	2.8	3.9	6.0
CV	%	2.9	2.2	1.9	1.6	1.7

Stability in blood levels from strip to strip was 1.5% or less.

Chemical Composition
TAG Glucose Dehydrogenase (Biosensor) ≥ 1.0 mg/L
Other ingredients (Buffer, reagents, etc.) > 0.01 mg

References
1. American Diabetes Association. Clinical Practice Recommendations: Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 2005; 28 (Suppl. 1):S14-S16.
2. Aditya SK, Banerjee A, Jaber MA, Choudhry M, Reddy J. Fingerstick glucose determination in check. Ann Int Med 1998; 129: 1361-1362.
3. Sander M, Line SW. Monitoring capillary glucose measurements. Practical Diabetes 7: 116, 1990.
4. Wickham KW, Arthur KM, Love DJ. Unreliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes 1: 100, 1984.

Description of Symbols

	Read instructions for use		Batch code
	Expiry date		Use by
	Manufacturer		Do not reuse
			In-vial diagnostic medical device

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Manufacturer / Manufactureur:
Abbott Diabetes Care Inc.
1400 South Loop West
Riverside, TX 74703 USA

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Manufacturer/Manufacturer:
Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502 USA

Customer Care is available 24 hours a day, 7 days a week
Customer Care is available 24 hours a day, 7 days a week

www.MyFreeStyle.com
Call Customer Care
Toll Free at 1-888-522-5226

www.MyFreeStyle.com
Call Customer Care
Toll Free at 1-888-522-5226

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US6,071,391; US6,120,676; US6,143,164; US6,156,173; US6,299,757; US6,336,790; US6,303,381;
US6,591,125; US6,607,668; US6,616,819; US6,618,934; US6,676,816; US6,749,740; US6,893,545;
US6,942,518; US7,058,437; US7,615,637; US0587,142; EP1119637; EP1145000.
Additional patents may be issued and/or pending.

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DOC20246 Rev. B 04/10

DOC20246 Rev-B-Cvr.indd 1-2

Freestyle Lite
Blood Glucose Monitoring System
Blood Glucose Monitoring System

No Coding Required
No Coding Required

Owner's Booklet
Owner's Booklet

Abbott

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LANGUAGE1

LANGUAGE2

Important Information About Your FreeStyle Lite Blood Glucose Monitoring System

How the FreeStyle Lite System Should Be Used

- The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm and venous whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.
- The FreeStyle Lite meter should only be used with FreeStyle Lite test strips and FreeStyle[®] control solution. Using other test strips and control solution with this meter can produce inaccurate results.

WARNING:

- We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.
- The FreeStyle Lite System contains small parts that may be dangerous if swallowed.

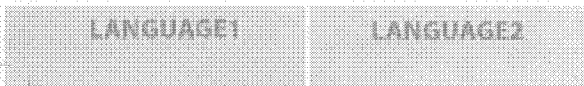
Caution: Please read all the instructions provided in this Owner's Booklet and practice the testing procedures before using the FreeStyle Lite[®] system. Blood glucose monitoring should be done with the guidance of a healthcare professional.

Important Health-Related Information

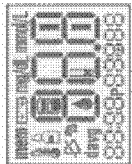
- Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL or higher than 240 mg/dL, you should contact your healthcare professional and follow his or her treatment advice.
- For additional information, consult your test strip product information.
- The expected glucose range for a non-diabetic, non-pregnant fasting adult is under 100 mg/dL.
- Two hours after meals, levels should be less than 140 mg/dL.
- Consult your healthcare professional to determine the range that is appropriate for you.

Reference

1 American Diabetes Association Clinical Practice Recommendations: Diagnosis and classification of diabetes mellitus. Diabetes Care 2005;28 (Suppl.1):S37-S42



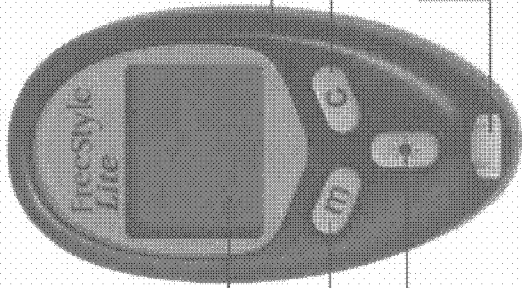
The FreeStyle Lite® Meter and How It Works



This screen always appears when the meter is turned on so that you can make sure the display is working properly. Do not use the meter if the system check screen does not match the example here. Please call Customer Care.

Data Port

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

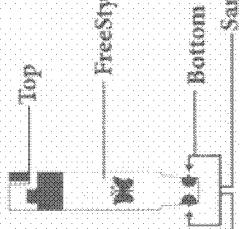


4 (Change) Buttons

- Marks a control solution test.
- Scrolls forward.
- Displays clock.
- Silence a reminder alarm.

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.



Mode/Back Buttons

Displays your test results and other important information.

Light Buttons

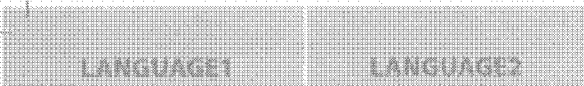
- Move to different mode settings.
- Scrolls backward.
- Silence a reminder alarm.

Light Indicator

Controls the display backlight and test light.

Sample Area Check (shown from example on page 51)

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



LANGUAGE1 LANGUAGE2

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Memory Memory

Shows you test results stored in the meter memory.

Control Solution Control Solution

Shows that you have marked a test result as a control solution test.

Battery Battery

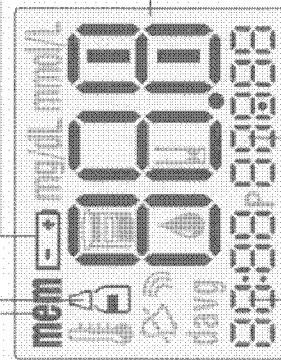
Appears when you should replace your meter battery.

Test Results Test Results

Displays test results.

Time Time

Displays date, time, and number of tests.



LANGUAGE1 LANGUAGE2

mg/dL mg/dL

Indicates unit of measurement.

Temperature Temperature

Appears if your meter is out of operating temperature range.

High/Low Symbols

Indicates high, low, or off sound volume.

High/Low Symbols

These symbols work together in an animation to tell you when the meter is ready for you to apply blood or control solution.

Time Time

Shows the average value of glucose readings from the last 7-, 14- or 30-days.

Time Time

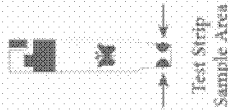
Indicates PM in 12-hour format only (for example 4:00 p.m.).

71

The FreeStyle Lite® Test Strip

Apply blood or control solution to **only one Test Strip Sample Area** per test.

Important: Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Lite meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

Operating Temperature

- The FreeStyle Lite System has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight and heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.

7 Call Customer Care Toll Free at 1-888-522-5226 www.MyFreeStyle.com

- Do not use test strips beyond the expiration date. This may cause inaccurate results.

- Do not bend, cut, or alter FreeStyle Lite® test strips.

Note: For further information, refer to the FreeStyle Lite test strip package insert.

The FreeStyle® Control Solution

Each FreeStyle control solution vial contains a red liquid with a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.



A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

There are three levels of control solution available (Low, Normal, High). For information on how to obtain control solution, call Customer Care at 1-888-522-5226.

Control Solution Information

FreeStyle® control solution is good for three months after opening the bottle or until the expiration date printed on the label, whichever comes first.

Important: Count forward three months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle.

Example: You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.

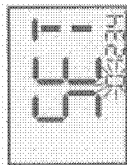
- Use only FreeStyle control solution with your FreeStyle Lite® system.
- Replace the cap on the control solution bottle immediately after using.
- Do not use control solution past the expiration date.
- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when used between 59° to 104° F (15° to 40° C).
- Control solution test results should fall within the range printed on the test strip vial label.

Important: The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.

- If control solution results are out of this range, repeat the test.
- If your control solution test results continue to fall outside the range printed on the test strip vial, do not use the FreeStyle Lite system to test your blood glucose. Contact Customer Care.

Caution: Results from FreeStyle control solution tests do not reflect your blood glucose level.

Meter Setup

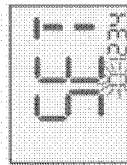


- **To Enter Setup Mode**
Start with the meter off (no test strip inserted). Press and firmly hold the "m" button until the 5 E I display screen appears.
- **To Exit at Any Time**
Press and hold the "m" button until the meter turns off.
- **To Move Through the Screens**
Press the "m" button to move through all the setup screens such as reminder alarms, sound level, time, date, and so on.
- **To Change Settings Within the Screen**
Press the "c" (configure) button.

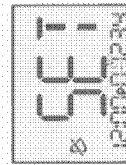
Setting the Reminder Alarms

You may set up any or all of the reminder alarms (1-4). Note: A reminder alarm will never sound during a test.

To set a reminder alarm or multiple reminder alarms, please follow these steps.

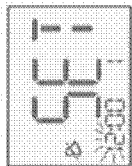


1. Start with the meter off. Press the "m" button and hold until the 5 E I display appears with 01234. You are now in the reminder alarm setting mode and the "0" is blinking.



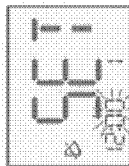
2. To move to the first reminder alarm press the "c" button once. You are now ready to set reminder alarm 1 ("1" is blinking).

Select reminder alarm



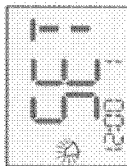
Select hour

3. Press the "m" button to move to the hour setting. With the hour blinking, press the "c" button until the correct hour appears.



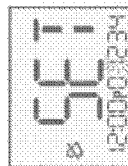
Select minute

4. Press the "m" button to move to the minute setting. With the minute blinking, press the "c" button until the correct minute appears.



Select reminder alarm volume

5. Press the "m" button to move to the reminder alarm volume setting. Default setting is off. Press the "c" button to select the desired volume setting: low, high, or off.



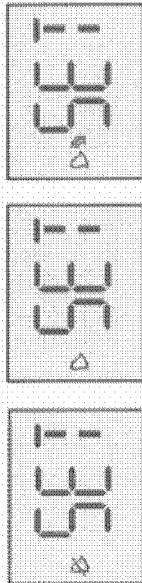
Select reminder alarm

6. Press the "m" button to finalize your alarm setting. This will bring you back to the reminder alarm setting SE 1 mode. If you wish to set multiple reminder alarms press "c" to move to reminder alarm 2. Repeat.

Note: To save your reminder alarm settings and exit setup mode, press and hold the "m" button until the meter turns off. Press the "m" button when "0" is blinking to move to the next setup screen without setting any reminder alarms.

Setting the Sprints

There are three (3) sound volume options:

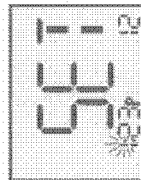


Off Low High

There are three sound volume options to let you know when the test strip is full, when the reading is done, and when an error occurs:

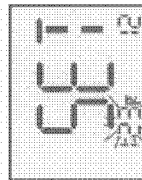
1. Press the "c" button until the desired sound level appears
2. Press the "m" button to move to "Setting the Time."

Setting the Time



Hour

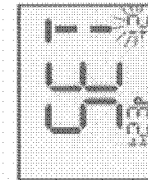
1. With the hour blinking, press the "c" button until the correct hour appears. The default for the meter is the 12-hour time format. The "p" displays for "PM" times.



Minute

2. Press the "m" button to move to minute setting.
3. With the minute blinking, press the "c" button until the correct minute appears.

Setting the Time Format

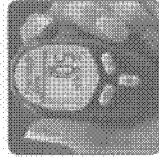


Time Format

4. Press the "m" button to move to "Setting the Time Format"
1. With the hour mode blinking, press the "c" button to move between 12-hour and 24-hour format. The time automatically updates to the format selected.
2. Press the "m" button to move to "Setting the Date."


Using Your Meters Lights

Depending on what mode your meter is in, pressing the light button () turns on either the display backlight or the test light.



Using the Display Backlight

Pressing the light button powers on the display backlight in all modes except when applying a sample. When applying a sample, the light button turns the test light on.

The display backlight goes out when you press the light button () again or when the meter is inactive for 10 seconds.



Using the Test Light

Pressing the light button while the Blood Drop and Test Strip symbols appear on the display screen powers on the test light.

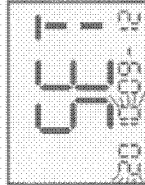
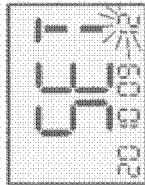
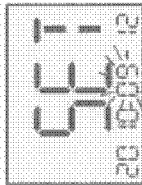
The test light goes out:

- When you press the light button again.
- When the meter receives the correct amount of blood for a test (the FreeStyle Lite® test strip is filled).
- After 60 seconds of no activity.
- When a FreeStyle Lite test strip is removed from the meter.

If you use either the backlight or the test light during the test mode, the backlight lights again to show you the test results after the measurement is complete.

Setting the Meter and Date Format

1. With the month blinking, press the "c" button until the correct month appears.
2. Press the "m" button to move to the day setting.
3. With the day blinking, press the "c" button until the correct day appears.
4. Press the "m" button to move to "Date Format."
5. With the date blinking, press the "c" button to select month-day or day-month format. The date automatically updates to the format selected.
6. Press the "m" button to move to the year setting.
7. With the year blinking, press the "c" button until the correct year appears.



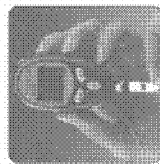
You have completed Meter Setup.

- To move to "Setting the User Reminder Alarms" press the "m" button.
- To exit press and hold the "m" button.

LANGUAGE1

LANGUAGE2

Performing a Control Solution Test



Insert the top of the test strip into your meter until it stops. This will power on the meter.

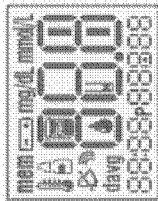
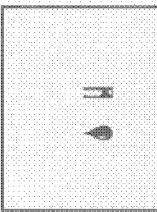


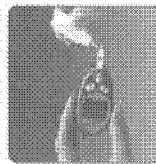
Figure 1: Control Solution

When the meter powers on, this screen will appear so that you can make sure the display is working properly.

System Check



Wait for the meter to display the Blood Drop and Test Strip symbols.



Gently touch only the *Sample Area* of the test strip to the control solution.

Important: Do not apply control solution to both Test Strip Sample Areas.

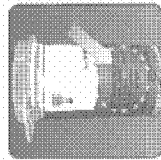
If the sound prompt is on, your meter will beep when the test strip is full. A short line then moves clockwise around the display screen while the sample is processing.

LANGUAGE1

LANGUAGE2

The result will appear on the display screen and if the sound is on, your meter will beep twice. To mark the result as a control solution result, press and hold the "c" button for two seconds until the control solution symbol (C) appears at the top left of the display screen.

If you have marked a blood glucose test as a control solution test by mistake, you can unmark it by pressing and holding the "c" button again for two seconds.



Compare your control solution test result to the range printed on your test strip vial label. Your control solution results should fall within the range printed on the side of your test strip vial.

- Out of range test results may be caused by:
- Error in performing the test.
 - Expired or contaminated control solution.
 - Test strip deterioration.
 - Meter malfunction.

LANGUAGE1

LANGUAGE2

Testing Your Blood Glucose

Important: To ensure accurate results, wash your hands and test site (for example, your upper arm) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

- With the FreeStyle Lite® meter, you can test your blood glucose on your upper arm, palm or fingers.
- Testing with the FreeStyle Lite meter requires a very small sample size, 0.3 microliters of blood; about the size of pinhead (example: •).

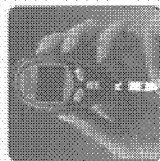
Times when you may be checking for low blood glucose include:

WARNING:

- We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.
- When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.
 - When you have delayed a meal after taking insulin.
 - When your healthcare professional advises you to do so.

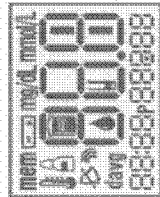
Performing a Blood Glucose Test

1 Prepare the meter



Insert a FreeStyle Lite® test strip into the meter until it stops. The meter will power on.

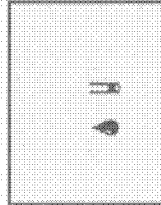
Note: If you do not start the test within two minutes, the meter will turn off. To restart your meter, take out the unused FreeStyle Lite test strip and reinsert it into the meter.



2 Prepare the hand to test

When the meter powers on, this screen will appear so that you can make sure the display is working properly.

System Check



The Blood Drop and Test Strip symbols will appear on the display screen. Your meter is now ready to apply blood sample.

Blood Drop and Test Strip Symbols

3 Perform the Blood Glucose Test

It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another test site.

LANGUAGE1

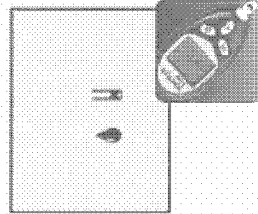
LANGUAGE2

2 Differences in Testing on Hypoglycemia

Select a test site. There are differences in testing on fingers versus other alternative sites.

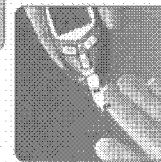
Use your lancing device to obtain a blood sample. Refer to the lancing device insert for detailed instructions on how to use the FreeStyle® lancing device.

WARNING: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.



3 Pulling the FreeStyle Lite Test Strip into the Meter

a. Make sure that the FreeStyle Lite test strip is in the meter and the meter is powered on. You are now ready to apply the blood sample.



b. Bring the FreeStyle Lite test strip to the blood sample at a slight angle.



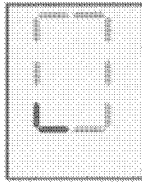
c. The FreeStyle Lite test strip pulls the blood into the strip through the sample area.

Test Strip Sample Area

4 Preparing the FreeStyle Lite Test Strip

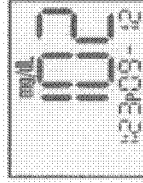
- Do not press the FreeStyle Lite® test strip against the test site.
- Do not scrape the blood onto the FreeStyle Lite test strip.
- Do not apply blood to the flat side of the FreeStyle Lite test strip.
- Do not apply blood to the FreeStyle Lite test strip when the FreeStyle Lite test strip is out of the meter.
- Do not put blood or foreign objects into the FreeStyle Lite test strip port.

5 Test Strip for Meter



- Do not pull the FreeStyle Lite test strip away from the sample until you hear one beep or see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.

If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same sample area of the test strip from which you started for up to 60 seconds from the time of the first application.

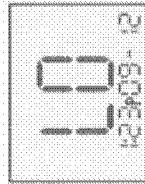


- The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps.
- The time that the meter takes to display a reading depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

11.3 Reading with Symptoms

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle Lite* meter displays results from 20 to 500 mg/dL.

If your test result is lower than 20 mg/dL, LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).



LO Reading

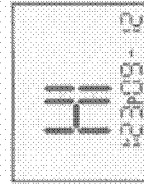
11.3 Reading with Symptoms

If you have a LO reading and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.

11.3 Reading with Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hypoglycemia.

If your test is above 500 mg/dL, HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).



HI Reading

11.3 Reading with Symptoms

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.

11.3 Reading with Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip on your fingers. If you still get a HI reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hyperglycemia.

11.3 Reading with Symptoms

Water Kept

- **To Enter**

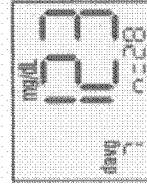
Start with the meter off (no test strip inserted). Press the "m" button and release; the first memory screen to appear will be your 7-day average.

- **To Exit**

Press and hold the "m" button until the meter turns off.

11.3 Reading with Symptoms

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)



Example:

7davg = your 7-day average

n = indicates the number of results included in your average

The "c" button allows you to scroll forward to 14- and 30-day averages. Continue to press the "c" button to view stored test results. Your most recent result will display first.

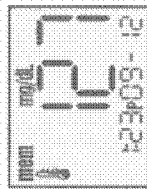
The "m" button allows you to scroll backward.

LANGUAGE1

LANGUAGE2

Test Results

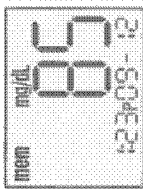
The meter stores the last 400 test readings with time and date. You may scroll through all of the readings by pressing and holding the "C" button. The first reading you see is the most recent result.



Temperature: A result with a thermometer symbol indicates that the reading was taken outside of the meter's specified operating temperature range and may not be accurate. This value is included in your 7-, 14- and 30-day averages.

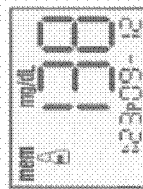
LO Reading: A LO reading (under 20 mg/dL) is included in the memory as LO.

HI Reading: A HI reading (over 500 mg/dL) is included in the memory as HI.



Control Solution Test

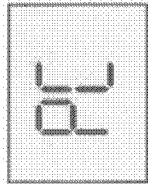
A result without a control solution symbol (A) indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.



Control Solution Test

A value with (A) indicates that you have marked this reading as a control solution test. The date and time of the control solution reading will appear on the bottom of the screen.

Data Download



The "PC" symbol displays when a data cable is inserted in the meter data port. You cannot perform a test while the data cable is in the meter data port.

The meter will display "PC" until the data cable is removed from the data port.

(Requires a compatible data management system.)

For more information, please go to our website or call Customer Care.

LANGUAGE1


LANGUAGE2

LANGUAGE1

LANGUAGE2

Battery Maintenance

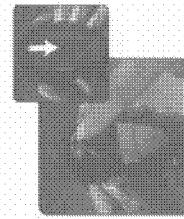
Battery

Your FreeStyle Lite[®] meter comes with one preinstalled, #2032, 3 volt, lithium battery. The battery provides enough power for the meter to perform about 500 tests. If your battery runs low, the battery symbol () appears on every display screen until you change the battery. When the battery runs low, the display backlight and test light may not power on.

Important: When this symbol appears, or when the backlight and test light begin to dim, you should replace the battery immediately.

- To avoid losing the time and date settings, replace the battery within one minute of removing the old battery.
- If you take more than one minute to replace the battery, you may need to reset the time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, the time and date displays flash 12:00 and 00-00 until they are reset.
- Removing the battery does not affect the meter's memory log or previously-stored user settings (such as date and time format).
- Even if you lose your time and date settings – you can perform a blood glucose test, and results will not be affected.

Replacing the Battery



Turn the meter over. Press in the battery door clip to open. Swing the battery door up to open and then off the meter.

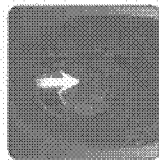
To remove the battery, push the battery downward to release the battery.

LANGUAGE1

LANGUAGE2

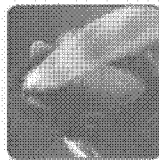
Replacing the Battery (continued)

2

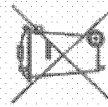


Install the battery with the positive (+) sign up toward you.

3



To close, angle the battery door back onto the meter and swing down until it snaps into place.



Note: The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

Caring for Your Meter

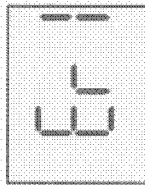
Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip and data ports.

Clean the outside of the meter using a cloth dampened with one of the following:

- Mild detergent/mild soap and water.
- 70% isopropyl alcohol.
- A mix of one part household bleach, nine parts water.

Important: Never immerse the meter in water or any other liquid.

System Troubleshooting Error 1



Possible Causes

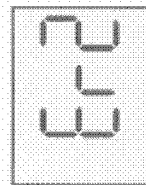
- Sample is too small.
- Problem with the FreeStyle Lite® test strip.
- Problem with the meter.
- Very low blood glucose (less than 20 mg/dL).

What You Should Do

1. If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your doctor's recommendation for treating hypoglycemia.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.

3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 2



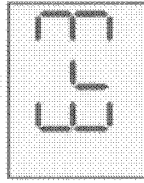
Possible Causes

- Problem with the FreeStyle Lite test strip.
- Problem with the meter.
- Very high glucose (above 500 mg/dL).
- HIGH control solution applied when temperature is too cold. (This applies only to control solution that is labeled as HIGH.)

What You Should Do

1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your doctor's recommendation for treating hyperglycemia.
2. Conduct a control solution test using a new FreeStyle Lite® test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite Test Strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 3



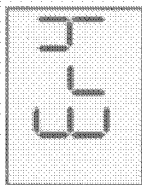
Possible Causes

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter or applying blood before the Blood Drop and Test Strip symbols display.
- Problem with the FreeStyle Lite test strip.
- Problem with the meter.

What You Should Do

1. Be sure you see the Blood Drop and Test Strip symbols on the display screen before you apply blood or control solution.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

FreeStyle Lite



Possible Causes

- Problem with FreeStyle Lite® test strip.
- Problem with the meter.

What You Should Do

1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite Test Strip.
2. If the retest using control solution does not work or the error persists, call Customer Care.

FreeStyle Lite

Meter does not enter the test mode after inserting a test strip.

Probable Cause	What to Do
The battery is dead.	Replace the battery (and reset the date and time, if necessary.)
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the FreeStyle Lite® test strip with the printed side up and the top of the strip in the meter.
Defective meter or test strips.	Call Customer Care.
Blood or foreign objects put into the test strip port.	Call Customer Care.

Test does not start after applying the blood sample.

Probable Cause	What to Do
Blood sample too small.	You may add blood to the same sample area of the FreeStyle Lite test strip from which you started for up to 60 seconds from the time of the first application. If necessary, repeat the test using a new FreeStyle Lite test strip and a larger blood sample.
Defective test strip.	Repeat the test with a new FreeStyle Lite test strip.
Sample applied after meter times out (two minutes) and turns off.	Repeat the test using a new test strip. Wait until you see the Blood and Test Strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Call Customer Care.

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LANGMUIR

FreeStyle Lite[®] System Specifications

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	500 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	mg/dL
Meter Storage Temp.	-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 #2032, 3 volt, lithium battery, replaceable
Result Range	20 to 500 mg/dL
Sample	Fresh capillary and venous whole blood samples
Sample Size	0.3 microliter (300 nanoliters)
Size	Width 1.57" x Length 2.9" x Depth 0.65"
Weight	1.0 to 1.1 ounces (28.3 to 31.2 grams) including battery

Manufacturer/Manufacturer:
Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502, USA

Customer Care is available 24 hours a day, 7 days a week.
Customer Care is available 24 hours a day, 7 days a week.

www.MyFreeStyle.com
Call Customer Care
Toll Free at 1-888-522-5226

www.MyFreeStyle.com
Call Customer Care
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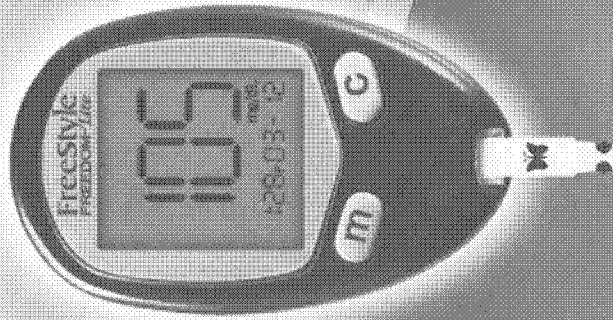
This product(s) and/or its use are protected by one or more of the following patents:
US6,071,391; US6,120,676; US6,143,164; US6,156,173; US6,299,757; US6,338,790; US6,503,381;
US6,591,125; US6,607,658; US6,616,819; US6,618,934; US6,676,816; US6,749,740; US6,893,545;
US6,942,518; US7,058,437; US7,615,637; US0987,142; EP1119637; EP1145000.
Additional patents may be issued and/or pending.
FreeStyle, FreeStyle Lite and FreeStyle Freedom Lite are trademarks of Abbott Group of Companies in
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DOC20125 Rev. B 04/10

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FreeStyle FREEDOM Lite

Blood Glucose Monitoring System
Blood Glucose Monitoring System



No Coding
Required

No Coding
Required

Owner's Booklet

Owner's Booklet



4/29/10 1:42 PM

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Important Information About Your FreeStyle Freedom Lite Blood Glucose Monitoring System

Use the FreeStyle Freedom Lite System Only as Directed

- The FreeStyle Freedom Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm and venous whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.
- The FreeStyle Freedom Lite meter should only be used with FreeStyle Lite[®] test strips and FreeStyle[®] control solution. Using other test strips and control solution with this meter can produce inaccurate results.

WARNING:

- We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.
- The FreeStyle Freedom Lite system contains small parts that may be dangerous if swallowed.

Caution. Please read all the instructions provided in this Owner's Booklet and practice the testing procedures before using the FreeStyle Freedom Lite[®] system. Blood glucose monitoring should be done with the guidance of a healthcare professional.

Important Health-Related Information

- Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL or higher than 240 mg/dL you should contact your healthcare professional and follow his or her treatment advice.
- The expected glucose range for a non-diabetic, non-pregnant fasting adult is under 100 mg/dL.¹
- Two hours after meals, levels should be less than 140 mg/dL.¹
- Consult your healthcare professional to determine the range that is appropriate for you.

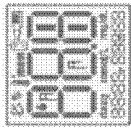
Reference

¹ American Diabetes Association Clinical Practice Recommendations: Diagnosis and classification of diabetes mellitus. Diabetes Care 2005;28 (Suppl.1):S37-S42

LANGUAGE1

LANGUAGE2

The FreeStyle Freedom Lite Meter and FreeStyle Lite Test Strips



Sample the check screen

This screen briefly appears each time the meter is turned on so that you can make sure the display is working properly. Do not use the meter if the system check screen does not match the example here. Please call Customer Care.

Display Messages

Displays your test results and other important information.

- Move to different mode settings.
- Scrolls backward.
- Silences a reminder alarm.

Info Menu

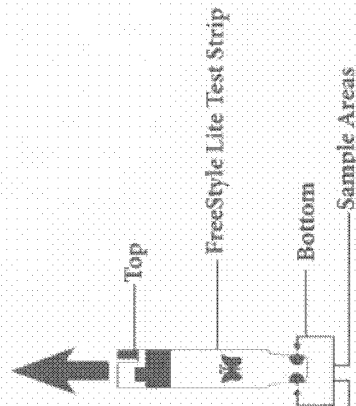
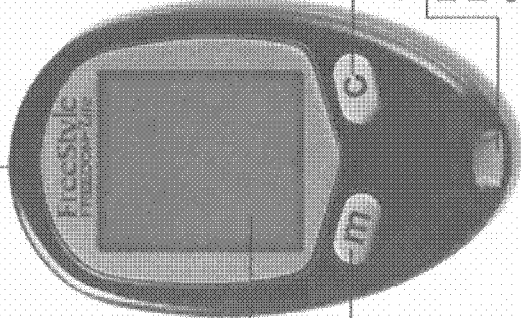
Download test results. Requires a compatible data management system. For more information, please go to our website or call Customer Care.

Test Strip Menu

- 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 Menu

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

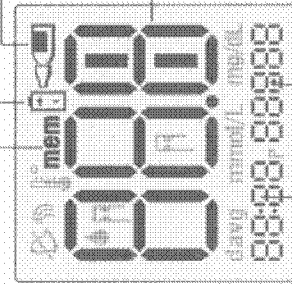
Apply blood or control solution to one sample area only. Insert strip into the meter printed side up (see image to the right).

LANGUAGE1 LANGUAGE2

The FreeStyle FreedomLine Meter Display

Shows you test results stored in the meter memory.

Appears when you should replace your meter battery.



Shows that you have marked a test result as a control solution test.

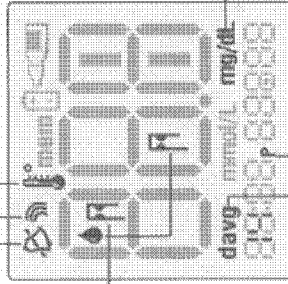
Displays test results.

Displays date, time, and number of tests.

Indicates high, low, or off sound volume.

Indicates if your meter is out of operating temperature range.

These symbols work together in an animation to tell you when the meter is ready for you to apply blood or control solution.



Shows the average value of glucose readings from the last 7-, 14-, or 30-days.

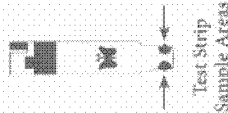
Indicates PM in 12-hour format only (for example 4:00 p.m.)

LANGUAGE1 LANGUAGE2

The FreeStyle Lite® Test Strips

Apply blood or control solution to only one test strip sample area per test.

Important: Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Freedom Lite® meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

- The FreeStyle Freedom Lite system has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight or heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.

- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter FreeStyle Lite® test strips.

Note: For further information, refer to the FreeStyle Lite test strip package insert.

The FreeStyle Control Solution

Each FreeStyle control solution vial contains a red liquid with a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.



A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

There are three levels of control solution available (Low, Normal, High). For information on how to obtain control solution, call Customer Care at 1-888-522-5226.

Control Solution Information

FreeStyle® control solution is good for three months after opening the bottle or until the expiration date printed on the label, whichever comes first.

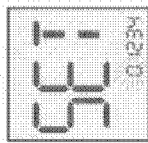
Important: Count forward three months from the date you open a new bottle of control solution. Write this date on the side of your control solution bottle. This is your discard date, unless the expiration date printed on the bottle comes first.

Example: You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.

- Use only FreeStyle control solution with your FreeStyle Freedom Lite® system.
- Replace the cap on the control solution bottle immediately after using.
- Do not use control solution past the expiration date.
- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when used between 59° to 104° F (15° to 40° C).
- Control solution test results should fall within the range printed on the test strip vial label.
- Important:** The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.
- If control solution results are out of this range, repeat the test.
- If your control solution test results continue to fall outside the range printed on the test strip vial, do not use the FreeStyle Freedom Lite system to test your blood glucose. Contact Customer Care.

Caution: Results from FreeStyle control solution tests do not reflect your blood glucose level.

Meter Setup
Setting Up Your Meter



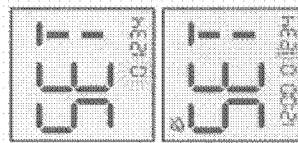
- **To Enter Setup Mode**
Start with the meter off (no test strip inserted). Press and hold the "m" button for two seconds until the SE I display screen appears.

- **To Exit at Any Time**
Press and hold the "m" button for two seconds until the meter turns off.
- **To Move Through the Screens**
Press the "m" button to move through all the setup screens such as reminder alarms, sound level, time, date, and so on.
- **To Change Settings Within the Screen**
Press the "c" button.

Setting the Reminder Alarms

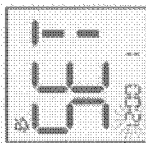
You may set up any or all of the reminder alarms (1-4). Note: A reminder alarm will never sound during a test.

To set a reminder alarm or multiple reminder alarms, please follow these steps.

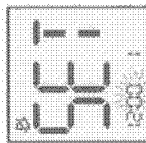


1. Start with the meter off. Press the "m" button and hold until the SE I display appears with 01234. You are now in the reminder alarm setting mode and the "0" is blinking.
2. To move to the first reminder alarm press the "c" button once. You are now ready to set reminder alarm 1 ("1" is blinking).

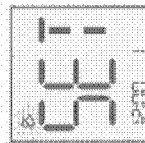
Select reminder alarm



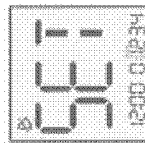
Select hour



Select minute



Select reminder alarm volume



Select reminder alarm

3. Press the "m" button to move to the hour setting. With the hour blinking, press the "c" button until the correct hour appears.

4. Press the "m" button to move to the minute setting. With the minute blinking, press the "c" button until the correct minute appears.

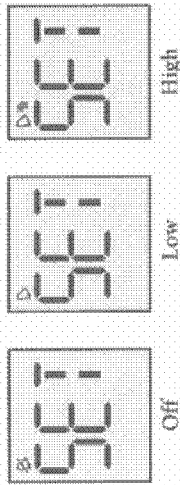
5. Press the "m" button to move to the reminder alarm volume setting. Default setting is off. Press the "c" button to select the desired volume setting: low, high, or off.

6. Press the "m" button to finalize your alarm setting. This will bring you back to the reminder alarm setting 5:00 mode. If you wish to set multiple reminder alarms press "c" to move to reminder alarm 2. Repeat.

Note: To save your reminder alarm settings and exit setup mode, press and hold the "m" button for two seconds until the meter turns off. Press the "m" button when "0" is blinking to move to the next setup screen without setting any reminder alarms.

Setting the Volume

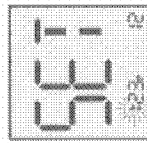
There are three (3) sound volume options:



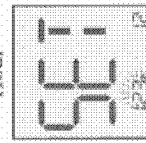
There are three sound volume options to let you know when the test strip is full, when the reading is done, and when an error occurs.

1. Press the "c" button until the desired sound level appears.
2. Press the "m" button to move to "Setting the Time."

Setting the Time



Hour



Minute

1. With the hour blinking, press the "c" button until the correct hour appears. The "p" displays for "PM" times.

2. Press the "m" button to move to minute setting. With the minute blinking, press the "c" button until the correct minute appears.

3. Press the "m" button to move to "Setting the Time Format."

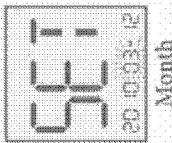
Setting the Time Format

1. With the hour mode blinking, press the "c" button to move between 12-hour and 24-hour format. The time automatically updates to the format selected.

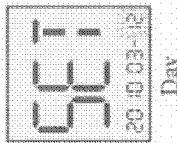
2. Press the "m" button to move to "Setting the Date and Date Format."

Setting the Date and Time Format

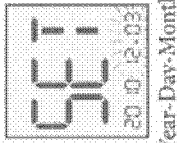
1. With the month blinking, press the "c" button until the correct month appears.



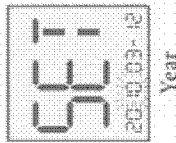
2. Press the "m" button to move to the day setting. With the day blinking, press the "c" button until the correct day appears.



3. Press the "m" button to move to "Date Format." With the date blinking, press the "c" button to select month-day or day-month format. The date automatically updates to the format selected.



4. Press the "m" button to move to the year setting. With the year blinking, press the "c" button until the correct year appears.

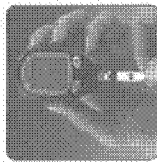


You have completed Meter Setup.

- To move to "Setting the User Reminder Alarms" press the "m" button.
- To exit press and hold the "m" button for two seconds.

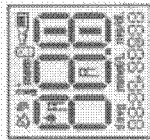
Performing a Control Solution Test

1. Insert the top of the test strip into your meter until it stops. This will power on the meter.



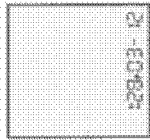
System Check Symbols

Each time the meter powers on, this screen briefly appears so that you can make sure the display is working properly.

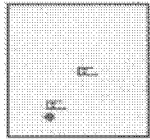


System Check

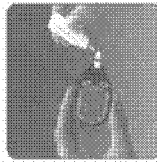
The date and time will briefly appear after the system check screen so that you can make sure your meter is set to the correct time and date.



2. Wait for the meter to display the blood drop and test strip symbols.



Gently touch only one of the sample areas on the test strip to the control solution.

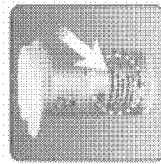


Important: Do not apply control solution to both test strip sample areas.

If the sound is on, your meter will beep when the test strip is full. A short line then moves clockwise around the display screen while the sample is processing.

The result will appear on the display screen and if the sound is on, your meter will beep twice. To mark the result as a control solution result, press and hold the "c" button for two seconds until the control solution symbol (☐) appears at the top right of the display screen.

If you have marked a blood glucose test as a control solution test by mistake, you can unmark it by pressing and holding the "c" button again for two seconds.



Compare your control solution test result to the range printed on your test strip vial label. Your control solution results should fall within the range printed on the side of your test strip vial.

Out of range test results may be caused by:

- Error in performing the test
- Expired or contaminated control solution
- Test strip deterioration
- Meter malfunction

Testing Your Blood Glucose

Important: To ensure accurate results, wash your hands and test site (for example, your upper arm) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

- With the FreeStyle Freedom Lite® meter, you can test your blood glucose on your upper arm, palm or fingers.
- Testing with the FreeStyle Freedom Lite meter requires a very small sample size; 0.3 microliters of blood, about the size of pinhead (example: •).

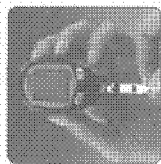
WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Times when you may be checking for low blood glucose include:

- When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.
- When you have delayed a meal after taking insulin.
- When your healthcare professional advises you to do so.

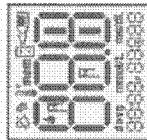
Performing a Blood Glucose Test



Prick Your Finger

Insert a FreeStyle Lite® test strip into the meter until it stops. The meter will power on.

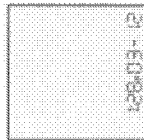
Note: If you do not start the test within two minutes, the meter will turn off. To restart your meter, take out the unused FreeStyle Lite test strip and reinsert it into the meter.



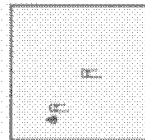
System Check Screen

Each time the meter powers on, this screen briefly appears so that you can make sure the display is working properly.

System Check



The date and time will briefly appear after the system check screen so that you can make sure your meter is set to the correct time and date.



Blood Drop and Test Strip Symbols

The blood drop and test strip symbols will appear on the display screen. Your meter is now ready to apply blood sample.

Possible Warning

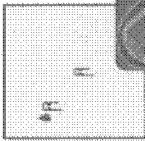
It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another test site.

Other Alternative Sites

Select a test site. There are differences in testing on fingers versus other alternative sites.

Use your lancing device to obtain a blood sample. Refer to the lancing device insert for detailed instructions on how to use the FreeStyle® lancing device.

WARNING: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.



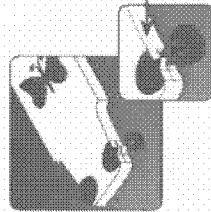
Following the FreeStyle Lite System Check, the meter is powered on.

a. Make sure that the FreeStyle Lite test strip is in the meter, the meter is powered on and the blood drop and test strip symbols are displayed. You are now ready to apply the blood sample.



b. Bring the FreeStyle Lite test strip to the blood sample at a slight angle.

Important: Use only one test strip sample area per test. Do not apply blood to both edges, or you may get an inaccurate result. Test strips may be used only once. Discard used test strips.



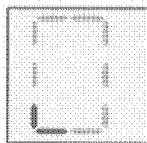
c. The FreeStyle Lite test strip pulls the blood into the strip through the sample area.

Test Strip Sample Area

Important: Test Strip Instructions

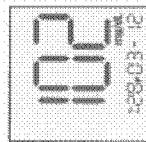
- Do not press the FreeStyle Lite® test strip against the test site.
- Do not scrape the blood onto the FreeStyle Lite test strip.
- Do not apply blood to the flat side of the FreeStyle Lite test strip.
- Do not apply blood to the FreeStyle Lite test strip when the FreeStyle Lite test strip is out of the meter.
- Do not put blood or foreign objects into the FreeStyle Freedom Lite® test strip port.

What About the Display?



- Do not pull the FreeStyle Lite test strip away from the sample until you hear one beep or see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.

If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same sample area of the test strip from which you started for up to 60 seconds from the time of the first application.

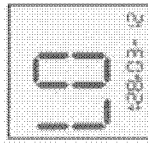


- The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps if the sound is on.
- The time that the meter takes to display a reading depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle Freedom Lite® meter displays results from 20 to 500 mg/dL.

If your test result is lower than 20 mg/dL, LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).



LO Reading

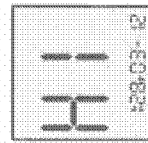
LO Reading without Symptoms

If you have a LO reading and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.

LO Reading without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hypoglycemia.

If your test is above 500 mg/dL, HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).



HI Reading

HI Reading without Symptoms

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.

Test Results

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip on your fingers. If you still get a HI reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hyperglycemia.

Test Results

To Enter

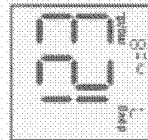
Start with the meter off (no test strip inserted). Press and release the "m" button; the first memory screen to appear will be your 7-day average.

To Exit

Press and hold the "m" button for two seconds until the meter turns off.

Test Results

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)



Example:

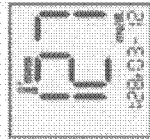
7 day avg = your 7-day average

n = indicates the number of results included in your average

The "c" button allows you to scroll forward to 14- and 30-day averages. Continue to press the "c" button to view stored test results. Your most recent result will display first.

Test Results

The meter stores the last 400 test readings with time and date. You may scroll forward through all of the readings by pressing the "c" button. The "m" button allows you to scroll backward. The first reading you see is the most recent result.

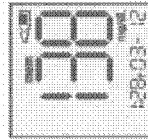


Temperature:

A result with a thermometer symbol (°C) indicates that the reading was taken outside of the meter's specified operating temperature range and may not be accurate. This value is included in your 7-, 14- and 30-day averages.

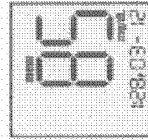
LO Reading: A LO reading (under 20 mg/dL) is included in the memory as LO; it is not included in your 7-, 14- and 30-day averages.

HI Reading: A HI reading (over 500 mg/dL) is included in the memory as HI; it is not included in your 7-, 14- and 30-day averages.



Control Solution Test

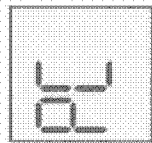
A value with (CS) indicates that you have marked this reading as a control solution test. The date and time of the control solution reading will appear on the bottom of the screen.



Read Control Test

A result without a control solution symbol indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.

Data Download



The "PC" symbol displays when a data cable is inserted in the meter data port. You cannot perform a test while the data cable is in the meter data port.

The meter will display "PC" until the data cable is removed from the data port.

Requires a compatible data management system. For more information, please go to our website or call Customer Care.

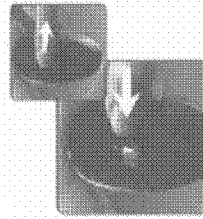
Meter Maintenance
Batteries

Your FreeStyle Freedom Lite® meter comes with one preinstalled, #2032, 3 volt, lithium battery. The battery provides enough power for the meter to perform about 1000 tests. If your battery runs low, the battery symbol (🔋) appears on every display screen until you change the battery.

Important: When this symbol appears, you should replace the battery immediately.

- To avoid losing the time and date settings, replace the battery within one minute of removing the old battery.
- If you take more than one minute to replace the battery, you may need to reset the time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, the time and date displays flash 12:00 and 00-00 until they are reset.
- Removing the battery does not affect the meter's memory log or previously-stored user settings (such as date and time formats).
- If the time and date settings are not reset, test results will be stored in memory with a time of 12:00 and a date of 00-00.
- Even if you lose your time and date settings – you can perform a blood glucose test, and results will not be affected.

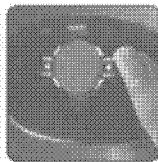
Replacing the Battery



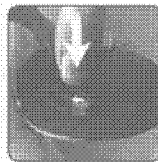
1 Turn the meter over. Slide the battery door to the right to open.

To remove the battery, pull the plastic tab up to release the battery.

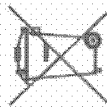
2 Replacing the Battery



Install the battery with the positive (+) sign up toward you.



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



Note: The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

3 Cleaning the Meter

Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip and data ports.

Important: Never immerse the meter in water or any other liquid. This may cause inaccurate reading or meter malfunction.

Do not try to clean the strip or data ports.

Do not pour liquid into the strip port, data port or buttons.

Do not place your meter in water or any other bath.

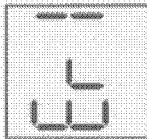
Clean the outside of the meter using a cloth dampened with one of the following:

- Mild detergent/mild soap and water.
- 70% isopropyl alcohol.
- A mix of one part household bleach, nine parts water.

System Troubleshooting

Error Messages

Error 1



Possible Causes

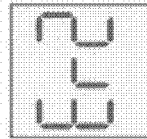
- Sample is too small.
- Problem with the FreeStyle Lite® test strip.
- Problem with the meter.
- Very low blood glucose (less than 20 mg/dL).

What You Should Do

1. If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your doctor's recommendation for treating hypoglycemia.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 2

Possible Causes

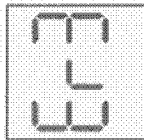


- Problem with the FreeStyle Lite test strip.
- Problem with the meter.
- Very high glucose (above 500 mg/dL).
- HIGH control solution applied when temperature is too cold. (This applies only to control solution that is labeled as HIGH.)

What You Should Do

1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your doctor's recommendation for treating hyperglycemia.
2. Conduct a control solution test using a new FreeStyle Lite® test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

EXHIBIT 3

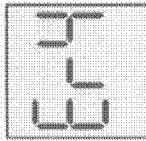
**Possible Causes**

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter or applying blood before the blood drop and test strip symbols display.
- Problem with the FreeStyle Lite test strip.
- Problem with the meter.

What You Should Do

1. Be sure you see the blood drop and test strip symbols on the display screen before you apply blood or control solution.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

EXHIBIT 4

**Possible Causes**

- Problem with FreeStyle Lite® test strip.
- Problem with the meter.

What You Should Do

1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
2. If the retest using control solution does not work or the error persists, call Customer Care.

FreeStyle Freedom Lite® System Specifications

Meter does not enter the test mode after inserting a test strip.	
Probable Cause The battery is dead. The battery is installed incorrectly or there is no battery in the meter. Test strip inserted upside down, wrong end in, or incompletely inserted into the meter. Defective meter or test strips. Blood or foreign objects put into the test strip port.	What to Do Replace the battery (and reset the date and time, if necessary). Check that the battery is installed correctly with the positive (+) sign facing upward, toward you. Insert the FreeStyle Lite® test strip with the printed side up and the top of the strip in the meter. Call Customer Care. Call Customer Care.
Test does not start after applying the blood sample.	
Probable Cause Blood sample too small. Defective test strip.	What to Do You may add blood to the same sample area of the FreeStyle Lite test strip from which you started for up to 60 seconds from the time of the first application. If necessary, repeat the test using a new FreeStyle Lite test strip and a larger blood sample. Repeat the test with a new FreeStyle Lite test strip. Repeat the test using a new test strip. Wait until you see the blood and test strip symbols on the display screen before you apply the blood sample. Call Customer Care.
Defective meter or test strips.	Call Customer Care.

FreeStyle Freedom Lite® System Specifications

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	1000 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	mg/dL
Meter Storage Temp	-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 #2032, 3 volt, lithium battery, replaceable
Result Range	20 to 500 mg/dL
Sample	Fresh capillary and venous whole blood samples
Sample Size	0.3 microliter (300 nanoliters)
Size	Width 2.00" x Length 3.30" x Thickness 0.63" (at thickest point)
Weight	1.4 to 1.6 ounces (39.7 to 45.4 grams) including battery



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Appendix 4

510(k) Summary

510(k) Summary

According to the requirements of 21 CFR §807.92, the following information provides sufficient details to understand the basis for a determination of substantial equivalence.

Company:	Abbott Laboratories
Division:	Abbott Diabetes Care, Inc.
Street Address:	1360 South Loop Road
City, State Zip:	Alameda, CA 94502
Telephone No:	510-749-5400
Fax No:	510-864-4791
Contact Person:	Arul Sterlin; Tel No. 510-864-4310; Fax No. 510-864-4791; arul.sterlin@abbott.com
Proprietary Name:	FreeStyle Lite Blood Glucose Test Strips
Common Name:	Reagent Test Strips
Classification Name:	Glucose Dehydrogenase, Glucose, Class II (21 CFR§ 862.1345) Product codes: NBW, LFR; Single Analyte Control Solution, Class I (21 CFR§ 862.1660) Product code: JJX
Predicate Device:	FreeStyle Lite Blood Glucose Monitoring System (K070850)
Manufacturing Site:	Establishment: Abbott Diabetes Care Inc. 1360 South Loop Rd. Alameda, CA 94502 Registration Number: 2954323 Establishment: Abbott Ireland Diabetes Care Donegal Town, Co. Donegal Donegal Town, IRELAND Donegal Registration Number: 3007031103

Description of the Device:

A chemistry change has been made to the FreeStyle Lite Blood Glucose Test Strip. The modified strip is to be marketed under the brand name, FreeStyle Lite, and is intended for use with the following Blood Glucose Monitoring Systems:

- FreeStyle Lite Blood Glucose Monitoring System
- FreeStyle Freedom Lite Blood Glucose Monitoring System

The meters and other system components contained within these systems have not been modified. Each of the aforementioned blood glucose monitoring systems are comprised of a handheld glucose meter, glucose reagent test strips, a quality control solution, a lancing device, lancets, lancing cap, and labeling for performing a blood glucose test. The intended uses and principles of operation for each of the systems remains the same as previously submitted and cleared for market entry. The systems utilize coulometric biosensor technology to quantitatively measure glucose concentration in whole blood samples. The systems are intended for self-monitoring of glucose in capillary and venous whole blood. The primary users are persons with diabetes. The systems are meant to aid in diabetes management and for healthcare professionals to aid in monitoring the effectiveness of diabetes control program. The FreeStyle Lite Blood Glucose Test Strip is an electrochemical biosensor that fits into a handheld meter. The blood sample volume is approximately 0.3 microliters (300 nanoliters), which can be obtained from the finger, upper arm, or palm. Test results display in accordance with the blood glucose meter's software algorithm (approximately 5 seconds). The internal volume of the test strip is precisely controlled, and a blood glucose result will not be displayed on the meter unless the internal sample chamber is filled. Once the measurement begins, the glucose is rapidly oxidized by the reagents that are present in the inside of the sample chamber. The electrochemical signal that results from this process depends only on the total amount of glucose present. The reagent chemistry enables electrolysis of glucose in the blood sample. A mediator molecule shuttles electrons rapidly between a glucose-oxidizing enzyme and the working electrode on the strip. The mediator is capable of reacting rapidly with both the electrode and the enzyme, resulting in a rapid reaction time and minimizing the total amount of mediator required. The small mediator load results in high accuracy at the low end of the glucose measurement range.

Description of Modifications:

The modifications to the system are comprised of changes to the blood glucose test strip which include chemistry, materials, appearance, and modification of the meter turn-on bar.

Chemistry:

The FreeStyle Lite Blood Glucose Test Strip chemistry for the new enzyme test strip is changed from GDH-PQQ with nPBI mediator (Osmium complex with n-pentyl benzimidazole ligand), to GDH-FAD with MAP mediator (ligand of mediator has changed to n-methyl pyridine). GDH-FAD does not show interference in the presence of carbohydrates such as maltose, lactose and galactose as compared with assays performed with GDH-PQQ. The n-pentyl benzimidazole ligand of the mediator has changed to n-methyl pyridine and a new source of carbon ink is used to make the new enzyme chemistry compatible with on-market meters.

Materials:

The modified FreeStyle Lite Blood Glucose Test Strip will utilize the same materials as the current FreeStyle Lite Blood Glucose Test Strip, with the exception of the spacer tape and source of carbon. A new adhesive system is utilized as the spacer tape. The new spacer tape uses the exact same base polymer resin as the current FreeStyle Lite adhesive coupled with a different crosslinking agent. Screen printed carbon electrodes are made using DuPont carbon ink instead of Ercon carbon. All other materials in the modified FreeStyle Lite Blood Glucose Test Strip, (that is, the melinex and the silver/silver chloride ink) are exactly the same as those used in the FreeStyle Lite Test Strip, currently being marketed.

Appearance:

The physical appearance of the test strip has been changed to aid customers to distinguish visually between the new enzyme version of the product from the current on-market product. Attachment below contains the image of current and new strip.

Meter Turn On Bar:

Blood Glucose Test Strips that are branded, FreeStyle Lite, will have a modified turn-on bar but will continue to require the same user interface no coding activities as those currently available in the market.

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FREESTYLE LITE® BLOOD GLUCOSE TEST STRIPS

FreeStyle Lite Blood Glucose Test Strip Product Information

Only for use with FreeStyle Lite and FreeStyle Freedom Lite Blood Glucose Systems To Test In Clinics or Whole Blood Blood Glucose Test Strip with Continuous Technology

IMPORTANT: PLEASE READ THE INFORMATION AND YOUR OWNER'S BOOKLET BEFORE USING THE FREESTYLE LITE TEST STRIPS TO TEST YOUR BLOOD SUGAR.

For help call Customer Care at 1-888-421-2226, 24 hours a day, 7 days a week.

The FreeStyle Lite Blood Glucose Test Strip is intended for use in the quantitative measurement of glucose in capillary whole blood from the upper arm and wrist and venous whole blood. It is intended for use by healthcare professionals and people with diabetes, written or oral, and is not intended for use on persons at risk of diabetes, and it is not intended for use on persons at arterial blood.

Do not use during x-ray or other radiation therapy.
Do not change medication based on FreeStyle Lite blood glucose test results without the consent and advice of a physician or healthcare professional as not recommended.
Product contains small components that might be considered a choking hazard.
The cap or vial contains drying agents to protect the test strips. Drying agents may be harmful if inhaled or swallowed and may cause skin or eye irritation.

If you get FreeStyle Lite control solution test results that fall outside the range printed on the test strip vial, repeat the test with a new test strip. If the test result is still outside the range printed on the test strip vial, the system may not be working properly. DO NOT use the system to test your blood until you get a control solution test result within the range printed on the test strip vial label.
Do not fill the test strip from both the left and right sample areas during a single test. This may cause inaccurate test results.

Do not use test strips beyond the expiration date printed on the package since this may cause inaccurate results. Physiological differences in the circulation between the finger and other test sites like the upper arm and palm. This may result in differences in blood glucose measurements from the other test sites and your finger. Differences in blood glucose measurements between the other test sites and your finger may be observed after eating, insulin administration or exercise. Changes in blood glucose may be observed in finger blood samples versus blood samples from alternate sites. Vigorous rubbing of the alternate test sites before leaving will help to minimize the difference between finger and alternate site test results. If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.

Do not use a sample from the palm or upper arm (consult your healthcare professional before you use any of these sites to test your blood glucose).

Do not use the current unit of measurement is displayed with each result. See Owner's Booklet for further detail.
Do not defibrillate or receive water iontophoresis (low level currents) from before you are sufficiently free from dehydration, contact or electrical interference.
Do not use a sample from the palm or upper arm (consult your healthcare professional before you use any of these sites to test your blood glucose).

Do not use test strips after the expiration date printed on the vial.
Do not use a test strip from the vial, replace the vial cap immediately and store it tightly. Use each strip immediately after removing from the vial.

Do not use test strips in their original foil only. The cap or vial contains drying agents to protect the test strips. Do not transfer test strips to another vial or other container.
Do not use test strips at temperatures below 40°F or 4°C to 104°F or 40°C. Use test strips only within the system operating temperature range as listed in your Owner's Booklet.

Do not expose test strips to extreme temperatures.
Do not bend, use, or use a FreeStyle Lite test strip in any way.
Do not clean, dry hands, or use any other device to touch the test strip anywhere when removing it from the vial or inserting it into the meter.

Using a Blood Glucose Test Strip
Method
The blood sample is applied to the test strip. The glucose in the blood reacts with the chemicals on the test strip, producing a small color change. The meter measures the current over time, calculates the electrical charge, and converts it to a glucose value.
See your blood glucose meter Owner's Booklet for a step-by-step guide on how to do the test.

The FreeStyle Lite system can be used in test on test on your finger, palm and upper arm.
Do not use the test strip on the palm or upper arm. Use warm, soapy water, rinse and thoroughly dry. To bring back blood to the surface, rub the site through the finger's skin. Do not use the test strip on the palm or upper arm. Use warm, soapy water, rinse and thoroughly dry. To bring back blood to the surface, rub the site through the finger's skin. Do not use the test strip on the palm or upper arm. Use warm, soapy water, rinse and thoroughly dry. To bring back blood to the surface, rub the site through the finger's skin.

Do not use the test strip on the palm or upper arm. Use warm, soapy water, rinse and thoroughly dry. To bring back blood to the surface, rub the site through the finger's skin. Do not use the test strip on the palm or upper arm. Use warm, soapy water, rinse and thoroughly dry. To bring back blood to the surface, rub the site through the finger's skin.

Do not use the test strip on the palm or upper arm. Use warm, soapy water, rinse and thoroughly dry. To bring back blood to the surface, rub the site through the finger's skin. Do not use the test strip on the palm or upper arm. Use warm, soapy water, rinse and thoroughly dry. To bring back blood to the surface, rub the site through the finger's skin.

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When a control solution test is done, you should get results within the expected range printed on the test strip vial. If control solution test results fall outside the range, repeat the test. Results that fall outside the range may be caused by:

- error in performing the test
- incorrect or contaminated control solution
- test strip deterioration
- meter malfunctions

WARNING: If you continue to get FreeStyle Lite control solution test results that fall outside the range printed on the test strip vial, the system may not be functioning properly. DO NOT use the system to test your blood until you get a control solution test result within the range printed on the test strip vial label. Contact Customer Care.

Performance Characteristics
The performance of these test strips has been tested both in laboratory and clinical studies. The testing range is 20 mg/dL to 300 mg/dL. The FreeStyle Lite test strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

Accuracy
Capillary blood glucose results obtained by lay users were compared with those obtained using the YSI Glucose Analyzer. Summary of system accuracy for finger samples with YSI glucose results lower than 75 mg/dL:

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
73% (47/11)	100% (11/11)	100% (11/11)

Summary of system accuracy for finger samples with YSI glucose results of 75 mg/dL or higher:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
80% (115/146)	95% (160/168)	99% (166/168)	99% (167/168)

Summary of system accuracy for alternate site samples with YSI glucose results lower than 75 mg/dL:

Test Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Palm	15 (10%)	37 (30%)	52 (50%)
Upper Arm	0 (0%)	17 (30%)	37 (50%)

Summary of system accuracy for alternate site samples with YSI glucose results of 75 mg/dL or higher:

Test Site	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Palm	12 (9 (66%))	24 (69 (79%))	30 (86 (84%))	37 (99 (87%))
Upper Arm	10 (7 (57%))	18 (52 (79%))	26 (74 (91%))	32 (86 (96%))

The regression statistics are derived from a plot of the lay user finger data versus YSI capillary data.

Slope: 0.95
y-intercept: 7.3 mg/dL
Correlation coefficient (R): 0.99
Number of samples tested: 175
Range tested: 39-173 mg/dL

Precision
Within-lot and between-lot precision of these test strips was measured with venous blood samples in the laboratory.

Within-Lot Precision						
Average Glucose Concentration	mg/dL	43.3	94.2	140.7	238.3	345.8
SD	mg/dL	1.5	3.7	2.9	4.8	6.8
CV	%	3.1	2.4	2.2	2.1	2.0

Between-Lot Precision						
Average Glucose Concentration	mg/dL	43.3	94.2	140.7	238.3	345.8
SD	mg/dL	1.1	2.6	2.4	3.9	6.0
CV	%	2.5	2.7	1.8	1.6	1.7

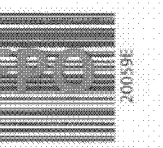
Variability in blood tests from strip to strip was 3.3% or less.
Chemical Composition
EAD Glycine Dehydrogenase (Aspartate) (EAD) ≥ 1.0 (20%)
Other ingredients: Barbitol, oxidant, etc. ≥ 0.07 mg

Reference
1. American Diabetes Association Clinical Practice Recommendations: Diagnosis and classification of diabetes mellitus. Diabetes Care 2005; 28 (Suppl 1):S5-S10.
2. Wilson DL, Srinivasan SR, Burke MA, Connor ML, Reddy S. Fingertouch glucose determination in blood. Am J Med 1994; 96(2):103-106.
3. Savelbergh M, Low-Beech C. Measuring capillary glucose measurements. Practical Diabetes 7; 210-21000.
4. Wickham MB, Asher EN, Goss DM. Reliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes 7; 150-1500.

Description of Symbols

	Consult instructions for use		Batch code
	Temperature limitation		Use by
	Manufacturer		Default meter
			In vitro diagnostic medical device

FPO



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Customer Care is available 24 hours a day, 7 days a week.

www.MyFreeStyle.com
Call Customer Care
Toll Free at 1-888-522-5226

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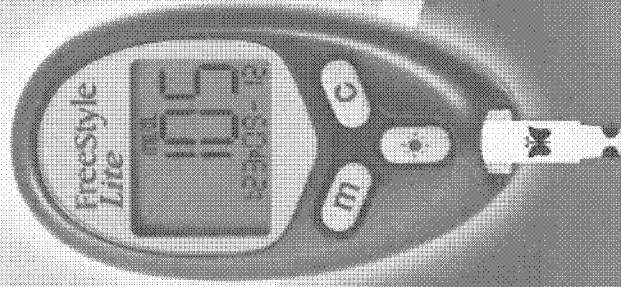
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US6,591,125; US6,607,658; US6,616,819; US6,618,934; US6,676,816; US6,749,740; US6,893,545;
US6,942,518; US7,058,437; US7,615,637; US6,587,142; EP1119637; EP1145000.
Additional patents may be issued and/or pending.

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FreeStyle Lite

Blood Glucose Monitoring System
Blood Glucose Monitoring System



No Coding
Required

No Coding
Required

Owner's Booklet

Owner's Booklet



4/28/10 2:13 PM

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Important Information About Your FreeStyle Lite[®] Blood Glucose Monitoring System

How the FreeStyle Lite System Should Be Used

- The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm and venous whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis or screening for diabetes mellitus, and it is not intended for use on neonates or arterial blood.
- The FreeStyle Lite meter should only be used with FreeStyle Lite test strips and FreeStyle[®] control solution. Using other test strips and control solution with this meter can produce inaccurate results.

WARNING:

- We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.
- The FreeStyle Lite System contains small parts that may be dangerous if swallowed.

Caution: Please read all the instructions provided in this Owner's Booklet and practice the testing procedures before using the FreeStyle Lite[®] system. Blood glucose monitoring should be done with the guidance of a healthcare professional.

Important Health-Related Information

- Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL or higher than 240 mg/dL you should contact your healthcare professional and follow his or her treatment advice.
- For additional information, consult your test strip product information.
- The expected glucose range for a non-diabetic, non-pregnant fasting adult is under 100 mg/dL.¹
- Two hours after meals, levels should be less than 140 mg/dL.¹
- Consult your healthcare professional to determine the range that is appropriate for you.

Reference

¹ American Diabetes Association Clinical Practice Recommendations: Diagnosis and classification of diabetes mellitus. Diabetes Care 2005;28 (Suppl.1):S37-S42

LANGUAGE1

LANGUAGE2

The FreeStyle Lite Meter and How It Works

System Check Results

This screen always appears when the meter is turned on so that you can make sure the display is working properly. Do not use the meter if the system check screen does not match the example here. Please call Customer Care.

FreeStyle Lite Meter

Displays your test results and other important information.

- Light Buttons**
- Move to different mode settings.
 - Scrolls backward.
 - Silence a reminder alarm.

Light Buttons

Controls the display backlight and test light.

Sample Area

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

LANGUAGE1

LANGUAGE2

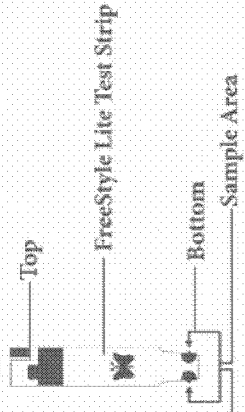
Test Strip

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

- Control Buttons**
- Marks a control solution test.
 - Scrolls forward.
 - Displays clock.
 - Silence a reminder alarm.

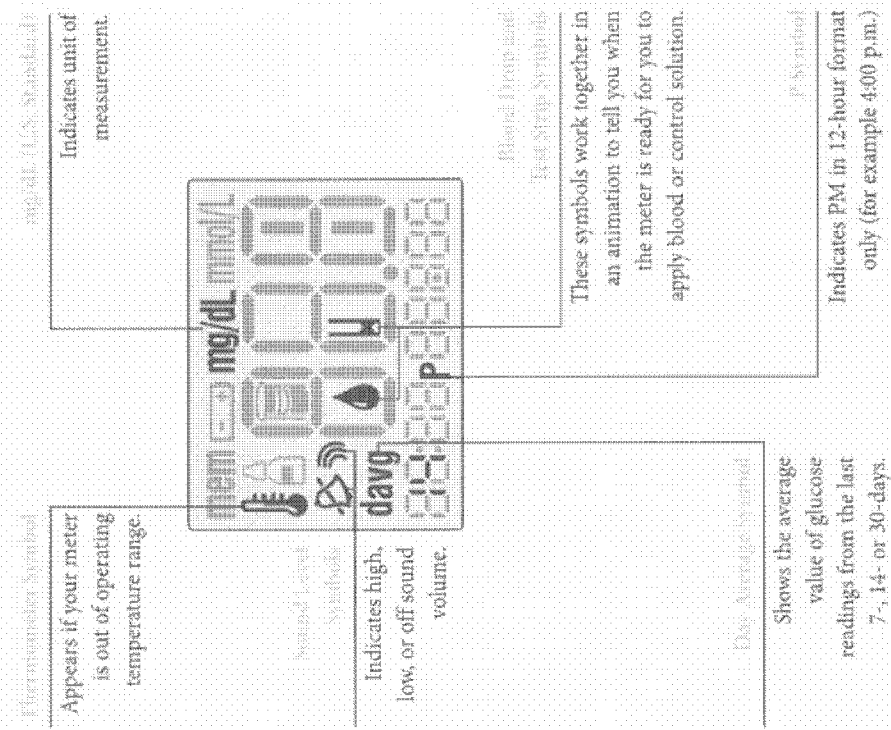
Test Strip Slot

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

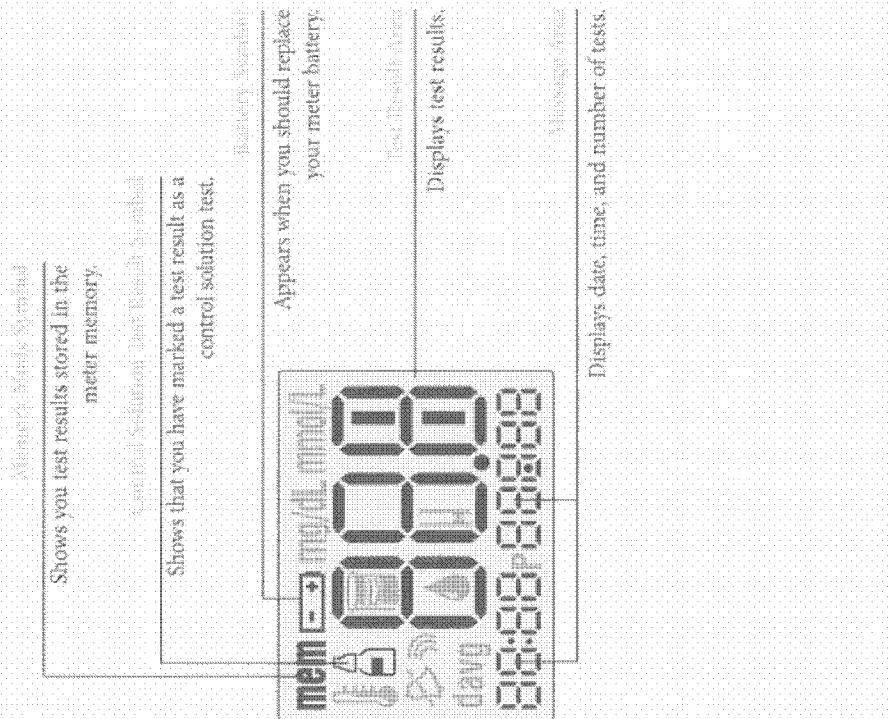


LANGUAGE1 LANGUAGE2

FreeStyle Libre Meter Display



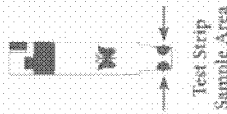
LANGUAGE1 LANGUAGE2



The FreeStyle Lite® Test Strip

Apply blood or control solution to only **one** Test Strip Sample Area per test.

Important: Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Lite meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

Operating and Storage Temperature

- The FreeStyle Lite System has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight and heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.

- Do not use test strips beyond the expiration date. This may cause inaccurate results.

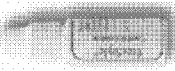
- Do not bend, cut, or alter FreeStyle Lite® test strips.

Note: For further information, refer to the FreeStyle Lite test strip package insert.

The FreeStyle Control Solution

Each FreeStyle control solution vial contains a red liquid with a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.



A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

There are three levels of control solution available (Low, Normal, High). For information on how to obtain control solution, call Customer Care at 1-888-522-5226.

Control Solution Information

FreeStyle® control solution is good for three months after opening the bottle or until the expiration date printed on the label, whichever comes first.

Important: Count forward three months from the date you open a new bottle of control solution. This is your discard date. Write this date on the side of the control solution bottle.

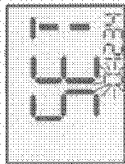
Example: You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.

- Use only FreeStyle control solution with your FreeStyle Lite® system.
- Replace the cap on the control solution bottle immediately after using.
- Do not use control solution past the expiration date.
- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when used between 59° to 104° F (15° to 40° C).
- Control solution test results should fall within the range printed on the test strip vial label.

Important: The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.

- If control solution results are out of this range, repeat the test.
- If your control solution test results continue to fall outside the range printed on the test strip vial, do not use the FreeStyle Lite system to test your blood glucose. Contact Customer Care.

Caution: Results from FreeStyle control solution tests do not reflect your blood glucose level.

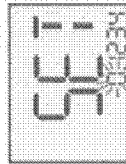
Meter Setup

- **To Enter Setup Mode**
Start with the meter off (no test strip inserted). Press and firmly hold the "m" button until the 5.51 display screen appears.
- **To Exit at Any Time**
Press and hold the "m" button until the meter turns off.
- **To Move Through the Screens**
Press the "m" button to move through all the setup screens such as reminder alarms, sound level, time, date, and so on.
- **To Change Settings Within the Screen**
Press the "c" (configure) button.

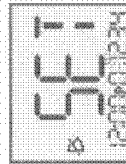
Setting the Reminder Alarms

You may set up any or all of the reminder alarms (1-4). Note: A reminder alarm will never sound during a test.

To set a reminder alarm or multiple reminder alarms, please follow these steps:

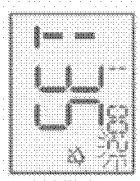


1. Start with the meter off. Press the "m" button and hold until the 5.51 display appears with 01234. You are now in the reminder alarm setting mode and the "0" is blinking.



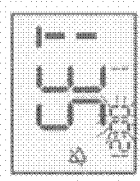
2. To move to the first reminder alarm press the "c" button once. You are now ready to set reminder alarm 1 ("1" is blinking).

Select reminder alarm



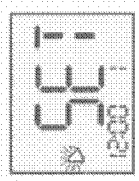
Select hour

3. Press the "m" button to move to the hour setting. With the hour blinking, press the "c" button until the correct hour appears.



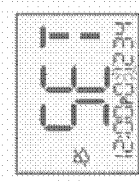
Select minute

4. Press the "m" button to move to the minute setting. With the minute blinking, press the "c" button until the correct minute appears.



Select reminder alarm volume

5. Press the "m" button to move to the reminder alarm volume setting. Default setting is off. Press the "c" button to select the desired volume setting: low, high, or off.



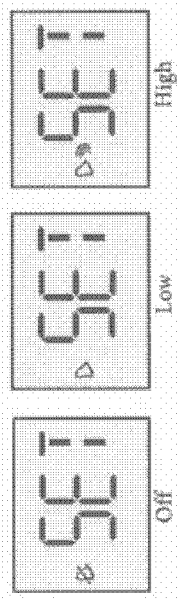
Select reminder alarm

6. Press the "m" button to finalize your alarm setting. This will bring you back to the reminder alarm setting SEI mode. If you wish to set multiple reminder alarms press "c" to move to reminder alarm 2. Repeat.

Note: To save your reminder alarm settings and exit setup mode, press and hold the "m" button until the meter turns off. Press the "m" button when "0" is blinking to move to the next setup screen without setting any reminder alarms.

Setting the Volume

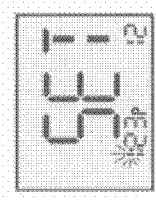
There are three (3) sound volume options:



There are three sound volume options to let you know when the test strip is full, when the reading is done, and when an error occurs:

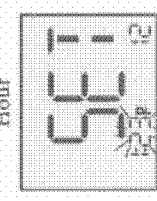
- 1. Press the "c" button until the desired sound level appears
- 2. Press the "m" button to move to "Setting the Time"

Setting the Time



Hour

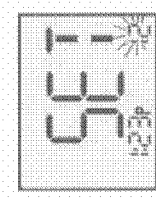
1. With the hour blinking, press the "c" button until the correct hour appears. The default for the meter is the 12-hour time format. The "p" displays for "PM" times.



Minute

- 2. Press the "m" button to move to minute setting.
- 3. With the minute blinking, press the "c" button until the correct minute appears.
- 4. Press the "m" button to move to "Setting the Time Format"

Setting the Time Format

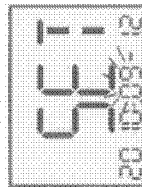


Time Format

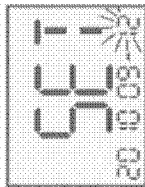
- 1. With the hour mode blinking, press the "c" button to move between 12-hour and 24-hour format. The time automatically updates to the format selected.
- 2. Press the "m" button to move to "Setting the Date"

LANGUAGE1

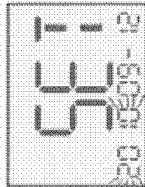
LANGUAGE2



Month



Day



Year

Setting the Date and Date Format

1. With the month blinking, press the "c" button until the correct month appears.
2. Press the "m" button to move to the day setting.
3. With the day blinking, press the "c" button until the correct day appears.
4. Press the "m" button to move to "Date Format."
5. With the date blinking, press the "c" button to select month-day or day-month format. The date automatically updates to the format selected.
6. Press the "m" button to move to the year setting.
7. With the year blinking, press the "c" button until the correct year appears.

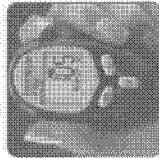
You have completed Meter Setup.

- To move to "Setting the User Reminder Alarms" press the "m" button.
- To exit press and hold the "m" button.

Using Your Meter's Lights

Depending on what mode your meter is in, pressing the light button () turns on either the display backlight or the test light.

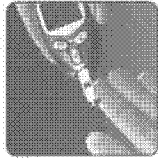
Using the Display Backlight



Pressing the light button powers on the display backlight in all modes except when applying a sample. When applying a sample, the light button turns the test light on.

The display backlight goes out when you press the light button () again or when the meter is inactive for 10 seconds.

Using the Test Light



Pressing the light button while the Blood Drop and Test Strip symbols appear on the display screen powers on the test light.

The test light goes out:

- When you press the light button again.
- When the meter receives the correct amount of blood for a test (the FreeStyle Lite™ test strip is filled).
- After 60 seconds of no activity.
- When a FreeStyle Lite test strip is removed from the meter.

If you use either the backlight or the test light during the test mode, the backlight lights again to show you the test results after the measurement is complete.

Testing Your Blood Glucose

Important: To ensure accurate results, wash your hands and test site (for example, your upper arm) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

- With the FreeStyle Lite® meter, you can test your blood glucose on your upper arm, palm or fingers.
- Testing with the FreeStyle Lite meter requires a very small sample size, 0.3 microliters of blood; about the size of pinhead (example: •).

Times when you may be checking for low blood glucose include:

WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

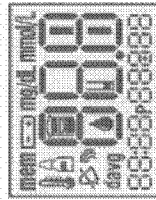
- When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.
- When you have delayed a meal after taking insulin.
- When your healthcare professional advises you to do so.

Performing a Blood Glucose Test

1 Prepare Your Meter

Insert a FreeStyle Lite® test strip into the meter until it stops. The meter will power on.

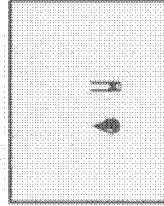
Note: If you do not start the test within two minutes, the meter will turn off. To restart your meter, take out the unused FreeStyle Lite test strip and reinsert it into the meter.



System Check

When the meter powers on, this screen will appear so that you can make sure the display is working properly.

System Check



Blood Drop and Test Strip Symbols

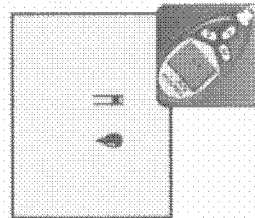
Performing a Blood Glucose Test

It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another test site.

2. Like with a lancing device

Select a test site. There are differences in testing on fingers versus other alternative sites. Use your lancing device to obtain a blood sample. Refer to the lancing device insert for detailed instructions on how to use the FreeStyle® lancing device.

WARNING: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.

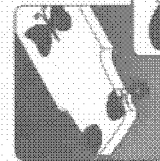


3. Pull from the FreeStyle Lite Test Strip with the Meter

a. Make sure that the FreeStyle Lite test strip is in the meter and the meter is powered on. You are now ready to apply the blood sample.



b. Bring the FreeStyle Lite test strip to the blood sample at a slight angle.



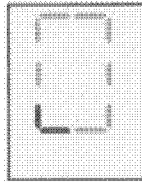
Test Strip Sample Area

c. The FreeStyle Lite test strip pulls the blood into the strip through the sample area.

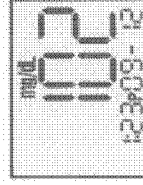
Important: Test Strip Information

- Do not press the FreeStyle Lite® test strip against the test site.
- Do not scrape the blood onto the FreeStyle Lite test strip.
- Do not apply blood to the flat side of the FreeStyle Lite test strip.
- Do not apply blood to the FreeStyle Lite test strip when the FreeStyle Lite test strip is out of the meter.
- Do not put blood or foreign objects into the FreeStyle Lite test strip port.

4. Waiting for Result



- Do not pull the FreeStyle Lite test strip away from the sample until you hear one beep or see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.
- If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same sample area of the test strip from which you started for up to 60 seconds from the time of the first application.

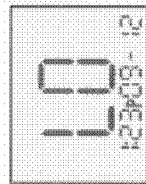


- The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps.
- The time that the meter takes to display a reading depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle Lite[®] meter displays results from 20 to 500 mg/dL.

If your test result is lower than 20 mg/dL, LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).



LO Reading

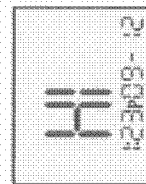
HI Readings with Symptoms

If you have a HI reading and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.

HI Readings without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hypoglycemia.

If your test is above 500 mg/dL, HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).



HI Reading

HI Readings with Symptoms

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.

HI Readings without Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip on your fingers. If you still get a HI reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hyperglycemia.

Meter Results

Meter Memory

To Enter

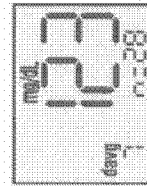
Start with the meter off (no test strip inserted). Press the "m" button and release; the first memory screen to appear will be your 7-day average.

To Exit

Press and hold the "m" button until the meter turns off.

To View 7-Day Average

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)



Example:

7davag = your 7-day average

n = indicates the number of results included in your average

The "c" button allows you to scroll forward to 14- and 30-day averages. Continue to press the "c" button to view stored test results. Your most recent result will display first.

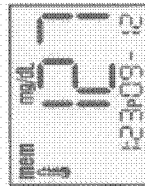
The "m" button allows you to scroll backward.

LANGUAGE1

LANGUAGE2

Test Results

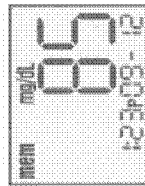
The meter stores the last 400 test readings with time and date. You may scroll through all of the readings by pressing and holding the "c" button. The first reading you see is the most recent result.



Temperature: A result with a thermometer symbol indicates that the reading was taken outside of the meter's specified operating temperature range and may not be accurate. This value is included in your 7-, 14- and 30-day averages.

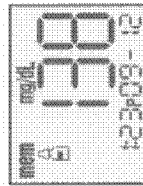
LO Reading: A LO reading (under 20 mg/dL) is included in the memory as LO.

HI Reading: A HI reading (over 500 mg/dL) is included in the memory as HI.



Test Alerts

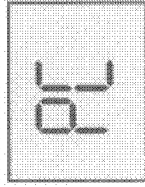
A result without a control solution symbol (A) indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.



Control Solution Test

A value with (A) indicates that you have marked this reading as a control solution test. The date and time of the control solution reading will appear on the bottom of the screen.

Data Download



The "PC" symbol displays when a data cable is inserted in the meter data port. You cannot perform a test while the data cable is in the meter data port.


The meter will display "PC" until the data cable is removed from the data port.

(Requires a compatible data management system.)

For more information, please go to our website or call Customer Care.

Meter Maintenance

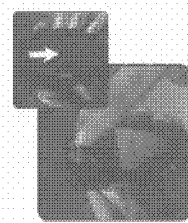
Battery

Your FreeStyle Lite® meter comes with one preinstalled, #2032, 3 volt, lithium battery. The battery provides enough power for the meter to perform about 500 tests. If your battery runs low, the battery symbol () appears on every display screen until you change the battery. When the battery runs low, the display backlight and test light may not power on.

Important. When this symbol appears, or when the backlight and test light begin to dim, you should replace the battery immediately.

- To avoid losing the time and date settings, replace the battery within one minute of removing the old battery.
- If you take more than one minute to replace the battery, you may need to reset the time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, the time and date displays flash 12:00 and 00-00 until they are reset.
- Removing the battery does not affect the meter's memory log or previously-stored user settings (such as date and time format).
- Even if you lose your time and date settings – you can perform a blood glucose test, and results will not be affected.

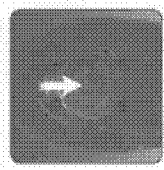
Replacing the Battery



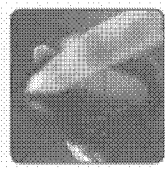
Turn the meter over. Press in the battery door clip to open. Swing the battery door up to open and then off the meter. To remove the battery, push the battery downward to release the battery.

Replacing the Battery (continued)

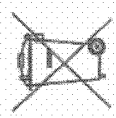
2 Install the battery with the positive (+) sign up toward you.



3 To close, angle the battery door back onto the meter and swing down until it snaps into place.



Note: The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.



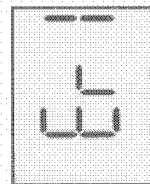
Caring for Your Meter

Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip and data ports.

Clean the outside of the meter using a cloth dampened with one of the following:

- Mild detergent/mild soap and water.
- 70% isopropyl alcohol.
- A mix of one part household bleach, nine parts water.

Important: Never immerse the meter in water or any other liquid.



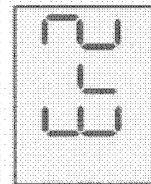
Possible Causes

- Sample is too small.
- Problem with the FreeStyle Lite[®] test strip.
- Problem with the meter.
- Very low blood glucose (less than 20 mg/dL).

What You Should Do

1. If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your doctor's recommendation for treating hypoglycemia.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 2



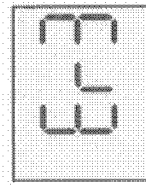
Possible Causes

- Problem with the FreeStyle Lite test strip.
- Problem with the meter.
- Very high glucose (above 500 mg/dL).
- HIGH control solution applied when temperature is too cold. (This applies only to control solution that is labeled as HIGH.)

What You Should Do

1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your doctor's recommendation for treating hyperglycemia.
2. Conduct a control solution test using a new FreeStyle Lite[®] test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite Test Strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 3



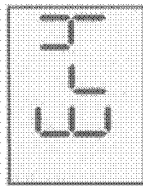
Possible Causes

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter or applying blood before the Blood Drop and Test Strip symbols display.
- Problem with the FreeStyle Lite test strip.
- Problem with the meter.

What You Should Do

1. Be sure you see the Blood Drop and Test Strip symbols on the display screen before you apply blood or control solution.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error #



Possible Causes

- Problem with FreeStyle Lite® test strip.
- Problem with the meter.

What You Should Do

1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite Test Strip.
2. If the retest using control solution does not work or the error persists, call Customer Care.

Troubleshooting

Meter does not enter the test mode after inserting a test strip.

Probable Cause	What to Do
The battery is dead.	Replace the battery (and reset the date and time, if necessary.)
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the FreeStyle Lite® test strip with the printed side up and the top of the strip in the meter.
Defective meter or test strips.	Call Customer Care.
Blood or foreign objects put into the test strip port.	Call Customer Care.

Test does not start after applying the blood sample.

Probable Cause	What to Do
Blood sample too small.	You may add blood to the same sample area of the FreeStyle Lite test strip from which you started for up to 60 seconds from the time of the first application. If necessary, repeat the test using a new FreeStyle Lite test strip and a larger blood sample.
Defective test strip.	Repeat the test with a new FreeStyle Lite test strip.
Sample applied after meter times out (two minutes) and turns off.	Repeat the test using a new test strip. Wait until you see the Blood and Test Strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Call Customer Care.

FreeStyle Lite[®] System Specifications

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	500 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	mg/dL
Meter Storage Temp.	-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 #2032, 3 volt, lithium battery, replaceable
Result Range	20 to 500 mg/dL
Sample	Fresh capillary and venous whole blood samples
Sample Size	0.3 microliter (300 nanoliters)
Size	Width 1.57" x Length 2.9" x Depth 0.65"
Weight	1.0 to 1.1 ounces (28.3 to 31.2 grams) including battery

31 Call Customer Care Toll Free at 1-888-522-5226 www.MyFreeStyle.com

Manufacturer/Manufacturer:
Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502, USA

Customer Care is available 24 hours a day, 7 days a week.
Customer Care is available 24 hours a day, 7 days a week.

www.MyFreeStyle.com
Call Customer Care
Toll Free at 1-888-522-5226

www.MyFreeStyle.com
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Toll Free at 1-888-522-5226

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US6,942,518; US7,058,437; US7,615,637; US0587,142; EP1119637; EP1165000.

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123

Freestyle
FREEDOM[®] Lite
Blood Glucose Monitoring System
Blood Glucose Monitoring System

No Coding Required

No Coding Required

Owner's Booklet

Owner's Booklet

Abbott

4/29/10 1:42 PM

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MANAGER

MANAGER

Important Information About Your FreeStyle Freedom Lite Blood Glucose Monitoring System

How the FreeStyle Freedom Lite System Should Be Used

- The FreeStyle Freedom Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm and venous whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. 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.
- The FreeStyle Freedom Lite meter should only be used with FreeStyle Lite[®] test strips and FreeStyle[®] control solution. Using other test strips and control solution with this meter can produce inaccurate results.

WARNING:

- We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.
- The FreeStyle Freedom Lite system contains small parts that may be dangerous if swallowed.

Caution: Please read all the instructions provided in this *Owner's Booklet* and practice the testing procedures before using the FreeStyle Freedom Lite[®] system. Blood glucose monitoring should be done with the guidance of a healthcare professional.

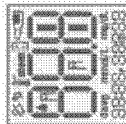
Important Health-Related Information

- Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL or higher than 240 mg/dL you should contact your healthcare professional and follow his or her treatment advice.
- The expected glucose range for a non-diabetic, non-pregnant fasting adult is under 100 mg/dL.¹
- Two hours after meals, levels should be less than 140 mg/dL.¹
- Consult your healthcare professional to determine the range that is appropriate for you.

Reference

¹ American Diabetes Association Clinical Practice Recommendations: Diagnosis and classification of diabetes mellitus. Diabetes Care 2005;28 (Suppl 1):S37-S42

The FreeStyle Freedom Lite Meter and How It Works



System Check Screen

This screen briefly appears each time the meter is turned on so that you can make sure the display is working properly. Do not use the meter if the system check screen does not match the example here. Please call Customer Care.

Flashes Test Results

Displays your test results and other important information.

Navigation Buttons

- Move to different mode settings.
- Scrolls backward.
- Silences a reminder alarm.

Flash Print

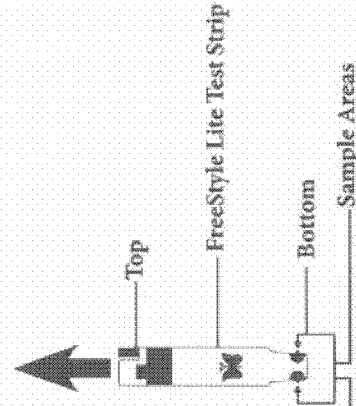
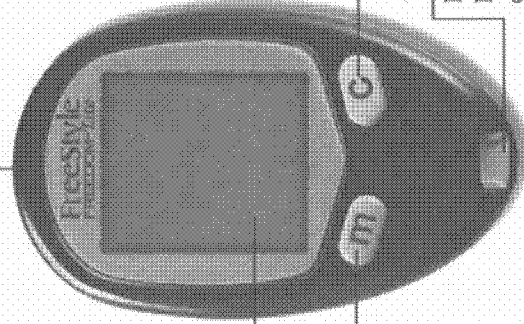
Download test results. Requires a compatible data management system. For more information, please go to our website or call Customer Care.

Test Strip

- 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.



Sample Area

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

LANGUAGE1

LANGUAGE2

The FreeStyle Freedom Lite Meter Display

Meters: Main Screen

Shows you test results stored in the meter memory.

Battery Symbol

Appears when you should replace your meter battery.

Control Solution Test Result Symbol

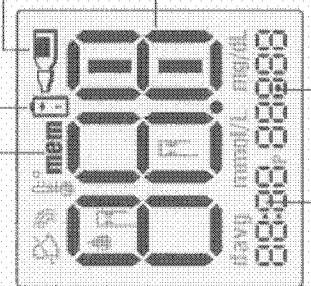
Shows that you have marked a test result as a control solution test.

Test Result Area

Displays test results.

MEMO DATE AND TIME

Displays date, time, and number of tests.



LANGUAGE1

LANGUAGE2

Temperature Symbol

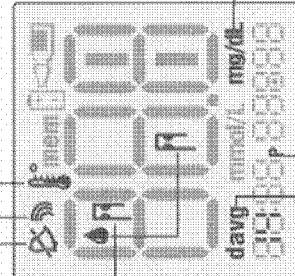
Appears if your meter is out of operating temperature range.

Sound Symbol and Test Strip Symbols

Indicates high, low, or off sound volume. These symbols work together in an animation to tell you when the meter is ready for you to apply blood or control solution.

mg/dL Unit Symbol

Indicates unit of measurement.



Average Symbol

Shows the average value of glucose readings from the last 7-, 14- or 30-days.

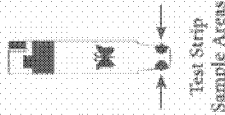
PM Symbol

Indicates PM in 12-hour format only (for example 4:00 p.m.)

The FreeStyle Lite® Test Strip

Apply blood or control solution to only one test strip sample area per test.

Important: Do not apply blood to both sample areas. Test strips may be used only once. Discard used test strips. You can continue to fill the test strip for up to 60 seconds. Be sure to reapply the sample to the same sample area.



WARNING:

The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important: The FreeStyle Freedom Lite® meter should only be used with FreeStyle Lite test strips. Using other test strips with this meter can produce inaccurate results.

Important Product Information

- The FreeStyle Freedom Lite system has an operating range of 40° to 104° F (4° to 40° C).
- Store the test strip package in a cool, dry place between 40° and 86° F (4° to 30° C).
- Use test strips only within the system operating temperature range.
- Keep away from direct sunlight or heat.
- Store your test strips in their original vial only; never transfer them to another vial or any other container.
- Never store individual test strips outside the vial.
- After removing a FreeStyle Lite test strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.

- Do not use test strips beyond the expiration date. This may cause inaccurate results.
 - Do not bend, cut, or alter FreeStyle Lite® test strips.
- Note:** For further information, refer to the FreeStyle Lite test strip package insert.

The FreeStyle® Control Solution

Each FreeStyle control solution vial contains a red liquid with a fixed amount of glucose that is used to:

- Practice testing without having to use your own blood.
- Ensure that your meter and test strips are working together properly.



A control solution test should be performed when you question your results and want to confirm that your monitor and test strips are working properly.

There are three levels of control solution available (Low, Normal, High). For information on how to obtain control solution, call Customer Care at 1-888-522-5226.

Control Solution Information

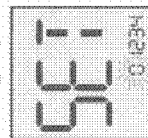
FreeStyle® control solution is good for three months after opening the bottle or until the expiration date printed on the label, whichever comes first.

Important: Count forward three months from the date you open a new bottle of control solution. Write this date on the side of your control solution bottle. This is your discard date, unless the expiration date printed on the bottle comes first.

Example: You open the control solution on January 15th. Count forward three months to April 15th. This is the discard date that you record on the bottle.

- Use only FreeStyle control solution with your FreeStyle Freedom Lite® system.
- Replace the cap on the control solution bottle immediately after using.
- Do not use control solution past the expiration date.
- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when used between 59° to 104° F (15° to 40° C).
- Control solution test results should fall within the range printed on the test strip vial label.
- Important:** The control solution range is a target range for control solution only. It is not a target range for your blood glucose level.
- If control solution results are out of this range, repeat the test.
- If your control solution test results continue to fall outside the range printed on the test strip vial, do not use the FreeStyle Freedom Lite system to test your blood glucose. Contact Customer Care.

Caution: Results from FreeStyle control solution tests do not reflect your blood glucose level.

Meter Setup**Setting Up Your Meter**

- **To Enter Setup Mode**
Start with the meter off (no test strip inserted). Press and hold the "m" button for two seconds until the SEI display screen appears.

- **To Exit at Any Time**

Press and hold the "m" button for two seconds until the meter turns off.

- **To Move Through the Screens**

Press the "m" button to move through all the setup screens such as reminder alarms, sound level, time, date, and so on.

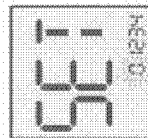
- **To Change Settings Within the Screen**

Press the "c" button.

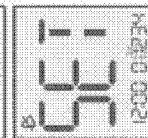
Setting the Reminder Alarms

You may set up any or all of the reminder alarms (1-4). Note: A reminder alarm will never sound during a test.

To set a reminder alarm or multiple reminder alarms, please follow these steps:



1. Start with the meter off. Press the "m" button and hold until the SEI display appears with 01234. You are now in the reminder alarm setting mode and the "0" is blinking.

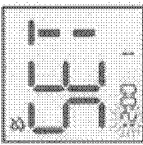


2. To move to the first reminder alarm press the "c" button once. You are now ready to set reminder alarm 1 ("1" is blinking).

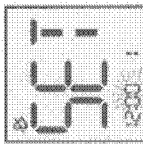
Select reminder alarm

LANGUAGE1

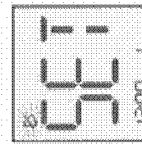
LANGUAGE2



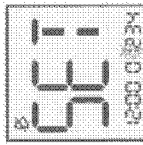
Select hour



Select minute



Select reminder alarm volume



Select reminder alarm

3. Press the "m" button to move to the hour setting. With the hour blinking, press the "c" button until the correct hour appears.

4. Press the "m" button to move to the minute setting. With the minute blinking, press the "c" button until the correct minute appears.

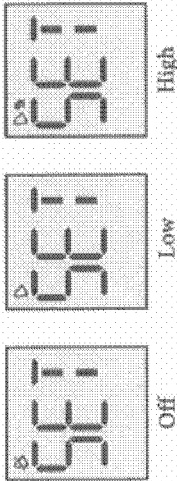
5. Press the "m" button to move to the reminder alarm volume setting. Default setting is off. Press the "c" button to select the desired volume setting: low, high, or off.

6. Press the "m" button to finalize your alarm setting. This will bring you back to the reminder alarm setting 5 E I mode. If you wish to set multiple reminder alarms press "c" to move to reminder alarm 2. Repeat.

Note: To save your reminder alarm settings and exit setup mode, press and hold the "m" button for two seconds until the meter turns off. Press the "m" button when "0" is blinking to move to the next setup screen without setting any reminder alarms.

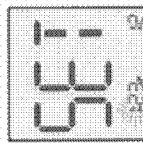
Setting the Alarm

There are three (3) sound volume options:

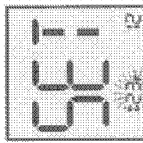


There are three sound volume options to let you know when the test strip is full, when the reading is done, and when an error occurs:

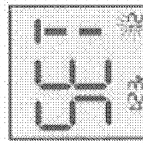
1. Press the "c" button until the desired sound level appears.
2. Press the "m" button to move to "Setting the Time."



Hour



Minute



Time Format

Setting the Time

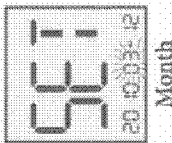
1. With the hour blinking, press the "c" button until the correct hour appears. The "p" displays for "PM" times.
2. Press the "m" button to move to minute setting. With the minute blinking, press the "c" button until the correct minute appears.
3. Press the "m" button to move to "Setting the Time Format."

Setting the Time Format

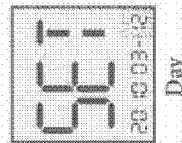
1. With the hour mode blinking, press the "c" button to move between 12-hour and 24-hour format. The time automatically updates to the format selected.
2. Press the "m" button to move to "Setting the Date and Date Format."

Setting the Time and Date Format

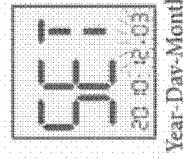
1. With the month blinking, press the "c" button until the correct month appears.



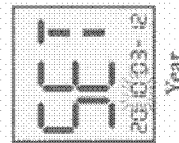
2. Press the "m" button to move to the day setting. With the day blinking, press the "c" button until the correct day appears.



3. Press the "m" button to move to "Date Format." With the date blinking, press the "c" button to select month-day or day-month format. The date automatically updates to the format selected.



4. Press the "m" button to move to the year setting. With the year blinking, press the "c" button until the correct year appears.

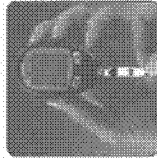


You have completed Meter Setup.

- To move to "Setting the User Reminder Alarms" press the "m" button.
- To exit press and hold the "m" button for two seconds.

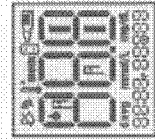
Performing a Control Solution Test

Insert the top of the test strip into your meter until it stops. This will power on the meter.



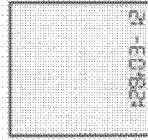
System Check Screen

Each time the meter powers on, this screen briefly appears so that you can make sure the display is working properly.

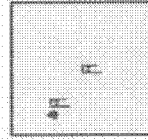


System Check

The date and time will briefly appear after the system check screen so that you can make sure your meter is set to the correct time and date.

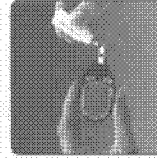


Wait for the meter to display the blood drop and test strip symbols.



Gently touch only one of the sample areas on the test strip to the control solution.

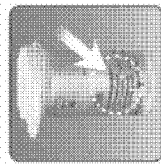
Important: Do not apply control solution to both test strip sample areas.



If the sound is on, your meter will beep when the test strip is full. A short line then moves clockwise around the display screen while the sample is processing.

The result will appear on the display screen and if the sound is on, your meter will beep twice. To mark the result as a control solution result, press and hold the "c" button for two seconds until the control solution symbol (☐) appears at the top right of the display screen.

If you have marked a blood glucose test as a control solution test by mistake, you can unmark it by pressing and holding the "c" button again for two seconds.



Compare your control solution test result to the range printed on your test strip vial label. Your control solution results should fall within the range printed on the side of your test strip vial.

Out of range test results may be caused by:

- Error in performing the test
- Expired or contaminated control solution
- Test strip deterioration
- Meter malfunction

Testing Your Blood Glucose

Important. To ensure accurate results, wash your hands and test site (for example, your upper arm) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

- With the FreeStyle Freedom Lite® meter, you can test your blood glucose on your upper arm, palm or fingers.
- Testing with the FreeStyle Freedom Lite meter requires a very small sample size, 0.3 microliters of blood, about the size of pinhead (example: •).

WARNING:

We recommend that you test on your fingers if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

Times when you may be checking for low blood glucose include:

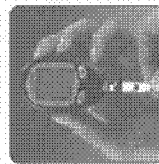
- When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.
- When you have delayed a meal after taking insulin.
- When your healthcare professional advises you to do so.

LANGUAGE1

LANGUAGE2

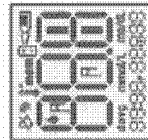
Performing a Blood Glucose Test

Prepare Your Meter



Insert a FreeStyle Lite[®] test strip into the meter until it stops. The meter will power on.

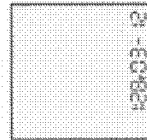
Note: If you do not start the test within two minutes, the meter will turn off. To restart your meter, take out the unused FreeStyle Lite test strip and reinsert it into the meter.



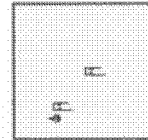
System Check

System Check Screen

Each time the meter powers on, this screen briefly appears so that you can make sure the display is working properly.



The date and time will briefly appear after the system check screen so that you can make sure your meter is set to the correct time and date.



Blood Drop and Test Strip Symbols

The blood drop and test strip symbols will appear on the display screen. Your meter is now ready to apply blood sample.

Potential Bruising

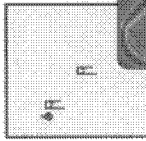
It is possible you may experience bruising at the test site. If bruising does occur, you may choose to lance another test site.

2. Choose a Blood Sample

Select a test site. There are differences in testing on fingers versus other alternative sites.

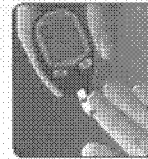
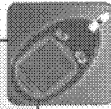
Use your lancing device to obtain a blood sample. Refer to the lancing device insert for detailed instructions on how to use the FreeStyle[®] lancing device.

WARNING: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers.



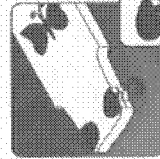
3. Pulling the FreeStyle Lite[®] Test Strip with Blood

a. Make sure that the FreeStyle Lite test strip is in the meter, the meter is powered on and the blood drop and test strip symbols are displayed. You are now ready to apply the blood sample.



b. Bring the FreeStyle Lite test strip to the blood sample at a slight angle.

Important: Use only one test strip sample area per test. Do not apply blood to both edges, or you may get an inaccurate result. Test strips may be used only once. Discard used test strips.



c. The FreeStyle Lite test strip pulls the blood into the strip through the sample area.



Test Strip Sample Area

LANGUAGE1

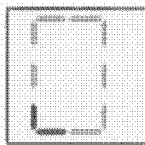
LANGUAGE2

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FreeStyle Lite Test Strip Information

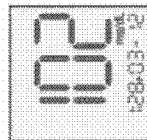
- Do not press the FreeStyle Lite® test strip against the test site.
- Do not scrape the blood onto the FreeStyle Lite test strip.
- Do not apply blood to the flat side of the FreeStyle Lite test strip.
- Do not apply blood to the FreeStyle Lite test strip when the FreeStyle Lite test strip is out of the meter.
- Do not put blood or foreign objects into the FreeStyle Freedom Lite® test strip port.

1. Waiting for Result



- Do not pull the FreeStyle Lite test strip away from the sample until you hear one beep or see the short line moving clockwise on your meter screen. This means you have enough blood and the meter is reading your glucose.

• If after five seconds your meter does not show a short line moving around the display screen, the sample may be too small. You may add blood to the same sample area of the test strip from which you started for up to 60 seconds from the time of the first application.



- The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps if the sound is on.
- The time that the meter takes to display a reading depends on your blood glucose level. The higher your glucose level, the longer it takes to get a result.

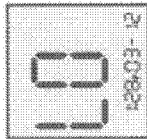
LO and HI Readings

Important: Low or high blood glucose readings can indicate a potentially serious medical condition. The FreeStyle Freedom Lite® meter displays results from 20 to 500 mg/dL.

If your test result is lower than 20 mg/dL, LO will appear on the meter display screen. This reading indicates severe hypoglycemia (low blood glucose).

LO Reading with Symptoms

If you have a LO reading and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.



LO Reading

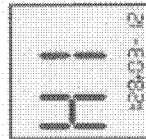
LO Reading without Symptoms

If you get a LO reading, but have no symptoms of low blood glucose, then retest with a new test strip on your fingers. If you still get a LO reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hypoglycemia.

If your test is above 500 mg/dL, HI will appear on the display screen. This indicates severe hyperglycemia (high blood glucose).

HI Reading with Symptoms

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.



HI Reading

Test Results

If you get a HI reading, but have no symptoms of high blood glucose, then retest with a new test strip on your fingers. If you still get a HI reading, perform a control solution test to ensure your system is functioning properly. If the system is functioning properly follow your doctor's recommendation to treat hyperglycemia.

Intermittent Glucose Monitoring

To Enter

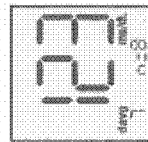
Start with the meter off (no test strip inserted). Press and release the "m" button; the first memory screen to appear will be your 7-day average.

To Exit

Press and hold the "m" button for two seconds until the meter turns off.

7-Day 7-Day Average

The first memory display screen you see is your 7-day average. This includes all the readings from the last 7 days starting from the current date and time shown on the meter. (Control solution, LO, and HI readings are not included in the average.)



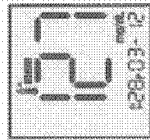
Example:

7day = your 7-day average
n = indicates the number of results included in your average

The "c" button allows you to scroll forward to 14- and 30-day averages. Continue to press the "c" button to view stored test results. Your most recent result will display first.

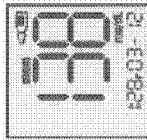
Test Results

The meter stores the last 400 test readings with time and date. You may scroll forward through all of the readings by pressing the "c" button. The "m" button allows you to scroll backward. The first reading you see is the most recent result.



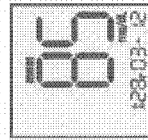
Temperature: A result with a thermometer symbol (🌡️) indicates that the reading was taken outside of the meter's specified operating temperature range and may not be accurate. This value is included in your 7-, 14- and 30-day averages.

LO Reading: A LO reading (under 20 mg/dL) is included in the memory as LO; it is not included in your 7-, 14- and 30-day averages.
HI Reading: A HI reading (over 500 mg/dL) is included in the memory as HI; it is not included in your 7-, 14- and 30-day averages.



Control Solution Test

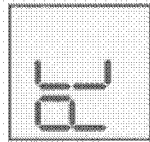
A value with (CS) indicates that you have marked this reading as a control solution test. The date and time of the control solution reading will appear on the bottom of the screen.



Blood Glucose Test

A result without a control solution symbol indicates that it is a blood glucose reading. The date and time of the test will appear on the bottom of the screen.

Data Download



The "PC" symbol displays when a data cable is inserted in the meter data port. You cannot perform a test while the data cable is in the meter data port.

The meter will display "PC" until the data cable is removed from the data port.


Requires a compatible data management system. For more information, please go to our website or call Customer Care.

LANGUAGE1

LANGUAGE2

Battery Maintenance



Your FreeStyle Freedom Lite® meter comes with one preinstalled, #2032, 3 volt, lithium battery. The battery provides enough power for the meter to perform about 1000 tests. If your battery runs low, the battery symbol () appears on every display screen until you change the battery.

Important: When this symbol appears, you should replace the battery immediately.

• **To avoid losing the time and date settings, replace the battery within one minute of removing the old battery.**

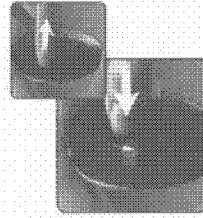
• If you take more than one minute to replace the battery, you may need to reset the time and date to get the correct 7-, 14- and 30-day averages. If the time and date settings are lost, the time and date displays flash 12:00 and 00-00 until they are reset.

• Removing the battery does not affect the meter's memory log or previously-stored user settings (such as date and time formats).

• If the time and date settings are not reset, test results will be stored in memory with a time of 12:00 and a date of 00-00.

• Even if you lose your time and date settings – you can perform a blood glucose test, and results will not be affected.

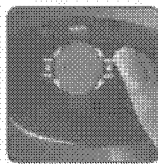
Replacing the Battery



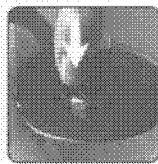
Turn the meter over. Slide the battery door to the right to open.

To remove the battery, pull the plastic tab up to release the battery.

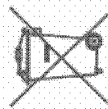
2 Verifying the Battery Connection



Install the battery with the positive (+) sign up toward you.



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



Note: The batteries in this product should be removed and disposed in accordance with local regulations for separate collection of spent batteries.

3 Cleaning the Meter

Avoid getting dirt, dust, blood, control solution, water, or any other liquid in the meter's test strip and data ports.

Important: Never immerse the meter in water or any other liquid. This may cause inaccurate reading or meter malfunction.

Do not try to clean the strip or data ports.

Do not pour liquid into the strip port, data port or buttons.

Do not place your meter in water or any other bath.

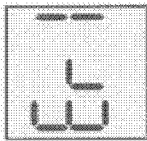
Clean the outside of the meter using a cloth dampened with one of the following:

- Mild detergent/mild soap and water.
- 70% isopropyl alcohol.
- A mix of one part household bleach, nine parts water.

System Troubleshooting

Error Message

Error 1



Possible Causes

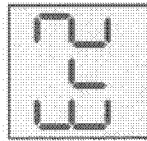
- Sample is too small.
- Problem with the FreeStyle Lite[®] test strip.
- Problem with the meter.
- Very low blood glucose (less than 20 mg/dL).

What You Should Do

1. If you have symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your doctor's recommendation for treating hypoglycemia.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Error 2

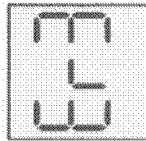
Possible Causes



- Problem with the FreeStyle Lite test strip.
- Problem with the meter.
- Very high glucose (above 500 mg/dL).
- HIGH control solution applied when temperature is too cold. (This applies only to control solution that is labeled as HIGH.)

What You Should Do

1. If you have symptoms such as thirst, fatigue, excess urination, or blurry vision, follow your doctor's recommendation for treating hyperglycemia.
2. Conduct a control solution test using a new FreeStyle Lite® test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

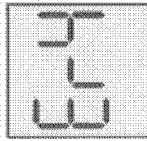
**Possible Causes**

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter or applying blood before the blood drop and test strip symbols display.
- Problem with the FreeStyle Lite test strip.
- Problem with the meter.

What You Should Do

1. Be sure you see the blood drop and test strip symbols on the display screen before you apply blood or control solution.
2. Conduct a control solution test using a new FreeStyle Lite test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
3. If the retest using control solution does not work or the error persists, call Customer Care.

Figure 4

**Possible Causes**

- Problem with FreeStyle Lite® test strip.
- Problem with the meter.

What You Should Do

1. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of your test strip vial, retest using blood and a new FreeStyle Lite test strip.
2. If the retest using control solution does not work or the error persists, call Customer Care.

Meter does not enter the test mode after inserting a test strip.	
Probable Cause The battery is dead.	What to Do Replace the battery (and reset the date and time, if necessary).
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the FreeStyle Lite® test strip with the printed side up and the top of the strip in the meter.
Defective meter or test strips.	Call Customer Care.
Blood or foreign objects put into the test strip port.	Call Customer Care.
Test does not start after applying the blood sample.	
Probable Cause Blood sample too small.	What to Do You may add blood to the same sample area of the FreeStyle Lite test strip from which you started for up to 60 seconds from the time of the first application. If necessary, repeat the test using a new FreeStyle Lite test strip and a larger blood sample.
Defective test strip.	Repeat the test with a new FreeStyle Lite test strip.
Sample applied after meter times out (two minutes) and turns off.	Repeat the test using a new test strip. Wait until you see the blood and test strip symbols on the display screen before you apply the blood sample.
Defective meter or test strips.	Call Customer Care.

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	1000 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	mg/dL
Meter Storage Temp.	-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 #2032, 3 volt, lithium battery, replaceable
Result Range	20 to 500 mg/dL
Sample	Fresh capillary and venous whole blood samples
Sample Size	0.3 microliter (300 nanoliters)
Size	Width 2.00" x Length 3.30" x Thickness 0.63" (at thickest point)
Weight	1.4 to 1.6 ounces (39.7 to 45.4 grams) including battery



(b)(4)



(b)(4),(b)(5)



(b)(4)