

DECLARATION OF NATHANIEL E FRANK-WHITE

1. I am a Records Request Processor at the Internet Archive. I make this declaration of my own personal knowledge.

2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.

3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.

4. The archived data made viewable and browseable by the Wayback Machine is obtained by use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.

5. The Internet Archive assigns a URL on its site to the archived files in the format http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL] aka an "extended URL". Thus, the extended URL http://web.archive.org/web/19970126045828/http://www.archive.org/ would be the URL for the record of the Internet Archive home page HTML file (http://www.archive.org/) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.

6. Attached hereto as Exhibit A are true and accurate copies of screenshots of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.



7. Attached hereto as Exhibit B are true and accurate copies of the Internet Archive's records of the archived files for the URLs and the dates specified in the following table.

Folder	URL
1	http://web.archive.org/web/20071023144033/http://www.abbottdiabetescare.com/static/content/document/ART03162-Rev-C.pdf
2	http://web.archive.org/web/20071023143201/http://www.abbottdiabetescare.com/static/content/document/ART06705-Rev-A.pdf
3	http://web.archive.org/web/20071023143138/http://www.abbottdiabetescare.com/static/content/document/ART06690-Rev-B-EN.pdf
4	http://web.archive.org/web/20100326114949/http://www.abbottdiabetescare.com/static/content/document/ART00903-Rev-C.pdf
5	http://web.archive.org/web/20071023143813/http://www.abbottdiabetescare.com/static/content/document/ART03978-Rev-A.pdf
6	http://web.archive.org/web/20070204032520/http://www.bayerdiabetes.com:80/us/prodServ/custService/pdf/BREEZE_eng.pdf
7	http://web.archive.org/web/20040217213153/http://www.lifescan.com/pdf/ultra_quick_start.pdf
8	http://web.archive.org/web/20070421182818/http://www.lifescan.com:80/pdf/ultra_ob.pdf
9	http://web.archive.org/web/20040205060705/http://www.lifescan.com/pdf/99183_otb.pdf

8. I declare under penalty of perjury that the foregoing is true and correct.

DATE: March 9, 2022

Nathaniel E Frank-White

Nathaniel E Frank-White

ONE TOUCH®
BASIC®

Complete Diabetes Monitoring System



Owner's Booklet

Convenience. Confidence. Control.

LIFESCAN
a Johnson & Johnson company

LifeScan, Inc.. Ex. 1020 - Page 3
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

INSIDE FRONT COVER

The ONE TOUCH® BASIC® Diabetes Monitoring System is intended for in vitro diagnostic use for quantitative determination of glucose in whole blood as an aid in monitoring effectiveness of diabetes management in the home and in clinical settings. It is not intended for use in the diagnosis of diabetes or for neonatal testing (newborns 0–4 weeks old).

LifeScan, Inc.. Ex. 1020 - Page 5
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

CAUTION: Before using any product to test your blood glucose (sugar), read all instructions and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional. These recommendations apply to all blood glucose monitoring systems and are supported by the American Association of Diabetes Educators, the American Diabetes Association, the U.S. Food and Drug Administration, and the Health Industry Manufacturers Association.

IMPORTANT: The ONE TOUCH® BASIC® System contains many small parts: test strip holder, battery door, batteries, lancets, control solution vial, test strips, test strip vial cap, etc. Keep the system out of the reach of small children because these parts may be dangerous if swallowed.

TABLE OF CONTENTS

INTRODUCTION		**1**
PRECAUTIONS AND LIMITATIONS		**2**
	Infection Control	3
GETTING STARTED		**4**
	The Complete ONE TOUCH® BASIC® Diabetes Monitoring System	4
	ONE TOUCH® BASIC® Blood Glucose Meter	6
	ONE TOUCH® Test Strips	8
	ONE TOUCH® Normal Control Solution	10
BEFORE TESTING		**11**
	Setting Meter Code	11
	Checking the System	13

LifeScan Customer Services: English 1 800 227-8862
Español 1 800 381-7226

LifeScan, Inc.. Ex. 1020 - Page 7
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

— Checking with the Check Strip 14
— Checking with Control Solution 18

TESTING YOUR BLOOD **25**

Abbreviated Test Procedure 25

Detailed Test Procedure 26
— Getting a Drop of Blood 27
— How to Test Your Blood 33
Special Messages 38
Checking the Amount of Blood on the Test Strip 39

COMPARING METER AND LABORATORY RESULTS **42**

USING THE METER MEMORY **45**

Entering the Memory Mode 45
Recalling Test Results 46

LifeScan Customer Services: English 1 800 227-8862
Español 1 800 381-7226

LifeScan, Inc.. Ex. 1020 - Page 8
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

SETTING METER OPTIONS **47**

Entering and Using the Set-Up Mode 47
Clock (Time and Date) 49
— Setting the Time 50
— Setting the Date 51
Beep Prompts 52
Language 53
Time Format 54
Date Format 54
Unit of Measure 55
Decimal Separator 55
Exiting the Set-Up Mode 56

SOLVING PROBLEMS **57**

Test Procedure Messages 57
Error Messages 62

LifeScan Customer Services: English 1 800 227-8862
Español 1 800 381-7226

LifeScan, Inc.. Ex. 1020 - Page 9
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

TAKING CARE OF YOUR METER **72**

Doing a Daily Check 73
Cleaning the Meter 73
Replacing the Batteries 78

SPECIFICATIONS **82**

GUARANTEE AND WARRANTY **83**

30-Day Money-Back Guarantee 83
Three-Year Warranty 83

INDEX **85**

LifeScan Customer Services: English 1 800 227-8862
Español 1 800 381-7226

LifeScan, Inc.. Ex. 1020 - Page 10
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

INTRODUCTION

Congratulations! You've chosen a very easy-to-use blood glucose monitoring system for home testing. When used properly, your ONE TOUCH® BASIC® System will give you the accurate test results you need, in just a few simple steps.

Everything you need to know about using the ONE TOUCH BASIC System is included in this booklet. A free instructional videotape is also available by calling LifeScan Customer Services.

Blood glucose monitoring plays an important role in controlling your diabetes. The results you get with the ONE TOUCH BASIC System can help you and your healthcare professional monitor and adjust your treatment plan (diet, exercise, and medication) to help you gain better control of your diabetes.

If you have any questions, please call LifeScan Customer Services at 1 800 227-8862.

Thank you for choosing the ONE TOUCH® BASIC® Diabetes Monitoring System.

P.S. Don't forget to complete and mail the warranty service card. When we receive your warranty card, we'll send you a complimentary gift to show our appreciation. See your warranty card for details.

LifeScan, Inc.. Ex. 1020 - Page 11
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

PRECAUTIONS AND LIMITATIONS

The following information will be useful to you and your healthcare professional when using the ONE TOUCH® BASIC® System to monitor your blood glucose level.

If you experience symptoms that are not consistent with your blood glucose test results AND you believe you have followed all instructions described in the owner's booklet, contact your healthcare professional immediately.

Never make significant changes to your medication program or ignore physical symptoms without consulting your healthcare professional.

If your test result is 60 mg/dL or lower, this indicates low blood glucose (hypoglycemia). The meter will display the test result along with the message danger calldr. You should immediately treat hypoglycemia as recommended by your healthcare professional.

If the message hi danger calldr. appears on the meter display, this indicates severe high blood glucose (hyperglycemia). Contact your doctor immediately.

LifeScan, Inc.. Ex. 1020 - Page 12
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Extremes in hematocrit (the amount of red blood cells in the blood) can affect test results. Very high hematocrits (above 60%) and very low hematocrits (below 25%) can cause false results.[1]

Abnormally high levels of Vitamin C or other reducing substances will cause false low blood glucose results.[2] Normal levels of reducing substances have little effect on blood glucose results.

Do not use blood samples with preservatives that contain fluoride (gray-top test tubes). You will get false low results.

When testing, removal of the test strip prior to display of the blood glucose result may give you a false result.

Infection Control

Use universal blood precautions. All patient samples and materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection. Follow proper precautions in accordance with federal, state, and local regulations when disposing of all materials.

LifeScan, Inc.. Ex. 1020 - Page 13
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

GETTING STARTED

The ONE TOUCH® BASIC® Diabetes Monitoring System consists of three main products: the ONE TOUCH® BASIC® Blood Glucose Meter, ONE TOUCH® Test Strips, and ONE TOUCH® Normal Control Solution. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Only LifeScan manufactures ONE TOUCH® BASIC® System products. Attempting to substitute other products may affect the accuracy of your test results and limit the ability of LifeScan to help you solve problems that may arise.

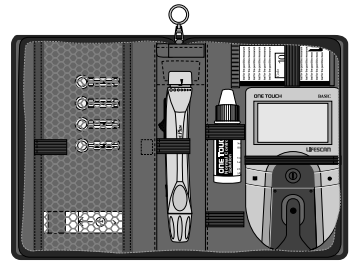
The Complete ONE TOUCH® BASIC® Diabetes Monitoring System

Your ONE TOUCH BASIC System includes:

- ONE TOUCH BASIC Meter with Two AAA Batteries (Installed)
- ONE TOUCH Test Strips
- ONE TOUCH Normal Control Solution

LifeScan, Inc.. Ex. 1020 - Page 14
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

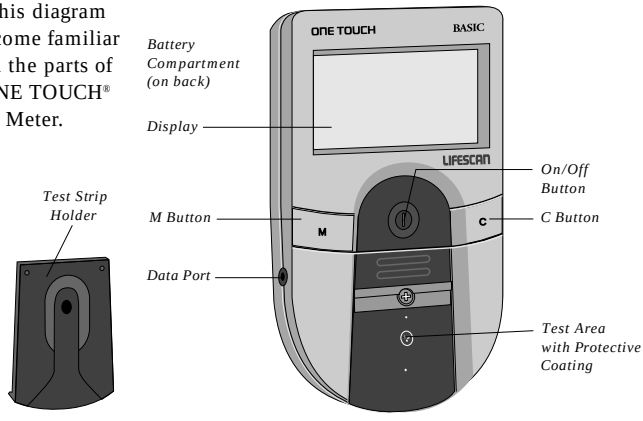
- Owner's Booklet and Quick Reference Guide
- Check Strip
- Penlet® *Plus* Adjustable Blood Sampler
- Lancets
- Carrying Case
- Logbook



LifeScan, Inc.. Ex. 1020 - Page 15
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

ONE TOUCH® BASIC®
Blood Glucose Meter

Study this diagram and become familiar with all the parts of your ONE TOUCH® BASIC® Meter.



LifeScan, Inc.. Ex. 1020 - Page 16
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

ON/OFF BUTTON. This button turns the meter on and off.

DISPLAY. The large, easy-to-read display is where you read the simple messages that guide you through testing. Your test results are displayed here.

BATTERY COMPARTMENT. Holds two AAA batteries. The batteries are already installed in your meter.

M BUTTON. The ONE TOUCH® BASIC® Meter automatically stores your test results. Use the M button to recall the information stored in your meter's memory and to review your meter's option settings.

C BUTTON. Use the C button to change the option settings on the ONE TOUCH BASIC Meter.

TEST STRIP HOLDER. The test strip holder holds a ONE TOUCH® Test Strip in place when you perform a blood glucose or control solution test. It must be removed to clean the meter.

TEST AREA. The test area is located under the test strip holder. There is a clear, protective coating over the test area that must be kept clean and undamaged for accurate results.

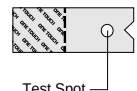
LifeScan, Inc.. Ex. 1020 - Page 17
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

DATA PORT. Allows you to transfer the information stored in the meter's memory to a computer to view, analyze, and print. Please contact the LifeScan Data Management Line at 1 800 382-7226 for more information about data management software products.

ONE TOUCH® Test Strips

The ONE TOUCH® BASIC® Diabetes Monitoring System measures the amount of sugar (glucose) in whole blood. When blood is applied to a ONE TOUCH Test Strip, certain compounds on the test strip react with the blood to form a blue color. The ONE TOUCH® BASIC® Meter reads the color to determine the blood glucose level.

Test Strip



LifeScan, Inc.. Ex. 1020 - Page 18
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

IMPORTANT TEST STRIP INFORMATION

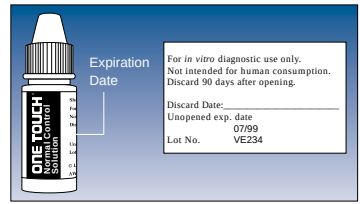
- ONE TOUCH® Test Strips can be damaged by heat and light. Keep them sealed in the original vial. Store the vial in a cool, dry place below 86°F (30°C). **Do not** refrigerate. **Do not** place in direct heat or sunlight.
- ONE TOUCH Test Strips are intended for use with fresh whole blood or ONE TOUCH® Normal Control Solution. **Do not** use them with plasma or serum samples. Results will not be accurate.
- **Do not** use test strips beyond the expiration date on the vial.
- When you open a new vial of test strips, record the discard date on the vial. The discard date for test strips is four months after first opening the vial.
- **Do not** use test strips that are bent, torn, cut, or changed in any way.
- Use each test strip immediately after removing it from the vial; replace the vial cap and close it tightly.
- Never transfer test strips to a new vial or any other container. **Always** carry test strips in their original container. **Do not** carry loose test strips in your meter case.
- **Do not** use bleach (or products containing bleach) near the test strips.
- For reliable results, use only ONE TOUCH Test Strips made by LifeScan.

LifeScan, Inc.. Ex. 1020 - Page 19
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

ONE TOUCH® Normal Control Solution

ONE TOUCH Normal Control Solution is an important part of the ONE TOUCH® BASIC® System. Use it in two ways:

1) to practice the test procedure, and
2) to make sure that the ONE TOUCH® BASIC® Meter and ONE TOUCH® Test Strips are working together properly.



(Example)

LifeScan, Inc.. Ex. 1020 - Page 20
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

BEFORE TESTING

Note: You **do not** have to enter the set-up mode to test. However, the ONE TOUCH® BASIC® Meter has a number of settings you can change, including the language, time and date, display formats, and the unit of measure. For a description of these options and how to set them, see page 47.

Setting Meter Code

Code numbers are used to enable your meter to provide consistent measurements. For this reason, it is important that the code is set correctly. You must code the meter before using it for the first time and then every time you change to another vial of ONE TOUCH® Test Strips.

CAUTION: If the code number on the meter display does not match the code number on the vial of ONE TOUCH Test Strips, test results may be false.

Code the ONE TOUCH BASIC Meter in these three easy steps:

LifeScan, Inc.. Ex. 1020 - Page 21
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Step 1: Press the On/Off Button.

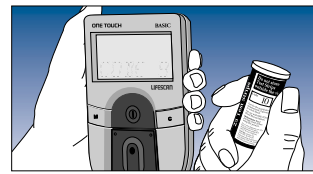
When turning meter on, all display symbols will appear. The last test result will then appear on the display for a moment. (If using the meter for the first time, the message code-- will appear on the display.) If you have already coded the meter, your current test strip code followed by the message check code will momentarily appear on the display. The following will then appear:



(Example)

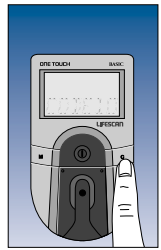
Step 2: Match the Code Numbers.

The code number on the test strip vial ranges from 1 to 16. If the code number on the meter display matches the code number on the test strip vial, you can begin testing. If the two code numbers do not match, follow Step 3. (When you first use the meter, code-- will appear, showing that there is no code stored in the memory.)



LifeScan, Inc.. Ex. 1020 - Page 22
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Step 3: Code the Meter.



While the meter displays code--, or after the word insert is displayed, press and release the C button; the code number will appear. Continue pressing the C button until the number on the display matches the code number on the test strip vial. The code number is now set for the test strips you are using. The meter will remember this code number until you change it. You are now ready to do a test.

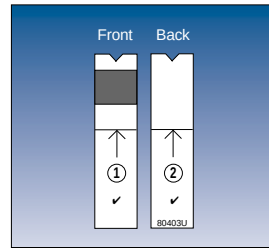
Checking the System

There are two ways to check that your ONE TOUCH® BASIC® System is working properly. The check strip is used to check that the meter is operating properly. ONE TOUCH® Normal Control Solution is used to check that both the meter and the test strips are working together as a system, and that you are doing the test correctly. It is very important that you do these simple checks routinely for accurate results.

LifeScan, Inc.. Ex. 1020 - Page 23
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Checking with the Check Strip

A purple and white check strip is included in the carrying case of your ONE TOUCH® BASIC® System. Before doing a check strip test, make sure the test strip holder, test area, and check strip are clean, dry, and lint-free. Do the check strip test at room temperature (between 64° and 79°F [18°–26°C]).



(Example)

LifeScan, Inc.. Ex. 1020 - Page 24
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Do a check strip test:

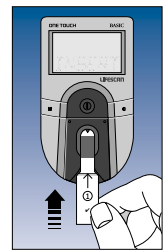
- At least once each day you test your blood
- After cleaning the meter
- Whenever your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate
- If you drop the meter
- If you get the meter wet
- Whenever the following message appears:



How to do a check strip test:

Step 1: Press the On/Off Button. Insert Side 1 of the Check Strip.

When `insert code 10` (Example) `strip` appears, slide the notched end of the check strip into the test strip holder with Side 1 (purple side) facing up. `wait` appears for a moment.

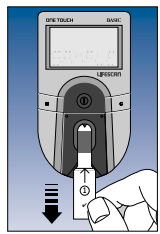


LifeScan, Inc.. Ex. 1020 - Page 25
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Step 2: When** apply sample **Appears, Remove the Check Strip from the Test Strip Holder.

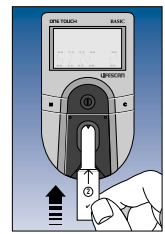
Note: This is the only time you should remove a strip **during** a test.

Note: **Do not** apply control solution to the check strip.

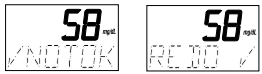


Step 3: When** insert side 2 **Appears, Turn the Check Strip Over and Slide It Back into the Test Strip Holder.

It should go in notched end first, Side 2 (white side) facing up. The meter counts down from four to zero and then gives you a check strip result.



LifeScan, Inc.. Ex. 1020 - Page 26
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



(Example)

If these messages appear, repeat the check strip test. If these messages appear again, clean your meter and repeat the test. If you do not obtain an acceptable (A ok) check strip reading, redo A will appear each time you turn on your meter, indicating that your last check strip test was outside of the check strip range printed on the back of the meter. This message will continue to appear until you perform a check strip test and get a reading that falls within the correct check strip range.

CAUTION: If your check strip test result is out of range, your meter may not be working properly. **Do not** use the meter to test your blood until you get a check strip reading that is within the correct range printed on the back of the meter. For assistance, call LifeScan Customer Services at 1 800 227-8862.

To clean and maintain the check strip:

- Make sure both sides of the check strip are clean. If necessary, wipe the check strip with a soft cloth or tissue dampened with water. Dry it completely.

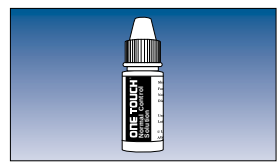
LifeScan, Inc.. Ex. 1020 - Page 27
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

- **Do not** get blood, alcohol, control solution, or any other fluid (except water) on the check strip.
- **Do not** scratch the check strip.
- **Do not** leave the check strip in sunlight.
- If you lose or damage the check strip, call LifeScan Customer Services at 1 800 227-8862 for a free replacement.

Checking with Control Solution

ONE TOUCH® Normal Control Solution contains a known amount of glucose that reacts with ONE TOUCH® Test Strips. Control solution should be used to practice the test procedure and to make sure your meter and test strips are working together properly as a system.

Before you use the ONE TOUCH® BASIC® Meter to test your blood glucose for the first time, practice the procedure using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.



LifeScan, Inc.. Ex. 1020 - Page 28
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Do a control solution test:

- For practice, before testing your blood with the ONE TOUCH® BASIC® Meter for the first time
- When you begin using a new vial of test strips
- At least once a week
- Whenever you suspect that the meter or test strips are not working properly
- When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate
- If you drop the meter
- If you get the meter wet

The control solution test procedure is just like blood glucose testing, except that you use ONE TOUCH® Normal Control Solution instead of blood.

Control solution test tips

- Shake the control solution vial thoroughly before using.
- If there are any bubbles on the top of the vial, wipe them off with a clean tissue.
- Apply a full drop of control solution to the center of the test spot and cover it completely. **Do not** dab, wipe, or smear control solution on the test spot.
- Avoid contaminating the control solution. **Do not** touch the test spot with the tip of the vial.

LifeScan, Inc.. Ex. 1020 - Page 29
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

IMPORTANT CONTROL SOLUTION TEST INFORMATION

- Use only ONE TOUCH® Normal Control Solution.
- Check the expiration date of the control solution. **Do not** use if expired.
- Record the discard date on the control solution vial. **Discard the vial three months after first opening.**
- The ONE TOUCH Normal Control Range printed on the test strip vial is for ONE TOUCH Normal Control Solution only. It is **not** a recommended range for your blood glucose level.
- Store the control solution at room temperature below 86°F (30°C). **Do not** refrigerate.
- Control solution should not be used as a cleaning solution for the meter.

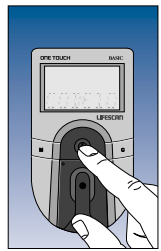
Warning

- For external use only. **Do not** swallow or inject control solution or put control solution drops into your eyes.

LifeScan, Inc.. Ex. 1020 - Page 30
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

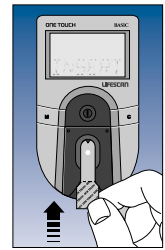
How to do a control solution test:

Step 1: Press On/Off Button. Insert Test Strip.



(Example)

The code number that appears on the meter display should match the code number on the test strip vial. When insert code10 (Example) strip appears, slide a ONE TOUCH® Test Strip into the test strip holder, notched end first, with the test spot facing up. Make sure you push the test strip in all the way until it stops. wait appears for a moment, then apply sample appears for five minutes or until you apply a drop of control solution to the test spot on the test strip.



LifeScan, Inc.. Ex. 1020 - Page 31
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

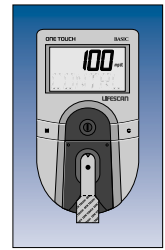
Step 2: Apply Control Solution.

Shake the control solution vial well before using. Remove the cap and apply a drop of control solution to the middle of the test spot, covering it completely.



Step 3: Control Solution Result Appears in 45 Seconds.

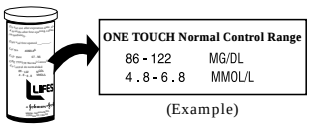
Compare the control solution test result with the ONE TOUCH® Normal Control Range printed on the test strip vial. When you get a control solution test result within the control range, you are ready to test your blood.



(Example)

LifeScan, Inc.. Ex. 1020 - Page 32
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Note: The control solution range is shown in two different units of measure—mg/dL (used in the United States) and mmol/L (used in Canada and some parts of Europe).



(Example)

Control solution test results are automatically stored with the word control. (If you use a logbook, indicate control solution tests by writing "C" after the result.)

Control solution results

If test results fall outside the range printed on the test strip vial, repeat the test. Results that fall outside the expected range may indicate:

- Procedural error
- Control solution that has not been shaken enough
- Expired or contaminated control solution
- Improper coding of the meter
- Dirt on test strip holder or on test area beneath the test strip holder
- Test strip deterioration
- Expired or contaminated test strip

LifeScan, Inc.. Ex. 1020 - Page 33
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

- Meter malfunction
- Extremes in testing temperatures

CAUTION: If your control solution test result falls outside the expected range, the system may not be working properly. **Do not** use the system to test your blood until you get a test result that falls within the expected range. If you are unable to resolve the problem, call LifeScan Customer Services at 1 800 227-8862.

LifeScan, Inc.. Ex. 1020 - Page 34
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

TESTING YOUR BLOOD

Abbreviated Test Procedure

You can test your blood by following this 3-step testing procedure.

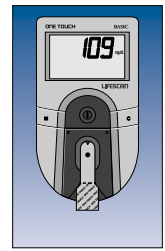
Step 1: Press on/off button. Make sure code displayed on meter matches code on test strip vial. If correct, insert strip.



Step 2: Gently apply sample to test spot. Do not press finger on test spot.



Step 3: Accurate results in 45 seconds.



(Example)

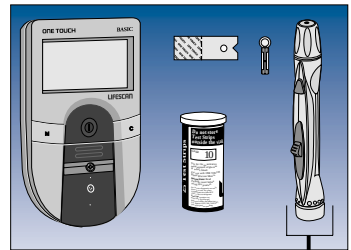
Be sure to read the following section carefully before testing.

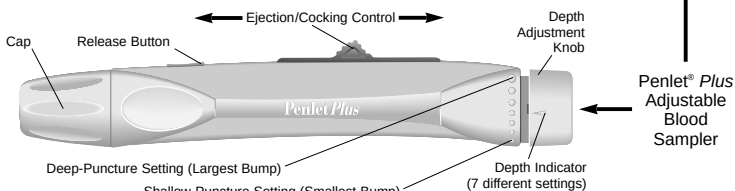
LifeScan, Inc.. Ex. 1020 - Page 35
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Detailed Test Procedure

Choose a clean, dry work surface. Make sure you have all the items needed to test:

- ONE TOUCH® BASIC® Meter
- ONE TOUCH® Test Strips
- Penlet® *Plus* Adjustable Blood Sampler
- Sterile lancet





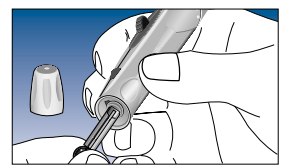
LifeScan, Inc.. Ex. 1020 - Page 36
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

CAUTION: To reduce the chance of infection:

- **Never share a lancet with another person.**
- Always use a new, sterile LifeScan Lancet. Lancets are for single use only.
- The Penlet® *Plus* Sampler should be used by only one person.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the Penlet *Plus* Sampler.

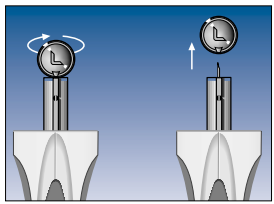
Step 1: Insert a Lancet into the Penlet® Plus Adjustable Blood Sampler.

Remove the Penlet® *Plus* Cap by twisting it counterclockwise. Insert a lancet into the lancet holder. Push down firmly until the lancet is fully seated in the holder. Do not twist the lancet. To avoid contamination and to prevent the cap from rolling away, set the cap down on a flat surface with its small hole pointing up.

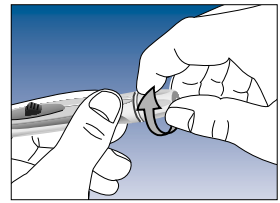


LifeScan, Inc.. Ex. 1020 - Page 37
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

While the lancet is in the Penlet® *Plus* Sampler, twist off the protective disk. Make two full turns to ensure that the lancet separates from the protective disk.

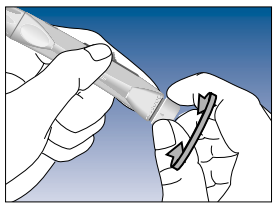


Replace the Penlet® *Plus* Cap. Turn the cap clockwise until it is snug but not overly tight.



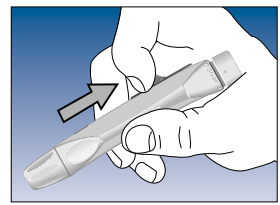
LifeScan, Inc.. Ex. 1020 - Page 38
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Adjust the puncture depth setting if necessary. Twist the knob counter-clockwise toward the smaller bumps for a shallower puncture. Twist the knob clockwise toward the larger bumps for a deeper puncture.



Step 2: Cock the Penlet® Plus Sampler.

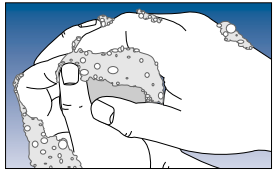
Slide the ejection/cocking control backward until it clicks. If it does not click, the Penlet *Plus* Sampler may have been cocked when the lancet was inserted.



LifeScan, Inc.. Ex. 1020 - Page 39
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

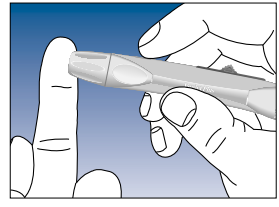
Step 3: Wash Your Hands.

Use warm, soapy water. Rinse and dry hands thoroughly. To increase blood flow to your fingertips, massage the hand from the wrist to the fingertip two or three times without touching the puncture site.



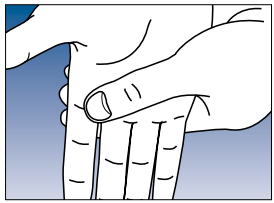
Step 4: Lance Your Finger.

Choose a spot on the side of a different finger each time you test. Repeated punctures in the same spot may cause soreness and calluses. Hold the Penlet® *Plus* Sampler **firmly** against the **side** of your finger. Press the release button. (Greater pressure of the device against the finger will also cause a deeper puncture.)



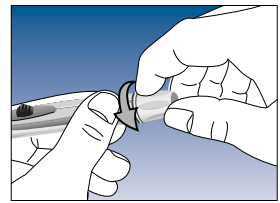
LifeScan, Inc.. Ex. 1020 - Page 40
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Gently massage your finger to obtain the required blood volume. Proceed with your blood glucose test.



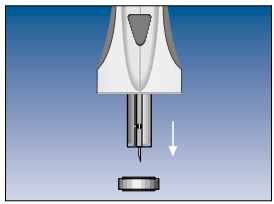
Step 5: Remove the Lancet.

Remove the cap. Twist it counter-clockwise.

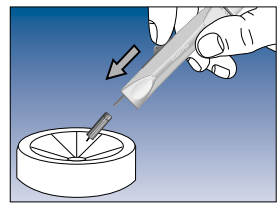


LifeScan, Inc.. Ex. 1020 - Page 41
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Optional: To replace the protective disk on the lancet, place the disk on a hard surface and push the exposed tip into the protective disk.



Always use caution when removing the lancet. Point the lancet down and away from you. Push forward on the ejection/cocking control and eject the lancet directly into a container for sharp objects.



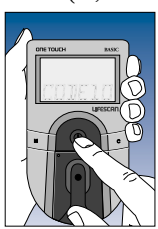
Return the ejection/cocking control to the middle position. Replace the cap.

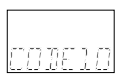
LifeScan, Inc.. Ex. 1020 - Page 42
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

How to Test Your Blood

Step 1: Press On/Off Button. Make Sure Code Number Displayed on Meter Matches Code Number on Test Strip Vial. Insert Test Strip.

Make sure the test strip holder is properly in place. (See page 77.) Turn your meter on. All display symbols will appear. The last test result (or, when you first use the meter, the message nodata) will then automatically appear on the display for several seconds. Your current test strip code appears next, followed by check code and then





(Example)

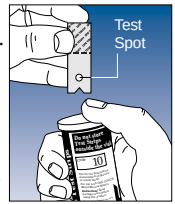


(Example)

Make sure the code number on the meter display matches the code number on the vial of ONE TOUCH® Test Strips you are using. (When you first use the meter, code-- will appear, indicating that there is no code stored in the memory.) If the code numbers do not match, code the meter. (See page 11.)

LifeScan, Inc.. Ex. 1020 - Page 43
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Remove a test strip from the vial. Replace the vial cap immediately. Do not touch the test spot on the test strip. The test spot should be white or ivory-colored, with no tears or wrinkles.

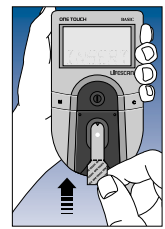


With the meter display showing



(Example)

slide the test strip into the test strip holder, notched end first, test spot facing up. Make sure you push the test strip in all the way until it stops.



LifeScan, Inc.. Ex. 1020 - Page 44
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



appears for a moment. Then

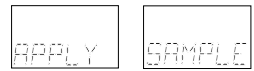


appears for five minutes or until you apply blood to the test spot.

Obtain a drop of blood from your finger using the Penlet® *Plus* Adjustable Blood Sampler. (See page 27.)

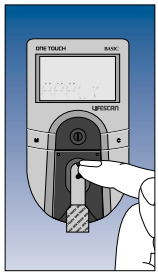
Step 2: Apply Blood Sample.

With the test strip in the meter and



on the display, apply a drop of blood to the test spot.

LifeScan, Inc.. Ex. 1020 - Page 45
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



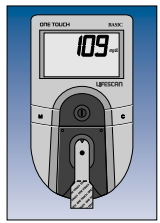
Be sure that you:

- Touch only the tip of the drop of blood to the test spot.
- Apply enough blood to form a round, shiny drop that covers the test spot completely and stays wet during the entire test.
- **Do not** smear blood on the test spot or apply a second drop after the test begins.
- **Do not** move the test strip as you are applying blood. If the test strip moves, push it back into its original position.
- **Do not** remove the test strip from the meter to apply blood.
- **Do not** touch or move the test strip once the count has begun.

If the Beep option is set to **On**, the meter will beep when the blood is applied to the test spot. See page 39, “Checking the Amount of Blood on the Test Strip.”

LifeScan, Inc.. Ex. 1020 - Page 46
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Step 3: Accurate Results in 45 Seconds.



(Example)

The meter then counts down from 45 to 0 seconds, beeps (if the Beep option is set to On), and displays your result. Remove the test strip only after the result is displayed.

Blood glucose test results are automatically stored in your meter's memory with the time and date they were performed. If you have chosen to turn the Clock option to OFF, your test results will appear without time and date. (See page 49.)

Note: The meter records the time and date of each test even when the Clock option is set to OFF. They can once again be seen by turning the Clock option to On.

Note: The first time you enter the set-up mode, the meter will automatically display the time as Pacific standard time (PST) when the Clock option is set to On. If you do not reset the time, the meter will accurately record each test result using PST.

LifeScan, Inc.. Ex. 1020 - Page 47
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Special Messages

The meter displays results from 0 to 600 mg/dL. If your blood glucose test result is 60 mg/dL or below, your meter will beep in a low tone (if the Beep option is set to On) and display a special message:



(Example)

The message is warning you of low blood sugar (hypoglycemia). You may need food or some source of glucose. Retest your blood glucose. If your blood glucose level is still 60 mg/dL or below, call your doctor immediately.

Blood glucose results greater than 600 mg/dL are displayed as hi and your meter will beep in a high tone (if the Beep option is set to On).



(Example)

This message indicates very high blood sugar (severe hyperglycemia). You should call your doctor immediately.

LifeScan, Inc.. Ex. 1020 - Page 48
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Test results below 60 mg/dL[3] (3.3 mmol/L) mean low blood glucose (hypoglycemia). Test results greater than 240 mg/dL[4] (13.3 mmol/L) mean high blood glucose (hyperglycemia). If you get results below 60 mg/dL or above 240 mg/dL, and do not have symptoms, first repeat the test. If you have symptoms and continue to get results that fall below 60 mg/dL or above 240 mg/dL, follow the treatment advice of your healthcare professional.

Checking the Amount of Blood on the Test Strip

Although the ONE TOUCH® BASIC® System requires only a small drop of blood, it is very important that the drop be large enough to cover the test spot completely.

In many cases, the meter can detect if the drop of blood was too small to give an accurate reading. However, it is important that you also look at the test strip to make sure that you applied enough blood.

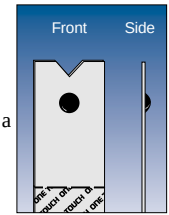
LifeScan, Inc.. Ex. 1020 - Page 49
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

If the following message



appears on the display, your drop of blood was too small, or smeared, or the test strip was not pushed all the way into the test strip holder. Repeat the test with a new test strip and enough blood to cover the entire test spot.

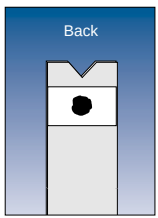
- Remove the test strip from the meter and look at the test spot. It should still have a wet, shiny drop that completely covers the test spot. If the blood sample has a dull, dry appearance, you may not have applied enough blood, or you may have smeared it.



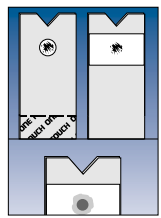
(Correct)

LifeScan, Inc.. Ex. 1020 - Page 50
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

- Look at the back of the test strip. You should see a full, dark circle. If there are any white patches or streaks, you may have smeared the blood or the drop was too small. **In either case, you may have a false low result. Repeat the test with a new test strip.**



(Correct)


(Incorrect)

LifeScan, Inc.. Ex. 1020 - Page 51
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

COMPARING METER AND LABORATORY RESULTS

The blood glucose test result you obtain from your meter may be different from your laboratory result due to normal variation; however, the two results should be within 20% of each other.[5] To make an accurate comparison between meter and laboratory results, follow these guidelines.

Before you go to the lab:

- Make sure your meter is clean.
- Perform check strip and control solution tests to make sure the meter is working properly.
- Comparisons will be more accurate if you have not eaten for at least four hours (and preferably eight hours) prior to doing the comparative tests.
- Take your meter with you to the lab.

While at the lab:

- Make sure that both tests are done within 15 minutes of each other.
- Wash your hands before obtaining a blood sample.
- Never use your meter with blood that has been placed in a gray-top test tube.

LifeScan, Inc.. Ex. 1020 - Page 52
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Comparing the results:

- When the lab tests your blood, only the serum or plasma portion is used. Your ONE TOUCH® BASIC® Meter uses only whole blood.
- Comparing serum or plasma to whole blood is like comparing a temperature of 98.6°F with the temperature of 37°C—in order to see if the values are equal, you have to adjust one of the results.
- Whole blood results are approximately 12% lower than serum or plasma results.
- To compare lab results with meter results, divide the lab result by 1.12.

Example:

- Assume that your lab result (plasma or serum) is 224 mg/dL.
- 224 divided by 1.12 = 200 (the lab value is now approximately equal to a whole blood result).
- Compare this figure to your meter result. The two should be within 20% of each other.

You may still have a variation from the result because blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication, or experienced stress.[6] In addition, if you have eaten

LifeScan, Inc.. Ex. 1020 - Page 53
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

recently, the blood glucose level from a fingerstick can be up to 70 mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.[7] Therefore it is best to fast for four to eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (severe dehydration) may also give a meter result different from a laboratory result.

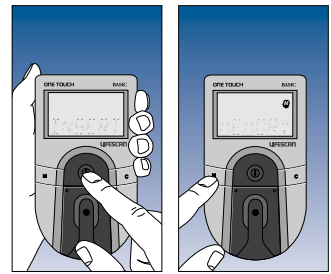
LifeScan, Inc.. Ex. 1020 - Page 54
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

USING THE METER MEMORY

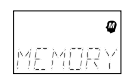
Your ONE TOUCH® BASIC® Meter automatically stores up to 75 test records. It stores blood glucose, check strip, and control solution test results with time and date. When you have stored more than 75 records, the oldest record is dropped from the memory as a new record is added.

Entering the Memory Mode

Turn the meter on by pressing the on/off button. You can access the meter's memory and recall test results at any time before or after performing a test by pressing the M button.



The word memory with the memory symbol will appear briefly.



LifeScan, Inc.. Ex. 1020 - Page 55
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

If you are using the meter for the very first time and have not used it for testing, or if you have used a software program to clear the meter's memory, the following message will appear, indicating that there are no results stored in the memory:



Recalling Test Results

Pressing the M button allows you to see each blood glucose, check strip, and control solution test stored in memory. The records will appear in order from the most recent to the oldest, up to the full 75-record capacity of the memory. Test results will appear on the meter display as follows:



(Examples)

When the memory returns to the most recent result, the meter will beep (if the Beep option is set to On). You can exit the memory mode at any time by pressing the on/off button.

LifeScan, Inc.. Ex. 1020 - Page 56
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

SETTING METER OPTIONS

You **do not** have to enter the set-up mode to test. However, you can customize the various option settings of your ONE TOUCH® BASIC® Meter to best meet your needs. This is done in the set-up mode. Option settings (default settings shown) that you can customize include:

- Clock (Time and Date): OFF
- Beep Prompts: On
- Language: ENGL
- Time Format: 24hr
- Date Format: M/D
- Unit of Measure: mg/dL
- Decimal Separator: DEC PT

To change the default settings, enter the set-up mode.

Entering and Using the Set-Up Mode

To enter the set-up mode, start with your meter turned off. Press and hold the on/off button for about three seconds until all display symbols appear and begin to flash. Release the on/off button. The set-up screen will then appear briefly.



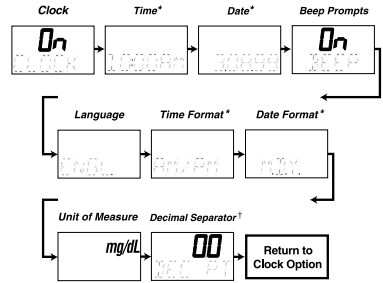


LifeScan, Inc.. Ex. 1020 - Page 57
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

The meter will then automatically present the first option screen. The options map will help guide you through the option screens.

- Use the M button to scroll through the options or move within an option.
- If you want to change an option setting, use the C button.

Note: You can exit the set-up mode at any time by pressing the on/off button. If after two minutes you have not made a selection, the meter will turn itself off automatically. All option settings are saved as they are made.



* Time and Date options appear only if the Clock option is on.

† The Decimal Separator option appears only if the unit of measure chosen is mmol/L. The standard unit of measure in the United States is mg/dL.

LifeScan, Inc.. Ex. 1020 - Page 58
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Clock (Time and Date)

The ONE TOUCH® BASIC® Meter has an internal clock that will record the time and date of each test you perform. Your meter has been set to automatically record tests in Pacific standard time (PST) both when the Clock option is set to OFF and when it is set to On.

If you are not in Pacific standard time (PST), you will need to change the time setting in your meter in order to have the correct time and date appear with your test result. If you are in mountain standard time (MST), add one (1) hour; central standard time (CST), add two (2) hours; eastern standard time (EST), add three (3) hours. If you do not reset the time, the meter will accurately record each test result using PST.

You will also need to reset the time whenever there is a change to or from daylight saving time.

Note: The accuracy of your test results will not be affected if you do not set the Clock option to the correct time and date *or* if you choose not to display the time and date.

LifeScan, Inc.. Ex. 1020 - Page 59
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Once the Clock option is set to On, you are ready to set the time.



Note: The first time you enter the set-up mode, the Clock option will be preset to OFF. To set the Clock option to On, see page 47, "Entering and Using the Set-Up Mode."

If you do **not** want to display the time and date, press the C button to turn the Clock option to OFF.

Note: The meter records the time and date of each test even when the Clock option is set to OFF. They can once again be seen by turning the Clock option to On.

Setting the Time

Enter the set-up mode and set the Clock option to On (see page 47). Use the M button to display the current time setting. Press the

LifeScan, Inc.. Ex. 1020 - Page 60
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

C button to change the time; the *hour* and am or pm will flash. Press the C button again to advance the hour to the correct setting. Press the M button and the *minutes* will flash. Use the C button to change the minutes. Press the M button to see the new time setting (the colon will flash).



Press the M button again to move to the date setting.

Setting the Date

Enter the set-up mode and set the Clock option to On (see page 47). Use the M button to set the date. The current date will show. Press the C button to change the date setting; the *year* will flash. Press the C button again to change the year to the correct setting. Press the M button and the *month* will flash. Use the C button to change the month. Press the M button and the *day* will flash. Press the C button to change the day. Pressing the M button again will display the new date setting.



LifeScan, Inc.. Ex. 1020 - Page 61
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

You may now turn the meter off or press the M button to move to the next option.

Beep Prompts

The meter is set to provide you with audio prompts, or “beeps,” during the test procedure to tell you that the meter has performed some function or to alert you to a special message. To change the Beep option setting, enter the set-up mode (see page 47). Use the M button to choose the Beep option. The current setting will appear on the display.



With the On setting, the meter will continue to provide beep prompts during the test procedure.

To change the Beep option setting so that the meter operates silently, press the C button.



OFF will appear on the display. You may now turn the meter off or press the M button to move to the next option.

LifeScan, Inc.. Ex. 1020 - Page 62
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Language

The ONE TOUCH® BASIC® Meter can display messages in 17 languages: English [engl], Spanish [espan], French [franc], Italian [italia], Hungarian [magyar], Dutch [neder], Norwegian [norsk], Polish [polski], Portuguese [port], Russian [pycck], Finnish [suomi], Swedish [svens], Turkish [turkce], Czech [cesky], Danish [dansk], German [deuts], and Greek [e⚠⚠/ka].

The meter is set to give prompts in English. To change the display language, enter the set-up mode (see page 47). Use the M button to choose the Language option. Press the C button until the language you want appears on the display. You may now turn the meter off or press the M button to move to the next option. Once a language is selected, all messages will be displayed in that language.

LifeScan, Inc.. Ex. 1020 - Page 63
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Time Format

The meter can be set to display the time in either a 12-hour (AM/PM) format or a 24-hour format.

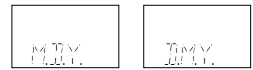


To change the time format, enter the set-up mode (see page 47). Use the M button to choose the Time Format option. Press the C button to change the time format. You may now turn the meter off or press the M button to move to the next option.

Note: To change the time and date, the Clock option must be set to .

Date Format

The meter is set to display the date as month-day-year (for example: June 1, 1999 reads as 6-01-99). You can set the meter to display day-month-year, as is common in Europe.



To change the date format, enter the set-up mode (see page 47). Use the M button to choose the Date Format option. Press the C button to change the date format. You may now turn the meter off or press the M button to move to the next option.

LifeScan, Inc.. Ex. 1020 - Page 64
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Unit of Measure

The meter is set to display test results in milligrams per deciliter (mg/dL), the standard unit used in the United States. You have the option to change to millimoles per liter (mmol/L), commonly used in Canada and parts of Europe.



To change the unit of measure, enter the set-up mode (see page 47). Use the M button to choose the Unit of Measure option. Press the C button to change the unit of measure. You may now press the M button to review or change any of the options you have chosen or press the on/off button to turn the meter off.

Decimal Separator

Note: The Decimal Separator option appears only if you have selected mmol/L as your unit of measure.

The meter is set to display millimoles per liter (mmol/L) using a decimal point. This option allows you to select a comma instead of a decimal point as a decimal separator.

LifeScan, Inc.. Ex. 1020 - Page 65
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



To change the decimal separator, enter the set-up mode (see page 47) and select mmol/L as the unit of measure. Use the M button to choose the Decimal Separator option. Make your selection using the C button. You may now press the M button to review or change any of the options you have chosen or press the on/off button to turn the meter off.

Exiting the Set-Up Mode

All options are automatically saved as they are made. After you have completed viewing or changing your option settings, simply turn the meter off. **The meter will automatically turn itself off after two minutes of no activity.**

LifeScan, Inc.. Ex. 1020 - Page 66
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

SOLVING PROBLEMS

The messages that appear on your ONE TOUCH® BASIC® Meter display guide you through the testing procedure, alert you to problems as they occur, and give you information about test results stored in the meter's memory. This section provides you with a complete listing of the display messages, what they mean, and what to do if there is a problem.

Test Procedure Messages

These messages appear during routine testing. Follow them carefully and they will guide you through the test.

MESSAGE	APPEARS WHEN
	Appears briefly when the meter is turned on. You can see that all of the display segments are working properly.

LifeScan, Inc.. Ex. 1020 - Page 67
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	APPEARS WHEN
code--	The meter is turned on and you have not previously coded the meter. This is a reminder that you should verify that the code displayed on the meter matches the code on the test strip vial before testing. If it does not, reset by pressing the C button.
check code	The meter is turned on. This is a reminder that prior to testing you should verify that the code displayed on the meter matches the code on the test strip vial. If it does not, reset by pressing the C button.
insert code10 (Example) strip	The meter is ready to perform a blood, check strip, or control solution test.

LifeScan, Inc.. Ex. 1020 - Page 68
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	APPEARS WHEN
wait	The meter is performing internal checks.
apply sample	The meter is ready to receive a blood or control solution sample. If performing a check strip test, this is your signal to remove the check strip from the meter.
45 0	The meter is counting down from 45 seconds to 0.
109 mg/dL (Example)	A blood test has been completed. This indicates a blood glucose result when the meter is set for mg/dL.
61 mmol/L (Example)	A blood test has been completed. This indicates a blood glucose result when the meter is set for mmol/L, the unit of measure used in Canada and parts of Europe.

LifeScan, Inc.. Ex. 1020 - Page 69
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	APPEARS WHEN
100 mg/dL (Example) contrl	A control solution test has been completed. (If you have just performed a blood glucose test, this means that the blood sample was too small and the meter read it as control solution. Repeat the test with a new test strip and a larger drop of blood.)
insert side 2	You are performing a check strip test. Turn the check strip over and insert Side 2.
80 mg/dL (Example) A ok	The check strip test result falls into the acceptable range. The check strip range is printed on the back of your meter.

LifeScan, Inc.. Ex. 1020 - Page 70
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	APPEARS WHEN
58 mg/dL (Example) danger alternating with 58 mg/dL (Example) calldr.	Your blood glucose test result is low, 60 mg/dL or below, possibly indicating hypoglycemia. You may need food or some source of glucose. Retest. If the test result is still 60 mg/dL or below, call your doctor.
hi mg/dL (Example) danger alternating with hi mg/dL calldr.	Your blood glucose test result is above 600 mg/dL. This level is severe hyperglycemia. Contact your doctor immediately.

LifeScan, Inc.. Ex. 1020 - Page 71
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

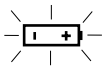
Error Messages

When any of these messages appear, there is a problem with the ONE TOUCH® BASIC® Meter or the way in which you are performing a test. These messages help to identify certain problems but do not appear in all cases when a problem has occurred. If you think your meter may not be operating properly, refer to page 13, “Checking the System.” If you are experiencing symptoms that are not consistent with your blood glucose test results AND you believe you have followed all of the instructions in the owner’s booklet, contact your healthcare professional.

In most cases, problems are easy to fix. If you have trouble, help is available from LifeScan Customer Services 24 hours a day, every day at 1 800 227-8862.

MESSAGE	PROBLEM	WHAT TO DO
	Some parts of the display are not working. The messages will be incomplete.	Call LifeScan Customer Services.

LifeScan, Inc.. Ex. 1020 - Page 72
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	PROBLEM	WHAT TO DO
	When this symbol appears and stays on the screen, it means the batteries are getting low. This symbol will remain on the display while the meter is on until the batteries are replaced.	You will still be able to test, but replace the batteries as soon as possible. If batteries get too low, the meter will **not** operate.*
 battry	When this symbol is flashing, the batteries are too low.	Replace the batteries immediately. The meter will **not** operate.*

*Neither dead batteries nor battery removal have an effect on information stored in the memory.

LifeScan, Inc.. Ex. 1020 - Page 73
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	PROBLEM	WHAT TO DO
clean test area	1. There is dirt, blood, or lint on the test area.	1. Clean the test area and test strip holder according to instructions.
	2. Your hand or an object covered the test area while the meter was turned on.	2. Repeat the test. Keep the meter's test area clear.
	3. The meter was used in very bright light.	3. Move the meter away from the light source. Repeat the test with a new test strip.
remove strip	The test strip was inserted before the word insert appeared on the display.	Repeat the test with a new test strip. Wait for the word insert before inserting a test strip.

LifeScan, Inc.. Ex. 1020 - Page 74
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	PROBLEM	WHAT TO DO
100 mg/dL (Example) contrl	If the word contrl appears after a blood test, your blood sample was too small, smeared, or another drop was added after the test began.	Repeat the test with a new test strip and a larger drop of blood.
error 1 retest	The sample was applied before the words apply sample appeared.	Repeat the test with a new test strip.
error2 retest	1. The test strip moved during the test. 2. The test strip was not inserted correctly.	1. Repeat the test with a new test strip. 2. Repeat the test with a new test strip.

LifeScan, Inc.. Ex. 1020 - Page 75
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	PROBLEM	WHAT TO DO
	3. The test strip was removed before the test was completed.	3. Repeat the test with a new test strip.
	4. There was not enough blood on the test strip.	4. Repeat the test with a new test strip.
	5. The meter was used in very bright light.	5. Move the meter away from the light source. Repeat the test with a new test strip.
	6. The check strip procedure was incorrect.	6. Repeat the check strip test.
	7. The meter may not be operating correctly.	7. Call LifeScan Customer Services at 1 800 227-8862.

LifeScan, Inc.. Ex. 1020 - Page 76
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	PROBLEM	WHAT TO DO
error3 retest	The test strip was removed during a test or the test strip was inserted with blood or control solution already applied.	Repeat the test with a new test strip. Insert the test strip into the meter and wait for the words apply sample to appear. Apply blood or control solution with test strip inserted in meter.
not enough blood retest	1. The blood or control solution sample was too small or smeared.	1. Repeat the test with a new test strip and a large, shiny drop of blood or control solution.

LifeScan, Inc.. Ex. 1020 - Page 77
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	PROBLEM	WHAT TO DO
	2. The test strip was not inserted far enough into the test strip holder.	2. Repeat the test with a new test strip, pushing the test strip all the way into the test strip holder.
	3. Your hand or an object covered the test area while the meter was turned on.	3. Repeat the test. Keep the meter test area clear.
not ok	1. If appearing when you turn your meter on, your meter may have an electronic problem.	1. Call LifeScan Customer Services at 1 800 227-8862.

LifeScan, Inc.. Ex. 1020 - Page 78
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	PROBLEM	WHAT TO DO
	2. If appearing at the end of a test, your meter may have been moved while applying blood or during the test process.	2. Repeat the test with a new test strip; try not to move the meter.
	3. If appearing during the test, the strip has been removed while the word `wait` is on the display.	3. Repeat the test with a new test strip.
58 mg/dL (Example) Anotok	The check strip test result is outside the acceptable range (printed on the back of the meter).	Clean the meter and check strip if necessary. Repeat the check strip test.

LifeScan, Inc.. Ex. 1020 - Page 79
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	PROBLEM	WHAT TO DO
redo A	The last check strip test was outside the acceptable range and an acceptable repeat test was not performed.	Repeat the check strip test.
retest	The last test failed after the countdown started.	Repeat the test with a new test strip.

LifeScan, Inc.. Ex. 1020 - Page 80
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

MESSAGE	PROBLEM	WHAT TO DO
code- -	The meter requires a test strip code (found on the test strip vial) to operate. (*Note:* This is not an error message when the meter has not yet been coded.)	Use the C button to reset the meter code to match the test strip vial code. You should also check all of your meter option settings to be sure they are correct. (If this continues to happen, there may be a problem with your meter. Call LifeScan Customer Services at 1 800 227-8862.)

LifeScan, Inc.. Ex. 1020 - Page 81
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

TAKING CARE OF YOUR METER

Your ONE TOUCH® BASIC® Meter is easy to maintain. These tips will help you keep it in good operating condition:

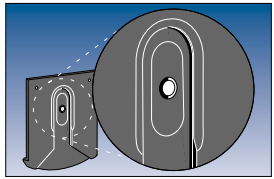
CAUTION:

- **Do not** get water or other liquids inside the meter.
- Never immerse the meter or hold it under running water or other liquids.

- Keep the test strip holder and test area clean (see page 73).
- Keep your meter dry and avoid exposing it to extremes in temperature or humidity. For example, **do not** leave it in your car.
- **Do not** drop the meter or get it wet, as this could damage the electronics. If you drop the meter or get it wet accidentally, make sure the test strip holder is still securely in place. If you drop the meter or get it wet, check the meter by doing check strip tests (see page 14) and control solution tests (see page 18) to be sure it is operating properly.
- **Do not** take the meter apart. Sensitive parts could be damaged, causing inaccurate results. *Taking the meter apart will void the warranty.*
- **Do not** clean the meter with alcohol. Alcohol will damage the meter.

LifeScan, Inc.. Ex. 1020 - Page 82
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Doing a Daily Check



Look through the small hole in the test strip holder to make sure there is no lint, dirt, or blood blocking it.

If there is anything blocking the hole, or if the test area has dirt, lint, or blood on it, remove the test strip holder and clean the test area by following the instructions in the next section. Then do a check strip test (see page 14).

Cleaning the Meter

Clean the meter and test strip holder:

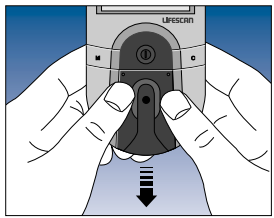
- At least once each week
- Whenever the test area looks dirty
- Whenever

clean
test
area

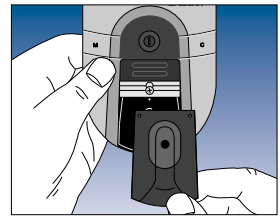
appears on the display

LifeScan, Inc.. Ex. 1020 - Page 83
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Step 1: Remove the Test Strip Holder from the Meter.



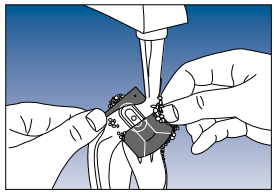
Hold the meter and place your thumbs on the two raised dots on the test strip holder. Press down on the raised dots and slide the test strip holder toward you.



Remove the test strip holder to expose the test area.

LifeScan, Inc.. Ex. 1020 - Page 84
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Step 2: Clean the Test Strip Holder.



Wash only the test strip holder with soap and water.

Clean the underside of the test strip holder. Using a damp cotton swab, clean the small hole from both sides to remove any dirt, blood, or lint. Rinse well. Dry completely with a soft cloth or tissue.

Step 3: Clean the Test Area.

CAUTION: Do not get water inside the meter. Do not immerse meter in water.

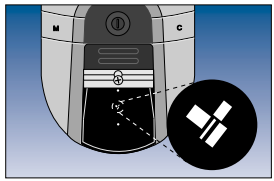
The following cleaning agents will damage the meter.

DO NOT USE:

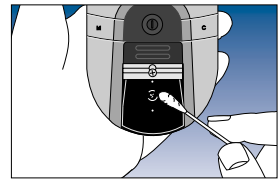
- Alcohol
- Cleansers with ammonia or phenol
- Windex® or other glass cleaners
- Abrasive cleansers

Windex is a registered trademark of The Drackett Products Company.

LifeScan, Inc.. Ex. 1020 - Page 85
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



Check the clear, protective coating over the test area to make sure it is not scratched or damaged.

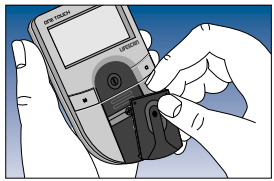


Rub the test area with a cotton swab or soft cloth dampened with water to remove all blood, dirt, or lint from the test area. If necessary, a mild liquid dishwashing detergent mixed with water may also be used. Do not apply full-strength detergent to the test area. Be careful not to scratch the test area.

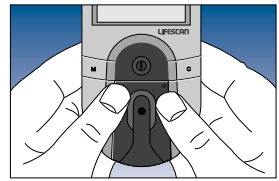
LifeScan, Inc.. Ex. 1020 - Page 86
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Dry the test area with a soft, dry tissue or cloth. Remove any lint.

Step 4: Replace the Test Strip Holder.



Hook the bottom of the test strip holder onto the square notch on the meter.



Press down on the raced dots of the test strip holder until it snaps firmly into place. Press forward on the base of the test strip holder to be sure it is properly in place. You are now ready to do a check strip test. If the check strip will not slide into the test strip holder, repeat this step.

LifeScan, Inc.. Ex. 1020 - Page 87
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Replacing the Batteries

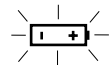


The ONE TOUCH® BASIC® Meter comes with batteries already installed. When the batteries need to be replaced, use two AAA, 1.5-volt alkaline batteries.

The batteries should last about 18 months when testing up to two (2) times a day. When the battery symbol appears on the meter display, the batteries are getting low.

You will still be able to test with low batteries, but you should replace them as soon as possible.

When



battry

appears flashing on the display, the meter will no longer give results and you must replace the batteries before you can perform another test.

The meter's current time and date settings are saved for a minimum of 30 minutes after the batteries have

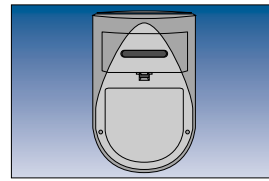
LifeScan, Inc.. Ex. 1020 - Page 88
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

been removed. After that you may need to reset the time and date. Dead batteries and/or battery removal will **not** erase or change test results, default settings, or codes stored in the meter.

To replace the batteries:

1. Make sure the meter is turned off before you remove the batteries.

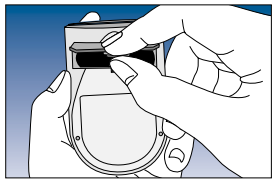
2. Turn the meter over so that the front of the meter is resting in the palm of your hand.



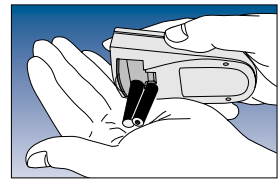
(Back of Meter)

3. With your thumb, press upward on the opening tab of the battery compartment door and lift upward until it releases from the clasp.

LifeScan, Inc.. Ex. 1020 - Page 89
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

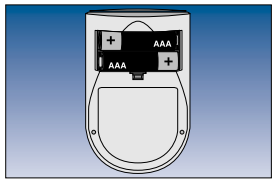


4. Remove the battery compartment door.



5. Remove the old batteries by gently slapping the meter against the palm of your hand. **Never tap the meter against a hard surface.**

LifeScan, Inc.. Ex. 1020 - Page 90
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



6. Insert the new AAA batteries into the battery compartment, being sure to align the plus (+) and minus (-) signs correctly.

To replace the battery compartment door, insert the tab on the top of the door into the slot in the top of the battery compartment. Press the opening tab upward toward the top of the meter. Lower the battery compartment door until it snaps shut.

Check to see that your meter is working. If the meter fails to turn on, the batteries may have been inserted incorrectly. Remove the batteries and reinsert them as illustrated.

References

1. LifeScan data on file.
2. LifeScan data on file.
3. Kahn, R., and Weir, G.: *Joslin's Diabetes Mellitus*, 13th ed. Philadelphia: Lea and Febiger (1994), 489.
4. Krall, L.P., and Beaser, R.S.: *Joslin Diabetes Manual.* Philadelphia: Lea and Febiger (1989), 261–263.
5. Clarke, W.L., et al.: *Diabetes Care,* Vol. 10, No. 5 (1987), 622–628.
6. Surwit, R.S., and Feinglos, M.N.: *Diabetes Forecast* (1988), April, 49–51.
7. Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R. (ed.), *Tietz Textbook of Clinical Chemistry.* Philadelphia: W.B. Saunders Company (1994), 959.

LifeScan, Inc.. Ex. 1020 - Page 91
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

SPECIFICATIONS

Power Supply: Two AAA alkaline batteries.

Battery Life: About 18 months when testing up to two (2) times a day.

Result Range: 0–600 mg/dL (0–33.3 mmol/L). Higher values are displayed as hi.

Display Type: Liquid crystal.

Blood Source: Whole blood (capillary or venous). **Do not** use samples that contain fluoride (gray-top tubes).

Hematocrit Range: 25–60%.

Dimensions: 4.3" x 2.6" x 1.2".

Weight: 4.1 ounces with batteries.

Operating Temperatures: 59–95°F (15–35°C).

Operating Humidity Range: 0–90% relative humidity (noncondensing).

Memory: Up to 75 results with time and date.

Data Port: RS-232 serial communications with special LifeScan cable for interface with a personal computer.

LifeScan, Inc.. Ex. 1020 - Page 92
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

GUARANTEE AND WARRANTY

30-Day Money-Back Guarantee

If you are not fully satisfied with the ONE TOUCH® BASIC® System, a full refund may be obtained by calling a LifeScan Customer Services Representative at the toll-free number within 30 days of purchase. You must return the ONE TOUCH® BASIC® Meter and a copy of your receipt to receive a refund.

Three-Year Warranty

If, at any time during the first three years after purchase, the meter does not work for any reason (except for obvious abuse), LifeScan will replace it with a new meter or equivalent product free of charge.

The warranty policy applies only to the original purchaser of this meter and does not include the batteries supplied with the meter.

LifeScan, Inc.. Ex. 1020 - Page 93
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Before you return your meter, or any product, call LifeScan Customer Services at 1 800 227-8862.

Please complete the warranty service card and mail it to LifeScan.

The ONE TOUCH® BASIC® Meter has a full three-year warranty from the original date of purchase. Write your date of purchase here:

_____

The warranty policy does not apply to the performance of the ONE TOUCH BASIC Meter when used with any test strip other than ONE TOUCH® Test Strips, or when the ONE TOUCH BASIC Meter or ONE TOUCH Test Strips are changed or modified in any way.

This warranty is in lieu of all other warranties, express or implied, including any implied warranty of merchantability or fitness for a particular purpose.

LifeScan, Inc.. Ex. 1020 - Page 94
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

INDEX

Batteries, Replacing the 78
Beep Prompts 52
Blood, Getting a Drop of 27
Blood, How to Test Your 33
Blood on the Test Strip, Checking the Amount of 39
C Button 6, 7
Check Strip, Checking with the 14
Check Strip, Test Result Range of 17
Cleaning the Meter 73
Clock 49
Code, Setting Meter 11
Control Solution, Testing with 18
Control Solution, ONE TOUCH® Normal 10
Control Solution Results 23
Control Solution Test Information, Important 20
Control Solution Test Tips 19
Data Port 8
Date, Setting the 51
Decimal Separator 55
Format, Date 54
Format, Time 54
Guarantee, 30-Day Money-Back 83
Hematocrit 3
Laboratory Results, Comparing Meter Results with 42
Lancet 27
Language 53
Limitations, Precautions and 2
M Button 6, 7
Measure, Unit of 55
Memory Mode, Entering the 45
Messages, Error 62
Messages, Special 38
Messages, Test Procedure 57
Meter, Cleaning 73
Meter Display 7

LifeScan, Inc.. Ex. 1020 - Page 95
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Meter, Doing a Daily Check of 73
Meter On/Off Button 7
Meter Options, Setting 47
– Beep Prompts 52
– Date Format 54
– Decimal Separator 55
– Language 53
– Time and Date 49
– Time Format 54
– Unit of Measure 55
Meter Specifications 82
ONE TOUCH® BASIC® Blood Glucose Meter 6
ONE TOUCH® BASIC® Diabetes Monitoring System 4
ONE TOUCH® Normal Control Solution 10
ONE TOUCH® Test Strips 8
– Code 11
– Expiration 9
Options, Setting Meter 47
Penlet® *Plus* Adjustable Blood Sampler 26
Penlet® *Plus* Adjustable Blood Sampler, Using the 27
Precautions and Limitations 2
Problems, Solving 57
Set-Up Mode, Entering and Using 47
Set-Up Mode, Exiting 56
System, Checking the 13
Test Area 7
Test Procedure, Abbreviated 25
Test Procedure, Detailed 26
Test Results, Recalling 46
Test Strip Holder 7
Test Strip Information, Important 9
Test Strips, ONE TOUCH® 8
Time, Setting the 50
Warranty, Three-Year 83

LifeScan, Inc.. Ex. 1020 - Page 96
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

INSIDE BACK COVER

El folleto para el propietario del ONE TOUCH® BASIC® se encuentra disponible en español. Para recibir su copia gratuita, favor de llamar al número gratis 1 800 381-7226.

The ONE TOUCH® BASIC® instructional materials are available in Spanish. To receive your free copy, please call toll-free 1 800 381-7226.

LifeScan Customer Services toll-free numbers:

U.S.A. English 1 800 227-8862
Español 1 800 381-7226
www.LifeScan.com

AW *05061302A*

Protected under U.S. Patents No. 4,935,346; 5,049,487; 5,059,394; 5,304,468
Perlet® *Plus* Adjustable Blood Sampler patent pending
© LifeScan, Inc. 1999 Milpitas, CA 95035 6/99 AW 050-613-02A

LIFESCAN
a Johnson & Johnson company

FreeStyle FREEDOM™

Blood Glucose Monitoring System

Sistema de monitoreo de glucosa en sangre

Virtually Pain-Free Testing

Pruebas prácticamente Sin Dolor



Owner's Booklet

Manual del propietario

Abbott

LifeScan, Inc.. Ex. 1020 - Page 99
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Table of Contents

Important Information About Your
FreeStyle Freedom™ Blood Glucose Monitoring System 3
Important Health Related Information 4-5

The FreeStyle Freedom Meter and FreeStyle® Test Strip
The FreeStyle Freedom Meter and How It Works 6-7
The FreeStyle Freedom Meter Display 8-9
The FreeStyle Test Strip 10

The FreeStyle Control Solution
The FreeStyle Control Solution 11-12
Performing a Control Solution Test 13-14

The FreeStyle Lancing Device
Using the Lancing Device 15-16

Testing Your Blood Glucose
Testing Your Blood Glucose 17
Performing a Blood Glucose Test 18-23
LO and HI Readings 24

Meter Set-Up
Setting Up Your Meter 25
Setting the Alarms 25-26
Setting the Sound, Time, Time Format 27
Setting the Date, Date Format 28
Unit of Measurement, Software Version Display 29

Meter Results
Meter Memory, 14 Day Average 30
Test Results (Blood Glucose, Control Solution), Transferring Data 30-31

Meter Maintenance
Battery 32
Replacing the Battery 32-33
Caring for Your Meter 33

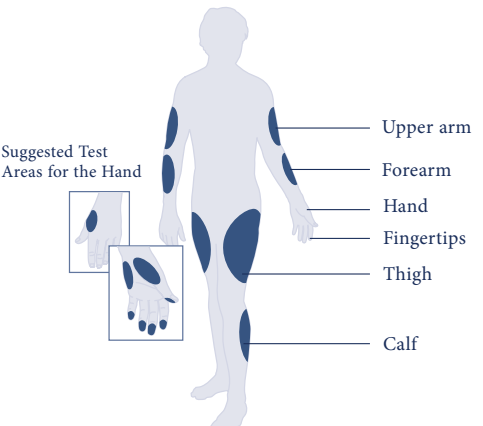
System Troubleshooting
Error Messages 34-37
Troubleshooting 38
FreeStyle Freedom System Specifications 39

LifeScan, Inc.. Ex. 1020 - Page 100
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

ENGLISH

The FreeStyle Freedom™ 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 all the FreeStyle Blood Glucose Monitoring Systems. Avoid moles, veins, bones and tendons.

WARNING:
We recommend that you test on your fingers or palm (at the base of the thumb) if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

LifeScan, Inc.. Ex. 1020 - Page 101
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Important Information About Your FreeStyle Freedom™ Blood Glucose Monitoring System

How the FreeStyle System Should Be Used

- The FreeStyle Freedom System is intended for use outside the body (in other words, *in vitro* diagnostic use only).
- The FreeStyle Freedom 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 Meter should only be used with FreeStyle® Test Strips and FreeStyle Control Solution. Using other brands of test strips and control solutions with the FreeStyle Meter can produce inaccurate results.

Do use the FreeStyle Freedom Meter for:

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

Do not use the FreeStyle Freedom Meter for:

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

WARNING:

- Patients receiving peritoneal dialysis solutions containing icodextrin should not use the FreeStyle Blood Glucose Monitoring System.
- The FreeStyle Freedom 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 System. Blood glucose monitoring should be done with the guidance of a healthcare professional.

LifeScan, Inc.. Ex. 1020 - Page 102
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

ENGLISH

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.
- The injection of solutions containing Galactose ≥13mg/dL or Maltose ≥20mg/dL (present in some human immunoglobulin preparations) will cause overestimation of blood glucose results.
- 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 Owner's Booklet,* call your healthcare professional.

LifeScan, Inc.. Ex. 1020 - Page 103
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Important Health-Related Information

- Changes in blood glucose may be observed in finger or palm (at the base of the thumb) blood samples sooner than blood samples from the forearm and other alternative sites. Vigorous rubbing of the alternative test sites before lancing will help to minimize the difference between finger or palm (at the base of the thumb) and alternative site test results. The palm (at the base of the thumb) is an alternative site that does not require vigorous rubbing before testing.
- Physiologic differences in the circulation between the finger or palm (at the base of the thumb) and other test sites like the forearm, upper arm, top of hand, thigh, and calf may result in differences in blood glucose measurements from these test sites and your finger or palm (at the base of the thumb). Differences in blood glucose measurement between the other test sites and your finger or palm (at the base of the thumb) may be observed after eating, insulin medication, or exercise.

WARNING:
We recommend that you test on your fingers or palm (at the base of the thumb) if you are testing for hypoglycemia (low blood glucose) or if you suffer from hypoglycemia unawareness.

LifeScan, Inc.. Ex. 1020 - Page 104
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

ENGLISH

The FreeStyle Freedom™ Meter and How It Works

Data Port

Download test results for diabetes data management. Refer to "Transferring Data" section for more information.

Display Screen

Displays your test results and other important information.

m (Mode) Button

- Move to different mode settings.
- Changes the test strip code (scrolls backward).
- Silences an alarm.

Sample Areas (dark-colored half-circles on Test Strip Edge)

Apply blood or control solution to one Test Strip Edge only. Insert printed side up (with the dark-colored rectangle going into the meter).

LifeScan, Inc.. Ex. 1020 - Page 105
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

System Check Screen



This screen always appears when meter is first powered 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.

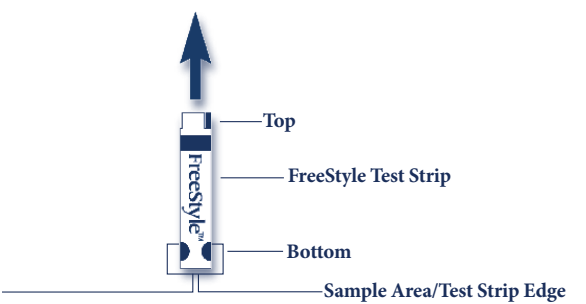


c (Configure) Button

- Marks a control solution test.
- Changes the test strip code (scrolls forward), date, time, alarm settings, sound options, and reviews stored readings.

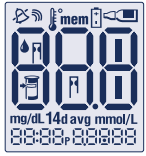
Test Strip Port

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



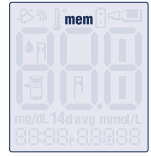
LifeScan, Inc.. Ex. 1020 - Page 106
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

The FreeStyle Freedom™ Meter Display



System Check Screen

This screen always appears when meter is first powered on so that you can make sure the display is working properly. All display elements should appear.



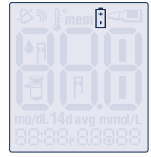
Memory Symbol

Shows you test results stored in the meter memory. The meter stores your last 250 blood glucose test results.



Sound Level Symbols

Indicates high, low, or off sound volume.



Battery Symbol

Appears when you should replace the battery.



Thermometer Symbol

Appears if your meter is out of temperature range.



Control Solution Test Symbol

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

LifeScan, Inc.. Ex. 1020 - Page 107
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

The FreeStyle Freedom™ Meter Display



Test Result Area
Test results appear here.



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.



14-Day Average Symbol
Shows the average value of glucose readings from the last 14 days.



Test Strip Code Symbol
Appears when you should check and set the test strip code.



Message Area
Displays date, time, number of tests, and software version.

ENGLISH

LifeScan, Inc.. Ex. 1020 - Page 108
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

ENGLISH

The FreeStyle® Test Strip

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

Important: *Use only one Test Strip Edge per test. Do not apply blood to both edges. 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 Test Strip Edge.*



Test Strip Edge

WARNING:
The vial cap is a choking hazard. The cap or vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Important Test Strip Information

- The FreeStyle Freedom™ System has an operating range of 40º to 104º F (4º to 40º C).
- Store the test strip package in a cool, dry place between 37º to 86º F (3º to 30º 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 Test Strip from the vial, immediately replace the vial cap and close tightly.
- With clean, dry hands, you may gently 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 Test Strips in any way.

Note: For further information, refer to the FreeStyle Test Strip package insert.

LifeScan, Inc.. Ex. 1020 - Page 109
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

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.

LifeScan, Inc.. Ex. 1020 - Page 110
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Ensuring Accurate Control Solution Results

- Use only FreeStyle® Control Solution with your FreeStyle Freedom™ System.
- Replace the cap on the control solution bottle immediately after using.
- Do not use control solution past the expiration date, this may cause inaccurate results.
- Do not add water or any liquid to control solution.
- Control solution tests are specified to be accurate only when performed between 59º to 104º F (15º to 40º C).
- The 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 test results only. It is not a target range for your blood glucose level or blood glucose test results.*

- If control solution results are out of this range, ***repeat the test***.
- If your control solution test results continue to fall out of range, do not use the FreeStyle Freedom System to test your blood glucose. Contact Customer Care at 1-888-522-5226.

Caution: Results from FreeStyle Control Solution tests do not reflect your blood glucose level.

LifeScan, Inc.. Ex. 1020 - Page 111
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Performing a Control Solution Test

1 

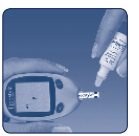
Insert the top of the test strip into your meter until it stops. This will power on the meter.

2 

The code number on the display must match the code number on the side of your test strip vial. (Refer to "Setting the Test Strip Code")

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

Note: Be ready to adjust the code on the meter to match the code number on the test strip vial.

3 

Gently touch only the ***Sample Area*** of the Test Strip Edge to the control solution.

Important: *Do not apply control solution to both Test Strip Edges.*

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

LifeScan, Inc.. Ex. 1020 - Page 112
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

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 test result, press and hold the "**c**" button for two seconds until the control solution symbol ( ) appears at the top of the display screen.

If you have marked a result 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. Your control solution test results should fall within this range. The range shown in picture is only an example.

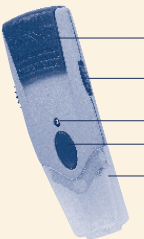
Out of range test results may be caused by:

- Expired or bad control solution
- Expired or bad test strip
- Error in performing test
- Watered-down control solution
- Code on test strip vial does not match code set in meter
- Meter malfunction
- Control solution test done outside 59º to 104º F (15º to 40º C)

To power off the meter, remove the test strip.

LifeScan, Inc.. Ex. 1020 - Page 113
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

The FreeStyle® Lancing Device





Dark Cap
(for finger testing)

Using the Lancing Device

1



Remove Cap

Snap off the cap on the lancing device at an angle.

2



Insert Lancet

Insert a new FreeStyle® Lancet firmly into the white lancet holder cup. (Pushing the lancet into the cup may cock the device; this is okay.)

3

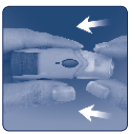


Twist Off the Rounded Top

Hold the lancet firmly in place with one hand; use your other hand to twist off the rounded top.

LifeScan, Inc.. Ex. 1020 - Page 114
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

4



Replace Cap

Replace the cap until it snaps or clicks into place. Be careful not to touch the exposed needle on the lancet.

Important: *Use the clear cap on the lancing device for the following test sites: forearm, upper arm, hand, thigh, and calf.*

Use the dark cap for finger tests.

5



Set the Lancing Level

The FreeStyle® Lancing Device offers four different settings. Move the dial to the desired setting as shown in the depth indicator window. For most test sites, we recommend that you start at Level 2.

Level 1 is the shallowest depth; Level 4 is the deepest.

To lance your finger, we recommend that you start at Level 1.

6



Cock the Handle

Pull the dark Cocking Handle out until it clicks. (You may have already cocked the handle in step 2; this is okay.)

You are now ready to perform a blood glucose test.

LifeScan, Inc.. Ex. 1020 - Page 115
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

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™ Meter, you can test your blood glucose on your forearm, fingers, upper arm, hand, thigh, or calf.
- Testing with the FreeStyle Freedom Meter requires a very small sample size, just 0.3 microliter of blood; about the size of a pinhead (**example:** •).
- Most healthcare professionals recommend testing when blood glucose values are stable: before meals and before bedtime. However, when blood glucose is changing, blood from the fingertips or palm (at the base of the thumb) may show these changes sooner than blood from other sites.

WARNING:
We recommend that you test on your fingers or palm (at the base of the thumb) 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.

LifeScan, Inc.. Ex. 1020 - Page 116
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Performing a Blood Glucose Test

1



Prepare Your Meter

Insert a new 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 power off. To restart your meter, take out the unused test strip and reinsert it into the meter.



System Check

Setting the Test Strip Code

When the meter powers on, four display screens appear.



Date and Time

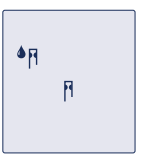
LifeScan, Inc.. Ex. 1020 - Page 117
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



Code Number

Setting the Test Strip Code *(cont)*

- When you see the word "COdE" and a code number on the display screen, use the "**c**" (configure) button to scroll forward or the "**m**" (mode) button to scroll backward until the number matches the number on your test strip vial. The FreeStyle Freedom™ Meter has a total of 50 codes.



Blood Drop and Test Strip Symbols

- After you set your code number, the Blood Drop and Test Strip symbols will appear on the display screen.
- If you want to return to the code number display screen after the Blood Drop and Test Strip symbols appear, press the "**c**" button.

Note: To ensure accurate test results, make sure the code number on your meter always matches the number in the box outlined in blue, located on the side of the test strip vial.

Caution: Take care to not press the "**c**" or "**m**" buttons when you are holding the meter while performing the blood test. If you do, you might change the code and get an incorrect reading or an Error 6.

LifeScan, Inc.. Ex. 1020 - Page 118
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

2





Lancing Your Forearm, Upper Arm, Hand, Thigh, or Calf

To bring fresh blood to the surface of the test site, rub the test site vigorously for a few seconds until you feel it getting warm. Lance the test site with the lancing device:

a. Hold the clear cap down against the top of your test site. Press the release button. **Do not lift up**.

b. Continue to hold the lancing device and **gradually** increase pressure for several seconds.

c. While holding the lancing device on your test site, look through the clear cap; the blood sample should be about the size of a pinhead (**example:** •).

d. Lift the lancing device straight up; be careful not to smear the blood sample on your test site.

Important:

- *Avoid lancing areas with obvious veins or moles to avoid excess bleeding.*
- *Avoid lancing areas where tendons or bones stick out (for example, hand bones and wrist bones).*

Lancing Your Palm

When lancing on the palm (at the base of the thumb) use the clear cap as you would for any alternative site, but there is no need for vigorous rubbing.

- Physiologic differences in the circulation between the finger or palm (at the base of the thumb) and other test sites like the forearm, upper arm, top of hand, thigh, and calf may result in differences in blood glucose measurements from these test sites and your finger or palm (at the base of the thumb). Differences in blood glucose measurement between the other test sites and your finger or palm (at the base of the thumb) may be observed after eating, insulin medication, or exercise.

LifeScan, Inc.. Ex. 1020 - Page 119
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



Lancing Your Finger

a. Set the depth setting on the lancing device to its shallowest depth (1).

b. Lightly touch the lancing device (with the dark cap) against your fingertip.



c. Press the release button.

d. Gently squeeze your finger, if needed, until a blood drop the size of a pinhead forms (**example:** •).

3



Filling the Test Strip with Blood

a. Make sure that the test strip is in the meter and the meter is powered on and the Blood Drop and Test Strip Symbols are showing. (If the meter is powered off, take out the test strip and reinsert into the meter.) You are now ready to apply the blood sample.



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

Important: *Use only one Test Strip Edge 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.*



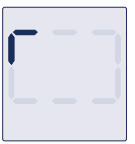
c. The test strip acts like a sponge and pulls the blood into the strip through the Test Strip Edge.

LifeScan, Inc.. Ex. 1020 - Page 120
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



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

4



Waiting for Result

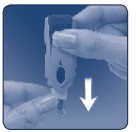
- Do not pull the test strip away until you see the short line moving clockwise on your meter screen and you may hear *one* beep (if your sound volume is on). This means you have enough blood and the meter is reading your glucose.
- If after five seconds your meter does not show a short line moving around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



- Your blood glucose test result is shown on the display screen. If the sound volume is on you will hear two beeps.
- 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.

LifeScan, Inc.. Ex. 1020 - Page 121
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

5



Removing the Lancet

When you have finished testing, snap off the cap from the lancing device.

Pinch the white clip that holds the lancet until the lancet falls out.

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.

Maintenance

Use isopropyl alcohol or soap and water to wipe the outside of the lancing device. If you wish, remove the cap, wash it in warm water and rinse well.

Important: *Do not immerse the body of the lancing device in water or any other liquid.*

LifeScan, Inc.. Ex. 1020 - Page 122
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

LO and HI Readings

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



LO Reading

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 recommendations to treat hypoglycemia.

LO Reading *without* Symptoms
IF you have a LO reading, but have no symptoms of low blood glucose, **THEN** retest with a new test strip on your fingers or palm (at the base of the thumb). If you still have a LO reading, follow your doctor's recommendation to treat hypoglycemia.



HI Reading

If your test result is higher than 500 mg/dL, HI will appear on the meter display screen. This reading indicates severe hyperglycemia (high blood glucose).

HI Reading *with* Symptoms
IF you have a HI reading and have 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 have a HI reading, but have no symptoms of high blood glucose, **THEN** retest with a new test strip. If you still have a HI reading, follow your doctor's recommendation to treat hyperglycemia.

LifeScan, Inc.. Ex. 1020 - Page 123
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Meter Set-Up



Setting Up Your Meter

- ***To Enter Setup Mode***
  Start with the meter off (and no test strip inserted). Press and firmly hold the "**m**" (mode) button until the set display screen appears. The first set screen is "Alarm Settings".
- ***To Exit at Any Time***
  Press and hold the "**m**" button until the meter powers off.
- ***To Move Through the Screens***
  Press the "**m**" button to move through all the setup screens such as sound level, time, date, and so on.
- ***To Change Settings Within the Screen***
  Press the "**c**" (configure) button.



Setting the Alarms

There are four alarms that you can set. When an alarm goes off, you hear the sound for up to 15 seconds. You can silence the alarm by pressing either the "**m**" or "**c**" buttons or by inserting a test strip. You may set up any or all of the alarms (1-4).



Select alarm

Note: An alarm will never sound during a test.

To set an alarm or multiple alarms follow these steps:

1. With the "0" blinking, press the "**c**" button to review the current alarm settings.

   To move to the first alarm press the "**c**" button once; "1" will blink. You are now ready to set alarm 1.

Note: Press the "**m**" button when "0" is blinking to move to the next set-up screen without setting any alarms.

LifeScan, Inc.. Ex. 1020 - Page 124
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



Select hour

2. Press the "**m**" button to move to the hour setting.
3. 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.
5. With the minute blinking, press the "**c**" button until the correct minute appears.



Select alarm volume

6. Press the "**m**" button to move to the alarm volume setting. Default setting is off.
7. Press the "**c**" button to select the desired volume setting: low, high, or off.
8. Press the "**m**" button to finalize your alarm setting. This will bring you back to the alarm setting SET mode.

   If you wish to set multiple alarms press "**c**" to move to alarm 2. Repeat steps 2-8 to set each of the 4 alarms.

Note: Press the "**m**" button when "0" is blinking to move to the next set-up screen without setting any alarms.

LifeScan, Inc.. Ex. 1020 - Page 125
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Setting the Sound



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



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."

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."

LifeScan, Inc.. Ex. 1020 - Page 126
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



Setting the Date

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 the year setting.
5. With the year blinking, press the "**c**" button until the correct year appears.
6. Press the "**m**" button to move to "Setting the Date Format."



Year-Month-Day

Setting the Date Format

1. With the date blinking, press the "**c**" button to select month-day or day-month format. The date automatically updates to the format selected.
2. Press the "**m**" button to move to the "Unit of Measurement."



Year-Day-Month

LifeScan, Inc.. Ex. 1020 - Page 127
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



Unit of Measurement

1. The Unit of Measurement for your FreeStyle Freedom™ Meter is milligrams per deciliter (mg/dL).
2. Press the "**m**" button to move to "Software Version Display."



Software Version Display

This is the software version programmed in your FreeStyle Freedom™ Meter. It is for display only, and cannot be changed. The picture here is an example. Your meter may have a different number.

You have completed Meter Set-Up.

- To move to "Setting the User Alarms" press the "**m**" button.
- To exit press and hold the "**m**" button.

LifeScan, Inc.. Ex. 1020 - Page 128
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

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 14-day average.
- ***To Exit at Any Time***
  Press the "**m**" button until the meter powers off.



14-Day Average

The first memory display screen you see is your 14-day average. This includes all the readings from the last 14 days starting from the current date and time shown on the meter. (Control solution, LO and HI readings are not included in the average.)

14d avg = your 14-day average
n = indicates the number of test results included in your 14-day average.

Test Results

The meter stores the last 250 test results with time and date. You may scroll through all of the test results by pressing and holding the "**c**" button. The first test result you see is the most recent.

As you continue to push the "**c**" button the meter will scroll back to older test results. Eventually it will scroll to the most recent test result.



Temperature: A test result with a thermometer symbol indicates that the reading was taken outside of the meter's specified operating temperature range and may be less accurate. This value is included in your 14-day average.

LifeScan, Inc.. Ex. 1020 - Page 129
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Test Results *(cont)*

LO Reading: A LO reading (under 20 mg/dL) is included in the memory; it is **not** included in your 14-day average. Values under 20 mg/dL are recorded in memory as LO.

HI Reading: A HI reading (over 500 mg/dL) is included in the memory; it is **not** included in your 14-day average. Values over 500 mg/dL are recorded in memory as HI.



Blood Glucose Test

A test 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 a control solution symbol (◁■) indicates that you have marked this reading as a control solution test.

This result is **not** included in your 14-day average. The date and time of the control solution reading will appear on the bottom of the screen.



Transferring Data

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 cable is removed from the data port. (Requires FreeStyle Data Cable and FreeStyle data management software or other software programs that accept FreeStyle Freedom data.)

LifeScan, Inc.. Ex. 1020 - Page 130
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Meter Maintenance

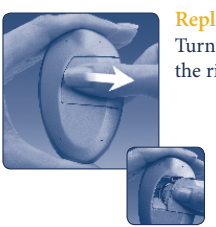
Battery

Your FreeStyle Freedom™ Meter comes with one #2032, 3 volt, lithium battery installed. The battery provides enough power to perform about 1,000 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 (1) minute*** of removing the old battery.
- If you take more than one (1) minute to replace the battery, you must reset the time and date to get the correct 14-day average.
- If the time and date settings are not reset, test results will be stored in memory with a time of 12:00 a.m. (00:00) and a date of 00-00.
- Removing the battery does not affect the meter's memory log or previously-stored user settings (for example, the calibration code and date format).

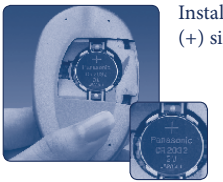
1



Replacing the Battery

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

LifeScan, Inc.. Ex. 1020 - Page 131
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

2 

Install the battery with the positive (+) sign facing up towards you.

3 

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

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 the immerse the meter in water or any other liquid.*

LifeScan, Inc.. Ex. 1020 - Page 132
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

System Troubleshooting

Error Messages



Error 1

Possible Causes

- Sample is too small.
- Problem with the 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 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 test strip.
3. If the retest using control solution does not work, or the error persists, call Customer Care.

LifeScan, Inc.. Ex. 1020 - Page 133
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



Error 2

Possible Causes

- Problem with the 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 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 test strip.
3. If the retest using control solution does not work, or the error persists, call Customer Care.

LifeScan, Inc.. Ex. 1020 - Page 134
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635



Error 3

Possible Causes

- Incorrect test procedure. For example, putting blood on the test strip before inserting the test strip into the meter, or blood applied before the Blood Drop and Test Strip Symbols display.
- Problem with the 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 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 test strip.
3. If the retest using control solution does not work, or if the error persists, call Customer Care.



Error 4

Possible Causes

- Problem with 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 test strip.
2. If the retest using control solution does not work, or if the error persists, call Customer Care.

LifeScan, Inc.. Ex. 1020 - Page 135
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Error 5

Note: Error 5 is not used.



Error 6

Possible Causes

A button on the meter was pushed when applying blood sample or control solution.

What You Should Do

1. Retest using a new test strip. Do not touch the "**m**" or the "**c**" button while applying blood or control solution to the test strip.
2. If the error persists, call Customer Care.

LifeScan, Inc.. Ex. 1020 - Page 136
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Troubleshooting

ISSUE: Meter does not power on 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.	Check that the battery is installed correctly with the positive (+) sign facing upward, toward you.
There is no battery in the meter.	Install battery.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the test strip with the printed side up and the top of the strip in the meter. Make sure the test strip is fully inserted.
Defective meter or test strips.	Call Customer Care.
Blood or foreign objects put into test strip port.	Call Customer Care.

ISSUE: Test does not start after applying the blood sample.	
Probable Cause	**What to Do**
Blood sample is too small.	You may add blood to the Test Strip Edge for up to 60 seconds from the time of the first application. If necessary, perform another test using a new test strip and a larger blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic shutoff (two minutes).	Repeat the test using a new test strip. Wait until you see the Blood Drop and Test Strip Symbols on the display screen before you apply the blood sample
Defective meter or test strips.	Call Customer Care.

LifeScan, Inc.. Ex. 1020 - Page 137
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

FreeStyle Freedom™ System Specifications

Assay Method	Coulometric electrochemical sensor
Automatic Shutoff	Two minutes after last user action
Battery Life	1,000 tests
Calibration	Plasma equivalent
Hematocrit	15% to 65%
Measurement Units	mg/dL (milligrams per deciliter)
Meter Storage Temp.	-4º to 140º F (-20º to 60º C)
Memory	250 blood glucose and control solution tests with date and time
Operating Relative Humidity	5% to 90% (non-condensing)
Operating Temperature	40º to 104º F (5º to 40º C)
Power Source	One #2032 battery, 3 volt lithium 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	1.43 oz. (including battery)

LifeScan, Inc.. Ex. 1020 - Page 138
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

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 está disponible las 24 horas del día, 7 días a la semana.

www.AbbottDiabetesCare.com

Call Customer Care
Toll Free at 1-888-522-5226

Llame al teléfono gratuito de atención
al cliente: 1-888-522-5226

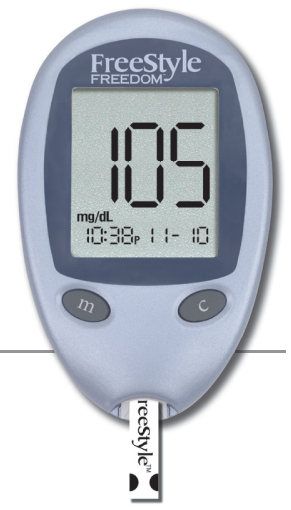
Covered by one or more of the following U.S. Patents:
Amparado por una o varias de las siguientes patentes estadounidenses:
D424,696; D426,638; 6,071,391; 6,120,676; 6,143,164; 6,299,757; 6,338,790; 6,071,391; 6,143,164; 6,299,757; 6,338,790; 6,461,496; 6,503,381; 6,591,125; 6,592,745; 6,616,819; 6,618,934; 6,676,816; 6,749,740; 6,893,545; 6,942,518; 6,156,051, 6,749,618
© 2005 Abbott Printed in U.S.A.

ART06690-Rev. B 11/05

LifeScan, Inc.. Ex. 1020 - Page 139
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Read Me First
Getting Started Guide

FreeStyle FREEDOM™ Blood Glucose Monitoring System

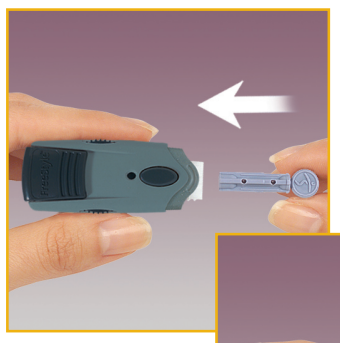


IMPORTANT: To ensure accurate results, clean your hands and the testing site (for example, your forearm) and dry thoroughly before testing.

1 Set-up the FreeStyle® Lancing Device



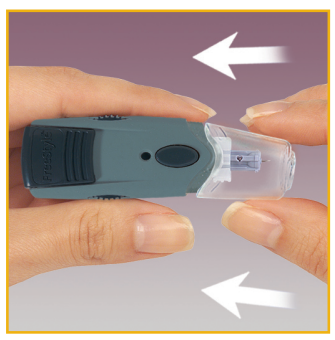
1 Snap off the cap on the lancing device at an angle.



2 Insert a new FreeStyle Lancet firmly into the white lancet-holder cup.



Hold lancet firmly in place with one hand; use your other hand to twist off the rounded top.



3 Replace the cap until it snaps or clicks into place. Be careful not to touch the exposed needle on the lancet.



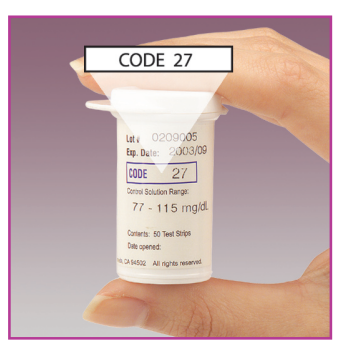


4 Look in the window of the lancing device and turn the settings dial to set the depth level.



5 Pull the dark Cocking Handle out until it clicks. You may have already cocked the device when you inserted the lancet. Set lancing device aside, proceed to the next step.

2 Prepare Your FreeStyle Freedom Meter



IMPORTANT: The code number on the display should match the code number on the side of your test strip vial. They must always match, or your results will be inaccurate.

Be ready to adjust the code on the meter to match the code number on the test strip vial. The picture on the left is only an example.



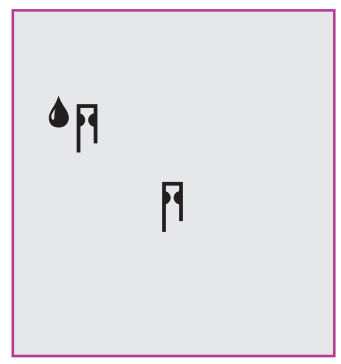
1 Insert a new test strip into the meter every time you test. The meter will turn on.



Insert only the **Top** end of test strip into the meter.



2 When you see the word "COdE" and a code number on the meter display, use the "**c**" button to scroll forward or the "**m**" button to scroll backward to the number that matches the number on your test strip vial. The picture to the left is an example. Your meter may have a different number.



3 **Wait** until you see the "blood drop and test strip" symbols appear on the meter display screen BEFORE lancing your test site. Set meter aside, proceed to the next step.

Continue on Other Side →

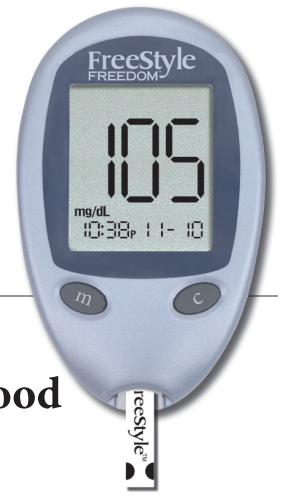
We're here to help. Please call Customer Care toll free at 1-888-522-5226 or visit us at www.AbbottDiabetesCare.com.

Abbott

LifeScan, Inc.. Ex. 1020 - Page 140
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

Read Me First
Getting Started Guide

FreeStyle FREEDOM™
Blood Glucose Monitoring System



IMPORTANT: Use the clear cap for testing on your forearm, upper arm, hand, thigh or calf.



3 Get the Blood Sample



1 To bring fresh blood to the surface of the test site, rub the site vigorously for a few seconds, until you feel it getting warm.



2 Hold the clear cap down against the top of your test site.

Depress the release button. **Do not lift up**.

Continue to hold the lancing device and ***gradually*** increase pressure for several seconds.



3 While holding the lancing device on your test site, look through the clear cap; the blood sample should be about the size of a pinhead (example: •).

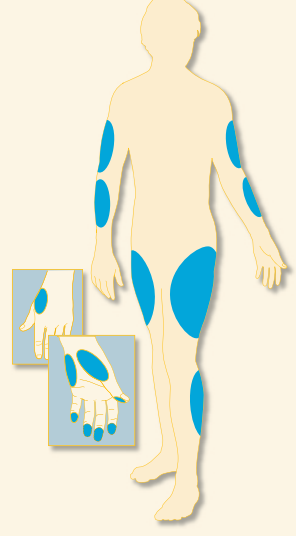
Lift the lancing device straight up; be careful not to smear the blood sample on your test site.

Important:
- *Avoid lancing areas with obvious veins or moles to avoid excess bleeding.*
- *Avoid lancing areas where tendons or bones stick out (for example, hand bones and ankle bones.)*

In clinical studies, most people said testing on their forearms was painless. (*Data on file: testing done on forearm.*)

Continue to Step 4

Most Test Sites Available



FreeStyle Freedom Testing Areas

The FreeStyle Freedom System can be used to test your blood glucose from your forearm, upper arm, thigh, calf, hand, as well as fingers (for more information see your Owner's Booklet).

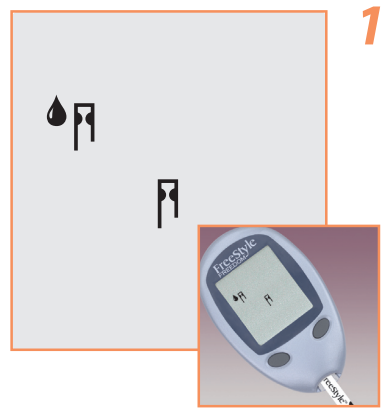
Warning: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers or palm (at the base of the thumb).

Testing on other sites is similar to testing on the forearm, which is demonstrated in this Getting Started Guide.

Refer to your Owner's Booklet for complete information about the FreeStyle Freedom Blood Glucose Monitoring System.

ART06705-Rev. A 05/05

4 Fill the Test Strip with Blood

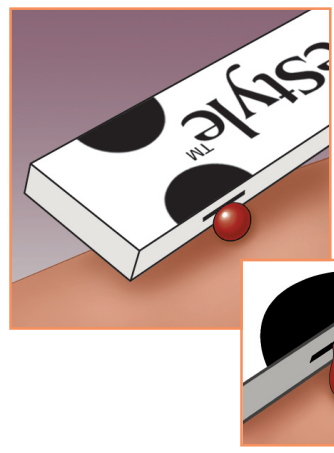


1 Make sure that the test strip is in the meter and the meter is powered ON. (If the meter is turned off, take out the test strip and reinsert into the meter.) Leave the test strip in the meter. You are now ready to apply the blood sample.



2 Bring the test strip to the blood sample at a slight angle.

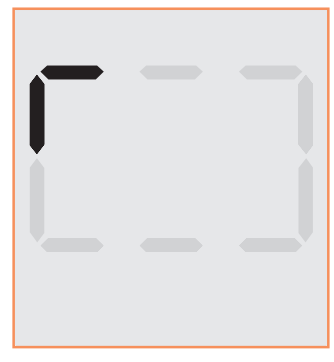
IMPORTANT: Use only one Test Strip Edge per test. Do not apply blood to both edges. Test strips may be used only once. Discard used test strips.



3 The test strip acts like a sponge and pulls the blood into the strip through the Test Strip Edge.

STOP

- **DO NOT** "press" the test strip against the test site.
- **DO NOT** scrape the blood onto the test strip.
- **DO NOT** apply blood to the flat side of the test strip.
- **DO NOT** apply blood to the test strip when the test strip is out of the meter.
- **DO NOT** put blood or foreign objects into the test strip port.



4 **DO NOT PULL THE TEST STRIP AWAY** until you see the short line moving clockwise on your meter screen and you may hear one beep (if your sound volume is on). This means you have enough blood and the meter is reading your glucose.



5 Your blood glucose test result is shown on the display screen. If the sound volume is on you will hear two beeps.

We're here to help. Please call Customer Care toll free at 1-888-522-5226 or visit us at www.AbbottDiabetesCare.com.

LifeScan, Inc.. Ex. 1020 - Page 141
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635