

ONE TOUCH[®] II

BLOOD GLUCOSE MONITORING SYSTEM
SYSTÈME DE CONTRÔLE DE LA GLYCÉMIE



a *Johnson & Johnson* company

une filiale de *Johnson & Johnson*

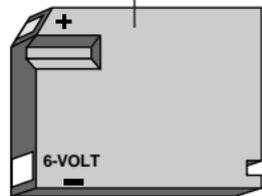
OWNER'S BOOKLET
MANUEL DU PROPRIÉTAIRE

ONE TOUCH[®] II

Blood Glucose Monitoring System

OWNER'S BOOKLET

"J" size Battery (installed)



Memory Button "M" Code Button "C"



Display

On/Off Button

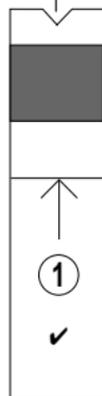
Data Port

Test Area



ONE TOUCH®
Normal Glucose
Control Solution
— Blue Formula

Check Strip



Test Strip

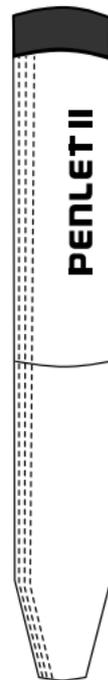


Test Spot

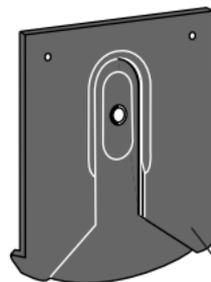
Lancet



PENLET® II with Cap



Test Strip Holder



Dear ONE TOUCH® II Owner:

Congratulations! You've selected a very sophisticated, yet easy-to-use, blood glucose monitoring system for home testing. Your ONE TOUCH II System will give you the accurate test results you need when you follow a few simple steps.

Everything you need to know about using the ONE TOUCH II System is included in this booklet.

If you would like a helpful/instructional audio cassette tape of the ONE TOUCH II test procedure, please call LifeScan Canada Customer Service at 1 800 663-5521.

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

Please make sure that you review this Owner's Booklet thoroughly before testing your blood glucose. If after reviewing the Owner's Booklet you still have questions, please feel free to call our toll-free number and speak with our Technical Service Department.

Thank you for choosing ONE TOUCH II.

Sincerely,

A handwritten signature in blue ink that reads "Jackie Graham". The signature is fluid and cursive, with the first letter of each name being capitalized and prominent.

Jackie Graham
Customer Service Manager
LifeScan Canada Ltd.

P.S. Don't forget to complete and mail the warranty registration card. When we receive your warranty card, we'll send you a handy carrying case to hold your Meter and testing supplies.

CAUTION: Before using any product to test your blood glucose (sugar), read all instructions and practice the test. Consult your diabetes healthcare professional for advice regarding selection of equipment, testing times, and procedures. These recommendations apply to all blood glucose monitoring systems and are supported by the Diabetes Educator section of the Canadian Diabetes Association.

The ONE TOUCH® II System is intended for *in vitro* diagnostic use only. (This legally required statement simply means that the Meter should be used only for testing purposes, and only outside the body.)

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1. TIPS FOR GETTING GOOD RESULTS

✔ **Carefully read this Owner's Booklet and all other instructional material** provided with your blood glucose monitoring system and test supplies.

✔ **Clean your Meter regularly** (at least once a week) by following the instructions in Chapter 8, *Cleaning and Maintaining the Meter*.

✔ **Use the Check Strip daily** to check the Meter, and use Control Solution periodically to test the system and your procedure. (See Chapter 3, *Checking the System*.)

✔ **Periodically review your use of the Meter** with your healthcare professional.

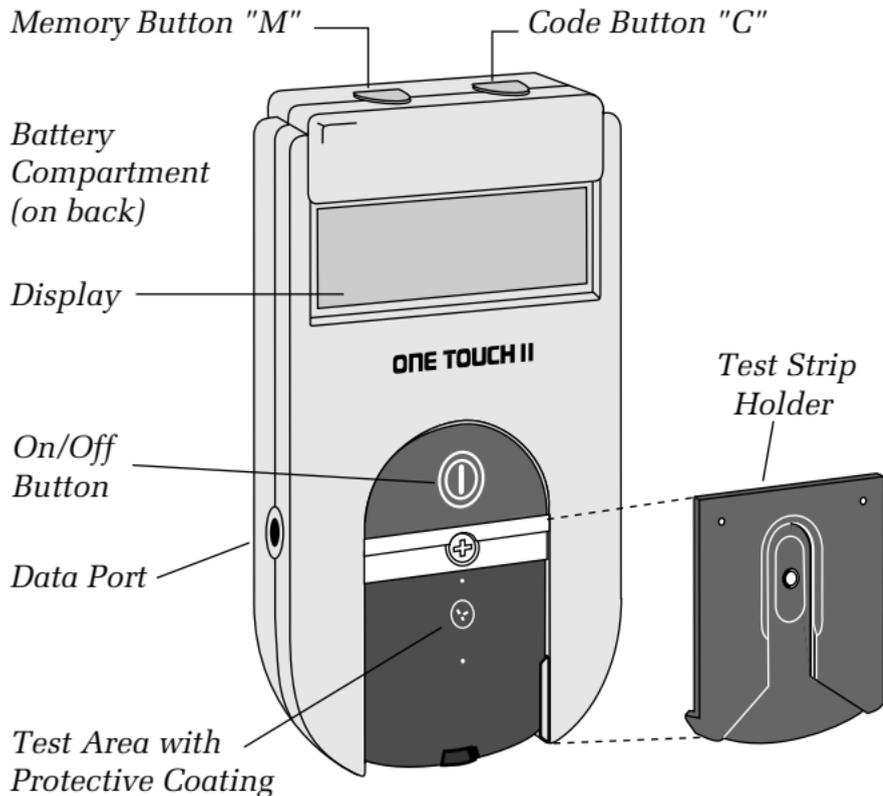
✔ **Never make any significant changes to your medication program without consulting your doctor or other healthcare professional.**

✔ **If the way you feel is not consistent with your blood glucose monitoring results, contact your physician or healthcare professional immediately.**

✔ **Do not store ONE TOUCH® Test Strips outside of the vial. Only foil-wrapped Test Strips can be stored in your carry case.**

2. GETTING STARTED

Before you read about the test procedure, please study this diagram to become familiar with the various parts of your ONE TOUCH® II Meter.



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

DISPLAY. This is where you read your test results and the simple messages that help guide you through the test procedure.

BATTERY COMPARTMENT. Holds one J-size battery. The battery is already installed in your Meter. (Replacement instructions are provided in Chapter 8, *Cleaning and Maintaining the Meter.*)

MEMORY BUTTON (M). The ONE TOUCH® II Meter automatically stores your test results. You push this button when you want to recall past test results. (See Chapter 10, *Recalling Tests from Meter Memory.*)

CODE BUTTON (C). Each package of Test Strips has a code number on the label. You will use the Code Button to set the Meter code to match the code number on the Test Strip package. (See Chapter 4, *Coding the Meter.*)

LANGUAGE CONVERSION. The ONE TOUCH II Meter can display messages in nineteen languages: English, Spanish, French, Italian, Dutch, Portuguese, Swedish, German, Danish, Finnish, Norwegian, Polish, Hungarian, Turkish, Czech, Greek, Russian, Japanese, and a Symbolic language. Your Meter is set at the factory in English. By using the Code Button and Memory Button, you can set the Meter in the language of your choice. (See Chapter 9, *Setting Date, Time, and Other Special Functions*, for instructions.) For further information regarding language displays, contact

the LifeScan Technical Service Department via the toll-free numbers listed below:

Canada 1 800 663-5521

U.S.A. 1 800 227-8862

MEASUREMENT

CONVERSION. The ONE TOUCH II Meter can display units either in mmol/L or mg/dL. To select the unit measurement of your choice, see Chapter 9, *Setting Date, Time, and Other Special Functions* for instructions. All example results in this Owner's

Booklet appear in mmol/L. Verify which unit of measure you are using **before** you begin testing.

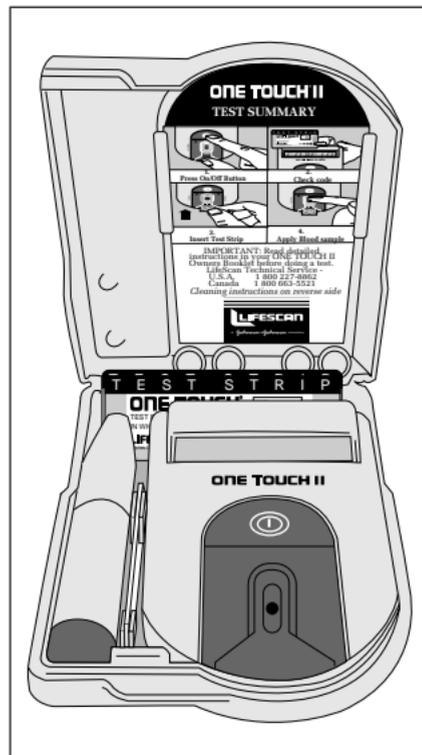
TEST STRIP HOLDER. The dark gray Test Strip Holder holds the Test Strip in place. The Meter reads the color of the reacted Test Strip through the small hole in the Test Strip Holder. The Test Strip Holder needs to be removed from the Meter for cleaning. (See the instructions in Chapter 8, *Cleaning and Maintaining the Meter.*)

TEST AREA. When the Test Strip Holder is removed, the Test Area is exposed. The Test Area has a clear, protective coating over the Meter optics that must be kept clean and lint-free for accurate results. Be careful not to scratch or damage this coating. (See Chapter 8, *Cleaning and Maintaining the Meter.*)

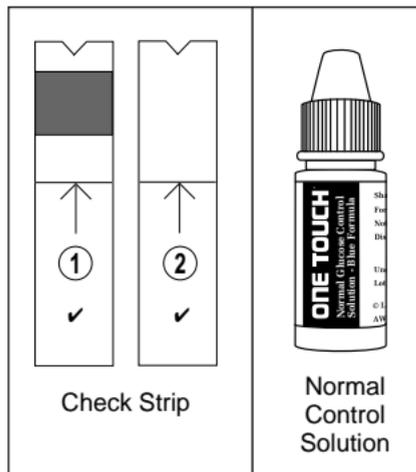
DATA PORT. This port lets you access the information stored in the Meter's memory with a Data Manager™ from LifeScan, or other data management

systems. (See Chapter 9, *Setting Date, Time, and Other Special Functions.*)

TEST STRIPS. ONE TOUCH® Test Strips come in a moisture-proof, light-protected vial or foil package. Because the Test Strips are sensitive to moisture and light, it's important to keep them sealed until you're ready to use them. **DO NOT** put unwrapped Test Strips in your Carry Case.



3. CHECKING THE SYSTEM



There are two ways to make sure your ONE TOUCH® II System is working properly.

The **Check Strip** is used to check that the *Meter* is operating properly. **ONE TOUCH® Normal Glucose Control Solution — Blue Formula** is used to check that both the *Meter* and the *Test Strips* are working *together as a system*, and that you are performing the test procedure correctly. These checks are simple but very important quality control steps that you must perform routinely to make sure you get accurate results.

CAUTION: If your **Control Solution** or **Check Strip** results fall outside of their expected ranges, the system is not functioning properly. **DO NOT** use the system to test your blood glucose until you get both a **Control Solution** and a **Check Strip** reading that falls within the expected ranges.

If either of these problems occur, you should first attempt to determine the cause of the problem by reviewing the instructions in this Owner's Booklet. If you cannot resolve the problem, contact the LifeScan Technical Service Department via the toll-free numbers listed below:

Canada 1 800 663-5521
U.S.A. 1 800 227-8862

IMPORTANT: The expected range* for the ONE TOUCH® Normal Glucose Control Solution — Blue Formula is printed on the Test Strip package.

* Note: The control range is shown in two different units of measure: mmol/L (used in Canada and European countries) and mg/dL (used widely in the U.S.). *This range is for the Glucose Control Solution only, it is not intended as a recommended range for your blood glucose test results.*

Checking your ONE TOUCH II System with Glucose Control Solution

ONE TOUCH Normal Glucose Control Solution — Blue Formula should be used *instead of blood* to practice the test procedure or to make sure your Meter and Test Strips are functioning properly. **Use only ONE TOUCH Normal Glucose Control Solution — Blue Formula.** Do not use ONE TOUCH Glucose Control Solution (clear formula) with the ONE TOUCH II Meter. You

can purchase **ONE TOUCH®
Normal Glucose Control
Solution — Blue Formula**
from your Authorized
LifeScan Distributor or
retail pharmacy.

To do a Control Solution
test, follow the same
procedure you would if you
were testing your blood, (as
described in Chapter 6,
Testing Your Blood), using
Control Solution instead of
blood. Your Control Solution
results will appear on the
Meter display as follows:

5.8
CONTROL
(example)

Before you use the Meter to
test your blood glucose,
practice using the Control
Solution until you can do
three tests in a row that are
within the expected glucose
control range. Then you
will know that you have
mastered the test procedure.

Thereafter, you should test
the Meter with the Control
Solution:

- ☑ At least once a week.
- ☑ When you begin using a
new package of Test Strips.
- ☑ Whenever you suspect
the Meter or Test Strips may
not be functioning properly;
e.g., whenever your results
are not consistent with how
you feel.

Checking the Meter with the Check Strip

A plastic (purple and white) Check Strip is included with your ONE TOUCH® II Meter. The Check Strip is used to check that your Meter is operating properly.

You must use the Check Strip:

- ✓ At least once a day.
- ✓ After cleaning the meter.
- ✓ Before adjusting your medication based on your Meter result.

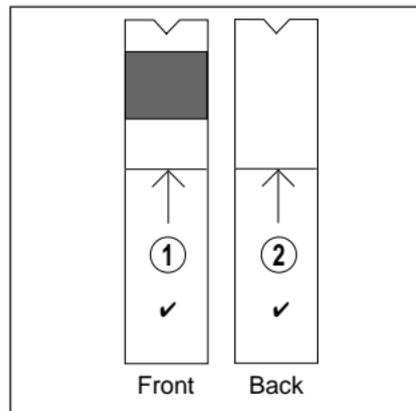
✓ Whenever your results are not consistent with how you feel or when you suspect that your results are not accurate.

✓ Whenever this message appears:

✓NOTOK
REDO ✓

Before doing a Check Strip test, make sure the Test Strip Holder and the Test Area are clean, dry, and lint-free. Check that the white and purple surfaces of the Check Strip are clean and

dry. For cleaning information, see *Cleaning and Maintaining the Check Strip* in this chapter. Do Check Strip tests at room temperature—between 18°C and 26°C (64°F–79°F).



How to use the Check Strip

Step 1:

Press On/Off Button.

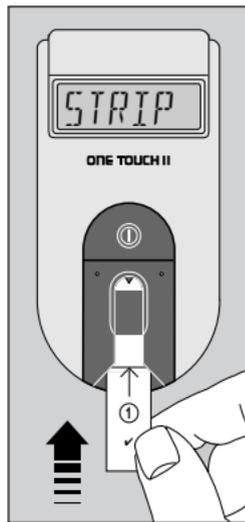
CODE 7
(example)

will appear on the display. (The code number does not need to be set to do a Check Strip test.)



INSERT
STRIP

appears. Slide the Check Strip into the Test Strip Holder with the notched end first, *Side 1* (purple) facing up.



WAIT

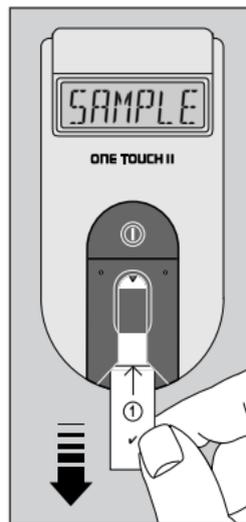
appears for a few moments.

Step 2:

When

APPLY
SAMPLE

appears, pull out the Check Strip from the Test Strip Holder.



Step 3:

When

INSERT
SIDE 2

appears, turn the Check Strip over and with Side 2 (white) facing up, insert it back into the Test Strip Holder, notched end first. The Meter counts down from 4 to 0, then



✓ 3.9
✓ OK
(example)

appears if the number falls within the acceptable Check Strip range. *The Meter automatically tells you if the reading falls within the correct Check Strip range. The range is also printed on the back of the Meter in both mmol/L and mg/dL.*

You may now proceed with a blood glucose test. These messages will continue to display until the Meter is

turned off, or for 2 minutes, when the Meter automatically turns off.

If the reading is not within the acceptable Check Strip range, the Meter display will read

✓ 2.1
✓ NOT OK
REDO ✓
(example)

Go back to Step 1 and repeat the Check Strip test. If this message appears again, clean your Meter by following the steps in

Chapter 8, *Cleaning and Maintaining the Meter*. For further assistance, call the LifeScan Technical Service Department toll-free.

Canada 1 800 663-5521

U.S.A. 1 800 227-8862

The next time you turn on your Meter

CODE 7
REDO ✓

(example)

will appear, indicating your Check Strip was out of

range at the last reading. This message will continue to appear each time the Meter is turned on until you perform a Check Strip reading that falls in the acceptable range.

CAUTION: Your blood glucose test result may be inaccurate if your Check Strip reading does not fall in the acceptable range.

Cleaning and Maintaining the Check Strip

- ✓ Check that the white and purple surfaces of the Check Strip are clean; if needed, wipe with a soft cloth or tissue dampened with water. Dry thoroughly.
- ✓ Do not put blood, alcohol, Control Solution, or any other fluid (except water) on your Check Strip.
- ✓ Avoid scratching the white and purple surfaces of the Check Strip.

☑ Do not expose the Check Strip to direct sunlight for extended periods of time.

☑ If you lose or damage the Check Strip, call the LifeScan Technical Service Department for a free replacement.

4. CODING THE METER

CAUTION: You must match the code number on the Meter display to the code number on the Test Strip package you're using. If the code number on the Meter display does not match the number on the Test Strip package, you will get an inaccurate result.

Set the code before using the Meter for the first time and every time you open a new package or change to a different package of Test Strips.

Step 1: Press On/Off Button

Push the On/Off Button to turn the Meter on.

CODE 7
(example)

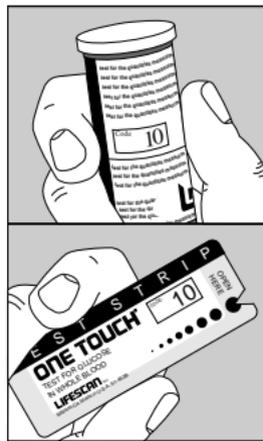


appears on the display for several seconds, then

INSERT
STRIP

The code numbers on Test Strip packages range between 1 and 16. If the number on the Meter

display is the same as the code number on your new Test Strip package, you may proceed with a blood test. (See Chapter 6, *Testing Your Blood*.) If it is **not** the same, go on to Step 2.



**Step 2:
Match the
code
number**

Press
the Code
Button (C).

CODE 7
(example)



will reappear on the display
for several seconds. With

CODE 7
(example)

on the display, press and
release the Code Button

again, and the number will
advance by one. Continue
pressing until the number
on the display matches the
code number on your Test
Strip package.

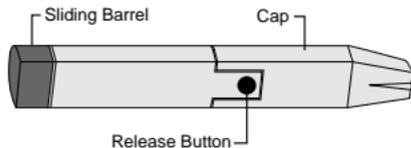
CODE 10
(example)

The Meter is now properly
coded, and you may
proceed with the test. From
now on, the Meter will
remember that code until
you change the code for a
new package of Test Strips.

5. GETTING A DROP OF BLOOD

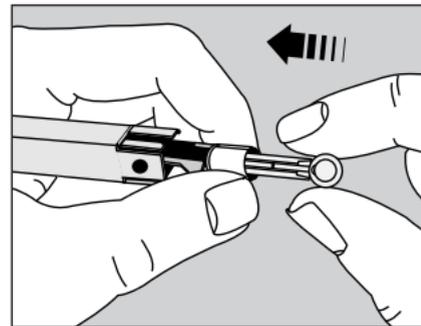
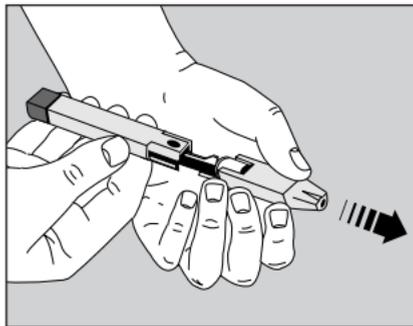
IMPORTANT: Getting a good drop of blood is one of the most important steps in getting an accurate blood glucose result.

The PENLET® II Automatic Blood Sampler is an easy, safe way to get a good drop of blood.



PENLET® II

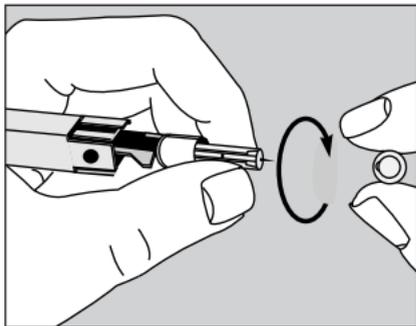
How to use the PENLET II:



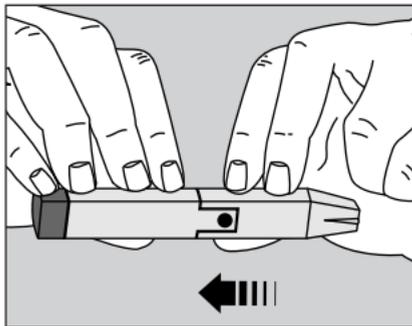
Step 1: Insert a Lancet

1. Remove the PENLET II cap by pulling it straight off.
2. Insert a sterile Lancet into the Lancet Holder. The Lancet will slide into the

Lancet Holder more easily if you **DO NOT** line up the ridges on the Lancet with the slots in the Lancet Holder. (Note: inserting the Lancet may automatically cock the PENLET II.)

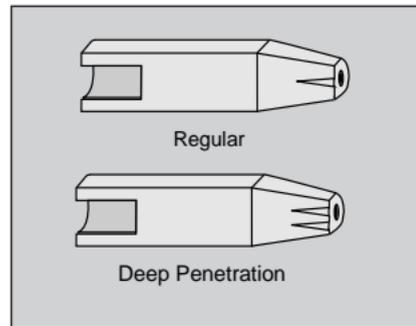


3. Remove the Lancet Protective Disk by holding the Lancet firmly and gently twisting off the Disk.

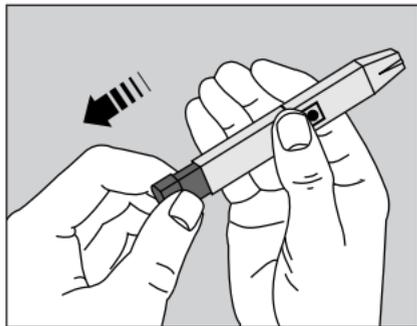


4. Replace the PENLET® II cap.

Note: The PENLET II includes two caps so that you may control the puncture depth. The cap which comes attached to the PENLET II has a single line

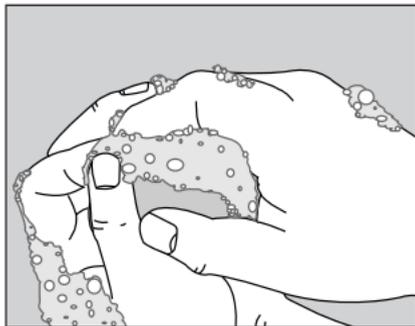


and works well for children and most adults. The other cap has a double line and works well for people with very thick or calloused skin, or where a deeper puncture is needed.



Step 2: Cock the PENLET® II

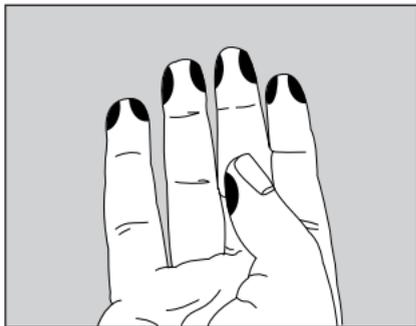
Holding the lower portion of the body of the PENLET II, pull out the dark gray sliding barrel until a click is heard. If you do not hear a click, the PENLET II may have been cocked when the Lancet was inserted.



Step 3: Get a drop of blood

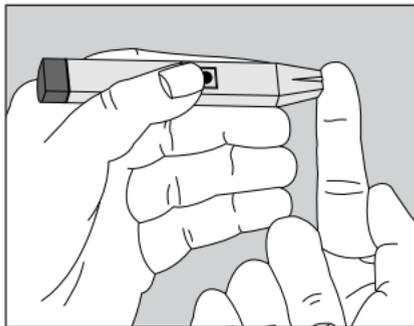
1. Wash your hands with soap and warm water and dry thoroughly. Warm water stimulates the flow of blood to the fingers, making it easier to obtain a sample for the test. Letting your arm hang down at your side for

10–15 seconds before the fingerstick will make it easier, too. If you use alcohol to clean your finger, make sure you let it dry before you lance your finger.



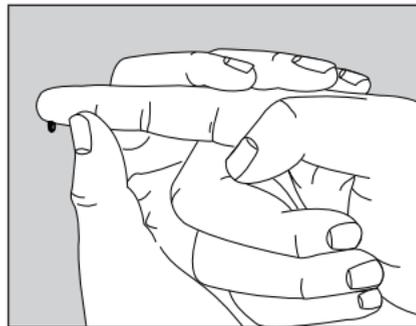
Choose a spot on the side of a different finger each time you take a blood sample.

Repeated punctures in the same spot can make your finger sore and calloused.



2. Hold the PENLET® II firmly on the side of the finger to be punctured, with the cap resting on the finger. (The greater the pressure of the PENLET II against the finger, the deeper the puncture.)

3. Push the dark gray Release Button.



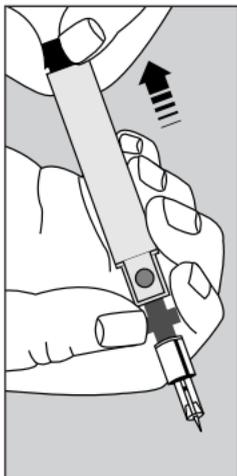
4. Gently squeeze the finger to obtain a large, hanging drop of blood.

Proceed with the blood glucose test. (Chapter 6, *Testing Your Blood*.)

Step 4: Remove the Lancet

*Always use
caution
when re-
moving the
Lancet.*

After the blood glucose test, remove the PENLET® II cap. Grip the dark gray T-shaped prongs. Point the Lancet downward and away from you. Pull back on the dark gray



sliding barrel until the Lancet drops out.

CAUTION:

- ☑ Dispose of the Lancet in an appropriate container for sharp objects.
- ☑ To reduce the chance of infection, always use a new sterile Lancet. Lancets are intended for single use only.
- ☑ **Never use a Lancet that has been used by someone else.**

☑ If the PENLET II is being shared with another person, **always** use a new sterile Lancet and a new or properly disinfected PENLET II cap for each person.

Cleaning the PENLET II

Clean the PENLET II and PENLET II cap with soap and water as needed.

(For use in hospitals or institutions with multiple patients, consult your institution's infection control procedure and the ONE TOUCH® II Hospital Manual.)

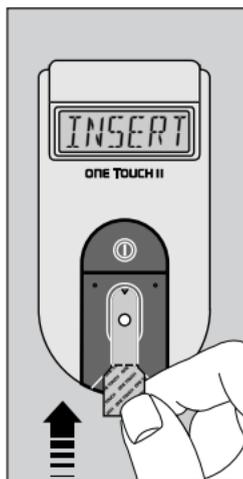
6. TESTING YOUR BLOOD

You can test your blood glucose by following these three simple steps:

Step 1: Press On/Off Button



Step 2: Insert Test Strip



Step 3: Apply blood sample



Be sure to read the following section carefully for detailed step-by-step instructions and important additional information.

Step-by-step instructions

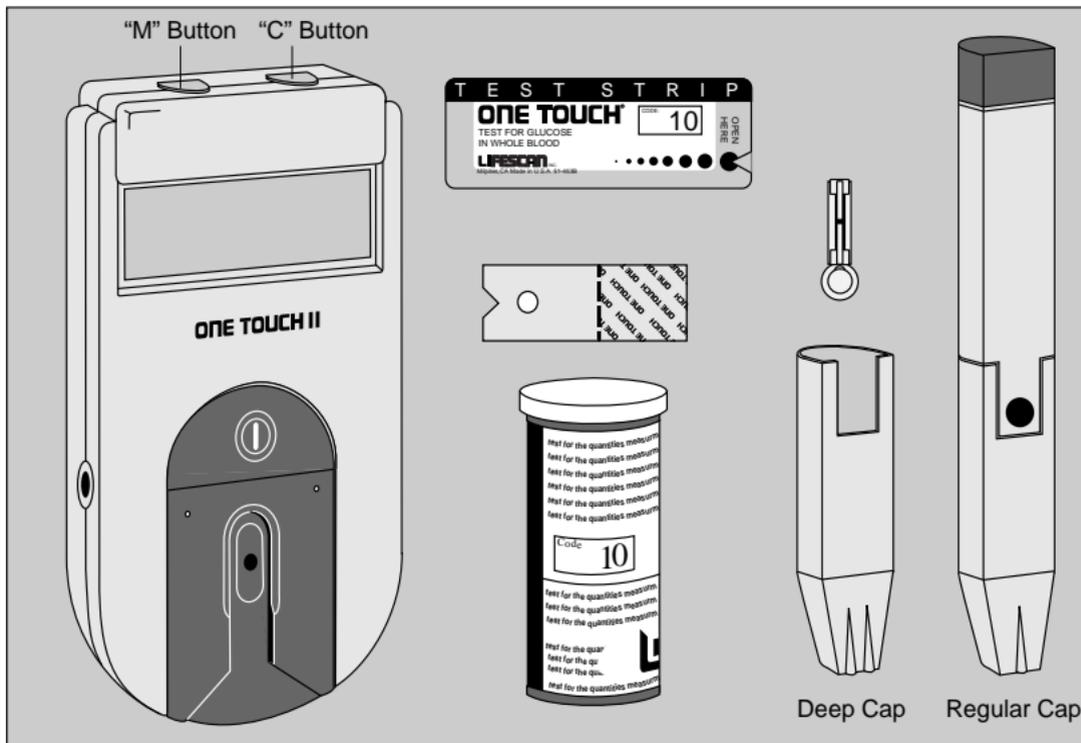
Choose a clean, dry work surface. Gather together all the materials you will need for a test:

ONE TOUCH® II Meter

ONE TOUCH® Test Strips

PENLET® II Automatic Blood Sampler (with choice of caps)

Sterile Lancet



IMPORTANT: Before testing, the Test Strip Holder and Test Area of the Meter must be clean and lint-free. (See Chapter 8, *Cleaning and Maintaining the Meter*, for more information.)

Check the expiration date on the Test Strip package. If the date has passed, discard the Test Strips and use a new package of Test Strips.

Step 1:

Press On/Off Button

CODE 10
(example)

appears on the display for several seconds, followed by



INSERT
STRIP

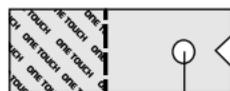
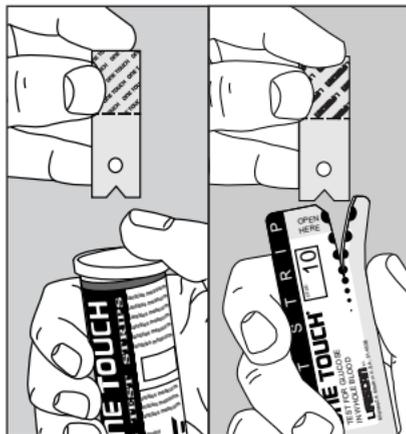
Make sure that the code number on the Meter display matches the code number on the Test Strip package. If they don't match, you will get an inaccurate result. Before doing a blood glucose test for the first time, or when you open a new package of Test Strips, you must match the code number on the Meter display to the number on the Test Strip package by following the instructions in Chapter 4, *Coding the Meter*.

Step 2:

Insert Test Strip

1. Remove a Test Strip from the package. Do not touch the white Test Spot (a small white circle in the center of the Strip). If using Strips from a vial, *replace the vial cap immediately*. If using foil-wrapped Test Strips, be careful not to tear the Strip when opening the foil.

The Test Spot should be white or ivory-colored, and free of tears or wrinkles. (Do not apply blood to the Test Spot yet.)



Test Spot

2. When

INSERT
STRIP

appears on the display, slide the Test Strip into the Holder, notched end first,

Test Spot side up. **Make sure you push the Test Strip all the way into the Holder until it stops.**



3. *WAIT*

will appear on the display for a few moments. Then,

4. *APPLY
SAMPLE*

appears on the display, and remains for five minutes or until you apply blood to the Test Spot on the Test Strip.

**Step 3:
Apply
blood
sample**

1. With the Test Strip in the Meter and

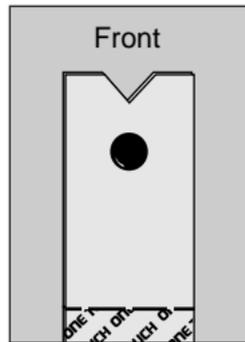


*APPLY
SAMPLE*

on the display, apply a drop of blood to the Test Spot. To learn how to obtain a drop of blood, see Chapter 5, *Getting a Drop of Blood*.

Make sure that you:

Apply enough blood to form a round, shiny drop which covers the Test Spot completely and stays wet during the entire test.



Do not move the Test Strip as you are applying blood. If the Test Strip moves during blood application, make sure that

it is pushed back to its original position as quickly as possible.

☑ **Do not smear the blood on the Test Spot or apply a second drop after the test has begun.**

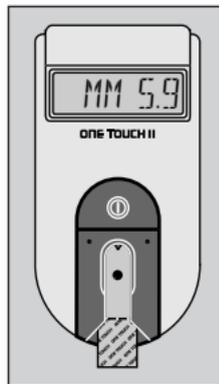
☑ **Do not remove the Test Strip from the Meter to apply blood.**

☑ **Touch only the tip of the drop of blood to the Test Strip.**

The Meter will beep when it detects that a sample of

blood has been applied to the Test Spot.

2. The Meter then counts down from 45 to 0 seconds, and you will hear a series of beeps when your result is displayed.



MM 5.9
(example)

Be sure to wait for the beeps before you note your result.

CAUTION: Always check that “MM” and a decimal point (or comma) are displayed with your blood glucose result. If not, you may have accidentally changed the unit of measurement to mg/dL, or an electronic malfunction may have occurred. (See Chapter 9, *Setting Date, Time, and Other Special Functions*, to reset the unit of measurement to mmol/L).

The Meter reads results which are between 0 and 33.3 mmol/L, indicated

with MM before the result (or 0–600 mg/dL, the unit of measure used in the United States). Results above 33.3 mmol/L (600 mg/dL) are displayed as *HIGH*.

To select an Event number now, follow the instructions in Chapter 10, *Recalling Tests from Meter Memory*.

3. Press the On/Off Button to turn Meter off.

Check the Amount of Blood on the Test Strip

Although the ONE TOUCH® II requires only a small drop

of blood, **it is very important that the drop be of adequate size and distributed completely over the Test Spot.**

In many cases, the ONE TOUCH II can detect if the drop of blood was too small, to give an accurate reading. If

*NOT
ENOUGH
BLOOD
RETEST*

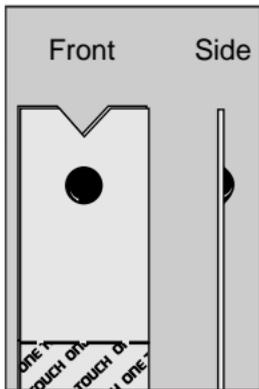
appears, it indicates that your drop of blood was too small, or it was smeared

rather than dropped onto the Test Spot. Repeat the test with a new Test Strip and a larger drop of blood.

Because the Meter cannot detect all incorrectly applied samples, it is also important to visually inspect the used Test Strip to make sure that you applied enough blood:

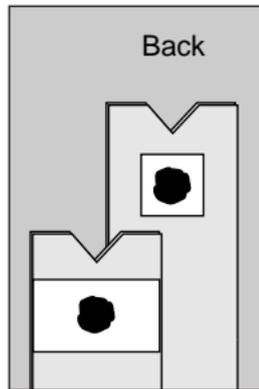
1. After the test, remove the Test Strip from the Meter.

2. Look at the Test Spot where you applied the blood sample. It should still have a wet, shiny



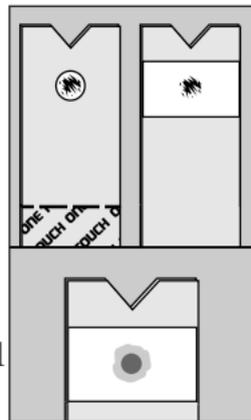
drop which completely fills the circle. If the blood sample has a dull, dry appearance, you may have smeared the sample or not applied enough blood.

3. Look at the back of the Strip; you should see a full, dark circle.



The white portion on the back of the Test Strip may also appear as a small square due to different manufacturing processes. This difference will not affect your blood glucose results.

If there are any white patches or streaks, you may have smeared the blood sample or not applied enough blood.



In either case, the drop of blood was too small and may give you an inaccurately low result. Repeat the test with a new Test Strip.

7. TROUBLESHOOTING

Special display messages during testing

If at any time during the test procedure the display reads *ERROR* or *NOT OK*, there is a problem which needs to be corrected:

NOT

Your blood or Control Solution sample was too small or smeared. **Repeat the test, using a larger, round and shiny drop.** (See Check the Amount of Blood on the Test Strip in Chapter 6, *Testing Your Blood*.)

ENOUGH

BLOOD

RETEST

CLEAN

The Test Strip Holder and Test Area need to be

cleaned. (See Chapter 8, *Cleaning and Maintaining the Meter*.)

NOTE: This message may **inadver-**

tently appear if your hand or any other object is placed above the Test Area immediately after the Meter is turned on. (A partially or fully inserted Test Strip can also cause this message to appear.) Do not insert a Test Strip until *INSERT STRIP* appears on the display.

TEST

AREA

ERROR1

The sample was applied before *APPLY SAMPLE* appeared on the display. (See Chapter 6, *Testing Your Blood*.)

RETEST

ERROR2

There has been an error in the test procedure. Some examples are:

RETEST

1. The Test Strip moved out of the correct position during the test and was not repositioned before the end of the test.
2. The Test Strip was not inserted correctly. **The Test Strip must be inserted notched end first, Test Spot side up, and pushed all the way into the Test Strip Holder.**

3. The Test Strip was removed before the test was completed.

4. You may not have applied enough blood. (See Check the Amount of Blood on the Test Strip in Chapter 6, *Testing Your Blood*, for more information.)

5. The Meter was turned on in very bright light. **Move out of direct light and repeat the test.**

6. The Check Strip procedure was incorrect. (See Chapter 3, *Checking the System*.)

7. The Meter may not be operating correctly.

Go Back to Step 1 in Chapter 6, *Testing Your Blood*, and start over with a new Test Strip. Make sure you are following the instructions carefully.

NOT OK

There may be an electronic problem with your Meter.

Call the LifeScan Technical Service Department.

Canada 1 800 663-5521
U.S.A. 1 800 227-8862

REMOVE

STRIP

The Test Strip was inserted before the Meter was ready for it. **Remove the Strip from the Test**

Strip Holder, wait for *INSERT STRIP* to appear, then insert the Test Strip again.

RESET

The Meter has lost some important information, including the current code number, mmol/L unit setting, date, time, and other special functions which you may have selected.

CODE

To reset the code number to match your test strips, see Chapter 4, *Coding the Meter*. To reset the unit of measurement to mmol/L, and other special functions, see Chapter 9, *Setting Date, Time, and Other Special Functions*. If the message *RESET CODE* appears again, contact LifeScan Technical Services.

The last Check Strip reading was outside the acceptable range of results. **The Check Strip test must be repeated.** (See Chapter 3, *Checking the System*.) **If the message continues, clean the Meter.** (See Chapter 8, *Cleaning and Maintaining the Meter*.)

For further assistance, call the LifeScan Technical Service Department for more information.

Usually indicates a test done with Control Solution. However, if this message appears after a blood test, it means that your blood sample was

(example)

too small, smeared, or a second drop was applied after the test began. *Your test result will not be accurate.* **Repeat the test using a larger drop of blood.** (See Check the Amount of Blood on the Test Strip in Chapter 6, *Testing Your Blood*.)

All segments on the display will appear when the On/Off Button is pressed and held. **If any part of the display does not appear, call the LifeScan Technical Service Department:**

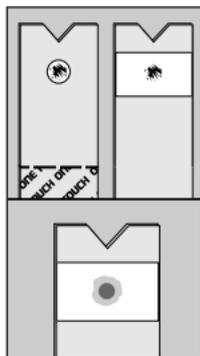
Canada 1 800 663-5521

U.S.A. 1 800 227-8862

What to do if you feel your test result may be wrong:

If you follow the instructions in this booklet, you will find that it is easy to get accurate results. If you suspect that you are not getting accurate results, you should do a Check Strip Test and a Control Solution Test to check the Meter operation, Test Strips, and your procedure. (See Chapter 3, *Checking the System*, for more information.) **If after performing these checks your results still are not consistent with how you feel, contact your physician or healthcare professional.**

There are a number of reasons why your test result may be wrong:



You may not have applied enough blood.

Look at the Test Spot where you applied the blood sample—it should still have a wet, shiny drop which completely fills the circle. If the blood sample has a dull, dry appearance, you may have

smear the sample or not applied enough blood—this could cause an inaccurately low result. (See Check the Amount of Blood on the Test Strip in Chapter 6, *Testing Your Blood*.)

The code number on the Meter display doesn't match the code on the Test Strip package. Reset the code

number displayed on the Meter by repeatedly pressing Code Button “C” or holding it down until the correct code appears in the display. (See Chapter 4, *Coding the Meter*, for more information.)

✔ **The Test Strips have expired.** Check the expiration date on the Test Strip package. If the expiration date has passed, discard the package and repeat the test with a Strip from a new package, being sure to reset the code number on the Meter.

✔ **The Test Strip vial was opened for the first time more than 4 months ago.** Discard Strips and open a new vial, or purchase individually foil-wrapped Test Strips.

✔ **The Test Strip Holder and Test Area are dirty.** (See Chapter 8, *Cleaning and Maintaining the Meter*.)

✔ **The test was performed outside of the acceptable operating conditions for testing.** The ONE TOUCH® II Meter may be used between 15°C and 35°C (59°F–95°F), with relative humidity under 90%.

✔ **The test result number is higher than 33.3 and the letters *MM* do not appear before the result.** This means you may have accidentally changed the unit of measurement or an electronic malfunction may have caused the Meter to reset to mg/dL. (See Chapter 9, *Setting Date, Time, and Other Special Functions*, to reset the unit of measurement to mmol/L.)

✓ You may have a special physical condition, such as extreme dehydration, which is affecting your results. (See Chapter 12, *Questions and Answers*, for more information.)

✓ The Test Strips were stored in an extremely high temperature (above 30°C or 86°F).

8. CLEANING AND MAINTAINING THE METER

IMPORTANT: Infection Control Information to reduce the risk of infection: If the ONE TOUCH® II Meter is being shared with another person, always use a new or properly disinfected Test Strip Holder for each person.

If the PENLET® II is being shared with another person, always use a new sterile lancet and a new or properly disinfected PENLET II cap for each person.

For disinfecting information, or an additional Test Strip Holder or PENLET II cap, please call the LifeScan Technical Service Department.

Canada 1 800 663-5521
U.S.A. 1 800 227-8862

Your ONE TOUCH® II Meter is simple to use and easy to maintain. However, like all precision instruments it must be handled carefully and cleaned frequently to remain in peak operating condition. You should observe these precautions at all times.

✔ **Keep the Test Strip Holder and Test Area clean.** Dirt, blood, or lint in these areas will cause inaccurate results. **Do not use alcohol to clean the Meter.** Clean the Meter regularly

according to the instructions on the following pages.

✔ **Carry the Meter in the Carry Case** at all times to protect it and keep it clean.

✔ **Do not drop the Meter or toss it casually onto a table.** The Meter's electronics could be damaged by such treatment. If you drop the Meter, make sure the Test Strip Holder is still securely in place and check the Meter with the Check Strip before doing a blood glucose test.

✔ **Avoid exposing the Meter or the Test Strips to extremes of temperature or humidity** for extended periods of time. For example, avoid leaving the Meter or Test Strips in your car for long periods.

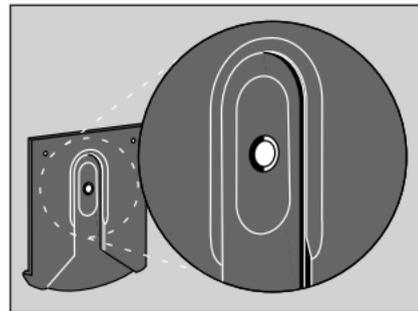
✔ **Never let your Meter get wet.** The Meter could be permanently damaged if water or other liquids get inside it.

✔ **Do not take the Meter apart.** Sensitive components could be damaged

and cause inaccurate results. If you take the Meter apart, your warranty will no longer be in effect.

How to do a daily check

1. Look through the small hole in Test Strip Holder to make sure there is no lint, dirt, or blood blocking any part of the hole.



2. 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 pages that follow.

3. Perform a Check Strip test by following the instructions in Chapter 3, *Checking the System*.

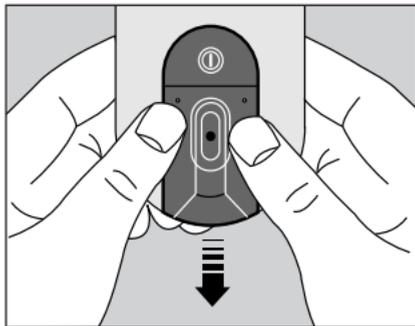
Cleaning the Meter

The Test Strip Holder must be removed for a complete cleaning:

- At least once a week,
- Whenever the Test Area looks dirty, and
- Whenever

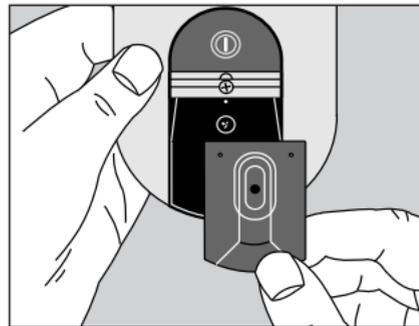
CLEAN
TEST
AREA

appears on the display.

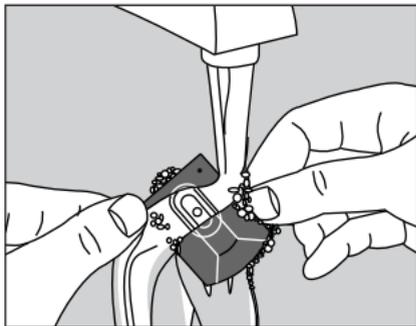


Step 1: Remove Test Strip Holder

1. As you hold the Meter, place your thumbs on the two raised dots on the Test Strip Holder.
2. Slide the Test Strip Holder toward you to remove.

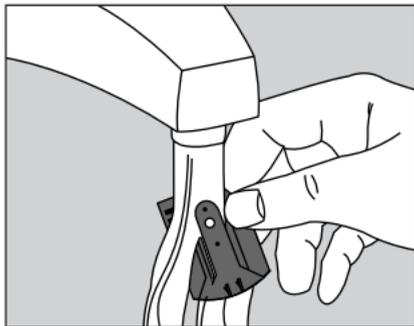


3. Remove the Test Strip Holder to expose the Test Area. You are now ready for cleaning.



Step 2: Clean Test Strip Holder

1. Wash the Test Strip Holder with soap and water.

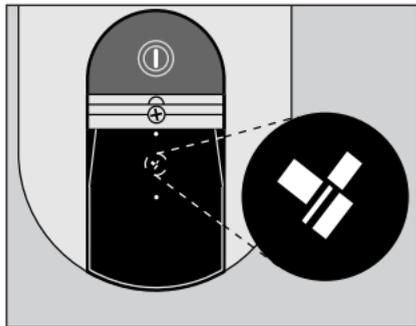


2. Clean the underside of the Test Strip Holder and check the small hole for any debris.

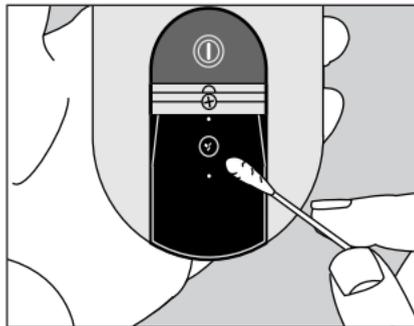
3. Dry completely with a soft cloth or tissue. Remove any lint.

Step 3: Clean Test Area

While the Test Strip Holder is still removed, clean the surface of the Test Area, normally covered by the Test Strip Holder. *This area may not look dirty to you, but it still needs to be cleaned.*



1. Check the clear protective coating over the Meter optics to make sure it is not scratched or damaged.



2. Use 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.)

The following cleaning agents will damage the Meter.

DO NOT USE:

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

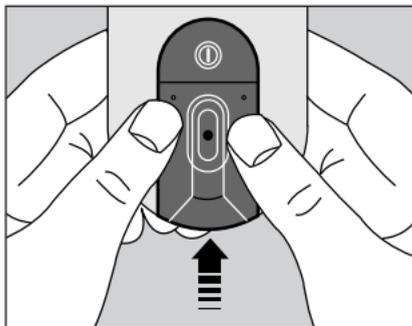
CAUTION: Be careful not to scratch this area, or get water inside the Meter.

3. Dry the Test Area with a soft, dry tissue or cloth. Remove any lint.



Step 4: Replace Test Strip Holder

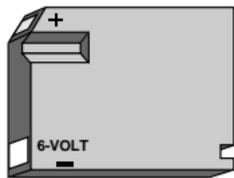
1. Hook the bottom of the Test Strip Holder onto the square notch on the Meter.



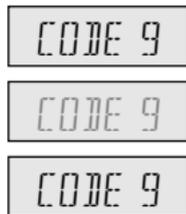
2. Place each thumb on the raised dots and push down on top of the Holder until it snaps firmly into place. You are now ready to do a Check Strip test. If the Check Strip will not slide into the Test Strip Holder, repeat this procedure.

Battery Replacement

The Meter comes with one J-size (6v) Duracell® brand alkaline battery already installed. The battery should last about one year with typical home use.



When the battery needs to be replaced, use only a Duracell® brand alkaline battery (J-size, 6 volts, part #7K67). This will ensure that you get the best performance from your ONE TOUCH® II Meter. Duracell® J-size batteries are available from most retail pharmacies and hardware stores.



When the battery is getting low, the display will flash on and off continuously while the Meter is on. The Meter will still provide accurate test results with a low battery, but you should replace it as soon as possible.

When

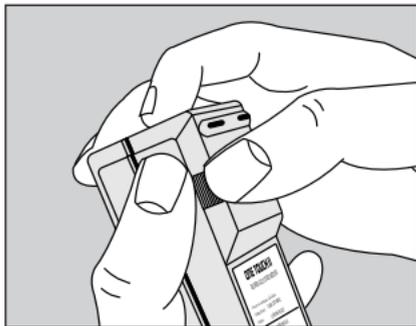
BATTERY

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

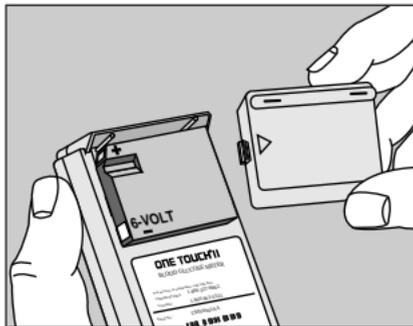
A dead battery or battery removal will not affect the information stored in the Meter's memory, as long as the battery is replaced within 30 days.

To replace the battery:

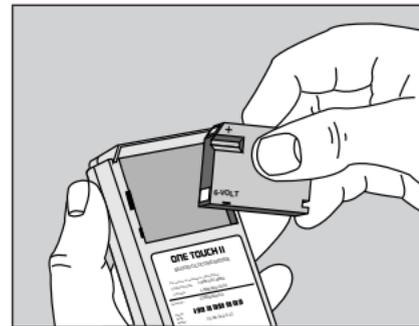
1. Make sure the Meter is turned off before you remove the battery.
2. Turn the Meter upside down.



3. With your thumb, firmly push the left side of the battery door to the right until it is released from the clasp, as indicated on the door.



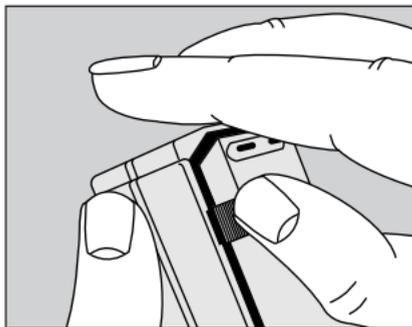
4. Completely remove the battery door.



5. Remove the old battery and discard properly. Insert a new J-size battery in the battery compartment as indicated.



6. To replace the battery door, insert the tab on the right side of the door into the slot in the battery compartment.



7. Swing the left side of the door over the battery, and insert the tab on the left side of the battery door into the slot, by applying pressure with your thumb until it snaps shut.

9. SETTING DATE, TIME, AND OTHER SPECIAL FUNCTIONS

Your ONE TOUCH® II Meter has special functions which enable you to customize the Meter to meet your own special needs. The Meter allows you to:

- Set the clock in your Meter so that your blood glucose results will be stored in memory along with the date and time they were taken.
- Turn the beeper on or off; the Meter is set at the factory with the beeper turned on.
- Select the language in which the display messages appear; English, Spanish, French, Italian, Dutch, Portuguese, Swedish, German, Danish, Finnish, Norwegian, Polish,

Hungarian, Turkish, Czech, Greek, Russian, Japanese, and a Symbolic language are available. The Meter is set at the factory in English.

- Select the unit of measure of blood glucose results; millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL). The Meter is set at the factory in mmol/L.
- Select the date format: Month-Day-Year or Day-Month-Year. The Meter is set at the factory for Month-Day-Year.

- Select AM/PM or 24:00 time. The Meter is set at the factory in AM/PM time.
- Select the type of data management system that the Meter will communicate with (described on the following pages). The Meter is set at the factory to communicate in the RS-232 Data Management Mode.

Around the clock

The Meter has an internal clock that will record the date and time with each test you perform. **You must set the clock to have the correct date and time appear with each test result that you recall from the Meter memory.** However, your test results will not be affected if you don't set the clock.

You will need to reset the date and time whenever there is a change to or from Daylight Savings Time. **The date and time of test results stored in the memory before you set the clock, will not change if you reset the date and time.**

You may also want to customize some of the other features mentioned above, based on your own needs. The following pages describe how to set the date and time, as well as other custom features.

To enter the date and time mode:

1. With the Meter turned off, *press and hold* Code Button “C” at the top of the Meter.



2. Press and release On/Off Button to turn the Meter on.

3. Release “C” Button. The year should be flashing. Continue with chart instructions on page 54.

Using the “**M**” and “**C**” Buttons on the top of your Meter, follow the instructions in the chart to set the clock in your Meter.

How the Chart Works



The “**C**” Button changes settings. For example, press “**C**” to change the year from 6.11.**93** to 6.11.**94**.



The “**M**” Button holds your setting selection and advances you to the next mode. For example, when the year (6.11.**94**) is selected, press “**M**” to hold and advance to the month selection (**6**.11.94).

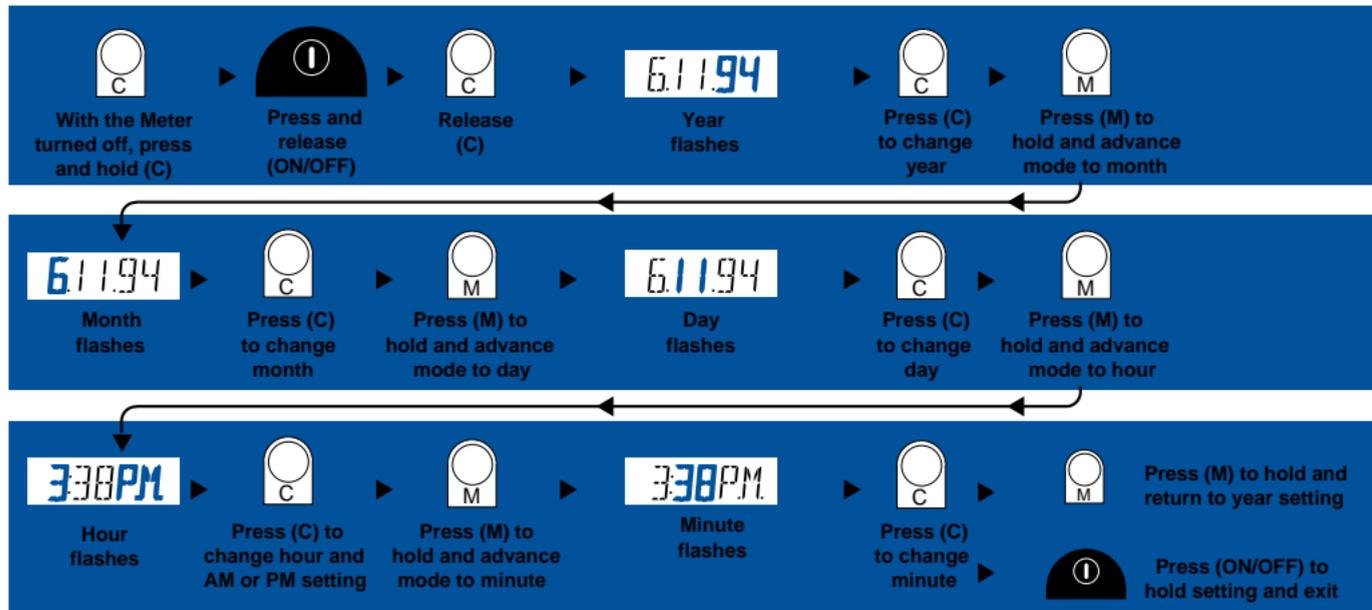
Press either button once to advance one step; press and hold to continue advancing or to go back to the beginning.



At any time you may press the On/Off Button to hold your selection and exit.

Note: When the date and time are changed, the average blood glucose value may also change. (See Chapter 10, *Recalling Tests from Meter Memory*.) The average is calculated from the 14 days preceding the current clock setting.

Setting Date and Time



There are several special features you may choose to personalize your ONE TOUCH® II Meter.

The following section will tell you how to set the beep feature, the international options (including language, unit of measure, and date format), and the data management interface.

Turning the beeps on and off (Beep Mode)

The beeper provides audio cues that the Meter has performed a function (for instance, detecting the blood on the Test Strip) or

to alert you to a special message (for example, that the Meter needs to be cleaned). Beeps are set “on” at the factory. However, after you are comfortable with the procedure, you may decide to turn the beeps off for more privacy.

To turn the beeper on or off, follow the chart on page 60.

Selecting the display language (Language Mode)

The ONE TOUCH II Meter can display messages in nineteen languages: English (*ENGL.*), Spanish (*ESPAÑ.*),

French (*FRANC.*), Italian (*ITALI.*), Dutch (*NE DER.*), Portuguese (*PORT.*), Swedish (*SVENS.*), German (*DEUTS.*), Danish (*DANSK.*), Finnish (*SUOMI.*), Norwegian (*NORSK.*), Polish (*POLSK I.*), Hungarian (*MAGYAR.*), Turkish (*TURKCE.*), Czech (*ČESKY.*), Greek (*ΕΛΛΗΝ.*), Russian (*РУССКИЙ.*), Japanese (日本語) and a Symbolic language (0×00×0). For more information about the symbolic language, call toll-free:

Canada 1 800 663-5521
U.S.A. 1 800 227-8862

The Meter is set at the factory to display messages in English. If you wish to change the display to another language, follow the instructions on the chart on page 60. Once a language is selected, all of the Meter messages will be displayed in that language.

Selecting the unit of measure (Unit of Measure Mode)

The Meter is set at the factory to give results in **mmol/L** (millimoles per liter), which is the unit of measure used in Canada. If you wish to set your Meter to **mg/dL** (milligrams per deciliter), which is the unit of measure used in the United States, follow the instructions on the chart on page 60.

Selecting decimal point or comma (Decimal Point/Comma Mode)

If you choose to have results displayed in mmol/L, you may also want to display the results with a comma (6,4 mmol/L) rather than a decimal point (6.4 mmol/L). Select this option by following the instructions on the chart on page 60.

Setting the date format (Date Format Mode)

Your Meter is set at the factory to display the **month, day, and year** (in that order) with each blood glucose result stored in the Meter memory (for example: *9.23.94*). You can set the Meter to display the **day, month, and year** (*23.09.94*), as is commonly read in Europe, by following the instructions on the chart on page 60.

Selecting AM/PM or 24:00 time (AM/PM/24:00 Mode)

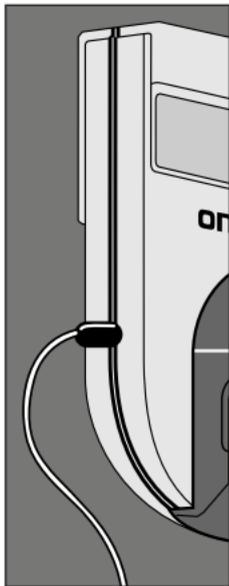
Your Meter is set at the factory to display time in **AM** and **PM** (for example: 8:00 PM). You may set the time to read in European/military format (for example: 20:00 hours) by following the instructions on the chart on page 60.

Selecting the data management interface (Data Management Mode)

The ONE TOUCH® II Meter has the ability to communicate with several types of data management systems, which makes it easier for you and/or your healthcare professional to review and analyze your results.

On the side of the Meter there is a port marked **Data**, which allows you to connect to various data management systems. To communicate with these systems, you will need to

select the correct mode for the kind of data management system you are using. The Meter is set at the factory in the RS-232 Data Management Mode.



In the RS-232 mode, you may also select the baud rate—the data communications rate for a specific application (300, 1200, 2400, or 9600).

- You may connect the ONE TOUCH® II Meter to the Data Manager™ from LifeScan by using the DTA MGR mode.

For information on other data management options, call the LifeScan Technical Service Department.

Canada 1 800 663-5521
U.S.A. 1 800 227-8862

**To enter the beeper/
international options/
and data management
interface mode:**

1. With the Meter turned off, press *and hold* Memory Button “M” at the top of the Meter.



2. Press and release On/Off Button to turn the Meter on.

3. Release “M” Button. The display should read *BEEP*. Continue with chart instructions on page 60.

Using the “**M**” and “**C**” Buttons located on top of your meter, follow the directional arrows through the following chart.

How the Chart Works



The “**M**” Button advances you from one mode to the next. For example press “**M**” to advance from the Beep Mode to the Language Mode. Use the “**M**” button to move *across* the page.



The “**C**” Button changes settings within a mode. For example, press “**C**” to change from *ENGL.* (English) to *ESPAÑ.* (Spanish) in the language mode. As long as you keep pressing the “**C**” button, you will continue cycling through the language settings. Use the “**C**” Button to move *up and down* the page.

To hold or save a setting, press “**M**” while the desired setting is on the display. For instance, to select the *NO BEEP* setting, press “**M**” while the words *NO BEEP* appear in the display.

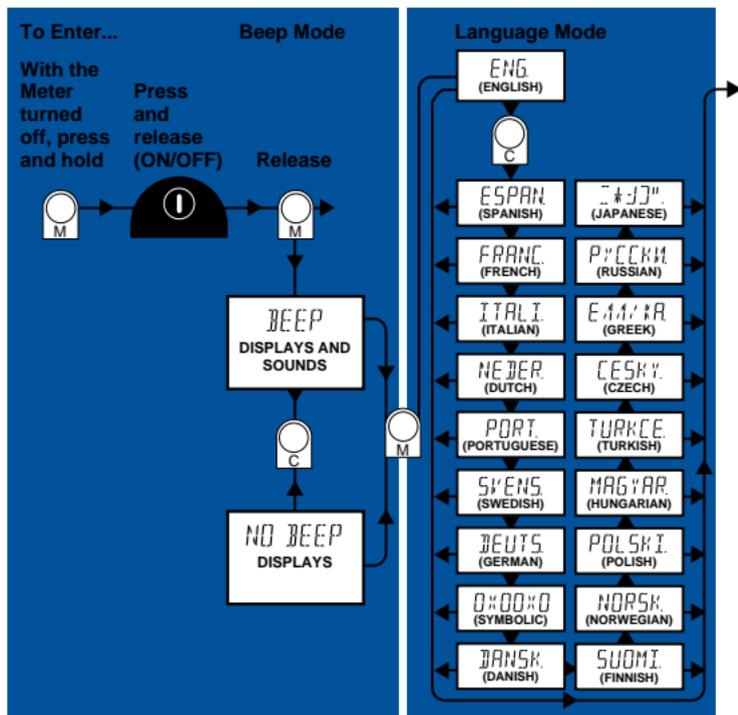
Press either button once to advance one step; press and hold to continue advancing or to go back to the beginning.



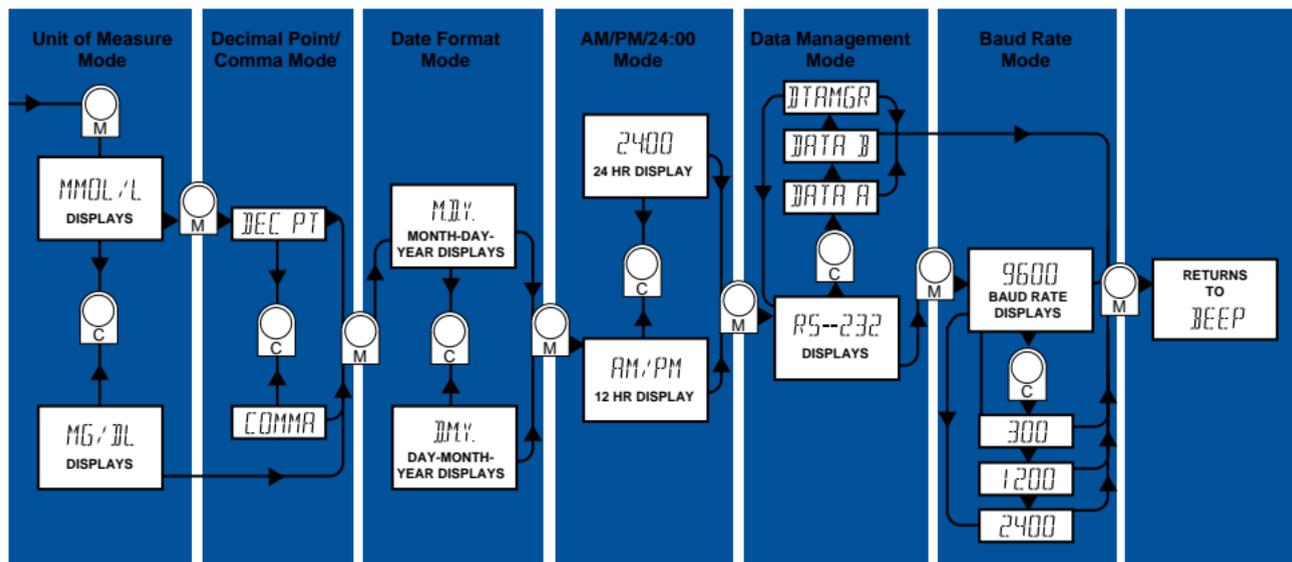
At any time you may press the **On/Off** Button to hold your selection and exit.

Note: Once a language other than English is chosen, all messages will appear in that language.

Selecting Beeps, International



Options, and Data Management Interface



10. RECALLING TESTS FROM METER MEMORY

Your ONE TOUCH® II Meter automatically stores up to 250 test results, the date and time of those results, plus an Event code, if selected. **The Meter will not display correct date and time until you set the clock.** (Refer to the chart Setting Date and Time in Chapter 9.)

Test results can be deleted from the memory by using a data management system.

When you have done more than 250 tests, the oldest test is dropped from the

memory as a new one is added. The most recent test result appears first.

To recall test results:

1. Press the On/Off Button.



2. After

CODE

and

*INSERT
STRIP*

appear on the display, press the "M" Button at the top of the Meter.



3. The word

MEMORY

appears briefly, followed by

AV 6.2

(example)

This number is the average of your blood glucose results for the past 14 days. Check Strip and Control Solution results are NOT included in the average.

Results above 33.3 mmol/L will read as *HIGH* and will be calculated into the average as 33.3 mmol/L.

If you wish to know the number of results in the memory, press the “C” Button.

N 225

(example)

will appear. This indicates the total number of readings stored in the memory, including Check Strip and Control Solution results.

NO DATA

will appear if no results are stored in the Meter memory.

4. Press “M” again, and the **date** of your most recent test appears, for example:

6.11.94

(June 11, 1994)

5. Press “M” again, and the **time** of your most recent test appears, for example:

1:20PM

(example)

6. Press “M” again, and the **result** of your most recent test appears, for example:

MM 5.2
(example)

✓ 3.9
(example)

indicates a Check Strip result.

C 5.8
(example)

indicates a Control Solution result.

7. Press “M” again, and

appears indicating the end of the test result record (date, time, and result).

8. Each time you press the “M” Button, the date, time, and result of the previous tests will appear in sequence.

6.11.94
1:20PM
MM 5.2

(example)

11.06.94 (11 June 1994) will appear if you have selected the Day-Month-Year format in Chapter 9, *Setting Date, Time, and Other Special Functions*.

If you wish to “scroll” quickly through the results, press and hold the “M” Button. To go back to the most recent result, it may be quickest to turn the Meter off, then turn it on and press “M” again.

Selecting Event numbers

You may choose to mark the blood glucose reading with an Event number (1–9). This allows you or your healthcare professional to analyze the trends in your blood glucose readings more easily. You can set up the Event categories to meet your own needs. For instance to highlight:

- Particular times of the day (readings taken when you are fasting, before or after a meal, or at bedtime)

- Physical activity (readings taken before or after exercise)

- Information about your condition (readings taken during illness, or when symptoms of high or low blood sugar occur)

- Information about the circumstances (a larger or smaller meal than usual, snacks, missed meals, missed medication)

Some examples of Event categories you might choose to use are:

Event 1. Fasting blood glucose readings

Event 2. Before-lunch glucose readings

Event 3. Before-dinner glucose readings

Event 4. Before-bedtime glucose readings

Event 5. 3:00 AM blood glucose readings

Event 6. Readings after exercise

Event 7. Readings during illness

Event 8. Readings during hypoglycemia symptoms

Event 9. Readings during hyperglycemia symptoms

You may select an Event number:

- After doing a blood test
- While reviewing your results from the memory.

To enter an Event number:

Suppose you want to mark a high test result of 19.2 mmol/L as *EVENT9*. With *MM 19.2* on the display, press “C” Button.

MM 19.2 *MM 19.2*
EVENT1 *EVENT1*

(example)

appears, (alternating with the result), for several seconds.

Continue pressing the “C” Button to advance the Event

number from 1 to 9 until the desired number is selected. (You can also hold down the C Button to scroll through the numbers.)

EVENT9

(chosen for hyperglycemia as an example) is selected.

Event numbers can be changed or cancelled at any time.

To cancel an Event number:

MM 6.2 MM 6.2
EVENT6 EVENT6

(example)

will alternate in the display.
Press “C” Button repeatedly
until

EVENT9

is reached. Press “C” again;
the next display is the test
result.

MM 6.2

(example)

The Event number for this
result has now been
cancelled.

When you are finished
using the memory function,
press the On/Off Button.

ONE TOUCH® Test Strips
include a log sheet that you
can use to keep a permanent
record of your test results,
along with information on
diet and medication.

A LifeScan Logbook can
be obtained from your
Authorized LifeScan
Distributor, retail pharmacy,
or directly from LifeScan.

11. SUMMARY OF DISPLAY MESSAGES

The following are messages that may appear on the Meter display. If you get a message that is not listed below, it is likely that the Meter was accidentally switched to another language or that another special function was accidentally changed. (For more information, see Chapter 9, *Setting Date, Time, and Other Special Functions.*)



appears when the On/Off Button is pressed and held.

All segments of the display should appear. If any portion is missing, call the LifeScan Technical Service Department.

Canada 1 800 663-5521
U.S.A. 1 800 227-8862

APPLY
SAMPLE

appears when the Meter is ready for your blood sample or Side 2 of the Check Strip. (See Chapter 6, *Testing Your Blood*, or Chapter 3, *Checking the System.*)

AV --

appears when there are no blood glucose results in the Meter's memory, or the results in the memory are more than two weeks old. However, there may be Control Solution results and Check Strip results stored in the memory.

AV 5.9
(example)

is the average of the past 14 days of blood glucose results. (See Chapter 10,

Recalling Tests from Meter Memory.)

BATTERY

appears when the battery is too low to perform another test. (See Battery Replacement in Chapter 8, *Cleaning and Maintaining the Meter.*)

CLEAN
TEST
AREA

appears when the Meter detects that there is dirt, lint, or blood on the Test Area, indicating that it must be cleaned. (See Chapter 8,

Cleaning and Maintaining the Meter.) This message may also appear if your hand or any other surface is placed above the Test Area immediately after the Meter is turned on; or if the Test Strip is partially or fully inserted before *INSERT STRIP* appears. (See Chapter 6, *Testing Your Blood.*)

CODE 9
(example)

appears when the Meter is first turned on. The code number is between 1 and 16, and must match the code number on the Test

Strip package to ensure accurate results. (See Chapter 4, *Coding the Meter.*)

5.4
CONTROL
(example)

appears when a Glucose Control Solution test is performed. This message may also appear after a blood test if the sample was too small. (See Check the Amount of Blood on the Test Strip in Chapter 6, *Testing Your Blood.*)

ERROR1
RETEST

appears if the sample was applied before *APPLY SAMPLE* appeared on the display. (See Chapter 6, *Testing Your Blood.*)

ERROR2
RETEST

appears if you made a mistake in the test procedure or if there is a problem with the Meter. (See Chapter 7, *Troubleshooting.*)

NOT
ENOUGH
BLOOD
RETEST

appears if your blood or Control Solution sample was too small or smeared. (See Check the Amount of Blood on the Test Strip in Chapter 6, *Testing Your Blood.*)

MM 7.5
EVENT6
(example)

will appear alternating back and forth when you select

an Event marker. (For further information see Selecting Event Numbers in Chapter 10, *Recalling Tests from Meter Memory.*)

APPLY
APPLY
APPLY

When the battery is getting low, display messages flash continuously. The Meter will still provide accurate test results. (See Battery Replacement in Chapter 8, *Cleaning and Maintaining the Meter.*)

HIGH

appears when a test result is above 33.3 mmol/L or 600 mg/dL. (See Chapter 12, *Questions and Answers.*)

Important: a HIGH result indicates severe hyperglycemia (blood sugar too high); contact your physician immediately.

INSERT
STRIP

appears on the display when the Meter is ready for

you to insert a Test Strip. (See Chapter 6, *Testing Your Blood.*)

INSERT
SIDE 2

appears when the Check Strip is removed from the Test Strip Holder. (See Chapter 3, *Checking the System.*) It also appears if you mistakenly remove the Test Strip from the Meter. **DO NOT** remove the Test Strip from the Meter to apply the blood sample.

MEMORY

appears when you press the Memory M Button. (See Chapter 10, *Recalling Tests from Meter Memory.*)

N 225
(example)

indicates the total number of readings stored in the memory, including Check Strip and Control Solution tests.

NO DATA

appears if you press the Memory **M** Button when there are no results stored.

NOT OK

appears when there is an electronic problem with your Meter. Call the LifeScan Technical Service Department.

Canada 1 800 663-5521

U.S.A. 1 800 227-8862

REMOVE
STRIP

appears if you mistakenly insert a Test Strip before you turn the Meter on. Remove the Strip and wait until the Meter display says *INSERT STRIP*. (See Chapter 6, *Testing Your Blood*.)

RESET
CODE

appears if the Meter has lost important information including code number, mmol/L unit setting, date,

time, and other special functions which you may have selected.

To reset the code number to match your test strips, see Chapter 4, *Coding the Meter*. To reset the unit of measurement to mmol/L, and other special functions, see Chapter 9, *Setting Date, Time, and Other Special Functions*. If the message *RESET CODE* appears again, contact LifeScan Technical Services.

WAIT

appears while the Meter is performing some internal checks. Wait until *APPLY SAMPLE* appears to continue. (See Chapter 6, *Testing Your Blood*.)

45...0
MM 6.3
(example)

The Meter counts down from 45 seconds until your result appears. Meters intended for use in Canada and other countries show test results in mmol/L with

the letters MM (for millimole) and a decimal point or comma; for example: *MM 6.3* or *MM 6,3*.

Note: mmol/L results for Check Strip, Control Solution, and average blood glucose will not include the letters MM in the display.

(To change the unit of measure, see Chapter 9, *Setting Date, Time, and Other Special Functions*.)

114
(example)

In Meters intended for use in the U.S., test results

appear with no decimal point: 114, for example. The unit of measure is mg/dL. (To change the unit of measure to millimoles per liter (mmol/L), see Chapter 9, *Setting Date, Time, and Other Special Functions*.)

3.30.94
3:21PM
MM 5.9
EVENT6
(example)

This is an example of a result stored in memory. The first message is the date of the test (March 30, 1994).

The second message is the time the test was done (3:21PM). The third message is the result 5.9 mmol/L (MM 5.9) as shown here in mmol/L. The fourth message means an Event number was selected for this particular result (Event 6). (See Chapter 10, *Recalling Tests from Meter Memory*.)

```
✓ 3.8
✓ OK
(example)
```

appears when a Check Strip reading is within the acceptable range. You may proceed

with a blood glucose test. (See Chapter 3, *Checking the System*.)

```
✓ 5.8
✓ NOT OK
REDO ✓
(example)
```

appears when a Check Strip reading is outside the acceptable range, and prompts you to repeat the Check Strip test. (See Chapter 3, *Checking the System*.)

```
REDO ✓
```

appears each time the Meter is turned on if the last Check Strip reading was outside the acceptable range. It will continue to appear until the Check Strip result, which is automatically detected by the Meter, falls within the acceptable range. The range is also printed on the back of the Meter. (See Chapter 3, *Checking the System*.)

12. QUESTIONS AND ANSWERS

In the following pages, we've provided answers to some of the most common questions people have about home blood glucose monitoring and the ONE TOUCH® II Meter. If you have a question that isn't covered here, consult your healthcare professional or call the LifeScan Technical Service Department.

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U.S.A.	1 800 227-8862

Caution: A blood glucose monitoring program should be conducted under the guidance of a healthcare professional. Always consult your healthcare professional before making changes in your diabetes control plan.

Q. What clinical information should a healthcare professional be aware of when using the ONE TOUCH® II Meter?

A. For use in hospitals, institutions, and clinics, refer to the ONE TOUCH® II Blood Glucose Monitoring System Manual-Hospital Programs.

The ONE TOUCH II Meter is **not** intended for monitoring neonatal whole blood samples.

ONE TOUCH® Test Strips should not be used with plasma or serum samples;

results will be inaccurate. ONE TOUCH Test Strips are intended for use with fresh whole blood or ONE TOUCH® Glucose Control Solution.

Reducing substances, such as ascorbic acid, do not significantly affect blood glucose results when occurring in normal blood concentrations. However, abnormally high concentrations of reducing substances in blood will cause inaccurately low blood glucose results.

Samples with preservatives that contain fluoride (gray-

top tubes) should not be used. The results will be inaccurately low.

Q. Why should I test my blood glucose (sugar)?

A. No doubt your healthcare professional has explained the importance of keeping your diabetes under control. Your ONE TOUCH® II System helps you check whether or not you are under control by monitoring your blood glucose levels.

The test results provide a good picture of how diet, exercise, and medication are affecting your diabetes.

Test results can also indicate whether your diabetes is changing in ways that might require an adjustment in your treatment program.

Always consult your healthcare professional before making changes in your diabetes control plan.

Q. How often should I test my blood glucose?

A. This is best decided by you and your healthcare professional. It may vary according to your age, the type of diabetes you have, any medication you are

using, whether you are ill, and any physical or emotional changes in your life.

Q. Should my test results always be the same?

A. No. Results will vary somewhat from test to test, depending on diet, activity level, and time of day. These variations provide useful clues about your condition and how well your treatment program is working.

With your healthcare professional, determine your own personal target blood glucose values, as

well as what an unusually high or low test result is for you. In most cases, your test results should stay within that range.

Q. What can I do to be sure I get accurate test results?

A. Make sure that you do the following:

Keep your Meter clean at all times. (Refer to Chapter 8, *Cleaning and Maintaining the Meter*.)

Use enough blood. The entire Test Spot must be completely covered with

blood. Touch the drop of blood lightly to the middle of the Test Spot to fill the entire spot. The drop of blood should have a shiny surface over the entire spot. **Do not smear the blood or touch the Test Spot with your finger.**

Do not use expired Test Strips. Never use Test Strips after the expiration date on the package label has passed.

Make sure your Meter code is set to match the code number on the package of Test Strips you are using.

Do not use ONE TOUCH® Test Strips that are discolored.

Periodically review your use of the Meter with your healthcare professional.

Q. How can I verify that my test results are accurate?

A. There are two very important checks that you should perform routinely to verify that your test results are accurate. You should use the Check Strip every day to verify correct Meter operation. ONE TOUCH®

Normal Glucose Control Solution—Blue Formula should be used at least once a week or more often as needed, to verify that the entire system (Meter and Test Strips) is working properly, and that you are performing the test correctly.

Instructions for performing both of these checks are provided in Chapter 3, *Checking the System*. **DO NOT use the system if either the Check Strip or the Control Solution results are outside of the expected ranges.**

Q. What should I do if test results seem unusually low or high?

A. First, troubleshoot by eliminating any of these potential problems:

- ☑ Clean your Meter Test Strip Holder and most importantly, the Test Area. (See Chapter 8, *Cleaning and Maintaining the Meter*.)
- ☑ Inspect the Test Spot on the Test Strip to be sure the drop of blood covered it completely.

☑ Check the expiration date on the Test Strip package. If it has passed, discard the package and use strips from a new package.

☑ Be sure the code number on the Meter matches the code number on your Test Strip package.

☑ Perform a check of the Meter operation using the Check Strip supplied with the Meter.

☑ Perform a test with Glucose Control Solution to verify that the Test Strip

and the Meter are working properly, and that you are performing the test correctly.

After troubleshooting, repeat the blood test with a new Test Strip.

Q. What do I do if test results still seem too low or too high?

A. Remember, the test results you obtain will vary from time to time depending on food intake, insulin dose, exercise, etc. Ask yourself the following questions:

“How do I feel?”

“Do I have symptoms of low blood sugar (hypoglycemia) or high blood sugar (hyperglycemia)?”

“What have I eaten?”

“How much exercise have I had?”

“Am I ill?” (i.e., common cold, flu, etc.)

In addition to the common factors listed above which cause real variations in blood glucose results, there

are certain abnormal conditions which will interfere with the accuracy of your blood glucose monitoring results. These limitations are described below and should be discussed with your physician.

Extremes in hematocrit (the amount of red blood cells in the blood) can affect test results. High hematocrits (above 60%) cause inaccurately low results. Very low hematocrits (below 25%) can also cause inaccurately low results.

Severe dehydration and excessive water loss may cause inaccurately low results. This has been reported in the medical literature for leading blood glucose monitoring products.^{1,2} Severe dehydration can lead to many serious medical complications. One complication which is of particular importance in diabetes management is a “hyperglycemic-hyperosmolar” state, with or without ketosis, which may be life-threatening if left untreated. The following are some of the

factors which could lead to severe dehydration:

- Vomiting and diarrhea
- Prescription drugs, e.g., diuretics
- Inability to recognize or respond to “thirst” sensations
- Sustained uncontrolled diabetes

Whenever inadequate fluid intake or excessive water loss occurs, CONSULT A PHYSICIAN IMMEDIATELY.

Remember, if you ever experience symptoms which are not consistent with your blood glucose monitoring results and you have eliminated common procedural errors described in this Owner’s Booklet as the cause, you should contact a physician immediately!

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

IMPORTANT: When the message *HIGH* appears on the Meter display, this indicates severe hyperglycemia (blood sugar too high); contact your physician immediately.

Q. What should I do if my blood glucose test results are consistently high for my own diabetes control plan?

A. The goal of diabetes management is to maintain a “near normal” amount of glucose in the blood. Normal, low, and high blood

glucose values for your individual treatment plan should be determined with your healthcare professional. If your blood glucose test results remain consistently high, contact your healthcare professional.

Q. What are the expected blood glucose values associated with well-controlled diabetes?

A. Fasting: 3.3–7.2 mmol/L (60–130 mg/dL).

After meals (1 hour):
Less than 10.0 mmol/L (180 mg/dL).

After meals (2 hours):
Less than 8.3 mmol/L (150 mg/dL).^{3,4}

Q. Why don't my Meter results exactly match the results that I got from my doctor's laboratory?

A. Many healthcare professionals believe that the result that you get on your Meter should fall within 15% to 20% of the result obtained on laboratory equipment when whole blood is tested.⁵ However, there are a number of reasons why the blood glucose result from your Meter may vary even more

than 20% from a laboratory result.⁶ One of the most common reasons is that laboratories use serum or plasma samples, while home blood glucose monitors use whole blood. Whole blood results are approximately 10%–12% lower than serum or plasma results from the same blood sample (at average hematocrit levels of 41%–45%). To adjust for this difference, divide the laboratory value by 112% or 1.12.⁷ (Example: a serum value of 8.3 mmol/L is comparable to 7.4 mmol/L whole blood value.)⁷

Another reason for variation may be that the Meter test was not done within 10 or 15 minutes of the laboratory test. Because blood glucose levels can change rapidly (especially if you've recently eaten), the two tests could have very different results.^{8,9}

- 1 Wickham NWR, et al: *Practical Diabetes* (1986) 3(2):100.
- 2 Cohen FE, et al: *Diabetes Care* (1986) 9(3):320–322.
- 3 Skyler JS, et al: *Postgraduate Medicine* (1987) 81(6):163–174.
- 4 Skyler JS, et al: *Diabetes Care* (1981) 4:311–318.
- 5 Clarke WL, et al: *Diabetes Care* (1987) 10:622–628.
- 6 Gadsen RH: *Challenges in Diabetes Management*. Milpitas CA., LifeScan, Inc. (1988) 63–66.
- 7 Caraway WT: Carbohydrates, in Tietz NW (ed). *Fundamentals of Clinical Chemistry*. Philadelphia, WB Saunders Company (1976) 242–244.
- 8 Surwit RS and Feinglos MN: *Diabetes Forecast* (1988) April: 49–51.
- 9 Nelson RL: *Diabetes Spectrum* (1989) 2:219–223.

13. SPECIFICATIONS

Performance

Characteristics:

See ONE TOUCH® Test Strip package insert for ONE TOUCH® II System accuracy and precision.

Power Supply:

One Duracell® brand alkaline battery, (J-size, 6 volts, part #7K67) included with Meter. Use only a Duracell® battery for replacement.

Battery Life:

Approximately one year (at two tests per day).

Result Range:

0–33.3 mmol/L (0–600 mg/dL). Higher values displayed as *HIGH*.

Display Type:

Alphanumeric;
6-character,
14-segment LCD.

Dimensions:

Length—12.07 cm (4-3/4").
Width—6.33 cm (2-3/8").
Height—2.7 cm (1-1/16").
Weight—Approx. 135 g (4.8 oz) (including battery).

Operating Temperature

Range:

15°C–35°C (59°F–95°F).

Operating Humidity

Range:

0%–90% relative humidity (non-condensing).

Memory:

Storage capacity: 250 test results including Check Strip and Control Solution results (oldest test deleted first).

Code Numbers:

1–16.

Data Port:

Communicates with Data Manager™ unit and other data management systems.

14. GUARANTEE AND WARRANTY

30-Day Money-Back Guarantee

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

Five-Year Warranty

The following warranty policy applies only to the original purchaser of this Meter and does not include the battery supplied with the Meter.

1. Please complete the warranty card and mail it to LifeScan.
 2. The ONE TOUCH II Meter has a full five-year warranty from the original date of purchase. Write your date of purchase here:
-

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

3. If the ONE TOUCH II Meter does not work and is returned by the original owner for service after the five-year period, a replacement Meter will be sent to the original owner.

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

5. Before you return your Meter for warranty replacement, call your LifeScan Technical Representative at the toll-free number listed on the back of this booklet for detailed instructions.

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