ONETOUCH®

UltraSmart™

Blood Glucose Monitoring System

Meter and Electronic Logbook In One

Owner's Booklet

LIFESCAN
a Johnson & Johnson company

ONETOUCH® UltraSmart™

Blood Glucose Monitoring System

Owner's Booklet

Symbols

SN	Serial Number
LOT	Lot Number
IVD	In Vitro Diagnostic Medical Device
	Expiration Date Symbol
STERILE R	Sterilized by irradiation Symbol

Dear OneTouch® UltraSmart™ System Owner:

You have chosen one of the best blood glucose monitoring systems available. This booklet has important information you must know about the OneTouch® UltraSmart™ Blood Glucose Monitoring System. Read it carefully.

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that keeping blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%*. The results you get with the OneTouch® UltraSmart™ System can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Your OneTouch® UltraSmart™ System requires a small drop of blood (at least 1 microlitre) and five seconds to provide you with an accurate plasma-calibrated test result.

The OneTouch® UltraSmart™ Meter also has a memory that allows it to function as an "electronic logbook." Now you can store such vital everyday information as insulin and oral medication doses, food intake, amount of exercise, illnesses, and other pertinent data. You can use your OneTouch® UltraSmart™ System simply to test or to serve as a complete storehouse of information regarding your diabetes treatment plan.

The makers guarantee that the OneTouch® UltraSmart™ Meter shall be free of defects in material and workmanship for a period of three years. This guarantee is valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable.

*American Diabetes Association position statement on the Diabetes Control and Complications Trial (1993).

INTENDED USE: The OneTouch® UltraSmart™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The OneTouch® UltraSmart™ System is intended for self-test use outside the body (for *in vitro* diagnostic use) by people with diabetes at home and health care professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. The OneTouch® UltraSmart™ System should not be used for the diagnosis of diabetes or testing of newborns.

The OneTouch® UltraSmart™ Blood Glucose Monitoring System provides the user with electronic logbook functions which serve to store such data as insulin and oral medication doses, food intake, amount of exercise, health information such as illnesses, and other pertinent data. The meter includes a data port that enables the user to download logbook data to a personal computer.

CAUTION: Before using any product to test your blood glucose, 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 U.S. Food and Drug Administration, and the Advanced Medical Technology Association.

Important Information

- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from dehydration, consult a healthcare professional immediately.

- Test results below 3.9 mmol/L mean low blood glucose (hypoglycaemia). Test results greater than 13.3 mmol/L mean high blood glucose (hyperglycaemia). If you get results below 3.9 mmol/L or above 13.3 mmol/L and do not have symptoms, first repeat the test. If you have symptoms or continue to get results that fall below 3.9 mmol/L or above 13.3 mmol/L, follow the treatment advice of your healthcare professional.

- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in the OneTouch® UltraSmart™ Owner's Booklet, call your healthcare professional.

- A red blood cell count (haematocrit) that is very high (above 55%) or very low (below 30%) can cause false results.

Table of Contents


OneTouch
UltraSmart

THE OneTouch® UltraSmart™ SYSTEM

The OneTouch® UltraSmart™ System uses the latest blood glucose monitoring technology. It measures the glucose content of a blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement. Test results are **"plasma-calibrated."** This makes it easier for you and your diabetes-care team to compare your meter results with laboratory tests. If you have been using another type of meter–one that provides whole-blood results–you may notice that your test results with the OneTouch® UltraSmart™ System are about 12% higher.

The OneTouch® UltraSmart™ Blood Glucose Monitoring System consists of three main products: the OneTouch® UltraSmart™ Meter, OneTouch® Ultra™ Test Strips, and OneTouch® Ultra™ Control Solution. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use no other test strips or control solution with your meter.

Your system includes:

- OneTouch® UltraSmart™ Meter
- 10 OneTouch® Ultra™ Test Strips
- OneTouch® Ultra™ Control Solution
- OneTouch® UltraSoft™ Adjustable Blood Sampler
- OneTouch® UltraClear™ Cap
- 10 OneTouch® UltraSoft™ Sterile Lancets
- Owner's Booklet
- Carrying Case
- Quick Reference Guide
- Warranty Registration Card
- Two AAA Alkaline Batteries (Installed)

OneTouch® UltraSmart™ Meter

OneTouch® Ultra™ TEST STRIP

TEST PORT
The meter turns on when you insert test strip here.

DATA PORT
Used to download logbook memory to a computer.

DISPLAY WITH BACKLIGHT
Test results, messages, symbols, and other data appear here.

SmartButtons™
(See pages 4–5 for description and use.)

Navigation Buttons

Note: Press and release buttons. Do not hold buttons down for an extended period of time.

BACK BUTTON
(OFF BUTTON)
Goes back to previous display on certain screens. Press and hold for two seconds to turn off the meter.

ARROW BUTTON
Scroll through menus, code numbers, and logbook.

OK BUTTON
(BACKLIGHT BUTTON)
Accept entries and move to next display. Press and hold for two seconds to turn on backlight.

SmartButtons™

The SmartButtons™ are your keys to getting the most out of your OneTouch® UltraSmart™ Meter. They allow you to enter information about your diabetes management plan into the large logbook memory. There are SmartButtons™ for exercise, health, medication, and food. The FastFacts™ SmartButtons™ is used to view the records in the logbook memory. You may press any SmartButtons™ to turn on the meter and move directly to the category.

EXERCISE SmartButton™
Enter exercise amount and level.

FOOD SmartButton™
Enter meal and snack information.

HEALTH SmartButton™
Enter information on health.

MEDICATION SmartButton™
Enter insulin and diabetes pill information.

FastFacts™ SmartButton™
Review test results and logbook memory.

Note: For complete information on using the Exercise, Health, Medication, and Food SmartButtons,™ please see pages 78–103. See pages 104–117 for more information on the FastFacts™ feature and the FastFacts™ SmartButton.™

Display Symbols

These symbols guide you while using your meter:

SYMBOL	MEANING
▲	Scroll (move) up only.
▼	Scroll down only.
▲▼	Scroll up or down.
	Scroll up or down.
— — —	No entry.
HIGHLIGHT	Shows where you are on the display. Press OK to accept highlighted area.

Display Contrast

You can change the contrast of the meter display. To make it darker, press and hold the Back button and the "up" Arrow button. To make it lighter, press and hold the Back button and "down" Arrow button.

OneTouch® Ultra™ Test Strips

The OneTouch® UltraSmart™ System measures the amount of glucose in whole blood. Blood is applied to the TOP EDGE of the OneTouch® Ultra™ Test Strip and is automatically drawn into the reaction cell where the reaction takes place.

Top Edge
Apply a drop of blood to the narrow channel here in the top edge of the test strip.

Confirmation Window
Check here to confirm if enough blood has been applied.

Contact Bars
Insert this end of the test strip, contact bars facing up, into the meter. Push it all the way in until it will go no further.

See pages 19–35, *Testing Your Blood*, for complete instructions.

Important Test Strip Information

- Store test strip vials in a cool, dry place below 30ºC. Keep away from direct sunlight and heat. Do not refrigerate.
- Store test strips in their **original vial only**. To avoid damage or contamination, do not transfer test strips to any other place.
- Do not use test strips beyond the expiration date printed on the package since they may provide inaccurate results.
- After removing a test strip from the vial, replace the vial cap immediately and close it tightly.
- With clean, dry hands, you may touch the test strip anywhere on its surface.
- Use each test strip immediately after removing it from the vial.
- Count three months from the date you first open a new vial of test strips and write this date on the vial label. Throw test strips and vial away after this discard date.
- Apply only OneTouch® Ultra™ Control Solution or a blood sample to the test strip.
- Do not bend, cut, or modify test strips in any way.
- OneTouch® Ultra™ Test Strips are for single use only. **Never reuse a test strip that has had either blood or control solution applied to it.**
- Refer to additional information in the OneTouch® Ultra™ Test Strip package.

BEFORE TESTING

Checking the Display

Each time you turn the meter on, the display background will quickly change from dark to light and form the words "OneTouch UltraSmart." This tells you that the system is performing several self-checks to confirm that the meter is working properly. If, at any time during the life of the meter, these graphics appear to be different, call your local LifeScan Customer Service office. See back cover for contact information.

Setting the Meter

The OneTouch® UltraSmart™ Meter is set at the factory to display results in the English language using millimole per litre (mmol/L) as the unit of measure. The time and date are also factory-set. If you are using the meter for the first time and simply wish to test, insert a test strip into the test port and begin by coding the meter. If you wish to change the date, time, or language, see *Meter Set-up*, pages 54–57. To customize your meter, see *Custom Meter Set-up*, pages 58–72.

Note: It is important that the time of day is correct and that your medication set up and mealtimes are set according to your personal daily schedule. Otherwise, some FastFacts™ information will not be correct.

Coding the Meter

Code numbers are used to calibrate the OneTouch® UltraSmart™ Meter with the OneTouch® Ultra™ Test Strips for accurate results. You must code the meter before using it for the first time and then every time you change to another vial of test strips. **Each time you test, check to be sure that the code number on the meter display matches the code number on the test strip vial.**

CAUTION: Failure to code the meter correctly will cause inaccurate test results.

STEP 1 Enter the Code Mode.

Insert a OneTouch® Ultra™ Test Strip to turn on the meter. Push it all the way in until it will go no further. "OneTouch UltraSmart" will appear on the display briefly.

STEP 2 See the Code Number.

The code number will appear on the display. (After every 25 tests the meter will display the correct code number and will prompt "Check Code Press OK." Press the OK button OK if the code number is still correct.)

(Example)

STEP 3 Match the Code Numbers.

Compare the code number on the meter display with the code number on the test strip vial. If the two code numbers match, you may begin testing. If they do not match, follow Step 4. (The first time you turn the meter on, three dashes [---] will appear, showing that there is no code stored in the memory.)

(Example)

Note: The code number appears on the display briefly. If you were unable to change the code in time or entered a code number in error, press the Back button to return to Step 3.

(Example)

STEP 4 Code the Meter.

Move up or down using the Arrow button to the code number that matches the code number on the test strip vial. The new code number will flash on the display for about three seconds, after which the meter will prompt you to "Apply Blood".

Checking the System

Note: Refer to additional information in the OneTouch® Ultra™ Control Solution package.

OneTouch® Ultra™ Control Solution is used to check that the meter and the test strips are working together as a system and that you are performing the test correctly.

OneTouch® Ultra™ Control Solution contains a measured amount of glucose that reacts with OneTouch® Ultra™ Test Strips. Compare your control solution test results with the range printed on the test strip vial label. It is very important that you do this simple check routinely to make sure you get accurate results.

Important Control Solution Test Information

- Use only OneTouch® Ultra™ Control Solution.
- Check the expiration date on the control solution bottle. Record the discard date (date opened plus three months) on the bottle label. Do not use after expiration or discard date, whichever comes first.
- Control solution, meter, and test strips should be at room temperature between 20 and 25°C before testing.
- Shake the bottle, discard the first drop of control solution, and wipe off the dispenser tip to ensure a good sample and an accurate result.
- Store the control solution tightly closed at temperatures below 30°C. Do not refrigerate.

CAUTION: The control solution range printed on the test strip vial is for OneTouch® Ultra™ Control Solution only. **It is not a recommended range for your blood glucose level.**

Before you use the OneTouch® UltraSmart™ Meter to test your blood for the first time, practice the procedure using control solution. When you can do three tests in a row and obtain a result within the expected range each time, you are performing the test correctly and you are ready to test your blood.

When to do a control solution test:

- Once a week.
- When you open a new vial of test strips.
- Whenever you suspect that the meter or test strips are not working properly.
- If your blood glucose test results are not consistent with how you feel.
- After dropping the meter.

How to do a control solution test:

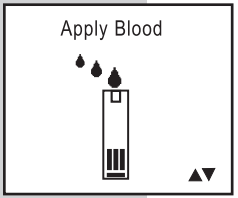
STEP 1 **Insert Test Strip.**

To turn on the meter, insert a test strip, contact bars end first and facing up, into the test port. Push it all the way in until it will go no further.

(Example)

"OneTouch UltraSmart" will appear briefly on the display.

Then "Code 9 (example), Check Code" is displayed. Be sure the meter and test strip codes match. If they do not, code the meter correctly (see page 10).

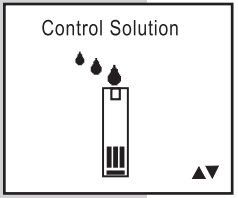


STEP 2 Select "Control Solution."

"Apply Blood" will appear on the display first. Use the Arrow button to select "Control Solution." The meter will automatically identify the test as a control solution test in the logbook.

There are three choices in test mode. Use the Arrow button to select one. Do not apply a sample until your choice appears on the display.

- "Apply Blood" for fingertip blood sample
- "Alternate Site" for arm blood sample
- "Control Solution" for checking the system

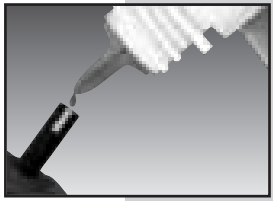


*Note: You must select "*Control Solution*" to distinguish control solution tests from blood glucose tests. Marked control solution tests will not be included in your averages. Do not use the Control Solution mode for testing blood.*

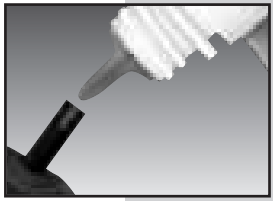
STEP 3 Apply Control Solution.

To ensure an accurate result:

- Shake the bottle well
- Discard the first drop
- Wipe the dispenser tip



Hold the drop to the narrow channel in the TOP EDGE of the test strip. When the confirmation window is full, the meter will begin to count down from 5 to 1.



Note: If you do not apply the control solution within three minutes, the meter will turn itself off. Remove the test strip and insert it back into the test port to restart the test procedure.

STEP 4 Result Appears in 5 Seconds.

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

(Example)

Comparing Control Solution Results

If test results fall outside the range printed on the test strip vial, repeat the test. When using control solution mode, very high or very low readings will be displayed as a number rather than a "HIGH" or "LOW" warning screen and stored in the logbook as "Control Solution High" or "Control Solution Low". Out-of-range results may be caused by one or more of the following:

- Error in performing the test.
- Failure to shake the control solution bottle well.
- Expired or contaminated control solution.
- Meter, test strips, or control solution that are too warm or too cold.
- Failure to discard the first drop of control solution and wipe the dispenser tip clean.
- Improper meter coding.
- Test strip deterioration.
- Meter malfunction.
- Testing blood in Control Solution mode.

CAUTION: If you continue to get control solution test results that fall outside of the range printed on the test strip vial, the system may not be working properly. **Do not** use the meter. Call your local LifeScan Customer Service office. See back cover for contact information.

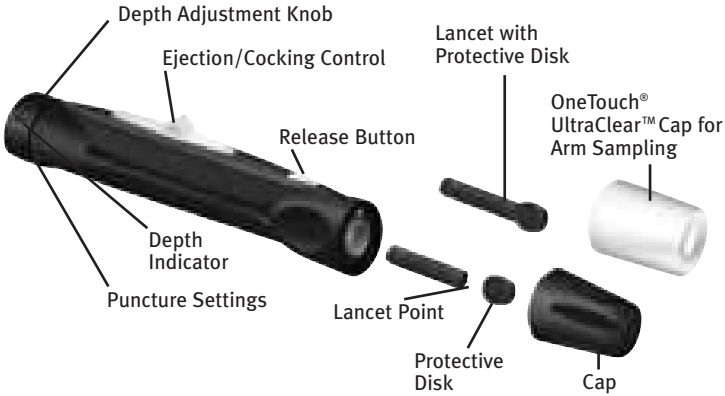
TESTING YOUR BLOOD

Read this section and the test strip package insert carefully before testing. Make sure you have all items needed to test.

- OneTouch® UltraSmart™ Meter
- OneTouch® Ultra™ Test Strips
- OneTouch® UltraSoft™ Adjustable Blood Sampler
- OneTouch® UltraClear™ Cap (for arm sampling)
- OneTouch® UltraSoft™ Sterile Lancet

CAUTION: It is important to learn the correct blood application technique (see page 30). If you do not apply blood to the test strip correctly you may get an inaccurately low or high test result or an error message. LifeScan recommends that you develop good technique by practicing with control solution prior to using the OneTouch® UltraSmart™ Meter for the first time.

Preparing the OneTouch® UltraSoft™ Sampler

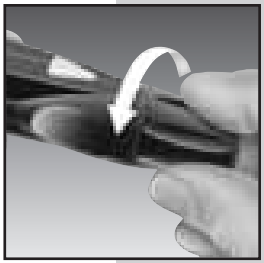


CAUTION: To reduce the chance of infection:

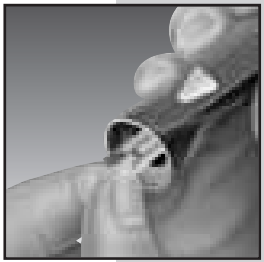
- Never share a lancet or the OneTouch® UltraSoft™ Sampler with anyone.
- Always use a new, sterile lancet. Lancets are for single use only.
- Keep the OneTouch® UltraSoft™ Sampler clean.

STEP 1 **Insert a Lancet.**

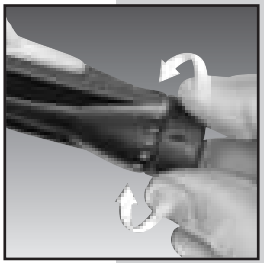
Turn the cap anti-clockwise to remove it.

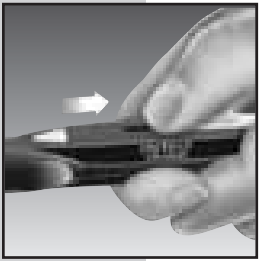


Insert the lancet into the lancet holder and push down firmly until it is fully seated. Do not twist the lancet. Twist the protective disk until it separates from the lancet. Replace the OneTouch® UltraSoft™ Cap. Turn it clockwise until it is snug.



Adjust the puncture depth setting if necessary. Twist the depth adjustment knob toward the smaller bumps for a shallower puncture or toward the larger bumps for a deeper puncture.





STEP 2 **Cock the Sampler.**

Slide the ejection/cocking control back until it clicks. If it does not click, the sampler may have been cocked when the lancet was inserted. The sampler is now ready for use.

STEP 3 **Wash Your Hands and the Puncture Site.**

Use warm, soapy water. Rinse and dry thoroughly.

Fingertip Blood Sampling

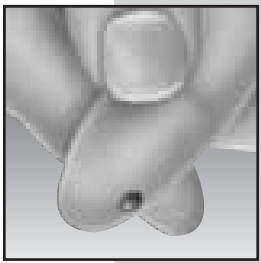
The OneTouch® UltraSmart™ System requires a very small blood drop to perform a test. You may obtain it from a **fingertip** or **arm**. There are important differences in the procedures for fingertip testing and arm testing. See page 24 for information on obtaining a blood sample from the arm. Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.

STEP 1 Position the Sampler.

Hold the OneTouch® UltraSoft™ Sampler **firmly** against the **side** of your finger. Press the release button.

STEP 2 Massage the Fingertip.

Massaging the fingertip gently will help you obtain a round drop of blood. Do not squeeze excessively on the puncture site. The blood sample must be at least one microlitre (1 µL) in volume (• actual size) or you may get an error message (see page 50) or an inaccurate test result. Do not smear the blood sample. Proceed with your blood glucose test.



Arm Blood Sampling ("Alternate Site")

The arm has fewer nerve endings than the fingertip so you may find that obtaining a blood sample from the arm may be much less painful than using the fingertip. The technique for arm sampling is different from fingertip sampling. Also there are differences between arm samples and fingertip samples that you should understand.

Important Information About Arm Testing

- Under certain conditions, blood glucose test results obtained using samples taken from your arm may differ significantly from fingertip samples.
- The conditions in which these differences are more likely to occur are when your blood glucose is changing rapidly such as following a meal, an insulin dose, or associated with physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than arm samples.
- When your blood glucose is falling, testing with a fingertip sample may identify a hypoglycaemic (low blood sugar) level sooner than a test with an arm sample.
- Use arm samples only for testing prior to, or more than two hours after, meals, insulin doses, or physical exercise.
- Testing performed within two hours after meals, insulin doses, or physical exercise, or whenever you feel that your glucose levels may be changing rapidly, should be done from the fingertip.

Important Information About Arm Testing *(continued)*

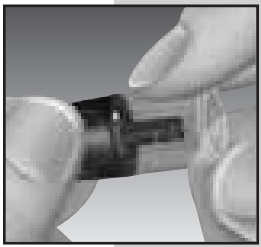
- You should also use fingertip testing whenever you have a concern about hypoglycaemia (insulin reactions) such as when driving a car, particularly if you suffer from hypoglycaemic unawareness (lack of symptoms to indicate an insulin reaction), as arm testing may fail to detect hypoglycaemia.

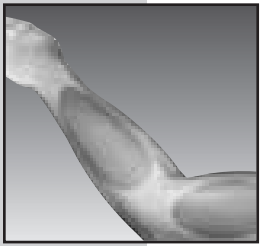
What you should do:

- Use arm or fingertip samples for testing prior to, or more than two hours after, meals, insulin doses, or physical exercise.
- Routine testing before meals can be done either at the fingertip or the arm.
- Consult your healthcare professional before you begin using the arm for testing.

STEP 1 **Install the OneTouch® UltraClear™ Cap.**

To aid in obtaining a blood sample from the arm, replace the regular sampler cap with the OneTouch® UltraClear™ cap. If necessary, set the sampler for a deeper puncture.



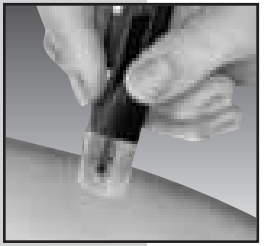


STEP 2 **Choose the Puncture Site.**

Select a soft, fleshy area on your arm that is away from bone and free of visible veins and hair. Wash and dry the area.

STEP 3 **Massage the Area.**

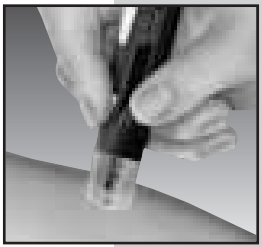
To increase blood flow to the puncture site, massage the area gently. For individuals who experience difficulty in getting sufficient blood for a test, rubbing the area more vigorously or applying heat briefly may be helpful.



STEP 4 **Position the Sampler.**

Press and hold the sampler against the arm for a few seconds. Press the release button.

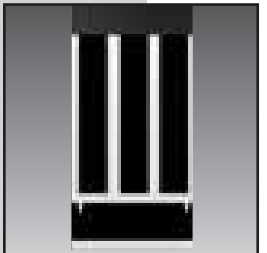
STEP 5 Allow Blood Drop to Form.



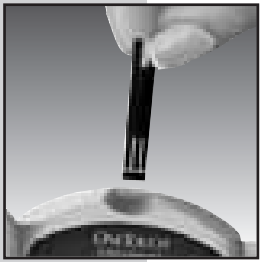
Continue holding the sampler against the skin for a few seconds until the blood drop forms. Allow enough blood to form under the cap until you have a blood sample that is sufficient to fill the confirmation window of the test strip (● actual size). If you must massage the area to obtain more blood, do not squeeze the site excessively.

Note: Blood is applied to the test strip in the same manner as described on page 30. However, you may find it more convenient to hold the arm still and bring the meter and test strip to the blood sample.

If bruising occurs, you may choose to lance a fingertip instead. If you are having difficulty obtaining blood from the arm, call your local LifeScan Customer Service office for assistance. See back cover for contact information.



Insert This End



STEP 1 **Insert Test Strip.**

Insert a test strip, contact bars end first and facing up, into the test port. Push it all the way in until it will go no further. The meter will turn on automatically. “OneTouch UltraSmart” will appear briefly on the display. Then the code number will appear. Be sure the meter and test strip codes match. If they do not, code the meter correctly.

STEP 2 Select Test Mode.

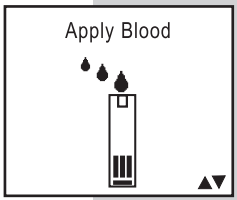
Note: There are three choices in test mode. For blood testing use the Arrow button to select:

- "Apply Blood" *for fingertip blood sample* **or**
- "Alternate Site" *for arm blood sample*

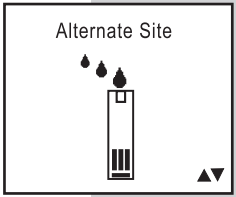
Do not use the Control Solution mode when testing blood.

- "Control Solution" *is for checking the system*

"Apply Blood" will appear on the display first. If you are testing with a fingertip blood sample, proceed to Step 3.



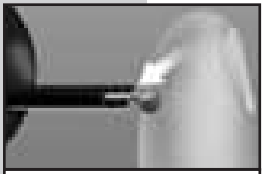
If you are testing with a blood sample from the arm, use the Arrow button to scroll to "Alternate Site."



Before you test with blood, make sure "Apply Blood" or "Alternate Site" is displayed on the screen. Correct test mode selection is important to ensure all blood and control solution tests are properly included or excluded from averages. Failure to select the correct test mode may cause blood averages to be incorrect.

STEP 3 **Apply Sample.**

Obtain a round drop of blood using the OneTouch® UltraSoft™ Adjustable Blood Sampler. **The blood sample must be at least 1 µL in volume** (• actual size) to fill the confirmation window.



Correct

Touch and hold the drop of blood to the narrow channel in the top edge of the test strip.

Incorrect

DO NOT:

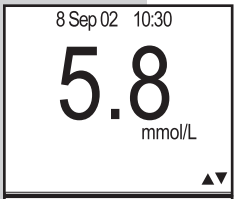
- Apply sample to the front or back of the test strip.
- Push your finger against the test strip.
- Apply a smeared sample.

Hold the blood drop to the top edge of the test strip **until the confirmation window is full before the meter begins to count down.**

If the confirmation window does not fill completely before the meter begins to count down, do not add more blood to the test strip; discard the test strip and retest. If you have trouble filling the test strip, contact your local LifeScan Customer Service office. See back cover for contact information.

If the confirmation window is not full, you may get an error message or an inaccurate test result.

Note: If you do not apply a blood sample within three minutes, the meter will turn off automatically. Remove the test strip and then insert it back into the meter to turn the meter back on.



Plasma-Calibrated Result
(Example)

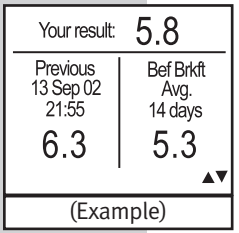
STEP 4 Accurate Results in Just 5 Seconds.

Your blood glucose test result will appear after the meter counts down from 5 to 1.

The test results are automatically stored in the meter logbook (memory). You may now:

- Use the Arrow button to compare results (see "Additional Feature" which follows); or
- Add comments to your result; or
- Remove the test strip to turn off the meter.

Note: If "Comment? Press OK" appears at the bottom of the display, your test result is outside the range of 5.0–7.2 mmol/L or a personal glucose range you set (see pages 58–72, Custom Meter Set-up*). To add a comment to the test result, see pages 73–77,* Your Meter Logbook.



(Example)

Additional Feature

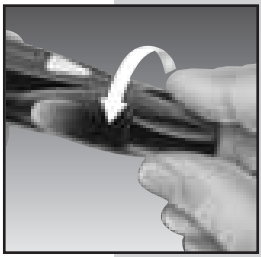
After you complete a blood glucose test, you can compare the result with your last test and your average for this time of day by pressing the Arrow button.

Used Lancet Disposal

CAUTION: It is important to discard the used lancet carefully to avoid injury or illness. Follow proper precautions in accordance with local regulations when disposing of all materials.

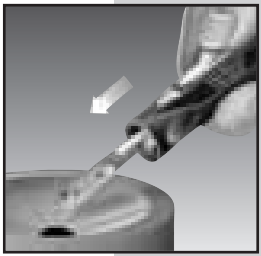
STEP 1 Remove the Sampler Cap.

Twist the cap counterclockwise. (Optional: Replace the protective disk on the used lancet by placing it on a hard surface and pushing the lancet tip into the disk.)

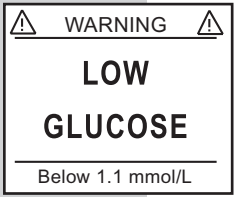


STEP 2 Eject the Lancet.

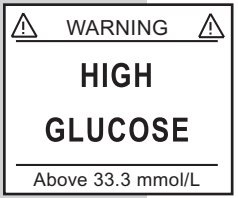
Point the sampler down and away. Push forward on the ejection/cocking control and eject the lancet directly into a container for sharp objects. Used test strips can go into the same container. Return the ejection/cocking control to the middle position. Replace the cap.



Special Messages



The OneTouch® UltraSmart™ Meter displays results between 1.1 mmol/L and 33.3 mmol/L. If your test result is lower than 1.1 mmol/L, "LOW GLUCOSE" will appear on the meter display. **This indicates severe hypoglycaemia (low blood glucose). You should immediately treat this condition as recommended by your healthcare professional.**



If your blood glucose test result is above 33.3 mmol/L, "HIGH GLUCOSE" will appear on the meter display. **This indicates severe hyperglycaemia (high blood glucose). You should recheck your blood glucose level. If "HIGH GLUCOSE" again appears on the display, call your doctor immediately.**

When your blood glucose test result is outside the range of 5.0–7.2 mmol/L or the personal glucose range you set in custom meter set-up, the meter will prompt you to add a comment.

(Example)

When your blood glucose test result is in the range of 13.3 mmol/L to 33.3 mmol/L "Check Ketones" will appear on the meter display. **This message does not mean that the system detected ketones but that testing with a ketone test strip may be advisable. Consult your healthcare professional about when and how to test for ketones.** "Comment? Press OK" will also appear.

(Example)

When your blood glucose result is between 1.1 mmol/L and 3.9 mmol/L, "Do you need a snack?" will appear on the display with the test result, reminding you that a meal or snack may be necessary.

(Example)

COMPARING METER AND LABORATORY RESULTS

OneTouch® UltraSmart™ Meter test results and laboratory test results are both expressed in plasma-equivalent units. However, your meter result may differ somewhat from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. Your OneTouch® UltraSmart™ Meter glucose value should agree with a laboratory measurement within ±20% most of the time under normal conditions. A result within that range is considered accurate when testing with the OneTouch® UltraSmart™ Meter. However, results can differ by more than ±20% in some situations. See the OneTouch® Ultra™ Test Strip package insert for typical accuracy and precision data and for important information on "Limitations of Procedure."

To make an accurate comparison between meter and laboratory results, follow these guidelines:

Before you go to the lab:

- Perform a control solution test to make sure the meter is working properly.
- It is best to fast for at least eight hours before doing comparison tests.
- Take your meter with you to the lab.

While at the lab:

- Make sure that the meter test and the lab test are performed within 15 minutes of each other.
- Wash your hands before obtaining a blood sample.
- Use only fresh capillary blood.

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.[1] In addition, if you have eaten recently, the blood glucose level from a fingerstick can be up to 3.9 mmol/L higher than blood drawn from a vein (venous sample) used for a lab test.[2] Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low haematocrit) or the loss of body fluid (severe dehydration) may also cause a meter result to be different from a laboratory result.

References

1. Surwit, R.S., and Feinglos, M.N.: *Diabetes Forecast* (1988), April, 49–51.
2. Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R. (ed.), *Tietz Textbook of Clinical Chemistry.* Philadelphia: W.B. Saunders Company (1994), 959.

CARING FOR YOUR SYSTEM

Maintenance

Your OneTouch® UltraSmart™ Meter does not require special maintenance or cleaning. Take care to avoid getting dirt, dust, blood, control solution, or liquids inside the meter through the test port or data port. LifeScan recommends that you store the meter in its carrying case after each use.

A cloth dampened with water and mild detergent can be used to wipe down the outside of the meter. Your OneTouch® UltraSmart™ Meter is a precision instrument. Please handle it with care.

OneTouch® UltraSoft™ Sampler

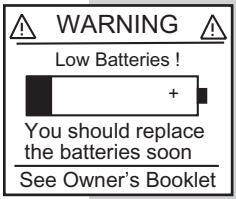
Clean the sampler and caps with soap and water as needed. To disinfect the sampler, prepare a disinfectant solution of one part household bleach to 10 parts water. Dampen a cloth with this solution and wipe the sampler thoroughly. **Soak only the cap or caps** for at least 30 minutes in the disinfectant solution. Do not soak the sampler in liquid. Rinse the sampler and cap with water and dry thoroughly.

Batteries

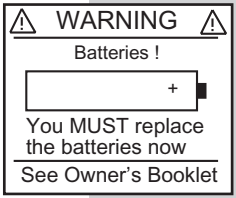
Your OneTouch® UltraSmart™ Meter comes with two AAA alkaline batteries already installed. The batteries will provide you with enough power to perform up to 540 tests, depending on backlight use. When replacing the batteries, use only two AAA alkaline batteries.

The meter will alert you when the power is getting low by displaying two different messages:

1. When this message appears on the display, the batteries are low and should be replaced as soon as possible. The backlight will no longer turn on.

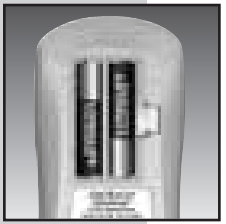


2. When this message appears on the display, you cannot test, enter data in your meter logbook, or use the FastFacts™ feature until you change the batteries.



To replace the batteries, first turn off the meter. Turn the meter over and locate the battery compartment.

1. Open the battery compartment by pressing the tab to the left and lifting the battery compartment cover to remove it.



2. Remove the old batteries. Insert two AAA alkaline batteries. Plus (+) and minus (–) signs will guide you in placing the batteries.

3. Place the battery compartment cover over the battery compartment. Push down on the battery compartment cover until you hear the tab click into place.

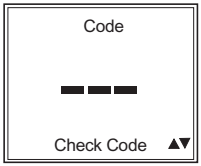
Note:

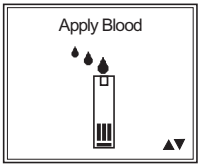
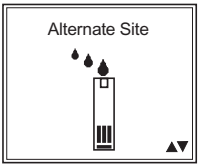
- *Replacing the batteries **does not** affect the meter logbook. However, the date and time settings may need to be updated.*
- *The first time you turn on the meter after replacing the batteries, the meter will go into the Set-up mode. At this time, you may update the date and time settings.*

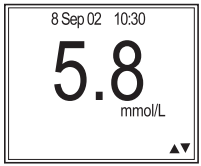
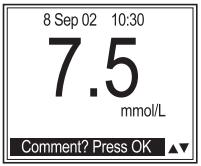
DISPLAY MESSAGES

Following is a summary of display messages and symbols.

MESSAGE	WHAT IT MEANS	ACTION
	Initial display that appears whenever the meter is turned on. It indicates that the system has performed several self-checks to confirm that the meter is working properly.	If, at any time during the life of the meter, these graphics appear to be different, call your local LifeScan Customer Service office. See back cover for contact information.

MESSAGE	WHAT IT MEANS	ACTION
	New meter not coded or meter lost power briefly and entered set-up mode.	See *Coding the Meter*, pages 10–12.
 (Example)	This is the code number stored in the meter.	Make sure that this code number matches the code number on the vial of the test strips you are using.
 (Example)	The meter is prompting you to confirm that the code number on the meter display matches the code number on the vial of test strips you are currently using.	Check to be sure the code number on the display matches the code number on the test strip vial. If they match, press OK to confirm the code number. If they do not match, scroll to the correct number using the Arrow button.

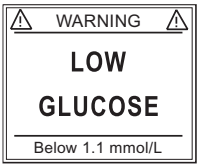
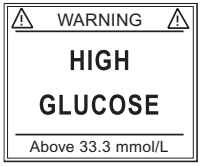
MESSAGE	WHAT IT MEANS	ACTION
	The system is ready to accept a blood sample from the fingertip.	You may now apply the fingertip blood sample.
	The system is ready to accept a blood sample from the arm.	You may now apply the arm blood sample.
	The system is ready to accept a control solution sample.	You may now apply the control solution.

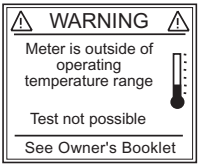
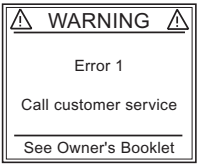
MESSAGE	WHAT IT MEANS	ACTION
	Five-second countdown. After the countdown, the meter will display the test result.	None required.
 (Example)	A blood glucose test result in mmol/L.	None required.
 (Example)	A test result outside of your target range with a message prompting you to add a comment.	If you wish to add a comment, press OK. (See page 74).

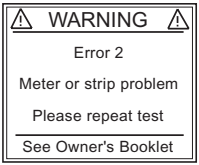
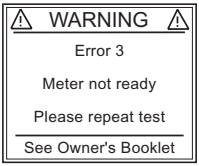
MESSAGE	WHAT IT MEANS	ACTION
 (Example)	A blood glucose test result in the range of 13.3 mmol/L to 33.3 mmol/L with a suggestion to check your ketone levels.	Follow the instructions of your healthcare professional regarding ketone testing.
 (Example)	When your blood glucose result is between 1.1 mmol/L and 3.9 mmol/L, “Do you need a snack?” will appear on the display with the test result, reminding you that a meal or snack may be necessary.	Follow the instructions of your healthcare professional.

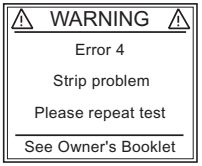
WARNINGS AND ERROR MESSAGES

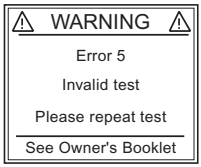
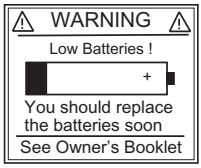
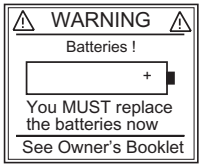
These messages help to identify certain problems but do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing a warning or an error message. In the event of a problem, refer to the information under ACTION. Assistance is available from your local LifeScan Customer Service office. See back cover for contact information.

MESSAGE	WHAT IT MEANS	ACTION
	You may have a very low blood glucose level, lower than 1.1 mmol/L.	You should treat this condition according to the recommendations of your healthcare professional.
	You may have a very high blood glucose level, exceeding 33.3 mmol/L.	You should recheck your blood glucose level. If “HIGH GLUCOSE” appears again on the display, call your doctor immediately.

MESSAGE	WHAT IT MEANS	ACTION
	The meter has detected that the temperature is outside the system operating range. Do not perform a test until the meter and test strips reach a temperature within the operating range of 6–44ºC.	Perform the test after the meter and test strips have reached a temperature within the operating range.
	There may be a problem with the meter or the meter may need to be reset.	To reset the meter, you must turn the meter off and enter set-up mode (see pages 54-57). Reset the language, time, and date. You must also reset the meter code to match the code on the test strip vial. If you continue to get an Error 1 message, do not use the meter. Call your local LifeScan Customer Service office. See back cover for contact information.

MESSAGE	WHAT IT MEANS	ACTION
	Error message that could be caused by either a used test strip or a problem with the meter.	Repeat the test with a new test strip. Refer to page 7–8 for test strip information. If the error message persists, contact your local LifeScan Customer Service office. See back cover for contact information.
	Error message that indicates that the blood or control solution sample was applied before “Apply Blood,” “Alternate Site,” or “Control Solution” appeared on the display.	Repeat the test with a new test strip. Apply the blood or control solution sample only after “Apply Blood,” “Alternate Site,” or “Control Solution” appears on the display. Refer to pages 30–31 for information on sample application.

MESSAGE	WHAT IT MEANS	ACTION
	1) You may have high glucose and have tested in an environment near the low end of the system's operating temperature range 6–44ºC.	If you tested in a cool environment, repeat the test in a warmer environment with a new test strip.
	2) There may be a problem with the test strip. For example, it may have been damaged or moved during testing.	If you were testing in a normal or warm environment, repeat the test with a new test strip. (See pages 7–8 for test strip information.)
	3) The sample was improperly applied.	If you applied the blood incorrectly, review pages 30–31, on blood application and repeat the test with a new test strip. If the error message appears again, contact your local LifeScan Customer Service office. See back cover for contact information.

MESSAGE	WHAT IT MEANS	ACTION
	Error message that indicates the meter has detected a problem with the test strip. Possible causes are test strip damage or an incompletely filled confirmation window.	Repeat the test with a new test strip. Refer to pages 30–31 for information on sample application.
	The battery sign appears on the display. The power of the batteries is getting low. The backlight will be disabled when the battery sign is displayed. You can complete about 100 more tests from the time this symbol first appears.	Test results will still be accurate, but replace the batteries as soon as possible.
	The power of the batteries is too low to run a test.	Replace the batteries at once.

If the meter does not turn on after inserting a test strip or the display is not active:	
POSSIBLE CAUSES	**WHAT TO DO**
Need batteries.	Replace the batteries.
No batteries or batteries incorrectly installed.	Check that the batteries are correctly installed.
Test strip inserted incorrectly. (For example, upside down, backward, or incompletely.)	Insert the test strip correctly with the contact bars end first and facing up. Push it in until it will go no further.
Defective meter or test strip.	Call your local LifeScan Customer Service office. See back panel for contact information.

If the test does not start after applying the sample:	
POSSIBLE CAUSES	**WHAT TO DO**
Insufficient blood sample.	Repeat the test with a new test strip and a larger sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic shutoff (three minutes after inserting a test strip).	Repeat the test with a new test strip; apply sample only after "Apply Blood", "Alternate Site" or "Control Solution" appears on the display.
Defective meter.	Call your local LifeScan Customer Service office. See back panel for contact information.

METER SET-UP

Note:

- *You need not change any of the meter settings in order to begin testing. Simply insert a test strip to turn on the meter and proceed with the test. (See pages 19–35.)*
- *It is important that the time of day is correct and that your medication set up and mealtimes are set according to your personal daily schedule. Otherwise, some FastFacts™ information will not be correct.*

The OneTouch® UltraSmart™ Meter was preset at the factory with the date, time and display language. The glucose units are preset at the factory and cannot be changed. You must enter Set-up mode to:

- Change the date, time, or display language. (Glucose units cannot be changed.)
- Customize the meter features that allow you to track diabetes pills, insulin doses, and insulin pump information.
- Customize advanced features such as averages, meal schedule, target glucose range, and hypoglycaemia level.

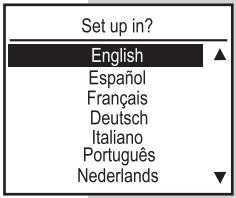
Entering Basic Set-up Mode

To enter Set-up mode, press and hold down the Back button and the OK button at the same time for three seconds.

This message will appear briefly. The language menu will follow immediately. The meter is now in Basic Set-up mode. The SmartButtons™ cannot be used while you are in Set-up mode. (You may still test at any time simply by inserting a test strip.)

Selecting Display Language

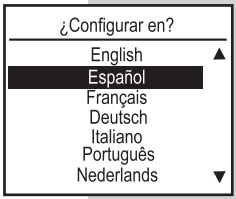
The meter is set at the factory to use English.



To use English, press OK OK.

You may choose one of six other languages in Set-up mode.

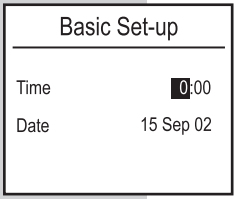
Spanish (Español)	Italian (Italiano)
French (Français)	Portuguese (Português)
German (Deutsch)	Dutch (Nederlands)



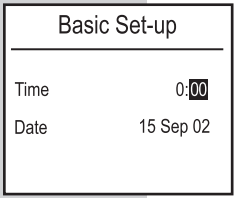
To change the language, use the Arrow button to scroll to the language. With your language choice highlighted, press OK OK.

Setting Date and Time

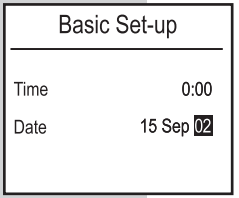
After the language has been set, the meter will display the factory-set time and date. If the date and/or time are incorrect, follow these steps in Set-up mode. (See page 54, *Entering Basic Set-up Mode*.)



Begin by setting the hour. Use the Arrow button to scroll to the correct hour. Press OK.



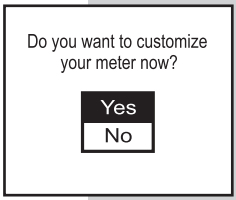
Use the Arrow button to scroll to the correct minutes and press OK.



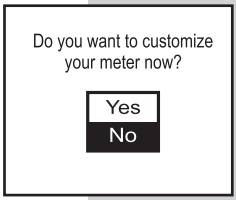
Then select the correct year and press OK. Repeat these steps to select the month and day.

Note: It is important to select the correct date and time or your logbook may not show the most recent result first.

The meter will ask you if you wish to customize it. Select "Yes" (press OK) if you wish to customize other meter settings. (See *Custom Meter Set-Up*, page 58.)



If you select "No" (use Arrow button and press OK), the meter will turn off and continue to use the factory settings.

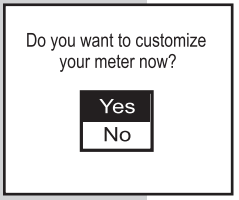


CUSTOM METER SET-UP

The OneTouch® UltraSmart™ Meter has a number of optional features that you may use to track all your diabetes information. The Set-up menu allows you to customize the meter with your personal diabetes management plan including the type and amount of medication you take; your target glucose range; your usual meal times, and much more information.

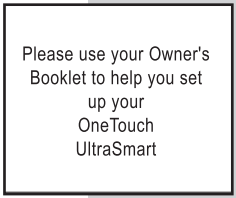
Note: If you are starting the custom set-up sequence with the meter off, you must press the Back button and the OK button at the same time to turn on the meter. To access the Set-up menu, you must go through Basic Set-up first. (See page 54–57.)

Set-up Menu

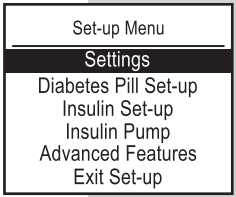


After completing Basic Set-up, choose "Yes" to customize your meter.

You should have your OneTouch® UltraSmart™ Owner's Booklet available to refer to while customizing the meter.



"Set-up Menu" will appear on the display with a list of options. "Settings" will be highlighted.



Following is a summary of meter settings:

Meter Settings		
OPTION	**FACTORY**	**CUSTOM**
Settings:		
Time Format	24-hour	AM/PM
Date Format	DD/MM/YY	MM/DD/YY
Begin Week	Monday	Monday
Cholesterol Units	mmol/L	mg/dL
Beep	ON	OFF
Diabetes Pill Set-Up:	Pill A Pill B	Pill A to E or Customize with OneTouch™ Software
Insulin Set-Up:	InsulinA InsulinB	Rapid, Regular, Lente, NPH, Ultralente, Premixed, Other, InsulinA, InsulinB, InsulinC, Customize with OneTouch™ Software
Insulin Pump:	OFF	ON

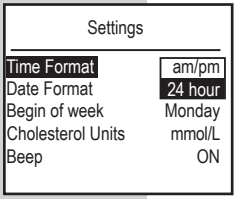
Meter Settings *(continued)*		
OPTION	**FACTORY**	**CUSTOM**
Advanced Features:		
Averages	14 days	7, 30, 60, 90 days
Schedule	Pre-set (see pages 70–71.)	Personal
Glucose Range		
Before Meal	5.0–7.2 mmol/L	Personal
After Meal	——	Personal
Hypo Level	3.9 mmol/L	Personal

Settings

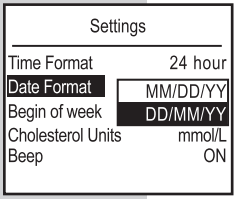
"Settings" include:

- Time format
- Date format
- Beginning of the week
- Cholesterol unit of measure
- Beep on or off

To change any of these settings, press OK with "Settings" highlighted on the Set-up Menu. Each setting has a pop-up menu of available choices. You must review all five settings and choose one for each. Press OK to save them. After setting the last setting, the Beep, press OK to save your settings before turning off the meter or allowing it to turn off automatically.

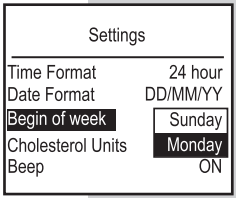


You may set your meter to use a 12-hour am/pm time format or a 24-hour military time format (24:00). Use the Arrow button to view the choices. Highlight your choice and press OK.

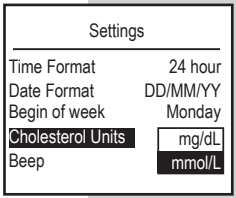


You may choose between the Month-Day-Year date format (e.g., July 5, 2002) or the Day-Month-Year format (e.g., 5 July 2002). Highlight your choice and press OK.

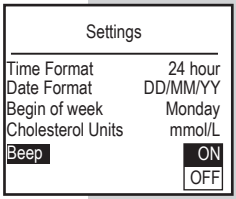
For record-keeping purposes you may begin your week on Sunday or Monday. Use the Arrow button to highlight your choice and press OK.



The cholesterol unit of measure may be either mg/dL (used in the U.S. and some European countries) or mmol/L (used in Canada and many other countries). Highlight your choice and press OK.

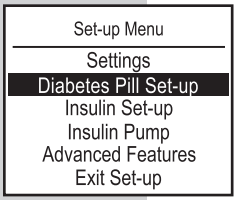


The meter was set at the factory to give audio signals (“beeps”) at key points in the test procedure. To keep the beeps, highlight ON and press OK. For silent meter operation, highlight OFF and press OK.

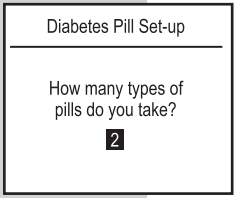


Diabetes Pill Set-up

You may record up to five types of diabetes pills. This feature helps you track when you have taken each of your medications. The names of the medications may be chosen from a menu (Pills A through E) or the brand or generic names entered using a personal computer and OneTouch™ Software*. If you do not customize your pill names, the factory settings of Pill A and Pill B will appear on your pill entry display.



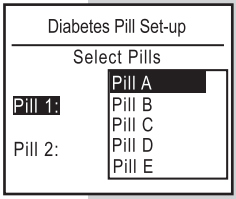
Using the Arrow button, scroll to "Diabetes Pill Set-up" and press OK.



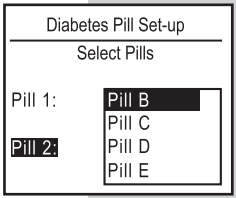
Enter the number of pill **types** you are taking (not the number of tablets you take each time). Scroll to the correct number and press OK. You can enter up to five types of pills. If you do not take pills or do not wish to use this feature, enter 0. If you enter 0, the diabetes pill choices will not appear on the display when you press the medication SmartButton™.

* You can download OneTouch™ Software online. See back cover for website address.

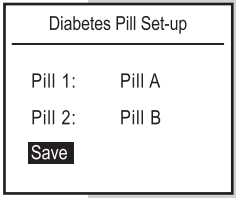
A pop-up menu of pill choices will appear on the display. Use Pills A-E to label up to five pills. For example, if you take glipizide pills you could label them as “Pill A.” You can enter the actual pill names using OneTouch™ Diabetes Management Software. Using the Arrow button, scroll down to your choice and press OK.



“Pill 2” will be highlighted automatically. To enter a second type of diabetes pill, choose Pill B-E to describe the second pill and press OK. Repeat these steps to enter other pill types.

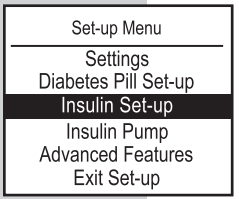


If you have completed your diabetes pill choices, select “Save” and press OK. If necessary, press the Back button to reenter pill types.

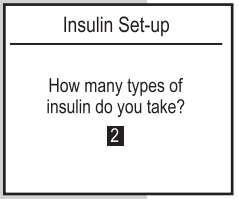


Insulin Set-up

You can record your daily insulin usage by type of insulin and number of units for up to three different insulin types. Insulin types may be chosen from a menu of ten choices. Eleven other insulin types (up to eight characters in length) may be entered using a personal computer loaded with OneTouch™ Software. If you do not customize your insulin names, the factory settings of Insulin A and Insulin B will appear on your medication entry display.



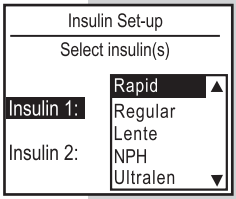
Choose Insulin Set-up on the Set-up menu and press OK.



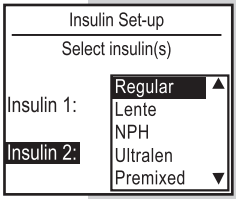
Scroll to the number of insulin types you use and press OK. You can choose up to three types of insulin. If you do not wish to use this feature, enter 0. If you select 0, no insulin names will appear on the display when you press the medication SmartButton™.

To enter your first insulin type, review the menu choices:

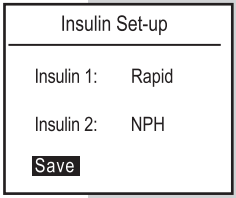
Rapid	Premixed
Regular	Other
Lente	InsulinA
NPH	InsulinB
Ultralente (Ultralen)	InsulinC



Use the Arrow button to scroll through the menu. Press OK on your selection. Repeat these steps until all of your insulin types have been selected.

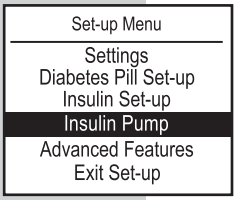


To save your insulin choices, use the Arrow button to scroll to “Save” and press OK.

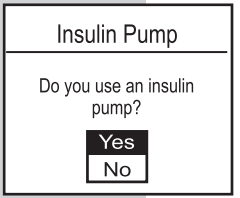


Insulin Pump Set-up

If you are using an insulin pump, the OneTouch® UltraSmart™ Meter allows you to store current information about your pump. The factory setting will be set as if you do not use a pump.



Select "Insulin Pump" on the Set-up menu and press OK OK.



Select "Yes" to use this feature and press OK OK. You can then use this feature to enter your bolus doses and total insulin amounts. If you do not use an insulin pump or you do not wish to set up this feature now, select "No" and press OK OK. After choosing Yes or No, the meter will return you to the Set-up menu.

Advanced Feature Set-up

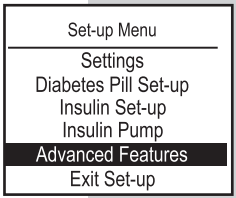
The final item on the Set-up menu is called "Advanced Features." These features allow you to:

- Choose the number of days included in your glucose test averages
- Input your usual meal schedule
- Include your target glucose range
- Customize your hypoglycaemic level

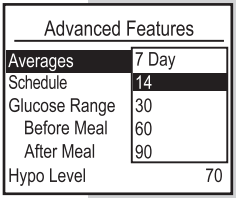
ADVANCED FEATURES	FACTORY	CUSTOM
Averages	14 days	7, 30, 60, 90 days
Schedule	Pre-set (see pages 70–71.)	Personal
Glucose Range		
Before Meal	5.0–7.2 mmol/L	Personal
After Meal	——	Personal
Hypo Level	3.9 mmol/L	Personal

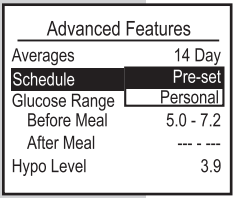
Select “Advanced Features” as follows:

Select “Advanced Features” and press OK OK.

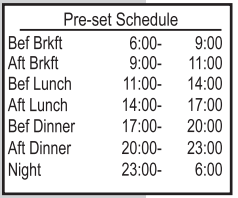


The first advanced feature is averages. Each time you test, the meter is set to display a 14-day average of your glucose tests along with your test result. You can change the number of days that make up this average to the last 7, 14, 30, 60, or 90 days. Scroll to the number of days you want to include in your test display average and press OK OK. You can still look at averages for all five time periods by reviewing your meter logbook.

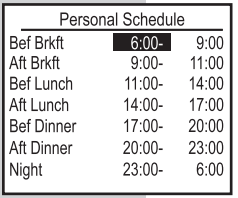




Next, the meter will prompt you to select time periods for your usual meal schedule. When you set this feature all of your test results will be tagged with the mealtime. To view a pre-set meal schedule select “Pre-set” and press OK.



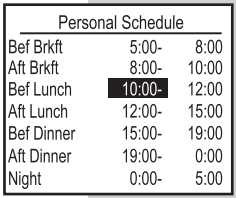
The pre-set schedule will appear on the display. Both before and after mealtimes are pre-set. Whenever you test, these mealtimes will be recorded in the logbook whether or not you are eating on schedule. To use the pre-set schedule, press OK.



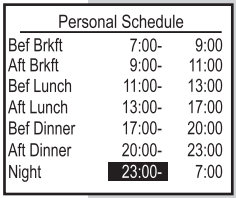
To personalize your schedule, press the Back button, choose “Personal,” and press OK. To change all or some of the personal meal schedule:

- Scroll through each mealtime
- Select the correct hours and minutes (in 15-minute steps)
- Press OK.
- If you make a mistake, press the Back button to return to the top of the schedule and make corrections.

You will only be able to set beginning or start times for each mealtime. End times will change to match the start time of the next time period. For example, if your lunch is usually at 12 noon, “Bef Lunch” could be 10:00am to 12:00pm.



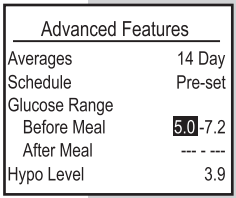
After changing the times, press OK to save your personal schedule.

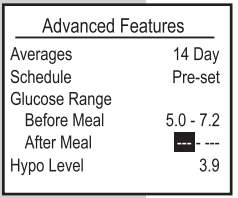


Note:

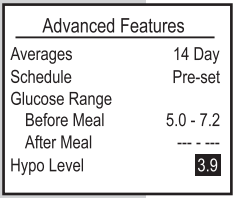
- *It is important that the time of day is correct and that your medication set up and mealtimes are set according to your personal daily schedule. Otherwise, some FastFacts™ information will not be correct.*
- *You have the option to modify the mealtime for any test if necessary.* *See page 75.*

Next, the meter will prompt you to set a before-meal blood glucose range. The meter is pre-set to 5.0–7.2 mmol/L. To use this range, press OK twice. You may change this range to one recommended by your healthcare professional. To change the lower and upper ends of the range in 0.1-mmol/L steps, scroll to the correct numbers and press OK.

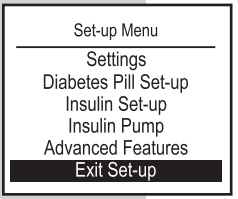




If you have an after-meal glucose range recommended by your healthcare professional and wish to enter it, use the Arrow button to scroll to your target numbers and press OK.



The factory-set hypoglycaemia level is 3.9 mmol/L. If your healthcare professional has advised you to use a different level, scroll to the correct number and press OK.



To exit Set-up mode, choose “Exit Set-up” and press OK.

YOUR METER LOGBOOK

The OneTouch® UltraSmart™ Meter logbook is the meter memory. It stores over 3,000 records. The SmartButtons™ allow you to enter information about your diabetes management plan, including exercise, health, medication, and food.

Comments

Information that you store in your meter logbook along with a test result is called a "comment." Following is a list of comments that you may store.

DEFINITION	COMMENTS ON GLUCOSE RESULTS		
Exercise	Before	During	After
Health	Stress Menses	Feel Hypo Vacation	Illness Other
Medication	None		
Food	Before Breakfast Before Lunch Before Dinner Night	After Breakfast After Lunch After Dinner	

Rules for Adding Comments

Following are rules for adding comments in your logbook.

- If you wish to add a comment to a test result, press OK while viewing the test result.
- Use the Arrow button to scroll up and down through the various menus and choices.
- Use the OK button to make a selection.
- You must save your selections by using the Arrow button to highlight "Save" and pressing OK.
- Prior to seeing the logbook display, you may press the Back button and return to the previous display to review or edit the information you have stored.
- To remove an entry, select [- - -] from the menu.
- Press and hold the Back button to turn off the meter.
- After one minute of no activity, the meter will turn off automatically. To go back into the logbook, press the FastFacts™ Smartbutton™. With "Logbook" highlighted, press the OK button.

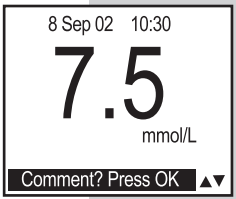
You can comment on a test as occurring before or after a meal, how you are feeling at the time of the test, and if there was any exercise involved. In all, you may add one food comment, one exercise comment, and up to six health comments to a test result.

How to Add a Comment

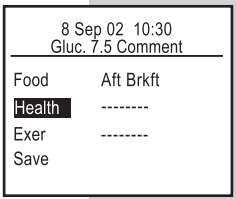
Following are the steps you take to comment on a test result. The meter will automatically prompt you

to add a comment when you have a test result outside of your glucose target range. You can, however, add a comment to a test result whether or not “Comment? Press OK” appears. In this example, we will comment on a test result with food, exercise, and health information.

With any test result (or test result with average) on the display, press the OK button OK. You will be able to add comments for food, health, and exercise.

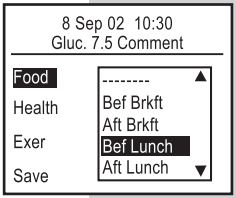


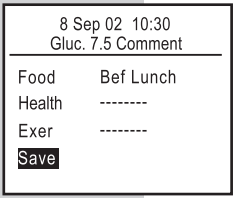
Health is always highlighted first since the food comment is automatically added based on your preset or personal schedule. (See Advanced Feature Set-up, pages 68–72.)



FOOD COMMENTS

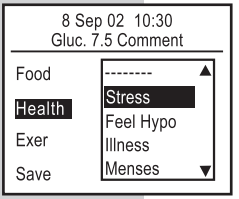
In this example we’ll use food. If you wish to change the food comment to a different mealtime, use the Arrow button to select “Food” and press OK OK. Use the Arrow button to select your food comment and press OK OK again. Your choices are Bef Brkft, Aft Brkft, Bef Lunch, Aft Lunch, Bef Dinner, Aft Dinner, and Night.





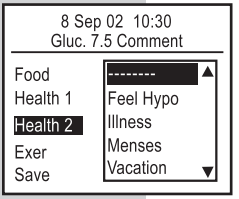
Once you select your mealtime, “Health” is automatically highlighted. If you are through commenting scroll to “Save” and press OK OK. If you do not press OK OK, your entries will not be saved.

HEALTH COMMENTS



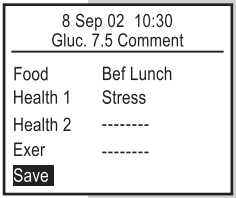
You can comment on the result with notes about your overall health at the time of the test. Press the OK button OK with “Health” highlighted. You may add up to six comments from this menu:

Stress	Menses
Feel Hypo	Vacation
Illness	Other



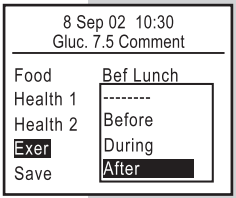
After adding your first health comment, “Health 2” will automatically appear on the display. To add additional health comments, press OK OK and select the comment from the menu. Note that your previous comment is no longer available.

When you have completed making comments, scroll to “Save” and press OK. If you do not press OK, your entries will not be saved.

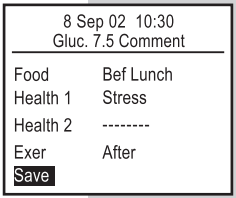


EXERCISE COMMENTS

You can comment on a test result as occurring before, during, or after exercise.



After you add the exercise comment, “Save” will automatically be highlighted. If you press OK, all of the comments you have entered will appear with the test result in the logbook.



Logbook Entries

"Logbook entries" are activities concerning exercise, health, medication, and food that are not associated with a test. **You do not have to perform a blood glucose test in order to add valuable diabetes information to your meter logbook.**

Using the SmartButtons™

The SmartButtons™ allow you to enter information about your diabetes management plan. There are SmartButtons™ for exercise, health, medication, and food. To make a logbook entry, press the appropriate SmartButton™ to turn on the meter and enter the menu for the type of entry.

Note: You may press any SmartButton™ to turn on the meter and move directly to the category.

Following is a list of logbook entries you can make.

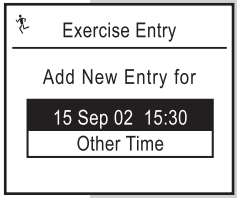
SmartButton™	LOGBOOK ENTRIES	
	Mild Moderate Hard	Duration *(enter length of time)*
	**Health Notes:** Stress Feel Hypo Illness	Menses Vacation Other
	Health Checks: Ketones HbA_{1c} Microalbumin Cholesterol Blood Pressure	Eye Exam Foot Exam Weight/Height Dr. Visit
	Pills *(1–5 and how many of each)* Insulin *(1–3 and units)* Insulin Pump	
	Carbs Calories	Fats Proteins

Rules for Logbook Entries

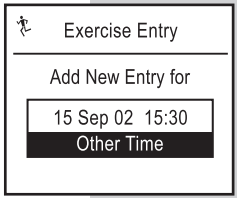
- If you wish to add a logbook entry, press a SmartButton™ to turn on the meter. The icon for the category you are choosing will appear in the upper-left-hand corner of the display and the title of the category will appear at the top of the display. If you press a SmartButton™ in error, either press another SmartButton™ or choose [- - -] from the selection menu.
- Before making a logbook entry, the time must be selected. Use the Arrow button to choose either the date and time displayed or "Other Time."
- Use the OK button to confirm your choices and the logbook display will appear. If no logbook display appears, your entries have not been saved.
- It is possible to enter the same logbook entry information more than once for a given date and time.
- To remove an entry, select [- - -] from the menu.
- Prior to seeing the logbook display, you may press the Back button and return to the previous display to review or edit the information you have stored.
- Press and hold the Back button to turn off the meter.

Entering the Date and Time

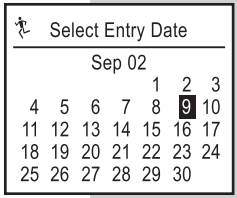
If the logbook entry is for the current date and time, press OK OK.



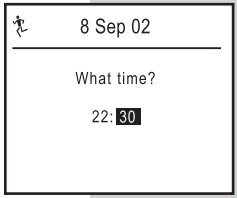
If the entry is for a previous date and time, select “Other Time” and press OK OK.



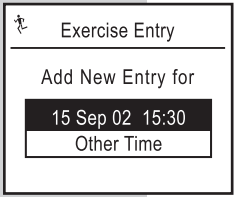
A calendar will appear on the display. Scroll to the correct month and day and press OK OK.



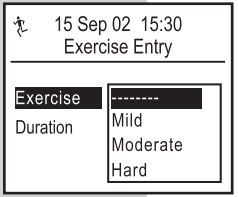
Record the time in hours and minutes and press OK OK. Then make your logbook entry.



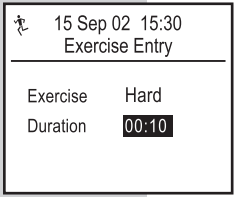
EXERCISE LOGBOOK ENTRIES



With the meter turned off, press the Exercise SmartButton™. These choices will appear on the display. Select the current date and time to add an exercise logbook entry at this time. Select “Other Time” if the logbook entry is for some time in the past and press OK OK.

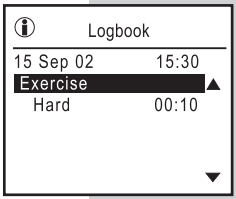


Note that the date and time is correct for your entry. You may rate the exercise you performed as mild, moderate, or hard. Press OK OK.



Then record the duration of the exercise to the nearest five minutes. Press OK OK to save the logbook entry.

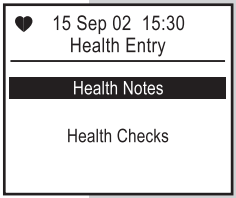
The exercise logbook entry you recorded will be saved this way in your meter logbook. You may also scroll through the logbook to view previous entries. Press OK while you are in the logbook to edit or delete the highlighted entry (see pages 101–103).



HEALTH LOGBOOK ENTRIES

After selecting the date and time, two menu choices will appear. You may make health logbook entries for the current time or another time (see page 81). "Health Notes" allow you to enter information about your day.

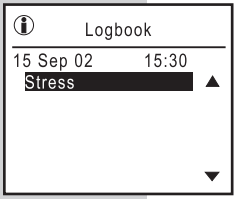
Select "Health Notes" and press OK.



Choose from this menu:

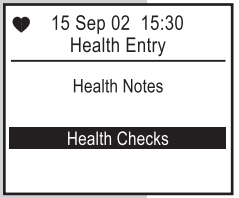
Stress	Menses
Feel Hypo	Vacation
Illness	Other

Press OK to save and view the logbook entry.



The logbook entry with your Health Note will be saved this way in the logbook.

"Health Checks" are another type of health logbook entry that you can record. Health Checks include home and laboratory tests as well as doctors' examinations. All of this information is vital to a good diabetes management plan. Health Checks may be stored in your meter logbook at the time they occur or at some later time.



To record check-up information, select "Health Checks" and press OK.

Choose from this menu:

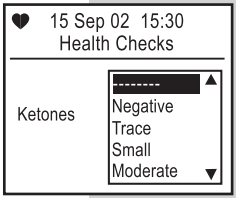
Ketones	Eye Exam
HbA_{1c}	Foot Exam
Microalbumin	Weight/Height
Cholesterol	Dr. Visit
Blood Pressure	

Many Health Checks allow you to input numeric values. In order to adjust the number, use the Arrow button to scroll up and down. Press OK to save your selection and return to the Health Checks menu. Following are sample entries under “Health Checks.” When you have completed your Health Check entries, scroll to “Exit Health Checks” and press OK. Your Health Check entry will be saved in the meter logbook.

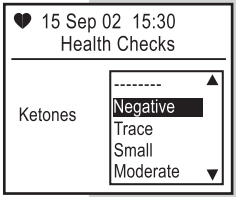
Ketones

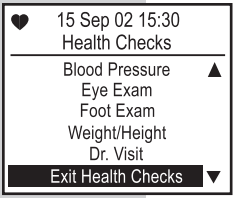
When you check ketones, you can enter the results in your logbook. Results may be:

Negative	Moderate
Trace	Large
Small	

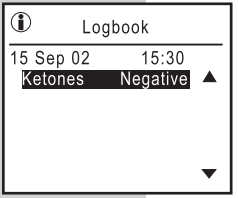


Scroll to your selection and press OK.





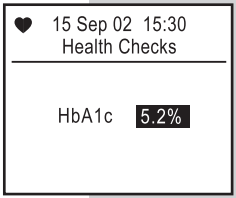
You will return to the Health Checks menu with “Exit Health Checks” highlighted. If you are finished with your entries, press OK OK with “Exit Health Checks” highlighted. If you wish to enter other Health Checks, use the Arrow button to scroll to the additional menu choice and press OK OK.



Your entry will be saved this way in the logbook.

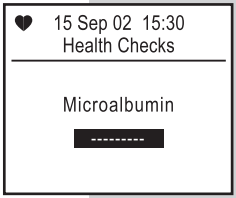
HbA_{1c}

Tests for haemoglobin A_{1c}, also known as HbA_{1c} or A_{1c}, can be recorded from 4 to 15% in .1 steps. When entering data, the value will start at the value you last saved. Scroll to your selection and press OK OK.

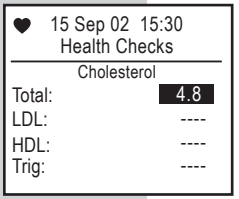


Microalbumin

You can enter your test results for microalbumin as normal, positive, or a numeric value from 1 to >1000. When entering data, the value will start at the value you last saved. Scroll to your selection and press OK OK.



Cholesterol



You may enter cholesterol test results in 1-mg/dL (0.1-mmol/L) steps for:

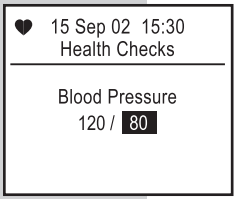
- Total (up to >25.9 mmol/L)
- LDL (up to >13.0 mmol/L)
- HDL (up to >13.0 mmol/L)
- Triglycerides (up to >33.9 mmol/L (Trig))

To advance to the next cholesterol entry, press OK OK. To return to a previous cholesterol entry on this display, press the Back button.

Note: When entering data, the value will start at the value you last saved.

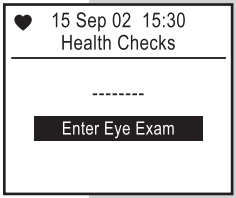
Blood Pressure

The logbook range for the first number (systolic) is 80–200 mmHg. The range for the second number (diastolic) is 40–150 mmHg. Both are in 1-mmHg steps. Blood pressure (B.P.) above or below these ranges will appear on the display as - - - and will not be recorded in the logbook.



When entering data the value will start at the value you last saved.

Eye Exam

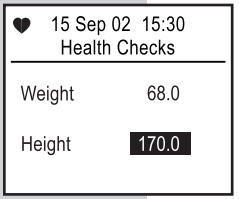


To record an eye examination, select "Enter Eye Exam" and press OK OK.

Foot Exam

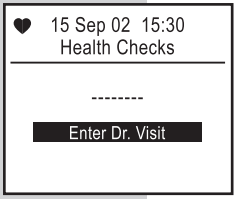
To record a foot examination, select "Enter Foot Exam" and press OK OK.

Weight/Height



Enter your weight in 0.5 kg steps and your height in 0.5 cm steps. When entering data, the value will start at the value you last saved.

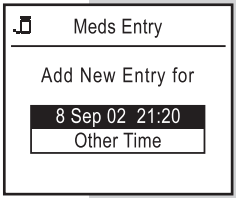
Doctor Visit



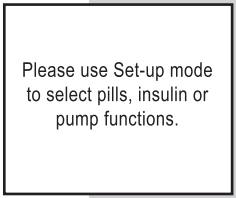
To record the date of your last visit to the doctor, select “Enter Dr. Visit.”

MEDICATION LOGBOOK ENTRIES

Press the Medication SmartButton™ to access the menu. You may track your diabetes pills, insulin types and dosages, and insulin pump information. Select the current date and time or "Other Time." (See page 81.)

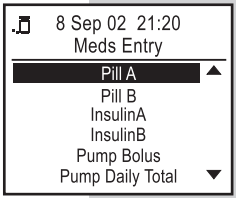


If you entered 0 pills, 0 insulin, and "No" for pump in the Set-up mode, this message will appear. To select your medications return to Set-up mode. (See *Custom Meter Set-up Sequence*, pages 58–72.)

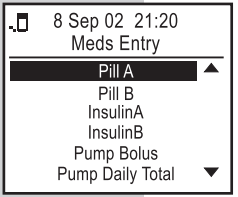


Medication Menu

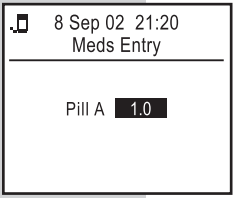
The medication menu reflects your input in the Set-up mode. (See pages 64–68.) If you entered diabetes pills, insulin, and/or insulin pump information, it will appear on the display as in this example.



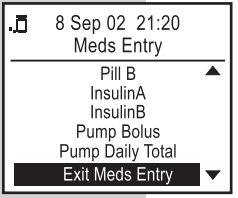
Diabetes Pills



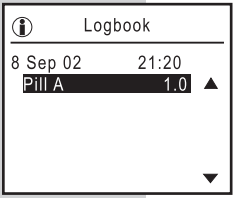
To enter your diabetes pills, select the pill you have taken and press OK OK.



Enter the number of pills you have taken (in 0.5- or one-half pill steps) and press OK OK. When entering data, the value will start at the value you last saved.



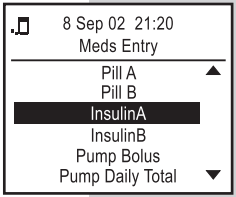
After your medication logbook entry, select “Exit Meds Entry” and press OK OK or select another item from the menu.



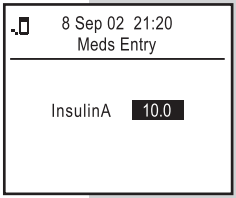
The logbook entry will be saved this way in your meter logbook.

Insulin Dosages

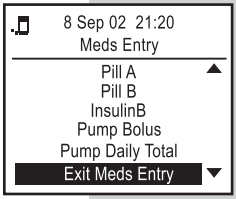
Enter an insulin dosage by highlighting an insulin type and press OK OK.



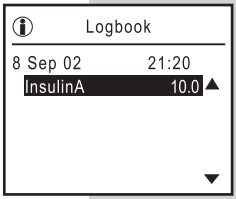
Then record the units of insulin. The meter was set at the factory to record units in 0.1 increments. When entering data, the value will start at the value you last saved.



If you wish to record a second insulin, choose from the list, and then enter the number of units. Repeat these steps as needed. After completing your insulin logbook entry, select “Exit Meds Entry” and press OK OK.

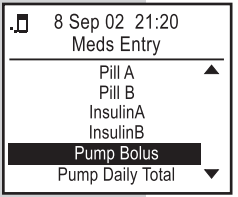


The insulin dosage will be saved this way in your meter logbook.

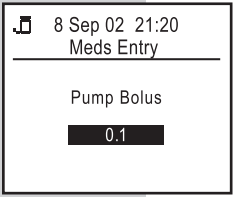


Insulin Pump

You can enter insulin pump information as bolus entries or as a daily total.

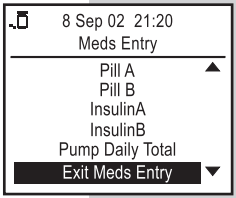


If you are entering bolus information, select “Pump Bolus” and press OK .

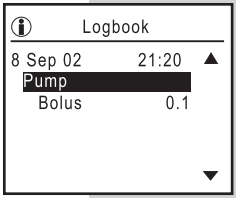


Then enter the units in 0.1 steps and press OK . When entering data, the value will start at the value you last saved.

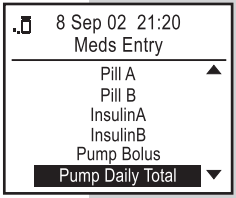
If you have completed your medication logbook entry, select “Exit Meds Entry.”

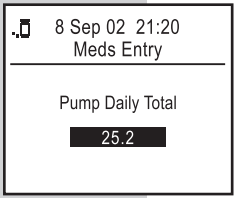


The dosage will be saved this way in your meter logbook.

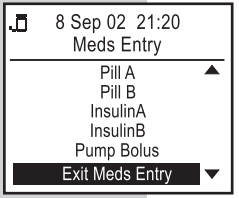


To enter your pump total for the day, scroll to “Pump Daily Total” and press OK.

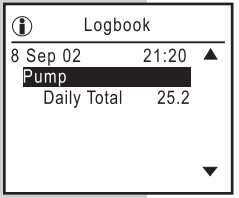




Use the Arrow button to scroll to the number of units you have taken over the past 24 hours and press OK. When entering data, the value will start at the value you last saved.



When you have completed your medication logbook entries, select "Exit Meds Entry."



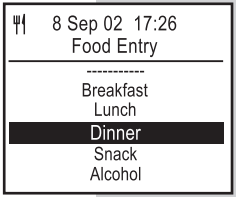
Your daily pump total will be saved this way in your meter logbook.

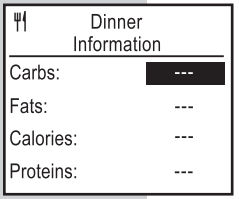
FOOD LOGBOOK ENTRIES

Food and blood glucose levels are closely linked. Logbook entries allow you to keep track of important nutritional information for each meal or snack by type of nutrient.

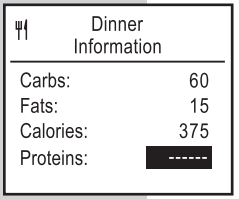
Press the Food SmartButton™ and select either the current date and time or "Other Time."

Then enter the type of meal from the meal menu. You may also record alcohol usage.



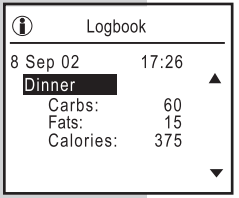


You may enter carbohydrates (carbs), fats, and proteins in the range of 0 to 250 in 1-unit steps. Carbohydrates may be entered as units or grams, whichever you prefer. Calories may be entered in 5-unit steps in the range of 0 to 2550. Use the Arrow button to change the units for each item. If you do not wish to enter units for an item, select - - - and press OK. **Do not enter 0 because it will be included in your FastFacts™ averages. (See page 104.)**



Press OK to advance to the next nutrient. To return to a previous nutrient, press the Back button.

Note: When entering data, the value will start at the value you last saved.



Your food logbook entry will be saved this way in the meter logbook.

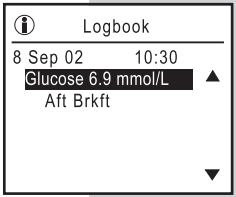
Adding, Changing, or Deleting Logbook Information

Step 1. Press the FastFacts™ button to enter the FastFacts™ menu.

Step 2. Select "Logbook" from the FastFacts™ menu and press OK. The most recent entry in your logbook will appear on the display.

Step 3. Use the Arrow button to scroll through your logbook entries.

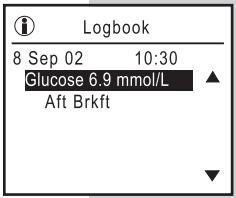
Note the location of the highlight in the logbook display. Note also on the right-hand margin the arrows (▲ ▼). They indicate the direction you may scroll through your logbook.

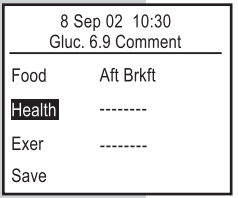


Step 4. Press OK to edit (add to or change) or delete logbook information.

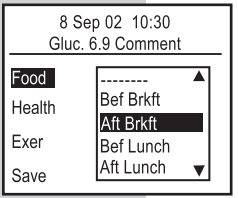
EDITING OR DELETING TEST COMMENTS *(Example)*

To edit or delete a comment, be sure the highlight is on the glucose test result to which the comment is attached. Press the OK button. (See page 101 for logbook entry example.)

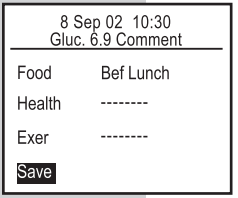




To change the mealtime, scroll to “Food” and press OK OK.

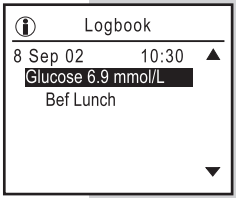


Scroll to the desired mealtime and press OK OK again.



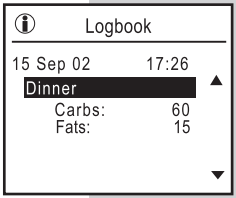
You may edit other comments at this time. To delete a comment, scroll to - - - and press OK OK. When you have completed editing the comments, scroll to “Save” and press OK OK.

Your edited comment will appear this way in your meter logbook.

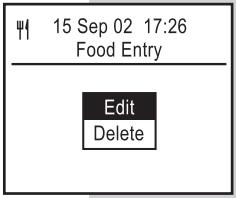


EDITING OR DELETING LOGBOOK ENTRY *(Example)*

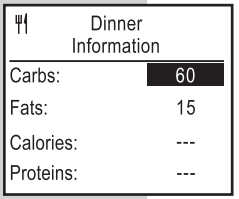
All logbook entries are edited or deleted in the same way. Use the Arrow button to highlight the logbook entry you wish to change and press OK.



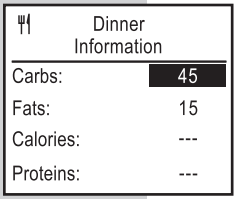
Press OK to edit.



Make sure the icon, date and time, and description are correct. (If you make an error, press the Back button to return to the menu.) Press OK on the selected mealtime. If you wish to change the entry to another mealtime, scroll to the mealtime and press OK .

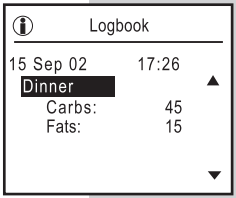


To keep the entry as it is, press OK .

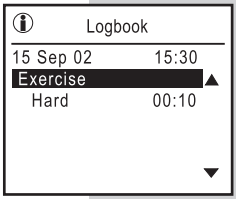


To change the entry, use the Arrow button and press OK .

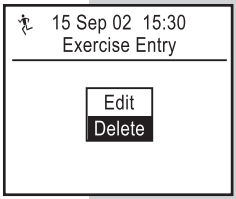
The edited entry will appear this way in your meter logbook.



To delete an entry, highlight the entry and press OK OK.



Use the Arrow button to select "Delete" and press OK OK.



Your entry will be deleted from the logbook.

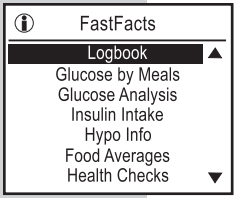
OneTouch® UltraSmart™ FastFacts™ FEATURE

FastFacts™ Menu

Enter FastFacts™ by pressing the FastFacts™ SmartButton™. This will put you in the meter memory. The FastFacts™ feature allows you to view charts and graphs of your test results and other logbook information you have entered.

FastFacts™ SmartButton™

Note: The meter will turn itself off after one minute of inactivity. Press any SmartButton™ to turn the meter back on.

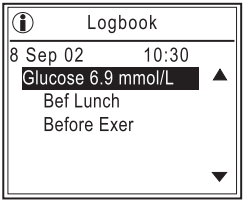


The FastFacts™ menu lists several choices. See next page for a description of what is available under each choice.

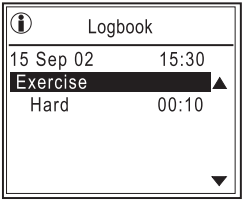
FastFacts™ Menu	
Logbook (Meter Memory)	■ Glucose test results with comments and logbook entries by date and time.
Glucose by Meals	■ Glucose test results by date before and after meals.
Glucose Analysis	■ **Graph of All Results.** Interactive graph of all glucose test results by date. ■ **Graph by Time of Day.** Graph of glucose results by time of day. ■ **Average of All Results.** Average of all results taken for the last 7, 14, 30, 60 and 90 days. ■ **Average by Time of Day.** Averages by time of day for the last 7, 14, 30, 60 and 90 days. ■ **Averages by Exercise.** Glucose averages before, during, and after exercise. ■ **Glucose Range Info.** Percent of glucose test results within, above, and below target range, before and after meals, for the last 7, 14, 30, 60 and 90 days.
Insulin Intake	■ Average insulin doses by insulin type, before and after meals, for the last 7, 14, 30, 60 and 90 days.
Hypo Info	■ Incidents of hypoglycaemia (blood glucose of 3.9 mmol/L or less) before and after meals for the last 7, 14, 30, 60 and 90 days.
Food Averages	■ Average daily intake of carbohydrates, fats, calories, and proteins for the last 7, 14, 30, 60 and 90 days.
Health Checks	■ Dates and results of medical tests.
Help	■ LifeScan Web site address

LOGBOOK MEMORY

To review the details of each glucose test, comments, and logbook entries, select “Logbook.” The logbook is the meter memory. You may review all entries in your meter logbook, by date and time, by pressing the Arrow button. In addition to reviewing records, you may also edit the records. (See pages 99–103.) Following are sample records. Comments are attached to a test result; logbook entries are not.



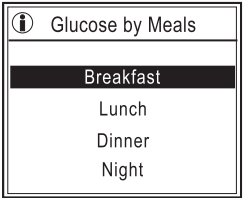
Test results with comments

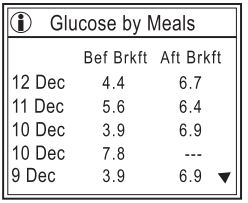


Logbook Entry

GLUCOSE BY MEALS

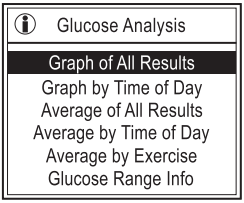
To review test results before and after meals, select “Glucose by Meals.” Highlight the desired mealtime and press OK. A summary of all test results by date before and after the chosen meal or at night will appear. Use Arrow button to view more entries.





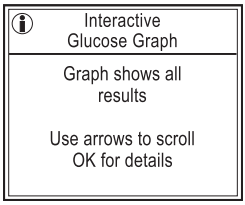
GLUCOSE ANALYSIS

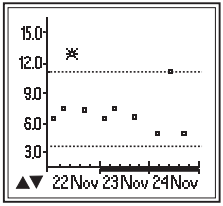
When you select “Glucose Analysis” on the FastFacts™ menu, an additional menu of choices appears. Use the Arrow button to move to the desired menu and press OK OK.



Interactive Graph of All Results

The interactive graph displays three days of test results at a time with the most recent test result flashing. A bold bar above the dates indicates a weekend. The two dotted lines indicate the lowest and highest values of your before- and after-meal glucose ranges (see *Advanced Feature Set-up*, pages 68–72). If you have not selected an after-meal range, only the before-meal range will appear. Results above 16.7 mmol/L or below 2.8 mmol/L are indicated by an arrow at the top or bottom edge of the graph.



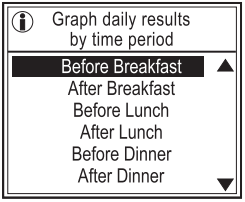


You may scroll backward or forward in time using the Arrow button to move from one point to another. Individual test results will flash as you scroll. To view the details of a test, press OK while that test result is flashing. Press the Back button to return to the graph. You may move back and forth between the graph and the logbook as often as you wish.

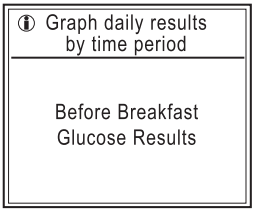
Note: If you press OK while in the logbook, you will begin to edit or delete test comments and will not be able to use the Back button to return to the graph.

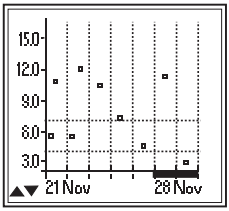
Graph by Time of Day

You may view test results on a graph by time period when you select "Graph by Time of Day."



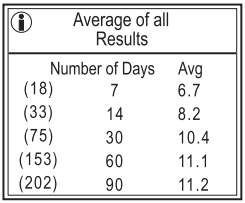
Results by time period are shown day by day, one week at a time. Each time you reach the end of the graph, it will move by one day. Weekends are noted by a bold bar above the dates.





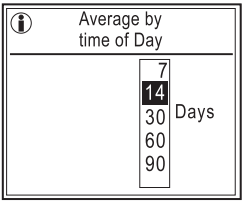
Average of All Results

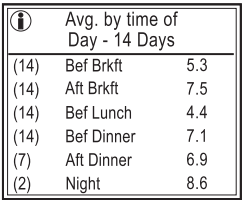
Test result averages are available for the last 7, 14, 30, 60, and 90 days with the number of tests completed during that time period included in parentheses.



Average by Time of Day

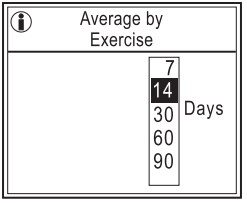
Test averages by time of day are available for the last 7, 14, 30, 60, and 90 days. The number of tests that make up each average are shown on the left in parentheses.

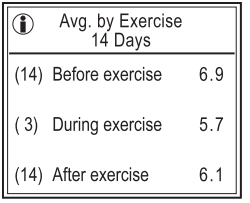




Average by Exercise

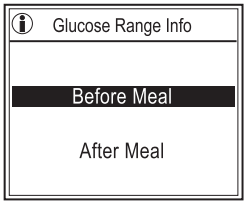
Test result averages before, during, and after exercise are available for the last 7, 14, 30, 60, and 90 days. The number of tests used for each average are shown to the left in parentheses.

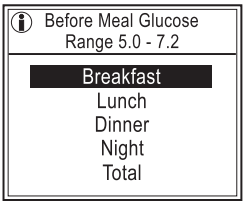


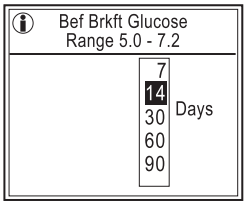


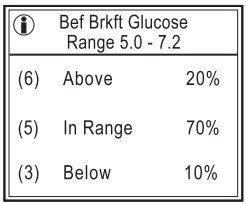
Glucose Range Info

If you entered your before- and after-meal glucose ranges in the Set-up mode, you may review the percentage of your test results that are above, below, and within your target ranges. Otherwise, before-meal ranges are factory-set at 5.0–7.2 mmol/L. After-meal target ranges must be set by the user (see pages 71–72).



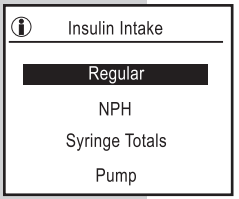




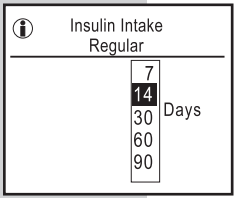


INSULIN INTAKE

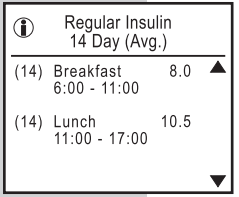
Choose insulin intake from the FastFacts™ Menu.



The individual insulins, in this example Regular and NPH, are based on insulins selected in the Set-up mode (see pages 66 and 67). Use the Arrow button to move to your selection and press OK.



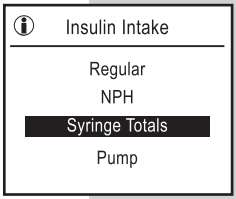
Choose the number of days you would like to review in your average by using the Arrow button to scroll through choices. Press OK to proceed.



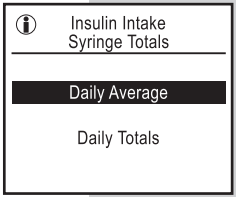
In this example, the average intake of Regular insulin over the past 14 days is displayed. The number in parentheses before the time segment is the number of logbook entries for that time period. Note that each time period includes the before and after period for that meal. (See pages 70–71 to change your schedule.)

Syringe Totals

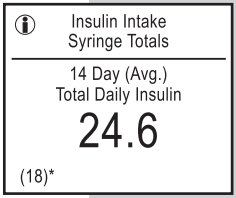
To view the total of all individual insulins taken by syringe or insulin pen that you have previously stored in the logbook, select “Syringe Totals” and press OK OK.

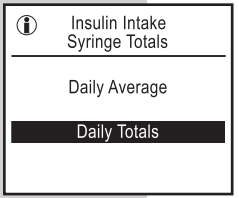


You may view the daily average of your insulin intake over the last 7, 14, 30, 60, and 90 days (example 14 days).

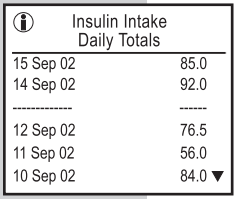


In this example, the average number of insulin units taken over the last 14 days appears. The number shown in parentheses is the number of syringe insulin entries over the time period. An asterisk (*) after the number means there has been at least one day in the time period without an entry.



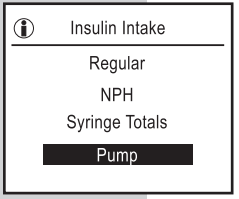


To view your total syringe insulin intake for each day, scroll to “Daily Totals” and press OK OK.



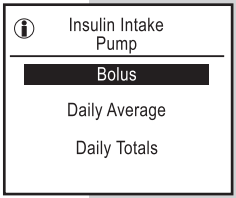
If you did not record a syringe insulin intake for a particular day, “- - -” will appear in both columns.

Insulin Pump

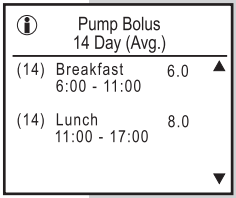


Select “Pump” to view bolus intake, daily averages, and daily totals. You can review the last 7, 14, 30, 60, or 90 days.

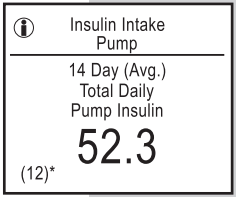
"Bolus" will display your average bolus intake for each mealtime (Breakfast, Lunch, Dinner, Night) based on your schedule (see pages 70–71).



This example shows the average bolus intake in units by time. The number of logbook entries appears in parentheses.

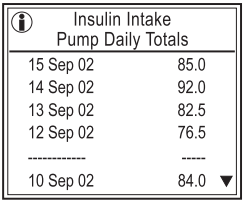


"Daily Average" displays the average of the total daily pump insulin. This example is for the last 14 days. The number of entries is listed in parentheses. An asterisk (*) means there are days with no entries.



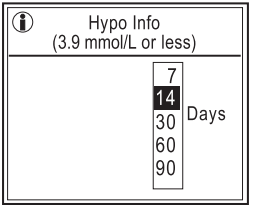
Insulin Intake Pump Daily Totals

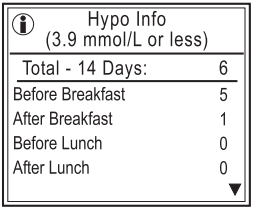
"Pump Daily Totals" gives the pump totals you have entered for each day. If you did not enter a pump total for a day, "- - -" will appear.



HYPOGLYCAEMIA INFORMATION

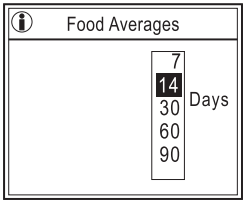
If you select "Hypo Info" from the FastFacts™ menu, the meter will display the actual number of hypoglycaemic events defined by the level set in Advanced Features (see page 72). The number of events before and after meals and during the night for the last 7, 14, 30, 60, and 90 days is displayed. Use the Arrow button to view the other time periods.

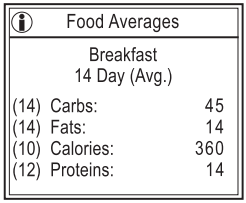




FOOD AVERAGES

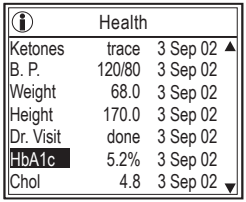
Select “Food Averages” to view average daily intake of carbohydrates, fats, calories, and proteins over the last 7, 14, 30, 60, and 90 days.

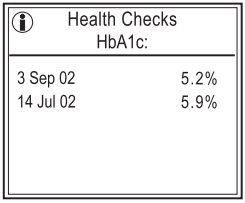


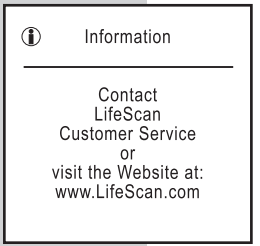


HEALTH CHECKS

To view results and dates of various check-ups, select “Health Checks.” Scroll to the type of health check using the Arrow button and press OK. The entries for each will appear on the display.







This choice prompts you to call your local LifeScan Customer Service office or visit our Web site when you need help with testing. See back cover for contact information.

Data Downloading

Transferring test results to your personal computer for home viewing requires OneTouch™ Diabetes Management Software from LifeScan and a LifeScan Interface Cable. (OneTouch™ Software, which includes the LifeScan Interface Cable, is not included with your OneTouch® UltraSmart™ System and must be purchased separately.)

STEP 1 Install OneTouch™ Software.

Install OneTouch™ Software on your computer following the instructions provided in the OneTouch™ Diabetes Management Software User's Manual.

STEP 2 Connect the LifeScan Interface Cable.

Connect the LifeScan Interface Cable to a serial port on the back of your computer. With the meter turned on, connect the LifeScan Interface Cable to the data port located on the upper left side of the meter. Be sure the cable plug is inserted all the way. PC will appear on the display once the first command is received, indicating that the meter is in the communication mode. You are now ready to transfer all test results—with date and time—stored in the meter memory to your computer.

Note: While in the communication mode, you will be unable to perform a blood glucose test.

STEP 3 Transfer Data.

Follow the instructions in the OneTouch™ Diabetes Management Software User's Manual to initiate the data transfer command. If the command is not received within one minute, the meter will turn itself off. You may also press and hold the Back button to turn off the meter.

To learn more about OneTouch™ Diabetes Management Software or to purchase a LifeScan Interface Cable separately, contact your local LifeScan Customer Service office. See back cover for contact information.

SPECIFICATIONS

Result Range:	1.1 to 33.3 mmol/L
Calibration:	Plasma-equivalent
Sample:	Fresh capillary whole blood
Sample Size:	Minimum 1 microlitre
Test Time:	5 seconds
Assay Method:	Glucose oxidase biosensor
Power Source:	Two AAA alkaline batteries
Battery Life:	About six months at three tests per day (one test using backlight)
Glucose Units:	mmol/L
Memory:	Over 3,000 records
Automatic Shutoff:	Three minutes after inserting a test strip if sample has not been applied; one minute after all other user actions
Size:	Approx. 97mm (L) x 58mm (W) x 23mm (H) [3.8in. (L) x 2.3in. (W) x 0.9in. (H)]
Weight:	75 grams (with batteries)
Operating Ranges:	Temperature 6–44°C Relative humidity 10–90% Haematocrit 30–55%

GUARANTEE

The makers guarantee that the OneTouch® UltraSmart™ Meter shall be free of defects in material and workmanship for a period of three years. This guarantee is valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable.

Authorised Representative
LifeScan Regulatory Affairs Europe
Division of Ortho-Clinical Diagnostics France
1, rue Camille Desmoulins
92787 Issy-les-Moulineaux Cedex 9, France

CE LifeScan Inc.
1000 Gibraltar Drive
Milpitas, CA 95035 U.S.A.

LifeScan self-test blood glucose monitoring device conform to the following EU Directives:

IVDD (98/79/EC):

CE 0336 Blood Glucose Meter, Test Strips, and Control Solution

MDD (93/42/EC):

CE 0120 Lancets

CE Blood Sampler

ONETOUCH® UltraSmart™

Customer Care Freephone:

UK **0800 121 200**
Ireland **1800 535 676**

www.LifeScan.co.uk

Distributed by:
LifeScan UK
A Division of Ortho-Clinical Diagnostics
Enterprise House, Station Road,
Loudwater, High Wycombe,
Buckinghamshire HP10 9UF
United Kingdom

LIFESCAN a Johnson & Johnson company

AW 06158108A