



User's Manual



LIFESCAN
a Johnson & Johnson company

www.InDuo.com



Diagram of the InDuo™ system

Look at the diagram inside this cover for the names of the different parts of the InDuo™ system. You can unfold the diagram to help you while you follow the instructions.

The **InDuo™** system should be used only in combination with products that are compatible with it and allow the InDuo™ system to function safely and effectively.

OneTouch® Ultra test strips are designed to be used with the InDuo™ blood glucose meter.

PenFill® 3 mL cartridges and **NovoFine®** needles are designed to be used with the InDuo™ insulin doser. PenFill® not included.

PenFill® and **NovoFine®** are trademarks of Novo Nordisk A/S.

IN TOUCH® and **OneTouch®** are trademarks of LifeScan, Inc.

InDuo™ is a trademark of Johnson and Johnson Co.

Protected by US Patent Nos. 5,957,889; 5,961,496; and 6,045,537.

Additional patents pending.

The CE-mark on the InDuo™ doser indicates that the product conforms with the provisions in the EC Directive for Medical Devices 93/42/EEC. The InDuo™ insulin doser fulfils the specification limits for dose accuracy according to ISO 11608-1. Pen-Injectors for Medical use, Part 1: Requirements and test methods.

InDuo™ SYSTEM AND ACCESSORIES



InDuo™
Blood Glucose Meter



OneTouch® *UltraClear*™
cap for alternate
puncture site



OneTouch® *UltraSoft*™
Sterile Lancet



OneTouch® *Ultra*
Control Solution



OneTouch® *Ultra*
Test Strips



OneTouch® *UltraSoft*™
Adjustable blood sampler



InDuo™
Insulin Doser

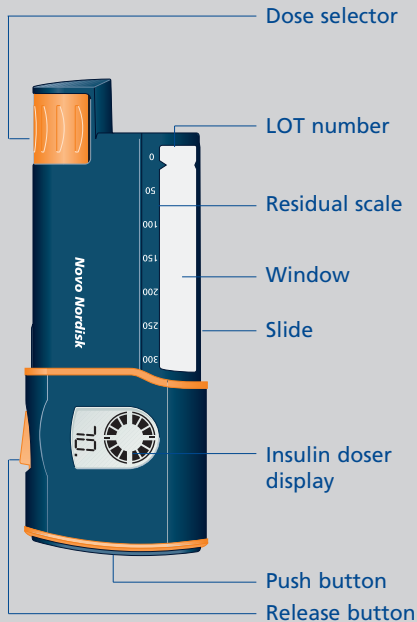


NovoFine®
Needles 10-pack



PenFill® 3 mL
Insulin Cartridge

InDuo™ BLOOD GLUCOSE METER AND INSULIN DOSER



InDuo™ METER AND INSULIN DOSER DISPLAY SYMBOLS

Ctl

Indicates a control solution test result.

Code

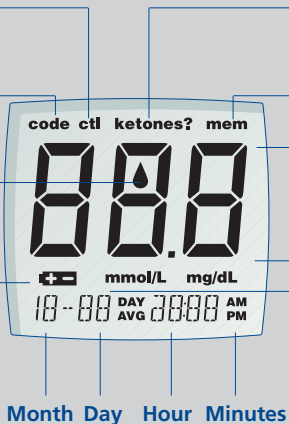
Appears with the code number of the OneTouch® Ultra Test strip currently in use.

Apply symbol

Tells when to apply the sample.

Battery symbol

Appears when the meter battery power is low or must be replaced.



Ketones?

Appears when a blood glucose test result falls above 240 mg/dL.

Mem

Indicates a test result stored in the memory.

Test result area

Test results are displayed here. (A decimal point appears when the unit of measurement is millimoles per liter.)

Unit of measurement

The meter has been pre-set in either mg/dL or mmol/L. Confirm that the unit of measurement is correct when the apply symbol appears during blood application.

Time segment

The segments indicate the time passed since delivery. 1 segment represents 1 hour.



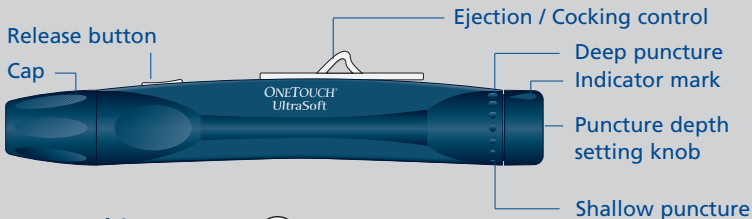
Circle

Confirms that the delivery has been completed.

Dose

Shows the number of insulin units dialed.

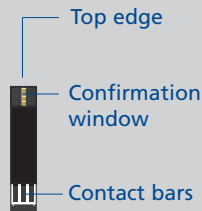
OneTouch® UltraSoft™ Adjustable blood sampler



OneTouch® Lancet

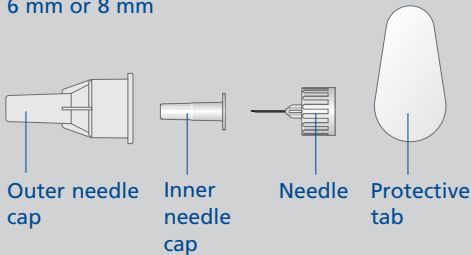


OneTouch® Ultra Test strip

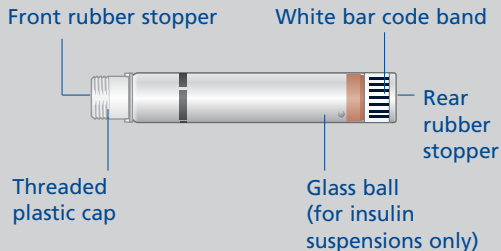


NovoFine®

6 mm or 8 mm



PenFill® 3 mL



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WELCOME

You have chosen the InDuo™ system, a system designed to simplify the way you manage your diabetes. Featuring an integrated blood glucose meter and insulin doser, InDuo™ will enable you to check your blood glucose levels and administer insulin using one compact system. This manual contains instructions for using, storing, and looking after your InDuo™ system. Read it carefully.

Your InDuo™ meter provides you with accurate, plasma-calibrated test results. This feature makes it easier for you and your doctor to compare your meter results with laboratory results. If you have been using another type of meter, you may notice that the results with the InDuo™ meter are about 12% higher than with your previous system. The InDuo™ meter is designed for use with OneTouch® *Ultra* test strips only.

Your InDuo™ insulin doser provides you with state-of-the-art insulin delivery including a memory to tell you how much

you injected, and how long ago you made your injection. By combining meter and insulin doser into one, the InDuo™ system helps you simplify your insulin therapy and increase your confidence in managing your diabetes.

A warranty registration card is included with your InDuo™ system. If you complete it and mail it to us, we will send you a gift.

We are sure that you will find your InDuo™ system simple and easy to use. If you have any questions regarding your InDuo™ system, please do not hesitate to call InDuo Customer Services at our toll free number 1-877-520-9056.

The InDuo™ meter is intended for use outside the body (in vitro diagnostic use). It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples. It should not be used for the diagnosis of diabetes or for the testing of newborns.

GETTING YOUR InDuo™ SYSTEM READY FOR USE

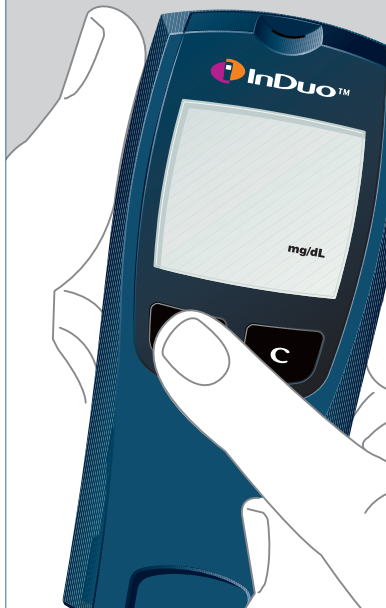
Preparing your InDuo™ meter

Setting the time, date, and unit of measurement

Your InDuo™ meter comes with pre-set values for the time, date, and **unit of measurement**. However, you can reset these if you need to change the date or time, or if you remove the meter battery. Since the InDuo™ meter also gives average values (14 days and 30 days) for your blood glucose tests (see page 53), you may find that changing the date and time will also alter the values for the 14-day and 30-day averages. To set the time, date, and unit of measurement, you must first enter the setting mode on the InDuo™ meter display.

Enter the setting mode

- Press and hold down **M** for 3 seconds.
- The InDuo™ meter is now in the setting mode and you are ready to change the time using the meter display.





Setting the hour

- The time will appear first, with the hour digits flashing.
- Press and release **C** until the correct hour is displayed.
- To scroll faster, hold **C** down.
- After setting the hour, press **M** to set the minutes. The minutes digits will start flashing.

Setting the minutes

- Press and release **C** until the correct minute is displayed.
- To scroll faster, hold **C** down.



Setting the time format

- Press **M** and the 12-hour format will start flashing.
- Your InDuo™ meter can display the time in either a 12-hour format **AM PM** or a 24-hour format **000** to **2359**.
- The 12-hour format is pre-set in the meter.
- If you wish to display the time in 24-hour format, press and release **C**. Pressing **C** again will return you to the 12-hour format.

Setting the year

Before setting the date you must first set the time.

- With the preferred time format on the display, press **M** and the year digits will start flashing.
- Press and release **C** until the correct year is displayed.
- To scroll faster, hold **C** down.





Setting the month

- Press **M** and the date will appear on the display with the month display flashing.
- Press and release **C** until the correct month is displayed.
- To scroll faster, hold **C** down.



Setting the day

- Press **M** and the day setting will start flashing.
- Press and release **C** until the correct day is displayed.
- To scroll faster, hold **C** down.

Selecting the unit of measurement

- With the correct day on the display, press **M** and the current unit of measurement will start flashing.

The InDuo™ meter can display test results in milligrams per deciliter (**mg/dL**) or in millimoles per liter (**mmol/L**). The **mg/dL** unit is standard in the United States. The **mmol/L** unit is commonly used in Canada and some European countries.

- Consult your healthcare professional before you change the unit of measure.
- If the units are incorrect or have been changed, press **C** to select the correct units. If the units are correct, just press the **M** button to exit the setting mode.



Top edge

Apply a sample here, where the narrow channel meets the top edge of OneTouch® *Ultra* test strip.

Confirmation window

This is where you confirm if a large enough sample has been applied to the **top edge**.

Contact bars

Insert this end of OneTouch® *Ultra* test strip into the InDuo™ meter.

**⚠ OneTouch® *Ultra* test strips**

Your InDuo™ meter is designed for use with OneTouch® *Ultra* test strips **only**.

- Store the OneTouch® *Ultra* test strip package in a cool, dry place below 30°C (86°F). Keep away from direct sunlight and heat. Do not refrigerate.
- Store your OneTouch® *Ultra* test strips in **their original vial only**; do not transfer them to a new bottle or any other container.
- After removing a OneTouch® *Ultra* test strip from the vial, immediately replace the vial cap and close it tightly.
- **With clean, dry hands, you may touch the test strip anywhere** on its surface when removing it from the vial or inserting it into the meter.
- Use each OneTouch® *Ultra* test strip immediately after removing it from the vial.
- Write the discard date on the vial label when you open it for the first time. Discard remaining OneTouch® *Ultra* test strips and the vial 3 months after the vial was first opened.

- Apply only control solution or a blood sample to the **top edge** of the OneTouch® *Ultra* test strip. Applying other substances to the **top edge** may cause inaccurate results.
- Do not use OneTouch® *Ultra* test strips beyond the expiration date printed on the package since using expired OneTouch® *Ultra* test strips may produce inaccurate results.
- Do not bend, cut, or alter a OneTouch® *Ultra* test strip in any way.

WARNING: Keep the test strip vial away from children; the cap is a choking hazard. Also, the cap may contain a pouch filled with drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

OneTouch® *Ultra* test strips are single use. Do not re-use a test strip that has had sample applied to it. Refer to your OneTouch® *Ultra* test strip insert for additional information.



(Example)



Coding your InDuo™ meter

Code numbers are used to calibrate the OneTouch® *Ultra* test strips with the InDuo™ meter. You must code the InDuo™ meter before using it for the first time, and then every time you change to another vial of OneTouch® *Ultra* test strips. Each time you do a blood glucose test, check that the code number on the meter display matches the code number on the OneTouch® *Ultra* test strip vial.

CAUTION: If the code numbers do not match, your blood glucose tests may be inaccurate.

Entering the code mode

- Start with the InDuo™ meter turned off.
- Insert a OneTouch® *Ultra* test strip to turn on the meter. Push the test strip in until it will go no further.
- All segments of the meter display will appear. When you first use the InDuo™ meter, 3 dashes --- will appear, showing there is no code stored in the meter memory.

Match the code numbers

The calibration code is stored in the meter memory until you change it. The current code number will appear on the display for 3 seconds.

- Compare the code number on the meter display with the code number on the OneTouch® *Ultra* test strip vial.
- If the 2 code numbers match, you may begin testing.
- If the code numbers do not match, follow the next procedure to recode the InDuo™ meter.

Code the InDuo™ meter

- Press **C** to select the correct code.
- Each time you press and release **C**, the number on the display will increase by one.
- To scroll faster, hold **C** down.
- After you have selected the correct code number, it will flash for 3 seconds and then appear solid for 3 seconds.
- The apply symbol  will appear with the units of measurement (**mg/dL** or **mmol/L**), indicating that the InDuo™ meter is ready for testing.

(Example)





The control solution test

OneTouch® *Ultra* Control Solution is used to check that the meter and the OneTouch® *Ultra* test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple test routinely to check that the system is providing accurate results.

The control solution test should be used to:

- check that your meter and OneTouch® *Ultra* test strips are working together properly.
- check that you are performing the test correctly.
- practice testing your blood.

The control solution test should be done:

- at least once a week.
- when you begin using a new vial of OneTouch® *Ultra* test strips.
- if you suspect that your InDuo™ meter or OneTouch® *Ultra* test strips are not working properly.
- when your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
- if you drop your InDuo™ meter.

 Caution

- Use only OneTouch® *Ultra* Control Solution
- Check the expiration date on the control solution vial. Do not use if expired.
- Store control solution tightly closed at temperatures below 86°F (30°C).
- Do not refrigerate control solution.
- The control solution, the InDuo™ meter, and the OneTouch® *Ultra* test strips should be at room temperature 68–77°F (20–25°C) before testing.
- Shake the vial, discard the first drop of control solution, and wipe off the dispenser tip with a clean tissue to obtain a good sample and an accurate result.
- Use only for 3 months after the first opening. Record the discard date (date opened plus 3 months) on the control solution vial. Discard after 3 months.
- **The control solution range printed on the OneTouch® *Ultra* test strip vial is for OneTouch® *Ultra* control solution only. It is used to test meter and OneTouch® *Ultra* test strip performance. It is not a recommended range for your blood glucose level.**



Before you use your InDuo™ meter to test your blood for the first time, practice the procedure using the control solution test. When you can do three tests in a row that are within the range printed on the OneTouch® *Ultra* test strip vial, you are ready to test your blood.

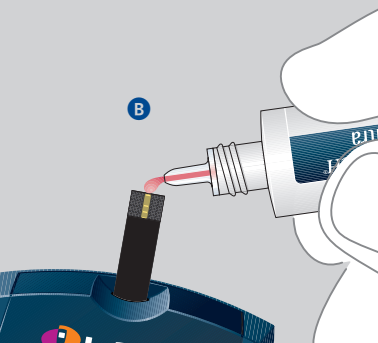
How to do a control solution test

Insert OneTouch® *Ultra* test strip

- Insert a OneTouch® *Ultra* test strip, contact bars end-first **A** and facing up, into the test port. Push the OneTouch® *Ultra* test strip in firmly until it will go no further.
- The InDuo™ meter will turn on automatically.
- All segments will appear briefly on the meter display. Then the code number is displayed, followed by the apply symbol  with the units of measurement (**mg/dL** or **mmol/L**).
- Verify that the calibration code and units of measurement are set correctly. (See page 5 and 9 for additional information on the unit of measurement.)

- After the apply symbol  appears on the display, press .
- The **ctl** symbol will appear on the display. With the **ctl** symbol on the display, the meter will mark your next test in the memory as a control solution test. If you decide not to perform a control solution test, press  again and the **ctl** symbol will disappear.
- Every time you perform a control solution test, you must mark the test result with the **ctl** symbol so that the test will be distinguished from a blood glucose test in the memory and not included in the 14-day and 30-day blood glucose test averages.





Apply control solution

- Shake the control solution vial well.
- Remove the cap.
- Squeeze the vial, discard the first drop, and wipe off the dispenser tip to obtain an accurate result.
- Squeeze the vial again to get a small hanging drop.
- Apply the hanging drop **B** to the **top edge** area of the OneTouch® *Ultra* test strip (where it meets the narrow channel) until the drop is drawn into the OneTouch® *Ultra* test strip, the confirmation window is filled, and the meter display begins to count down.



(Example)

Read test results

- The meter will count down from 5 to 1 and the control solution test result will appear **C**.
- Compare the result with the range printed on the OneTouch® *Ultra* test strip vial label. The result should fall within this range.

 Caution

- If the control solution test result falls outside the range printed on the OneTouch® *Ultra* test strip vial, repeat the test.
- If you continue to get control solution test results that fall outside of the range printed on the vial, the InDuo™ system may not be working properly.
- Do not use the InDuo™ system to continue testing your blood if the control solution test results continue to fall outside the expected range.
- If you are unable to resolve the problem, call InDuo Customer Services at our toll free number 1-877-520-9056.

The control solution test troubleshooting

There are several reasons why a control solution test result may fall outside the expected range (as printed on the OneTouch® *Ultra* test strip vial label).

Probable reasons	Action
Error in performing the test	Repeat the test, closely following the instructions on pages 16–18
Failure to shake the OneTouch® <i>Ultra</i> control solution vial vigorously	Shake the control solution vial and repeat the test
Expired or contaminated OneTouch® <i>Ultra</i> control solution	Check the expiration date or use new control solution
InDuo™ meter, OneTouch® <i>Ultra</i> control solution, or test strips that are too warm or too cool	Check that the room temperature is between 68–77°F (20–25°C)
Failure to discard the first drop of OneTouch® <i>Ultra</i> control solution	Repeat the test
OneTouch® <i>Ultra</i> test strip deterioration	Repeat the test with a new vial of test strips. Remember to recode the meter
InDuo™ meter malfunction	Call InDuo™ Customer Services at 1-877-520-9056
Improper coding of the meter	Check that the meter is coded correctly

PREPARING YOUR InDuo™ INSULIN DOSER TO INJECT INSULIN

Before you are ready to inject your insulin, the InDuo™ insulin doser must be loaded with a PenFill® insulin cartridge. A needle must be attached and the InDuo™ insulin doser must be primed by doing an air shot.

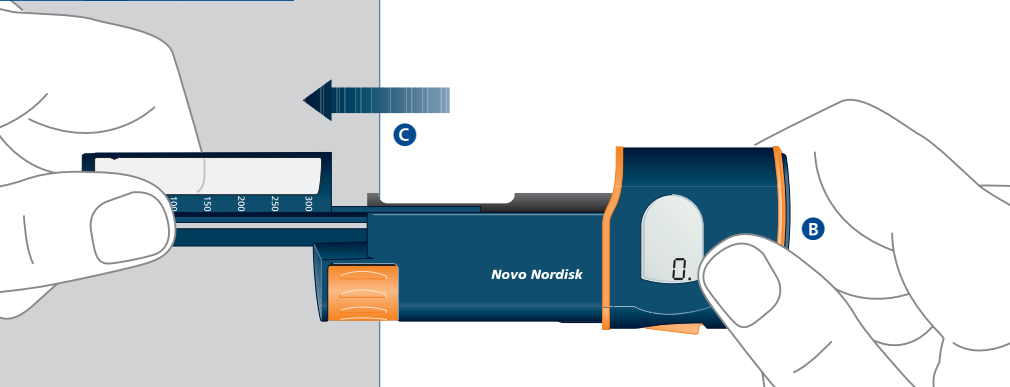
How to load your PenFill®

- Before loading PenFill®, read the Information For The Patient that accompanies it carefully. In the Information For The Patient, you will find instructions on how to:
 - Check that the PenFill® is full and intact. If not, do not use it.
 - Resuspend the insulin, if PenFill® contains an insulin suspension (cloudy insulin).
-  Use only a new PenFill® when loading the InDuo™ insulin doser. Never load a partially filled PenFill®.
-  Each PenFill® is for single person use only. Do not use the same PenFill® for more than one person, even though you attach a new NovoFine® needle for each injection.

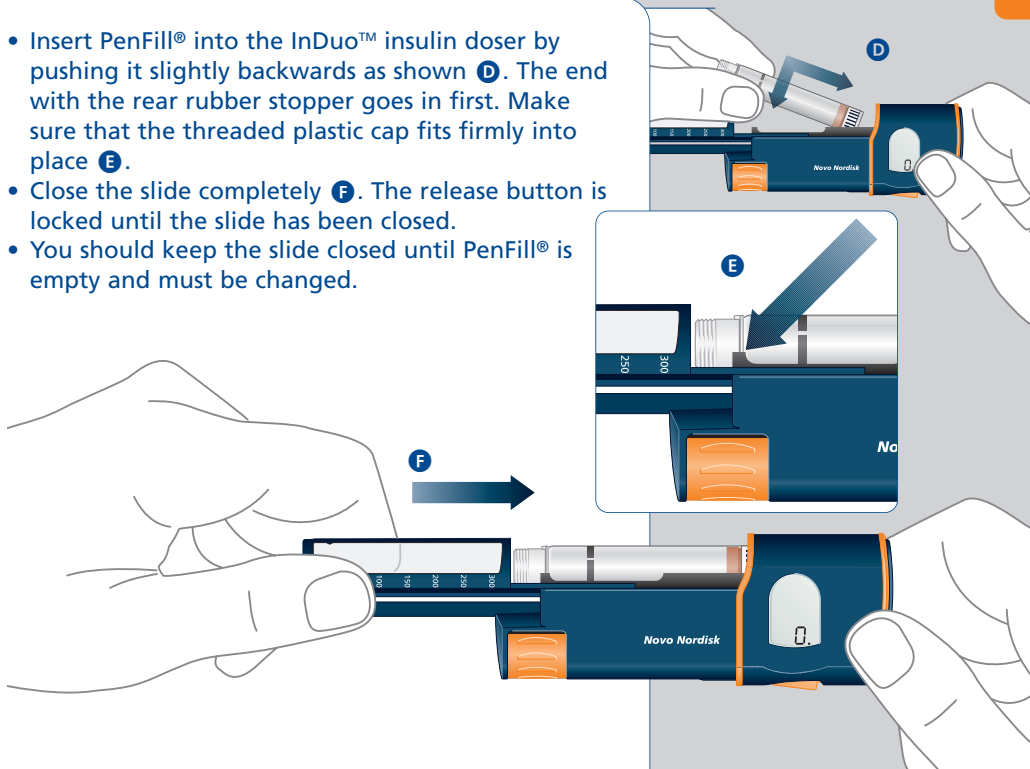


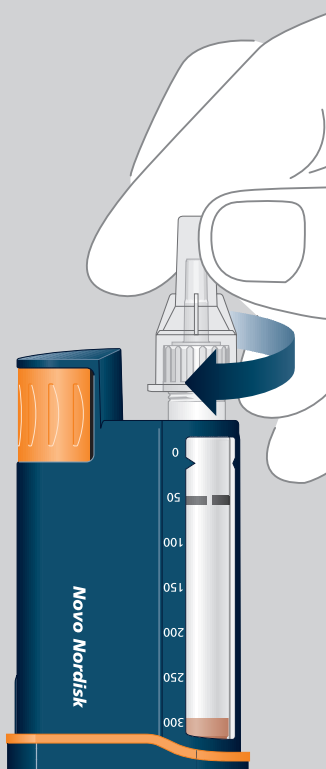
To load PenFill®:

- Pull out the InDuo™ insulin doser **A**.
- The very first time the insulin doser is pulled out, the insulin doser display stays blank until the slide is opened.
- Make sure that the push button is pressed completely in **B**. Otherwise the slide will remain locked.
- Open the slide in the direction of the arrow shown below **C**. The insulin doser display now shows **0.**



- Insert PenFill® into the InDuo™ insulin doser by pushing it slightly backwards as shown **D**. The end with the rear rubber stopper goes in first. Make sure that the threaded plastic cap fits firmly into place **E**.
- Close the slide completely **F**. The release button is locked until the slide has been closed.
- You should keep the slide closed until PenFill® is empty and must be changed.





How to attach a NovoFine® needle

- Never place a NovoFine® needle on your InDuo™ insulin doser until you are ready to prime your InDuo™ insulin doser by doing an air shot before giving an injection.
- Wipe the front rubber stopper of the PenFill® with an alcohol swab.
- Take the protective tab off a NovoFine® needle.
- Screw the NovoFine® needle tightly onto the threaded plastic cap.
- Pull off the outer and inner needle caps before priming the InDuo™ insulin doser by doing an air shot.

How to prime the InDuo™ insulin doser by doing an air shot

Priming the InDuo™ insulin doser is a method of making sure that the insulin is ready to flow when you make your injection. Otherwise, you will not receive the full insulin dose. You will know that the InDuo™ insulin doser has been primed when a drop of insulin appears at the tip of the NovoFine® needle.

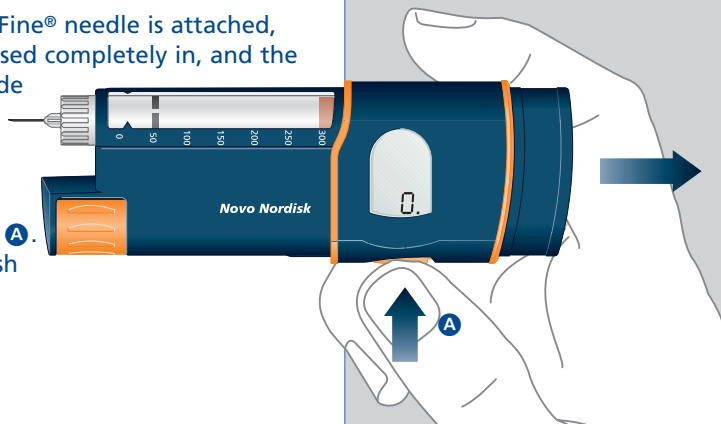
⚠ The InDuo™ insulin doser should always be primed:

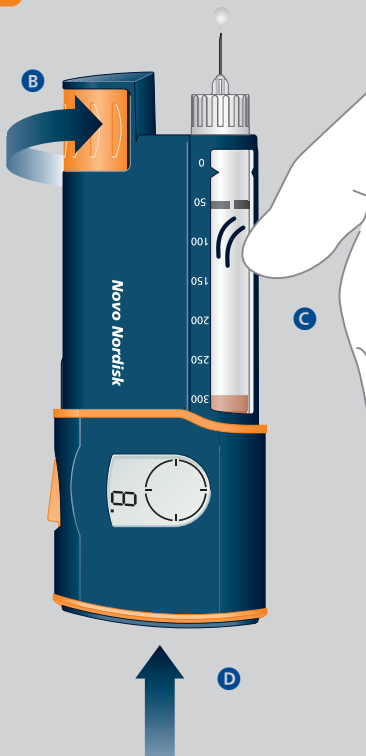
- Before each injection.
- After changing PenFill®.
- After changing the NovoFine® needle.
- After opening and closing the slide on the InDuo™ insulin doser.

Priming your InDuo™ insulin doser for the first time

⚠ Make sure that a NovoFine® needle is attached, the push button is pressed completely in, and the slide is closed. If the slide is not closed, the release button will be locked.

- Press the release button **A**. You will see that the push button jumps out.





- Dial 8 units **B**.
- Hold the InDuo™ insulin doser with the NovoFine® needle upwards and tap the slide gently with your finger a few times **C**, to ensure that any air in PenFill® rises to the top.
- Press the push button completely in until it locks **D**.
- A drop of insulin should appear at the needle tip.

If the drop of insulin does not appear, repeat the priming procedure dialing 1 unit at a time until a drop of insulin appears.

- If not injecting immediately, discard the NovoFine® needle safely.
- If you are injecting immediately, the NovoFine® needle will remain on the insulin doser until you have completed the injection. Following your injection discard the NovoFine® needle safely.

TESTING YOUR BLOOD GLUCOSE LEVELS

Be sure to read this section, Important Information on page 65, and the OneTouch® *Ultra* test strip package insert found in this system kit box carefully before testing.

Before using your InDuo™ meter to test your blood glucose level, check that you have all the items needed to complete the procedure.

These are:

- InDuo™ meter
- OneTouch® *Ultra* test strips
- OneTouch® *UltraSoft*™ Sterile Lancets
- OneTouch® *UltraSoft*™ Adjustable Blood Sampler
- OneTouch® *UltraClear*™ Cap for alternate puncture site





Check that the InDuo™ meter display is working properly. You will know the meter display is working properly because each time the InDuo™ meter is turned on, all the segments of the meter display appear briefly (see “InDuo™ meter and insulin doser display symbols” in cover flap).

After checking that the InDuo™ meter display is working, you are ready to obtain a drop of blood and to do a blood glucose test. When carrying out a blood glucose test, keep the risk of infection to a minimum by observing the following precautions:

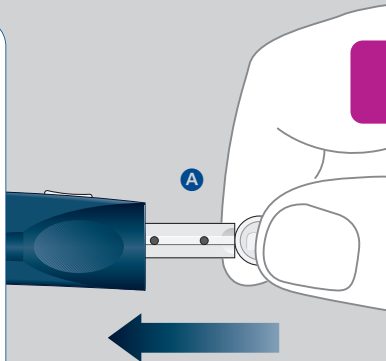
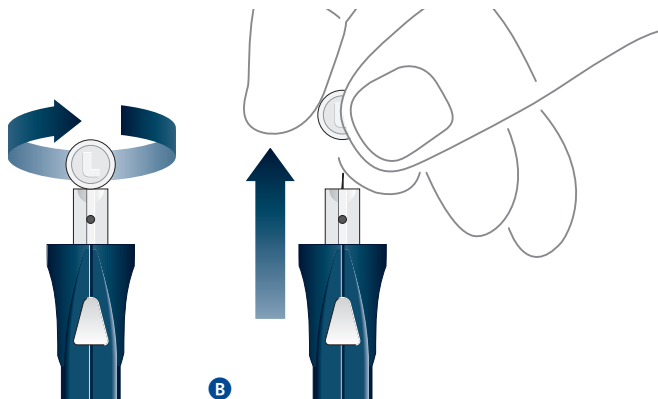
⚠ Caution:

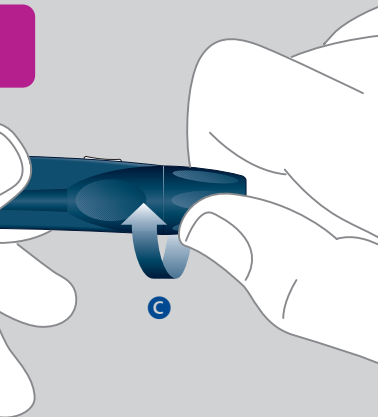
- **Never share a lancet or the blood sampler with anyone.**
- **Always use a new sterile lancet every time you take a blood sample. Lancets are for single use only.**
- **Avoid getting hand lotion, oils, dirt, or debris on the lancets or on the meter.**

Obtaining a drop of blood

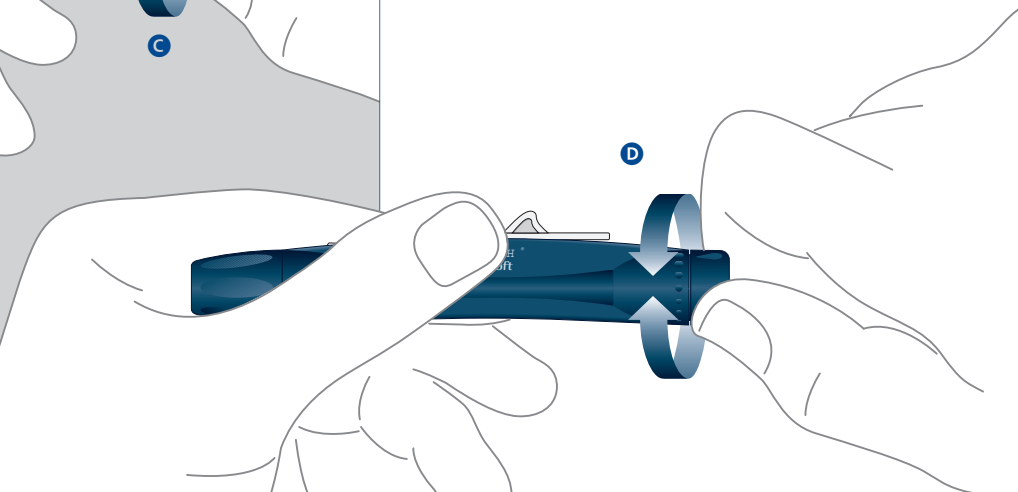
Insert a lancet in the blood sampler

- Twist the cap of the blood sampler counter-clockwise to remove it.
- Insert a new lancet into the lancet holder, and push down firmly until it is fully seated **A**. Do not twist the lancet.
- Twist the protective disk until it separates from the lancet **B**.





- Replace the cap **C**.
- Turn the cap clockwise until it fits snugly but not too tight.
- Adjust puncture depth setting if necessary. Twist the knob toward the smaller bumps for a shallower puncture or toward the larger bumps for a deeper puncture **D**.

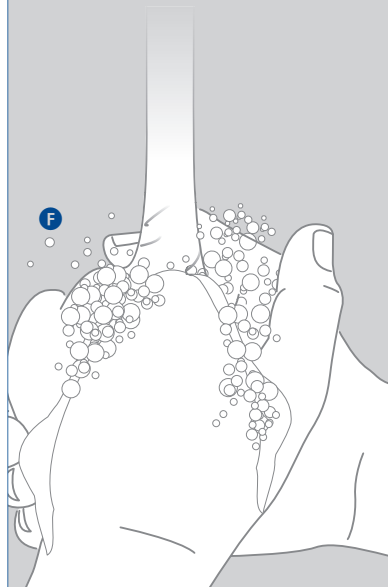
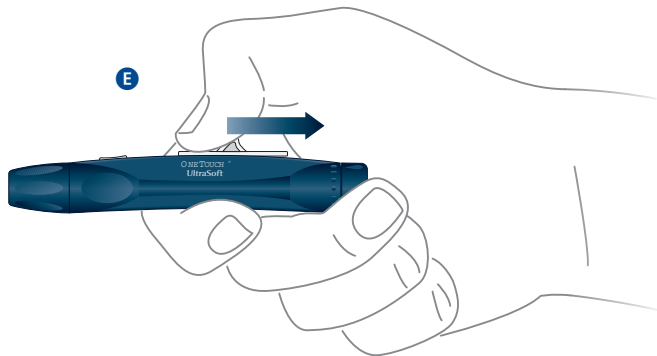


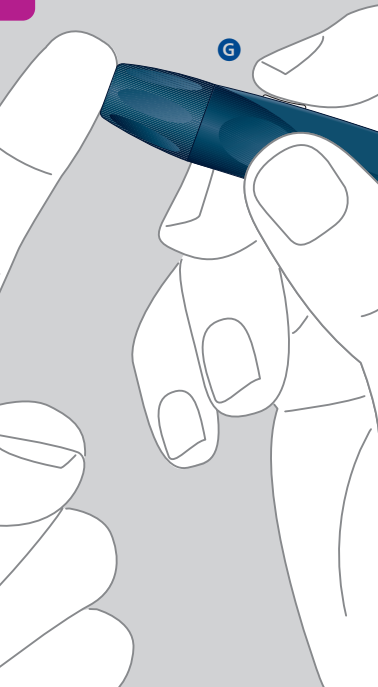
Cock the blood sampler

- Slide the ejection/cocking control back until it clicks **E**.
- If it does not click, the blood sampler may have been cocked when the lancet was inserted.

Wash your hands and the puncture site

- Use warm, soapy water to wash your hands and the puncture site **F**.
- Rinse and dry thoroughly.





Getting a Fingertip Blood Sample

The InDuo™ System requires a very small blood drop to perform a test. You may obtain it from a fingertip or arm. (See page 33 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.

Position the Sampler

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

Massage the Fingertip

Massaging the fingertip gently will help you obtain a round drop of blood.

The blood sample must be at least 1 microliter in volume [• actual size] to fill the confirmation window or you may get an **Err** message (see page 40) or possibly an inaccurate test result. **Do not smear the blood sample.** Proceed with your blood glucose test.



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 hypoglycemic (low blood sugar) level sooner than a test with an arm sample.
- Use arm samples only for testing prior to, or more than 2 hours after, meals, insulin dose, or physical exercise.
- Testing performed within 2 hours after meals, an insulin dose or

physical exercise, or whenever you feel that your glucose levels may be changing rapidly, should be done from the fingertip.

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

What you should do:

- Use arm or fingertip samples for testing prior to, or more than two hours after, meals, insulin dose, 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.



Actual size of required blood volume (rounded drop).



Getting a Blood Sample From The Arm

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 obtaining a blood drop from the arm is different from fingertip sampling. Also there are differences between arm samples and fingertip samples that you should understand. Please read “Important information about arm testing” on the previous page carefully.

Install the Clear Cap

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

Choose the Puncture Site

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

Massage the Area

Massaging the area gently or applying heat to it briefly will increase blood flow to the puncture site.

Position the Sampler

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

Allow Blood Drop to Form

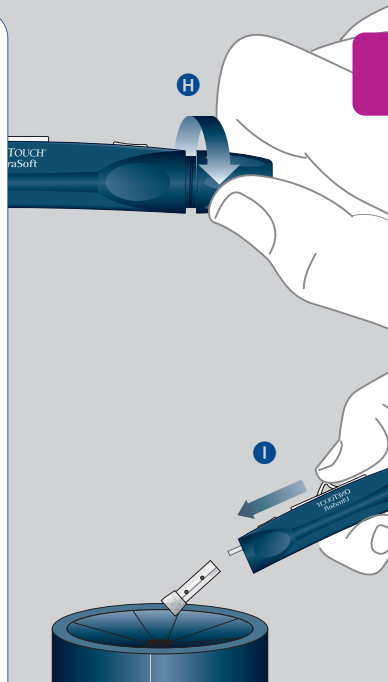
Continue holding the sampler against the skin for a few seconds until the blood drop forms. Allow enough blood to form under the cap until you have a blood sample that is sufficient to fill the confirmation window of the test strip. If bruising occurs, you may choose to lance a fingertip instead. If you are having difficulty obtaining blood from the arm, call InDuo™ Customer Services at 1-877-520-9056 for assistance. The blood sample must be at least 1 microliter in volume or you may get an **Err** or possible inaccurate test result.

Removing the lancet

- To remove the cap, twist it counterclockwise **H**.
- Optional: To replace the protective disk on the lancet, place the disk on a hard surface and push the exposed tip into the protective disk.

⚠ Always use caution when removing the lancet.

Point the lancet down and away. Push forward on the ejection/cocking control and eject the lancet directly into an appropriate container for sharp objects **I**. Return the ejection/cocking control to the middle position. Replace the cap.





Cleaning the OneTouch® *UltraSoft*™ blood sampler

- Clean the sampler with soap and water as needed. To disinfect the sampler, prepare a disinfectant solution of 1 part household bleach to 10 parts water. Dampen a cloth in this solution and wipe the sampler thoroughly. Soak only the cap 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.

Performing a blood glucose test on your blood sample

Insert the OneTouch® *Ultra* test strip

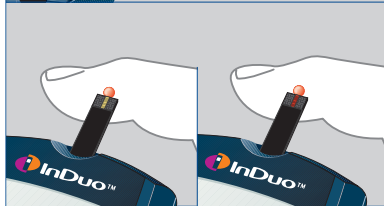
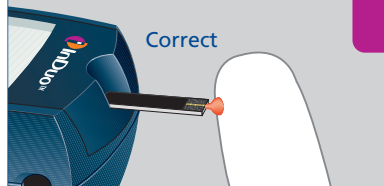
- Insert the OneTouch® *Ultra* test strip, contact bars end-first and facing up, into the test port. Push the OneTouch® *Ultra* test strip in firmly until it will go no further.
- The InDuo™ meter will turn on automatically. All segments on the meter display will appear briefly. Then the code number is displayed, followed by the apply symbol  with the units of measurement (**mg/dL** or **mmol/L**). Verify that the calibration code and units of measurement are set

correctly. (See page 9 for additional information on the units of measurement.)

- Code the meter if necessary.

Apply blood sample

- Obtain a rounded drop of blood from your finger using the blood sampler. The blood sample must be at least 1 microliter in volume (• actual size of rounded drop) to fill the confirmation window or you may get an $E_r 5$ or possible inaccurate test result. See page 32 for how to obtain a drop of blood.
- When the apply symbol  appears on the display, touch and hold the drop of blood to the top edge of the OneTouch® Ultra test strip where it meets the narrow channel. Do not push your finger against the test strip or try to apply a smeared sample. Do not apply blood to the front or back of the test strip.
- Hold the blood drop to the **top edge** of the test strip until blood has **completely filled** the confirmation window before the meter begins to count down. The InDuo™ meter display will begin to count down from 5 to 1.



Good sample Sample too small



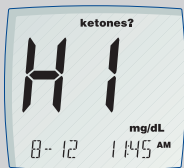
- If the confirmation window does not fill completely before the meter begins to count down, **do not add more blood to the test strip**; discard the test strip and repeat the test with a new test strip.
- Ensure sufficient sample.
- Do not use a smeared sample.
- Hold the test strip in contact with blood.
- If you have trouble filling the test strip, call InDuo™ Customer Services at 1-877-520-9056 for assistance.
- If you do not apply a blood sample within 2 minutes, the meter will turn off automatically. You must remove the test strip and insert it back into the InDuo™ meter to restart the test.

Read the results

- Your blood glucose test result will appear after the InDuo™ meter counts down from 5 to 1.
- Turn off the InDuo™ meter by removing the OneTouch® *Ultra* test strip.
- Blood glucose test results are automatically stored in the InDuo™ meter memory.
- The InDuo™ meter provides accurate, plasma-calibrated test results that can be compared directly with laboratory results.
- Record all test results in your logbook. This helps keep track of your test results.



Plasma-Calibrated Test Result
(Example)



Special messages

HI: If your blood glucose test result is above 600 mg/dL (33.3 mmol/L), **HI** will appear on the meter display. **This indicates severe hyperglycemia (high blood glucose). You should re-check your glucose level, and if HI call your health care professional immediately.**

When your blood glucose test result is above 240 mg/dL (13.3 mmol/L) or reads **HI**, **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.

LO: If your test result is lower than 20 mg/dL (1.1 mmol/L), **LO** will appear on the meter display. **This indicates severe hypoglycemia (low blood glucose). You should treat this condition according to recommendations of your health care professional.**

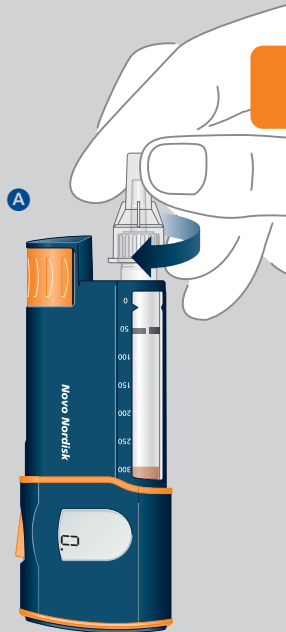
INJECTING YOUR INSULIN

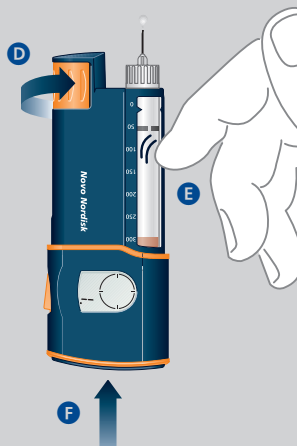
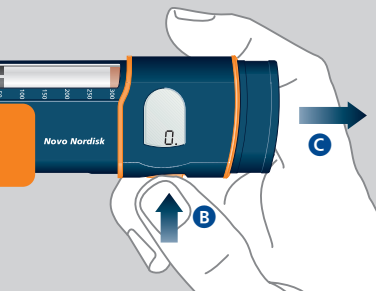
⚠ Before beginning, read Important Information on page 65.

To begin preparation for injecting your insulin, pull out the InDuo™ insulin doser. Do not press any buttons on the meter cap while you remove the insulin doser. Attach a NovoFine® needle. You will then be ready to prime your insulin doser and dial your insulin dose. **If your InDuo™ insulin doser contains an insulin suspension (cloudy insulin) you must resuspend the insulin by turning the InDuo™ insulin doser up and down as described in the PenFill® Information For The Patient.**

How to attach a NovoFine® needle

- Pull out the InDuo™ insulin doser.
- Wipe the front rubber stopper of the PenFill® with an alcohol swab.
- Take the protective tab off the NovoFine® needle and screw the needle tightly onto the insulin doser **A**.
- Pull off the outer and inner needle caps before priming your insulin doser.





How to prime your InDuo™ insulin doser

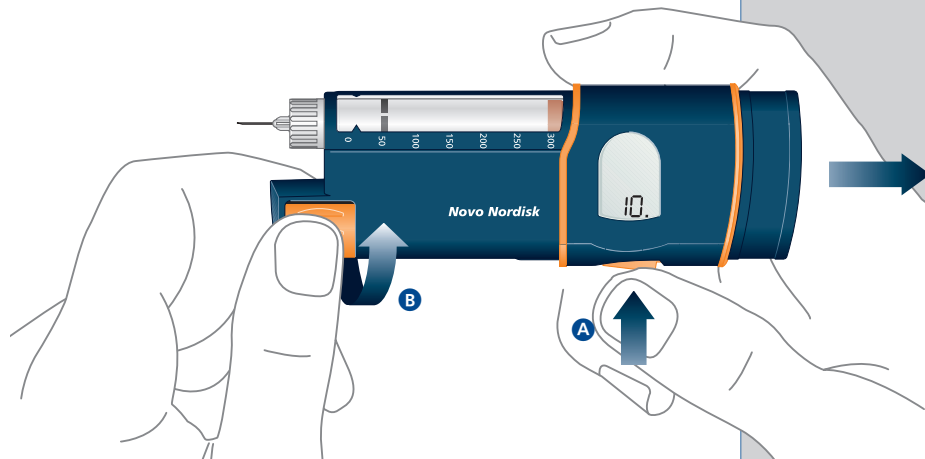
- Make sure that a NovoFine® needle is attached (see page 24), the push button is pressed in completely, and the slide is closed. If the slide is not closed, the release button will be locked.
- Press the release button **B**. You will see that the push button jumps out **C**.
- Dial 1 unit **D** (When inserting a new PenFill® start with 8 units)
- Hold the InDuo™ insulin doser with the needle upwards and tap the slide gently with your finger a few times **E**.
- Press the push button completely in until it locks **F**.
- A drop of insulin should appear at the needle tip.

If not, repeat the priming procedure until a drop of insulin appears. If you had opened the slide and your PenFill® is not new, you may need to repeat the procedure several times.

Please be aware that priming is not finished until a drop of insulin appears.

How to dial your dose

- Make sure that a NovoFine® needle is attached and that the push button is pressed completely in.
- Press the release button **A** and the push button will jump out. The display will show 0.
- Dial the number of units you need by turning the dose selector at a steady speed **B**. In the example below a dose of 10 units has been dialed.

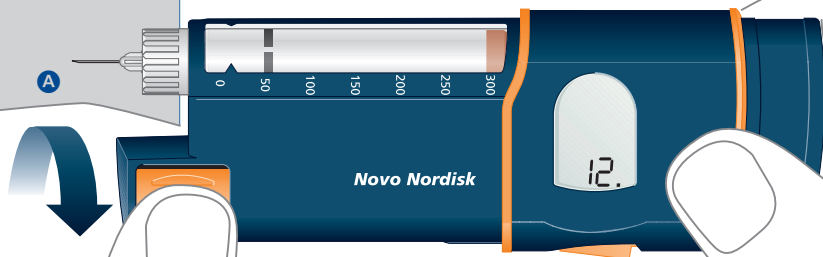


How to change a dose dialed

- If you accidentally dial a larger dose than you need, dial back to the correct number of units **A**.
- The dose dialed can be changed until you press the push button.

How to cancel a dose dialed

- If you want to cancel a dose dialled, dial back to 0 and press the push button completely in.
- Your last delivered dose (or priming) and the time passed since its delivery will reappear on the display.
- Begin again with "How to dial your dose".
(See page 43)



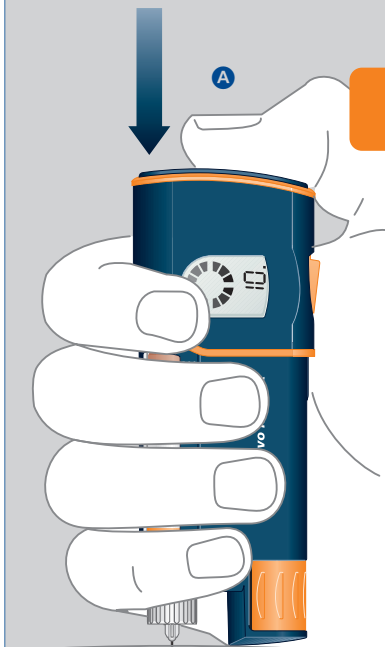
How to give an injection

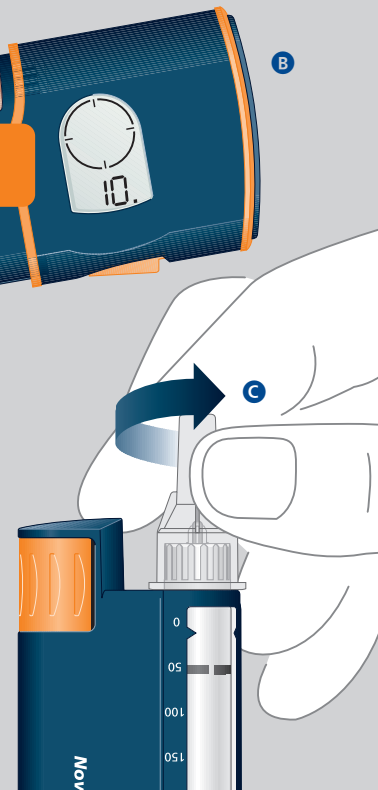
It is important that you follow the injection method recommended by your healthcare professional.

To inject, press the push button completely in until it locks **A**. You will probably feel that the push button becomes a little harder to press at the end of the injection. This is normal.

 Do not change the dose after you have pressed the push button.

- With all insulin injection systems, the needle should be left under the skin for at least 6 seconds to ensure that the full insulin dose has been delivered. The InDuo™ insulin doser helps you to do this by providing a built-in timer.





- When the push button is pressed completely in, the segments turn on two by two  telling you to leave the needle under your skin.
- When the circle symbol  appears **B**, the full insulin dose has been delivered and you can withdraw the needle.

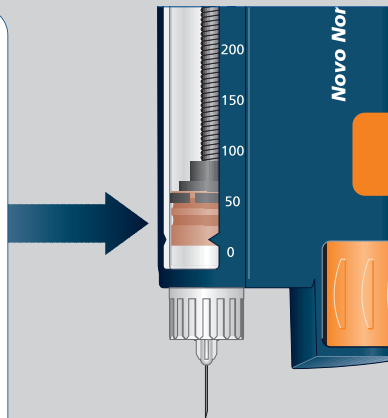
After the injection follow the instructions of your health care professional to:

- Carefully replace the outer needle cap on the needle.
- Unscrew the needle and discard it properly **C**.
- Always replace the insulin doser into the meter cap.

What to do when PenFill® is nearly empty

- Do not try to inject an insulin suspension (cloudy insulin) if the rear rubber stopper is below the arrow marks on the slide as shown in the picture. The glass ball must have adequate space to resuspend the insulin. In this situation, you must change PenFill®.
 - The InDuo™ insulin doser will not let you dial a larger dose than that remaining in PenFill®.
- ⚠ Do not force the dose selector to turn, instead change PenFill®.

If you need more insulin than the amount left in PenFill® you need to:



either

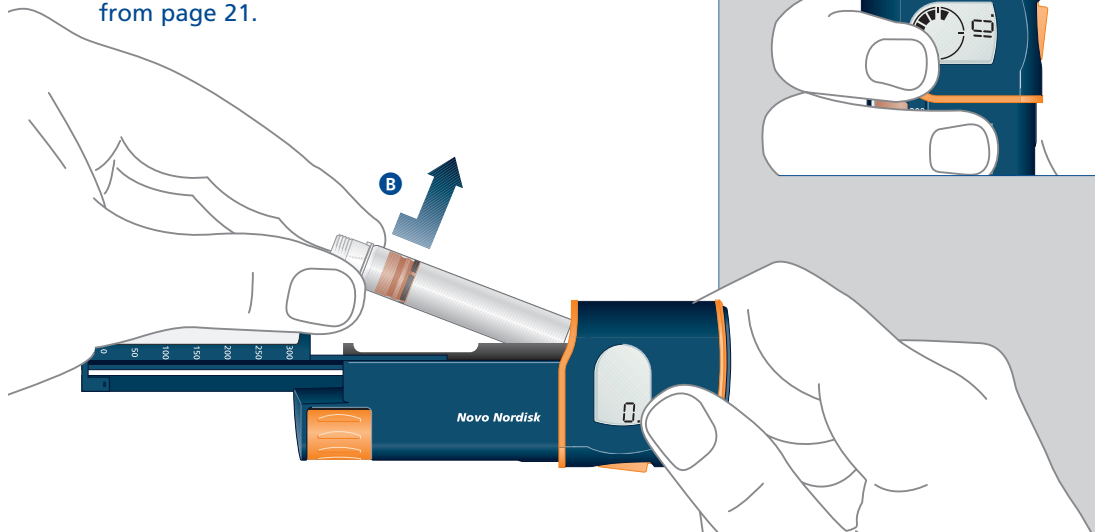
- Change PenFill® (see page 49).
- Prime the InDuo™ insulin doser (see page 24).
- Inject the whole dose at once.

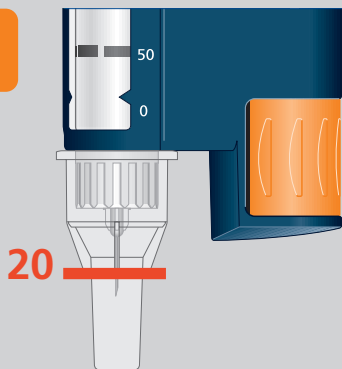
or

- Inject the remaining insulin, making a note of the amount of insulin you have injected.
- Insert a new PenFill® for the rest of your dose (see page 47).
- Prime the insulin doser (see page 24).
- Dial the remaining number of units to complete your dose.
- Inject, making sure that you have now injected your full dose.
- If you have changed PenFill® so that your total dose was divided into 2 doses, note that the insulin doser memory will only remember the second of the 2 doses given.

How to change PenFill®

- Make sure that the push button is pressed in completely **A**.
- Make sure there is no needle on the insulin doser.
- Open the slide.
- Take out the used PenFill® **B**.
- Take a new PenFill® and continue as described from page 21.





InDuo™ insulin doser function check

You should regularly check the functioning of your InDuo™ insulin doser. For example, once a month, or before starting a new box of PenFill® cartridges. You should also check the functioning of the InDuo™ insulin doser if you think that it is not working properly.

- Screw on a new NovoFine® needle, as described on page 41.
- Prime the insulin doser as described on page 42.
- Put the outer needle cap over the needle.
- Dispense 20 units into the outer needle cap. The insulin should fill the lower part of the outer needle cap.
- If too much or too little insulin is released, repeat the test.
- If the InDuo™ insulin doser again releases too much or too little insulin, do not use your insulin doser. Do not try to repair a faulty insulin doser. Call InDuo Customer Services at our toll free number 1-877-520-9056.

USING THE InDuo™ MEMORY FUNCTIONS

Both the InDuo™ meter and the InDuo™ insulin doser have memory functions.

Checking your previous test results

Your InDuo™ meter has a memory that can store the 150 most recent blood glucose and control solution test results, together with the date and time at which they were carried out.

Using the memory mode

Enter the memory mode

- With the meter turned off, press **M**.
- The 14-day average will appear, indicating that you are in the memory mode **A**.
- After 3 seconds, the 30-day average will appear for 3 seconds **B**.
- You can now recall the last 150 test results in the meter memory (see page 52).
- You can also enter memory mode from the test mode. After completing a blood glucose or control solution test, and while the test result is still on the display, press **M** to enter the memory mode.

(Example)





(Example)

How to recall test results

- After 3 seconds, the 30-day average will be replaced by the most recent test result with date and time.
- Press **C** once and the next most recent test result will appear.
- Each time you press and release **C**, the meter will recall your last test results in order up to 150.
- When the meter memory is full, the oldest result is dropped as the newest is added.
- To scroll through the test results more quickly, press and hold **C**.
- Control solution test results will appear on the display with **ctl mem**.
- When using the meter for the first time, **mem** --- will appear, showing that there are no test results in the memory.

Exit the memory mode

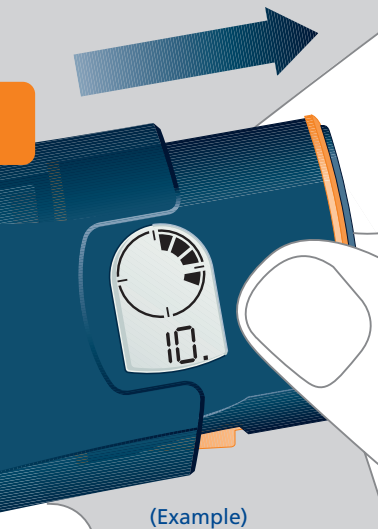
- Press **M** to turn off the meter.

Other memory functions of the InDuo™ meter

The InDuo™ meter can provide valuable information on variations in your blood glucose levels.

Average blood glucose test results over 14 days and 30 days

- The meter provides 2 averages of your blood glucose tests.
- The first average, **14 DAY AVG** is calculated from tests performed over the last 2 weeks (14 days).
- The second average, **30 DAY AVG** is calculated from tests performed over the last month (30 days).
- The meter ignores control solution test results when properly marked as control tests and uses only blood glucose test results to calculate these averages.
- The meter also tells you how many blood glucose tests were performed and therefore used to calculate the average. For example, if you see **64n** on the meter display, this means 64 tests were performed.
- When the meter is used for the first time, you will see **14 DAY AVG ---** and **30 DAY AVG ---**, showing that there are no test results stored yet in the meter memory.



Checking your previous injection

- Pull out the InDuo™ insulin doser.
- After the display test (see page 80), your previous dose (or priming) and the time passed since delivery can be seen on the insulin doser display. Each segment represents 1 hour.
- For example, if 4 segments are displayed , 4 hours have passed since the previous injection.
- If 12 segments are displayed , 12 hours or more have passed.
- Always replace the insulin doser into the meter cap.

VIEWING BLOOD GLUCOSE TEST RESULTS ON A PERSONAL COMPUTER

You can transfer blood glucose test results to your PC for home viewing. This requires a LifeScan Interface Cable and IN TOUCH® Diabetes Management Software which is available from LifeScan.

IN TOUCH® Software and the LifeScan Interface Cable are not included with your InDuo™ system and must be obtained separately.





How to transfer glucose test results to your PC

Install IN TOUCH® software

- Install IN TOUCH® software on your computer following the instructions provided in the IN TOUCH® user's manual.

Connect the LifeScan Interface Cable

- Connect the LifeScan Interface Cable to a serial port on the back of your computer.
- With the InDuo™ meter turned off, connect the LifeScan Interface Cable to the data port located on the top-right corner of the InDuo™ meter.
- PC will appear on the display once the first command is received, indicating that the InDuo™ meter is in the communication mode.
- You are now ready to transfer all test results (together with the date and time they were made) from the memory in your InDuo™ meter to your computer.

- While the InDuo™ meter is in the communication mode, you cannot use the InDuo™ meter to perform a blood glucose test. Similarly, when the InDuo™ meter is in either the memory mode or the setting mode, it is unable to respond to computer commands.

Data transfer to computer

- Follow the instructions in your IN TOUCH® user's manual to begin transferring your blood glucose test results to your computer.
- If no command is received within 2 minutes, the InDuo™ meter will turn off automatically.
- Pressing **M** will also turn off the InDuo™ meter.
- Follow the instructions in your IN TOUCH® user's manual to view your blood glucose test results on your computer.

IN TOUCH® Software, which includes the LifeScan Interface Cable, must be purchased separately. To obtain the software and a LifeScan Interface Cable, call InDuo™ Customer Services at 1-877-520-9056.

COMPARING THE InDuo™ METER AND LABORATORY RESULTS

The InDuo™ meter blood glucose test results and laboratory results are both expressed in plasma-equivalent units. However, you may notice a normal variation between the results you obtain using your meter and your usual laboratory results. InDuo™ test results can be affected by factors and conditions that do not affect laboratory results in the same way. Your InDuo™ 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 InDuo™ 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.

Making an accurate comparison between the InDuo™ meter and laboratory results

Before going to the laboratory

- Perform a control solution test to check that the InDuo™ meter is working properly.
- It is best to fast for at least 8 hours before doing comparison tests.
- Take your InDuo™ meter with you to the laboratory.

At the laboratory

- Make sure that the samples for both tests (the meter test and the laboratory test) are taken and tested within 15 minutes of each other.
- Wash your hands before obtaining a blood sample.

- Never use your InDuo™ meter with blood that has been collected in a grey-top blood collection tube.
- Use fresh capillary blood only.

Other reasons for variation

Besides the factors listed in the OneTouch® *Ultra* test strip package insert there are other reasons for variations:

- Blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication, or experienced stress.¹
- If you have eaten recently, the blood glucose level from a fingertip blood sample can be up to 70 mg/dL higher than blood drawn from a vein (venous sample) used for a laboratory test. It is therefore best to fast for 8 hours before doing a comparison test

between an InDuo™ meter result and a laboratory result.²

- Physical factors, such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluids (severe dehydration) may also cause an InDuo™ meter test result to be different from a laboratory result.

References

1. Surwitt RS, Feinglos, MN. *Diabetes Forecast*. April, 1988: 49–51.
2. Sacks DB. Carbohydrates. Burtis CA, Ashwood BR ed. *Tietz Textbook of Clinical Chemistry*. Philadelphia, PA: W.B. Saunders Company; 1994: 959.

CARING FOR YOUR InDuo™ SYSTEM

- Your InDuo™ is a precision instrument. To ensure it works accurately and safely, handle it with care.
- Avoid situations where your InDuo™ component parts can be damaged.
- Store InDuo™ in its carrying case after each use.
- Always replace the meter cap after using your InDuo™ insulin doser.
- Please read the Information for The Patient in the PenFill® pack. This will tell you how to store PenFill® cartridges and how long to keep them.
- With a PenFill® cartridge inserted, store your InDuo™ at room temperature [up to 77°F (25°C)]. Follow the guidelines on insulin storage supplied in the PenFill® Information for The Patient.
- Do not refrigerate your InDuo™
- As no blood or control solution comes in contact with the meter, there is no special cleaning required.
- Take care to avoid getting dirt, dust, blood, control solution, or water inside the InDuo™ through the test port or data port.
- Clean off dirt and dust with a dry, soft brush or cloth.
- Use a cloth dampened with water and mild detergent to wipe down the outside of the meter.
- Do not soak, wash, or lubricate the InDuo™ system. This will damage the mechanism.
- InDuo™ system will be damaged if wiped with alcohol.

Power supply

The InDuo™ system is powered by batteries making it portable and self-contained. The InDuo™ system comes with two battery systems already installed.

- The **meter battery** provides you with enough power to perform approximately 1000 blood glucose or control solution tests. When the meter battery expires, it is easily replaced using a 3.0 V (#2032 or equivalent) lithium battery.
- The **insulin doser battery** cannot be replaced and has an extended life allowing it to operate for about 4 years. When the insulin doser battery is due to expire, the insulin doser display will begin flashing (see page 64) and your InDuo™ insulin doser should then be replaced within 30 days.



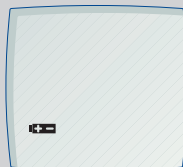
Replaceable battery



Non-replaceable battery



A



B

When to change your InDuo™ meter battery

Your InDuo™ meter will alert you when the power is getting low by displaying the following messages.

- A** This message appears when the meter display is turned on and all the other display messages are functional.

It is time to change the meter battery. From the time you see the battery symbol  change the battery as soon as possible. There is enough power left in the battery for about 50 tests. The meter will not operate if the battery is allowed to expire.

- B** This message means that the meter battery does not have enough power left for a test. Change the battery immediately with one 3.0 V (#2032 or equivalent) lithium battery.

How to replace the InDuo™ meter battery

- To replace the meter battery, make sure that the InDuo™ meter is turned off.
- Turn your InDuo™ meter over and locate the battery compartment.
- Open the battery door on the back of the meter **A**.
- Remove the old battery. Insert one 3.0 V (#2032 or equivalent) lithium battery, making sure the positive (+) side of the battery is facing up **B**.
- Slide the battery door closed.
- Replacing the meter battery does not affect test results already stored in the InDuo™ memory. However, the time, date, and unit-of-measurement settings may need to be updated. (See page 5)
- The first time you turn on the InDuo™ meter after replacing the battery, the meter display may go into the setting mode automatically. At this time, you should update the time, date, and unit-of-measurement settings.





(Example)

When to replace your InDuo™ insulin doser

A flashing display indicates that the insulin doser battery power is low.

- Be sure to replace your InDuo™ insulin doser within 30 days. The battery cannot be changed. Call InDuo™ Customer Services at 1-877-520-9056 to obtain a new InDuo™ insulin doser.

IMPORTANT INFORMATION

- As a precautionary measure, always carry a spare insulin delivery system in case your InDuo™ doser is lost or damaged.
- Always prime your InDuo™ insulin doser (see page 24) to ensure the insulin flow:
 - Before each injection.
 - After changing PenFill®.
 - After changing the needle.
 - After opening and closing the slide.
- When a PenFill® is in the insulin doser, never press the push button unless a needle is attached.
- Before injecting always make sure the push button is pressed completely in and locks.
- The insulin doser display confirms completed delivery when the segments turn on two by two  and then the circle symbol  appears.
- Do not change the dose after you have pressed the push button.
- Always make sure that the insulin doser is inserted completely into the meter cap when not in use. This shuts the power off.
- Your InDuo™ insulin doser is designed to work accurately and safely. In the unlikely event that you cannot release the push button on your InDuo™ insulin doser, it may be due to a malfunction and you should use another method, such as a spare insulin delivery system to take your scheduled insulin doses.

- The InDuo™ system is tough but could still be damaged. Handle it with care, do not drop it, and avoid knocking it against hard surfaces. If the InDuo™ system has been dropped or knocked, you must carry out a function check of the insulin doser (see page 50) and a control solution test (see page 14).
- Never use your InDuo™ system unless you are sure that it is working properly.
- Do not play with the dose selector or the push button as this can cause the InDuo™ insulin doser to wear out.
- Keep the InDuo™ system, PenFill®, and NovoFine® needles out of the reach of children.
- Your InDuo™ system is for use by one person only.
- Before each injection make sure that you are using the right type of insulin.
- If you are treated with more than one type of insulin in PenFill® 3 mL cartridges, you should use an InDuo™ insulin doser for one type of insulin, e.g. a rapid acting analogue, and a different insulin delivery device, such as Innovo®, for the other e.g. long acting insulin.

- Take the needle off the InDuo™ insulin doser immediately after each injection. If you do not remove it, temperature changes may cause liquid to leak out of the needle. With an insulin suspension (cloudy insulin), a leak of liquid may change the concentration of the insulin.
- Do not start injecting an insulin suspension (cloudy insulin) if the rubber stopper is below the arrow marks on the slide. The glass ball must have adequate space to resuspend the insulin. Instead, you must replace the old PenFill® with a new one.
- Do not use the residual scale to measure the amount of insulin to be injected.
- Do not try to repair a faulty InDuo™ component.
- The InDuo™ system must only be used according to the instructions in this manual. The manufacturer will not be held responsible for any equipment problems if you have not followed the instructions.
- Healthcare professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles to minimize the risk of unintended needle penetration.
- Keep the InDuo™ meter, OneTouch® *Ultra* strips, and OneTouch® *Ultra* control solution at the same relative temperature before testing. Testing before the meter, strips, and control solution reach the same relative temperature may result in an inaccurate glucose reading.

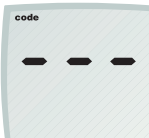
DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE

There are a number of messages and symbols that appear on the insulin doser and meter displays during use of the InDuo™ system. The following is a summary of all display messages. The meter gives an error message when it detects a problem which could cause an inaccurate result. However, the meter cannot detect all problems, and for those it can detect, may not produce an error message every time the problem occurs. There may also be causes for the display of an error message that are not listed here.

Assistance is available from InDuo™ Customer Services. Please call our toll free number at 1-877-520-9056

The InDuo™ meter

Here is a summary of the different messages given on the InDuo™ meter display.

Meter display	What it means	Action
	This indicates that the meter is running a system check. It appears whenever a OneTouch® <i>Ultra</i> test strip is inserted and when the InDuo™ blood glucose meter is turned on. It verifies that all segments on the display are working.	If segments are missing, call InDuo™ Customer Services at 1-877-520-9056 for further action. Missing segments can lead to the wrong interpretation of the displayed test result.
	This message appears immediately after the system check if your meter has not been coded.	See “Coding your InDuo™ meter” on page 12.

Meter display**What it means****Action**

(Example)

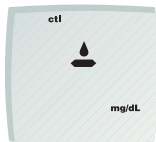
This is the code number stored in the InDuo™ meter.

Make sure that this code number matches the code number on the vial of the OneTouch® *Ultra* test strips you are using. If not, you must recode the meter (see page 11).



The system is ready to accept a blood sample.

You may now apply the blood sample.



The system is ready to accept a control solution test sample.

You may now apply the control solution.

Meter display

What it means

Action



Five-second countdown. The meter is calculating the result. At the end of the countdown, the meter will display the test result.

No action required.



A blood glucose test result in mg/dL.

No action required.

(Example)



A blood glucose test result in mmol/L.

No action required.

(Example)

Meter display**What it means****Action**

(Example)

A blood glucose test result with a suggestion to check your ketone levels.

You may want to check your ketone levels. Act according to the instructions of your healthcare professional



Indicates that you may have a very high blood glucose level, possibly exceeding 600 mg/dL (33.3 mmol/L).

You should recheck your blood glucose level and if *HI*, call your healthcare professional immediately.



Indicates that you may have a very low blood glucose level, possibly lower than 20 mg/dL (1.1 mmol/L).

You should treat this condition according to the recommendations of your healthcare professional.

Meter display

What it means

Action



A blood glucose test result stored in the memory.

No action required.

(Example)



A control solution test result stored in the memory.

No action required.

(Example)



There is no test result stored in this place in the InDuo™ memory.

No action required.

Meter display**What it means****Action**

(Example)

Average of the last 14 days.
(64_n means that 64 tests were performed within this period).

No action required.



(Example)

Average of the last 30 days.
(138_n means that 138 tests were performed during this period).

No action required.



Error message that indicates that there is a problem with the InDuo™ meter.

Do not use the InDuo™ meter. Call InDuo™ Customer Services at 1-877-520-9056 for replacement.

Meter display**What it means****Action**

Error message could be caused by a used or damaged OneTouch® *Ultra* test strip, or there is a problem with the meter.

Repeat the test with a new OneTouch® *Ultra* test strip. Refer to page 10 for OneTouch® *Ultra* test strip information. If the error message appears again call InDuo™ Customer Services at 1-877-520-9056.



Error message that indicates that the blood sample or control solution was applied before  appeared on the display.

Repeat the test with a new OneTouch® *Ultra* test strip. Refer to page 16 (for control solution application) and page 37-38 (for blood application, for proper time to apply sample).



Error message that indicates that there may be a problem with the test, e.g. the OneTouch® *Ultra* test strip may have been damaged or moved during testing, or the sample has been improperly applied.

Check the OneTouch® *Ultra* test strip for damage. Refer to page 34 and 38 for proper sample application. Repeat the test. If the error message appears again, call InDuo™ Customer Services at 1-877-520-9056.

Meter display**What it means****Action**

Error message that indicates that the InDuo™ meter has detected a problem with the test. Possible causes are incompletely filled confirmation window or a damaged OneTouch® *Ultra* test strip.

Repeat the test with a new OneTouch® *Ultra* test strip. Refer to page 34 and 37 for proper sample application procedure. If the error message appears again, call InDuo™ Customer Services at 1-877-520-9056.



The battery symbol  appears on the display with the unit of measure. It means that the power of the battery is getting low. You can complete about 50 more tests from the time this symbol first appears.

Test results will still be accurate, but replace the battery as soon as possible.



The battery symbol  appears on the display by itself. The power of the battery is too low to run a test.

Replace the battery immediately. The InDuo™ meter will not operate until the battery is replaced.

Meter display**What it means****Action**

The InDuo™ meter has detected that the temperature is below the operating range. You cannot perform a test until the InDuo™ meter and the OneTouch® *Ultra* test strips reach a temperature within the operating range of 43–111°F (6–44°C).

Repeat the test after the InDuo™ meter and OneTouch® *Ultra* test strips have reached a temperature within the operating range.



The InDuo™ meter has detected that the temperature is above the operating range. You cannot perform a test until the InDuo™ meter and the OneTouch® *Ultra* test strips reach a temperature within the operating range of 43–111°F (6–44°C).

Repeat the test after the InDuo™ meter and OneTouch® *Ultra* test strips have reached a temperature within the operating range.

Here are the answers to some questions you might ask when using your InDuo™ meter:

What should I do if the InDuo™ meter does not display a message after a OneTouch® *Ultra* test strip has been inserted?

Probable reasons

Action

Battery exhausted

Replace the battery.

Battery incorrectly installed or absent

Check that the battery is correctly installed with the positive (+) side up.

OneTouch® *Ultra* test strip partially inserted or inserted upside-down

Insert the OneTouch® *Ultra* test strip correctly with the contact bars end-first and facing up. Push the strip in firmly until it will go no further.

Defective meter

Call InDuo™ Customer Services at 1-877-520-9056.

What should I do if the InDuo™ meter does not start running the blood glucose test after the OneTouch® *Ultra* test strip has been inserted?

Probable reasons

Action

Insufficient blood sample

Repeat the test with a new OneTouch® *Ultra* test strip and a larger sample.

Defective OneTouch® *Ultra* test strip

Repeat the test with a new OneTouch® *Ultra* test strip.

Sample applied after automatic shut-off (2 minutes after last used)

Repeat the test with a new OneTouch® *Ultra* test strip; apply sample only when the apply symbol  appears on the display.

Meter malfunction

Call InDuo™ Customer Services at 1-877-520-9056.

The InDuo™ insulin doser

As with the meter display, a number of messages and symbols appear on the InDuo™ insulin doser display during use of the insulin doser.

Message	What it means	Action
	The very first time the insulin doser is removed from the meter cap, the display stays blank until the slide is opened. However, if the display goes off having already come on, carry out the correction measures described in the next column. If the display still remains off, the insulin doser is not working. Do not use the insulin doser. Call InDuo™ Customer Services at 1-877-520-9056.	If the display goes off, press the release button, and the push button will jump out. Press the push button completely in and the display should reappear. If the display does not reappear, open and close the slide. Prime the InDuo™ insulin doser as described on page 24.
	When the insulin doser is removed from the meter cap, all the display segments are turned on, telling you that the display is fully functional (display test).	No action required.

Message**What it means****Action**

The display shows the number of insulin units dialed.

No action required.



The segments turning on two by two tell you how long to leave the needle under the skin during injection.

No action required.



The display shows the number of insulin units delivered. The circle confirms that the delivery has been completed.

No action required.

Message**What it means****Action**

The display shows the number of insulin units delivered. The segments indicate the time passed since delivery. 1 segment represents 1 hour. In this example 4 hours have passed since the insulin doser delivered the previous dose.

No action required.



A flashing display indicates that the battery power is low.

Be sure to replace your insulin doser within 30 days. The battery in the insulin doser cannot be changed. Call InDuo™ Customer Services at 1-877-520-9056 to get a new insulin doser.



A minus symbol on the display tells you that the dose selector has been dialed below zero .

Dial forward until the display shows the number of units required.

Here are answers to some questions you might ask about your InDuo™ insulin doser display:

Why has the display turned off?

If the display goes off, press the release button, and the push button will jump out. Press the push button completely in, and the display should reappear. If the display does not reappear, open and close the slide. Prime the InDuo™ insulin doser as described on page 24. If the display remains off, the insulin doser is not working. Do not use the insulin doser. Call InDuo™ Customer Services at 1-877-520-9056 to get a replacement.

Why is the display showing a minus symbol?

The dose selector has been dialed below zero . Dial forward until the display shows the correct number of units.

Why does the display not respond when I turn the dose selector?

Press the release button so that the push button jumps out before a dose can be dialed.

Here are the answers to some questions you might ask about priming the insulin doser and injecting insulin:

Why does no insulin appear when I try to prime the InDuo™ insulin doser?

The needle may be blocked. Change the needle and prime the InDuo™ insulin doser until insulin appears at the needle tip. Check that the push button is pressed completely in and locked. Open the slide and make sure that PenFill® is inserted correctly. If PenFill® is damaged or empty, change it. Check that the slide is closed, and prime the InDuo™ insulin doser until insulin appears at the needle tip.

Why does no insulin appear when I prime the InDuo™ insulin doser and the push button will not go in?

The needle may be blocked. Change the needle and prime the InDuo™ insulin doser until insulin appears at the needle tip. To open the slide, dial back to zero 0, and press the push button completely in until it locks. Then change PenFill® as described on page 49.

Why does the push button not release?

Make sure that the slide is closed completely. The release button is locked until the slide is closed.

How do I cancel or change the dialed dose?

Dial back to zero 0, and press the push button completely in. Your last dose and the time passed since delivery will reappear on the display. You can increase, decrease, or cancel the dialed dose until you press the push button. Do not change the dose after you have pressed the push button.

Why is insulin delivered when the dose selector is turned?

You have dialed the maximum dose of 70 units and then continued dialing. If you need to inject a dose of insulin larger than 70 units, you must divide the dose into amounts equal to, or less than, 70 units.

Why does the push button block during the injection?

Do not try to force the push button in. The needle may be blocked. Change the needle and prime the InDuo™ doser as described on page 42. Check to see if PenFill® is damaged. Dial back to zero  and press the push button completely in until it locks. Then open the slide and change PenFill® as described on page 49. Prime the InDuo™ insulin

doser until insulin appears at the needle tip (see page 24). Please note that part of the insulin dose may have been injected. If the push button still cannot be pressed completely in, call InDuo™ Customer Services at 1-877-520-9056.

Why does the slide not open when changing PenFill®?

Put on a new needle. Press the push button completely in until it locks. Remove the needle and open the slide. If the slide still cannot be opened, call InDuo™ Customer Services at 1-877-520-9056. Do not try to force the slide open.

SPECIFICATIONS InDuo™ system

Size: 123 mm x 54 mm x 35 mm (4.84 in x 2.13 in x 1.38 in)

Weight: 4.40 ounces with battery (125g)

Operating ranges:

Temperature: 43–104°F (6–40°C)*

Relative humidity: 10–90%

Hematocrit: 30–55%

InDuo™ meter

Result range: 20–600 mg/dL (1.1–33.3 mmol/L)

Calibration: Plasma-equivalent

Blood sample: Fresh capillary whole blood

Min. sample size: 1 microliter

Test time: 5 seconds

Assay method: Glucose oxidase biosensor

Power source: One replaceable 3.0V (#2032 or equiv.) lithium battery

Battery life: 1000 tests, or about 1 year at 3 tests per day

Units of measurement: Either mg/dL or mmol/L

Memory: 150 blood glucose and control solution tests

Automatic shut-off: Two minutes after last user action

* However the meter will allow for testing at temperatures up to 111°F (44°C).

InDuo™ doser	
Cartridge:	3mL PenFill®
Needle:	NovoFine® max 8 mm length
Dose:	1 IU increment, minimum = 1 IU, maximum = 70 IU
Memory:	1 (last dose and time since)
Power source:	Internal non-replaceable lithium battery
Battery life:	4 years + 1 year of shelf life

WARRANTY

The manufacturers warrant that the InDuo™ device shall be free of defects in material and workmanship for a period of three years. Should your InDuo™ device be defective in materials or workmanship within three years of purchase, the manufacturers will replace it at no charge.

No other warranty is made with respect to InDuo™. This warranty is valid from date of purchase. The warranty extends only to the original purchaser and is not transferable. This warranty will become invalid and the manufacturers assume no responsibility in the case of defects or damages arising from: (1) the use of InDuo™ with products other than those specifically recommended by the manufacturers, (2) the use of InDuo™ in a manner other than in strict accordance with the instructions in this User's Manual or other instructions issued by the manufacturers and (3) physical damage to InDuo™ caused by neglect, misuse, unauthorized repair, accident or other breakage.

BLOOD VALUE TARGETS

Times of day	Glucose ranges for people without diabetes (mg/dL)	Your target ranges (mg/dL)
Before breakfast	70–105	
Before lunch or dinner	70–110	
1 hour after meals	Less than 160	
2 hours after meals	Less than 120	
Between 2 and 4 am	Greater than 70	

Source: Krall, L.P., and Beaser, R.S.: *Joslin Diabetes Manual*, Philadelphia: Lea and Febiger (1989), 138.

For assistance or further
information please call InDuo™
Customer Services at our toll free
number:

(English) 1-877-520-9056

(Español) 1-800-381-7226

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