ACCU-CHEK® FastClix

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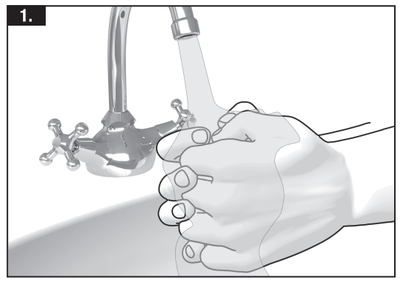
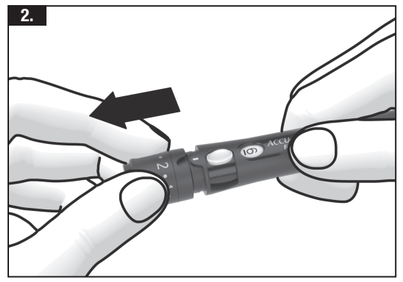
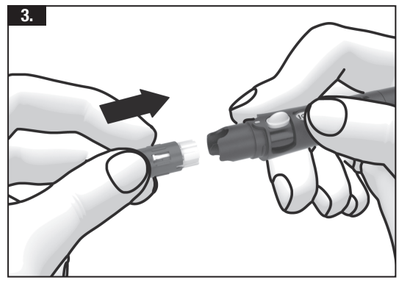
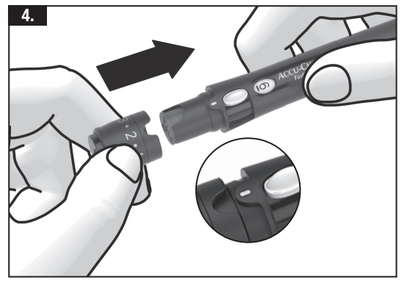
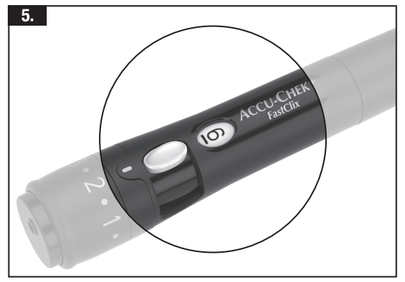
Lancing device

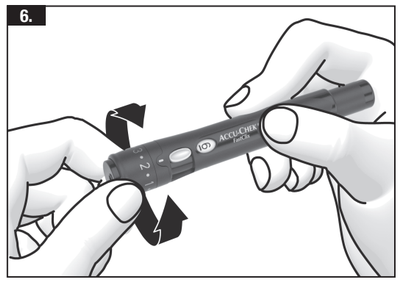


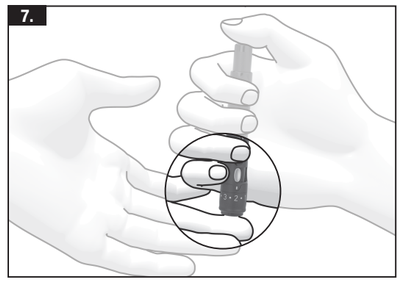


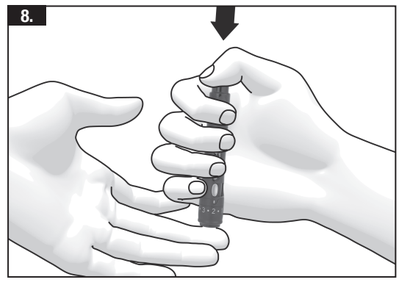


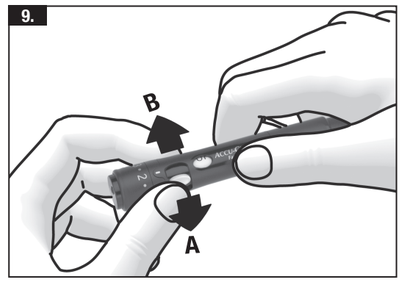


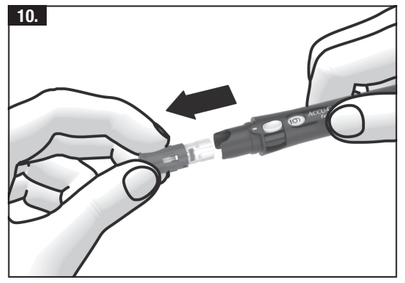


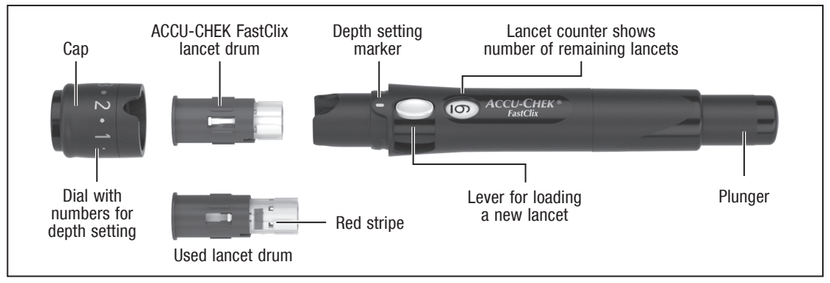


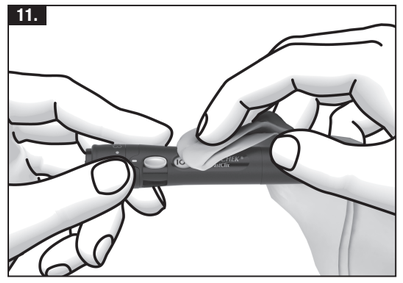


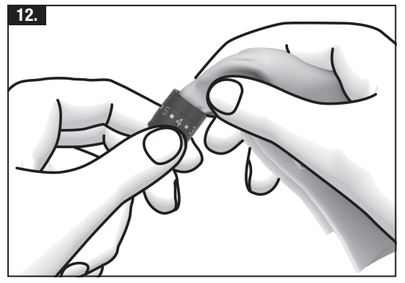












Instructions for Use

The ACCU-CHEK FastClix lancing device uses a lancet to obtain a drop of blood from a fingertip. It is designed to make obtaining a drop of blood as comfortable as possible. The lancing device is loaded with a drum containing 6 sterile lancets. Use a new, sterile lancet each time you test. Lancet reuse can dull or bend the tip of the lancet, causing damage to your skin, scarring and greater pain. Using a new lancet each time you obtain a blood sample will help prevent infection and sore fingertips. You can adjust the lancet depth to your individual skin type by dialing 1 of the 11 settings.

- **The ACCU-CHEK FastClix lancing device is intended for patient self-monitoring by a single person only. It must not be used for obtaining blood from more than one person due to the risk of infection.**
- Keep the lancing device with all its parts out of reach of children under 3 years. There is a risk of suffocation if small parts (e.g. cap or similar objects) are swallowed.
- Use only ACCU-CHEK FastClix lancet drums with the ACCU-CHEK FastClix lancing device. Using other lancets or lancet drums may impair operation of the lancing device or damage it permanently.

Preparation

Wash and dry your hands (see **1.**). Warm water helps to increase blood flow. If you use an alcohol wipe, be sure your finger is completely dry before continuing.

Inserting a Lancet Drum

You must first insert a lancet drum into the lancing device to get it ready for use.

A new drum is gray and white. A used drum has a red stripe, and cannot be reinserted into the lancing device.

Remove the cap by pulling it straight off (see **2.**).

Insert a new drum, white end first, into the device until it stops (see **3.**). You will hear and feel it click into place.

Slide the cap back on until it stops (see **4.**), lining up the notch on the cap with the notch on the device.

You are now ready to use the first lancet. The lancet counter shows the number “6”, which means you have 6 new lancets remaining (see **5.**).

Obtaining a Blood Sample

Use a new lancet when collecting blood. When you use a new lancet each time, you avoid infection and get a virtually pain-free test.

Adjust the depth setting by turning the dial on the cap to the desired depth (see **6.**). The depth setting marking shows the current depth selection. Higher numbers mean greater penetration depth. If you have soft skin, start at a depth of 2. If your skin is calloused or thick, try a higher setting.

Hold the lancing device firmly against the side of your fingertip (see **7.**). The side of your fingertip is less sensitive than the middle of the fingertip. Remember that the pin-hole opening where the lancet comes out is not in the center of the cap.

Press the plunger all the way in (see **8.**). This releases the lancet to create a blood sample.

Gently massage your finger in the direction of your fingertip to assist the flow of blood. This helps you to get a blood drop.

Apply the blood drop to your test strip.

If you don’t get enough blood, try putting more pressure on your finger with the cap or switch to a higher depth setting. If you get too much blood, switch to a lower depth setting.

Advancing to a New Lancet

To advance to a new lancet, push the lever at the side of the lancing device as far as it will go in direction “A” and then back in direction “B” (see **9.**).

The next lancet is now ready to be used.

Each time you advance to a new lancet, the number showing in the lancet counter decreases by one. This is the number of remaining lancets. When the number “1” is visible in the lancet counter, you are using the last lancet in that drum.

Changing the Lancet Drum

When you have used the sixth and last lancet, you should change the drum.

Remove the cap from the lancing device by pulling it straight off.

Hold the drum between your thumb and index finger and pull it straight out of the lancing device (see **10.**).

A red stripe is visible on the white drum, showing that the drum has been used and cannot be reinserted into the lancing device.

Used lancet drums should always be disposed in accordance with local regulations.

Insert a new drum, white end first, until it stops and clicks into place.

NOTE
A used drum cannot be reinserted into the lancing device. This helps prevent potential infections.

Non-fingertip Testing

For information about non-fingertip testing, please contact the ACCU-CHEK Customer Care Service Center at 1-800-858-8072.

Caring for Your Lancing Device

- Your lancing device requires very little care.
- Keep it away from extreme temperatures.

Cleaning and Disinfecting the Lancing Device

The lancing device can spread infection if it becomes soiled with blood.[1,2] During normal testing any lancing device may come in contact with blood. For this reason, it is important to keep the lancing device clean and disinfected.

NOTE
- Do not throw away the lancing device cap after each use. Use approved cleaning and disinfecting products on it (as described below).
- Remove the lancet drum before cleaning and disinfecting the lancing device.
- For technical assistance or questions on cleaning and disinfecting please contact the ACCU-CHEK Customer Care Service Center at 1-800-858-8072.

What is the difference between cleaning and disinfecting?

- Cleaning is the removal of dirt from the lancing device.[3]
- Disinfecting is the removal of most, but not all, disease-causing and other types of microorganisms from the meter or lancing device.[3]

To clean and disinfect without damaging the lancing device, follow these procedures carefully.

When to Clean and Disinfect the Lancing Device

- Clean the lancing device to remove visible dirt or other material prior to disinfecting.
- Clean and disinfect the lancing device once per week or when it has visible signs of dirt or other material.
- Clean and disinfect the lancing device before allowing anyone else to handle the lancing device, for instance, if you have someone assisting you. **Do not allow anyone else to use your lancing device to obtain their blood sample.**

Approved Cleaning and Disinfecting Solution Product

The following product has been approved for cleaning and disinfecting the lancing device:

- Super Sani-Cloth (EPA* reg. no. 9480-4)
  * Environmental Protection Agency

Super Sani-Cloth can be purchased from the following sources:

- Amazon.com
- Officedepot.com
- Walmart.com

WARNING
Always use Super Sani-Cloth (EPA reg. no. 9480-4) to clean and disinfect the lancing device. Do not use any other cleaning or disinfecting solutions. Using solutions other than the Super Sani-Cloth could result in damage to the lancing device.

NOTE
- If you notice any of the following signs of deterioration after cleaning and disinfecting your lancing device, please contact the ACCU-CHEK Customer Care Service Center at 1-800-858-8072: residue around buttons.
- You might observe a slight discoloration of the lancing device after multiple cleaning and disinfecting cycles. This does not affect the functionality of the device.

What to Clean and Disinfect

The following parts of the lancing device may be cleaned and disinfected:

- The entire lancing device surface
- The cap

How to Clean and Disinfect the Lancing Device

WARNING
Do not get any moisture into openings.
Failure to follow these instructions will damage the lancing device and stop it from working properly.

1. Wash hands thoroughly with soap and water.
2. Wipe the entire lancing device surface with the approved cleaning and disinfecting product (see **11.**). Make sure that no liquid enters any opening.
3. Remove and wipe the inside of the cap (see **12.**).
4. Dry the lancing device and cap with a soft cloth or gauze. Make sure that no solution is seen in any opening.
5. For disinfecting the lancing device, get a new cloth. Repeat steps 2 and 3 following the manufacturer’s instructions for disinfecting.
6. Wash hands thoroughly with soap and water.

NOTE
Roche has tested the approved product for a total of 520 cycles which is equal to cleaning and disinfecting once per week for a 5 year period.

We Are Here to Help

If you need assistance, please contact the ACCU-CHEK Customer Care Service Center toll-free, 24 hours a day, 7 days a week. We offer assistance in Spanish and many other languages.

1-800-858-8072 phone

1-800-858-8074 TDD/TTY
(for hearing impaired)

One (1) Year Warranty

Roche warrants the ACCU-CHEK FastClix lancing device against defects in materials and workmanship for a period of one (1) year from the date of purchase. The liability of Roche under this warranty is limited to the repair or replacement, at Roche’s option, of all parts or materials proven to be defective. This warranty does not cover repair or replacement of ACCU-CHEK FastClix lancing devices which have been subjected to alteration, misuse, tampering, or abuse.

THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED, OR STATUTORY. ROCHE DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Roche’s entire liability with respect to the ACCU-CHEK FastClix lancing device shall be the repair or replacement of nonconforming devices, at Roche’s option. In no case shall Roche be liable for incidental, indirect, special, or consequential damages. This warranty gives you specific legal rights, and you may have other rights which vary from state to state so the above limitation and exclusion may not apply to you. All inquiries about the ACCU-CHEK FastClix lancing device under the above warranty or service policy must be directed to ACCU-CHEK Customer Care Service Center by calling 1-800-858-8072. You will be informed of the procedure necessary for replacement. Please DO NOT return any device to Roche without authorization.

IMPORTANT – Read carefully before use. Caution: A restricted license limits use of the ACCU-CHEK FastClix lancing device in the United States.

The ACCU-CHEK FastClix system (device and lancet drums) and its use are protected by U.S. Patent Nos. Re. 35,803 (expires 9-December-2012); 7,322,998 (expires 3-March-2020); and 7,785,338 (expires 5-January-2026). A license to use the ACCU-CHEK FastClix system is required until the last-to-expire patent listed above and is only granted when ACCU-CHEK FastClix lancet drums are used with the ACCU-CHEK FastClix lancing device.

ACCU-CHEK FastClix lancet drums are high precision components that are produced to the close tolerances required for satisfactory operation with the ACCU-CHEK FastClix lancing device. Use of other lancet drums with the ACCU-CHEK FastClix lancing device may prevent or impair proper function of the ACCU-CHEK FastClix lancing device.

Using the ACCU-CHEK FastClix lancing device indicates your acceptance of the restricted license to use the ACCU-CHEK FastClix lancing device only with ACCU-CHEK FastClix lancet drums. Further, if you have purchased an ACCU-CHEK FastClix lancing device that includes this restricted license, then this restricted license applies regardless of any additional offers found in ACCU-CHEK FastClix lancing device packages. If you do not agree to the terms and conditions of the restricted license, you may return, at the place of purchase, the unused ACCU-CHEK FastClix lancing device for a full refund. If you have any questions, please call the ACCU-CHEK Customer Care Service Center at 1-800-858-8072.

Except where prohibited by statute, all warranties covering the ACCU-CHEK FastClix lancing device are voided by use of the ACCU-CHEK FastClix lancing device with any lancet drums other than ACCU-CHEK FastClix lancet drums.

Visit our web site at www.accu-chek.com.

References

1 *FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication,* Update November 29, 2010. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. Accessed May 26, 2011.

2 *CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens,* (2010). http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html. Accessed May 26, 2011.

3 Healthcare Infection Control Practices Advisory Committee (HICPAC), William A. Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H. Centers for Disease Control and Prevention, 2008. *Guideline for Disinfection and Sterilization in Healthcare Facilities.* Atlanta.

CE 0088

This product fulfils the requirements of the European Directive 93/42/EEC on medical devices.

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