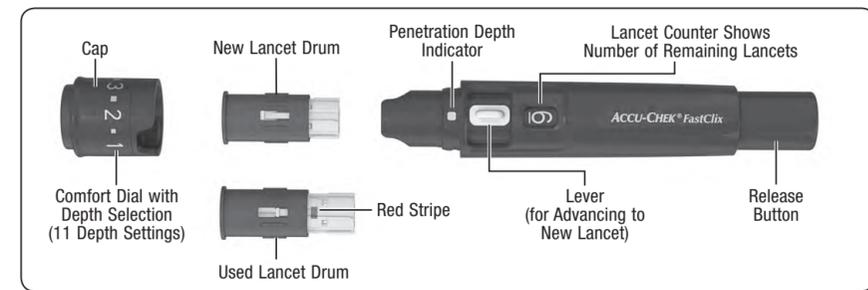
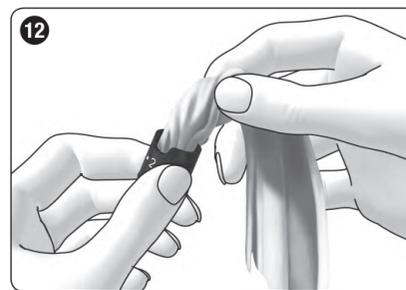
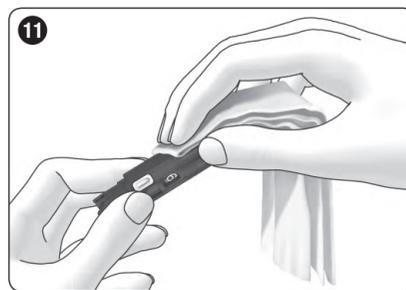
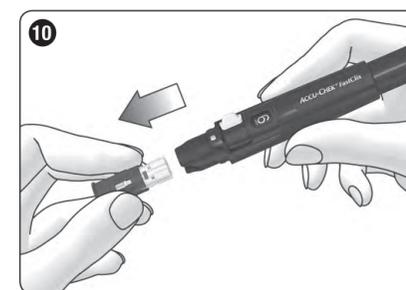
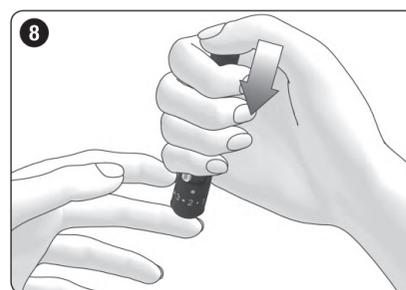
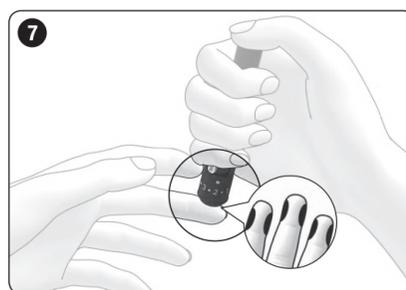
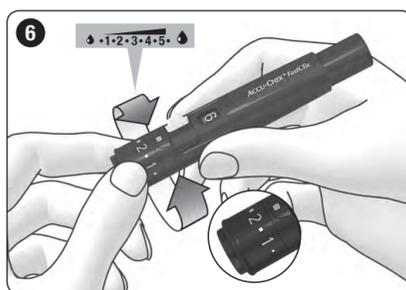
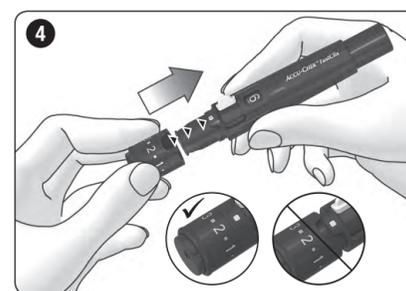
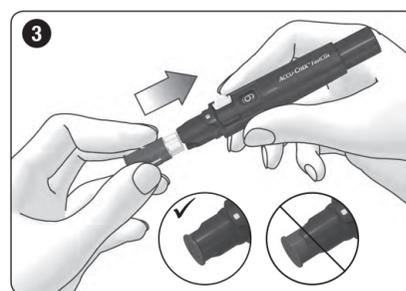
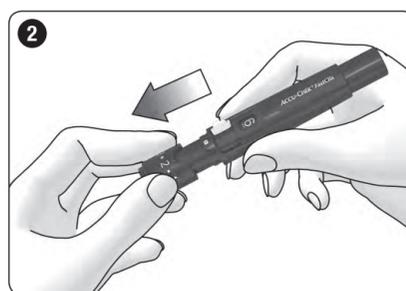


ACCU-CHEK® FastClix

Lancing device



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Instructions for Use

The Accu-Chek FastClix lancing device is a device for simple, virtually pain-free collection of capillary blood from the fingertips. The lancing device has 11 different penetration depths so that you can adjust the penetration depth to the texture of your skin. With the release button, you can prime the lancing device and trigger a lancet in a single step. When a lancet is triggered, it penetrates the skin. You insert a lancet drum with 6 lancets into the lancing device. You can obtain blood using a new, sterile lancet 6 times before the lancet drum needs changing.

WARNING

- The Accu-Chek FastClix lancing device is intended for personal use only! It is only allowed to be used to obtain blood from one person. There is a risk of infections being transmitted if the lancing device is used by other people, even by family members, or if healthcare professionals use this lancing device to obtain blood from different people. This lancing device is therefore not suitable for professional use in healthcare facilities and institutions.
- Keep the lancing device with all its components away from children under the age of 3 years. There is a risk of suffocation if small parts (e.g. caps or similar objects) are swallowed.
- Only insert Accu-Chek FastClix lancet drums into the Accu-Chek FastClix lancing device. Other lancets or lancet drums may impair the operation of the lancing device or damage it permanently.

Preparation

- ▶ Wash your hands with warm water and soap before you obtain blood (see 1). Dry your hands thoroughly. This reduces contamination of the puncture site and stimulates blood flow.

Inserting a Lancet Drum

- You have to insert a lancet drum to be able to obtain blood with the lancing device.
- ▶ Remove the cap from the lancing device (see 2).
- ▶ Insert a new lancet drum – white end first – into the lancing device (see 3).

The lancet drum is properly inserted when it is completely inside the lancing device, and only the projecting edge protrudes from the lancing device at the front (see 3).

WARNING

- You must not insert the lancet drum into the lancing device and simultaneously press the release button or hold the lancing device with the release button resting on a surface such as a tabletop. This could release a lancet and inadvertently cause injury.
- ▶ Place the cap back on again, lining up the notch on the cap with the notch on the lancing device (see 4).

The cap is on correctly when it is pushed back as far as it will go, and you hear and feel it click into place.

WARNING

The cap can only be correctly placed on up to the stop position when the lancet drum is completely inside the lancing device. Do not use any force to place the cap on as

this might damage the cap and the lancing device. Correct the position of the lancet drum instead.

Each lancet drum contains 6 lancets. The first lancet is now ready to be used. The lancet counter shows the number 6; there are now 6 lancets available (see 5).

NOTE

Do not remove the lancet drum before all 6 lancets have been used. The lancet drum cannot be reinserted once it has been removed from the lancing device.

Setting the Penetration Depth

You can set 11 penetration depths (0.5 to 5.5). The silver square (penetration depth indicator) on the lancing device indicates the current penetration depth setting. The larger the number, the greater the penetration depth.

If you have no experience with this lancing device, we recommend setting a low penetration depth, such as penetration depth 2.

- ▶ Rotate the comfort dial until the desired penetration depth lines up with the indicator (see 6).

Obtaining a Blood Drop

In general, blood can be obtained from any finger. Certain fingers can be unsuitable if, for example, a skin or fingernail infection is present. We recommend obtaining capillary blood from the sides of the fingertips as these areas are the least sensitive to pain.

WARNING

- Always use a new lancet when you obtain blood. In doing this, you reduce the risk of infection, and obtaining blood remains virtually pain free.
- Only use the lancing device when the cap is attached. Without the cap, the lancet penetrates too deeply and may cause discomfort.
- In individual cases, the lancet may protrude from the cap after obtaining blood. There is a risk of injury or infection if you or another person touches the protruding lancet. If the lancet protrudes from the cap, carefully set the lancing device aside. Keep the lancing device out of reach of other people and contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

- ▶ Press the lancing device firmly against the selected puncture site (see 7).
- ▶ Press the release button all the way down (see 8).

The lancet is released and it penetrates the skin.

- ▶ Massage the finger in the direction of the fingertip to encourage a blood drop to form.

The amount of blood that emerges depends on the penetration depth and the pressure used to hold the lancing device against the skin.

- If not enough blood emerges, apply more pressure on the lancing device when you next obtain blood. If that is not sufficient, increase the penetration depth progressively in addition.
- If too much blood emerges, decrease the penetration depth.
- ▶ Test your blood glucose immediately after you obtain blood, according to the instructions for use for your blood glucose meter.

We recommend protecting the puncture site from contamination afterwards.

Advancing to a New Lancet

If you have already used the lancing device to obtain blood, you will need a new lancet the next time you obtain blood.

- ▶ 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.

The lancet counter shows the new number of available lancets, which has decreased by one, for example, 5 instead of 6.

- ▶ Proceed as in the previous step each time you need to change the lancet.

Each time you advance to a new lancet, the number of available lancets shown in the lancet counter decreases by one, for example, from 4 to 3. When you have loaded the sixth and last lancet, the lancet counter shows the number 1.

Replacing a Used Lancet Drum

When you have used the sixth and last lancet, you need to replace the used lancet drum with a new one.

- ▶ Remove the cap from the lancing device (see 2).
 - ▶ Remove the lancet drum from the lancing device (see 10).
- When a lancet drum has been used, a red stripe is visible on the white cylinder.
- ▶ Insert a new lancet drum (see section "Inserting a Lancet Drum").
 - ▶ Dispose of used lancet drums according to local regulations.

WARNING

A used lancet drum has a built-in lock that stops you from using it again.

Storing the Lancing Device

Do not store the lancing device at extreme temperatures, for example, in a hot car. This can impair the operation of the lancing device.

Non-Fingertip Testing

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

Cleaning and Disinfecting the Lancing Device and Cap

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 the approved cleaning and disinfecting product 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, visit our web site at www.accu-chek.com/support or call 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 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 residue around the buttons after cleaning and disinfecting your lancing device, visit our web site at www.accu-chek.com/support or call the Accu-Chek Customer Care Service Center at 1-800-858-8072.
- 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 260 cycles, which is equal to cleaning and disinfecting once per week for a 5-year period.

We Are Here to Help

If you have any questions about your lancing device or any procedure in these instructions, visit our web site at www.accu-chek.com/support or call the Accu-Chek Customer Care Service Center.

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. 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.

Patent Information

U.S. Pat.: <http://www.roche-diagnostics.us/patents>

References

- 1 FDA Public Health Notification: Use of Fingertip 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 Fingertip Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens. (2010). <http://www.cdc.gov/injectionsafety/Fingertip-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.

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