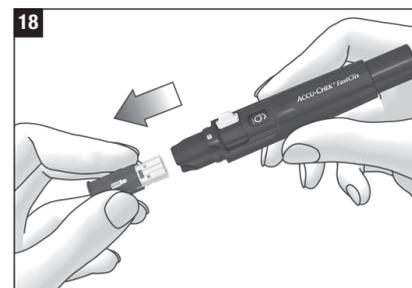
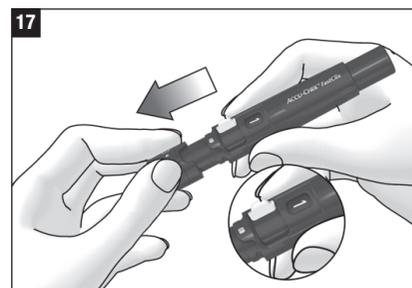
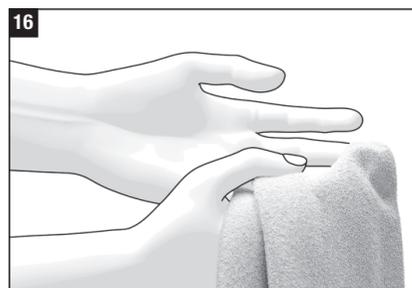
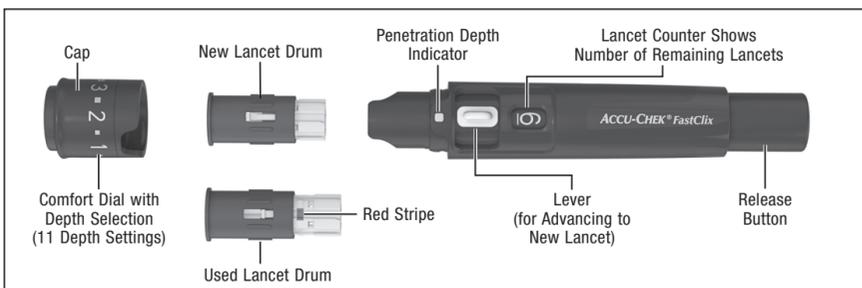
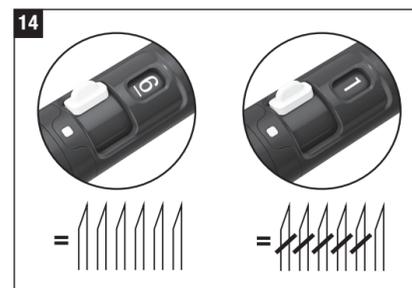
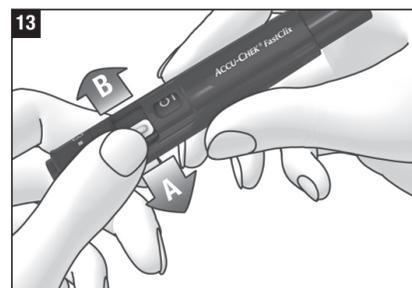
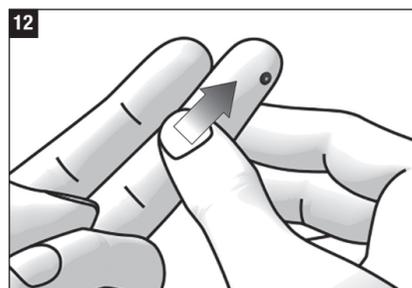
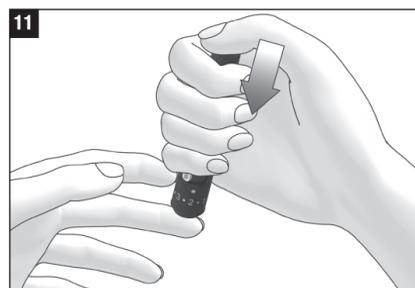
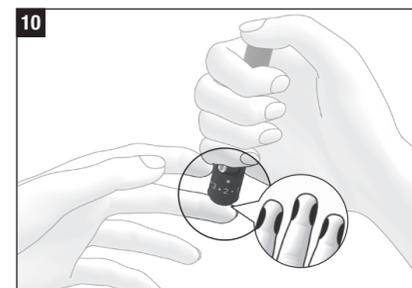
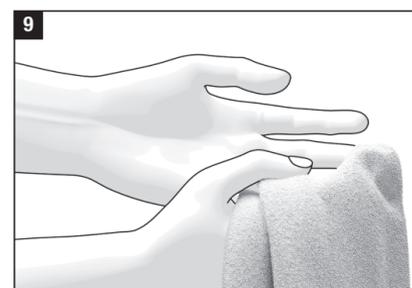
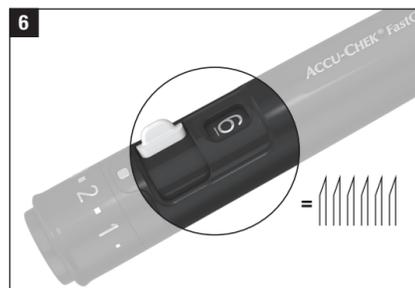
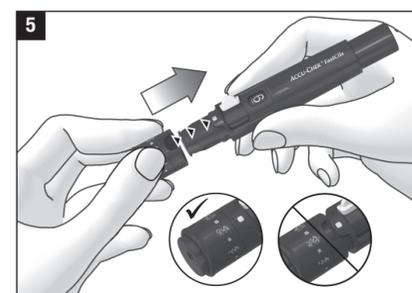
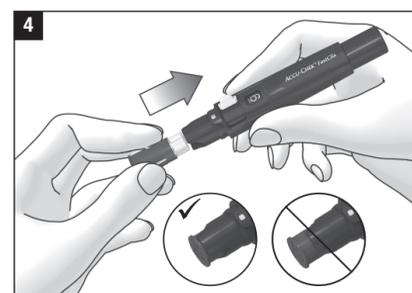
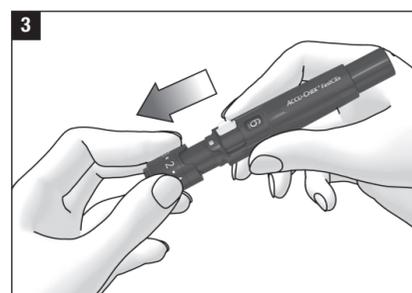
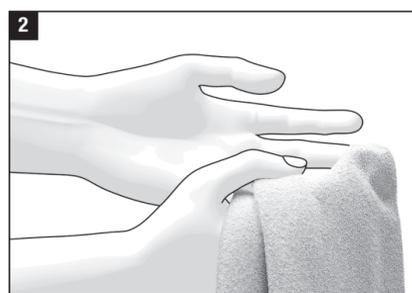


ACCU-CHEK® FastClix

Lancing device



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Instructions for Use

Read these instructions for use before you obtain a blood drop.

For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use.

Each lancet may only be used once to obtain blood. Used lancet drums must be safely discarded after all six lancets have been used.

WARNING
Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient.

Intended Use

The Accu-Chek FastClix blood lancing system is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternate sites, such as the palm, the upper arm, and the forearm. Six sterile, single-use lancets are in a drum. The lancet drum is to be used with the reusable lancing device that is to be cleaned and disinfected between each use. When all six lancets are used, the lancet drum is to be discarded. This system is for use only on a single patient in a home setting. This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.

General Safety Information

The instructions for use contain warnings and precautions:

A **WARNING** indicates a foreseeable serious hazard.

A **PRECAUTION** describes a measure you should take to use the product safely and effectively or to prevent damage to the product.

WARNING

Risk of suffocation

This product contains small parts that can be swallowed. Keep the small parts away from small children and people who might swallow small parts.

Risk of injury

If the penetration depth is too deep, the puncture can injure children.

Before using the lancing device for the first time on children, ask your healthcare professional. Start with the lowest penetration depth.

Risk of infection

If the lancing device or the lancet drum has come into contact with blood, it can transmit infections.

The lancing device and the lancet drum must not be used by other people, even by family members. Healthcare professionals must not use them to obtain blood from different people.

If the lancing device or the lancet drum was dropped or exposed to other mechanical stress, check it for damages. If the lancing device or the lancet drum is damaged or if a lancet protrudes from the lancet drum, do not use the lancing device or the lancet drum.

PRECAUTION

Risk of injury

• Skin contact to the lancing device or lancet drum can cause skin irritation.

If your skin becomes irritated or inflamed, consult your healthcare professional.

• If the lancet is pricked into a hard surface and not into the skin, the needle can be damaged.

Only use the lancet to obtain a blood drop.

• Parts of the lancing device, for example, the release button, can shoot away during use.

Do not point the lancing device at your face or other people.

If the lancing device is being operated by a second person who is providing testing assistance to the user, the lancing device should be cleaned and disinfected prior to use by the second person. The second person must wear protective gloves for all the steps when providing testing assistance.

If you find lancets in the packaging, do not use them. Discard them. You can use all lancet drums from the packaging. If you happen to insert a lancet drum with missing lancets, you cannot obtain blood each time you load a new lancet. In this case, simply load the next lancet.

Only insert Accu-Chek FastClix lancet drums into the Accu-Chek FastClix lancing device. Other lancets or lancet drums can impair the operation of the lancing device or damage it permanently.

Features

The lancing device has 11 different penetration depths so that you can adjust the penetration depth to the texture of your 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. 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. Afterwards, the lancet retracts automatically into the lancet drum. This helps prevent accidental fingersticks.

Before Using the Lancing Device

1. Wash your hands with warm water and soap.

2. Dry your hands well.

Inserting a Lancet Drum

You have to insert a lancet drum to be able to obtain blood with the lancing device.

WARNING

Risk of infection

If the lancet drum is damaged, the lancets can be unsterile and lead to infection.

Visually inspect the lancet drum. If the lancet drum is deformed, cracked, or otherwise damaged, do not use it. Discard the lancet drum.

PRECAUTION

Risk of infection

If the use by date of the lancet drum has expired, the lancets can be unsterile.

Insert only lancet drums that are within the use by date. The use by date is printed next to the symbol on the packaging.

3. Pull the cap off the lancing device.

4. Insert a new lancet drum – white end first – into the lancing device.

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.

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 **4**).

5. Place the cap back on again, lining up the notch on the cap with the notch on the lancing device.

The cap is on correctly when you push it as far as it goes. You must hear and feel the cap click into place.

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.

6. 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.

NOTE

Do not remove the lancet drum before all 6 lancets are used. You cannot re-insert the lancet drum.

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, start with a low penetration depth, such as penetration depth 2.

7. Rotate the comfort dial until the desired penetration depth lines up with the indicator.

Obtaining a Blood Drop

WARNING

Risk of infection

• A used lancet can transmit infections.

Use a lancet only once to obtain blood.

• In rare cases, the lancet is not pulled back into the lancing device after you obtained blood.

Check that the lancet does not protrude after you obtained blood. If the lancet protrudes, 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.

PRECAUTION

Risk of infection

A puncture site that was not cleaned can lead to infection.

Before obtaining blood clean the puncture site.

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

Only use the lancing device when the cap is attached. Without the cap, the lancet penetrates too deeply and may cause discomfort.

8. Wash your hands with warm water and soap before obtaining blood. This reduces contamination of the puncture site and stimulates blood flow.

9. Dry your hands well.

10. Press the lancing device firmly against the selected puncture site.

11. Press the release button all the way down. The lancet is released and it penetrates the skin.

12. Massage the finger in the direction of the fingertip to encourage a blood drop to form. Do not press or squeeze the finger. This can cause tissue fluid to mix with the blood and can falsify the values.

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.

If too much blood emerges, decrease the penetration depth.

► Test your blood immediately after you obtain blood, according to the instructions for use for your diagnostic device.

► Protect 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.

13. 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**.

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.

14. 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.

After Using the Lancing Device

15. Wash your hands with warm water and soap.

16. Dry your hands well.

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.

17. Pull the cap off the lancing device.

18. Pull the lancet drum out of the lancing device.

When a lancet drum has been used, a red stripe is visible on the white cylinder. A used lancet drum has a built-in lock that stops you from using it again.

► Insert a new lancet drum (see section "Inserting a Lancet Drum").

► Discard used lancet drums according to local regulations.

Operating Conditions

Use the lancing device including accessories under the following operating conditions:

Temperature range: +5 to +45 °C (+41 to +113 °F)

Relative humidity range: 5 to 90 %

Storing the Lancing Device and Lancet Drums

Do not store the lancing device and lancet drums at extreme temperatures, or in excessive humidity, sunlight, and heat; for example, in a hot car. This can impair the operation of the lancing device and lancet drums. Store and use at room temperature.

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 can come in contact with blood. For this reason, it is important to keep the lancing device clean and disinfected.

PRECAUTION

Risk of infection

If the lancing device or the cap has come into contact with blood, it can transmit infections.

Clean and disinfect the lancing device and the cap always before someone else handles them, for example, to assist you.

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

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 (bloodborne pathogens) from the lancing device.³

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, and Walmart.com

- 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.
- The effect of using more than one product interchangeably to clean and disinfect the lancing device has not been tested. Always use Super Sani-Cloth to clean and disinfect the lancing device.
- Roche has demonstrated that the product is good for 5-year use, after testing in a total of 260 cleaning and disinfection cycles (equal to cleaning and disinfecting once per week for 5 years) plus an additional 105 cycles to total 365 cycles.

NOTE

For technical assistance or questions on cleaning and disinfecting, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

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 at least once per week to remove visible dirt or other material for safe handling.
- 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 the lancing device.

NOTE

- Do not throw away the cap after each use. Use the approved cleaning and disinfecting product on the cap.
- Always remove the lancet drum before cleaning and disinfecting the lancing device.
- Using cleaning and disinfecting products could result in damage to the lancing device. If you notice any of the following signs of deterioration after cleaning and disinfecting your lancing device, stop using your lancing device and contact the Accu-Chek Customer Care Service Center at 1-800-858-8072: residue around buttons, difficulty in inserting the lancet drum.
- 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 should be cleaned and disinfected:

- The entire lancing device surface
- The cap

How to Clean and Disinfect the Lancing Device

Failure to follow these instructions can damage the lancing device and stop it from working properly.

- **Do not get any moisture into openings.**
- **Always use the same product for both cleaning and disinfecting.**

A separate Super Sani-Cloth should be used for cleaning and disinfection.

1. Wash hands with soap and water and dry thoroughly.
2. Wipe the entire lancing device surface and the inside of the cap with a Super Sani-Cloth (see [19](#) and [20](#)).
3. For disinfecting the lancing device, use a new cloth. Repeat step 2 making sure that the surface stays wet for 2 minutes.
4. Wash hands with soap and water and dry thoroughly.

Discarding the Lancet Drum and Lancing Device

PRECAUTION

Risk of infection

If the lancet drum or the lancing device has come into contact with blood, it can transmit infections.

Discard the used lancet drum or the used lancing device as infectious material according to local regulations.

Any product coming in contact with blood is considered contaminated (potentially infectious).* During obtaining a blood drop, any lancet drum and lancing device can come in contact with blood. Lancet drums and lancing devices can also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions.

Roche is committed to recycling and sustainability. Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used lancet drums and used lancing devices.

Remove the lancet drum, before discarding the lancing device.

*29 CFR 1910.1030 – Bloodborne pathogens

Need Help?

For questions, contact the Accu-Chek Customer Care Service Center toll-free at 1-800-858-8072. Hours of operation are Monday through Friday between 8:00 am and 8:00 pm eastern time (ET). We offer assistance in many languages. You can also visit accu-chek.com for product demonstrations.

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 the 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 No. 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, contact 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 Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). Update 11/29/2010." <http://wayback.archive-it.org/7993/20161022010458/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>. Accessed January 8, 2021.

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 January 8, 2021.

³ William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC). "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008." Update May 2019. Centers for Disease Control and Prevention, Atlanta. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed January 8, 2021. considered sharps. Disposal of sharps is regulated by law in many jurisdictions.

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 Global Trade Item Number

 Unique Device Identifier

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