# ACCU-CHEK® Softclix

## Lancing device

Front side

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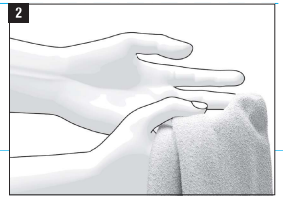
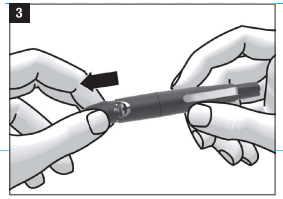
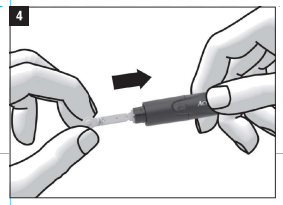
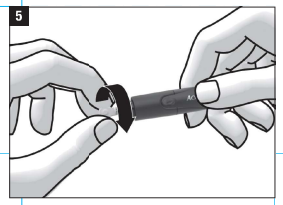
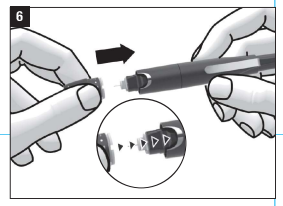
Back side

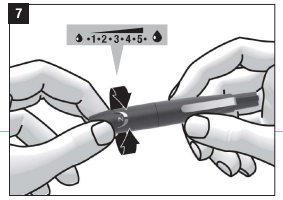


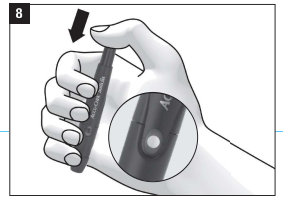



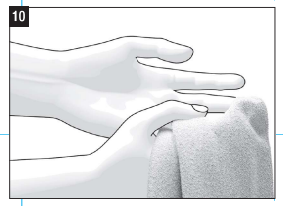



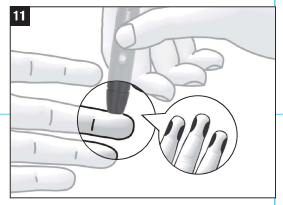



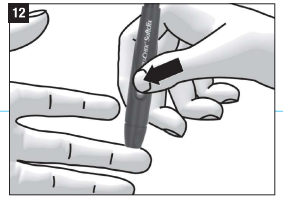



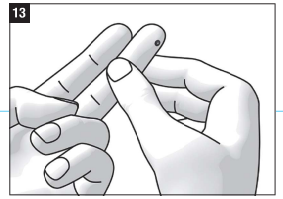



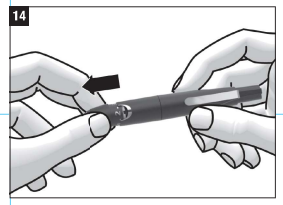



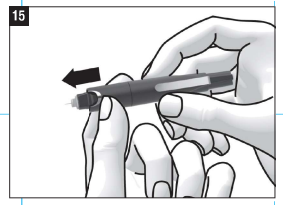


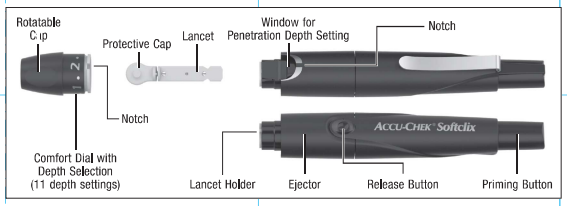



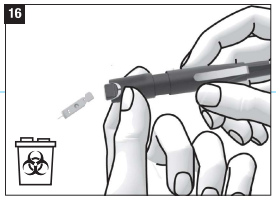



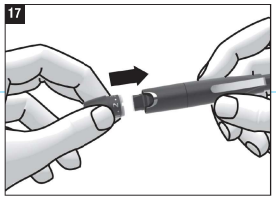



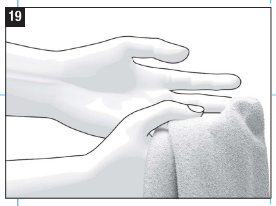






## Instructions for Use

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 lancets must be safely discarded after a single use.**

**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 Softclix 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. The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are 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 has come into contact with blood, it can transmit infections.

The lancing device and the lancet 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 was dropped or exposed to other mechanical stress, check it for damages. If you spot damages such as cracks, do not use the lancing device or the lancet and discard it.

**⚠ PRECAUTION**

**Risk of injury**

- Skin contact to the lancing device or lancet can cause skin irritation.
  If your skin becomes irritated or inflamed, consult your healthcare professional.
- If the lancet is stabbed into a hard surface, the needle can be damaged.
  Only use the lancet to obtain a blood drop.
- Parts of the lancing device, for example, the priming button, can shoot away during use.
  Do not point the lancing device at your face or other people.

Patients younger than 18 years old should be supervised by adults when using the lancing device, or adults should perform the procedure on patients younger than 18 years old.

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.

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

If the lancing device falls with a lancet inserted, the lancet may become loose in the lancet holder. You cannot use it anymore to obtain blood. In rare cases, the lancet could protrude from the opening in the cap and you could injure yourself on it. Therefore, do not touch the front of the cap. If the lancing device falls, pick it up with care. Remove the cap from the lancing device. Pay attention to the lancet so that you do not injure yourself on it. Always eject the lancet and discard it.

### 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 into the lancing device. With the priming button, you prime the lancing device. With the release button, you trigger a lancet. When a lancet is triggered, it penetrates the skin. Afterwards, the lancet retracts automatically into the lancing device. 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

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

**⚠ WARNING**

**Risk of infection**

- If the protective cap is damaged or missing, the needle can be unsterile and lead to infection.
  Visually inspect the lancet. If the protective cap is deformed, cracked, or otherwise damaged, do not use the lancet. If the protective cap is missing or any part of the needle is exposed, do not use the lancet. Discard the lancet.
- A used lancet can transmit infections.
  Use a lancet only once to obtain blood. After obtaining blood, always eject and discard the used lancet.

**⚠ PRECAUTION**

**Risk of infection**

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

Insert only lancets 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 into the lancet holder as far as it will go. The lancet must audibly click into place.
5. Twist the protective cap off of the lancet.
6. Place the cap back on again, lining up the notch on the cap with the notch on the lancing device. The cap must audibly click into place.

### Setting the Penetration Depth

You can set 11 penetration depths (0.5 to 5.5). The penetration depth set is shown in the window. 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 is set.

### Priming the Lancing Device

In order to be able to obtain blood, you must prime the lancing device. Only prime the lancing device just before obtaining blood.

8. Press the priming button all the way down. Do not press the release button simultaneously.

The lancing device is primed when the center of the release button is yellow.

### Obtaining a Blood Drop

**⚠ WARNING**

**Risk of infection**

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

Check that the lancet does not protrude after you obtain blood. If the lancet protrudes, remove the cap with care. Eject and discard the lancet.

**⚠ 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 can cause discomfort.

9. Wash your hands with warm water and soap before obtaining blood. This reduces contamination of the puncture site and stimulates blood flow.
10. Dry your hands well.
11. Press the lancing device firmly against the selected puncture site.
12. Press the release button.
    The lancet is released and it penetrates the skin.
13. 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 progressively.

▶ 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.

### Ejecting the Used Lancet

14. Pull the cap off the lancing device.
15. Slide the ejector forward.
16. The used lancet is ejected.
17. Place the cap back on again.

▶ Discard the used lancet according to local regulations.

**⚠ PRECAUTION**

**Risk of infection**

The needle of a used lancet is not protected and can be touched accidentally.

Discard the used lancet in such a way that the lancet does not cause injury to anyone. Place the lancet, for example, into a sharps container.

### After Using the Lancing Device

18. Wash your hands with warm water and soap.
19. Dry your hands well.

### 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 %

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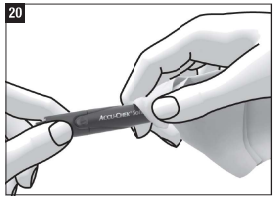

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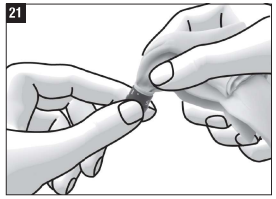

## Storing the Lancing Device and Lancets

Do not store the lancing device in a primed state. Store the lancing device only without a lancet inserted. Do not store the lancing device and lancets 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 lancets. 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 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 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 priming the lancing device, difficulty in inserting the lancet.
- 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 20 and 21).
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 and Lancing Device

**⚠ PRECAUTION**

**Risk of infection**

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

Discard the used lancet 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 and lancing device can come in contact with blood. Lancets 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 lancets and used lancing devices.

Remove the lancet 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 Softclix 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 Softclix 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 Softclix 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 Softclix 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.

**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. https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf. Accessed January 8, 2021.


These symbols may appear on the packaging and in the instructions for use.

| | |
|---|---|
| | Consult instructions for use or consult electronic instructions for use |
| | Caution, refer to safety-related notes in the instructions for use accompanying this product. |
| | Use by |
| STERILE R | Sterilized using irradiation |
| | Use only once |
| | Single patient multiple use |
| | Wash your hands |
| | Biological risks |
| | Date of manufacture |
| MD | Medical device |
| | Manufacturer |
| UDI | Unique device identifier |
| REF | Catalogue number |
| LOT | Batch code |
| GTIN | Global Trade Item Number |
| CE | Complies with the provisions of the applicable EU Legislation |


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