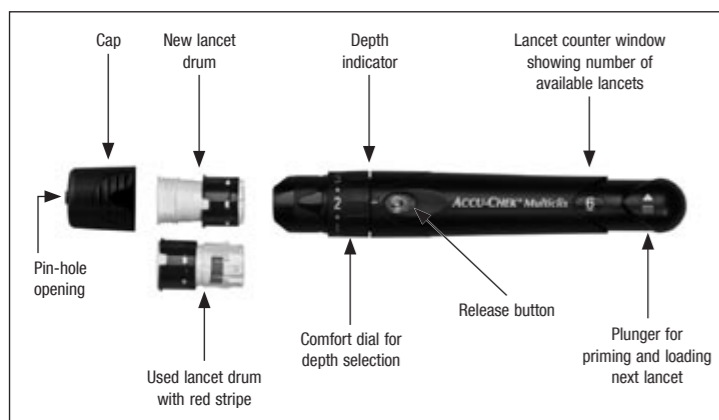


# ACCU-CHEK® Multiclix

## LANCING DEVICE



### Instructions for Use

The ACCU-CHEK Multiclix lancing device uses a lancet to obtain a drop of blood from a fingertip or other site. 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. For virtually pain-free testing, we recommend that you advance to a new, sterile lancet after each test. You can adjust the lancet depth to your individual skin type by dialing 1 of the 11 settings. There are 2 different caps: 1 is for a fingerstick, and the other is for other sites on the body. Refer to your meter owner's booklet to determine what other sites are approved for your meter.

The colored cap is for fingerstick testing only.



The clear cap is for testing from other sites of the body, not the fingertip.



**Note: The ACCU-CHEK Multiclix cap was not designed to be replaced after each use. The ACCU-CHEK Multiclix lancing device is intended for use by a single person and is not suitable for testing multiple persons due to the risk of infections.**

### Inserting a Lancet Drum

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

A new drum has a blue ring that does not move.



A used drum has two visible red stripes and the blue ring can rotate on the white drum. You cannot insert a used drum into the lancing device.



- 1 Remove the cap by pulling it straight off. It is not a twist cap. The easiest way to do this is to place your thumb on the cap grippers to the side of the notch as seen in the illustration.



- 2 Before you insert a drum, be sure that the release button is not yellow. Insert a new drum, blue ring first, until it stops. It clicks into place.



- 3 Slide the cap back on until it stops by aligning the notch on the cap with the notch on the device.



- 4 You are now ready to use the first lancet. The lancet counter window on the plunger shows the number 6, which means you have 6 new lancets remaining.



### Performing a Fingerstick

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

- 1 Make sure the colored cap is on the lancing device. Do not use the clear cap for fingerstick testing.

- 2 Adjust the depth by turning the comfort dial. The depth indicator shows the current depth selection. Higher numbers make the penetration deeper. If you have soft skin, start at a depth of 2. If your skin is calloused or thick, try a higher setting.



- 3 Press the plunger in as far as it will go, like a pen.



- 4 The release button turns yellow. Do not press the release button while pressing the plunger.

- 5 Wash and dry your hands. Warm water helps to increase blood flow. If you use an alcohol wipe, be sure your finger is completely dry before continuing.

- 6 Hold the lancing device firmly against the side of your fingertip. Remember that the opening where the lancet comes out is not in the center of the cap. Note: The side of your fingertip is less sensitive than the middle.



- 7 Press the yellow release button.



- 8 Gently squeeze your finger to assist the flow of blood. This helps you to get a blood drop.



- 9 Apply the blood drop to your test strip.

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

### Loading the Next Lancet

- 1 Twist the plunger one quarter turn forward (until it stops), then twist it back all the way. The lancet drum rotates to the next lancet.



- 2 The number in the lancet counter window decreases by 1 and now shows the number 5.



- 3 Each time you use a lancet and twist the plunger, the number showing in the lancet counter window decreases by 1. When the number 1 is visible in the lancet counter window, you have used 5 lancets. The sixth (and final) lancet is loaded and ready to be used.

### Notes:

- Only twist the plunger when the lancing device is not primed. You can see if the lancing device is primed by the color of the release button. A primed device has a yellow release button. When the lancing device is primed, the drum cannot rotate and twisting the plunger would damage the device. In rare cases, the lancet could protrude from the cap and you could injure yourself on it.
- Only twist the plunger when at least "2" is displayed in the lancet counter window. If the number displayed in the lancet counter window is "1," the last lancet is ready to be used. A built-in safety block stops you from twisting the plunger when the lancet counter window displays "1," indicating there are no lancets left to load. Do not twist the plunger forcibly past the safety block. Damage to the lancing device may occur. This can override the protection against reusing used lancets.
- For safety reasons, once you advance to a new lancet, you cannot go back to a previously used lancet. Therefore, the plunger (and drum) cannot be twisted backwards. This built-in safety block prevents an infection risk, as used lancets cannot be reused.

### Changing the Lancet Drum

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

- 1 Take the colored cap off the lancing device by pulling it straight off. It is not a twist cap. The easiest way to do this is to place your thumb to the side of the notch as seen in the illustration.

- 2 Hold the drum between your thumb and index finger and pull it straight out of the lancing device. Two red stripes are visible on the white drum, indicating that the drum has been used.



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

- 4 Insert a new drum, blue ring first, until it stops and clicks into place.



### Notes:

- Due to safety reasons, a used drum cannot be reinserted into the lancing device. A built-in safety block prevents this. This rules out a potential infection risk.
- In rare instances, if a used drum is dropped on a hard surface, the lancets may protrude slightly from the drum. If you drop a drum, always pick it up at the red-striped end.

### Getting Blood from a Site Other Than Your Fingertip

Capillary blood for blood sugar testing can be obtained not only from the fingertips but also from other sites (the palm, the forearm, the upper arm, the calf or the thigh), which is referred to as alternative site testing (AST). We recommend palm as the nonfingertip test site.

Use the clear ACCU-CHEK Multiclix AST cap together with the ACCU-CHEK Multiclix lancing device to collect blood from nonfingertip test sites.

Your ACCU-CHEK blood glucose monitoring system is designed to test blood glucose also from sites other than your fingertip. Please refer to your test strip insert or your meter owner's booklet for specific blood glucose and AST testing instructions.

**IMPORTANT** – There is a delay (lag time) in the delivery of blood glucose to nonfingertip sites when compared to fingertip. Therefore, there is a potential for a significant difference between fingertip and AST results. The length of delay (lag time) is strongly impacted by lifestyle, foods eaten or any other event having impact on blood glucose levels. It is important that people considering nonfingertip testing understand the following:

- Talk to your doctor if you are considering testing on sites other than your fingertip.
- AST is not recommended during periods of rapid decreases or increases in blood glucose levels.
- AST is not recommended for people with a history of recurrent hypoglycemia, who suspect their blood glucose is extremely low, or who are unaware of hypoglycemic events.
- Never ignore symptoms of high or low blood sugar.
- Do not change your treatment based on one result.
- If the AST reading does not match how you feel, perform a fingertip test to confirm your results. If your blood glucose still does not reflect the way you feel, contact your doctor. For more information on AST please contact the ACCU-CHEK Customer Care Service Center at 1-800-858-8072.

Do not test blood from the alternative sites:

- Up to 2 hours following a meal, when blood glucose values can change quickly
- After exercise
- If you have a temperature or if a medical condition is limiting your mobility, e.g. after breaking a leg or being confined to bed
- If you suspect that your blood glucose is extremely low (hypoglycemia)
- During peak action time of short-acting insulin (up to approximately 4 hours after the injection) or rapid-acting insulin analogues (up to approximately 2 hours after the injection)

- 1 Remove the colored cap from the lancing device by pulling it straight off.
- 2 Put the clear cap on by lining up the notched sections on the cap and the lancing device.
- 3 Adjust the depth setting dial to the highest setting (5.5).
- 4 Press the plunger in as far as it will go, like a pen.
- 5 The release button turns yellow. Do not press the release button while pressing the plunger.
- 6 Wash the nonfingertip site with warm water and dry it thoroughly.
- 7 Press and hold the lancing device **FIRMLY** against the fleshy area on the chosen AST site. Press the lancing device up and down in a slow, pumping motion to assist the flow of blood.
- 8 Keep steady pressure on the area and press the yellow release button. Don't be afraid to apply pressure to the area with the lancing device or with the clear AST cap alone to assist the flow of blood. Continue to press the lancing device or the clear cap against the site for a few seconds to allow blood to come to the surface.
- 9 Perform a blood sugar test with your meter as instructed in your meter owner's booklet.

*Don't be afraid to apply strong pressure to the area with the lancing device or with the clear AST cap alone to get a good blood drop.*

### Having Trouble Testing from Sites Other Than Your Fingertip?

If you experience difficulty obtaining a sufficient drop of blood while testing from a site other than your fingertip, please contact our ACCU-CHEK Customer Care Service Center at 1-800-858-8072 for assistance. We will guide you through the testing procedure step by step. If you continue to have difficulty, we can also offer you, free of charge, our ACCU-CHEK Softclix lancing device. Due to the ACCU-CHEK Softclix lancing device using a thicker diameter needle than the ACCU-CHEK Multiclix lancing device, you may have better success with the ACCU-CHEK Softclix lancing device when trying to test from sites other than your fingertip.

### Caring for Your Lancing Device

- Your lancing device requires very little care.
- Keep it away from extreme temperatures.
- Clean the outside of your lancing device regularly and always if any blood gets on it with 70% isopropyl (rubbing) alcohol to keep it in good working condition. In addition, thoroughly wipe the inside of the cap using a cotton ball lightly moistened with the 70% isopropyl (rubbing) alcohol. After cleaning, allow the lancing device

time to dry thoroughly. Never dip the lancing device or the caps (colored cap and clear AST cap) in cleaning liquid. Doing so may damage the internal parts of the lancing device so affecting its operation.

- Do not dip the lancing device in liquid.
- Do not use bleach to clean the lancing device or caps.

### Assistance Available

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/TYY (for hearing impaired)

### One (1) Year Warranty

Roche warrants the ACCU-CHEK Multiclix 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 Multiclix 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 Multiclix 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 Multiclix 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 Multiclix lancing device in the United States. The ACCU-CHEK Multiclix lancing device and its use are protected by U.S. Patent Nos. Re.35,803; 6,419,661; 7,077,828; 7,223,276; 7,322,998. A license to use the ACCU-CHEK Multiclix lancing device is only granted when ACCU-CHEK Multiclix lancets are used with the ACCU-CHEK Multiclix lancing device.

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

Using the ACCU-CHEK Multiclix lancing device indicates your acceptance of the restricted license to use the ACCU-CHEK Multiclix lancing device only with ACCU-CHEK Multiclix lancets. Further, if you have purchased an ACCU-CHEK Multiclix lancing device that includes this restricted license, then this restricted license applies regardless of any additional offers found in ACCU-CHEK Multiclix 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 Multiclix 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 Multiclix lancing device are voided by use of the ACCU-CHEK Multiclix lancing device with any lancets other than ACCU-CHEK Multiclix lancets.

Visit our Web site at [www.accu-check.com](http://www.accu-check.com).

This product is protected by the following US Patents: 6,419,661; 7,077,828; 7,223,276; 7,322,998; Re. 35,803.

 0088 This product fulfills the requirements of Directive 93/42/EEC on medical devices.

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