

ACCU-CHEK® Softclix Plus

LANCING DEVICE

Comfort Dial with Depth Selection –

This shows the number of the setting on the Comfort Dial



Lancing Device

Plunger (3 functions: priming, firing, and releasing of lancet)



Protective Cover

Lancet

Instructions for Use

The ACCU-CHEK Softclix Plus lancing device uses ACCU-CHEK Softclix lancets to obtain a drop of blood from the fingertip. The penetration depth can be selected to match any type of skin.



This cap is for fingertip testing only.



The clear cap is for testing on sites other than the fingertip. Do not use the clear cap for fingertip testing.

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

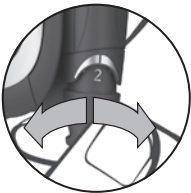
Selecting the Depth

The depth on the ACCU-CHEK Softclix Plus lancing device may be adjusted by turning the Comfort Dial. The current depth selection is shown in the center of the depth indicator window. You can find the depth indicator window as a semi-circular cutout on the ejector.

The ACCU-CHEK Softclix Plus lancing device offers 11 depth settings. The settings are shown in the depth indicator window by the numbers 1 to 5 with additional levels marked with dots to enable you to precisely adjust to your individual skin type. The higher the number visible in the Comfort Dial, the greater the depth setting.

Note: If you are using the ACCU-CHEK Softclix Plus lancing device for the first time, start by selecting 1 or 2 to see if the amount of blood obtained is enough to perform a test. If your skin is calloused or thick, you may need to try a higher setting.

- 1 To select the desired depth setting, turn the Comfort Dial so that the desired setting is in the center of the depth indicator window.



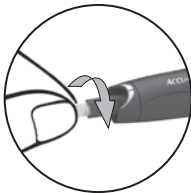
- 2 Select a new depth setting by turning the Comfort Dial. The cap will snap into a new position, preventing any accidental change of the depth setting.

Performing a Fingertick

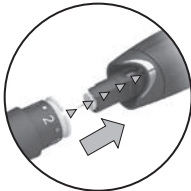
- 1 Remove the colored cap of the lancing device by using your thumb and finger to pull on the recessed area. If there is already a lancet in the device, remove it by holding the lancing device so that the lancet points downward and pressing the plunger. Refer to the section called “Removing the Lancet”.
- 2 Firmly insert a new ACCU-CHEK Softclix lancet in the lancet holder until it snaps into place.



- 3 Twist the protective cap on the lancet several times and pull gently to remove it.



- 4 Snap on the colored cap after lining up the notches. The cap snaps easily into place.



- 5 Select the desired depth setting as instructed in the section “Selecting the Depth”. Then, press the plunger on the end of the lancing device all the way down until it stops, like a pen. The lancing device is now ready for use.

- 6 Now, wash your hands and dry them thoroughly. Also warm the fingers to increase blood flow. If you are using alcohol wipes, make sure your finger is completely dry before continuing.

- 7 Grasp your finger near the area to be pricked and gently massage for three seconds.

- 8 Hold the lancing device firmly against the side of your fingertip, then press and release the plunger. Gently squeeze your fingertip to get a small drop of blood.



The best place to test on the fingertip is the side, because it has the best blood supply, yet allows for the least painful fingertick. Any finger may be used for a fingertick.

- 9 Touch and hold the blood drop to the black notch on the end of the ACCU-CHEK Compact test strip. (Consult the section “Running a Blood Sugar Test with Blood from Your Fingertip” of your ACCU-CHEK Compact Plus system’s owner’s booklet to learn more.)

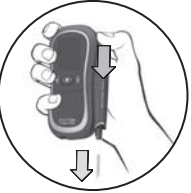
- 10 Immediately remove used lancet. To avoid accidental injury, do not store lancet in device.

Removing the Lancet

- 1 To remove the lancet, pull off the cap of the ACCU-CHEK Softclix Plus lancing device.



- 2 Hold the meter so the lancet points downward. Press the plunger to release the lancet into a puncture-proof container. Always dispose in accordance with the local regulations.

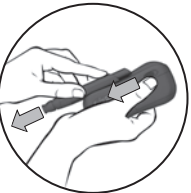


To avoid infection, use a new lancet each time you perform a fingertick.

Reminder

Remember, you can use your lancing device attached to or detached from the ACCU-CHEK Compact Plus meter.

- 1 To remove lancing device, slide and hold down on the release button and, at the same time, pull down on the lancing device to remove it from the meter.



- 2 Attach the lancing device by lining up the notches and sliding it until it locks into place. The lancing device locks easily into place.



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 non-fingertip test site. Use the clear ACCU-CHEK Softclix Plus AST cap together with the ACCU-CHEK Softclix Plus lancing device to collect blood from non-fingertip test sites.

Your ACCU-CHEK Compact Plus system is designed to test blood glucose also from sites other than your fingertip. Please refer to the ACCU-CHEK Compact test strip insert or your ACCU-CHEK Compact Plus system's 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 non-fingertip 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 non-fingertip testing understand the following:

- Talk to your doctor if you are considering testing on sites other than your fingertip.
- AST testing is not recommended during periods of rapid decreases or increases in blood glucose levels.
- AST testing 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 testing please contact ACCU-CHEK Customer Care service center at 1-800-858-8072.

Do **not** test blood from the forearm, the upper arm, the calf and the thigh:

- up to two 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

- 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)
- ❶ Remove the colored cap from the lancing device.
- ❷ Insert a new lancet into the lancing device as described in the section “Performing a Fingerstick” of this package insert.
- ❸ Attach the clear plastic AST cap. As with the colored cap, the locating notch in the cap must be directly aligned with the locating line on the lancing device. The AST cap must click into place.
- ❹ Adjust the clear AST cap to the highest setting.
- ❺ Wash the non-fingertip site with warm water and dry it thoroughly.
- ❻ Prime the lancing device by pressing down the plunger all the way down until it stops.
- ❼ Press and hold the lancing device against the fleshy area on the chosen AST site. Press the release button again and continue to apply steady pressure to the site.
- ❽ Perform a blood sugar test with your ACCU-CHEK Compact Plus meter as instructed in the section “Running a Blood Sugar Test with Blood from Your Fingertip” of your ACCU-CHEK Compact Plus system's owner's booklet.

Don't be afraid to apply strong pressure to the area with the lancing device to get a good blood drop.

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 bud 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.

Also Available from Roche Diagnostics

ACCU-CHEK Compact Plus System

ACCU-CHEK Softclix Lancets

100/box

200/box

ACCU-CHEK Compact Test Strips

51/box

102/box

ACCU-CHEK Compact Blue Control Solution

2 x 3 mL/box

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 Softclix Plus 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 Plus 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 Plus 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, so the above limitation and exclusion may not apply to you. This warranty gives you specific legal rights, and you may have other rights which vary from state to state. All inquiries about the ACCU-CHEK Softclix Plus 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 the use of this ACCU-CHEK Softclix Plus lancing device in the United States.

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

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

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

Visit our website at www.accu-chek.com.

This product is covered by the following U.S. Patents: 6,419,661; 7,077,828; 7,322,998; 6,464,649 and Re. 35,803.



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

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