

# ACCU-CHEK B00926EYPA FastClix Lancing Device Instruction Manual

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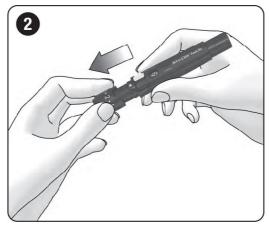
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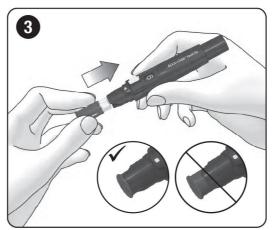


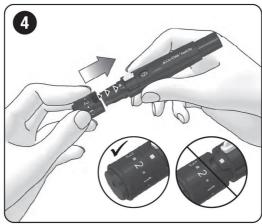
# ACCU-CHEK B00926EYPA FastClix Lancing Device Instruction Manual



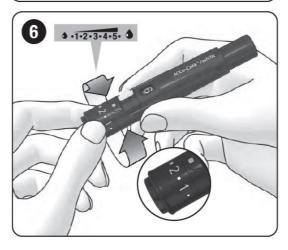


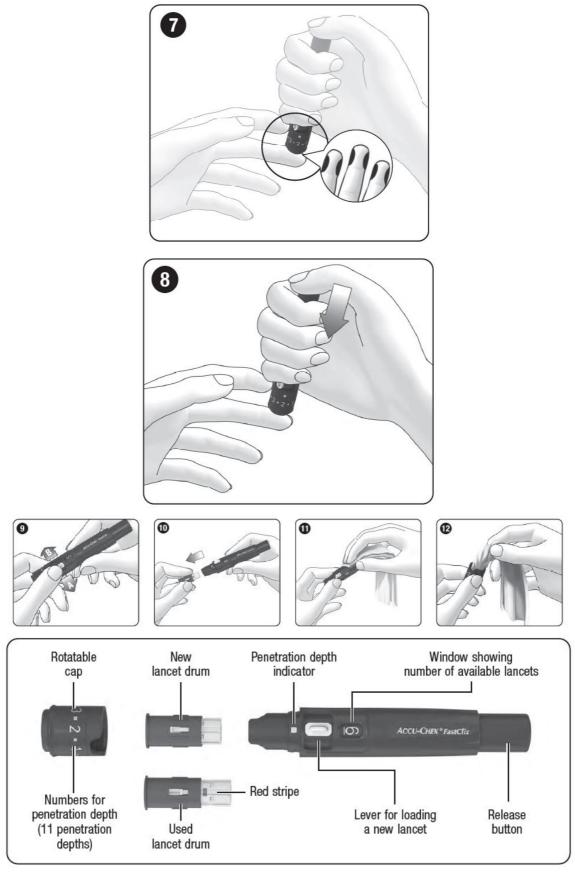












Instructions for Use

# **Intended Use**

# **Lancing Device**

The AccuChek FastClix lancing device is a device for simple, virtually pinfire collection of capillary blood from the fingertips. The AccuChek FastClix lancing device is intended for single patient 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. It is not a sterile product. People in the area of diabetes telemonitoring are considered as target group.

#### Lancet

Six AccuChek FastClix lancets are in a drum. The lancet drum is intended to be used with the AccuChek FastClix lancing device. The lancet drum is a disposable part. Each lancet in it is intended to be used only once. The AccuChek FastClix lancet drum includes 6 lancets and is intended to be used with the AccuChek FastClix lancing device for simple, virtually painfree collection of capillary blood. The lancet drum is a disposable article with 6 lancets each intended to be used only once. Each lancet has a protective cap that guarantees sterile condition until its first use. The lancets are sterilized using irradiation. The used lancet drum is protected against reuse.

# **Features of the Lancing Device**

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.

### **Before You Get Started**

Read these instructions for use before you obtain a blood drop from your fingertip. Information describing a situation for which there is a foreseeable serious hazard with the use of the device, is preceded by the following heading:

#### **WARNING**

Information regarding any special care you should exercise for the safe and effective use of the device, or to avoid damage to the device that could occur as a result of use, including misuse, is preceded by the following heading:

#### **PRECAUTION**

### **WARNING**

# Risk of suffocation

This product contains small parts that can be swallowed. Keep this product away from people who might swallow small parts, for example, small children.

# Risk of infection

During obtaining a blood drop, the lancing device may come into contact with blood. To prevent infections from being transmitted, the lancing device must not be used by other people, even by family members. Healthcare professionals must not use the lancing device to obtain blood from different people.

#### Risk of infection

The lancing device or lancet drum has come into contact with blood and has protruding sharps due to damage. To prevent infections from being transmitted, check the lancing device and lancet drum for damages. Dispose of a damaged lancing device or lancet drum as infectious material according to the regulations applicable in your country.

#### **PRECAUTION**

### Risk of injury

Skin contact to the lancing device, lancet drum or lancet may cause skin irritation. If your skin becomes irritated or inflamed, consult your healthcare professional. Risk of injury The needle of the lancet is damaged due to use on a hard surface. Only use the lancet to obtain a blood drop.

### Risk of injury

Parts of the lancing device, for example, the release button, may shoot away during use. Do not point the lancing device at your face or other people. If the lancing device or lancet drum was dropped or exposed to other mechanical stress, check them for damages, for example, cracks. Do not use them if they are damaged. Only insert AccuChek FastClix lancet drums into the AccuChek 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 the Lancet Drum**

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

#### WARNING

#### Risk of infection

Lancets in a damaged lancet drum may not be sterile anymore. If the lancet drum is damaged or shows cracks do not use it to obtain blood.

- Remove the cap from the lancing device (see 2).
- Insert a new lancet drum white end first into the lancing device (see 3).

Do not insert a lancet drum and press the release button at the same time. Do not insert a lancet drum with the release button resting on a surface, for example, a table top. This could release a lancet which could inadvertently prick you.

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).

 Place the cap back on again. The cutout section at the edge of the cap must fit around the correspondingly shaped curvature with the penetration depth indicator (silver square) (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.

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 window showing the number of available lancets shows 6; there are now 6 lancets available (see 5).

# Tip

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.

#### WARNING

#### Risk of injury

If the penetration depth is too large, 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.

• Rotate the cap until the desired penetration depth lines up with the indicator (see 6).

# **Obtaining a Blood Drop**

#### WARNING

#### Risk of infection

The lancet was used several times to obtain blood. To prevent infections from being transmitted, use the lancet only once to obtain blood.

Risk of infection In rare cases, the lancet is not pulled back into the lancing device after you obtained blood. To prevent infections from being transmitted, check that the lancet does not protrude from the cap after you obtained blood. If the lancet protrudes from the cap, carefully set the lancing device aside. Keep the lancing device out of reach and contact customer support.

#### **PRECAUTION**

### Risk of infection

The puncture site was not cleaned. Before obtaining blood clean the puncture site.

# Risk of infection

The use by date of the lancet has expired. Use only lancets that are within the use by date. The use by date is printed next to the E symbol on the packaging. 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. Use a new lancet each time you obtain blood so that 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 the puncture can become painful.

- 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 obtained blood, according to the instructions for use for your blood glucose meter. We recommend protecting the puncture site from contamination afterwards.

# Loading 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 window next to the lever 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 a new lancet is loaded, the number of available lancets shown in the window decreases by one, for example, from 4 to 3. When you have loaded the sixth and last lancet, the window shows 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 0).

When a lancet drum has been used, a red stripe is visible on the white cylinder. A used lancet drum has a builtin lock that stops you from using it again. Used lancet drums can be disposed of in household waste if no other regulations apply in your country.

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

# **Operating Conditions**

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

Temperature range: +5 to +45 °C
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, for example, in a hot car. This can impair the operation of the lancing device and lancet drums.

# Cleaning and Disinfecting the Lancing Device and Cap

#### **PRECAUTION**

# Risk of infection

The lancing device and cap may have come into contact with blood. To prevent infections from being transmitted,

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

To prevent infections from being transmitted, you must clean and disinfect the lancing device and cap regularly:

- · At least once a week
- When there is blood on the lancing device or cap
- Always before someone else handles the lancing device, for example, to assist you.

You need lint free cloths in which you can wrap the whole lancing device, water and 70 % isopropanol. Before you disinfect the lancing device and the cap, you first have to clean them to remove blood and other dirt.

To avoid damaging the lancing device and the cap:

- Do not dip the lancing device and the cap in the fluids.
- Use only water for cleaning and only 70 % isopropanol for disinfecting.
- Remove the cap from the lancing device (see 2). X Remove the lancet drum from the lancing device (see 0).

# Cleaning

- · Moisten a cloth with water.
- Wipe the lancing device and the cap thoroughly. Wipe the lancing device from the outside only (see q) and the cap from the outside and the inside (see w).
- Dry the lancing device and the cap with a dry cloth.

#### Disinfecting

- Dampen a cloth with 70 % isopropanol.
- Wipe the lancing device and the cap thoroughly for 2 minutes each. Wipe the lancing device from the outside only and the cap from the outside and the inside.
- · Place the cap back on again.
- Wrap the whole lancing device in the cloth.
- Leave the lancing device wrapped for 8 minutes.
- Unwrap the lancing device and let it dry in the air.

# **Disposing of the Lancing Device**

#### **PRECAUTION**

#### Risk of infection

The lancing device has come into contact with blood and is disposed of improperly. To prevent infections from being transmitted, dispose of the used lancing device as infectious material according to the regulations applicable in your country. During obtaining a blood drop, the lancing device may come into contact with blood. A used lancing device therefore carries a risk of infection. Dispose of an unused lancing device as plastic waste. For information about correct disposal, contact your local council or authority.

# **Alternative Sites for Obtaining Blood**

You can obtain capillary blood for blood glucose testing not only from the fingertips, but also from other sites (palm, forearm, upper arm, calf or thigh), so-called alternative site testing (abbreviated as AST). To be able to obtain capillary blood from other sites, you have to replace the regular cap by a special cap, the AccuChek FastClix AST cap.

# **Ordering Information**

If you want to order an AccuChek FastClix lancing device, AccuChek FastClix lancet drums or an AccuChek FastClix AST cap, contact customer support (see section Customer Support ). Before you decide to use blood from alternative sites, consult your healthcare professional.

# Reporting of Serious Incidents

For a patient/user/third party in the European Union and in countries with identical regulatory regime; if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

# **Last Update**

202103

# **Customer Support**

Roche Diabetes Care Australia Pty. Limited 2 Julius Avenue, North Ryde NSW 2113, **Australia** ABN 69 602 140 278 AccuChek Enquiry Line: 1800 251 816 <a href="https://www.accuchek.com.au">www.accuchek.com.au</a>

Roche Diabetes Care division of Hoffmann LA Roche Limited 201 Armand Flappier Blvd. Laval (Quebec) H7 V 4A2 **Canada** AccuChek Customer Care: 18003637949 <a href="https://www.accuchek.ca">www.accuchek.ca</a>

**Hong Kong** Enquiry hotline: +8522485 7512 (office hours) <a href="www.accuchek.com.hk">www.accuchek.com.hk</a> Malaysia Customer Support and Service Centre: Toll-free Line: 1800881313 <a href="www.accuchek.com.mv">www.accuchek.com.mv</a>

Roche Diabetes Care **South Africa** (Pty) Ltd. Hertford Office Park, 90 Becker Road Vorna Valley, 1686 South Africa Tel: +27 (11) 504 4600 Email: <a href="mailto:info@accuchek.co.za">info@accuchek.co.za</a> <a href="https://www.accuchek.co.za">www.accuchek.co.za</a> <a href="https://www.accuchek.co.za">www.accuchek.co.za</a> <a href="https://www.accuchek.co.za">www.accuchek.co.za</a> <a href="https://www.accuchek.co.za">www.accuchek.co.za</a>

Thailand Customer Service Line: +66 (0) 2791 2222 www.accuchek.co.th

- 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
- · Sterilized using irradiation
- · Use only once
- · Single patient multiple use
- Medical device M Manufacturer
- Unique device identifier
- Catalogue number
- · Batch code
- Complies with the provisions of the applicable EU Legislation

# **Documents / Resources**



ACCU-CHEK B00926EYPA FastClix Lancing Device [pdf] Instruction Manual B00926EYPA FastClix Lancing Device, B00926EYPA, FastClix Lancing Device, Lancing Device, Device

# References

- Chek Personas La única billetera que necesitas
- C Chek Confecções : Chek Confecções
- O The domain name chek.fr is for sale
- A Thailand
- Accu-Chek Diabetes Care Products Home | Accu-Chek

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