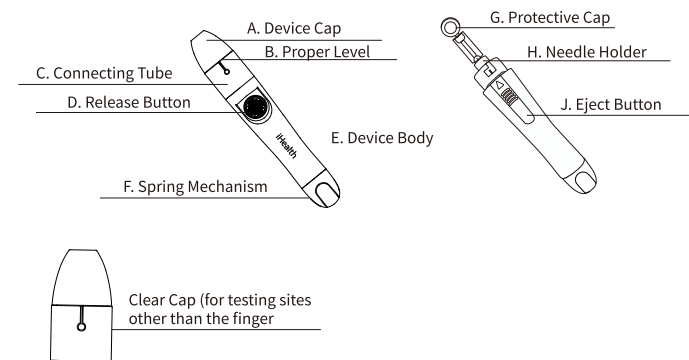


iHealth® Lancing Device

Intended Use

The iHealth Lancing Device and iHealth Lancets are specifically designed to use with the Gluco-Monitoring System. It is intended for use taking blood samples from fingertips or other sites of the body when testing blood glucose levels. Important: The iHealth Lancing Device is for, self-use only, and should not be used by healthcare professionals. Do not share or re-use lancets.

Parts and Display



1

Using the Lancing Device

1. Remove Cap

Remove the Device Cap and the Connecting Tube. Turn the Connecting Tube and ensure the "△" is aligned with the "▽" on the Eject Button. At this time, hear the sound of "click", and remove the Device Cap and the Connecting Tube.

2. Insert Lancet

Insert the lancet into the Needle Holder, and push down firmly until it is fully inserted.

3. Twist Off the Protective Disk (Do not discard)

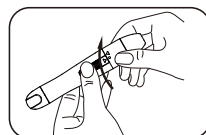
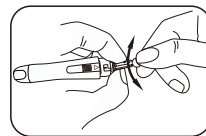
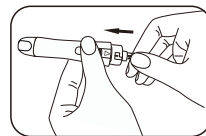
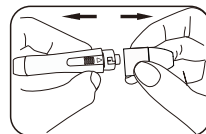
Twist off the Protective Cap and save it for lancet disposal.

4. Replace Lancing Device Cap

Place the Device Cap and Connecting Tube back on the device. Turn the Connecting Tube and ensure "▽" on the Eject Button is aligned with "○" on the Connecting Tube. At this time, hear the sound of "click".

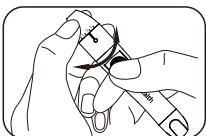
Use the Device Cap on the lancing device for finger tests. Use the Clear Cap for forearm, upper arm, hand, thigh and calf test sites.

2



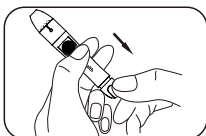
5. Set the Lancing Level

Hold the Device Cap in one hand, and the Device Body in the other, and adjust it to the proper level (usually 3). The depth display window is on the same side as the Release Button.



6. Load the Handle

Pull back on the device's Spring Mechanism. You are now ready to perform a blood glucose test.



Select Your Preferred Test Site

Warning: If you are testing for hypoglycaemia (low blood glucose) or if you suffer from hypoglycaemia unawareness, we recommend that you test on your fingers.

For Finger Lancing

- Lightly touch the lancing device (with the cap) against the side of your fingertip. For best results, lance in shaded areas.
- Press the Release Button.
- Gently squeeze your finger, if needed, until a blood drop the size of a pinhead forms (example: ●).
- Refer to your Owner's Manual for further information on blood glucose testing with the Gluco-Monitoring System.

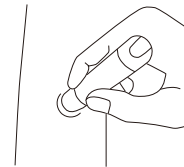
Notes: Blood glucose results from the forearm, upper arm, hand, thigh and calf are not always the same as results from fingertips. Do not use sites other than fingertips for testing when blood sugar is rapidly rising or falling, within 2 hours of eating, after taking insulin, immediately after exercise, or when you are ill or under stress.

3

Lancing Your Forearm, Upper Arm, Hand, Thigh or Calf

To bring fresh blood to the surface of the test site, rub the test site vigorously for a few seconds until you feel it getting warm. Lance the test site with the lancing device by:

- Holding the Clear Cap down against the top of your test site. Press the Release Button. Do not lift up.
- Apply a firm pressure on the lancing device until an adequate blood drop is formed.
- Lift the lancing device straight up being careful not to smear the blood sample on your test site.



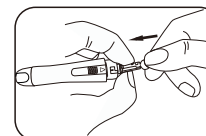
Important:

- Avoid lancing areas with obvious veins or moles to avoid excess bleeding.
- Avoid lancing areas with tendons or bones such as hands and ankles.
- A blood sample of 0.7uL about the size of a pinhead (example: ●) is required.
- Refer to the Gluco-Monitoring System Owner's Manual for further information.

Removing a Used Lancet

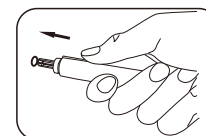
a. Prior to disposal, stick the lancet into the cover.

Remove the Device Cap and the connecting tube and stick the lancet tip into the Protective Cap.



b. Discard the used lancet properly.

Push the Eject Button, then push back the Protective Cap to its original position and discard the used lancet in an appropriate container.



4

Warning:

- Please avoid the accidental injuries to yourself or others when you use the device.
- Keep the lancing device and the lancet away from children.
- When you install the lancet, please do not press the Release Button if the Device Cap is removed.
- Please do not keep the lancet in the device after using it.
- Please do not share the device with others or reuse the lancet.
- Please disinfect the device before using it, but do not immerse the device into any liquid.
- Please pull the plug of the device gently to avoid shedding.
- The lancing device should press against the skin vertically and firmly, or it will affect the blood taking.

Cleaning and Disinfection

Cleaning and disinfection is absolutely necessary for the test procedure to be accurate because cleaning can insure the lancing device works well and disinfection can avoid infection or cross-infection to you or to other people.

We strongly recommend that the meter and lancing device be cleaned and disinfected following every use. We also suggest you use the following product: CaviWipes (EPA registration number: 46781-8).

CaviWipes, with Isopropanol and Diisobutyl-phenoxy-ethoxyethyl dimethyl benzyl ammonium chloride as the active ingredient, have been shown to be safe for use with the Glucose Meter and lancing device.

For product and technical information and to purchase this product visit www.metrex.com or contact Metrex at 1-800-841-1428.

- Before the test, the user should clean and wash hands.
- After testing, use the Cavi Wipes™ (Metrex® Research Corporation, EPA Reg. No.46781-8, EPA Est. No. 56952-WI-001) to clean and disinfect lancing device for 180 seconds.

Note:

- Each disinfection step requires a pre-cleaning step.
- Do not immerse the body of the lancing device in water or any other liquid. Store in a dry, clean well-ventilated room.
- The users should wash hands thoroughly with soap and water after handling the lancing device.
- If you have any questions please contact +7-855-816-7705
- Please refer to the following link for detailed information:

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"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) <http://www.fda.gov/medical-devices/safety/alerts-and-notices/lucm224025.htm>

"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>

Product Model: HH-XVI-T

Manufactured for iHealth Labs, Inc.

USA:

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1-855-816-7705

(8:30 AM-5:30 PM PST, Monday to Friday)

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Eiffestrasse 80, 20537 Hamburg, Germany

Tianjin Huahong Technology Co., Ltd.
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Made in China

SYMBOLS:

Authorised representative in the European community

Complies with the requirements of the European IVD Directive (98/79/EC)

Serial number

MANUFACTURER

Consult instructions for use

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