

DiVi Lab Pen

DV-I-006/25

Manual Book



Produced by:

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3.

Note: The Lancing device should be cleaned and disinfected before each use and after every use. If blood gets on the lancing device, clean and disinfect it before anyone else touches it.

Note: If there is residual soil on the device, repeat step 2 and step 3 above to repeat the cleaning and disinfecting of the device.

Note: If the site selected for puncture is visibly dirty, wash the area with soap and water, and then wipe it dry.

Apply alcohol to disinfect the skin to be pierced and allow to air dry before blood sampling.

Caution :

- Please read the instructions carefully before using the device.
- If the use by date of the lancet has expired, the lancet may be unsterile. Insert only lancets that are within the use by date.
- Please avoid accidental injuries to yourself or others when you use the device.
- 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.
- If the lancing device has come into contact with blood, it can transmit infections. The lancing device and 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, for example, cracks. If the lancing device or lancet is damaged, do not use it. Discard it.

4.

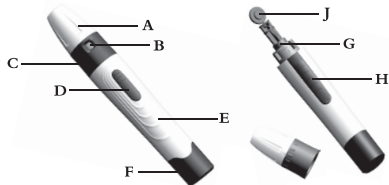
- Keep the lancing device with all components away from children under the age of 3 years. There is a risk of suffocation if small parts (e.g. caps or similar objects) are swallowed.
- Do not point the lancing device at your face or other people.
- If the lancing device falls with a lancet inserted, 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.
- If the lancet is stabbed into a hard surface, the needle can be damaged.
- 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.

Symbol	Title of symbol	Symbol	Title of symbol	Symbol	Title of symbol
	Manufacturer		Consult instructions for use		Date of manufacture
	Caution		Batch code		Do not use if package is damaged and consult instructions for use
	Medical device				

1.

Please read the instructions carefully before using the device

Main Structure of Lancing Device:



- A. Device Cap D. Release Button G. Lancet Carrier
 B. Depth Level E. Device Body H. Lancet Ejector
 C. Connecting Collar F. Rear Handle J. Lancet Cap

Penetration depth range

The below depth range is for reference only assuming that you use DiViLab device with DiViLab lancet. If you use other manufacturer's lancet, please adjust depth according to skin status and blood volume needed.

Level	Level 1	Level 2	Level 3	Level 4	Level 5
Penetration depth range	0.60mm	1.00mm	1.40mm	1.70mm	2.00mm
Deviation: ±0.30mm					

Intended Use: Along with a lancet, the lancing device is used to collect a capillary blood sample.

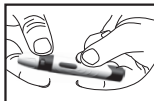
Contraindications: None.

Storage: The products should be stored in a dry, well-ventilated room. Keep away from any corrosive gas.

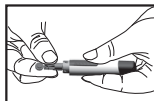
Shelf Life: No more than 5000 times or 10 years, whichever is first-come.

Operation Instructions:

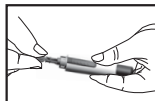
Please read the instructions carefully before using the device, wash hands before and after each use.



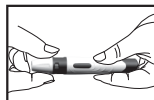
1. Remove the device cap together with connecting collar



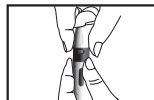
2. Insert the lancet into the lancet carrier and push down firmly until it is fully inserted



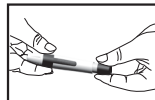
3. Twist off the lancet cap and save it for lancet disposal



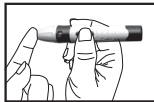
4. Put the device cap and the connecting collar back on the device and make sure they are fully seated



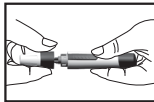
5. Adjust to the proper level, usually mid-level



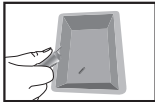
6. Pull back the device's rear handle



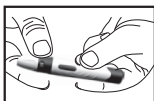
7. Hold the lancing device firmly and vertically against the blood sampling site, then press the release button



8. Remove the device cap and the connecting collar and stick the lancet tip into the lancet cap



9. Push the lancet ejector and discard the used lancet in an appropriate container



10. Put the device cap and connecting collar back on the lancing device

2.



Compatible lancets must be used with the lancing device. When using DiViLab lancing device with another manufacturer's sterile lancets, the operator must ensure that these products are compatible. We recommend that you shall consult a health care professional before use.

Note :

- The puncture depth can be adjusted.
- Increasing the number increases the depth of lancet penetration.
- Please adjust it according to the user's skin to reduce the pain.
- The lancing device should press against the skin vertically and firmly to obtain a blood drop.
- If sufficient blood cannot be collected, please adjust the puncture depth according to the instruction of the lancing device, and repeat the blood collection steps.

Warning :

1. When you insert the lancet, please do not press the release button if the device cap is removed.
2. Please do not keep the lancet in the device after using it.
3. Please do not share the device with others or reuse the lancet.
4. Please do not immerse the device into any liquid.
5. For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use.
6. Used lancet must be safely discarded after a single use.
7. 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.
8. If an individual is under the age of 18, the lancing device must be used by an adult or under the supervision of the adult.
9. 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.

Cleaning and Disinfecting :

Please clean the device before using it. 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 is suggested to 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.
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.