VASCULAR LOCALIZATION AND PUNCTURING DEVICE (VLPD)

1 INTRODUCTION

The VLPD facilitates localizing and puncturing blood vessels under real time ultrasound guidance and indicates acoustically and optically bi-directional blood flow. This feature provides clear distinction between arteries and veins. Therefore, you don't need to rely exclusively upon the traditional anatomical landmark method.

This is particularly useful for puncturing blood vessels like the Internal Jugular Vein, the Sub-Clavian Vein or the Femoral Vein, which are neither visible nor palpable.
The VLPD is also useful for arterial punctures when the pulses are hardly palpable.

2 CAUTIONS

2.1 Important preliminary remarks.

The needle guide is designed for:
Catheter-over-guide wire (Seldinger technique).
18 gauge (G) puncturing needles (outer diameter 1.2 mm). Smaller needles (20 G and more) may be used but they are less precisely guided.
Larger needles (16 G or less) cannot be used with the present needle guide.

The ultrasound probe is optimized for locating blood vessels lying 10 to 35 mm under the skin.

Do not use the single use disposable if the protective bag is damaged.

Precautions and warnings

Ultrasonic waves penetrate deep into the biological tissue. The effects of ultrasound on living tissue and organisms have yet to be fully researched, although many years of use in a wide variety of clinical applications areas have shown it to be harmless. Ultrasound should be employed with care and used only in situations where the results outweight the risks. Patients should not be subjected to unnecessary high doses. Do not leave the unit on line with the Doppler probes on the patient if it is not necessary for the appropriate diagnostic procedure.

Factors influencing ultrasound power output

With continuous wave ultrasound, a transducer sends continuous ultrasound pulses into tissue and a second transducer continuously receives the reflected back ultrasound wave. Ultrasound waves dissipate energy in the form of heat and can therefore cause tissue warming. This effect is very low with peripheral Doppler because of the very low and constant ultrasonic power . It is not controlled by the user. The manufacturer has always endeavoured to use as low an ultrasonic power output for our products as is practical. All power levels are significantly below currently established FDA limits. Major governing bodies in ultrasound have issued statements to the effect that there are no known adverse effects from the use of diagnostic ultrasound. However, exposure should always be limited As Low As Reasonably Achievable (ALARA principle).

3 PRODUCT DESCRIPTION

The VLPD consists of a 2 part construction including an ultrasound Doppler device and a single use disposable.

The Doppler device comprises an ultrasound probe and a control unit incorporating

- three buttons: "power on/off" "volume down" and "volume up"
- a loudspeaker
- 7 LEDs which light during 1 second when the device is switched on

The yellow LED

- lights continuously when the battery is operational
- flashes if the battery is low, indicating the need for a battery replacement

Three red LED indicate flow towards the transducer and three blue LED flow away from the transducer.
The number of lindicated LED provides information about the flow intensity.
Since the device is bi-directional, the red and blue LED might light simultaneously. This would indicate that an artery and a vein have been located simultaneously.

The sterile single use diposable allows for use of the non sterile Doppler device in a sterile field. It consists of the following parts:

- sheath which wraps the Doppler device, in particular the ultrasound probe
- needle guide to be fixed on the wraped utrasound probe
- pouch of sterile gel

4 OPERATION

4.1 Before vascular localization and puncture

Test the battery **prior to** inserting the device in the sterile sheath.
Change the battery if indicated by the flashing yellow LED. Switch the device off.

All preparations for conventional blood vessel cannulation remain unchanged.

Preparation of the device for sterile use

- Insert the device in the sheath (fig. 1, fig. 2, fig 3) and close the open end with a sterile clamp
- Introduce the slitted probe carefully into the tip of the sheath (fig. 4) and carefully remove possible air bubbles between the transducer surface and the sheath)

- Gently introduce the needle guide in the slitted probe and fix it (fig. 5 to 7)

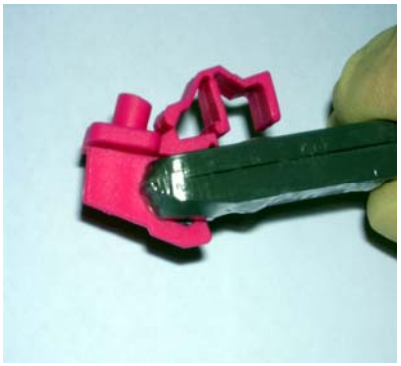


Fig 5

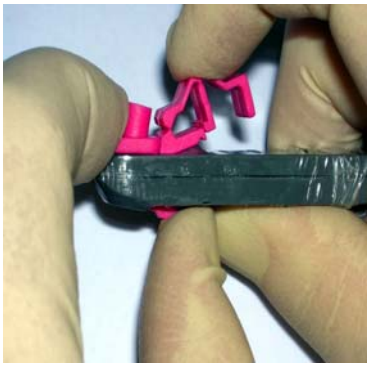


Fig 6

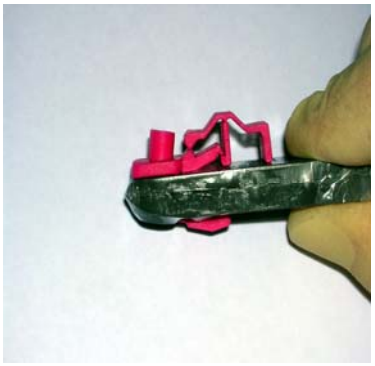


Fig 7

- Put a generous amout of sterile gel on the wraped probe, switch the device “on” and begin with the localization of the blood vessel to be punctured

4.2 During vascular localization and puncture

Localization of the blood vessel

- Position the transducer at an usual puncturing site, with the face of the transducer at an angle of about 45° to the skin: this will be the angle of the needle with that of the blood vessel
- Gently move the probe until the acoustical signal is clearly venous or arterial. Arterial sounds are pulsatile and have high pitched sounds. Veins give a less pulsatile sound, rather like roaring wind (low pitched sound)
- In case of doubt, the optical indication of the flow direction (red or blue LEDs lightening) is very useful to distinguish between veins and arteries
- If the acoustical and optical outputs are not clear, then move the transducer a few millimeters away and repeat the procedure until the blood vessel is clearly located and identified
- Advance then the needle through the needle guide and **proceed from now on in the usual manner**

Caution ! The device indicates the puncture direction but not the depth of the vessel !

Puncture of the blood vessel

- As soon as the blood vessel has been punctured, introduce the guide wire in the needle and **proceed from now on in the usual manner**. When finished switch the device off; you will save battery life!

5 DISINFECTION OF THE PROBE

5.1 Cautions

CAUTION: DO NOT USE THE FOLLOWING METHODS OF STERILZATION AND DISINFECTION. THEY WILL DAMAGE THE PROBES:

STERILIZATION	DISINFECTION
AUTOCLAVE	CHLORINE 100 %
ULTRASOUND	GLUTARALDEHYDE AT 100 %
	HYDROGEN PEROXIDE 100 %
	IODINE AT 100 %

Cleaning and high level disinfection of the probe
The connector must not be immersed. It is advised to immerse the probe and 20 cm of cable.

It is advised to limit the immersion in the disinfectant to one hour at most. Because of the high corrosive powers of most of the disinfectants there are some infiltration risks of the disinfectant into the probe.

Perform an examination of the probe after each disinfection and/or sterilization for visible cracks and leaks. If such damage is found do not use the probe. Your dealer will advise you if the probe can be repaired.

CAUTION: For USA, use a FDA cleared liquid sterilant and disinfectant.

5.2 Process of the high level disinfection

Step 1: Cleaning
Careful cleaning is crucial since it helps ensure the effectiveness of any subsequent microbicidal process.

- Carefully clean manually the probe after its use with a gause or paper humidified with a detergent/disinfectant
- Soak the probe (except the connector) in this detergent/disinfectant during 20 min according to the notified instructions of use of the manufacturer of the detergent (for example SALVANIOS)
- Remove the probe from the detergent/disinfectant and rinse it manually with clear and lukewarm running water
- Dry all the external surfaces of the probe with non sterile gause

Step 2: Disinfection

- Immerse the probe in a peracetic acid solution (for example Anioxyde).
- Soak the probe in this bath taking into account the notified user instructions from the disinfectant manufacturer (The duration of this immersion must not exceed one hour. The advised duration is 20 min.)
- Put on sterile gloves
- Remove the probe from cleaning solution

Step 3: Rinse

- Rinse manually the external surfaces of the probe with good microbiological quality or filtered water
- Dry all the external surfaces of the probe with a clean and dried sterile gause

Step 4: Storage

- Put the probe in a disposable sterile bag
- Store the probe in a appropriate place

5.3 Sterilization: ethylene oxide process

Before the sterilization process, clean and dry the probe according to the disinfection instructions provided in the previous chapter (Chapter 5.2 step #1).

CAUTION: Careful cleaning is crucial; if the probe is not adequately cleaned, the subsequent sterilization process may not achieve the desired result.

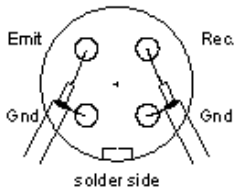
Put the probe in a special sterilization container or on a tray.

Sterilization conditions must not exceed:
Temperature: 52°C
Humidity: 50 ± 10 %
Pressure: 1.7 kg/m^2
Duration: 3 h ± 1/0 h
Gas concentration EtO: 600 mg/l
Mechanical aeration(post-process aeration time): 12 h at 54°C or 72 h at 24°C
The aeration must be operated after the EtO exposure

6 SERVICE

For service, return your VLPD device to your resailer.

probe connector :
LEMO type FGG 1B 304 CLAD42Z
Connector pin assignment : Fig. 14
The common cable shielding is connected to the back side connector, mechanically.



7 TECHNICAL SPECIFICATIONS

7.1 DOPPLER

Continuous emission probe.
Ultrasound frequency : 4 MHz
Ultrasound power

$I_{SPTA.3}$ (Max value)	167
Power (mW)	14.7
fo (MHz)	4.0
Z_{sp} (cm)	0.98
$X_{-6}Y_{-6}$	0.24, 020
Az (cm)	0.8
Ele (cm)	0.4

Audio amplifier 500 mW RMS

7.2 TEMPERATURE CONDITIONS

- Operating : 15 to 25 °C, 10-80 %Hr
- Storage: 10 to 40 °C, 10-80 % Hr

7.3 POWER SUPPLY

- Switch on using the ON/OFF switch

Auto - power off after 30s without signal
Battery type : 9 V alkaline - 6LR61 or PP3
Battery life : 5 h full charge.

7.4 DIMENSIONS

- casing Width = 80 mm, Depth =145 mm, Height = 36.5 mm
- weight 300 g

7.5 STANDARD/SAFETY

- Class: internally powered, Type : BF.
- IEC 601-1, **CE 0459,** Mechanical protection index : IP20.
- Radiated immunity, radiofrequency following IEC61000-4-3 is limited to Level 1