Medical Device Regulation (MDR) - VenoPulse

Manufacturer: STR Teknikk, Einar Stranden PhD, Skåtalia 15, 6010 Ålesund, Norway
Class I medical device: VenoPulse

1. VenoPulse is a medical device used in conjunction with ultrasound venous investigation**.** The VenoPulse inflates a pneumatic pressure cuff placed at calf level, during ultrasound scan investigation of venous function of the legs. The inflation is evoked by a foot-switch or a front panel switch, activating a high bore solenoid valve which is feeded by a precision pressure regulator set by the user (130-150 mmHg). The pressure to be applied is given by a display at the front panel. See below for more information.

2. VenoPulse is a class I medical device, not belong to the class I devices that must involve a notified body (sterile devices, measuring devices or reusable surgical instruments).

3a: General safety and performance. VenoPulse has no electrical contact with the investigated patient or ultrasound operator. The only connection to the patient is rubber tubes to a pneumatic pressure cuff. The pressure cuff is operated by a foot-switch (12V) or a front panel switch (12V). There is no electrical connection between VenoPulse and the ultrasound scanner or other devices.
The device conforms to REGULATION (EU) 2017/745, Annex I: General safety and performance requirements.

3b: Clinical evaluation. VenoPulse was designed and developed 1990 (Einar Stranden PhD) for use at Section of Vascular Investigation, Aker University Hospital (now Oslo University Hospital Aker), Oslo, Norway (head: Prof. Einar Stranden PhD) for standardizing ultrasound investigations for venous disorders of the legs (varicose veins, venous leg ulcers). Since then, the device has been delivered to more than 50 hospitals or medical centres in Scandinavia and Finland. Thus, the unit has been used clinically for more than 30 years. During these years no complaints or incidences for patients have been reported. VenoPulse has been reported useful in oral presentations and in the scientific publication by Rikke Broholm and co-workers: Observer Agreement of Lower Limb Venous Reflux Assessed by Duplex Ultrasound Scanning using Manual and Pneumatic Cuff Compression in Patients with Chronic Venous Disease and Controls. Eur J Vasc Endovasc Surg (2011) 41, 704-710.

3c: Technical documentation. Please contact the manufacturer. User manual is provided at delivery, presented later in this document, and in Norwegian and English language in the manufacturer website: https://strteknikk.no.

3d: Notified body involvement. VenoPulse does not belong to the class I devices that must involve a notified body (ref. #2).

3e: Instructions and labelling. VenoPulse user manual, see #3c. Each produced VenoPulse is provided with a unique serial number at the rear cabinet plate. Since 2004 It also include the following symbols according to the EU declaration of conformity, dated April 8 2004:

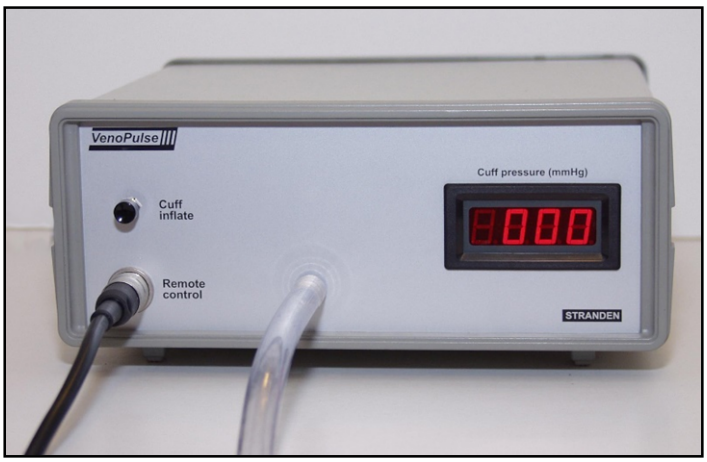
4: Manufacturer. STR Teknikk, Einar Stranden PhD, is a small scale manufacturer of electro medical diagnostic devices (https://strteknikk.no) which was needed when establishing the first vascular diagnostic laboratory in Norway 1980 (Section of Vascular Investigation, Aker University Hospital, Oslo. Head: Prof. Einar Stranden PhD). Medical doctors of other vascular surgical departments became interested in some of these units, and STR Teknikk was established to make a formal delivery to other hospitals possible. STR Teknikk has never made active advertisements of these units, they are delivered on direct request only ("jungle telegraph").

- STR Teknikk was registered 1981, and continued in the Norwegian business registry 1995 (https://www.brreg.no). Registry number 965883185.
- VenoPulse was developed 1990, and by February 2025 84 units have been produced, most frequently for Norwegian hospitals and medical centres.
- VenoPulse has for practical reasons been decided limited to Scandinavia and Finland.
- A database keeps track of each produced unit, as well as technical issues (1) or patient complaints (0).

Venous investigations with

VenoPulse

venous compression unit



User manual

1. The unit may be attached to the ultrasound scanner. Preferably fasten the unit using the inbuilt attachment brackets.

2. Connect the unit to mains power (230 V). Turn on unit. The display should read approximately 000 mmHg. A few mmHg offset is quite acceptable. The zero level may be adjusted by the control screw at the rear panel.

3. Connect the unit to pressurized air (4-12 bar). A weak leak is heard – and is normal (adjustment bypass leak). The display indicates cuff compression pressure. Normally 130-150 mmHg is used. The pressure is adjusted at the back, after unlocking the locking nut and carefully turning the wheel. Fasten the locking nut after adjustment!

4. The cuff is connected to the front outlet and placed around the calf of the extremity to be investigated. The patient is best investigated standing, or lying at a very steep angle.

5. Locate the stem vein or side branch to be investigated by the ultrasound scanner. Preferably start investigation with colour flow mode (Fig. 1A, 1B) and finalize with spectral Doppler (Fig 1C).

6. Inflate cuff by the front cover switch “Cuff inflate” or the foot switch (Fig. 1A). Keep it pressed for 2-3 seconds, and then release. Note flow status following release (Fig. 1B). Normally there is a short distal reflux while the venous valves close; a reflux exceeding 0.5 seconds is usually defined pathological (Fig. 1C).

No special maintenance is required.

Replacement of pneumatic cuff:
Welch Allyn (Tycos) #5082-26, Cuff & Bag, Large Adult - 2 tubes, or similar with 2 tubes.

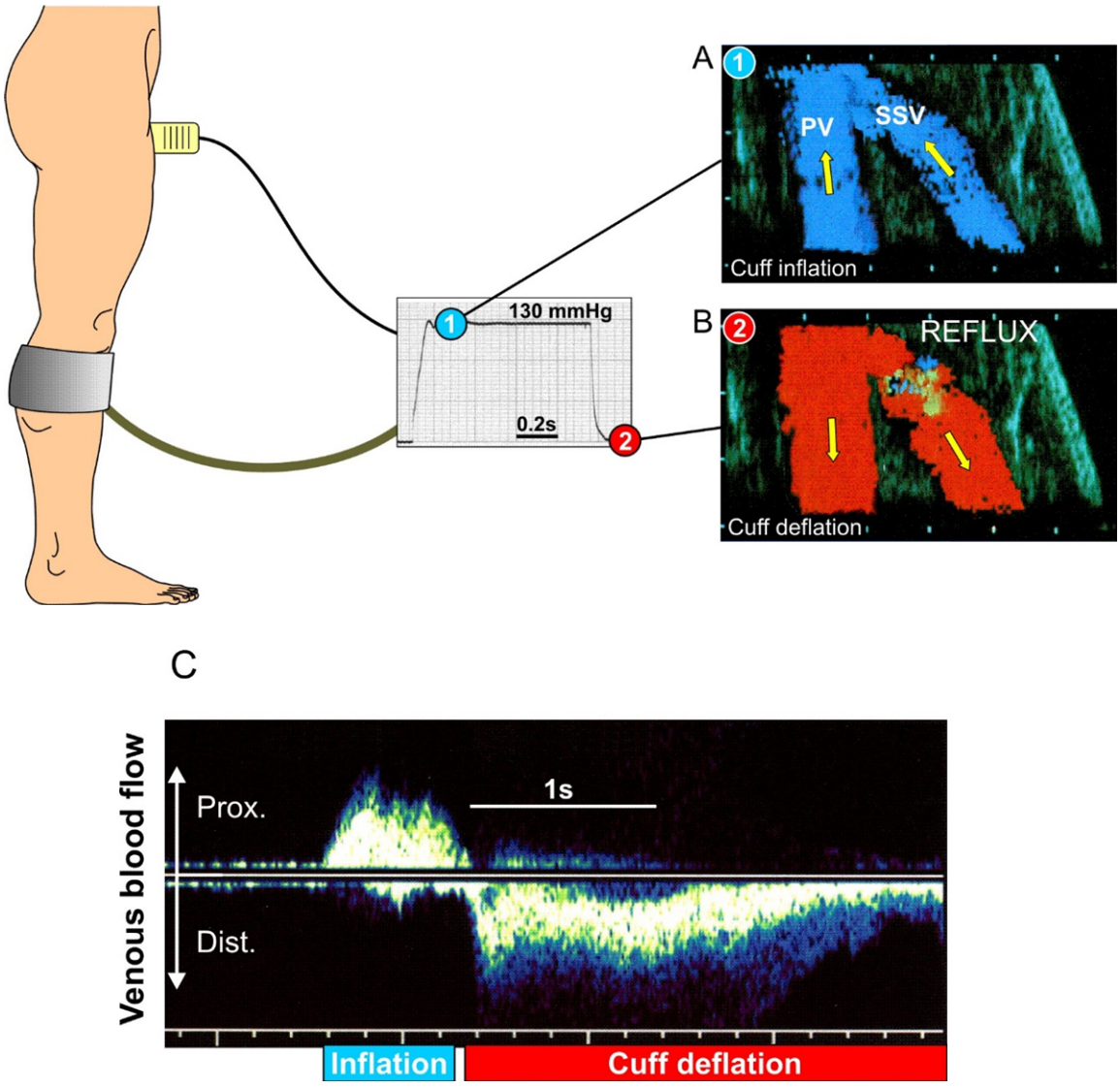


Fig. 1. Investigation procedure with VenoPulse unit.

STR Teknikk
Einar Stranden PhD
Skåtalia 15
6010 Ålesund, Norway

Phone: +47 9074 2199
E-mail: einar.stranden@mimer.no
Web: https://strteknikk.no