

Medical Device Technical File (MDD-12) – Checklist

Manufacturer: STR Teknikk, E. Stranden PhD, Skåtaia 15, 6010 Ålesund, Norway
Class I medical device: Venopulse

The technical file must contain documents defining the product specifications or refer to the location of this documentation.

Upon request, this documentation must be made available to the relevant national authorities, as part of their market surveillance programmes.

This checklist contains the main items to be included. The manufacturer must decide if additional items are relevant for the MDD requirements.

Item	Documentation and location reference	Responsible person/ department in Company
General description of the product	The Venopulse inflates a pneumatic pressure cuff placed at calf level, during ultrasound scan investigation of venous function of the lower extremity. The inflation is evoked by a footswitch or a front panel switch, activating a high bore solenoid valve which is feeded by a precision pressure regulator set by the user. The pressure to be applied is given by a display at the front panel. See below for more information.	E. Stranden
Design drawings, circuit schematics etc.	Available at request	E. Stranden
Description and explanations necessary to understand the above mentioned drawings and diagrams and operation of the device	No extra description necessary	E. Stranden
For sterile products, a description of the methods used	NA	
List of standards (enclosed) applied in full or in part accompanied by descriptions of the solutions adopted to meet the relevant essential requirements in the Directive		
Design master file		
Device life as determined by the manufacturer	20 years or more	E. Stranden
Risk Analysis (model given in EN 1441)	There is very small risk for the patient. No electrical connection,	E. Stranden

	solely pressure cuff. The cuff pressure used is only appr. 50-80 % of what is normally used during a standard blood pressure measurement	
Results of design calculations and inspections performed on any other equipment that the device must be connected to in order to operate properly	VenoPulse has no electrical connected to other devices.	E. Stranden
Test reports and/or clinical data to support compliance with the appropriate portions of the MDD and the relevant technical standards	The unit has been used for more than 10 years at hospitals without any complaints or incidences	E. Stranden
Labels and instructions for use	User manual	E. Stranden
Declaration of Conformity (when prepared)	EU Declaration of conformity VenoPulse	E. Stranden
Vigilance system		

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.

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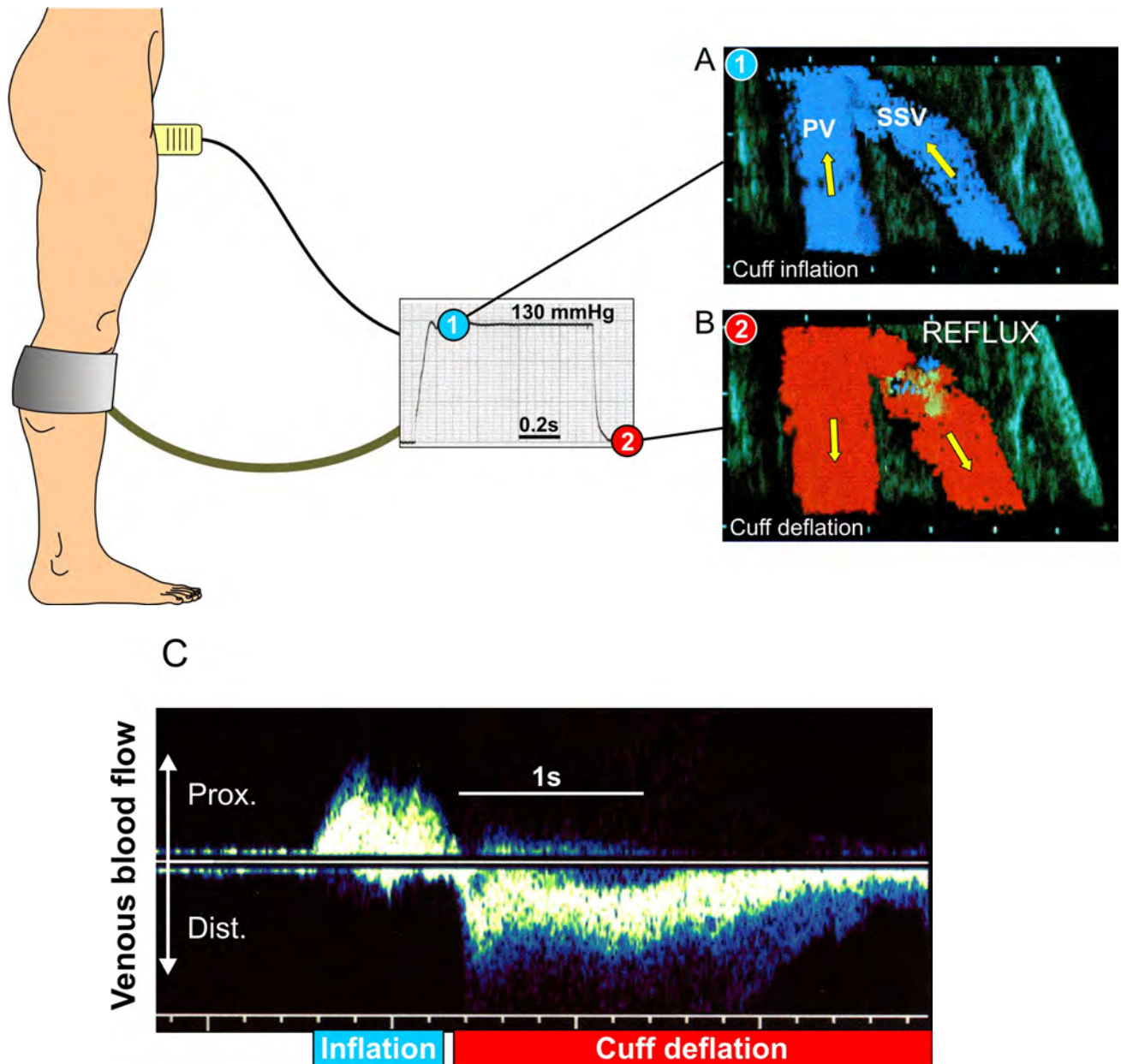


Fig. 1. Investigation procedure with VenoPulse unit.

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