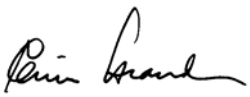
EC DECLARATION OF CONFORMITY

Manufacturer / Fabrikant: (name + address)	**STR Teknikk** **Skotalia 15** **N-6010 Aalesund** **Norway**
– herewith declare that the produkt: ***– bekrefter med dette at produkt:***	**VenoPulse**
Model/type:	.
Technical data / Tekniske data:	**0.5A, 230VAC, 50Hz, Class 1 equipment.**
Standards used / Standarder benyttet:	**MDD-12**
– is in conformity with the provisions of mentioned Directives: ***– er produsert i henhold til krav i følgende direktiver:***	**- Medical Device Directive 93/42/EEC**
CE marking is affixed from year: ***CE merked er påført fra år:***	**April 2004**

Place: Aalesund

Date : 08 April 2004



Dr. philos. Einar Stranden
Technical, and Managing Director

Medical Device Technical File (MDD-12) – Checklist

Customer: STR Teknikk, E. Stranden, Skotalia 15, 6010 Aalesund, Norway
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 pneumatic pressure cuffs placed at calf level, during investigation of venous function of the lower extremity. The inflation is evoked by depressing 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. The pressure to be allied is given by a display at the front panel. See below for more information.	E. Stranden
Design drawings, circuit schematics etc.	Available	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	10 years	E. Stranden
Risk Analysis (model given in EN 1441)	There is very small risk for the patient. No electrical connection, solely pressure cuff. The cuff pressure used is only appr. 50-80 % of what is normally used during a standard blood pressure measurement	E. Stranden
Results of design calculations and inspections performed on any other equipment that the device must be connected to in order to operate properly	The device is not 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 com-plaints or incidences	E. Stranden
Labels and instructions for use	User manual	E. Stranden
Declaration of Conformity (when prepared)	CE Declaration Venopulse.DOC	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

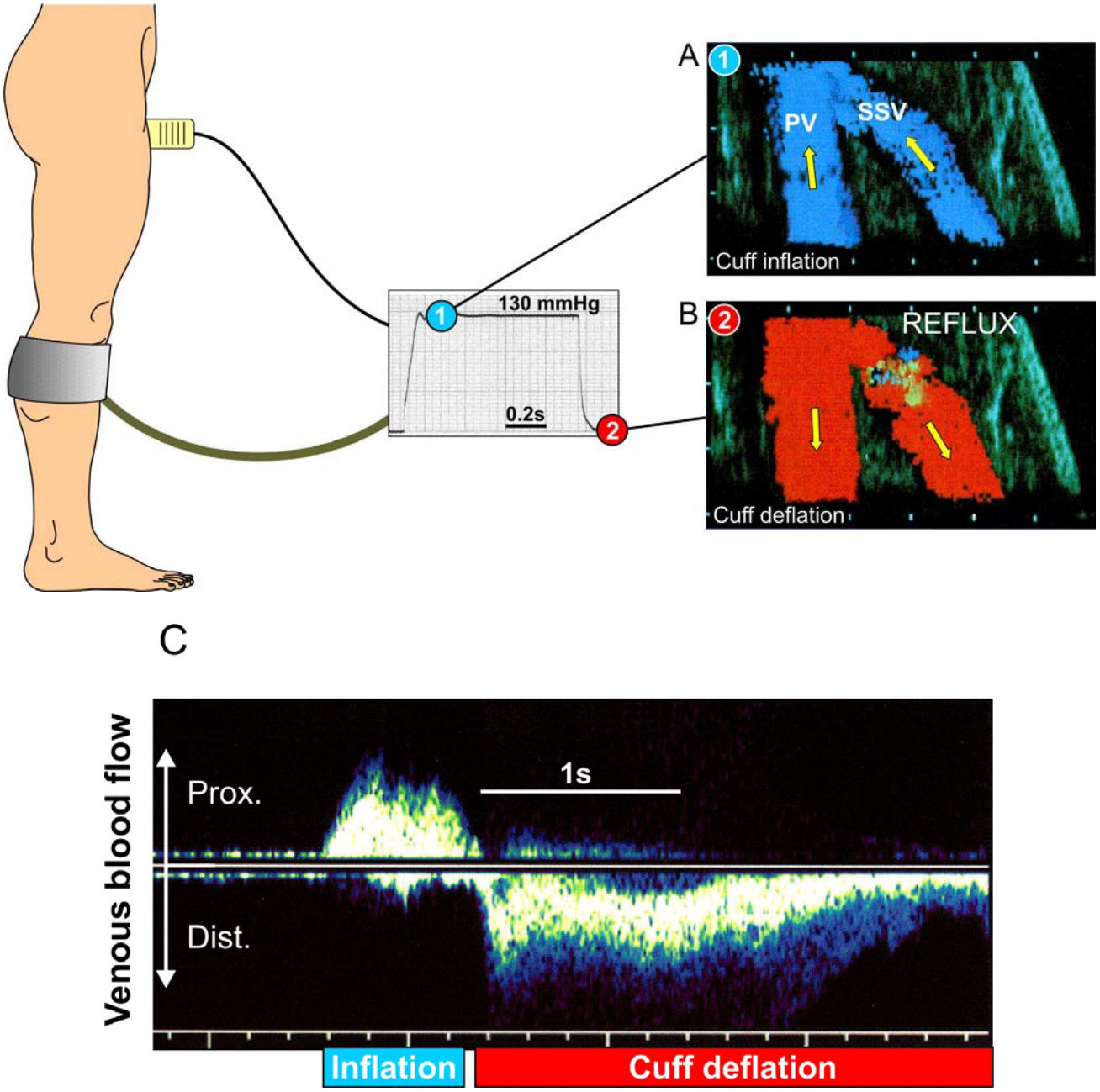


Fig. 1. Investigation procedure with the VenoPulse unit.

Einar Stranden PhD
STR Teknikk
Skotalia 15
6010 Aalesund, Norway
Ph. +47 7015 1683
E-mail: ein.stra@online.no