

## VALIDATION OF AN OPTOELECTRONIC LIMB VOLUMETER (PEROMETER®)

A.W.B. Stanton, J.W. Northfield, B. Holroyd, P.S. Mortimer, J.R. Levick

Division of Physiological Medicine, Department of Medicine (AWBS, JWN, BH, PSM) and Department of Physiology (JRL), St. George's Hospital Medical School, London, United Kingdom

### ABSTRACT

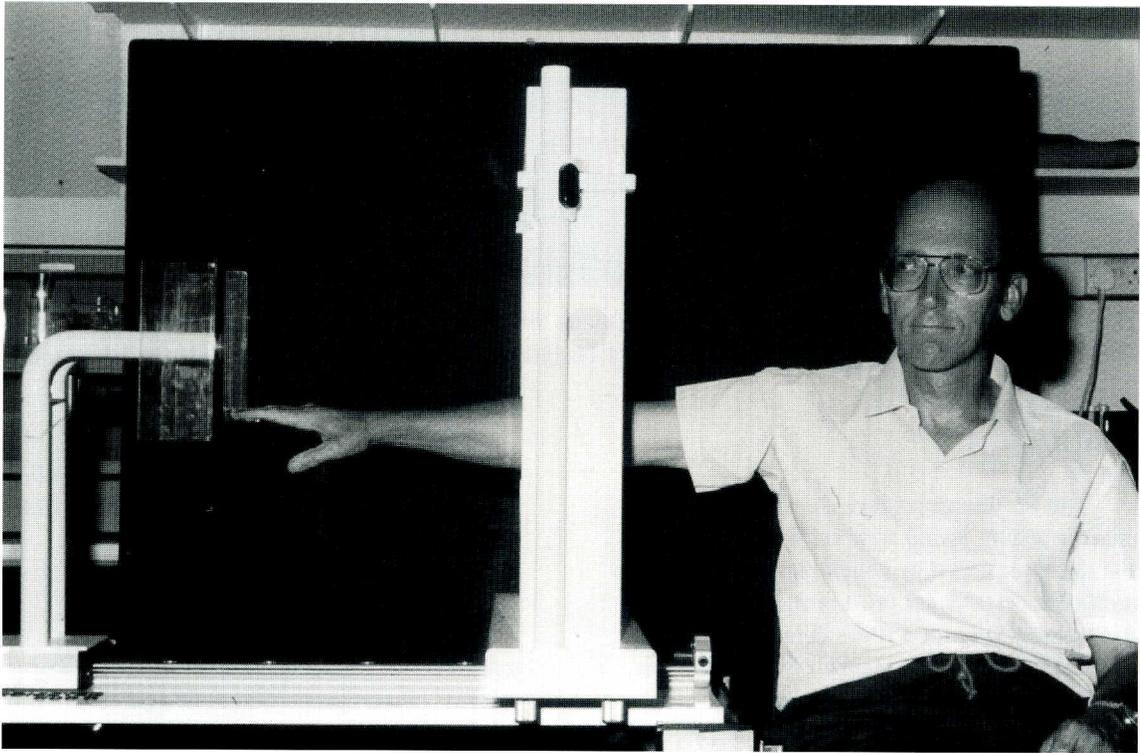
*The Perometer, a device designed for the measurement of limb volume, has been rigorously assessed by comparison with other methods. Differences in the volume of geometric shapes and limbs determined by the Perometer and a tape measure/meter rule (i.e., Perometer minus direct measurement) were -0.8 to -2.4% (cylinders), -4.6% (truncated cone), -3.3% (mannequin limbs), 6.1% (normal human arms) and 6.8% (lymphedema arms). The larger differences were likely to be due to deviation from circular or elliptical cross-section (Perometer or tape method) and compression of the arm (tape method). Errors arising from incorrect positioning within the measuring frame were generally small, but larger errors occurred when a cylinder was partially rotated within the frame (i.e., no longer perpendicular to the light beams). The Perometer was highly reproducible, each measurement taking only a few seconds.*

*When recording the change in volume with time of a segment of arm during venous occlusion (blood flow measurement by venous occlusion plethysmography) using the Perometer plus a mercury strain gauge, between-method differences for individual blood flow recordings were apparent. The source of these differences is discussed. However, using the average of a number of blood flow recordings the Perometer and the strain gauge agreed fairly closely for both the normal and lymphedema arms.*

*The Perometer is thus a reliable and convenient tool for the measurement of limb volume, and may also be used to measure the rate of swelling during venous occlusion plethysmography.*

The Perometer® is an imaging system marketed for the measurement of arm or leg volume, circumference, contour and cross-sectional area (1). Such information is potentially of great value to the lymphedema specialist, enabling the initial size and shape of the limb and its response to treatment, e.g., by compression hosiery, to be assessed conveniently and quickly. In most lymphedema clinics a tape measure is used to assess limb size and shape. The Perometer can also record the change in volume (swelling rate) of a short segment of arm or leg over a period of a few seconds to several minutes when venous outflow from the limb is occluded. This technique, venous occlusion plethysmography (VOP), is widely used to estimate limb blood flow and capillary filtration rate per unit volume of tissue. The result can be converted to whole-limb values if total limb volume is determined separately. Traditionally, the method of recording limb swelling rates in VOP has been to attach a water jacket (2, 3) or a mercury strain gauge (4-6) around the limb.

Briefly, the Perometer consists of a vertically-oriented square measuring frame which can be moved freely to and fro by hand along a horizontal base plate. The frame contains rows of infra-red light emitting



*Fig. 1. The Perometer. The subject holds his arm out horizontally with the hand resting on the perspex support. The measuring frame is moved by hand along the length of the limb towards the shoulder and then back towards the wrist. The Perometer computes the volume from a large number of vertical and horizontal diameter measurements.*

diodes on two sides and rows of corresponding light sensors on the opposite two sides. The patient sits at one end of the base plate with the arm or leg held out horizontally and the hand or foot resting on an adjustable support (see *Fig. 1*). With the limb in the center of the frame the latter is moved along the length of the limb from the wrist or ankle towards the top of the arm or thigh, and then back again. The limb casts shadows in two planes and, using the cross-sectional information obtained from a large number of serial segments 3.1 mm thick, the computer builds up a picture of the entire limb. Calculations are based on the assumption of a circular or elliptical cross-section. The hand and the foot cannot be reliably measured (because they deviate markedly from the circle or ellipse in section), and it is difficult

to record volume right to the top of the arm or thigh because of the thickness of the frame and the necessary abduction of the legs required.

For VOP, the frame is positioned around the muscular part of the calf or forearm and not subsequently moved. This may be carried out with the frame on its base (as above) or with the frame detached from the base if an orientation other than the vertical is more convenient. The change in volume of one 3.1 mm segment with time is recorded. The Perometer is easy to operate and does not require calibration before use, although an internal 'test of function' may be performed.

Data on the accuracy and reliability of the Perometer and similar devices are sparse (1,7). We have therefore determined the accuracy and reliability of the Perometer 300

S (Pero-System GmbH, Wuppertal, Germany) by measuring the volumes of a variety of shapes and human limbs and comparing these with direct measurements using a tape measure and a meter rule. When carefully performed, the tape method agrees well with volume displacement (8-10). The accuracy of the calculation of limb segment swelling rates (i.e., change in volume over time) was examined, both by simulating the swelling of a limb as would occur during venous occlusion and by comparison with a mercury strain gauge in VOP on human arms.

## MATERIALS AND METHODS

### *Human Subjects*

The healthy subjects for this study were medical students and staff from St George's Hospital Medical School. Women with post-mastectomy edema of the arm were recruited from the Lymphoedema Clinic, The Royal Marsden NHS Trust, London and Surrey. Local Ethics Committee approval was obtained.

### *Geometric Shapes and Their Orientation*

A range of cylindrical, cuboidal and conical shapes, opaque to infra-red light, were measured using both the Perometer and a plastic tape measure and wooden meter rule (direct measurement). For each method, an average of 3 measurements was used. The tape measure had an error of 0.1 % per meter (1 mm/m) when placed against the meter rule. The measuring frame of the Perometer was shielded from direct sunlight from the window as recommended in the instruction manual (see later). Volumes determined using the tape measure/meter rule were calculated using standard geometrical formulae. The possible effect on recorded volume of displacing the cylinders 5 and 10 cm radially from the center of the frame in the horizontal and vertical planes (but still perpendicular to the light beams) was determined. In addition,

the smallest cylinder was rotated so that its axis lay at 15° and 30° in each plane to the normal central orientation and was no longer perpendicular to the light beams.

### *Mannequin Arms and Human Arms (Normal and Lymphedema)*

The same operator performed all of the following measurements.

(i) *Limb volume.* Six mannequin arms, 3 mannequin legs, and the normal plus the lymphedematous arms of 12 women previously treated for breast cancer were measured from the wrist to the mid upper arm using both the Perometer and a tape measure. With the tape measure, circumference was measured sequentially every 4 cm along the axis of the arm, and volume was calculated from the formula for a series of truncated cones of this length:

$$V = \frac{\sum (X^2 + Y^2 + XY)}{3\pi}$$

where V is limb volume, X is the circumference at one point on the limb and Y is the circumference at a point 4 cm proximal to X. Errors arising from the use of this formula are usually small (9). Equivalent start and end points on the limb were used when comparing the two methods. For the Perometer measurement, each subject placed his/her hand on the hand support with the palm facing downwards and the fingers fully extended, the tip of the middle finger touching the back of the support (as illustrated in *Fig. 1*). The arm was maintained in this position for the sequential circumference measurements. Thus, muscle tension and venous blood volume were the same for direct comparison of these two methods.

To assess the effect of muscle tension (required to hold the arm horizontally for measurement by the Perometer) on volume, the forearm of the same subject was measured by the Perometer (only) in the

standard position (*Fig. 1*) and with the arm suspended by a loop of tape around the wrist, i.e., with postural muscles relaxed.

(ii) *Errors with repeated measurement.*

To assess the possible variation in recorded volume with repeated measurement of the same arm, including intrinsic equipment variation, the normal arm of 3 subjects and one mannequin arm were measured repeatedly. (a) Each subject was asked to place his/her arm inside the frame 20 times at will, with instructions to touch the back of the support with the middle finger, and 20 measurements were performed. This took 5 minutes. (b) The arm was placed 20 times inside the frame according to a fixed schedule (hand placed on support, wait 15 s, measure, arm placed on lap, wait 15 s, repeat) and using a colored target dot on the back of the support touched with the middle finger to ensure accurate repositioning of the arm. (c) The mannequin arm was left undisturbed inside the frame and measured 20 times.

(iii) *Errors arising from incorrect longitudinal (axial) positioning.* Using the Perometer software, possible errors with incorrect longitudinal positioning of the arm were determined. By moving the two cursors (which define the start and end point of the desired segment of the arm to be measured) superimposed on the image of the arm profile, incorrect positioning of the arm (for instance the middle finger not in contact with the back of the hand support), could be simulated. This method of assessment eliminated other variables in arm position when a subject's arm was repeatedly measured, e.g., shoulder position. Secondly, by measuring the circumference of the arm at several adjacent positions from the stored image, the result of the forearm moving relative to the frame during VOP could also be assessed. Thus, (a) the volumes of 7 segments of arm of equal length but each displaced by 3.1 mm (i.e., an arbitrary middle position plus 3 cursor movements in the direction of the wrist and three movements in the direction of the shoulder) were measured and the change in volume of

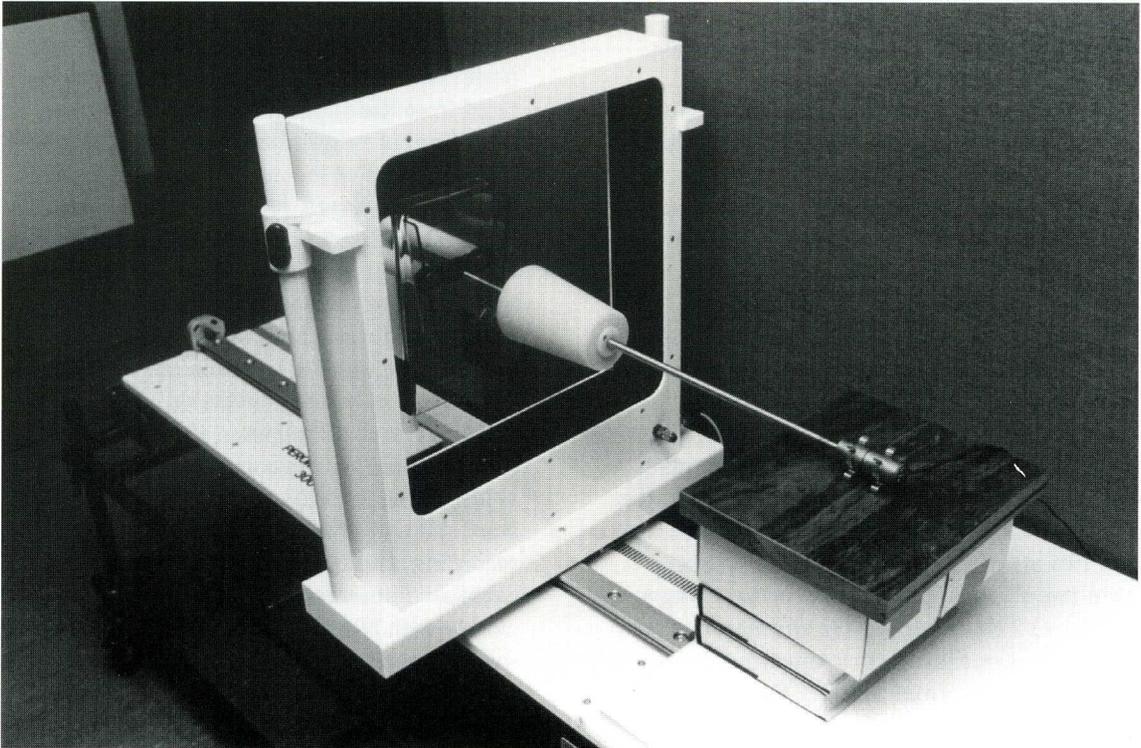
the segment for every 3.1 mm shift calculated, and (b) the circumference and change in circumference every 3.1 mm at three points on either side of the point of maximum circumference were determined in both the normal and the lymphedema arms of the women previously treated for breast cancer.

*Change in Volume with Time*

(i) *Measurement of mannequin arms, and effect of sunlight.* Using the venous occlusion plethysmography mode of the Perometer, the volumes of a segment of 3 mannequin arms (constant size) were continuously recorded for the maximum period of 17 minutes to assess drift. The influence of bright sunlight on the recording was also studied.

(ii) *Simulation of swelling rate in VOP using a frustum of a cone.* A nylon frustum of a cone, i.e., a truncated cone, was threaded onto a screwed rod which was positioned in the center of the frame as shown in *Fig. 2*. The rod was rotated at 10 different speeds using a small electric motor and the frustum moved along the rod and through the frame, the attached weight preventing it from rotating with the rod. The segment of the frustum (3.1 mm thick) presented to the light beams thus increased in size with time simulating the increasing girth of the forearm or calf during venous occlusion. The apparent change in volume per 100 ml of 'tissue' was plotted by the Perometer against time, and 'blood flow', i.e., the apparent swelling rate of the frustum, was automatically calculated when the sloping volume recording was marked off using the two cursors on the computer display. The volumes of the initial and final segments of the frustum presented to the light beams were also determined from the circumferences, obtained with a tape measure, and change in volume was calculated over the period of movement through the frame to give swelling rate in units of ml/100 ml/min (as for the Perometer).

(iii) *Measurement of forearm blood flow*



*Fig. 2. A nylon frustum of a cone (truncated cone, overall dimensions: length, 15.3 cm; radius of base 1, 5.0 cm; radius of base 2, 3.8 cm) is positioned in the center of the Perometer frame. The frustum has a screwed collar at one end which is threaded onto a rod. The latter is rotated by a small electric motor which moves the frustum slowly through the frame. A heavy weight attached to the frustum prevents it rotating as a result of friction with the rod. The small but rapid increase in circumference of the arm during venous occlusion plethysmography can thus be simulated.*

(rapid arm swelling on venous occlusion) by Perometer and mercury strain gauge in the normal and lymphedema arms. Twenty-seven arms of 14 normal subjects (8 male and 6 female, aged 18-49 years) and the lymphedema arms of 17 women (aged 46-85 years) were studied. The subject reclined on a couch at 45° in a temperature controlled laboratory (ambient temperature 25.5-27.6°C, relative humidity 28-57%). In contrast to the static measurement of arm volume (Fig. 1), the arm was supported, fully relaxed, at the wrist and elbow in two padded U-shaped rests, so that the Perometer frame could be positioned over the muscular part of the forearm with the forearm in the center of the frame. A mercury strain gauge (Lectromed, St Peter, Jersey)

was secured around the mid-forearm with the mercury loop (Esco silicone tubing, bore 0.5 mm, wall thickness 0.5 mm, Bibby Sterilin, Stone, Staffordshire, UK) resting over a series of thin plastic strips (4 x 0.75 cm) secured to the skin at intervals of 2 cm with skin glue ('It stays', Sigvaris, Vienna, Austria). This prevented the loop from sinking into the arm. The gauge was connected to a bridge box (St George's Hospital Medical Physics Department) and an amplifier (3559, Lectromed, St Peter, Jersey). Calibration was performed to obtain the relationship between length of loop and pen deflection on the chart recorder. A blood pressure cuff (adult size; Accoson, London) was secured around the upper arm and connected using thick-walled pressure

tubing to an adjustable inflating unit (St George's Hospital Medical Physics Department) and a compressor (Jun-Air Compressor, Nørresundby, Denmark). Cuff pressure was recorded from a side-arm using a pressure transducer (Sensonor 840 Physiological Pressure Transducer) and an amplifier (PM-1000 Transducer Amplifier, CWE Inc., both from Linton Instrumentation, Diss, Norfolk, UK). The cuff was enclosed in a non-expandable plastic corset which ensured inward inflation, and it took no more than 1.5 s to inflate fully. The forearm was supported 10-15 cm below the manubriosternal angle. When measurements were performed on both arms of a subject, the distance below the manubriosternal angle for the two arms was within 1.5 cm. Forearm skin temperature ( $T_{sk}$ ) was recorded using a Model 43 Tele-thermometer and reusable skin probe (Yellow Springs Instruments, OH, USA); for the normal subjects  $T_{sk}$  was  $33.5 \pm 1.5^\circ\text{C}$  ( $n = 27$ ) and for the PMO subjects  $T_{sk}$  was  $33.5 \pm 1.7^\circ\text{C}$  ( $n = 17$ , means  $\pm$  s.d.). All parameters except Perometer swelling rates were recorded on a chart recorder (SE-400, Servogor, Goerz, Vienna, Austria).

It was not possible to record blood flow from the same site using the strain gauge and Perometer simultaneously because of the difficulty in subtracting the volume of the strain gauge (which would be registered by the frame) from the Perometer recording of swelling rate. Most experiments were therefore performed with the Perometer frame 3 cm proximal to the mid-forearm strain gauge site. The possible influence on blood flow of differing soft tissue composition of the arm at different recording sites was determined by (a) recording blood flow at 2, 4, 6, 8 and 10 cm from the antecubital crease using the Perometer alone (healthy subjects), and (b) recording blood flow at the same mid-forearm site at closely following times (within 30 minutes) using the Perometer and then the strain gauge in turn (normal arms of lymphedema subjects).

Following a 20 minute-period of acclima-

tization, the cuff was inflated to 45 cm  $\text{H}_2\text{O}$  for 15 s and then deflated for 10 s. This was performed 8-9 times. Blood flow was calculated from the strain gauge and Perometer recordings of volume/time over the period 0-5 s after inflation of the cuff, or over the period 2-7 s if, as occurred very occasionally, an 'inflation' artifact was present (see below). For the strain gauge, the slope was measured by hand from the paper record using a ruler. Paper speed was 12 cm/min and slope was measured in units of mm/min (typically 30-195 mm/min) before conversion to ml/100 ml/min. For the Perometer, the two cursors superimposed on the computer display of the volume/time recording were positioned at the start and end of the first section of the recording, and blood flow (ml/100 ml/min) calculated automatically. The latter agreed closely with blood flow calculated from the same slopes measured by hand from the hard copy. One problem with the Perometer was the small size of the recordings and the steepness of the slopes, typically 50-385 mm/min and in some cases apparently vertical at the start of the slope, when up to 8-9 recordings were saved on one computer file. This consecutive set of recordings was displayed graphically on one screen, the time scale (unalterable after saving the data) being 0-4.2 min (0-250 s). In these cases the subsequent gradient of the non-vertical section of the slope was determined. This led to less accurate blood flow measurement compared with the strain gauge (see Results). Slopes were approximately 40 % of the above, and quasi-vertical slopes uncommon, when only three individual blood flow recordings were saved on one file. In this case, the set of recordings was displayed on a time scale of the same width, but lasting only 0-1.7 min (0-100 s). Each recording was thus wider, and had a lower slope.

An 'inflation' artifact was occasionally present at the start of recordings made from lymphedema arms (this was presumably related to the shape of the arms), and very occasionally from normal arms. If present,

**TABLE 1**  
**Volume Measurements\* of Geometric Shapes Using a Tape Measure/  
 Meter Rule and a Perometer (ml)**

	Small	Cylinders Medium	Large	Cuboid	Frustum
Tape measure/meter rule	755	1648	4094	2757	835
Perometer:					
centered in frame	737	1615	4062	2429	798
5 cm horizontally	732	1638	4056	-	-
10 cm horizontally	728	1643	4073	-	-
5 cm vertically	760	1660	4064	-	-
10 cm vertically	756	1656	4080	-	-
15° in horizontal plane	771	-	-	-	-
30° in horizontal plane	869	-	-	-	-
15° in vertical plane	778	-	-	-	-
30° in vertical plane	880	-	-	-	-

\*Each value is the mean of three measurements  
 Perometer measurements were performed with shapes in different positions within the frame.

the first 1-2 s of the slope was ignored. Some recordings were spoiled by movement artifact, and were discarded.

#### *Statistical Analysis*

Results are presented as mean  $\pm$  standard deviation (s.d.) or standard error of the mean (s.e.m.), or as individual values. Paired analysis of blood flow determined by the two methods was performed using Student's *t* test. Analysis of variance (ANOVA) was performed for the multiple site blood flow measurements (Perometer). Regression analysis and calculation of the correlation coefficient was performed on volume measurements obtained using the two methods. Because of the difficulty in assessing between-method differences from a scatter diagram, the degree of agreement was assessed by calculating the difference between the Perometer and the tape method and by plotting each difference (as a percentage) against the mean of the two methods. The latter value provides the best available estimate of the true volume (11).

Differences were considered significant if  $P < 0.05$ . All analysis was performed using Excel 5.0 software (Microsoft).

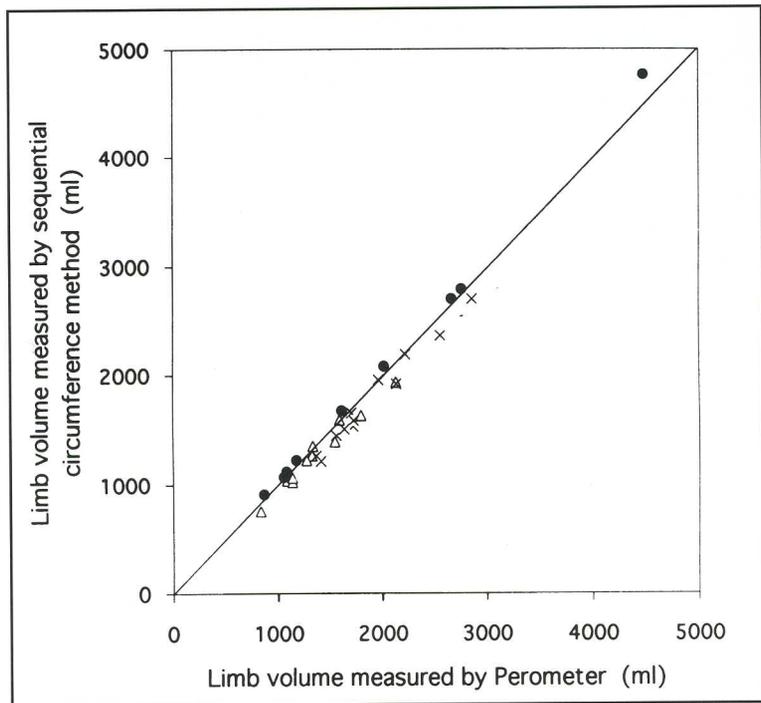
#### *RESULTS*

##### *Static Volume Measurements of Geometric Shapes*

The volumes obtained with each method of measurement are shown in *Table 1*. There was good agreement for the cylinders and for the frustum of a cone. For the former, the Perometer gave a marginally smaller value than the direct measurement but the difference was only 0.8-2.4%. The difference for the frustum volume was slightly greater (4.6%), the Perometer again giving the smaller value. For the cuboid, agreement was less good; the Perometer volume being 13.5% (328 ml) smaller than the direct measurement.

*Table 1* also shows the cylinder volumes obtained using the Perometer (only) when the cylinder was not centrally located within the measuring frame. For displacement along the horizontal and vertical axes (but remaining

Fig. 3a) Scatter diagram of mannequin limb (●), normal human arm (Δ) and lymphedema arm (×) volumes measured using the Perometer and the sequential circumference method using a tape measure. The relationship of the points to the line of equality can be seen. Equations describing the regression lines for the three limb types are:  $y = [1.05 \pm 0.02]x - [36.5 \pm 34.41]$  (mean  $\pm$  s.e.m.),  $r = 0.999$ ,  $P < 0.0001$ ,  $n = 9$  (mannequin limbs);  $y = [0.91 \pm 0.05]x + [43.4 \pm 70.3]$ ,  $r = 0.985$ ,  $P < 0.0001$ ,  $n = 12$  (normal human arms);  $y = [0.99 \pm 0.05]x - [100.2 \pm 94.1]$ ,  $r = 0.988$ ,  $P < 0.0001$ ,  $n = 12$  (lymphedema arms).

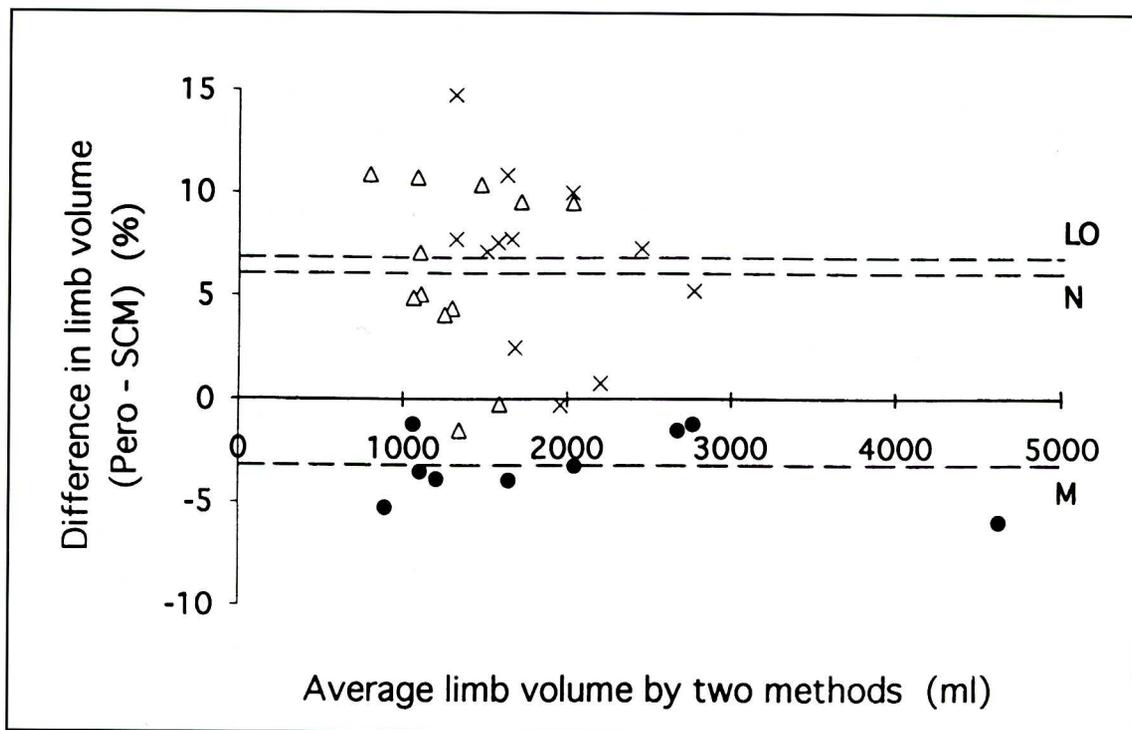


perpendicular to the light beams), differences between central and off-central positions were small (maximum of 3.1% for the smallest cylinder, 2.8% for the medium cylinder, 0.4% for the largest cylinder). For displacement at an angle to the axis of movement of the frame (small cylinder only), differences were greater for the larger angle: 4.6% (15° in the horizontal plane), 17.9% (30° in the horizontal plane), 5.6% (15° in the vertical plane) and 19.4% (30° in the vertical plane).

#### Static Volume Measurements of Mannequin Limbs and Human Arms

(i) *Limb volume.* The volumes of the mannequin arms and legs, normal human arms and lymphedema arms as determined by the two methods are plotted on a scatter diagram where their relationship to the line of equality can be seen (Fig. 3a). The two methods correlated very strongly for each of the three types of limbs ( $r = 0.999$  for the

mannequin limbs, 0.985 for the normal human arms, and 0.988 for the lymphedema arms). Regression equations are given in the figure legend. To assess more precisely the degree to which the methods agreed, the difference in volume (Perometer minus sequential circumference method) for each pair of measurements was plotted against the average volume of the two methods as recommended by Bland & Altman (11) (Fig. 3b). For the mannequin limbs the Perometer reading was  $70 \pm 79$  ml ( $3.3 \pm 1.7\%$ ; mean  $\pm$  s.d.) less than the sequential circumference measurement. One mannequin measurement point (from a mannequin leg flexed at the knee by approximately 40°) was greater than 2 standard deviations from the mean. The Perometer tended to give slightly higher volume readings for human limbs. The bias for the individual limb types was: Perometer measurement  $81 \pm 65$  ml ( $6.1 \pm 4.2\%$ ) greater than sequential circumference measurement for normal human arms;  $117 \pm 69$  ml ( $6.8 \pm 4.3\%$ ) greater for lymphedema arms.



3b) Differences between the Perometer (Pero) and the sequential circumference method (SCM), calculated as (Perometer volume minus SCM volume)/mean volume  $\times 100\%$ , plotted against the average of the two methods. Symbols are as in Fig. 3a. Differences for the individual limb types were - mannequin limbs:  $-3.3 \pm 1.7\%$  ( $-70.1 \pm 79.3$  ml); normal human arms:  $6.1 \pm 4.2\%$  ( $81.2 \pm 64.6$  ml); lymphedema arms:  $6.8 \pm 4.3\%$  ( $116.9 \pm 69.4$  ml) (mean  $\pm$  s.d.). The means are indicated as dotted lines labeled M, N and LO, respectively.

The volume of the forearm in the standard measuring position was 937 ml (mean of 4 measurements from one subject), whereas the volume of the same forearm fully relaxed was 968 ml, an increase of 3.3%.

(ii) *Errors with repeated measurement.*

(a) When the arm was measured 20 times at random intervals over 5 minutes (3 subjects), volumes were  $1603.3 \pm 9.7$  ml (mean  $\pm$  s.d.) with a coefficient of variation (c. of v., s.d./mean) of 0.6% (subject 1);  $1148.6 \pm 6.7$  ml, c. of v. = 0.6% (subject 2);  $1257.6 \pm 14.1$  ml, c. of v. = 1.1% (subject 3). (b) On measuring the arm according to the fixed schedule (2 subjects), volumes were  $1596.1 \pm 7.6$  ml, c. of v. = 0.5% (subject 1);  $1141 \pm 6.3$  ml, c. of v. = 0.6% (subject 2). (c) For the assessment of intrinsic equipment variability, mannequin arm volume was  $1358.0 \pm 0.9$  ml, c. of v. = 0.1%.

(iii) *Errors arising from incorrect longitudinal positioning.* A typical profile of a lymphedema arm (side view), obtained using the Perometer, is shown in Fig. 4. The cursors can be moved in 3.1 mm steps along the long axis of the limb. Thus, the segment volume and circumference could be determined at intervals of 3.1 mm. (a) Fig. 5 shows the volume of equivalent lengths of the lymphedema arm from 12 subjects when both cursors are moved by 3.1-mm steps. For the normal arm the mean change in displayed volume for a longitudinal shift in position of 3.1 mm for both cursors was  $13.2 \pm 3.6$  ml ( $1.0 \pm 0.2\%$ ; mean  $\pm$  s.d.), range 8-21 ml (1.0-1.2%). For the lymphedema arm the mean change was  $19.2 \pm 5.7$  ml ( $1.1 \pm 0.3\%$ ), range 11-31 ml (0.7-1.2%). (b) When one cursor was positioned over the thickest part of the normal

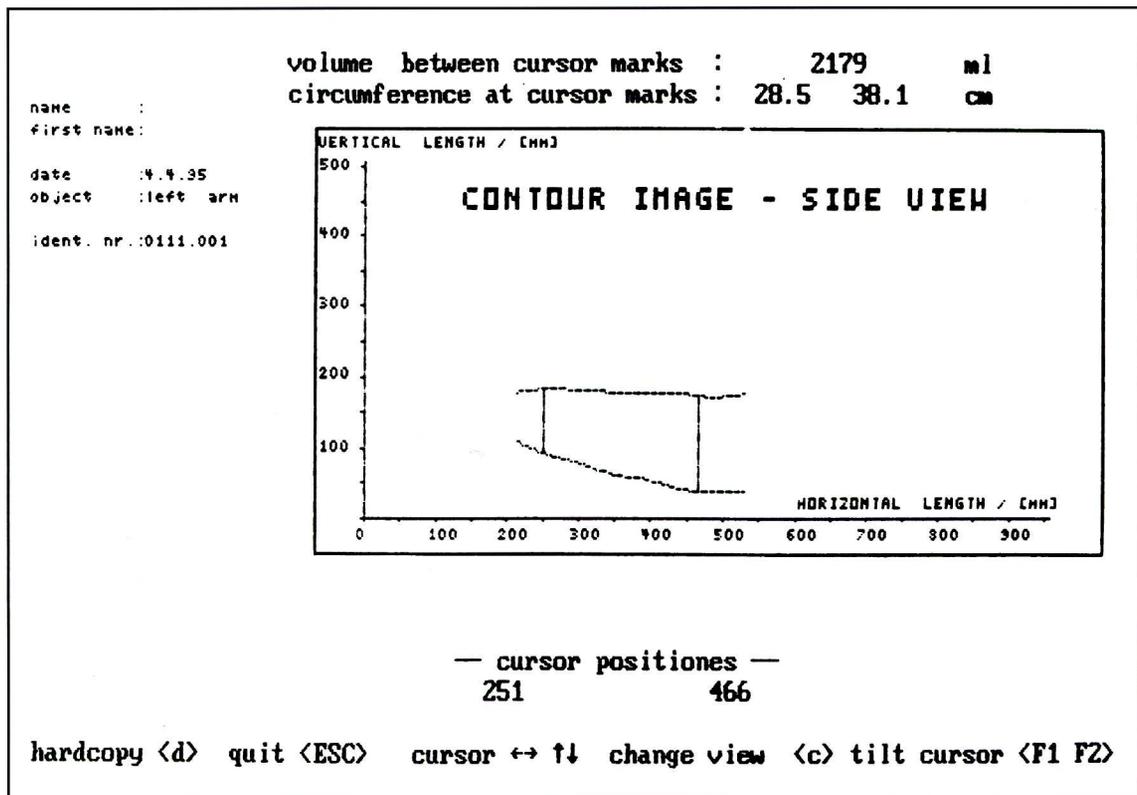


Fig. 4. Profile (side view) of a lymphedema arm generated by the Perometer. The circumferences at the two cursor positions and the volume of the enclosed segment are given. The hand cannot be accurately recorded, and is not shown.

forearm image and moved three steps both towards and away from the hand, the mean change per step in the displayed circumference value was  $0.12 \pm 0.12$  cm ( $0.4 \pm 0.4\%$ ), range 0-0.6 cm (0-2.2%). For the lymphedema forearm the mean change was  $0.13 \pm 0.10$  cm ( $0.40 \pm 0.33\%$ ), range 0-0.4 cm (0-1.3%)

#### Change in Volume with Time

(i) *Measurement of mannequin limbs, and effect of sunlight.* In VOP mode, the Perometer sampled the volume once every 0.66 s. The display of the continuously recorded volumes of 3.1 mm thick segments of 3 mannequin arms, initial volumes 20.74, 16.30, and 12.39 ml, fluctuated in a random

manner by up to 0.012, 0.006, and 0.021 ml, respectively (0.06, 0.03, 0.17%) during recordings made with the window blinds closed (absence of sunlight), and by up to 0.045, 0.016, and 0.026 ml (0.22, 0.10, 0.21%) with the window blinds open (presence of sunlight). In general, an increase in the intensity of sunlight caused the recorded volume to fall.

(ii) *Simulation of swelling rate in VOP.* The change in volume of the frustum segment per minute as determined by the Perometer and by direct measurement is plotted as a scatter diagram in Fig. 6a. Correlation of the two methods was very strong ( $r = 0.998$ ). Using the analysis described by Bland & Altman (11) (Fig. 6b), the difference between the two estimates of swelling rate, i.e.,

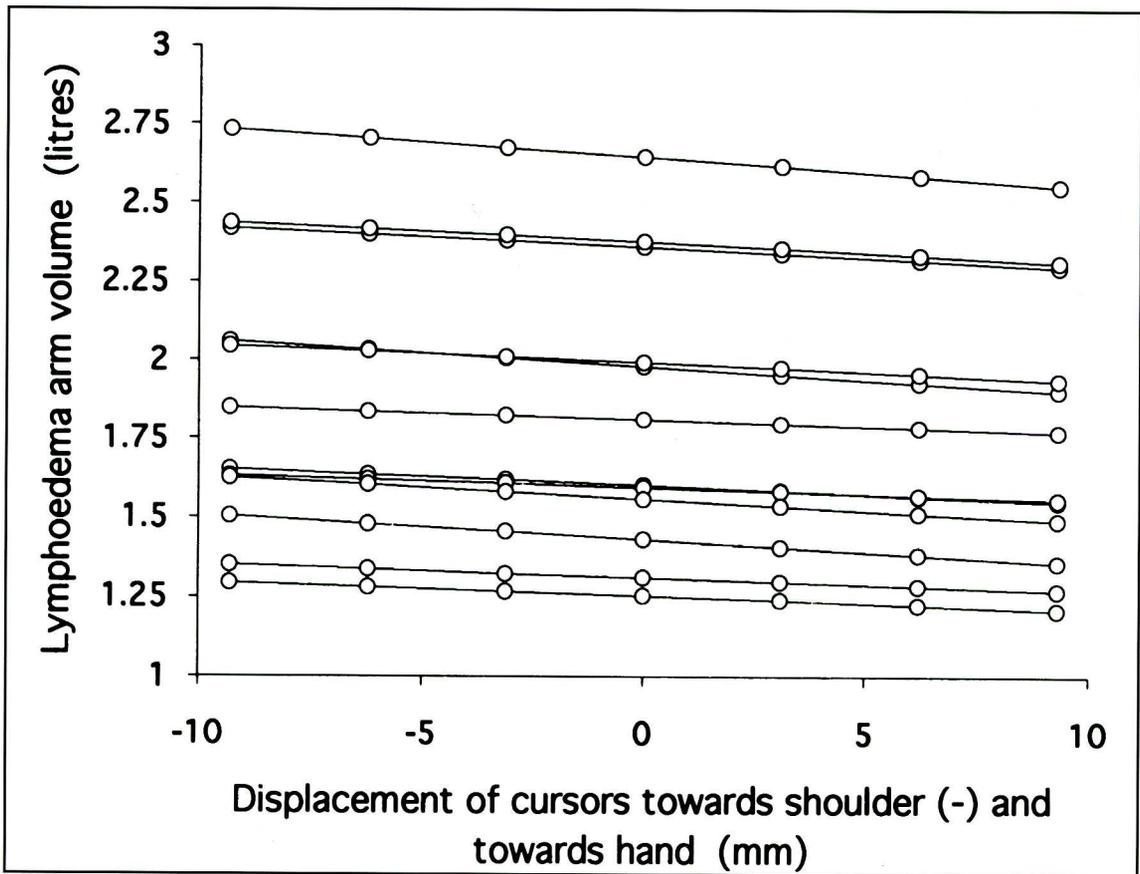


Fig. 5. Volumes of 12 lymphedema arms given by the Perometer at different cursor settings. Inter-cursor distance is constant. Both cursors are moved towards the shoulder and towards the wrist from an arbitrary intermediate position. This simulates incorrect longitudinal positioning of the arm, i.e., the arm positioned too far through the frame (as if fingers flexed on support) or not positioned far enough through (as if fingers not touching support). Errors arising from incorrect positioning were small.

Perometer minus direct measurement, was  $0.83 \pm 2.37$  ml/100 ml/min ( $-0.8 \pm 7.8\%$ ; mean  $\pm$  s.d.).

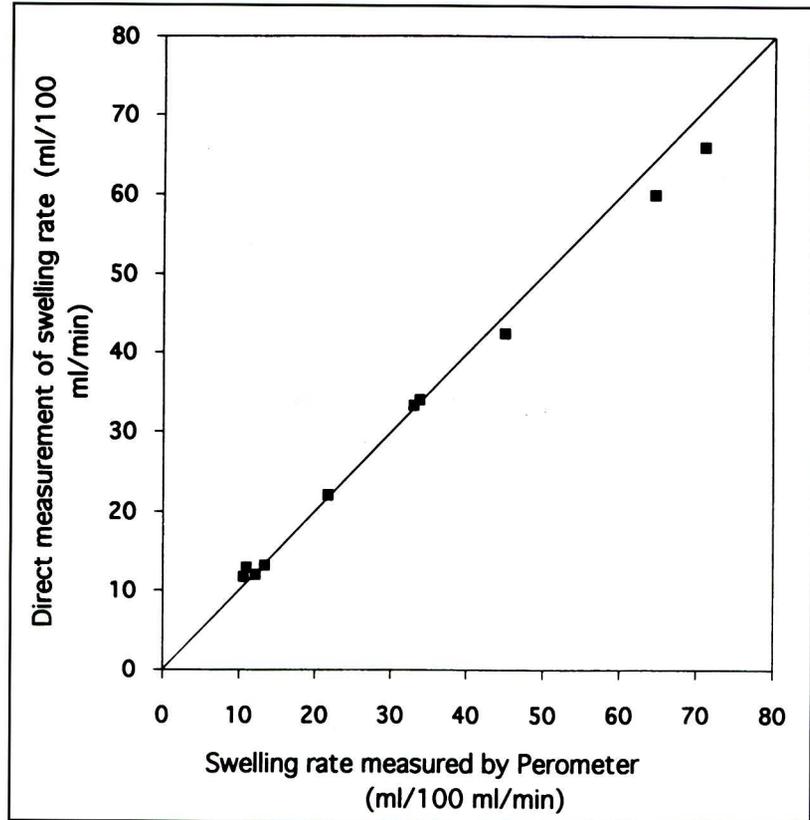
(iii) *Measurement of forearm blood flow (rapid arm swelling on venous occlusion) by Perometer and mercury strain gauge in the normal and lymphedema arms.*

(a) Normal arms of healthy subjects.

With simultaneous measurement at sites 3 cm apart, forearm blood flow per 100 ml of tissue in the normal arms of 14 healthy volunteers (right and left arms pooled) was  $4.50 \pm 2.20$  ml/min (mean  $\pm$  s.d.) using the mercury strain gauge, and  $3.40 \pm 1.00$  ml/min using

the Perometer ( $n = 27$ ; on one arm the quality of recordings was poor). These means differed significantly ( $P = 0.007$ , paired t test; see Table 2). The saving of up to 9 Perometer blood flow recordings on each file resulted in spatially (in terms of width)-compressed volume/time displays, some with initially vertical sections before developing a measurable slope; equivalent strain gauge slopes were consistently measurable and non-vertical. When these pairs of measurements (higher flows) were omitted from the calculation of average blood flow for each arm, the two methods agreed more closely,

Fig. 6a) Scatter diagram of swelling rates, produced by passing a frustum of a cone through the Perometer frame, measured by the Perometer and by direct measurement of that segment of the frustum presented to the light beams. The relationship to the line of equality is shown. The regression line is described by  $y = [0.90 \pm 0.01]x + [2.29 \pm 0.53]$  (mean  $\pm$  s.e.m.),  $r = 0.999$ ,  $P < 0.0001$ ,  $n = 10$ .

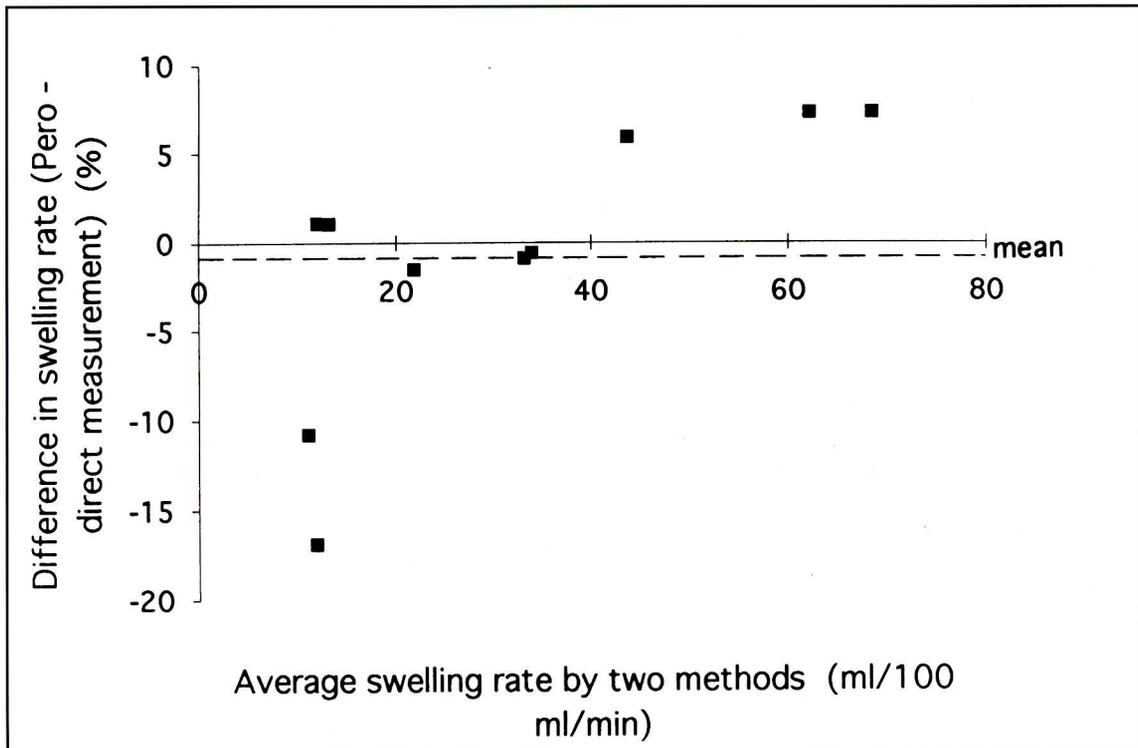


suggesting that inclusion of the higher flows resulted in an underestimation of flow by the Perometer. The modified blood flows per 100 ml tissue were  $4.54 \pm 2.38$  ml/min for the strain gauge and  $4.12 \pm 1.69$  ml/min for the Perometer ( $P = 0.23$ ). Subsequently, a maximum of 3 blood flow recordings was saved on each file because with a shorter time-scale filling the same screen, slopes were lower (in mm/min), unmeasurable slopes were uncommon and it was generally possible to identify an approximately straight section of the slope from its inception. Fig. 7 shows an example of a typical blood flow recording. A degree of serration or irregularity of the volume recording was usual.

It is worth noting that the range of individual blood flows obtained from the same arm (from which the average for each arm was derived) varied somewhat with

either method. The mean coefficient of variation for the individual recordings was 33% (range 11-66%) for the Perometer and 31% (range 11-58%) for the strain gauge. In Fig. 8a, each individual blood flow recording made with the two methods from the arms of healthy subjects (recordings with unmeasurable slopes omitted) has been plotted on a scattergram. Whereas overall there is fair correlation ( $r = 0.63$ ), which is highly significant ( $P < 0.0001$ ), for individual measurements, the strain gauge and the Perometer sometimes differed markedly. This was especially true at higher flows.

The average blood flows from the 27 arms of the healthy subjects (obtained from the individual recordings from each arm) had a coefficient of variation of 41% for the Perometer and 52% for the strain gauge. The average blood flows have been plotted in



6b) Differences in apparent swelling rate obtained from the Perometer (Pero) and by direct measurement (i.e., tape measurement of circumferences) of the frustum, calculated as  $(\text{Perometer minus direct measurement})/\text{mean swelling rate} \times 100\%$ , plotted against the average of the two methods. The mean difference (indicated by a dotted line) was  $-0.8 \pm 7.8\%$ , or  $(+)0.83 \pm 2.37 \text{ ml/100 ml/min}$ .

scattergram form in Fig. 8b. The correlation coefficient was 0.68 ( $P = 0.0001$ ); the difference between the arm averages obtained using the two methods, i.e., Perometer minus strain gauge, was small ( $-0.42 \pm 1.75 \text{ ml/100 ml/min}$ , or  $-2.08 \pm 34.42\%$ ; mean  $\pm$  s.d.).

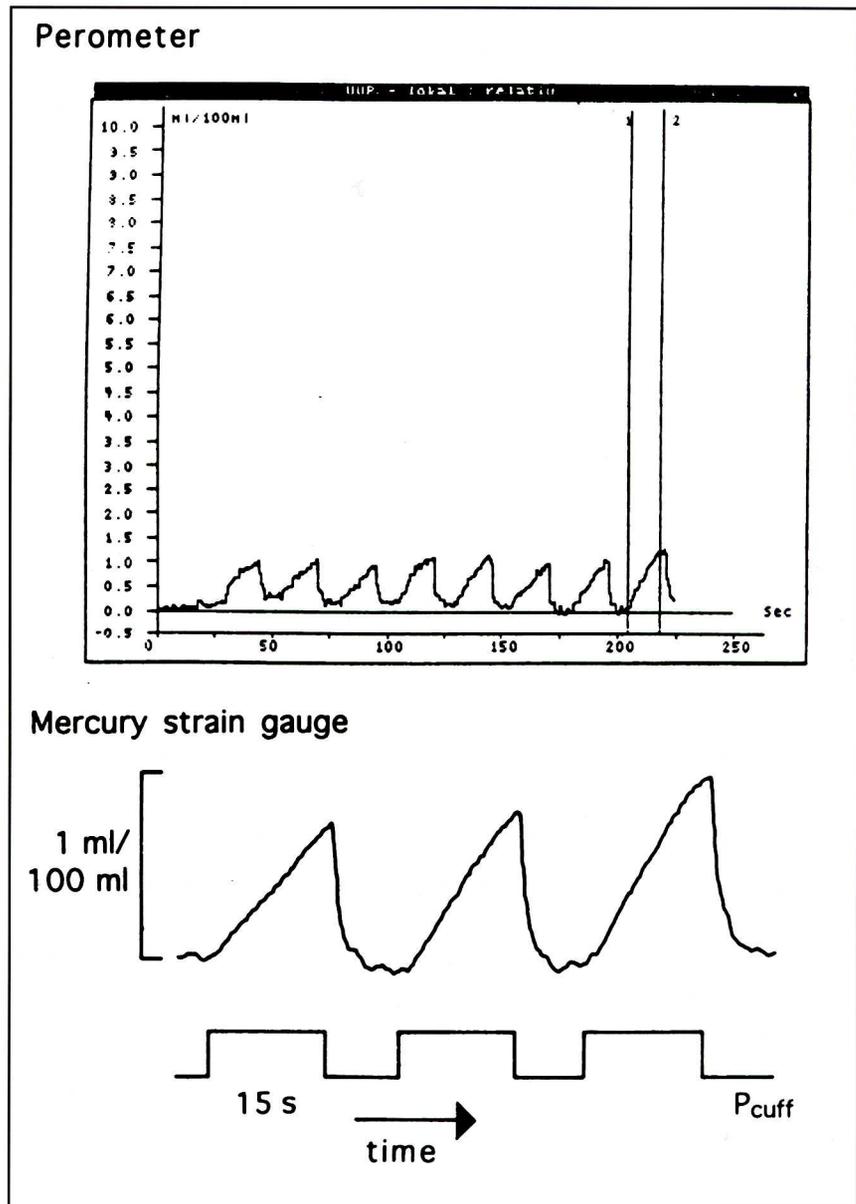
The recordings made using the Perometer (only) at 5 different sites on the normal forearm indicated that although blood flow per unit volume of tissue tended to fall with increasing distance from the antecubital crease (and markedly so in one subject), the trend was not statistically significant ( $P = 0.63$ , ANOVA; see Fig. 9).

(b) Normal arms of lymphedema subjects. In contrast to the initial findings in healthy volunteers, with optimum use of the Perometer graphics recordings made with the

two methods from the same mid-forearm site (normal arms of 17 women with unilateral postmastectomy edema) resulted in very similar mean blood flows per 100 ml tissue. These were  $3.54 \pm 2.91 \text{ ml/min}$  with the strain gauge and  $3.46 \pm 1.80 \text{ ml/min}$  (mean  $\pm$  s.d.) with the Perometer ( $P = 0.93$ ; Table 2).

(c) Lymphedema arms. Forearm blood flow was  $2.44 \pm 1.43 \text{ ml/100 ml/min}$  using the strain gauge, and  $3.11 \pm 1.43 \text{ ml/100 ml/min}$  using the Perometer. Again these values did not differ significantly ( $P = 0.26$ ; see Table 2). The two methods (average values for each arm) did not correlate significantly ( $r = 0.31$ ,  $P = 0.23$ ). The difference between the averages for each arm obtained by the two methods was  $0.65 \pm 2.26 \text{ ml/100 ml/min}$  ( $25.89 \pm 48.65\%$ ; mean  $\pm$  s.d.).

Fig. 7. Simultaneous blood flow recordings made with the Perometer and the mercury strain gauge (healthy subject). Eight Perometer recordings are shown. The strain gauge recordings of the last 3 of these are reproduced in the lower panel. The first and seventh Perometer slopes have almost vertical initial sections, and the second is interrupted by a vertical step. All strain gauge recordings were easily measurable.  $P_{cuff}$  represents the step increase in the pressure of the occluding cuff (to 45 cmH<sub>2</sub>O).



## DISCUSSION

Careful assessment and validation of the Perometer is essential before it can be accepted by lymphedema specialists as a reliable method for determining limb volume, and for use interchangeably with other methods in routine clinical work. The advantages of the Perometer are its speed of

use (one measurement takes seconds) and the information it can supply in addition to volume. The latter is determined most commonly by the use of a tape measure, and occasionally by water displacement.

We also explored the potential of the Perometer to measure rapid but very small changes in limb volume, because the use of venous occlusion plethysmography to

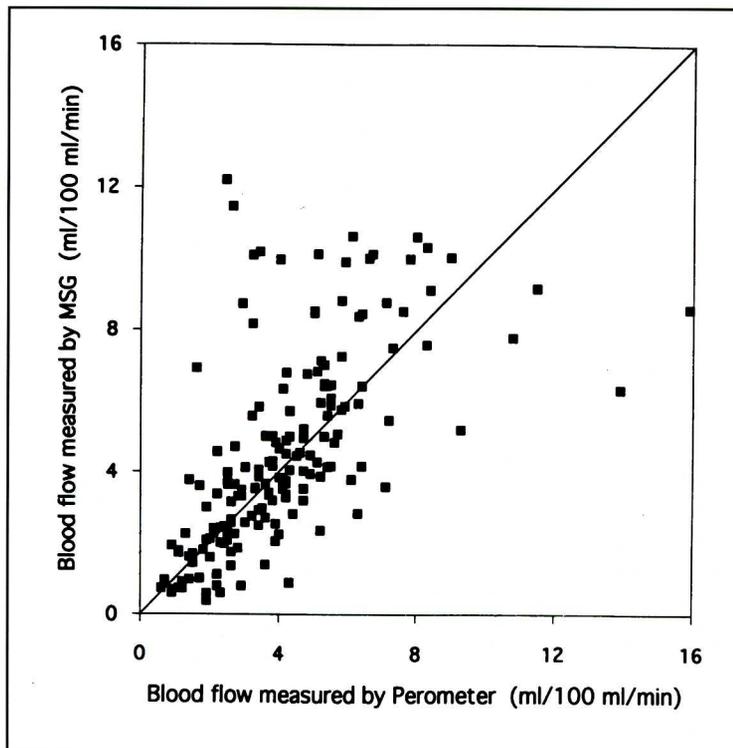
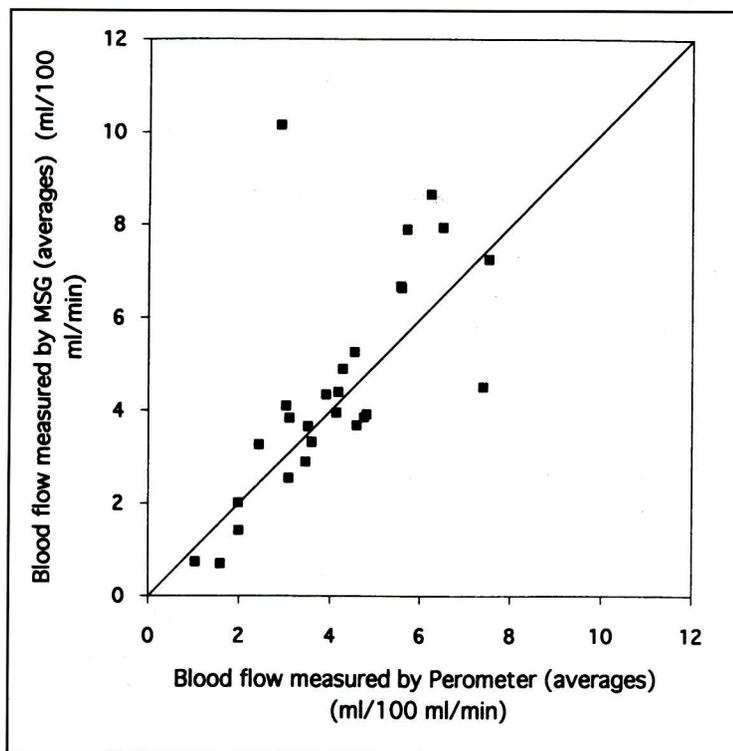
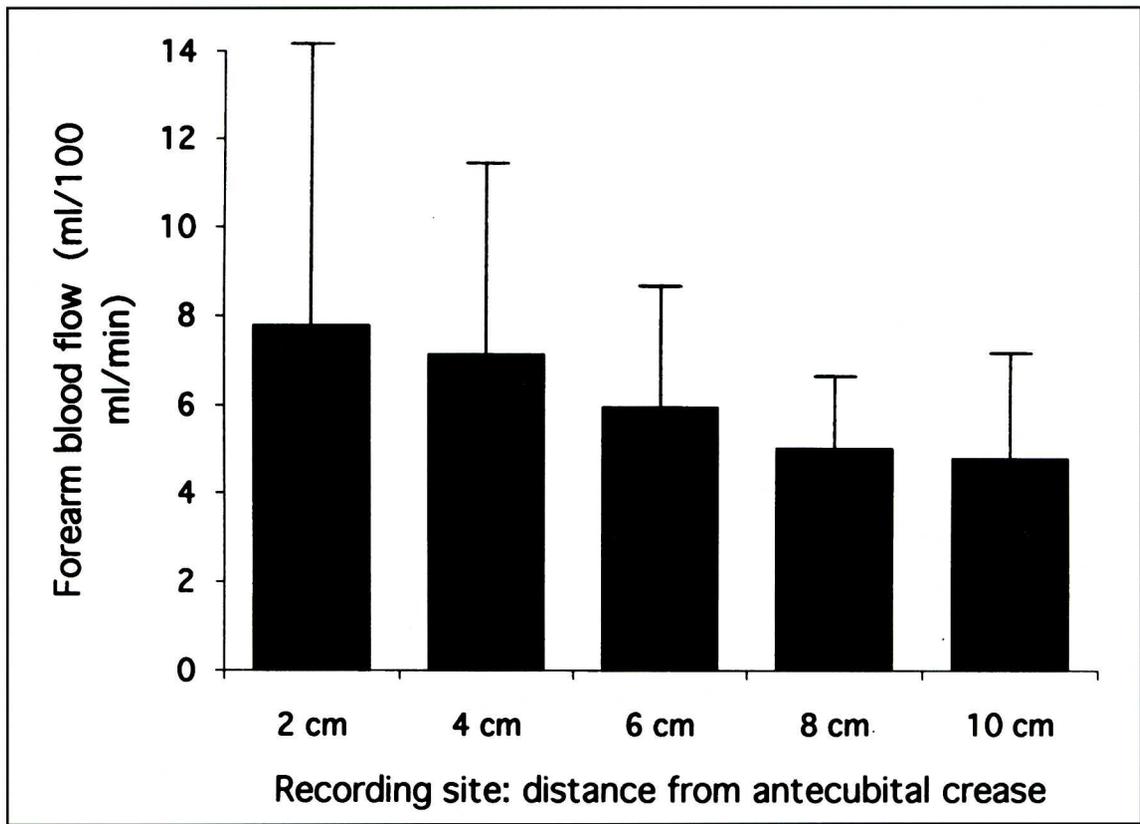


Fig. 8a) Scatter diagram of all the individual blood flow measurements (recordings with initial vertical slopes omitted) obtained from the arms of healthy subjects using venous occlusion plethysmography. The Perometer and the mercury strain gauge (MSG) have been compared. Considerable scatter is evident. The equation describing the regression line is  $y = [0.75 \pm 0.07]x + [1.43 \pm 0.33]$  (mean  $\pm$  s.e.m.),  $r = 0.63$ ,  $P < 0.0001$ ,  $n = 174$ .



8b) Scatter diagram of average blood flow measurements (same subjects as in Fig. 7a) comparing the Perometer and the mercury strain gauge (MSG). The scatter of the results is less than in Fig. 7a. The regression equation is now  $y = [0.95 \pm 0.21]x + [0.61 \pm 0.92]$  (mean  $\pm$  s.e.m.),  $r = 0.68$ ,  $P = 0.0001$ ,  $n = 27$ .



9. Bar diagram of blood flows determined by venous occlusion plethysmography using the Perometer to record swelling rates at 5 sites (2-10 cm from the antecubital crease) on the forearm of 6 healthy subjects (mean  $\pm$  s.d.). The trend to reduction in flow towards the hand was not significant ( $P = 0.63$ , ANOVA).

determine arterial blood flow and capillary filtration rates is of particular interest to those studying the physiology and pathophysiology of the circulation. A theoretical drawback of traditional VOP methods used to measure forearm or calf swelling rates is the necessity to attach physically-constricting measuring devices to the limb. The water jacket method requires a water-tight seal with the skin and the water contained in the jacket exerts pressure on the limb. The water temperature must be carefully controlled. The stretchable mercury-containing loop of the mercury-in-rubber (or silastic) strain gauge, which is in widespread use, must be secured around the limb under slight tension so as to respond to the smallest increase in circumference when venous return is halted. Thus,

each of these methods causes compression of the limb before any measurement has taken place, and while this may be of little significance for healthy tissue, the problem may be much greater in soft, highly edematous (ergo easily compressible) limbs. The Perometer, which determines limb size using infra-red light beams, seems an ideal alternative in that no physical force is applied to the limb during volume measurement.

#### *Geometric Shapes and Their Orientation*

When centrally located within the frame and with the exception of the cuboid, differences between the Perometer and direct measurement were small (0.8-2.4%) but with the Perometer consistently reading less than

**TABLE 2**  
**Forearm Blood Flow Recorded by Venous Occlusion Plethysmography Using**  
**the Mercury Strain Gauge and the Perometer (ml/100 ml/min)**

		Normal arms		P*	Lymphedema arms		P
		Mean	s.d. (n)		Mean	s.d. (n)	
Different recording sites¶:	MSG	4.50	2.20 (27)	0.007	2.44	1.43 (16)	0.26
	Pero	3.40	1.00 (27)		3.11	2.25 (16)	
Same recording site‡:	MSG	3.54	2.91 (11)	0.93	-	-	-
	Pero	3.46	1.80 (11)		-	-	

MSG=mercury strain gauge, Pero=Perometer; \*Paired t test; ¶Simultaneous measurement: pooled right and left arms of healthy subjects and lymphedema arms of patients; ‡Perometer measurement followed by MSG: normal arms of lymphedema patients

the direct measurement. This discrepancy was also observed with the mannequin limbs (see later) and may have arisen either from small errors in the use of the tape measure or from Perometer inaccuracies. The larger error with the cuboid presumably arose from the calculation of volume from what are assumed to be diameters of a circle or ellipse, and such a shape would be less than that of a cuboid. Radial displacement of the cylinders did not affect accuracy. However, when the smallest cylinder was angled to 15° and 30°, the recorded volume increased by up to 143 ml (19.4%). This deviation from the ideal orientation within the frame (the measured object being no longer perpendicular to the light beams) apparently resulted in the accumulation of errors.

#### *Static Measurements of Mannequin Limbs and Human Arms*

Whereas the limb volumes recorded by Perometer and tape measure (sequential circumference measurement) clustered fairly closely around the line of equality in *Fig. 3a*, and correlation between the methods was almost perfect for each limb type, analysis of the degree of agreement revealed small but

important biases. Thus, for the mannequin limbs the Perometer gave a volume 70 ml less than the tape measure and for the human arms the Perometer gave a volume 81 ml (normal) and 117 ml (lymphedema) greater than the tape measure. Taken together, a reasonable assumption would be that there is a tendency for the tape measure to be pulled too tightly around the arm with resulting distortion and underestimation of each circumference (greater for the lymphedema arm). A further point to note is that with only one support for the arm (*Fig. 1*), some degree of muscular tension is required to maintain the posture. With the arm fully relaxed, but in the same position in the frame (and relative to heart level), volume increased by 3.3%. This can be accounted for by an increase in venous blood volume, as the veins and venules are no longer compressed by contracting muscles.

The comparison on mannequin limbs probably reflects a discrepancy based on the assumptions made about shape in the calculation of volume. The tape measure formula assumes each truncated cone to have circular bases. Arms will obviously deviate from this contour, areas of the bases being less than that of circles of equal circumference. Errors

may also arise from the Perometer (deviation from a circular or elliptical cross-section), the size of the error being to some extent dependent on the degree of deformity in lymphedema. In percentage terms the discrepancy between the methods was small, but the magnitude of the absolute difference indicates that the methods ought not to be used interchangeably. A correction factor based on a mean difference from a sample of suitable size could in theory be applied.

Inter-observer differences are prone to occur in the use of the tape measure to calculate limb volume. In addition to those mentioned above, there are several possible sources of error in the use of a tape measure (for instance, inaccurate marking of the limb at 4-cm intervals along its axis and failure to wrap the tape measure around the limb at right angles to its axis). On the basis of the present findings, the application of a standard tension or load to the tape measure when wrapping it around the limb (so that compression is constant and minimal) would be expected to reduce error. This refinement is already performed in some clinics.

Twenty volume measurements of the same arm were comfortably performed over a 5 minute period. This illustrates the speed of operation and convenience of the Perometer. Coefficients of variation were small for repeated measurement. The fixed schedule of measurement produced no further improvement, although we recommend the use of a colored dot on the hand support (to touch with the middle finger) so as to reduce variation in hand position. Intrinsic equipment variation was very small.

By moving the cursors superimposed on the recorded image of the normal and lymphedema arms it was possible to simulate the effect of recording arm volume at different longitudinal (axial) positions within the frame. The effect of this manipulation was not marked, being up to 1.2% per 3.1 mm shift. The change in volume would be undoubtedly greater for arms with more marked muscular contour, and for arms

grossly misshapen (as well as enlarged) by lymphedema. Similar analysis applied to circumference also gave small errors. However, when measuring swelling rate (VOP mode), for instance to determine capillary filtration rate, such an error arising from a slight longitudinal movement of the limb relative to the frame might influence the slope of the volume recording.

#### *Venous Occlusion Plethysmography*

Spontaneous fluctuation of up to 0.17% (average 0.09%) occurred during the recording of the volume of a segment of a mannequin arm over the maximum recording period of 17 minutes. This drift of the recording, which was not due to change in natural light intensity (and not consistently in one direction), would be unlikely to affect the slope of a blood flow or a capillary filtration recording. However, under conditions of bright sunlight the percent fluctuation in volume of the slice increased by an average of 2.75 times. This presumably arises from the infra-red component of sunlight which activates sensors on the frame. Although the effect of sunlight on static measurement of whole limb volume was not assessed it would seem prudent, as recommended in the user manual, to exclude bright natural light when using the Perometer for any purpose.

Comparison of methods to record rapid limb swelling due to arterial blood inflow during VOP, tested by simulation using the mechanically advancing frustum, yielded close agreement between the Perometer and direct measurement. The shape of the volume response of an arm in response to increased venous pressure is far more complex than that obtained from the frustum (which was essentially straight). The time-course of the initial, rapid volume response has been studied by Gamble et al (6) who subjected it to computer analysis, with the assumption of an exponential fit. This assumption enables calculation of flow at the earliest moment after the imposition of increased pressure. In

the present study, flow was determined by eye from the volume change over the first 5 s (or occasionally from 2 to 7 s). We have found that fitting a line between 0 and 5 s (or 2-7 s) to a theoretical exponential curve (one reconstructed from the data in references 5 and 6) for the size of pressure step used here, yields a slope that is not notably different (approximately 3% less for 0-5 s, and 5 % less for 2-7 s) from initial slopes fitted by the exponential model of Gamble et al.

Forearm blood flow was determined from the average of 8-9 individual recordings, and in the healthy subjects the Perometer yielded an average flow 24% less than that obtained using the strain gauge. The origin of this difference is thought to lie in the relatively low sampling frequency of the Perometer (once every 0.66 s, a point not noted in the manual, resulting in only 22 volume recordings over 15 s) and in the resolution of the Perometer graphics. High blood flows recorded from the healthy arms, leading to rapid initial increases in volume of the arm slice, often resulted in quasi-vertical initial slopes of the volume versus time recordings made by the Perometer, but easily measurable strain gauge recordings. It was not possible to expand the time-scale of the Perometer record after the experiment, although the program could in principle be developed to do this, and seems needed together with faster volume sampling (which would give a smoother recording). By saving a maximum of only 3 blood flow recordings per file, the displayed time-scale was 0-100 s. The improved resolution resulted in less steeply sloping blood flow recordings (i.e., in terms of mm/min) and the quasi-vertical sections almost disappeared, although the serrations persisted. The apparent difference between the average arm values determined by the two methods for healthy subjects (*Table 2*) disappeared when the individual recordings with an initial unmeasurable section (higher flows) were excluded from the calculation of the averages for each arm. The scatter of the (remaining) individual blood flow recordings

(*Fig. 8a*) was still marked, especially at higher flow rates. Another possible source of variability is the strain gauge.

The importance of making multiple recordings of blood flow from one arm (to obtain an average) is evident from the substantial coefficient of variation (66% for one arm with the Perometer) for the individual recordings. Inter-subject variation was also marked.

The difference in blood flow using the two methods simultaneously might have been due to different recording sites. Sites 3 cm apart would be expected to have slightly differing proportions of skin, muscle and bone. This was examined using the Perometer alone at several different recording sites, but mean blood flow did not change significantly with increasing distance from the antecubital crease. If anything, flow tended to fall distally (not rise, which would have helped explain the original difference with the simultaneous measurement) and in 2 of the 6 subjects a marked tendency to fall in flow was evident. Furthermore, average blood flow did not differ when recorded using the two methods one after the other at the same site. Overall, it appears that the position from which the recording was made does not significantly influence flow, but in some individuals trends may occur.

The Perometer and strain gauge correlated weakly when used to record blood flow simultaneously in lymphedema arms, but the mean difference was small and blood flow did not differ significantly (*Table 2*). A likely reason for the poor correlation is the difficulty in obtaining satisfactory strain gauge recordings from arms of unusual shape. There is a potential for the mercury loop, which is under tension, to sink into an edematous arm (or even a normal arm) over a period of time, but this was obviated in the present experiments by the use of plastic strips beneath the loop to spread the load. Sinking of the loop into the arm (normal or lymphedema) would be more likely to affect recordings of capillary filtration rate, which

require much longer periods of venous occlusion. The Perometer is immune to this problem, and appears to be superior to the strain gauge for this purpose (12).

### CONCLUSIONS

It can be concluded that differences between the Perometer and the sequential circumference method for the measurement of limb volume are small, and that the Perometer is highly consistent. The Perometer could be used to replace the tape measure, but a small correction factor should ideally be applied when changing from one method to the other during a course of lymphedema therapy. When the VOP mode of the Perometer was employed to measure the change in volume of a frustum of a cone and compared with direct measurement, there was strong correlation and close agreement. The difference between the Perometer and strain gauge in recording blood flow from the arms of healthy subjects appeared to derive from the relatively slow Perometer sampling rate and the poor resolution of the graphics, influencing the results more at higher flows (faster forearm expansion). Agreement was good when higher flows were omitted from the comparison. Correlation of the two methods for average blood flow from each arm was weaker on the lymphedema arms compared with the arms of healthy subjects, but the close agreement of the means (*Table 2*) on lymphedema arms indicates that either method is suitable for blood flow measurement. The problem of the slow sampling rate would be less important for the slower forearm swelling rates obtained with measurement of capillary filtration rate (5, 12).

The Perometer is an expensive but convenient, reliable and accurate device for recording limb volume; it may also be used to record limb swelling rates during venous occlusion plethysmography. Because of its size, use is confined to the clinic or laboratory; the strain gauge offers clear advantages

in settings where portability is required, or space limited. At present, the measurement of rapid arm expansion during VOP is limited by the slow sampling rate, but with modification the value of the Perometer would be enhanced and it would become a useful tool in the assessment of the limb circulation.

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**A.W.B. Stanton, Ph.D.**  
**St. George's Hospital Medical School**  
**Division of Physiological Medicine**  
**Department of Medicine**  
**Cranmer Terrace**  
**London SW17 0RE, UK**  
**Telephone: +44(0)181 725 5438/9**  
**Fax: +44(0)181 725 5955**