

Instructions for Use

***HVLab* Multi-Channel Plethysmograph**

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Multi-Channel Plethysmograph

Instructions for Use

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1 System Information

This manual was supplied with the following system:

Device: *HVLab* Multi-Channel Plethysmograph

Model Number: PG4.0

Manufacturer and Contact Details:



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2 Product Specification

The Multi-Channel Plethysmograph provides computer-based measurement of finger systolic blood pressures (FSBP) following cold provocation of the fingers. Finger systolic blood pressures measured at different temperatures can be used to detect problems in the vascular response to cold.

The Multi-Channel Plethysmograph also provides the means for measurement of finger blood flow (FBF) using venous occlusion plethysmography. Blood flow measured at sub-diastolic occlusion pressure can be used to detect problems in the vascular response to vibration.

The system controls finger temperature by rapid heating and cooling of water flowing through specially designed pressure cuffs. During FSBP and FBF tests the Plethysmograph is controlled by a personal computer.

The instrument is designed to operate in a laboratory or clinic, where the air temperature can be controlled between specified limits. All of the system components are suitable for use in the patient environment.

The Multi-Channel Plethysmograph complies with BS ISO 14835-2:2005 (Mechanical vibration and shock - Cold provocation tests for the assessment of peripheral vascular function - Part 2: Measurement and evaluation of finger systolic blood pressure).

2.1 Test Parameters

The ranges of the test parameters that can be selected in the software are as follows.

Finger Systolic Blood Pressure Test:

Data sampling rate	<i>10 readings per second</i>
Number of test fingers	<i>1 - 5</i>
Temperature range	<i>5°C to 35°C</i>
Pressure reduction rate	<i>0.4 to 4.0 mmHg per second</i>
Occlusion pressure during cooling	<i>50 - 250 mmHg</i>
Cooling period	<i>30 – 600 seconds</i>

Finger Blood Flow Test:

Data sampling rate	<i>10 readings per second</i>
Number of test fingers	<i>1 - 5</i>
Occlusion pressure	<i>30 - 200 mmHg</i>
Measurement time	<i>5 - 20 seconds</i>
Number of measurements per run	<i>1 - 10</i>

2.2 Power requirements

Isolation Transformer

Input voltage (240V option)	<i>220 to 250 V ac</i>
Input voltage (100V option)	<i>94 to 106 V ac</i>
Input frequency	<i>50-60 Hz</i>
Maximum input power	<i>1500 VA</i>

Plethysmograph Control Unit (supplied from isolation transformer output)

Input voltage	110 (55-0-55) V ac
Input frequency	50-60 Hz
Maximum input power	1500 VA

2.3 Technical specifications

Ambient temperature for normal use:

Ambient temperature	15 - 25°C
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Air Pressurisation:

Maximum inflation pressure	250 mmHg
Over-pressure safety limit	270 ± 15 mmHg
Accuracy in pressure setting	± 10 mmHg
Accuracy of pressure indication in software	± 10 mmHg
Range of pressure indication on panel meter	0 - 500 mmHg
Accuracy of pressure indication on panel meter	± 10 mmHg
Accumulator charging rate	> 20 mmHg per second
Cuff inflation rate	> 250 mmHg per second

Water circulation and temperature control:

Flow rate	2 - 15 ml per second
Range of flow rate indication on panel meter	0 - 16.7 ml per second (0 – 1 l per min)
Accuracy of flow rate indication on panel meter	± 10 % of reading
Range of temperature control	10 - 35°C
Lower temperature safety limit	5.5 ± 1.5 °C
Upper temperature safety limit	47.5 ± 1.5°C
Accuracy in temperature setting	± 1°C
Accuracy of temperature indication in software	± 1°C
Range of temperature indication on panel meter	0 - 50°C
Accuracy of temperature indication on panel meter	± 1°C
Temperature variation between cuffs	< 0.5°C
Time to cool from 30°C to 10°C	< 3 minutes
Estimated cooling efficiency	25%

Strain gauges:

Data sampling rate	10 readings per second per channel
Range of gauge resistance	0.04 - 0.9Ω
Accuracy of strain measurements in software	± 10 % of reading

Dimensions:

Control unit	Height 1034 mm, length 492 mm, width 552 mm, weight 80.9 kg
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Isolation transformer *Height 273 mm, length 240 mm, width 198 mm, weight 15.5 kg*

Compliance with standards:

EN 60601-1:2006 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

ISO 14835-2:2005 *Mechanical vibration and shock - Cold provocation tests for the assessment of peripheral vascular function - Part 2: Measurement and evaluation of finger systolic blood pressure*

2.4 Equipment Classification

Medical equipment classification *Class IIa active diagnostic medical device*

Type of Protection against Electric shock *Class I*

Degree of Protection against Electric shock *Type BF*

Classification according to the degree of protection against ingress of water *Not Protected (IPX0)*

Degree of safety of application in the presence of a Flammable Anaesthetic Mixture with Air or with Oxygen or Nitrous Oxide *Equipment not suitable for use in the presence of flammable mixtures*

Mode of operation *Continuous*

3 Installation and commissioning

3.1 System components

If any of the following items are missing, please contact the manufacturer (the system components are illustrated in Figure 1).

(a) Multi-Channel Plethysmograph Control Unit



Figure 1 System components (see Section 3.1)

- (b) Strain gauges
- (c) Air pressure cuff
- (d) Water-cooled pressure cuffs
- (e) Isolation transformer and power cable
- (f) Additional protective earth cable
- (g) Footswitch
- (h) USB-2527 Computer Interface
- (i) USB Isolator for supplied USB-2527 Computer Interface
- (j) Computer Interface Cables
- (k) Bypass tube and filler (not shown in Figure 1)

3.2 Panel displays

3.2.1 Front panel

On the left of the front panel are warning lights indicating **Pressure too high**, **Temperature too high**, **Temperature too low**, **Bypass operational** and **Circulation Failure** (see Section 7.1 of this manual).

At the top of the panel are the **Power On** (power indicator) light, green **On** switch and red **Off** switch. Press the green **On** Switch to power the Multi-Channel Plethysmograph. Press the red **Off** Switch to switch off the plethysmograph.

The **Temperature** gauge displays the water temperature in the water cuffs during a finger systolic blood pressure test. The **Pressure** gauge displays the pressure in all cuffs. The Flow gauge displays the rate of flow of the water in the water cuffs during a finger systolic blood pressure test.

On the right is a set of lights that indicate the **Water level**. The minimum and maximum water levels are marked (see section 7.1 of this manual). A red or amber light indicates no water and a green light indicates water. A socket above the water level indicators enables the user to add water or remove water using the **Bypass tube**.

There are 5 **Transducers** sockets for strain gauge inputs. A red warning light illuminates if a strain gauge is broken (see section 7.1 of this manual).

The **Air** socket is used to plug in the air cuff during the finger systolic blood pressure test or to attach the loop of air cuffs during a finger blood flow test.

The **Water In** and **Water Out** sockets are connected to a loop of water cuffs during a finger systolic blood pressure test.

3.2.2 Rear panel

A green **Power Connected** light on the rear panel is illuminated when the Multi-Channel Plethysmograph is connected to mains power. Two re-settable fuses protect the Multi-Channel Plethysmograph from mains surges (see section 7.1 of this manual). The binding post labelled with the symbol  is for the connection of the protective earth lead to the Multi-Channel Plethysmograph. The power socket enables the transformer to be plugged into the Multi-Channel Plethysmograph. The **Computer Interface (1)** and **Computer Interface (2)** sockets are for the **Computer Interface Cable** from the **USB-2527 Computer Interface** to the Multi-Channel Plethysmograph. The **Computer Interface Cable** can be connected to either socket. There is labelled socket for the **Footswitch** to connect the footswitch to the Multi-Channel Plethysmograph.

3.3 Setting up the Multi-channel Plethysmograph

3.3.1 Controlling computer and software

The Multi-Channel Plethysmograph is controlled by the *HVLab* Diagnostic Instruments Manager software, running on a suitable personal computer. The computer should have the following minimum specification:

- Must comply with IEC 60950-1:2005 (Information technology equipment - Safety - Part 1: General requirements)
- Pentium processor (1.5 GHz or more)
- Microsoft Windows XP operating system
- Display resolution of at least 1024x768 pixels
- CD-ROM drive
- More than 100 MB free on drive C:
- One USB2.0 port (for connection of a USB-2527 interface board)

Follow the instructions in Annexe A of this manual for installing the interface board and in Annexe B for installing the Diagnostic Instruments Manager Software.

As well as controlling the Multi-Channel Plethysmograph, the *HVLab* Diagnostic Instrument Manager provides database software with a simple interface for entry of patient details and health surveillance information, and for storing test results. The database has been designed to interact with the whole range of *HVLab* series of diagnostic instruments, allowing test results to be automatically added to the database. For further information on the database software see the *HVLab* Diagnostic Instruments Manager Database instructions for use.

3.3.2 Connecting the Plethysmograph

Connect the **Computer Interface Cable** between one of the sockets marked **Equipment Interface** on the USB-2527 Computer Interface and one of sockets marked **Computer Interface** on the rear panel of the Plethysmograph. Connect the USB-2527 Computer Interface to a USB2.0 (or higher) port on your computer via the supplied USB isolator (see Figure 1) using the two supplied USB cables. To ensure patient safety, the USB-2527 Computer Interface should never be connected directly to the Computer.

Connect the transformer power cable to the power socket on the rear panel of the. Connect the transformer to a mains 220-240v AC supply and switch on. You should see a green power light rear panel of the Multi-Channel Plethysmograph.

Connect the ring connector of the **additional protective earth cable** to the green earth terminal on the rear panel of the Multi-Channel Plethysmograph by removing the binding-post nut. Put the ring connector through and then reassemble the binding-post nut with a 2BA spanner. The other end of the protective earth cable is fitted with a mains plug that should be connected to an additional mains socket. Alternatively, the plug may be removed and the cable connected to a fixed and permanently installed Protective Earth Conductor. The additional protective earth **MUST** be connected at all times when the system is in use for testing patients or experimental subjects.

Press the button marked **On** on the front of the Multi-Channel Plethysmograph to switch on. You should see the following:

- A green power light marked Power On on the front of the Multi-Channel Plethysmograph.

- Green, amber and red lights on the front of the multi-channel plethysmograph, indicating the water level. Add water into the fill socket, using the bypass tube and syringe.

Your *HVLab* Multi-Channel Plethysmograph is now ready for use. Please refer to the troubleshooting guide if necessary.

DO NOT connect any items to the Plethysmograph that are not specified and labelled as part of the system.

3.3.3 Avoiding interference between the Plethysmograph and other devices

HVLab equipment complies with the requirements of EN 60601-1-2:2001 (Electromagnetic compatibility - Requirements and tests) with respect to Electromagnetic immunity and Electromagnetic Emissions. For further information see *HVLab* document number PG 008 (standards applied to the *HVLab* Multi-Channel Plethysmograph).

However, the instruments contain sensitive circuits that can be affected by high-intensity radiated and conducted electromagnetic energy, and should not be operated close sources of radio frequency and microwave radiation such as:

- Wireless, radio and cell phone transmitters
- Television and Radio Receivers
- Industrial equipment

The Plethysmograph should not be installed in close proximity to very sensitive medical equipment so as to avoid the possibility of interference by emissions from the Plethysmograph or connected computers.

3.4 Setting up the pressure cuffs and strain gauges

The cuffs and gauges must be set up according to the following instructions in order to obtain optimum results.

Double-inlet cuffs have been supplied with the *HVLab* Multi-channel Plethysmograph. The cuffs can be adapted for measurements in air using the sealed connector supplied with the system. Three sizes of cuff have been supplied with the *HVLab* Multi-Channel Plethysmograph. The smallest cuffs (coloured red and with a single groove around the middle), the medium cuffs (coloured green with two grooves around the middle) and the large cuffs (coloured yellow with three grooves around the middle).

Three sizes of strain gauges have been supplied with the *HVLab* Multi-Channel Plethysmograph: small, coloured red; medium, coloured green and large, coloured yellow.

3.4.1 Arrangement of pressure cuffs and strain gauges for FSBP measurement

- (a) **The reference air cuff** is placed on the proximal phalanx of the thumb on the hand to be tested.

If using the supplied rigid cuff, select the correct size cuff to fit the thumb (see (b), below) and push a sealed cuff connector onto one of the two inlets. Push the free end of a 60cm length of tube with non-sealing plug (i.e. without a spring-loaded valve) onto the second cuff inlet. The tube should cover at least two of the barbs on the inlet. Connect the plug to the Air socket on the front panel of the Plethysmograph.

If using a soft plastic air cuff instead of the provided double-inlet cuff (Figure 2a), wrap the cuff around the finger so that it fits comfortably without applying pressure to the skin. Use the Velcro strip to secure the cuff. Push the 60cm length of tube with non-sealing plug (i.e. without a spring-loaded valve) onto the cuff inlet, and connect the plug to the **Air** socket on the front panel of the Plethysmograph.

- (b) **The water-cooled provocation cuffs** are placed around the medial phalanges of the test fingers.

Select the appropriate size double-inlet cuff for each of the subject's fingers. Cuffs placed tightly around the fingers will inhibit blood flow when not pressurised, whereas very loose cuffs will not completely occlude the arteries when they are pressurised.

Figure 2b shows the selection of a green cuff for the left middle finger. Ensure that the correct size has been selected for each finger. It may be necessary to use a smaller cuff for the little finger (as shown in Figure 2c).

Place the four cuffs in a row and link them with three pieces of 15 cm length tubing. Push the tubing on to the inlets on each side of the cuff so as to cover at least two barbs.

Push the free end of a 60 cm length of tubing with a sealing plug (i.e. with spring-loaded valve) onto the free socket of each outer cuff.

Connect one plug to the **Water In** socket on the front panel of the Plethysmograph and connect the other plug in the **Water Out** socket.

Place the cuffs around the medial phalanx of each test finger. Figure 2d shows the connections and recommended placement of cuffs for water perfusion.

The hand and lower arm should be supported



Figure 2a Mounting a soft plastic reference cuff on the thumb

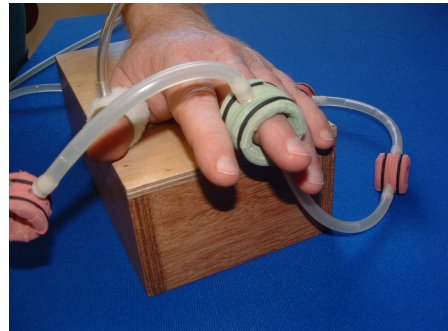


Figure 2b Mounting a green cuff on the middle finger

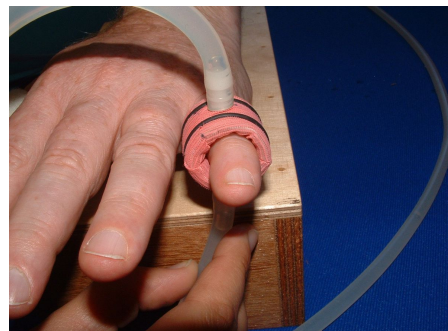


Figure 2c It may be necessary to use a smaller cuff for the little finger

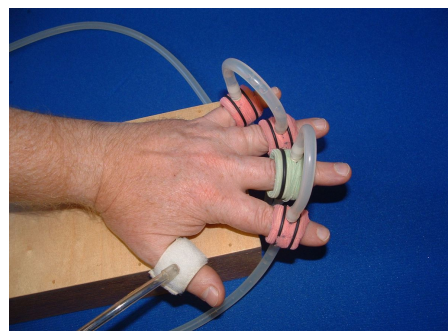


Figure 2d The recommended placement of cuffs for water perfusion

during the test. Position the hand so that the cuffs are just over the edge of the support. Ensure the tube is not kinked as this can prevent the cooling water from flowing freely. The tubing can be arranged 'over and under' the cuff (Figure 2e).

- (c) A **Strain Gauge** should now be fitted to each of the digits and the reference digit.

Select the appropriate size strain gauge for each finger that requires measurement. Figure 2f shows the recommended placement of gauges. Although the picture shows a green gauge, the tension of the gauge around the finger should be the same for all colour gauges.

Too tight a strain gauge will result in interference with the blood flow in the fingertip. The strain gauge should be selected so it applies light external pressure around the finger. Care should be taken when placing the strain gauge that the subject is not caused discomfort, the strain gauge is not overstretched and movement artefacts are avoided.

The strain gauges should be placed around the distal phalanx of the digits, at the base of the nail.

A good position can be achieved by bending the white connecting lead so that the gauge and first section of the lead is perpendicular to the finger (Figure 2g).

Make sure that the lead will not be disturbed by any movement of the cuff or pipes during pressurisation (Figure 2h).

The strain gauges must not be overstretched or twisted around the finger as this will limit the lifespan of the gauges and produce an inaccurate response.

Once a strain gauge is correctly positioned, hold it in place by sticking it to the dorsal side of the hand using micropore tape. It may be easier to stick the micropore tape for the thumb strain gauge on the wrist (Figure 2i).

Connect the strain gauge on the thumb to the first **Transducer** socket on the Plethysmograph front panel, and the gauges on the index, middle, ring and little fingers to sockets 2, 3, 4 and 5 respectively.

- (d) The Cuffs and Gauges are now ready to make an FSBP measurement as described in Section 4 of this manual.

The water pipes should not touch the skin. Avoid movement of the hand during the measurements.

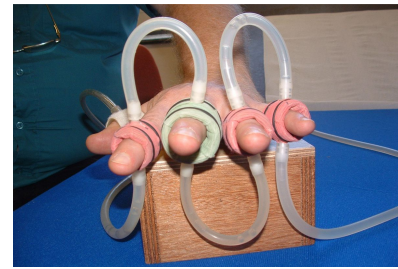


Figure 2e The hand and lower arm should be supported during the test



Figure 2f The recommended placement of strain gauges

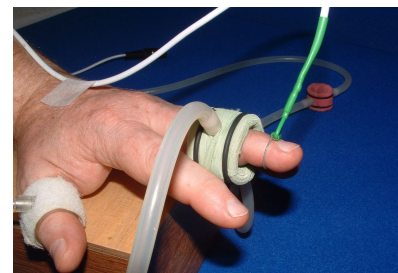


Figure 2g The gauge should be perpendicular to the finger

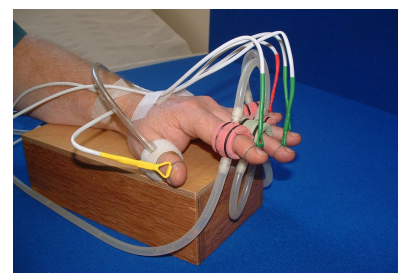


Figure 2h The completed setup for FSBP measurements

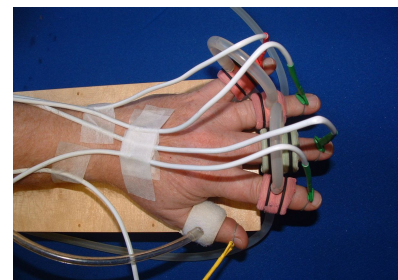


Figure 2i The lead of the thumb strain gauge may be attached to the wrist

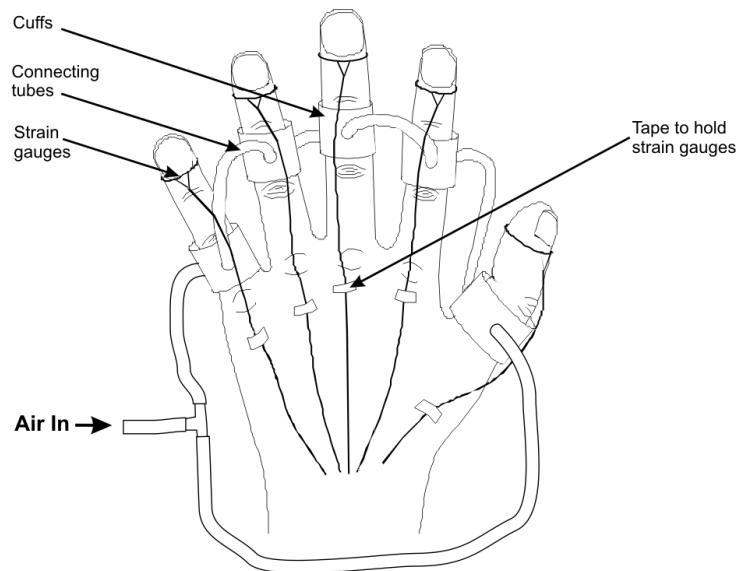


Figure 3 Mounting pressure cuffs and strain gauges for finger blood flow measurements

3.4.2 Arrangement of pressure cuffs and strain gauges for FBF measurements

- (a) The arrangement of pressure cuffs and strain gauges for measurement of finger blood flow (FBF) on the five digits of one hand is similar to that for FSBP measurements. However, for FBF measurements all five cuffs are connected to the **Air** outlet and the water cooling circuit is not used (see Figure 3).
- (b) Select the appropriate size pressure cuff for each of the test fingers. See section 3.5.1b for selecting the correct cuff. Cuffs placed too tightly around the fingers will inhibit blood flow when not pressurised and very loose cuffs will not completely occlude the arteries when they are pressurised. It may be necessary to use a smaller cuff for the little finger.

Place the five cuffs in a row and link them with 15 cm lengths of tubing. Push the tubing over the inlets on each side of the cuff so as to cover at least two barbs.

Push a 15 cm length of tubing onto the free inlet of each outer cuff.

Join one of the outer pieces of tube to the cross bar of the supplied T-coupler. Join the other piece of tube to the opposite end of the T-coupler as shown in Figure 3.

Push the free end of the 1m tube with non-sealing plug on to the base outlet of the T-coupler so as to cover at least two barbs.

Connect the plug to the **Air** socket on the front panel of the Plethysmograph. You should now have created a loop of cuffs, incorporating the T-coupler, with one longer piece of tube linking the loop to the Plethysmograph. Connect the supplied bypass tube between the **Water In** and **Water Out** sockets.

Place the cuffs around the medial phalanges of the test fingers. Ensure that the tube is not kinked as this can impede the pressurisation of the cuffs.

- (c) Select the appropriate size strain gauge for each finger (see section 3.5.1 for information on gauge selection).

The strain gauges should be placed around the distal phalanx of each measurement sites, between the knuckle and the base of the nail (Figure 2f).

A good position can be achieved by bending the white connecting lead so the gauge and start of the lead is perpendicular to the finger. Make sure that the lead will not be

moved by movement from the air cuff. The strain gauges must not be overstretched or twisted around the finger as this will limit the lifespan of the gauges and produce an inaccurate response (Figure 2g).

Once a strain gauge is correctly positioned hold it in place by attaching it to the dorsal side of the hand using micropore tape. Use a strain gauge on each of the test sites and on the reference site (Figure 2i).

Connect the strain gauge on the thumb to the first **Transducer** socket on the Plethysmograph front panel, and the gauges on the index, middle, ring and little fingers to sockets 2, 3, 4 and 5 respectively.

The Cuffs and Gauges are now ready to make an FBF measurement as described in Section 5 of this manual.

3.5 Disconnecting devices and shutting down

After the tests have completed, the *HVLab* Multi-channel Plethysmograph can be shut down by pressing on the **Off** switch.

The plethysmograph must be shut down before disconnecting the Isolation Transformer plug, the additional earth plug cable and the Computer Interface cable.

Strain gauges, the plugs to the Air socket and the plugs to the Water In or Water Out sockets can be disconnected at any time. It is also advisable to disconnect the water-cooled provocation cuffs over a sink as there will be excess water within the tubes and the cuffs.

4 Running a finger systolic blood pressure test

Before running a test, the user is advised to carry out the cleaning and performance checks specified in Sections 6.1 and 6.3 respectively.

Finger systolic blood pressure measurements are controlled from the *HVLab* Diagnostic Instruments Manager software. The Diagnostic Instruments Manager programme integrates the software that controls the Multi-Channel Plethysmograph and other *HVLab* diagnostic instruments, with a relational database of subjects/patients and test results. When you start the *HVLab* Diagnostic Instruments Manager software the **Control Panel** window opens as shown in Figure 4. The window is divided into three sections – Current Subject, which shows the currently active record in the subject or patient database; Diagnostic Tests, which provides access to the individual tests and databases of test results; and Clinical Information, which launches a health surveillance information database where this has been provided.

Please see the accompanying *HVLab* Diagnostic Instruments Manager Database manual for more detailed instructions on operation of the database.

4.1 The Control Panel Window

4.1.1 Current Subject

Before running a test it is necessary to enter the details of your test subject or patient into the database by clicking on **Add New Subject** to open the **Subject Details** window and complete the subject details fields (Figure 5). After completing the necessary information click **Save** to save and return to the **Control Panel**. If the subject has already been entered into the database, locate the subject record using the navigation buttons in the lower left corner of the **Control Panel** window, or click on **Find Subject** in the **Current Subject** section.

The screenshot shows the 'HVLAB Diagnostic Instruments - [Control Panel]' window. It features a menu bar (File, Edit, View, Tools, Help) and a title bar. The main interface is divided into three primary sections: 'Current Subject', 'Diagnostic Tests', and 'Clinical Information'. The 'Current Subject' section includes input fields for Surname (Other), Forename (Andrew N.), Date of Birth, Reference Number (A0215), Date of Entry (31 August 2005), Gender (radio buttons for Male and Female), and Preferred Hand (radio buttons for Right, Left, and Neither). It also contains buttons for 'View Full Details', 'Add New Subject', and 'Find Subject'. The 'Diagnostic Tests' section has a 'Test' dropdown menu currently set to 'Finger Systolic Blood Pressure', along with buttons for 'Start New Test', 'Manual Data Entry', 'View Test Results', and 'Print All Records'. The 'Clinical Information' section includes a 'Questionnaire' dropdown menu set to 'Health Surveillance Questionnaire', and buttons for 'Add New Record', 'View Records', and 'Print All Records'. At the bottom of the window, there is a 'Current User' field displaying 'Administrator', a 'Record' navigation bar showing '2 of 19', and buttons for 'User Details', 'Log Off', and 'Exit Database'.

Figure 4 Control Panel window

Subject Details Subject Number: 217

Surname: Other
Forename: Andrew
Reference Number: 11203568
Date of Birth: 13 October 1950
Gender: Male
Height (m): 1.9 Weight (kg): 90
Preferred hand: Right
Marital status: Single
Ethnic group: European

Address:
NI Number:
Report submitted to:
Appointment date: 16 November Time: 09:34
Entered by: Administrator Date: 31/08/2005

History of changes and other information:
Missed last appointment on 10th November

Delete Subject Undo Changes Close

Form View

Figure 5 Subject Details Window

4.1.2 Diagnostic Tests

The controls in the Diagnostic Tests section allow you to launch a new test, or to retrieve the results of existing tests from the test results database, or manually enter data.

After entering or finding your subject or patient, select **Finger Systolic Blood Pressure** in the **Test** list box. Click on **Start New Test** to open the Finger Systolic Blood Pressure Test window as shown in Figure 6. To retrieve the results of existing tests on the current subject, select **Finger Systolic Blood Pressure** and click on **View Test Results**.

4.2 Finger Systolic Blood Pressure Test Window

4.2.1 Subject Details

The Subject Details section of the Finger Systolic Blood Pressure Test Window (Figure 6) shows the details of the current subject, which cannot be edited here. The new test record that will be created in the finger systolic blood pressure test results database will be linked to this subject record.

4.2.2 Test Parameters

The Test Parameters section shows parameters of the finger systolic blood pressure test measurements that will be performed in the current test. Combinations of parameter settings should be saved as a parameter set. These parameters may be altered from the default values by selecting different parameter sets using the **Parameter Set** list box. Additional parameter sets may be entered into the database and saved so they can be used again. Existing parameter sets may be altered or deleted, by clicking the **Add New** or the **Edit/Delete** controls (see *Editing and creating new test parameters*, below). The **Test Parameters** section includes the following values:

HVLAB Diagnostic Instruments - [Finger Systolic Blood Pressure Test]

File Edit View Tools Help

Finger Systolic Blood Pressure Test

Subject Number: 217
Test Number: 482

Subject Details

Surname: Other
Forename: Andrew
Date of Birth: 13/10/1950
Reference No: 11203568
Date of Entry: 31/08/2005

Test Parameters

Parameter Set Name: Default
No. of Measurements: 4
No. of Measurement Sites: 5
Inflation Pressure: 250 mm Hg
Deflation Rate: 2.5 mm Hg/second
Cooling Period: 300 seconds

Test Details

Room temperature: 21 °C
FST (Left): 34 °C
FST (Right): 34 °C
Test Date: 12/01/2006 14:22:57
Tester: Administrator
Data File: No file selected
Run as a simulation: ☒

Test Results

Finger Systolic Blood Pressures

Air Measurement:	22 °C	30 °C	15 °C	10 °C
Reference:				
thumb				
index				
middle				
ring				
little				

Percentage Finger Systolic Blood Pressures

Control Temperature:	0	0	0	0
index	0	0	0	0
middle	0	0	0	0
ring	0	0	0	0
little	0	0	0	0

Notes

Save and Exit Calibration Cancel

Form View

Figure 6 Finger Systolic Blood Pressure Test window opened by “Start New Test” button

4.2.2.1 Parameter Set Name

The name of the current parameter set. The parameter settings for the objective testing of finger systolic blood pressure for HAVS assessment is entitled ‘default’.

4.2.2.2 Number of Measurements

The number of measurements to be completed in one test.

4.2.2.3 No. of measurement sites

The number of fingers where FSBP is measured.

4.2.2.4 Inflation Pressure

The inflation pressure of the cuffs during cooling.

4.2.2.5 Deflation rate

The rate at which the pressure in the cuffs will be released after cooling has ceased.

4.2.2.6 Cooling period

The duration of the cooling and pressurisation of the cuffs in a measurement.

4.2.2.7 Editing and creating new test parameters

To create a new set of test parameters, click on the **Add New** button to open the **FSBP Test Parameters** window (Figure 7). This contains four sections: **Parameter Set**, **General Settings**, **Settings for Individual Measurements** and **Settings for Individual Measurement Sites**.

To define a unique parameter set, alter the values within the **General Settings** section (see 4.2.2.1 to 4.2.2.6 for definitions of parameter settings).

The **Settings for Individual Measurements** box allows you to define the temperature for each of the measurements. Specify the temperature for each measurement by selecting the measurement number, then select the temperature required for that measurement. Tick air measurement if an air temperature measurement is required (22 °C). To move to the next measurement click **+**. Set the temperature for each measurement.

The **Settings for Individual Measurement Sites** allows you to define the site of each of the measurement sites. Specify the location for each measurement site by selecting the measurement number, then type the name of the site required for that measurement. To move to the next measurement site click **+**. Set the location for each measurement site.

If a measurement site is not being used e.g. you are only measuring on four fingers, delete any wording in the Site and Details boxes – this will ensure the report does not contain extra sites that have not been tested on.

Once you have finished defining your parameters, label the parameter set in the **Parameter Set Name** field and click on **Save**.

To edit the parameters in the currently selected Parameter Set, click on **Edit/Delete** in the Finger Systolic Blood Pressure Test window, change the desired parameter and then click on **Save Change**.

It should be noted that any alterations to the test parameters might affect the finger systolic blood pressures obtained.

Measurement no.	Temperature [°C]	Air measurement
1	22.0	☒

Measurement site number	Site	Details
1	thumb	Air (Reference) Site

Figure 7 Finger Systolic Blood Pressure Test Parameters Window

4.2.3 Test details

The Test Details section (see Figure 6) includes values for **Room Temperature** and **Finger Skin Temperature** (left and right). These should be entered before the test results are finally saved: a warning will be given by the software if values have not been entered. The values are entered manually are automatically imported if the tester has entered them in a previous test. The test date field contains the test date and time and is entered automatically.

The **Tester** field can be used to identify the user who performed the test. The **Data File** field is used by the software to store the name of the data file containing the FSBP graph data for the individual measurements.

Check **Run as a simulation** if you wish to run a simulated test without a subject (for demonstration).

4.2.4 Test Results

The controls in this section allow you to start and repeat finger systolic blood pressure measurements.

N.B. If using a PCL-812 board, before commencing a FSBP test set the switch on the distribution box to FSBP measurement.

There are two tables showing the test results. The upper table shows the absolute finger systolic blood pressures for each measurement site at each measurement temperature. The fields in the left column of the results table show the measurement sites that will be used. The fields at the top of each column show the provocation temperature of the measurement.

Click on the **Start** button located underneath the measurement temperature you require to launch a finger systolic blood pressure measurement at the selected temperature.

Clicking on **Start** opens the **Pressure and Temperature Control** window, which guides the user through the sequence of actions to prepare to perform a finger systolic blood pressure measurement.

N.B. You may briefly see the Transferring Measurement Results screen. Please ignore this screen at this point. It will automatically be hidden by the next window.

Go to the **Pressure and Temperature Control** window (Section 4.3 of this manual) for instructions on running finger systolic blood pressure measurement.

The lower table shows the % FSBP for each measurement site at each measurement temperature. The % FSBP for each measurement site at each location is calculated automatically by the software. Check the required Control Temperature to select the Control Temperature for the calculation of % FSBPs.

The notes section enables the user to add any comments on the test if necessary.

When all the measurements have been completed, click on the **Save and Exit** button, in the bottom left corner of the window, to save the test record to the database and return to the **Control Panel** window. Alternatively, clicking **Cancel Test** will return to the **Control Panel** window without saving the test results.

4.2.5 Calibration Window

The Calibration Window provides a means for the technician to control the Multi-Channel Plethysmograph during calibration and is not required for diagnostic testing. Calibration should only be performed by a certified *HVLab* technician.

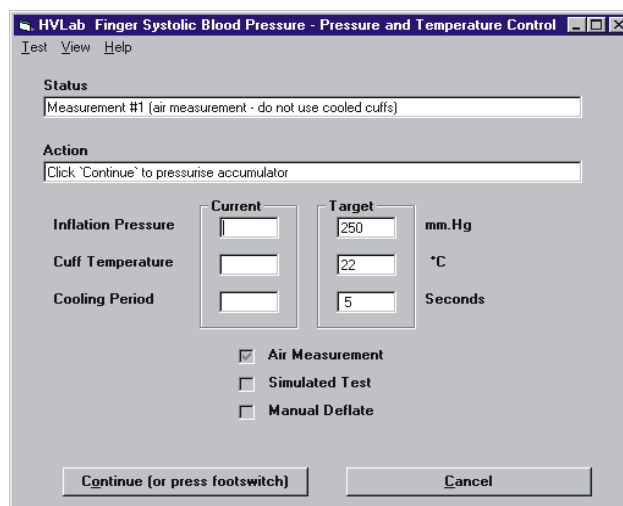


Figure 8 Pressure and Temperature Control Window

4.3 The Pressure and Control Window

The **Pressure and Control** window contains the **Status** and **Action** instructions and the **Current** and **Target Inflation Pressure**, **Cuff Temperature** and **Cooling Period** indicators (Figure 8). The number of the current measurement is shown in the Status box. The air measurement box, simulated test box or manual deflate box may be checked - these indicate the type of measurement being conducted.

Precautions that should be taken to ensure reliable measurements are outlined in Section 6.4 of this manual.

Follow the instruction in the **Action** box and click **Continue** (or use the footswitch) for the next instruction to prepare for running a measurement. The series of instructions are:

- (i) Click 'Continue' to pressurise the accumulator
- (ii) Pressurising accumulator – please wait
- (iii) Place cuffs and gauges on fingers then click 'Continue'
- (iv) Squeeze fingers then click 'continue' to inflate cuffs
- (v) Remove squeezer and wait for the cooling to elapse.

The Current column displays the current state of the parameter settings. The Target column displays the target parameter settings as set in the General Settings in the FSBP Parameters Window. As the actions are followed the current settings will change to match the target settings.

Once the preparation instructions are complete the Finger Systolic Blood Pressure Measurement Window (Figure 9) will open automatically and the pressure in the cuffs will start to release.

IMPORTANT: If the plethysmograph has been turned off unexpectedly or if there is a system power failure, there will be an error message (Figure 30) informing you that there is residual pressure in the cuffs which will prevent you from being able to remove the cuffs from the subject's fingers. Please see section 7.1.3 for further information.

4.4 The Finger Systolic Blood Pressure Measurement Window

At the top of the screen are the buttons to **Start**, **Stop**, **Cancel** or **Save** the current measurement. The name and reference number of the current subject, and the date of test,

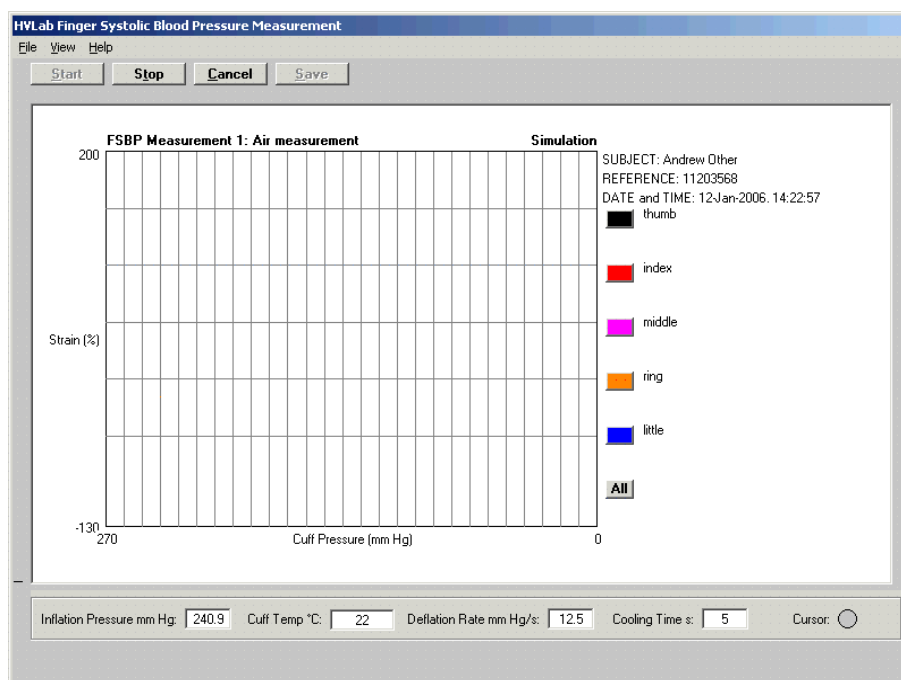
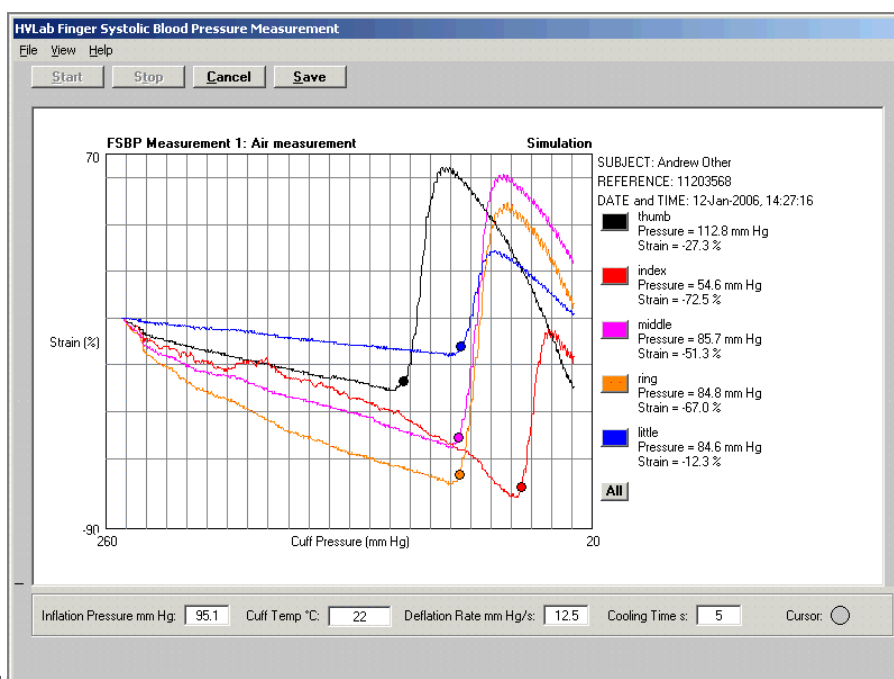


Figure 9 The Finger Systolic Blood Pressure Measurement Window

are also displayed. At the bottom of the screen are the **Inflation Pressure (mm Hg)**, **Cuff Temp (°C)**, **Deflation Rate (mm Hg/s)** and **Cooling Time (s)** of the current measurement. The colour of the cursor is shown in the cursor indicator. The measurement location and colour of traces are indicated on the right of the graph. If there is a problem with a gauge it can be identified immediately.

The test can be interrupted at any time, by clicking on **Stop**. By then clicking on **Cancel** the user will be returned to the **Finger Systolic Blood Pressure Test** window and any data will be lost. The percentage strain of the strain gauge is measured and displayed in real time as the cuff deflates.

Once the measurement is complete, the software automatically places a cursor at the appropriate point on the graph for each measurement location. Arterial inflow is permitted when cuff pressure is equal to, or less than, systolic pressure. Inflow is detected by an increase in volume indicated by the strain gauge signal. The finger systolic blood pressure corresponds to that pressure at which a volume increase is detected by the strain gauge, or



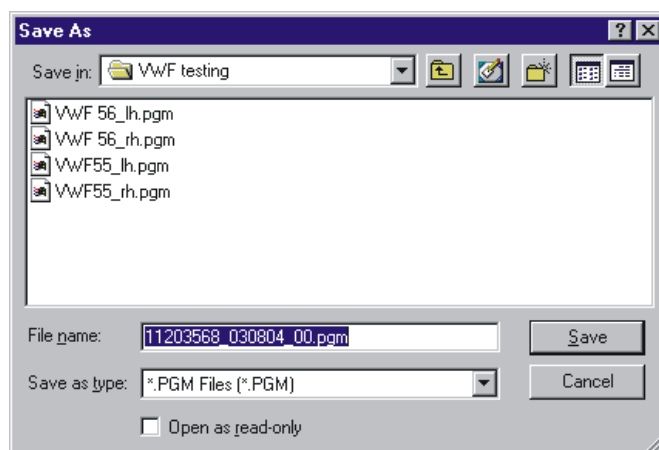


Figure 11 Dialogue for saving finger systolic blood pressure data file

the first pulse is observed.

The cursor can be repositioned by the user (see 4.4.2. of this manual). Cursor positions can be changed immediately after the data has been collected or at a later date.

The percentage strain and finger systolic blood pressure are displayed for each measurement site (Figure 10).

Click **Restart** if you need to run the current FSBP measurement again, (check guidelines for repeating cold provocation stimuli).

Click **Save** to save the datafile. You will be prompted to save the complete graph as a .pgm file: the software will automatically suggest a filename in the Data folder, but you may choose a different filename and/or location (Figure 11).

The FSBP test results will be transferred automatically to the database and displayed in the relevant fields. The **Importing Measurement Results** dialogue is shown while the results are being transferred (Figure 12). This process can take several seconds. See section 4.4.1

4.4.1 The Running Test and Importing Results dialogue

The test results will be transferred automatically to the database and displayed in the relevant fields. The **Running Test and Importing Results** dialogue is shown while the results are being transferred. This process can take several seconds.

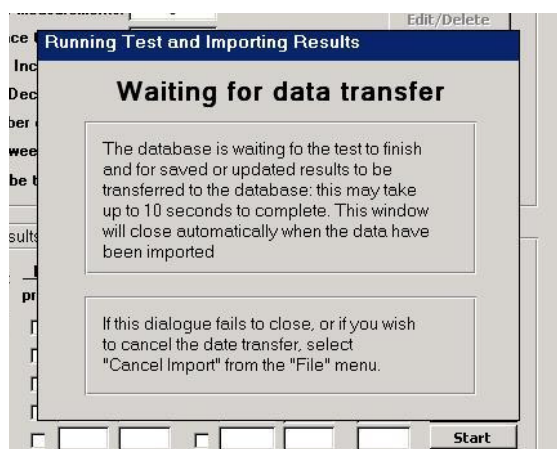


Figure 12 Waiting for data transfer

If this dialogue fails to close because there was a failure in data transfer or because you cancelled a test, you will need to close the dialogue by selecting **Cancel Import** from the **File** menu on the top left-hand corner.

4.4.2 Repositioning the cursor

To change the estimated blood pressure values for a measurement, click once on the required cursor. The key to the selected cursor is displayed in the cursor indicator at the bottom right of the window. Click once on the point of the finger systolic blood pressure trace that the cursor should be positioned. Click once off any trace to clear the cursor. Do this for all channels necessary.

Click **All** before saving or exiting the window. Further instructions are available in the **View Cursor Help** menu.

4.5 Viewing Previously Collected Test Results

To view the results for a particular subject, ensure that the correct subject is displayed in the **Current Subject** section of the **Control Panel** window. Select **Finger Systolic Blood Pressure** from the drop down list in the **Diagnostic Tests** box and then click on **View Test Results** to display the **Finger Systolic Blood Pressure Test** window (Figure 13). This is the same window that was used to launch the measurements, except that the **Start** buttons for each measurement are now replaced by **View** buttons. If there is more than one test record for the current subject, you can use the **navigation buttons** in the bottom left corner of the screen to scroll to the required record set.

If there is no data file name shown in the Test Details section, an Open File dialogue window

HVLAB Diagnostic Instruments - [Finger Systolic Blood Pressure Test]

File Edit View Tools Help

Finger Systolic Blood Pressure Test Subject Number: 217 Test Number: 485

Subject Details

Surname: Other Forename: Andrew Date of Birth: 13/10/1950 Reference No: 11203568 Date of Entry: 31/08/2005

Test Parameters

No. of Measurements: 4 No. of Measurement Sites: 5 Inflation Pressure: 250 mm Hg Deflation Rate: 2.5 mm Hg/second Cooling Period: 300 seconds

Test Details

Room temperature: 21 °C FST (Left): 34 °C FST (Right): 34 °C Test Date: 12/01/2006 14:30:27 Tester: Administrator Data File: C:\HVLwin7\Data\11203568_1 20106_02.pgm Run as a simulation: ☒

Test Results

Finger Systolic Blood Pressures

Air Measurement: ☒ ☐ ☐ ☐

Reference:	Site	22 °C	30 °C	15 °C	10 °C	
	thumb	112.8	112.8	111.6	109.4	mm Hg
	index	54.6	54.6	50.7	39.6	mm Hg
	middle	85.7	85.7	80.3	60.6	mm Hg
	ring	84.8	84.8	78.7	61.7	mm Hg
	little	84.6	84.6	76.9	66.2	mm Hg

View View View View

Percentage Finger Systolic Blood Pressures

Control Temperature: ☐ ☒ ☐ ☐

	100		95	77	%
index	100		95	77	%
middle	100		95	74	%
ring	100		94	76	%
little	100		92	82	%

Notes

Save and Exit Print Record Cancel

Record: 1 of 5 Form View

Figure 13 FSBP Test window opened by "View Test Results" button

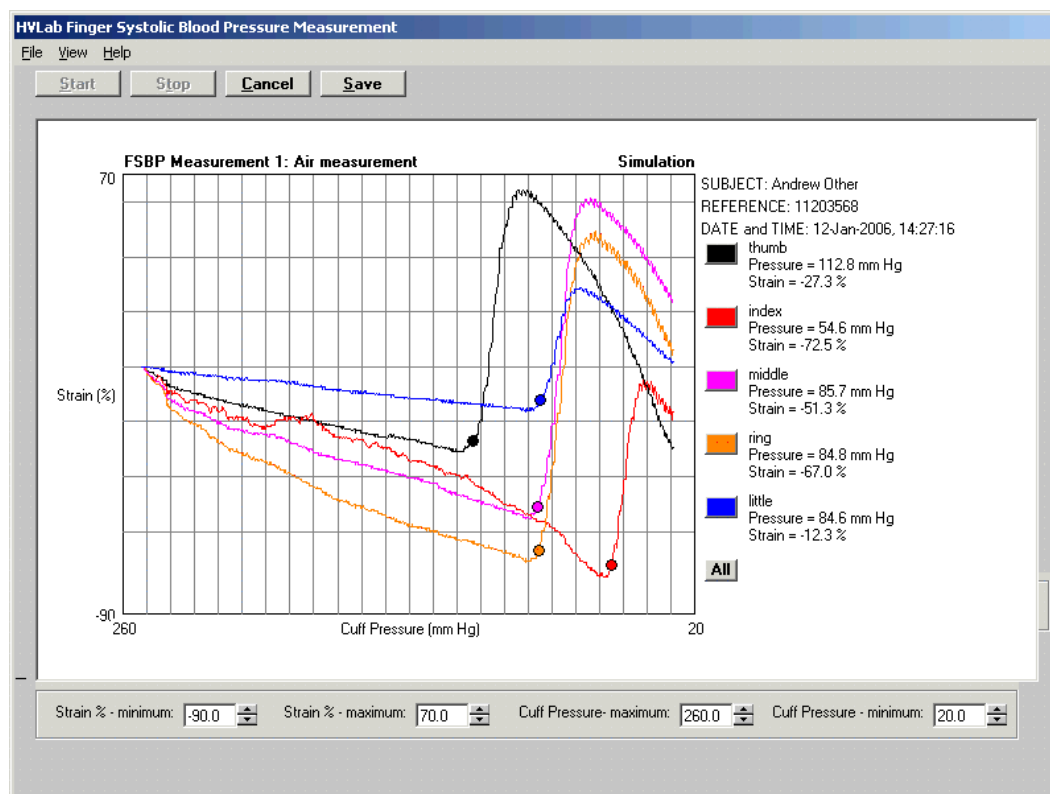


Figure 14 Rescaling controls can be turned on via the “View” menu

will appear in which you can relocate the correct file.

Click each **View** button to display the individual finger systolic blood pressure graphs for each measurement (in the *HVLab* Finger Systolic Blood pressure Measurement window), which are saved in the **Data File** shown in the **Test Details** section.

The **View** buttons open the *HVLab* Finger Systolic Blood pressure Measurement (Figure 13) window the position of the cursor can be edited (see 4.4.2. of this manual). The scaling of the FSBP graph (i.e. the x- and y-axis limits) may be adjusted by selecting Rescale Graph from the View Menu. This replaces the status fields at the bottom of the window by text controls, showing the current axis limits, which can be incremented or decremented by clicking on the associated scroll buttons.

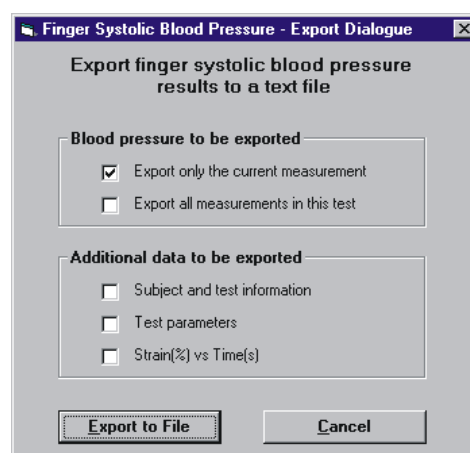


Figure 15 Export options window available from the “File” menu

HVLab Finger Systolic Blood Pressure Test

PERSONAL DETAILS

Surname: Other Date of birth: 13/10/1950
 Forenames: Andrew Reference number: 11203568

TEST RESULTS

Test date: 12/01/2006 14:30:27 Room temperature: 21.0 °C
 Tester: Administrator Finger skin temp.(left): 34.0 °C
 Finger skin temp.(right): 34.0 °C

Measurement site	Dysfunction	FSBP at 15 °C		FSBP at 10 °C		% FSBP at 15 °C		% FSBP at 10 °C		Criteria for dysfunction (% FSBP)	
		15 °C	10 °C					Possible	Definite		
thumb				111.6	109.4	-	-	-	-	-	-
index	o x	x	x	50.7	39.6	95.0	77.4	<80	<60		
middle	o x	x	x	80.3	60.6	95.1	73.7	<80	<60		
ring	o x	x	x	78.7	61.7	94.2	75.9	<80	<60		
little	o o	o	o	76.9	66.2	92.3	81.5	<80	<60		

o = No dysfunction found
 x = Possible dysfunction
 xx = Definite dysfunction

NOTES:

TEST PARAMETERS

Number of measurements: 4 Deflation rate: 2.5 mm Hg/sec.
 Number of measurement sites: 5 Cooling period: 300 sec.
 Inflation pressure: 250 mm Hg

Page: 1 Ready

Figure 16 Previewing and printing a test report by clicking the “Print Record” button

Click **Save** to save changes and exit the HVLab Finger Systolic Blood pressure Measurement window and return to the FSBP Test Results window. Click Cancel to return, via the **Importing Measurement Results window** (see section 4.4.1) to the FSBP Test Results window without saving.

4.5.1 Printing and exporting

4.5.1.1 FSBP graphs and data

The finger systolic blood pressure graphs can be printed (to the default printer on your computer), or exported as a bitmap, by selecting **Print Graph** or **Export Graph** from the **File Menu**.

The FSBP data may also be exported to a text file by selecting **Export Results** from the **File Menu** (Figure 14). Check the information that is required and click **Export to File**. The **Save As** dialogue box will appear. Enter the file name where indicated and select the required file location. Click **Save** to save data or **Cancel** to return to the graphs.

After the finger systolic blood pressure graph has been displayed, click **Cancel** to return to the **Finger Systolic Blood Pressure Test** screen without saving changes. Click **Save** to save any changes and to update the **Test Results** table in the **Finger Systolic Blood Pressure Test Window**.

4.5.1.2 Printing test reports

A test report, of the test record that is stored in the database, can also be previewed and printed (see Figure 16) from the **Finger Systolic Blood Pressure Test Window** (Figure 13) by selecting the required test record and clicking the **Print Record** button at the bottom of the window.

The **Starting Page Number window** will open. Please enter the first page number required for the report.

Click **Close** to exit the print preview.

5 Running a finger blood flow test

Before running a test, the user is advised to carry out the cleaning and performance checks specified in Sections 6.1 and 6.3 respectively.

Finger blood flow measurements are controlled from the *HVLab* Diagnostic Instruments Manager software. The Diagnostic Instruments Manager programme integrates the software that controls the Multi-Channel Plethysmograph and other *HVLab* diagnostic instruments, with a relational database of subjects/patients and test results. When you start the *HVLab* Diagnostic Instruments Manager software the **Control Panel** window opens as shown in Figure 2. The window is divided into three sections – Current Subject, which shows the currently active record in the subject or patient database; Diagnostic Tests, which provides access to the individual tests and databases of test results; and Clinical Information, which launches a health surveillance information database where this has been provided.

5.1 The Control Panel Window

See section 4.1

5.1.1 Current Subject

See section 4.1.1

5.1.2 Diagnostic Tests

The controls in the Diagnostic Tests section allow you to launch a new test, or to retrieve the results of existing tests from the test results database.

After entering or finding your subject or patient, select **Finger Blood Flow** in the **Test** list box. Click on **Start New Test** to open the Finger Blood Flow Test window. To retrieve the results of existing tests on the current subject, select **Finger Blood Flow** and click on **View Test Results**.

5.2 Finger Blood Flow Test Window

5.2.1 Subject Details

The Subject Details section (see Figure 17) shows the details of the current subject, which cannot be edited here. The new test record that will be created in the finger blood flow test results database will be linked to this subject record.

5.2.2 Test Parameters

The Test Parameters section shows parameters of the finger blood flow test measurements that will be performed in the current test. These parameters may be altered from the default values by selecting different parameter sets using the **Parameter Set** list box. Additional parameter sets may be entered into the database, and existing parameter sets may be altered or deleted, by clicking the **Add New** or the **Edit/Delete** controls (see *Editing and creating new test parameters*, below). The **Test Parameters** section includes the following values:

5.2.2.1 Parameter Set Name

The name of the current parameter set.

5.2.2.2 Number of Runs

The number of runs to be completed in one test.

HVLAB Diagnostic Instruments - [Finger Blood Flow Test]

File Edit View Tools Help

Finger Blood Flow Test

Subject Number: 217
Test Number: 824

Subject Details

Surname: Other
Forename: Andrew
Date of Birth: 13/10/1950
Reference No: 11203568
Date of Entry: 31/08/2005

Test Parameters

Parameter Set Name: Default
No. of Runs: 20
No. of Measurement Sites: 5
No. Measurements per Run: 3
Inflation Pressure: 60 mm Hg
Pre-Inflation Time: 0 seconds
Measurement Time: 5 seconds

Test Details

Room temperature: 21 °C
FST (Left): 34 °C
FST (Right): 34 °C
Test Date: 12/01/2006 15:45:59
Tester: Administrator
Data File: No file selected
Run as a simulation: ☒

Test Results

Average Blood Inflow (%/sec.)

Comments	thumb	index	middle	ring	little	Individual Data	
Run 1:						Start	Open
Run 2:						Start	Open
Run 3:						Start	Open
Run 4:						Start	Open
Run 5:						Start	Open
Run 6:						Start	Open
Run 7:						Start	Open
Run 8:						Start	Open
Run 9:						Start	Open
Run 10:						Start	Open
Run 11:						Start	Open
Run 12:						Start	Open
Run 13:						Start	Open

Save and Exit Calibration Cancel

Form View

Figure 17 Finger Blood Flow Test window opened by “Start New Test” button

5.2.2.3 No. of measurement sites

The number of fingers where FBF will be measured.

5.2.2.4 No. of measurements per run

The number of measurements in each run. The database acquires the finger blood flow in the chosen number of measurements and calculates an average finger blood flow per run.

5.2.2.5 Inflation Pressure

The inflation pressure of the cuffs during occlusion.

5.2.2.6 Pre-inflation time

The time between the start of the measurement and the onset of occlusion.

5.2.2.7 Measurement time

The duration of the pressurisation of the cuffs whilst finger blood flow is being measured.

5.2.2.8 Editing and creating new test parameters

To create a new set of test parameters, click on the **Add New** button to open the **FBF Test Parameters** window (Figure 18). This contains three sections: **Parameter Set**, **General Settings**, and **Settings for Individual Measurement Sites**.

Finger Blood Flow Test Parameters

Parameter Set

User Name: Administrator

Parameter Set Name: Default

General Settings

No. of Runs: 2

No. of Measurement Sites: 5

Number of Measurements per Run: 3

Inflation Pressure (mm Hg): 60

Pre-Inflation Time (seconds): 0

Measurement Time (seconds): 5

Settings for Individual Measurement Sites

Measurement site	Site name
1	thumb

Save Delete Cancel

Figure 18 Finger Blood Flow Test Parameters Window

To define a unique parameter set, alter the values within the **General Settings** section (see 4.2.2.1 to 4.2.2.7 for definitions of parameter settings).

The **Settings for Individual Measurement Sites** allows you to define the location of each of the measurement sites. Select the measurement number 1 and type in the site name. Click + by the measurement site number to progress to the next measurement site. Add the site name etc. Repeat until all measurement sites have the correct location. If a measurement site is not being used e.g. you are only measuring on four fingers, delete any wording in the Digit box.

Once you have finished defining your parameters, label the parameter set in the **Parameter Set Name** field and click on **Save**.

To edit the parameters in the currently selected Parameter Set, select the required parameter set, click on **Edit/Delete** in the Finger Blood Flow Test window, change the desired parameter and then click on **Save Change**. If **Cancel** is clicked the screen will return to the test window. The existing parameter set can be used. If this parameter set is not the required parameter set click **Cancel** again to return to the Control panel and re-enter the Test window.

It should be noted that any alterations to the test parameters may affect the finger blood flow measures obtained.

5.2.3 Test details

The Test Details section (see Figure 17) includes values for **Room Temperature**, **Finger Skin Temperature** (left and right). These should be entered before the test results are finally saved: a warning will be given by the software if values have not been entered. The values are entered manually are automatically imported if the tester has entered them in a previous test.

The test date and time will be added automatically.

The **Tester** field can be used to identify the user who performed the test. The **Data File** field is used by the software to store the name of the data file containing the FBF graph data for the individual measurements.

Check **Run as a simulation** if you wish to run a simulated test without a subject (for demonstration).

5.2.4 Test Results

The controls in this section allow you to start and repeat finger blood flow runs.

The test results table shows the Run number, and the average blood inflow at each measurement site. Click on the **Start** button to launch a finger blood flow run.

Clicking on **Start** opens the **Pressure and Temperature Control** window, which guides the user through the sequence of actions to prepare to perform a finger blood flow measurement.

N.B. If the data import window is seen please ignore.

Go to the **Pressure and Temperature Control** window (Section 5.3 of this manual) for instructions on running finger blood flow measurement.

When all the measurements have been completed, click on the **Save and Exit** button, in the bottom left corner of the window, to save the test record to the database and return to the **Control Panel** window. Alternatively, clicking **Cancel Test** will return to the **Control Panel** window without saving the test results.

5.2.5 Calibration Window

The **Calibration** button opens the **Calibration** window

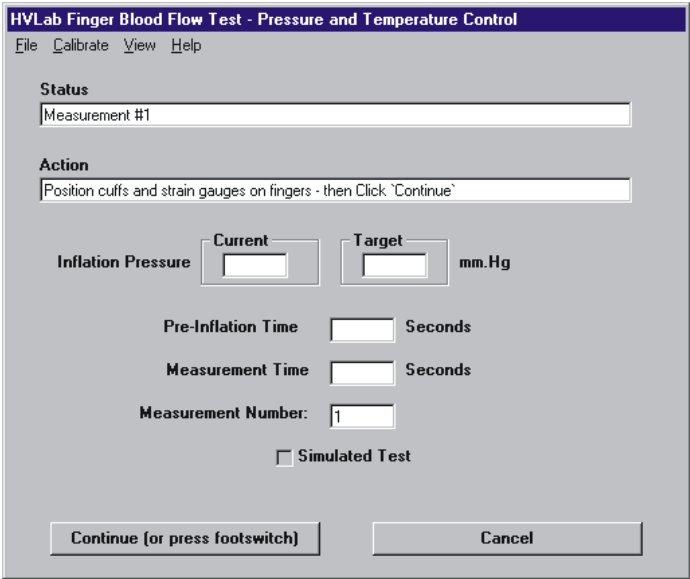
This is a means for you to control the Multi-Channel Plethysmograph during calibration and is not required for diagnostic testing. Calibration should only be performed by a certified *HVLab* technician.

5.3 The Pressure and Control Window

The pressure and control window contains the **Status** and **Action** instructions and the **Current** and **Target Inflation Pressure**, **Pre-inflation Time**, **Measurement Time** and **Measurement Number** indicators (Figure 19).

Precautions that should be taken to ensure reliable measurements are outlined in Section 6.4 of this manual.

Follow the instruction in the **Action** box and click **Continue (or use the footswitch)** for the next instruction to prepare for running a measurement. The sequence of instructions is:



The screenshot shows a software window titled "HVLab Finger Blood Flow Test - Pressure and Temperature Control". It features a menu bar with "File", "Calibrate", "View", and "Help". The main area contains several sections: "Status" with a text box showing "Measurement #1"; "Action" with a text box showing "Position cuffs and strain gauges on fingers - then Click 'Continue'"; "Inflation Pressure" with two sub-sections, "Current" and "Target", each with a text box and a unit label "mm.Hg"; "Pre-Inflation Time" with a text box and a unit label "Seconds"; "Measurement Time" with a text box and a unit label "Seconds"; "Measurement Number:" with a text box showing "1"; and a checkbox labeled "Simulated Test". At the bottom, there are two buttons: "Continue [or press footswitch]" and "Cancel".

Figure 19 Pressure and Temperature Control Window

- (i) Position cuffs and strain gauges on fingers – then click ‘Continue’
- (ii) Click ‘Continue’ to continue
- (iii) Please wait – computing pressure decrement.

The Current box displays the current inflation pressure. The Target column displays the target inflation pressure as set in the General Settings in the FBF Parameters Window. As the actions are followed the current inflation pressure will change to match the target inflation pressure.

Once the preparatory actions are complete the **Finger Blood Flow Measurement** window (Figure 20) will open automatically.

IMPORTANT: If the plethysmograph has been turned off unexpectedly or if there is a system power failure, there will be an error message (Figure 30) informing you that there is residual pressure in the cuffs which will prevent you from being able to remove the cuffs from the subject’s fingers. Please see section 7.1.3 for further information.

5.4 The Finger Blood Flow Measurement Window

At the top of the screen are the buttons to **Start**, **Stop**, **Cancel** or **Save** the current measurement. Click **Start** to begin cuff inflation. The name and reference number of the current subject, and the date of test, are displayed. To the right the key for each gauge is displayed. At the bottom of the screen are displayed the **Status**, **Inflation Pressure (mm Hg)** and **Inflation duration (s)** of the current measurement and the resistance of each strain gauge. The **Include in Average** box is also displayed.

At each measurement the percentage strain of the strain gauge at each measurement site is measured and displayed in real time on a graph (Figure 20).

Once the measurement is complete, the software automatically places a line on the graph

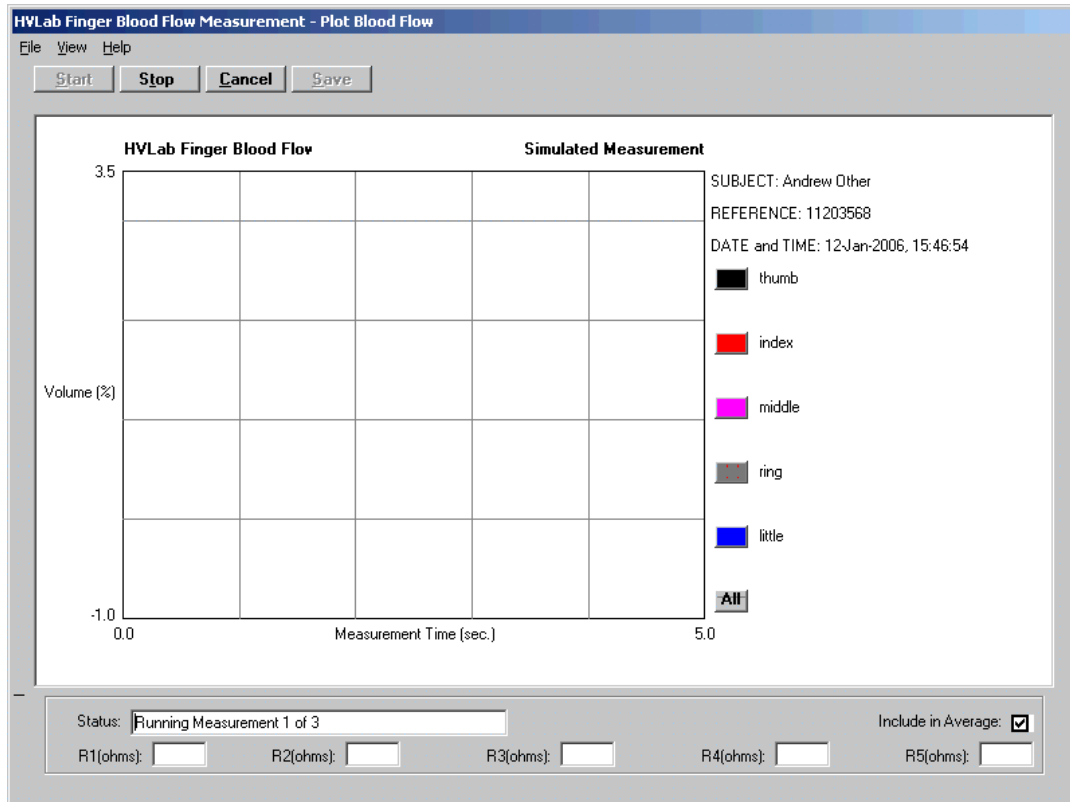


Figure 20 The Finger Blood Flow Measurement Window

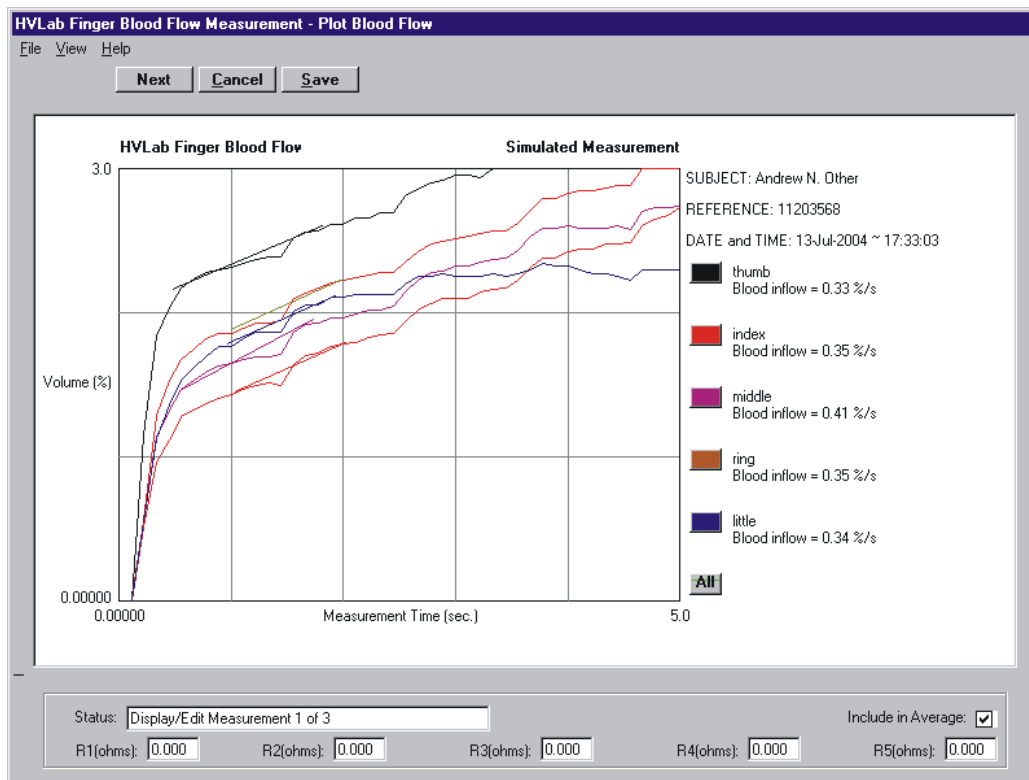


Figure 21 Results of finger blood flow measurement

between the 1st and 2nd seconds of the trace for each measurement location. The line can be repositioned by the user (see 5.4.1. of this manual). The finger blood flow (ml/100 ml/sec) is calculated from the percentage strain and is displayed for each measurement site (Figure 20).

To include the finger blood flow data from the current measurement in the average blood inflow for the run check the **Include in Average** box in the graph window. If the data should not be included in the average uncheck the **Include in average** box. The measurements from each measurement site are averaged and displayed in the test results table in the Test Window.

Click **Start** to run the next FBF measurement in the run. The test can be interrupted at any time, by clicking on **Stop**. By then clicking on **Cancel** the user will required to answer the

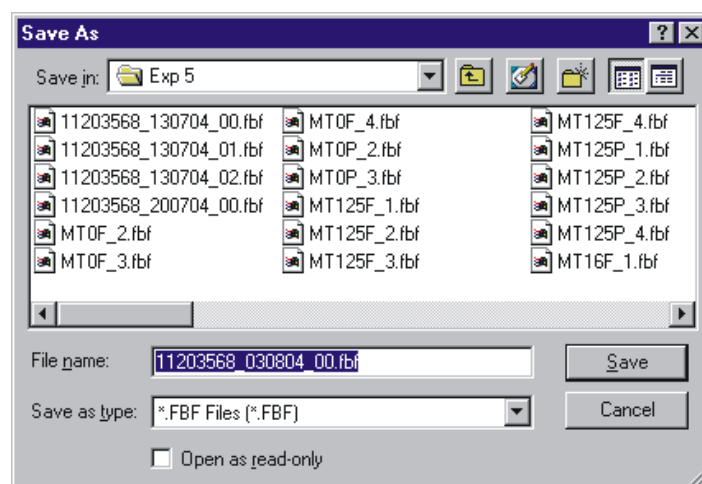


Figure 22. Dialogue for saving finger blood flow data file

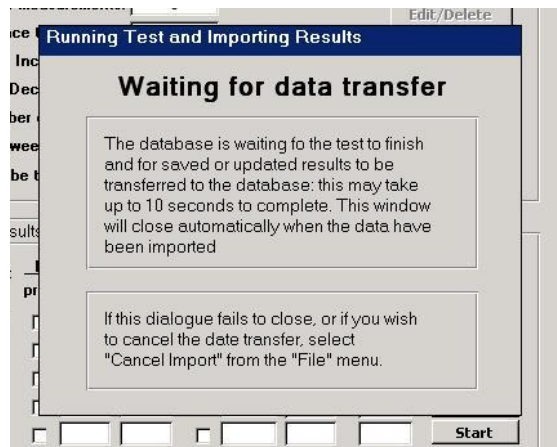


Figure 23 Waiting for data transfer

question 'Are you sure you want to exit without saving? Y/N'. This is to ensure Cancel has not been pressed by mistake.

Once the number of measurements for the run is complete, click **Save** to save the datafile. You will be prompted to save the complete graph as an .fbf file: the software will automatically suggest a filename in the Data folder, but you may choose a different filename and/or location (Figure 22).

5.4.1 The Running Test and Importing Results dialogue

The test results will be transferred automatically to the database and displayed in the relevant fields. The **Running Test and Importing Results** dialogue is shown while the results are being transferred. This process can take several seconds.

If this dialogue fails to close because there was a failure in data transfer or because you cancelled a test, you will need to close the dialogue by selecting **Cancel Import** from the **File** menu on the top left-hand corner.

5.4.2 Repositioning the line cursor

The line cursor can be repositioned immediately after the measurement has been recorded or in View mode. Click once at either end of the line and drag the end of the line to the required point on the trace and release the mouse. Do the same with the other end of the line cursor. Click once away from any trace to clear the cursor. Do this for all traces as necessary. Traces can be individually selected by clicking the matching coloured button in the key. Click on All to see all traces.

N.B. Do not position the cursor so the FBF value is less than 0.01.

5.5 Viewing Previously Collected Test Results

To view the results for a particular subject, ensure that the correct subject is displayed in the **Current Subject** section of the **Control Panel** window. Select **Finger Blood Flow** from the drop down list in the **Diagnostic Tests** box and then click on **View Test Results** to display the **Finger Blood Flow Test** window (Figure 24). This is the same window that was used to launch the measurements, except that the **Start** buttons for each measurement are now replaced by **View** buttons.

If there is more than one test record for the current subject, you can use the **navigation buttons** in the bottom left corner of the screen to scroll to the required record set.

HVLAB Diagnostic Instruments - [Finger Blood Flow Test]

File Edit View Tools Help

Finger Blood Flow Test

Subject Number: 217
Test Number: 817

Subject Details

Surname: Other
Forename: Andrew
Date of Birth: 13/10/1950
Reference No: 11203568
Date of Entry: 31/08/2005

Test Parameters

No. of Runs: 20
No. of Measurement Sites: 5
No. Measurements per Run: 3
Inflation Pressure: 60 mm Hg
Pre-Inflation Time: 0 seconds
Measurement Time: 5 seconds

Test Details

Room temperature: 0 °C
FST (Left): 0 °C
FST (Right): 0 °C
Test Date: 07/12/2005 09:15:12
Tester: Administrator
Data File: G:\HVLW\in620\Data\11203568_071205_03.fbf
Run as a simulation: ☒

Test Results

Average Blood Inflow (%/sec.)

Comments	thumb	index	middle	ring	little	Individual Data
Run 1:	1.300	0.163	0.053	0.684	0.106	View Open
Run 2:						View Open
Run 3:						View Open
Run 4:						View Open
Run 5:						View Open
Run 6:						View Open
Run 7:						View Open
Run 8:						View Open
Run 9:						View Open
Run 10:						View Open
Run 11:						View Open
Run 12:						View Open
Run 13:						View Open

Record: 2 of 4
Form View

Save and Exit Print Record Cancel

Figure 24 Finger Blood Flow Test window opened by “View Test Results” button

Click each **View** button to display the individual finger blood flow graphs for each measurement, which are saved in the **Data File** shown in the **Test Details** section. Click **Individual Measurements** to view the Individual Measurements Window for a particular run.

Traces can be individually viewed by clicking the matching coloured button in the key. Click

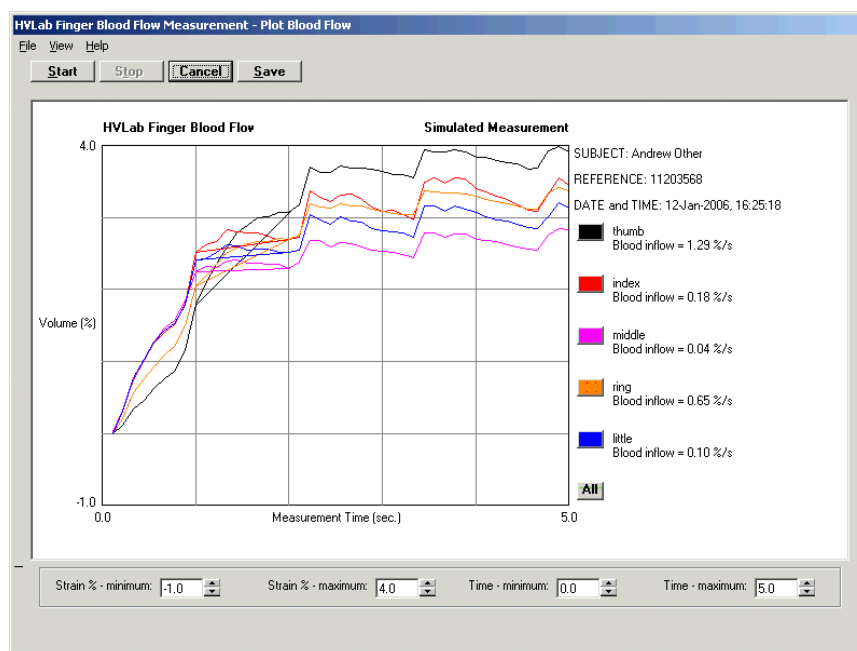


Figure 25 Rescaling controls can be turned on via the “View” menu

on View All to see all traces.

The position of the line cursor can be edited in View mode (see 5.4.2. of this manual). The scaling of the FBF graph (i.e. the x- and y-axis limits) may be adjusted by selecting **Rescale Graph** from the **View Menu**. This replaces the status fields at the bottom of the window by text controls, showing the current axis limits, which can be incremented or decremented by clicking on the associated scroll buttons (Figure 25).

Always click on All to see all traces before Saving or Cancelling. After the finger blood flow graph has been displayed, click **Cancel** to return to the **Finger Blood Flow Test** screen without saving changes. Click Save to save any changes and to update the **Test Results** table in the **Finger Blood Flow Test Window**

5.5.1 Finger Blood Flow - Individual Measurements Window

The Individual Measurements Window (Figure 26) contains a table of the blood flow at each measurement location at each measurement during the run.

If the measurement has been included in the average the **Enabled** box will be checked. To include measurements in the average blood inflow for the run, return to the **Finger Blood Flow Test** window and view the graph of the required measurement. Return to the Finger Blood Flow Test window in View mode by clicking **Close**.

5.5.2 Printing and exporting

The finger blood flow graphs can be printed (to the default printer on your computer), or exported as a bitmap, by selecting **Print Graph** or **Export Graph** from the **File Menu**.

The FBF run averages and individual measurement data may also be exported to a text file by selecting **Export Results** from the **File Menu**.

	thumb	index	middle	ring	little	Enabled
Measurement 1:	1.287	0.133	0.055	0.694	0.124	☒
Measurement 2:						☐
Measurement 3:						☐
Measurement 4:						☐
Measurement 5:						☐
Measurement 6:						☐
Measurement 7:						☐
Measurement 8:						☐
Measurement 9:						☐
Measurement 10:						☐
Measurement 11:						☐
Measurement 12:						☐
Measurement 13:						☐
Measurement 14:						☐
Measurement 15:						☐
Measurement 16:						☐
Measurement 17:						☐

Figure 26 Individual measurements window

6 Maintenance

6.1 Cleaning

The outside case of *HVLab* Multi-Channel Plethysmograph, *HVLab* Multi-Channel Plethysmograph cuffs and *HVLab* Multi-Channel Plethysmograph strain gauges must be cleaned. Table 1 shows the regularity of cleaning required and the cleaning substances to be used.

Table 1 Regularity of cleaning, cleaning substances to be used and member of staff responsible for cleaning

	Regularity of cleaning	Cleaning substances to be used	Member of staff responsible for cleaning
Outside case of <i>HVLab</i> Multi-Channel Plethysmograph	Monthly	Damp cloth with water and fairy liquid detergent	Technician
<i>HVLab</i> Multi-Channel Plethysmograph cuffs	After every use	Alcohol wipe/solution	Technician
<i>HVLab</i> Multi-Channel Plethysmograph strain gauges	After every use	Alcohol wipe/solution	Technician
Isolation Transformer	Monthly	Alcohol wipe/solution	Technician
Computer Interface	Monthly	Alcohol wipe/solution	Technician
USB Isolator	Monthly	Alcohol wipe/solution	Technician

To clean the outside case of the *HVLab* Multi-Channel Plethysmograph dampen a clean cloth with a solution of water and fairy liquid detergent. Wipe all four vertical sides and the top of the *HVLab* Multi-Channel Plethysmograph. Ensure water does not enter the plethysmograph through air vents or transducer sockets.

To clean the *HVLab* Multi-Channel Plethysmograph cuffs use an alcohol wipe to wipe all sides of each plethysmograph cuff used. It is not necessary to dismantle the cuffs nor separate them from the set-up for FSBP or FBF measurement.

Take care when cleaning the *HVLab* Multi-Channel Plethysmograph strain gauges as the silastic loop of the strain gauges that goes round the finger and the link between the silastic loop and the cable is very fragile. Ensure not to over stretch or pull at the fragile silastic loop. Clean each used gauge individually by laying an alcohol wipe flat on a clean surface. Lay the silastic loop of the strain gauge on the alcohol wipe. Fold the alcohol wipe over the gauge so the silastic loop is encased then gently press on the alcohol wipe thereby cleaning the silastic loop and the link between the silastic loop and the cable.

Wipe the length of the cable of each plethysmograph gauge used.

Finger Systolic Blood Pressure Test

Subject Number: 1
Test Number: 144

Subject Details

Surname: Subject
Forename: Test
Date of Birth: 01/01/1960
Reference No: TS1
Date of Entry: 30/08/2005

Test Parameters

Parameter Set Name: Default
Add New
No. of Measurements: 4
No. of Measurement Sites: 5
Inflation Pressure: 250 mm Hg
Deflation Rate: 2.5 mm Hg/second

Test Details

Room temperature: 0 °C
FST (Left): 0 °C
FST (Right): 0 °C
PG Serial No:
Test Date: 30/09/2010 14:03:28
Tester: Administrator
Data File: No file selected
Browse...
Run as a simulation: ☐

Plethysmograph Pressurisation Test

This performs a diagnostic test of the pressurisation system.
Make sure the cuffs are disconnected from the plethysmograph before proceeding with the test.
The pressurisation test may take a few minutes.
Please click OK to proceed, or CANCEL to exit.

	First Stage Amplifier V1 [V]	Second Stage Amplifier V2 [V]	Percentage Change	Gauge Resistance (Ohms)
Target Pressure mmHg	200			
Target Temperature °C	-1.23	0.04	0.42	0.25
A			100.00	0.31
			100.00	0.30
			3.11	0.25
T			-0.19	0.35

Control Word: 00000100
Return Word: 00111110
Pressurisation Test
Exit

Save and Exit Calibration Cancel

Figure 27 Pressurisation Test

6.2 Calibration

All *HVLab* Diagnostic Instruments are calibrated and quality controlled prior to delivery. A full calibration report is attached to this manual as Annexe 1.

It is recommended that the system is re-calibrated by the manufacturer or the manufacturer's agent at 12-monthly intervals and also if the equipment is moved to a new site. Additionally, regular performance checks should be carried out by the user, as described in Section 6.3.

The manufacturer bears no liability for injury to any person resulting from removal of equipment casings. The manufacturer does not guarantee that calibrations carried out by any person other than one designated by the manufacturer will result in satisfactory performance of the system.

6.3 Regular performance checks by the user

During the pressurisation and cooling phase of each test (see Section 4.3) the user should compare the pressure, temperature and flow displays with those displayed on the controlling computer once a week to ensure that there is no discrepancy.

Each day, before the instrument is used, the user should also run a Plethysmograph Pressurisation Test (Figure 27) which performs a diagnostic test of the pressurisation system in the plethysmograph. Please make sure all the cuffs are DISCONNECTED from the

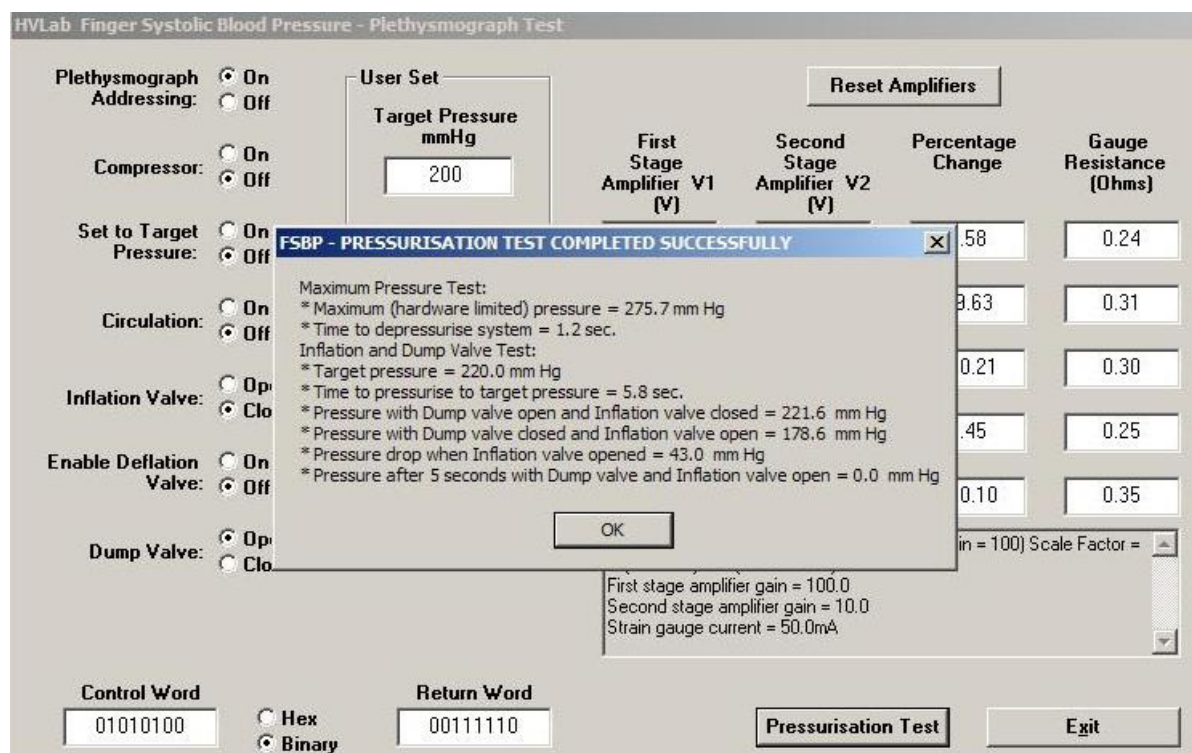


Figure 28 Pressurisation Test Successful

plethysmograph before performing this test to prevent damage to the cuffs. The Plethysmograph Pressurisation Test can be accessed through the Calibration window by clicking on **Calibration** at the bottom of the FSBP Test window and then clicking on **Pressurisation Test** at the bottom right of the Calibration window.

At the end of the Pressurisation Test, the software will inform the user that the test has been completed successfully. However, if the software encountered any errors during this diagnostic test, an error message (e.g. in Figure 29) will pop up informing the user to contact the manufacturer. Please advise the manufacturer of the details in the error message to assist the manufacturer in diagnosing the fault in the Multi-Channel Plethysmograph.

There are no other checks that can be performed by persons other than the manufacturer or manufacturer's agent.

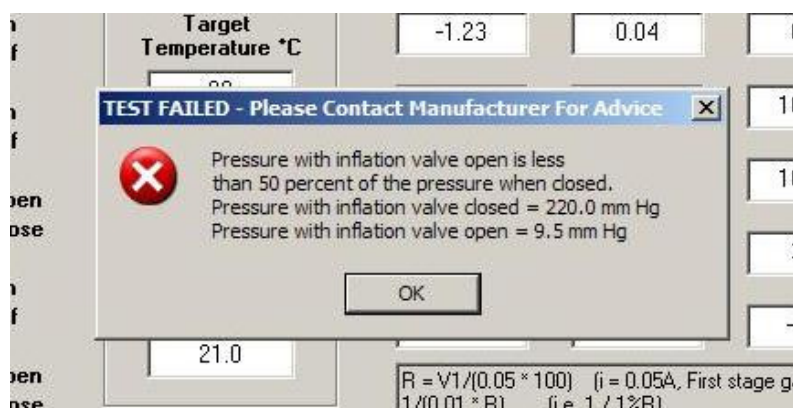


Figure 29 Pressurisation Test Error Message

6.4 Regular preventative inspections by the user

Each day, before the instrument is used, the user should check that water is not leaking from the instrument, or connected cuffs and tubing. Damaged cuffs and tubes should be replaced immediately. None of the red indicator lights next to the strain gauge connectors should be lit: this indicates that the adjacent strain gauge is open-circuit and should be replaced immediately. Also, ensure that the protective earth cable is connected at all times.

6.5 Faults and Repairs

If a fault is detected the user should contact the manufacturer, or the manufacturer's agent, for advice.

There are no parts that can be repaired by the user or user's technical personnel. All repairs must to be performed by the manufacturer or an appointed agent.

7 Warnings and Precautions

7.1 Hardware

7.1.1 Ambient temperature for normal use

Care should be given to avoid an inflow of hot air into the cooling fans of the Multi-Channel Plethysmograph during operation as this will cause the cooling system to excessively strain. For this reason the ambient room temperature for normal use should be between 15°C to 25°C during operation.

7.1.2 Power On and Power Connected light

The Power On and Power Connected light should be illuminated if the plethysmograph is switched on and connected to the mains.

7.1.3 Plethysmograph turned off unexpectedly

If the plethysmograph has been turned off unexpectedly or if there is a system power failure, there will be an error message (Figure 30) informing you that there is residual pressure in the cuffs which will prevent you from being able to remove the cuffs from the subject's fingers. This residual pressure will have to be removed manually. This can be done by first disconnecting the tubes to both the AIR and WATER cuffs from the main unit. Then, open the one-way valves in the connectors by pressing the tube ends inwards to release the pressure. Please take care to contain any water that will spill from the tubes.

Click OK to continue to download the diagnostic information (see 7.2 for further instructions) and contact the manufacturer.

7.1.4 Pressure too high indicator

If the pressure too high light becomes illuminated;

Stop the measurement immediately by clicking **Stop** and **Cancel** in the finger systolic blood pressure measurement window or finger blood flow measurement window. Cancel will dump the pressure. Remove the cuffs from the patient and switch off machine and mains power supply.

Please contact the manufacturer by telephone on +44 (0) 2380 592277



Figure 30 Plethysmograph Fault Detected Message

7.1.5 Temperature too high indicator

If the temperature too high light becomes illuminated stop the measurement immediately by clicking **Stop** and **Cancel** in the finger systolic blood pressure measurement window. Cancel will dump the pressure. Remove the cuffs from the patient and switch off machine and mains power supply.

Please contact the manufacturer by telephone on +44 (0) 2380 592277

7.1.6 Temperature too low indicator

If the temperature too low light becomes illuminated stop the measurement immediately by clicking **Stop** and **Cancel** in the finger systolic blood pressure measurement window. Cancel will dump the pressure. Remove the cuffs from the patient and switch off machine and mains power supply.

Please contact the manufacturer by telephone on +44 (0) 2380 592277

7.1.7 Bypass operational indicator

The bypass is open and the light will be illuminated until pressurisation. If the bypass light becomes illuminated during pressurisation a circulation failure may have occurred. Complete procedures in section 7.1.5.

If there is no circulation failure stop the measurement immediately by clicking **Stop** and **Cancel** in the finger systolic blood pressure measurement window. Cancel will dump the pressure. Remove the cuffs from the patient and switch off machine and mains power supply.

Please contact the manufacturer by telephone on +44 (0) 2380 592277

7.1.8 Circulation Failure indicator

Check the tubing between the pressure cuffs is not kinked and is stopping the flow. Give the tubing a wiggle to dislodge any air bubbles.

Press the circulation failure button on the front of the Multi-Channel Plethysmograph. This can be pressed repeatedly.

If the circulation does not restart, stop the measurement immediately by clicking **Stop** and **Cancel** in the finger systolic blood pressure measurement window. Cancel will dump the pressure. Remove the cuffs from the patient and switch off machine and mains power supply.

Please contact the manufacturer by telephone on +44 (0) 2380 592277

7.1.9 Water minimum and maximum indicators

The water level should be illuminated up to a maximum of 5 green lights. The minimum water level for finger systolic blood pressure testing is 2 green lights. If only one water level light is illuminated green then operating the device may cause damage as this is below the minimum water level. The top light should remain amber as this is above the maximum level.

If less than 2 lights are illuminated green add water using the **Fill** socket on the front of the Multi-Channel Plethysmograph. If the maximum light is green drain some water to the recommended level by using the **Fill** socket as well.

7.1.10 Re-settable fuses

If a mains surge greater than 10 Amps has occurred, the re-settable fuses will unseat. Switch off the Multi-Channel Plethysmograph and the mains power supply.

Please contact the manufacturer by telephone on +44 (0) 2380 592277



Figure 31 Plethysmograph Fault Detected Message

7.1.11 Protective earth lead

The protective earth lead must be connected at all times for conformance with EN 60601-1.

7.1.12 Strain gauge warning indicators

The strain gauge indicators illuminate if a strain gauge has become faulty. Remove the strain gauge from the patient as soon as possible. For spillages of mercury and disposal of strain gauges refer to section 7.3.

7.2 Software

During the test, please contact the manufacturer if the software produces any error messages (e.g. Figure 31). Please take note of the details of the error message and then click OK to display and download diagnostic information.

The Diagnostic Information window (Figure 32) will open and contain information on the status of the plethysmograph prior to the fault occurring. Click **Save to Clipboard** to copy all the information provided and then paste this information into a text document e.g. Notepad in

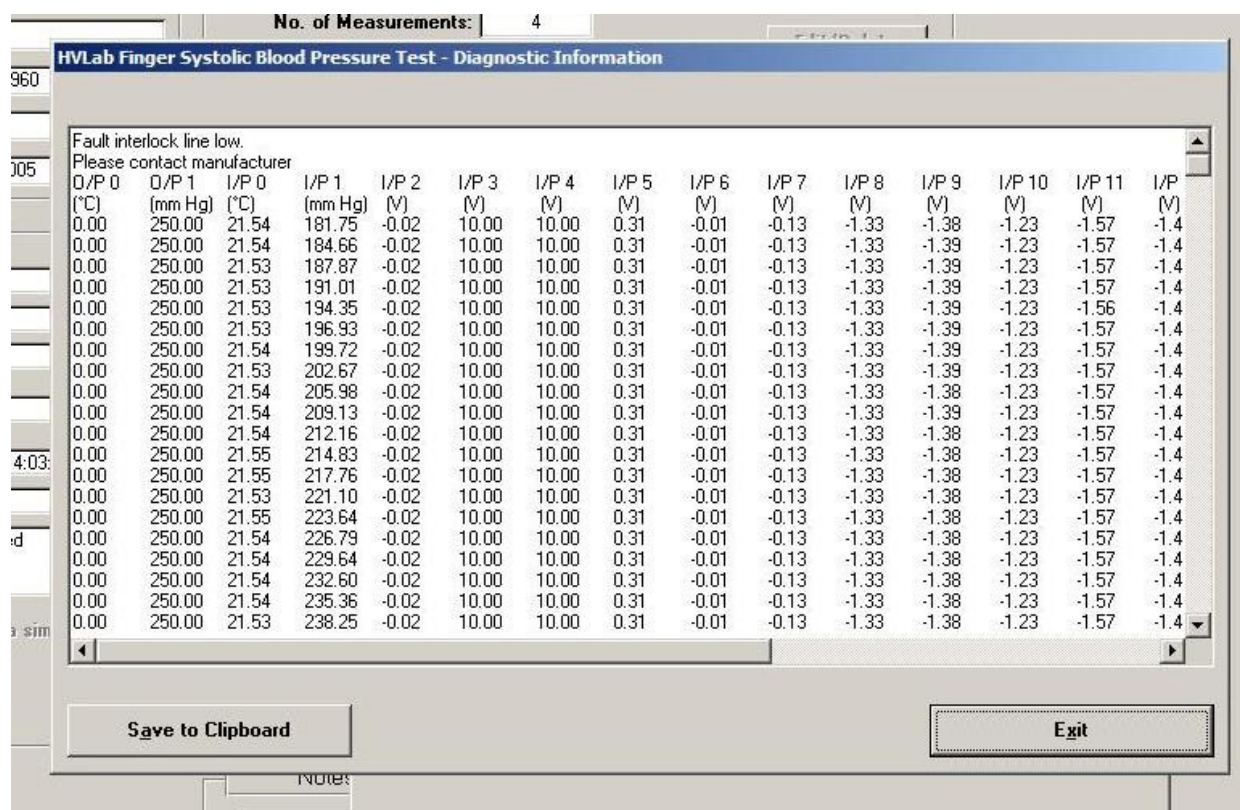


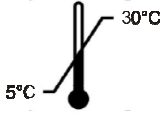
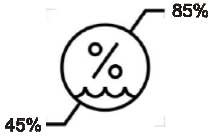
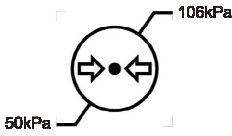
Figure 32 Diagnostic Information Window

Windows OS. Please provide this document to the manufacturer to assist in diagnosing the fault with your Multi-Channel Plethysmograph.

7.3 Handling and Storage

7.3.1 Multi-Channel Plethysmograph

Environmental conditions for transport and storage for the Multi-Channel Plethysmograph are as follows:

Temperature range	5°C to 30°C	
Humidity range	45% to 85%	
Atmospheric pressure range	50kPa to 106kPa	

During transport, the plethysmograph must be kept upright at all time. The plethysmograph contains fragile glass components fragile on the inside and should not be exposed to any shocks or excessive vibrations.

Always drain the water from the plethysmograph prior to moving.

When not in use the Multi-Channel Plethysmograph should be switched off using the power button on the front panel. This will also remove power to the strain gauges. The mains supply to the transformer should also be switched off.

The Multi-Channel Plethysmograph can be left connected to the computer or the distribution box whilst not in use. It is preferred that the connection between the Multi-Channel Plethysmograph, the distribution box and the PC is disturbed as little as possible as this may cause damage to the connections.

Care should be given to the handling of the Multi-Channel Plethysmograph at all times.

7.3.2 Accessories

Strain gauges are very fragile. Ensure not to over stretch or pull at the fragile silastic loop or the link between the silastic loop and the cable during use. If the strain gauge is indenting the finger it will be overstretched and could damage the gauge and will restrict the blood supply. Strain gauges should be stored in a fridge after use.

The pressure cuffs should not be over-inflated as this will cause them to burst. Prior to testing check the gauge is not too loose for the finger. **Never** inflate the cuffs when they are not surrounding a finger/cylindrical object of appropriate finger width.

After use, pressure cuffs should be disconnected from the Multi-Channel Plethysmograph and emptied of water.

7.4 Disposal of accessories

Strain gauges contain mercury, which is a hazardous substance. Dispose according to local environmental health guidelines.

In the event of a spillage remove the strain gauge from the finger and place broken component into a sealable plastic bag, and sweep the spilled mercury into the same bag.

Handle the mercury carefully. Wear rubber gloves and scoop it onto a sheet of paper or suck it up with an eyedropper. The scoop, paper or eyedropper should also be bagged and disposed properly according to guidance provided by environmental officials or your local health department. If possible, ventilate the room to the outside and use fans for a minimum of one hour to speed the ventilation.

Wash the patient's and the operator's hands thoroughly with soap and water.

Pressure cuffs contain latex however under normal use the latex does not come into contact with the skin of the patient or operator. In the even of a breakage remove the pressure cuff from the finger and dispose according to local environmental health guidelines.

7.5 Precautions and contra-indications

Please ensure that before the Multi-Channel Plethysmograph is used on patients:

The Multi-Channel Plethysmograph is calibrated to the required standard and is functioning correctly (see section 6.2)

There is no obvious damage to the device, the strain gauges or pressure cuffs.

The additional protective earth terminal should be connected to earth via a mains power socket, or a permanently connected protective earth conductor.

Patients must complete a medical questionnaire prior to testing to ensure they do not have a medical condition that could be aggravated by cold provocation e.g. cardiovascular problems. Seek medical advice before commencing the test if necessary.

7.6 Obtaining reliable measurements

In order to obtain repeatable measurements of finger systolic blood pressure and finger blood flow, attention should be given to various factors, these include:

7.6.1 *USB2527 Computer Interface*

If the USB2527 Computer Interface has been disconnected from the computer, please check that the interface settings are correct (see Annex A).

7.6.2 *Finger skin temperature*

Finger skin temperatures at the measurement locations should not be below 22° C.

7.6.3 *Previous exposure to vibration*

Exposure to vibration immediately prior to measurement of FSBP or FBF measurement might result in a temporary vasoconstriction.

7.6.4 *Previous exposure to extremes of temperature*

The subject should be allowed to acclimatise to the temperature of the room for a suitable amount of time before testing to ensure thermal equilibrium.

7.6.5 *Previous exposure to vaso-active substances and alcohol*

Exposure to vaso-active substances e.g. caffeine, medication might result in temporary vasoconstriction.

7.6.6 *Room temperature*

The diagnostic tests should be performed in a room temperature of 21 ± 1° C. For the FBF test, in summer it may be necessary to increase the room temperature to the external

temperature to avoid vasoconstriction. The subject should not be exposed to perceptible air movement.

7.6.7 Posture

It is recommended that the hand is supported at the height of the heart to avoid pooling of the blood in the fingers. This is most easily achieved by the subject being supine or seated.

If measuring on both hands ensure both hands and the arm if necessary are supported. Moving the height of the hand relative to the heart can affect the blood flow reading – this can be a way of improving the quality of the blood flow measurement.

7.6.8 Size of strain gauges and pressure cuffs

Ensure that the strain gauges do not overly indent the finger as this can restrict blood flow. If the strain gauges are too loose small increases in strain will not be measured.

Pressure cuffs should not be too tight or the blood supply could be restricted. If pressure cuffs are too loose the required inflation pressure may not be achieved and the cuffs may burst.

7.6.9 Position of strain gauges

Ensure that the strain gauges are not resting on the tubing that links the pressure cuffs as this can cause the strain gauges to move when the cuffs are inflated.

For FBF measurement a good guide is to take a few readings prior to testing to ensure that the gauges are giving consistent measurements. Moving the location of the cuff and the gauge on the finger can give better more reliable results.

7.6.10 Instructions to subjects

All subjects should be given a medical questionnaire prior to testing to check for contraindications. All subjects should be given a set of written instructions so they are aware of what the test involves. The subject should be informed that the strain gauges are very sensitive to movement and that moving the fingers during a measurement will cause the strain gauges to give a random signal and make the graph impossible to read.

8 Spares and ancillary services

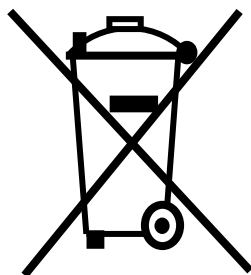
The following accessories are available from the manufacturer. Please refer to the contact details at the beginning of this guide. If you wish to replace or have spares of a specific component, please contact us and we will endeavour to help you.

- Strain gauges
- Pressure cuffs
- Sealed cuff connectors
- Tubing

We can also provide training, calibration and auditing of the operation of all diagnostic instruments. Please contact the manufacturer for a quotation.

9 Disposal

9.1 Information on Disposal for Users of Waste Electrical & Electronic Equipment (excluding private households)



Used electrical and electronic products must not be mixed with general waste.

Disposing of this product correctly will save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling if you are unsure of your national requirements with respect to disposal. Please contact your local authority, dealer or supplier for further information.

Penalties may be applicable for incorrect disposal of this waste, in accordance with national legislation.

The above information is based on the European waste electrical and electronic equipment directive 2002/96/EC

9.2 Information on disposal in other countries outside the European Union

This information is only valid in the European Union. If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

10 Troubleshooting guide

Problem	Possible Cause	Solution
No Power	The AC power lead has become disconnected from the plethysmograph There is no mains power supply to the control box	Check that the AC power lead is connected to the plethysmograph and that the power supply is connected to the mains.
The water level gradually drops during a test	Leaking cuff	Stop the test, identify the leaking cuff and replace.
The air pressure gradually reduces during occlusion	Leaking cuff.	Stop the test, identify the leaking cuff and replace.
The flow suddenly drops	Water or air tubes are kinked. There is an air bubble in the system.	Check the tubing for kinks. Wiggle the tubing to dislodge air bubbles.
The water temperature is not reached	Overheating. Fault with cooling mechanism	Check the fans are not covered. Remove any possible heat sources.
One measurement site gives a straight line response or no response.	K-type thermocouple is not connected K-type thermocouple is faulty	Check that you have connected a k-type thermocouple to the front of the control box Replace with a spare thermocouple if necessary
I get a message saying "Plethysmograph is not responding"	The plethysmograph is not switched on. The power supply is not connected. The computer interface cables are damaged.	Check the plethysmograph is switched on and that the power supply is connected to the plethysmograph and the mains. Check the computer interface cable connections at the plethysmograph and the computer.
Cuffs do not deflate	Dump Valve problem	Open to Calibrate screen and click on Dump Valve Off, this will Open the dump valve and release the pressure. Click again to close the dump valve.

If any of the above suggestions do not solve your problem, please contact the manufacturer by telephone on +44 (0) 2380 592277.

11 Explanation of terms

Finger systolic blood pressure: The arterial blood pressure in the finger.

Finger systolic blood pressure measurement: The measurement of finger systolic blood pressure following arterial occlusion at one provocation temperature

Finger systolic blood pressure test: A set of finger systolic blood pressure measurements

FSBP Record: Finger systolic blood pressure test completed on a subject on a particular date stored in the HVLab Diagnostic Instruments Manager software.

Cooling: Temperature provocation of the fingers with pressurised cuffs

Finger blood flow: The rate of arterial inflow in the finger

Measurement: The measurement of arterial inflow in the finger following venous occlusion.

Run: A set of finger blood flow measurements that have had some measurements used to for the calculation of average finger blood flow.

FBF Record: A set of FBF runs completed on a subject on a particular date stored in the HVLab Diagnostic Instruments Manager software

12 Symbols used in labels and instructions on the HVLab Multi-channel Plethysmograph and accessories



Attention, consult accompanying documents for important information



Consult instructions for use for information



Type BF Applied Parts (Meets Type BF leakage current requirements of Clause 19 of IEC 60601-1)



Protective Earth



Alternating Current



Direct Current



Temperature limitation



Humidity limitation



Atmospheric pressure limitation



Year of manufacture

13 CE Declaration of Conformity

**Declaration of Conformity to the
Medical Device Directive 93/42 EEC as amended 2007/47/EC
for *HVLab* Diagnostic Instruments**

Comprising:

- **Vibrotactile Perception Meter**
- **Thermal Aesthesiometer**
- **Multi-Channel Plethysmograph**

This is to certify that the class IIa equipment specified above conforms to the above Directives as transposed into national regulations and statutes of the United Kingdom, such compliance having been demonstrated via:

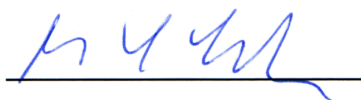
- A Technical File compliant to Annex VI
- Compliance to the Essential Requirements
- Quality Assurance procedures in accordance with BS EN ISO13485
- Compliance to Annex VI and VII Product Quality Assurance

The CE marking of product being subject to the achievement and maintenance of a Annex VI certification by British Standards Institution Notified Body Number 0086 located at Maylands Avenue, Hemel Hempstead, HP2 4SQ.

The devices do not include animal or human tissue or derivatives, blood products, products that would be considered to be medicinal products or phthalates as defined in annex I clause 7.5 nor are such materials used during their manufacture

This is to certify that the above statement is true and relates to product manufactured from this date.

Signed:



Name: Professor M J Griffin

Position: General Manager

Date: 30th June 2010

for and on behalf of the Human Factors Research Unit, being a duly authorised officer of the company.

Human Factors Research Unit

Institute of Sound and Vibration Research, University of Southampton, Highfield Campus, Southampton
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Annexe A Installation of the USB-2527 computer interface

A PC which is to be connected to one or more *HVLab* Diagnostic Instruments must first be installed with a USB-2527 computer interface board according to the instructions below.

- (i) Put the **Measurement Computing** CD supplied with the **USB-2527** interface into your CD-ROM drive. The installation process should start automatically. Uncheck all boxes (TracerDaq, DirectX, Hardware Manuals and Microsoft .NET framework) **except InstaCal and Universal Library**. Follow through the installation. Click **Yes** when you are prompted to restart your computer.
- (ii) Connect the USB-2527 to a USB2 port on your computer. **Do Not** connect the USB-2527 until the **InstaCal** software has been successfully installed.
- (iii) When you first connect the USB-2527, Windows will launch the 'Found New Hardware Wizard'. Select **No, not this time** when asked if you want to "connect to Windows Update to search for software" and click on Next. Then click on **Install the software automatically** when Windows detects the **MCC USB2 Loader Device**.
- (iv) After clicking **Finish**, Windows will again launch the 'Found New Hardware Wizard'. Select **No, not this time** when asked if you want to "connect to Windows Update to search for software" and click on Next. Then click on **Install the software automatically** when Windows detects the **USB-2527**. After installing the USB-2527, click **Yes** when Windows prompts you to restart your computer.
- (v) After installing the USB-2527, run the **InstaCal** programme by clicking on the shortcut in **Start\Programs\MeasurementComputing** (it is recommended that the InstaCal shortcut be copied to the desktop for easy access) to configure and self-calibrate the analogue inputs and outputs. **InstaCal** should automatically detect and list the **USB-2527** on the USB bus. Make sure that USB-2527 is checked and click OK to continue. To work with *HVLab* software the **USB-2527** board number must be designated as **Board#0** (i.e. board zero). If you find that another board (e.g. a Demo Board) is currently board zero, then right-click on this board and select **Remove Board** to delete it. Right-click on the **USB-2527**, select **Change Board#** and select board zero.
- (vi) Make sure your **USB-2527** is configured for 16 Single Ended analogue input channels. Click on the **USB-2527** to highlight it, then right-click on this and select **Configure**. Check that **No. of Channels = "16 Single Ended"**.
- (vii) After installing and configuring your **USB-2527** interface, you will need to calibrate the analogue inputs. Make sure nothing else is connected to your board during the calibration. Click on your **USB-2527** to highlight it, then click on **A/D** button to self-calibrate the analogue inputs. Click on **Calibrate** and then OK when calibration is complete. This procedure should not need to be repeated unless the board is replaced or moved. The USB-2527 is now ready to be used.
- (viii) The **USB-2527** should always be connected to the **same port** that it was installed to. If it is moved to another USB port on the same computer the **InstaCal** and *HVLab* software will not be able to find the interface unless it is re-installed and re-configured. You will need to follow steps 3 to 7 to reinstall the interface again.

Annexe B Installing and setting up the software

B.1 Software installation options

Before performing the installation of the software, decide whether you want to perform:

- A **new** installation – this would mean that the PC has never been installed with the *HVLab* Diagnostic Instruments Manager software. This is explained in Section B.2.
- An installation on a **distributed network** – this means that you would be able to perform different tests and view the test results with the same database using separate computers which work over a network. This is explained in Section B.3.

B.2 Performing a new installation

- (i) The **USB-2527** interface supplied with your system should be installed before the *HVLab* software (please refer to Annex A Interface board installation).
- (ii) The *HVLab* Diagnostic Instruments Manager stores test and questionnaire data in a MS ACCESS database. MS ACCESS 2003 can be installed on your computer, but it is not needed to run the *HVLab* software. However, all earlier versions of MS ACCESS are not compatible with *HVLab* and must be removed.
- (iii) Some computers with P4 processors are capable of “**HyperThreading** Technology”. HyperThreading is not compatible with *HVLab* software and must be disabled in the computer’s BIOS setup program.
- (iv) Close any Windows programs that are running.
- (v) Put the installation CD into your CD-ROM drive (Assumed to be drive D:).
Note: If your CD-ROM drive is not drive D: or if you are installing from a network drive, then replace D: in the following with the drive letter corresponding to your installation drive.
- (vi) If the installation process does not start automatically, select ‘**Run**’ from the *Microsoft Start Menu*. This will open the **Run** dialogue window. Enter **D:\Setup.Exe** then click on OK.
- (vii) Follow through the installation. When choosing the setup type, it is recommended that you choose a ‘**Typical**’ installation. By default, the software will be installed into **C:\My Documents\HVLwin84** for version 8.4. Choose a ‘Custom’ installation if you want to install *HVLab* into a different directory. After clicking **Finish**, the *HVLab* Diagnostic Instruments Manager is ready to be used.
- (viii) To be able to access the *HELP* documents from the *HVLab* software you will need to install Acrobat Reader (version 6.0 or above) on your computer. If you do not already have it, you can install Acrobat Reader from the CD by running **D:\Acrobat Reader\AdbeRdr910_en_US_Std.exe** from the **Run** dialogue or using Windows Explorer.
- (ix) Start the *HVLab* software by selecting **HVLab diagnostic instruments** from the **Start/Programs** menu or by clicking on the **HVLab diagnostic instruments** icon on the desktop.
- (x) When the software is launched for the first time, Windows may display a security warning asking if you want to block unsafe expressions: you should always click on **Yes**. You may then be asked to restart the application.

- (xi) Windows may then display another security warning stating *"This file has been digitally signed by HVLab ... This publisher has not been authenticated ..."*. To prevent recurrences of this warning you should install a digital certificate by clicking on **Details**. Click on **View Certificate** in the **Digital Signature Details** dialogue, then on **Install Certificate** in the **Certificate Information** dialogue. This will launch the **Certificate Import Wizard**. Accept all the default options and click **Yes** to confirm that you want to *"...install the certificate from a certification authority claiming to represent HVLab"*. Close the **Digital Signature Details** dialogue and the **Certificate Information** dialogue so as to return to the original security warning.
- (xii) At this point, you might or might not have the option to check the box for **'Always trust files from this publisher...'**. If you do have the option, check the box and click on **Open** to launch the *HVLab* software. If you don't have the option, then you will have this option when you launch the *HVLab* software the second time. If you do not check the box, then Windows will always prompt you every time you launch the software.
- (xiii) You will be required to enter a valid User ID and Password: the default **Personal ID** is **"admin"** with **Password "hvlab"**. Additional users can be added or deleted after the software has been successfully set up (see *HVLab* Diagnostic Instruments Manager Database User Manual for further details).
- (xiv) Click on **Continue**. The first time that the software is run, the location of all the software components will be automatically detected and displayed in the **Database Components** window. The default location for all the components is in **(InstallPath)** and **(InstallPath)\Data** where **(InstallPath)** is the folder into which the software was installed, which defaults to **C:\My Documents\HVLwin84** for version 8.4. It is possible to move the database components to a different location, such as the data folders to a folder on a shared network drive (see *HVLab* Diagnostic Instruments Manager Database User Manual for further details).
- (xv) Scroll down the **Database Components** window until you see the **Available Tests and Health Surveillance Questionnaires** table and make sure that the boxes in the **Enabled** column are checked for all the tests or questionnaires which you want to be available on your computer. An appropriate instrument should be selected in the **Instrument** column for each test that has been enabled. Make sure that the serial numbers of each instrument connected to your computer are entered in the **Serial No.** column. The **Interface** column should be set to **MCC** for each of these instruments. Tests for which you do not have the necessary instrument hardware connected can be run in simulation mode (check the boxes for these tests in the **Simulation** column) or they can be left unchecked.
- (xvi) When you are satisfied that all the components are located correctly, click on **'Save'**. This will link the database program to the tables and open the main **Control Panel** window.

B.3 Performing an installation over a distributed network

- (i) Before launching the database on any of the computers it is necessary to create a common database table on the network. On one computer only, locate the **Data** folder in the folder into which the *HVLab* Diagnostic Instruments Manager software was just installed. Copy this folder to a location on the network that can be accessed by all the test computers. Please note that all the computers which need to use the database over a network must have full-access rights to this location on the network.

- (ii) Start the *HVLab* software on each computer by selecting **HVLab Diagnostic Instruments** from the **Start/Programs** menu or from the desktop. You will be required to enter a valid User ID and Password: the default Personal ID is “**Admin**” with Password “**hvlab**”. Additional users can be added or deleted after the software has been successfully set up (see *HVLab Diagnostic Instruments Manager Database User Manual* for further details).
- (iii) The first time that the software is launched on each computer, the location of all the software components will be automatically detected and displayed in the **Database Components** window. The default location for the file containing the data tables - **HVLab_di_tables.mdb** - is **(InstallPath)\Data** where **(InstallPath)** is the folder into which the software was installed, which defaults to **C:\My Documents\HVLwin84 for version 8.4**. Use the browse button to the right of the displayed data path to find the copy of the data tables that have been moved to the network (see (ii), above). The five data folders for the individual test data should also be relocated to the data folder on the network (see *HVLab Diagnostic Instruments Manager Database User Manual* for further details).
- (iv) Scroll down the **Database Components** window until you see the **Available Tests and Health Surveillance Questionnaires** table and make sure that the boxes in the **Enabled** column are checked for all the tests or questionnaires which you want to be available on your computer. An appropriate instrument should be selected in the **Instrument** column for each test that has been enabled. Make sure that the serial numbers of each instrument connected to your computer are entered in the **Serial No.** column. The **Interface** column should be set to **MCC** for each of these instruments. Tests for which you do not have the necessary instrument hardware connected can be run in simulation mode (check the boxes for these tests in the **Simulation** column) or they can be left unchecked.
- (v) When you are satisfied that all the components, tests and boards have been specified correctly, click on ‘**Save**’. This will link the database program to the tables and open the main **Control Panel** window.