

VICORDER

Instructions for Use

Issue 5.0

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The Vicorder



The Vicorder instrument is a Medical Device intended for the investigation of vascular disorders by allowing a simple to operate handheld box to be used with common Laptop PC's via a USB link. The Laptop will run the Vicorder software. All immediate functional controls are available as buttons on the instrument case to provide a powerful easy to use package which is light in weight and can therefore be easily transported.

The Vicorder provides two blood pressure measurement channels and two Photoplethysmography (PPG) channels for the measurement of blood flow. There is also provision for a stereo audio input for connection of a proprietary instrument.

The electronics are housed within an aluminium box, which may be hand held, with front panel pneumatic and PPG connectors, rear panel USB socket and Stereo Audio socket plus top panel User controls.

Various haemodynamic parameters may be measured by using one of the many protocols available. The reports may be stored, printed or electronically communicated. The stored reports may also be reviewed and manipulated post Patient examination.

The Vicorder is intended to run under the control of the Vicorder software. The Vicorder software is run from a User supplied Laptop PC. The Laptop PC also provides power and communicates with the Vicorder via a USB link.

Features

Top panel 7 buttons for User "immediate" controls.

Two front panel PPG sockets to connect to Skidmore Medical PPG sensors.

Two front panel Pressure connectors to connect to proprietary blood pressure cuffs via pneumatic hoses.

Rear panel USB cable connector via an 8 way Lemo connector.

Rear panel Stereo Audio input via an RJ11 connector.

The Vicorder draws its power requirements from the Laptop USB 5V DC supply.

The Vicorder must be connected to the Laptop to enable the User software to be loaded and to control and gather Patient physiological data. Patient files may subsequently be re-examined and manipulated without the Vicorder connected.

Note

The recorded data used in the screen shots throughout these Instructions for Use is for illustration purposes only and is not necessarily indicative of what might be expected under examination conditions.

2. SAFETY CONSIDERATIONS

The Patient environment

Observe National or local regulations regarding the use of Laptop PC's in the Patient environment.

Warnings or contra-indications

- When using the Neckpad or other cuffs the Patient should be advised that a mild constriction will be felt when they inflate.
- There are no other special pre-warnings or contra-indications which need Patient explanation.

Pressure settings

- The Pressure screens have a preset pressure included, Users may alter this at their discretion.
- The maximum settable pressure is 200mmHg.
- There is precautionary software overpressure protection, in the event of operation a warning message is displayed.
- There is further hardware overpressure protection, if this operates the Vicorder system will be locked out and it will be necessary to restart your Laptop PC / Vicorder.
- On operation of either overpressure device the cuffs will automatically deflate and the pump will stop.
- If the cuffs do not automatically deflate unplug the pneumatic cuff connectors.
- If either overpressure device operates and there is not an obvious reason it is advisable to have the equipment examined, see section 29. Cleaning, Calibration and Service.

Safe use of Ultrasound

Although the Vicorder exerts no controlling influence over Ultrasound levels Users are reminded when using Doppler Ultrasound monitoring equipment plugged into the Auxiliary Stereo input to follow the ALARP (As Low As Reasonably Practicable) principle for Ultrasound power output.

Latex

Certain cuffs use Latex in their construction, contact with the active area is intended to be transient as defined in the MDD 93/42/EEC.

3. PACKAGE CONTENTS

Hardware

- Vicorder Instrument
- USB lead, 8 way to twin USB A types
- 2 Pressure cuffs and associated hoses
- 2 PPG sensors
- 5MHz and 8MHz Doppler probes plus lead
- Instructions for Use, paper copy (if requested)

CD

- Vicorder software on CD
- Instructions for Use included on the CD in .pdf

You will need

- Laptop or PC meeting the Minimum System Requirements given in Section 4.

4. MINIMUM SYSTEM REQUIREMENTS

The minimum system requirements to run the Vicorder software satisfactorily are :

Microsoft Windows 2000 with SP2 or higher, Windows XP with SP1 or higher :

- Computer : 1.2GHz Intel Pentium 4 or AMD equivalent processor.
- Memory : The Vicorder software requires 256 MB of RAM.
- Controls : Keyboard and mouse.
- Drives : Hard drive with 100 MB of free space, a 4x or faster CD-ROM drive are required for installation.
- Video : DirectX 9.0c-compatible 64 MB video card.
- DirectX : DirectX version 9.0c or higher.
- Sound : 16-bit sound device.

Recommended System Requirements :

- Computer : 1.7GHz Intel Pentium 4 or AMD equivalent processor or better.
- Memory : 512 MB of RAM.
- Video : DirectX 9.0c-compatible 64 MB video card.
- Sound : 16-bit sound device.

Vista :

- Computer : 2.0GHz Intel Pentium 4 or AMD equivalent processor.
- Memory : The Vicorder software requires 512 MB of RAM.
- Controls : Keyboard and mouse.
- Drives : Hard drive with 100 MB of free space, a 4x or faster CD-ROM drive are required for installation.
- Video : DirectX 9.0c-compatible 64 MB video card.
- DirectX : DirectX version 9.0c or higher.
- Sound : 16-bit sound device.

Recommended System Requirements :

- Computer : 2.0GHz Intel Pentium 4 or AMD equivalent processor or better.
- Memory : 1GB of RAM.
- Video : DirectX 9.0c-compatible 64 MB video card.
- Sound : 16-bit sound device.

Notes :

If your Laptop or PC has the minimum memory size fitted it is recommended that prior to running the Vicorder software any other open applications are closed otherwise some display latency may be observed.

Do not connect the Vicorder to your Laptop PC via a hub.

Installation

Note : as a precaution it is recommended that any existing Patient Files are backed up prior to installation.

Any previously installed version of the Vicorder software will be overwritten (excluding Patient Files).

If installing over an older version

Back up any existing Patient Files. If you have previously used the default install setup then your data files will be found in :

C:/Program Files/Skidmore Medical/DopStudio/Data

The entire data folder contents may be saved, copied and pasted into your new setup.

For a clean install, uninstall the previous version using the “add/remove software” tool in the Control Panel and delete the “Skidmore Medical” folder from the “Program Files” directory.

Program installation

Note : the Vicorder must be connected to the Laptop via its USB lead to enable the program to be installed, connect as follows :



1. Plug the USB Cable bifurcated end into any two free USB ports on your Laptop or PC. Important : Do not connect the Vicorder to your Laptop or PC via a hub.



2. Plug the other end of the USB cable into the 8 way socket on the rear panel of the Vicorder. After a short pause the blue power LED on the front panel will light.

Web based version

Full instructions are included as part of the download.

CD based version

1. Close any open applications. Place the CD in the CD drive and close the tray, the system will auto start the CD load.
2. Follow the on-screen prompts, during installation you will be prompted to make selections or to input information, defaults are provided in some cases which can be accepted or changed as required.

Both versions

The Vicorder software may be activated by double clicking on the Vicorder icon in the Control Panel or by launching it from the Start menu.

It is recommended that your computer is backed up to a secure source on a regular basis.

Hardware setup

Vicorder Top and Front Panel User functions



Connecting the Vicorder :

1. Connect the USB Cable to your Laptop or PC per 1 and 2 of the Program Installation in section 5.
2. Connect the 2 colour coded pneumatic hoses to Press1 and Press2 on the Vicorder front panel.
3. Connect the 2 colour coded PPG connectors to PPG1 and PPG2 on the Vicorder front panel.
4. The Auxiliary Stereo input on the rear panel enables an external audio device to be connected, which may also be powered from the Vicorder.

The RJ11 connections and basic specification are :

Pin 1	Right audio input	} sensitivity 100mV } bandwidth 240 to 7500Hz (-3dB)
Pin 3	Left audio input	
Pin 2	Ground	
Pin 4	6.5V DC output	75mA maximum current

5. The Vicorder software may be activated by double clicking on the Vicorder icon in the Control Panel or by launching it from the Start menu.

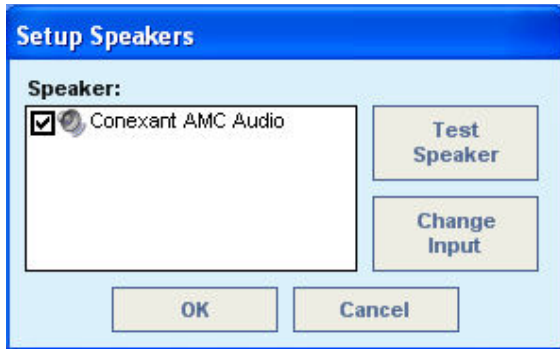
It is recommended that your computer is backed up to a secure source on a regular basis.

Audio setup

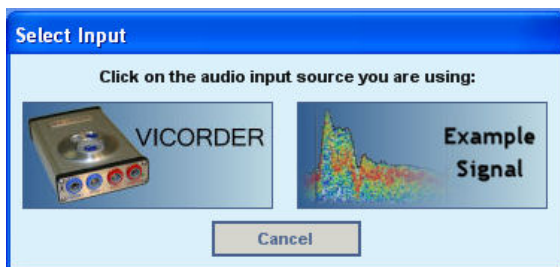
On first start up or after changing the audio device an audio configuration dialogue box will appear.

Before clicking on ok ensure the sound on your Laptop is enabled and the volume level set approximately mid scale.

Click on Config , the Setup Speakers menu will appear which will enable you check the speaker connection or to change the input to sample sounds :

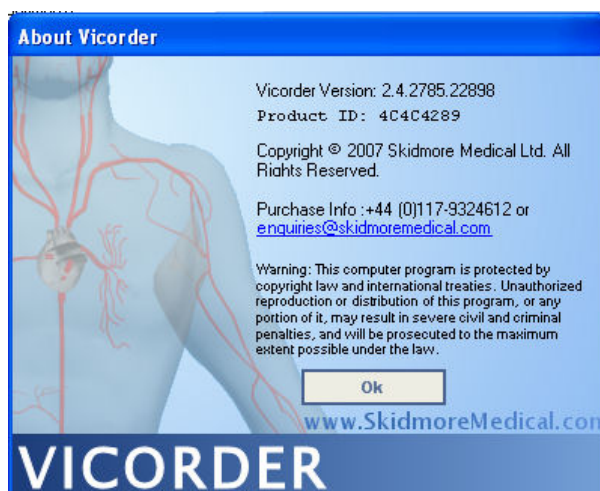


Using Example Signals



1. Full instruction on the use of the various protocols is contained within these Instructions for Use.
2. Open the required protocol and click on the highlighted site to open the acquire screen.
3. Click on Config and select Speaker Setup from the drop down menu.
4. Click on Change Input and select Example Signal and follow the on screen instructions.
5. Sample sound should be heard over the Laptop speakers which will repeat until Freeze is selected or the acquire window is closed.
6. These sample signals may be saved and manipulated as described within these Instructions for Use.

6. VICORDER INFORMATION



Vicorder information

Clicking on Help and About will bring up the Vicorder information window. Here you can view your product id which is unique to your computer and the version number of the software installed.

Section 30 has Helpline contact information.

Navigation and setting

Navigate and set within the screens :

Screen buttons

To move left / right use the Laptop left / right arrow keys or the Vicorder left / right quadrant keys or the Laptop Function keys or the mouse pointer and left click.

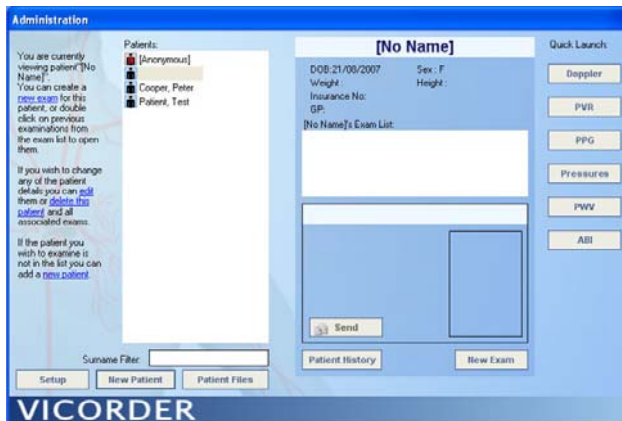
Settings

To change up / down use the Laptop up / down arrow keys or the Vicorder up / down quadrant keys or the left / right mouse keys.

Other keys and functions are as called within these Instructions for Use.

You are now ready to start using your Vicorder as described in Section 7. Getting Started.

7. GETTING STARTED



Administration window

On initial setup the Patients list would be empty. It is advisable at this stage to take a few moments to set up your Hospital information that you would like printed at the top of your reports. Click on Setup to bring up the Hospital set up window.

Clicking on Patient Files enables you to view by exam.

Clicking on Patient History enables you to review Patient details.

The function of the other buttons are explained elsewhere within these Instructions for Use.



Institute Setup window

Enter your Institute data accordingly.

You may also import into the Print Logo area a picture, logo or caption by clicking on the open folder icon. This will be displayed at the top of any reports.

The screenshot shows the 'Patient History Page'. It is divided into three main sections: 'Patient Details', 'Patient History', and 'Surgical History/Medication'. 'Patient Details' includes fields for Hospital Address, Last Name, First Name, Sex, DOB, Age, ID, Insurance No., Weight, Height, and Doctor. 'Patient History' includes a list of conditions with checkboxes and detail boxes. 'Surgical History/Medication' includes fields for Surgical History and Medication. There are buttons for 'Symptom Page' and 'Finish' at the bottom.

New Patient entry screen

Having completed all the set up procedures click on the New Patient button on the Administration page to bring up the Patient History Page, enter the Patient Details accordingly.

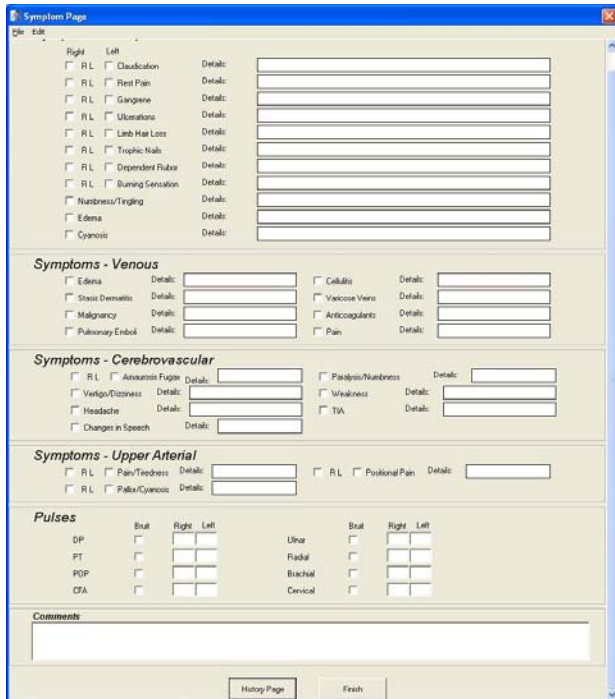
Select the Symptom Page (overleaf) and enter the Patient symptoms.

It is possible to switch between the Patient History Page and the Symptom Page by clicking on the appropriate box.

Click Finish when done.

Enter Yes in the New Exam box if you want to perform an examination of the Patient.

Symptom screen

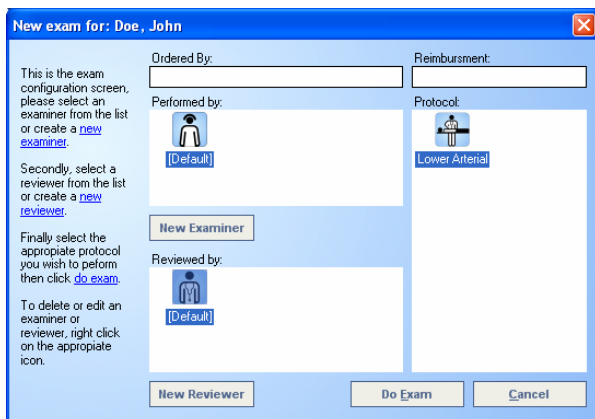


The Symptom screen is a form for recording various symptoms. It is divided into several sections:

- Right / Left:** A list of symptoms with checkboxes for Right (R.L.) and Left (L.) sides. Symptoms include Claudication, Rest Pain, Gangrene, Ulcerations, Limb Hair Loss, Trophic Nails, Dependent Rubor, Burning Sensation, Numbness/Tingling, Edema, and Cyanosis. Each symptom has a corresponding 'Details' field.
- Symptoms - Venous:** A section for venous symptoms including Edema, Stasis Dermatitis, Malignancy, Pulmonary Embol, Cellulitis, Varicose Veins, Arterioembolism, and Pain. Each has a 'Details' field.
- Symptoms - Cerebrovascular:** A section for cerebrovascular symptoms including R.L. Anomalous Flap, Vertigo/Dizziness, Headache, Changes in Speech, Paralysis/Weakness, and TIA. Each has a 'Details' field.
- Symptoms - Upper Arterial:** A section for upper arterial symptoms including R.L. Pain/Tiredness, R.L. Pulse/Cyanosis, and Positional Pain. Each has a 'Details' field.
- Pulses:** A section for recording pulses at different sites: DP, PT, POP, CFA, Brach, Right, Left, Ulnar, Radial, Brachial, and Cervical. Each site has a checkbox for 'Brach' and 'Right' or 'Left'.
- Comments:** A text area for additional comments.
- Buttons:** 'History Page' and 'Finish' buttons at the bottom.

Examiner and Reviewer and Test Protocol selection

If you wish to enter the name of the person requesting the test click the Ordered By box and enter the name. Similarly enter the Reimbursement code if required.



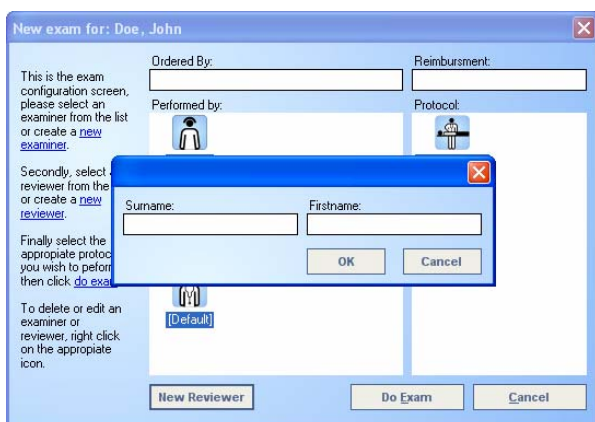
The New exam configuration screen is used to set up a new exam. It includes the following fields and buttons:

- Ordered By:** A text field for the name of the person requesting the test.
- Reimbursement:** A text field for the reimbursement code.
- Performed by:** A dropdown menu with a 'Default' icon.
- Protocol:** A dropdown menu with a 'Lower Arterial' icon.
- New Examiner:** A button to create a new examiner.
- Reviewed by:** A dropdown menu with a 'Default' icon.
- New Reviewer:** A button to create a new reviewer.
- Do Exam:** A button to proceed with the exam.
- Cancel:** A button to cancel the exam.

New Examiner and Reviewer entry window

You can insert the examiner and the reviewer by clicking on the respective icons or create new icons by clicking on the New Examiner or New Reviewer buttons.

Select Protocol at this stage if you want to do more than one protocol and then press Do Exam.



The New exam configuration screen is shown with a pop-up window for entering the examiner or reviewer details. The pop-up window has the following fields and buttons:

- Surname:** A text field for the surname.
- Firstname:** A text field for the first name.
- OK:** A button to confirm the entry.
- Cancel:** A button to cancel the entry.

Protocols available :**1. Lower Arterial**

Allows Doppler waves and pressures to be collected for the lower arterial tree.

2. Lower Arterial PVR

Allows PVR waves and pressures to be collected for the lower arterial tree.

3. Lower Digits PPG

Allows PPG waves and pressures to be collected for the 10 lower digits.

4. Lower Digits PVR

Allows PVR waves and pressures to be collected for the 10 lower digits.

5. Lower Limb Stress Test

The Lower Limb exercise programme allows the User to produce a Lower Limb Stress report. The programme has been design to allow the user first to record resting systolic pressure at both Brachial (B) sites and at both Dorsalis Pedis (DP) and Posterior Tibial (PT) sites. During the exercise period the onset of symptoms is recorded as well as the exercise time. During the post exercise period waveforms for the DP and PT site can be recorded followed by pressure recordings at the B, DP and PT sites. There is a real time display of the results which can be in the form of pressures versus time or ABI versus time.

6. Carotid

The Carotid screen allows collection of data from the Carotid region using a pre-determined set of sites and "guided probe". The order in which the test is conducted is User-definable.

7. Upper Arterial

Allows Doppler waves and pressures to be collected for the arms.

8. Upper Arterial PVR

Allows PVR waves and pressures to be collected for the arms.

9. Upper Digits PPG

Allows PPG waves and pressures to be collected for the 10 upper digits.

10. Upper Digits PVR

Allows PVR waves and pressures to be collected for the 10 upper digits.

11. Generic Protocol Editor

The Generic Protocol Editor has been designed so that Users can generate their own test protocols. The screen allows the collection of data for up to 20 User designated sites, vessel names can be assigned as can the order in which the test is conducted. It allows for the entry of probe frequency and insonation angle, vessel size and pressures enabling volume flow and peripheral resistance calculations to be performed. Stored data can be recalled at any time for further analysis or re-processing.

12. Pulse Wave Velocity

Allows measurement of the Pulse Wave Velocity between the Aorta and various arterial segments.

13. ABI / TBI

Allows left and right ABI / TBI indices for three different body segments to be collected.

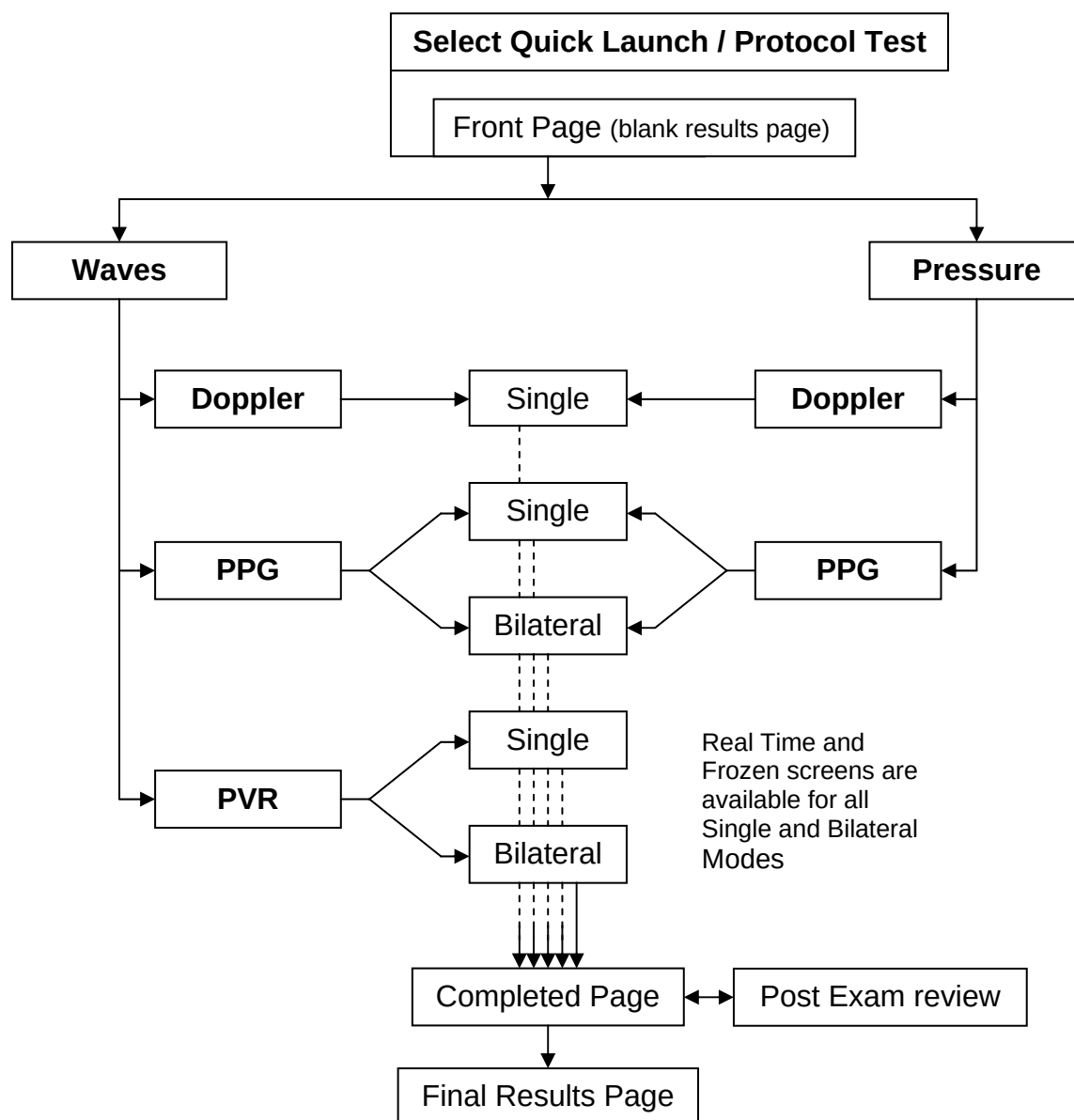
The Reports generated for any of the above Protocols may be stored, printed or electronically communicated. The Reports may also be reviewed and manipulated post Patient examination (the Vicorder does not need to be present for this activity).

9. PROTOCOL MODALITIES AVAILABLE

Available Protocols :

Protocol	Doppler	PPG	PVR	Stress
Lower Arterial	✓	✗	✓	✓
Lower Digits	✗	✓	✓	✗
Upper Arterial	✓	✗	✓	✗
Upper Digits	✗	✓	✓	✗
Carotid	✓	✗	✗	✗
Pulse Wave Velocity	✗	✓	✓	✗
ABI / TBI	✗	✗	✓	✗
Generic Protocol Editor				

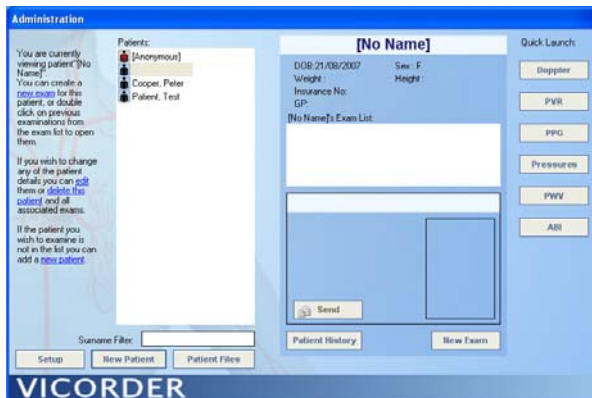
Flow Chart of the Modalities :



10. TEST PROTOCOL SELECTION

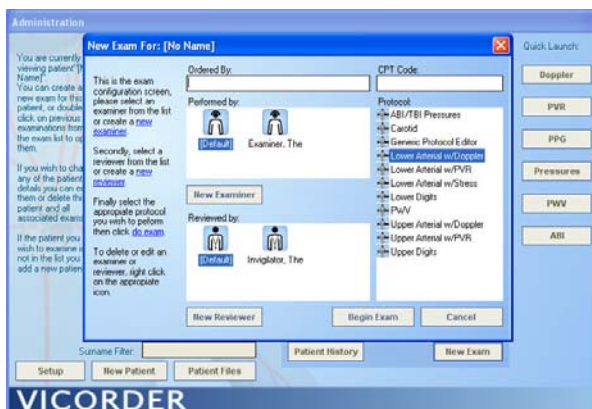
Quick Launch Selection

From the Administration Window any of the six tests listed on the right hand side under Quick Launch: may be selected. Click on the relevant box. The tests will be unilateral / bilateral single site format.



Protocol Selection

Clicking on New Exam in the Administration Window will bring up the Protocol list. The required Protocol may be selected from the list in the Protocol box and activated by double clicking on the name or by selecting and then clicking on Begin Exam.



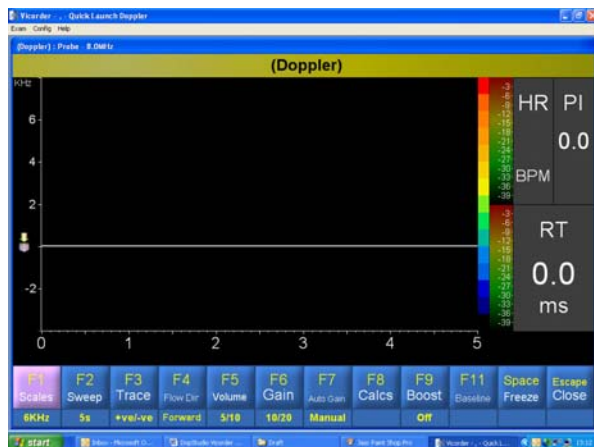
Lower Limb Report page

This page allows the user to select either the Doppler or Pressure site using the mouse. The 3-D man dynamically moves showing the User where to make the recordings. Clicking on a site will bring up the Real Time Doppler screen.

The function of the buttons is explained in The Completed Report, section 21.



11. DOPPLER MEASUREMENT



Real Time Doppler Screen :

The Doppler controls are activated either by the Vicorder keys or the 4 keyboard arrow keys or the mouse or function keys. The current value of each control is shown on the bottom of each control. The real time controls from left to right are :

Scales

Increase or decreases the spectrum analyser range, i.e. the size of the spectrum.

Sweep

Increases or decreases the sweep speed of the display.

Trace

Activates the maximum frequency tracker providing a trace for forward and reverse bi phasic flow or a trace for mono phasic flow which is above the baseline.

Flow Dir

Inverts the spectral display.

Volume

Controls the volume of the sound output.

Gain

Controls the sensitivity of the spectral display.

Auto Gain

Spectral sensitivity automatically set by software for optimum display.

Calcs

Brings up the calculation window, allows setting of the probe frequency and insonation angle.

Boost

Increases the overall sensitivity.

Baseline

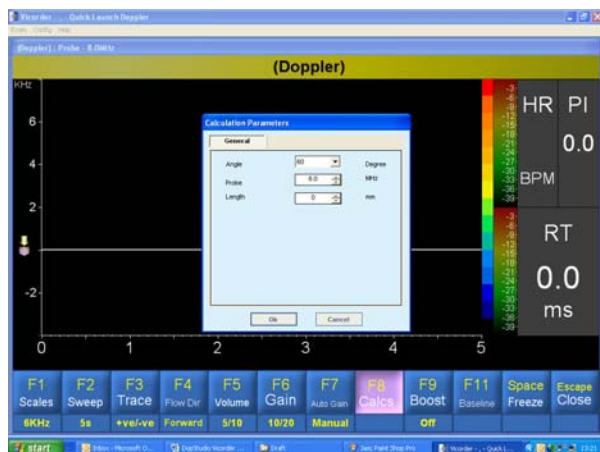
Moves the zero baseline.

Space

Freezes the display.

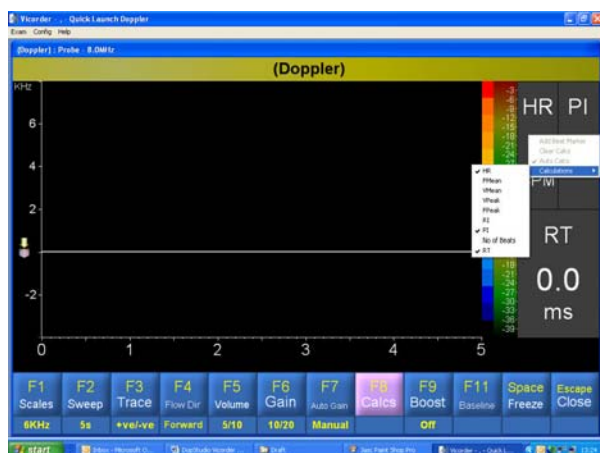
Escape

Return to report window.



Input screen for Calculations

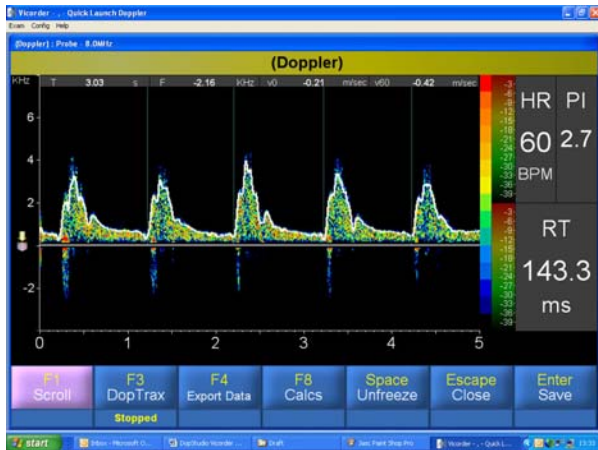
Once selected this screen allows the user to input probe angle and probe frequency which are both necessary constants for the calculation of velocity.



Selection of Calculations

Computed indices may be selected or de-selected by right clicking over the Calculations Site area and selecting from the resultant list.

12. DOPPLER SCREEN FROZEN



Once a satisfactory Doppler display has been achieved for three or four screen widths pressing the Spacebar will freeze the screen. The frozen controls operate in the same way as in the Real Time display and their functions are :

Scroll Scrolls spectral display.

DopTrax

Allows replay of the spectral display.

Export data

Launches the “Save” dialogue box enabling saving, as a bitmap, of the screen.

Calcs

Brings up the calculation window, allows setting of the probe frequency and insonation angle.

Space

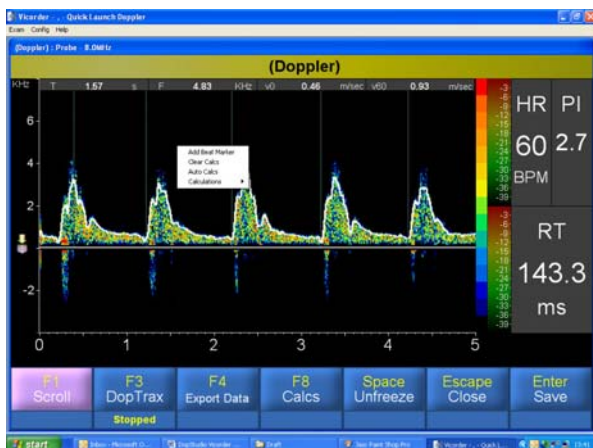
Unfreezes the display.

Escape

Return to Report window.

Enter

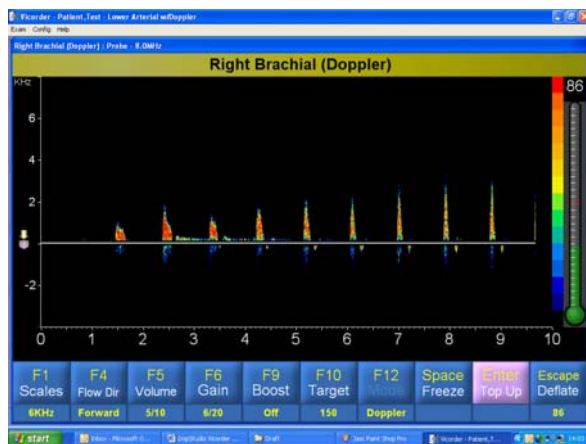
Saves the Doppler spectrum and associated data.



Inserting and clearing Beat markers

The beat markers that identify each cardiac cycle can be manually inserted by first placing the mouse arrow at the start of a beat then clicking the right mouse button.

13. DOPPLER PRESSURE MEASUREMENT



Real Time Doppler Pressure

This screen combines the real time Doppler modality with controls for the cuff inflation and automated cuff bleed and deflation.

A cuff is placed around the limb of interest and a Doppler signal obtained distal to the cuff. By depressing the Spacebar the cuff automatically inflates to the pre-selected target pressure. Once systolic pressure has been achieved the Doppler signal disappears and reappears when the cuff again reached systolic pressure in its bleedback phase. Once systolic pressure has been identified the display may be frozen by pressing the Spacebar and the exact reappearance of the Doppler signal and systolic Doppler pressure is marked by the on screen cursor which, although automatically picked, can be manually placed with the left and right scroll keys and left click of the mouse.

Press the Enter key to store the result.

Keys :

Scales

Increase or decreases the spectrum analyser range, i.e. the size of the spectrum.

Flow Dir

Inverts the spectral display.

Volume

Controls the volume of selected speakers.

Gain

Allows the manual setting of the gain.

Boost

Increases the overall sensitivity.

Target

Set target Pressure.

Mode

Selects between Doppler and PPG.

Space

Start the inflation cycle/freeze display.

Enter

Allows re-inflation of the cuff to the set target pressure.

Escape

Will immediately deflate the cuff.



Frozen Doppler Pressure

The function of the keys is :

Scroll

Allows scrolling of the displayed cursor left or right.

Enter

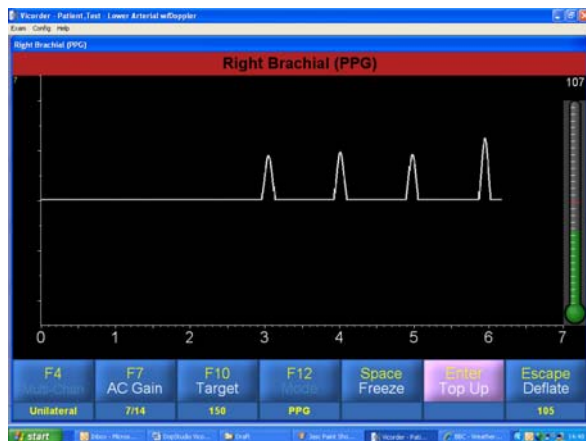
Save and return to Report page.

Calcs

Allows setting of Probe frequency and insonation angle.

Other functions as frozen Doppler screen.

14. PPG PRESSURE MEASUREMENT



Real Time PPG Pressure

This screen combines the real time PPG modality with controls for the cuff inflation and automated cuff bleed and deflation.

A cuff is placed around the limb of interest and a PPG signal obtained distal to the cuff. By depressing the Spacebar the cuff automatically inflates to the pre-selected target pressure. Once systolic pressure has been achieved the PPG signal disappears and reappears when the cuff again reached systolic pressure in its bleedback phase. Once systolic pressure has been identified the display may be frozen by pressing the Spacebar and the exact reappearance of the PPG signal and systolic PPG pressure is marked by the on screen cursor which, although automatically picked, can be manually placed with the left and right scroll keys and left click of the mouse.

Key functions :

Multi Chan

Switches between unilateral and bilateral operation.

AC Gain

Controls the amplitude of the PPG signal.

Target

Sets the target pressure.

Mode

Selects the Doppler or PPG probe.

Space

Start the inflation cycle/freeze display.

Enter

Allows re-inflation of the cuff to the set target pressure.

Escape

Will immediately deflate the cuff.

Frozen PPG Pressure

Key functions :

Scroll

Allows scrolling of the displayed cursor left or right.

Space

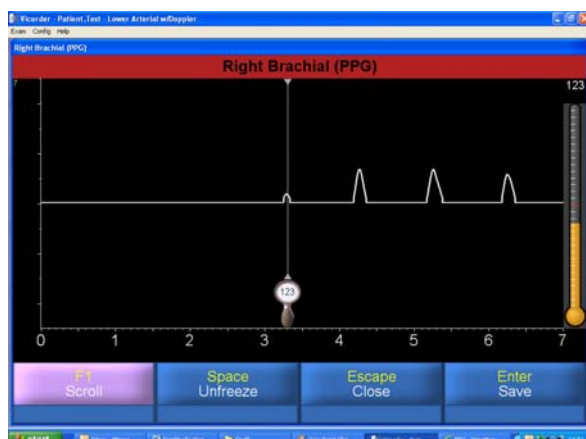
Unfreezes the trace.

Escape

Exits the screen.

Enter

Save and return to Report page.



15. DUAL CHANNEL PPG PRESSURE MEASUREMENT

Real Time Dual PPG Pressure

Once in PPG pressure mode the dual channel bilateral mode can be selected which allows two limbs to be measured simultaneously. It is important when in dual channel mode that the channel of interest is first selected with the site button before applying the appropriate controls such as gain and cursor positioning using the arrow keys. The selected site is highlighted by the illumination of the bar either red or blue, all other controls are the same as for single channel PPG operation.

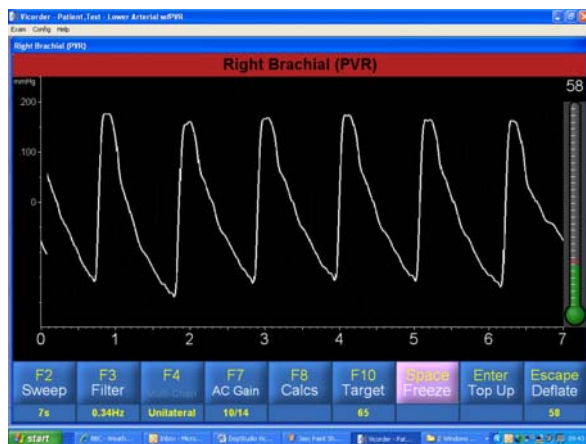


Frozen Dual PPG Pressure

The pressure cursors are positioned once a PPG pulse is detected or the cursor can be positioned manually and the resultant pressure stored using the Enter key.



16. PVR MEASUREMENT



PVR Single Real Time

This screen allows the display of a single channel PVR signal, once a cuff has been tightly wrapped around the limb of interest depressing the Spacebar automatically inflates the cuff to the selected target pressure which is normally set at 65mmHg and once the target has been reached the PVR wave is displayed on the screen.

Key functions :

Sweep

This controls the sweep time across the screen.

Filter

Normally set at 0.34Hz but can be increased to 1.0Hz to remove excessive venous modulation.

Multi Chan

Switches between unilateral and bilateral modes

AC Gain

This controls the amplitude of the PVR signal.

Calcs

Brings up the calculation window.

Target

Sets target pressure.

Space

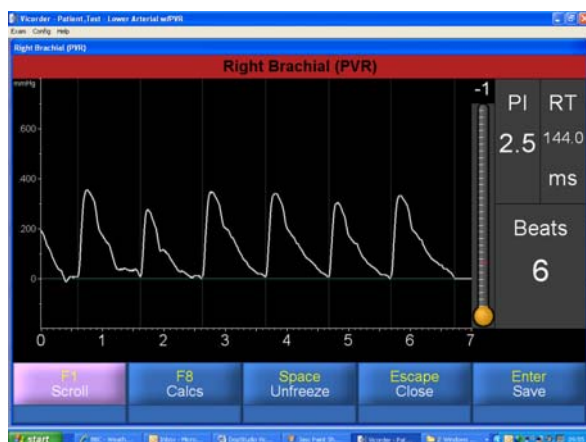
Freezes the display and deflates the cuff.

Top up

Tops up to target level.

Escape

Deflates the cuff.



PVR Single Frozen

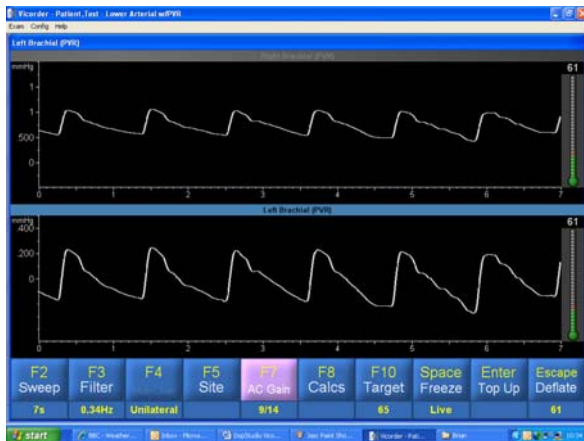
Once the real time display has been frozen the trace is normalised to the baseline each heartbeat is identified and the calculations are performed. Scrolling left or right allows selection of the trace which can be saved by pressing the Enter key.

Computed indices may be selected or de selected by right clicking over the Calculations Site area and selecting from the resultant list.

17. DUAL CHANNEL PVR MEASUREMENT

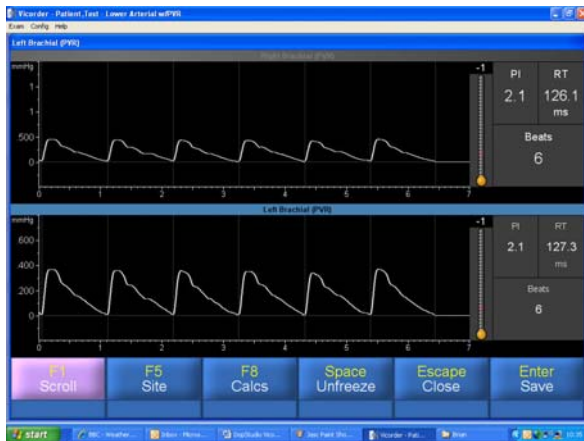
PVR Bilateral Real Time

Once selected two PVR channels can be displayed in real time and using the site button can be individually controlled as per single channel operation.



PVR Bilateral Frozen

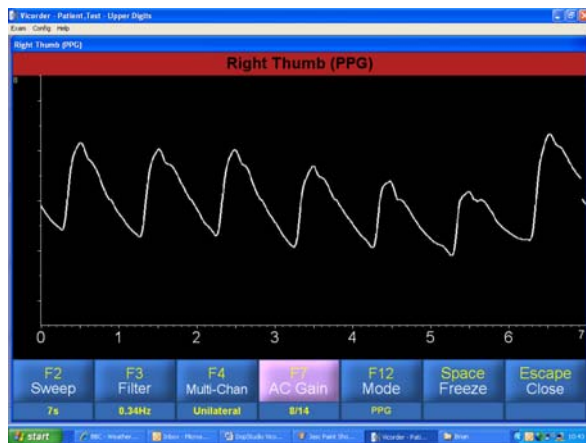
Control of the bilateral frozen requires site selection and once the real time display has been frozen the traces are normalised to the baseline, each heartbeat is identified and the calculations are performed. Scrolling left or right allows selection of the trace which can be saved by pressing the enter key.



18. PPG MEASUREMENT

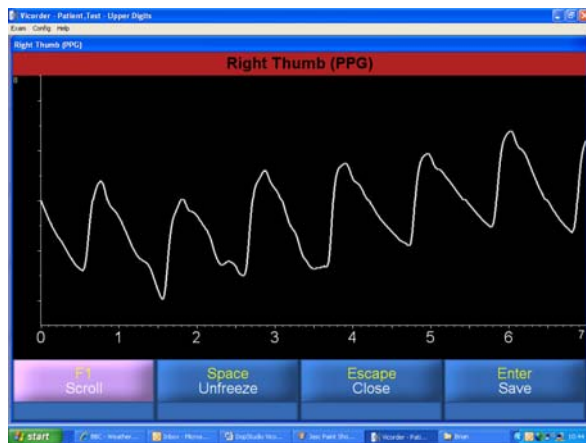
PPG Real Time Single

PPG measurement requires the positioning of the PPG sensor on an appropriate digit thereby producing a real time waveform. The operation of the buttons are as already described for PVR.



PPG Single Frozen

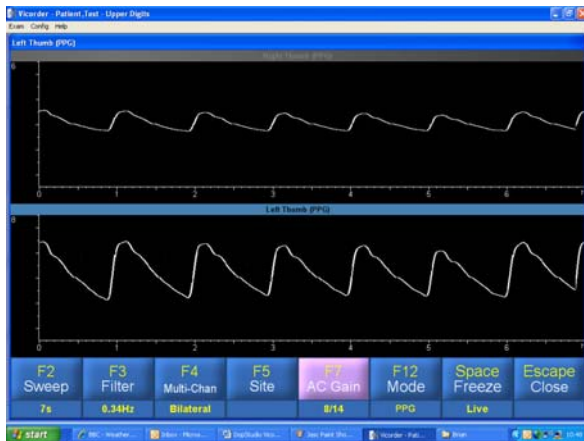
The frozen signal is stored using the Enter key.



19. DUAL CHANNEL PPG MEASUREMENT

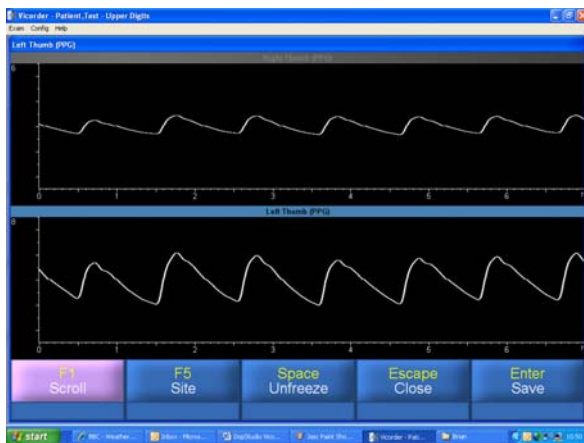
PPG Dual Real Time

The PPG may also be operated in Dual channel mode, once again it is important to remember site selection for the individual trace controls.



PPG Dual Frozen

The frozen display may also be scrolled left and right and the resultant screen saved using the Enter key.



20. PWV MEASUREMENT

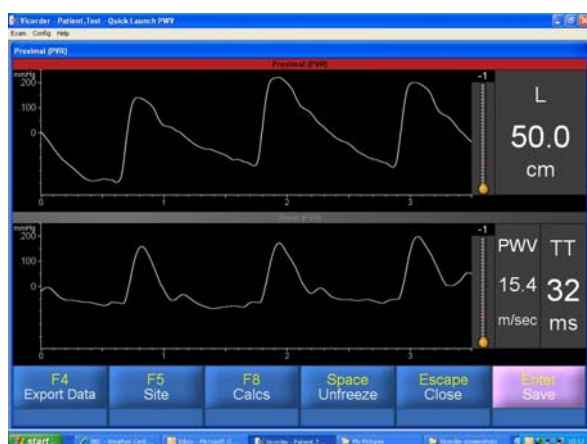


Real Time PWV

By placing the PVR Press2 cuff proximal and Press1 distal to the selected arterial segment the time delay between the two simultaneously measured cardiac cycles is computed and displayed when the display is frozen. The distance between the cuffs in centimetres is entered via the Calcs button.

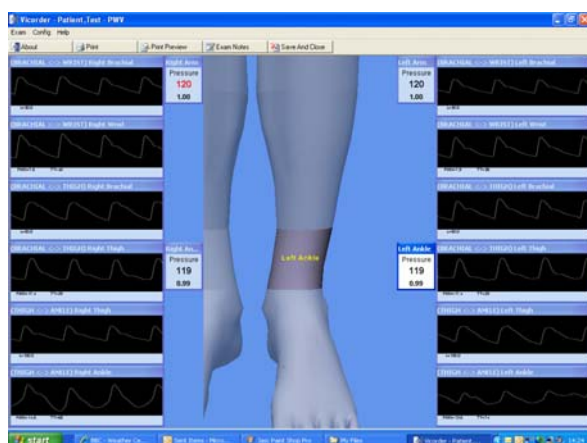
In PWV mode the display is always Dual channel.

Note : it is possible to use the PPG sensors or combination PVR-PPG to obtain PWV timings, select by clicking Site to activate the required area and selecting the required mode with the Mode button.



The frozen screen

After acquiring several steady pulses of data pressing the Space bar will freeze the display, the Pulse Wave Velocity in metres per second and the Transit Time in milliseconds will then be displayed.



Whole Body PWV

Entering PWV via New Exam will enable data from three segments on each side of the body to be collected and stored.



Aortic Pulse Wave Velocity measurement using the Neckpad

The Neckpad is placed around the Patients neck with the pressure pad over the right Carotid area.....



.....and secured with the Velcro fixing, do not over-tighten.



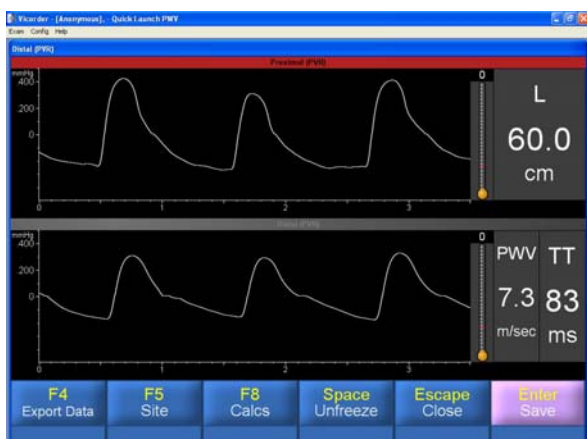
A cuff is placed around the Patients upper right thigh.



Both Neckpad and thigh cuff are connected to the Vicorder.

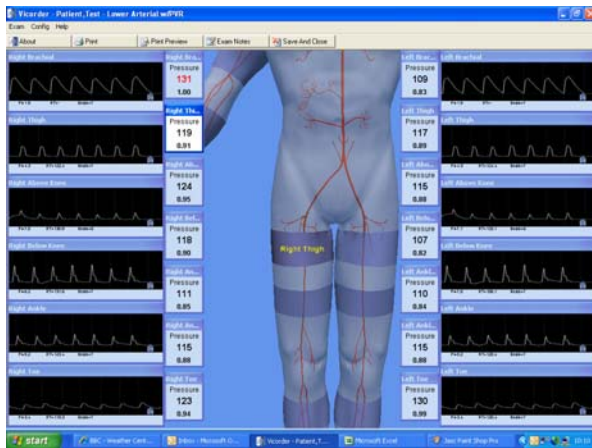


Measure the distance between Supra-Sterna Notch and thigh cuff in centimetres and enter via the Calcs button.



1. Inflate the cuffs, adjust the displayed waveforms for amplitude if required.
2. Acquire several steady pulses of data and freeze.
3. Pulse Wave Velocity and Transit Time are automatically computed and displayed.

21. THE COMPLETED REPORT



Completed Report Page

The completed Report Page will look similar to the specimen given.

About

Here you can view your product id which is unique to your computer and the version number of the software installed.

The function of the icon buttons :

Print

Sends a copy of the Report page to the Printer.

Print Preview

Enables pre-viewing of the Report prior to printing.

Exam Notes

Allows the Examiner to add Patient notes to the Report.

Save and Close

Saves a copy of the Report and returns to the Administration window.

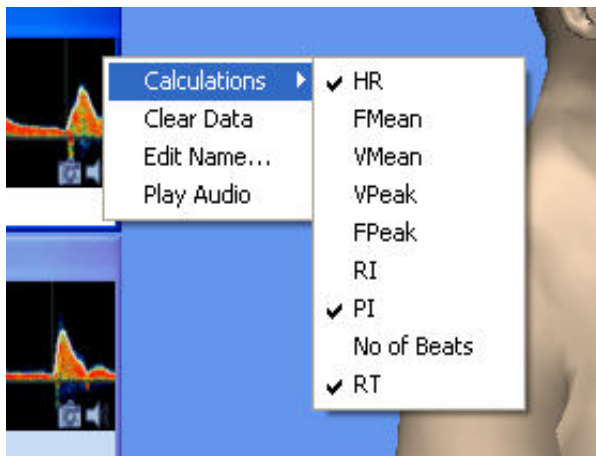
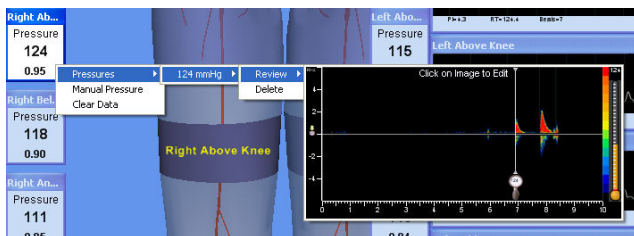
Calculation selection for reports

The reported calculations for each site can be selected by right clicking on the site window. Similarly the site data can be deleted.

The data for that site can be deleted.

The site name may be edited.

The audio may be replayed.



Pressure editing

Right clicking on a pressure site allows pressures to be reviewed.

Clear data will remove the pressure(s) recorded at that site.

The pressure may be obtained by other means and entered manually.

The pressure data window allows adjustment of the cursor position if necessary.

Note : for more than one pressure recorded at any site the resultant pressure displayed is the mean of all the pressures and is indicated with a bar over the number.

Exam Notes

Exam Date : 04/01/2006 01:45	Weight : 95.25kg
First Name : Dick	Height : 1.52m
Last Name : Jones	ID : jon3394554-3353
Date Of Birth : 12/10/1957	Reviewed By : [Default],
Age : 48	Examined By : [Default],
Sex : M	Ordered By :

Existing conditions :

Doctors Summary :

Notes Reporting page

From the Lower Limb reporting page click on the Exam Notes icon to bring up the notes boxes.

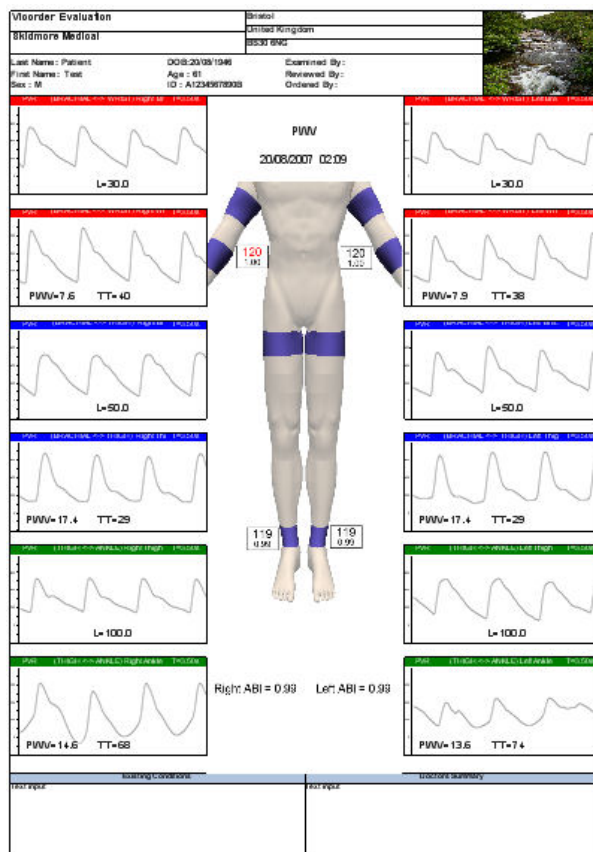
Completed and stored patient data files may retrieved at a later time for analysis and manipulation. This activity does not require the Vicorder to be connected. See Section 23 Retrieving Patient Reports.

22. THE PRINTED REPORT

Typical Printout

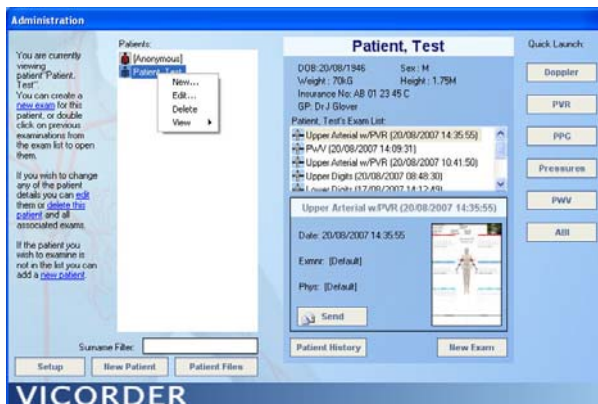
The picture shows a typical Printed Report, in this case for a PWV Exam.

From your Exam Report Page click on the Print icon to obtain a printout.



23. RETRIEVING PATIENT REPORTS

Retrieving, reviewing and manipulation of Patient Reports can take place without the Vicorder being connected.



Individual Patient retrieval and editing

An individual Patients Tests may be retrieved by left clicking on a Patient name.

Right click on a selected patient provides an editing drop down window.

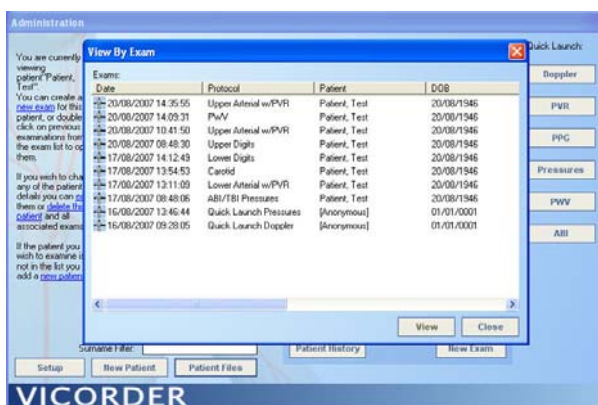
Clicking on Patient History brings up the Patient History data.



Individual Test retrieval and editing

An individual Patient Test may be retrieved by double clicking on the required test which will in turn bring up the selected Report Page.

Right clicking on selected test provides an editing drop down window.



Displaying the View By Exam screen

Click on the Patient Files button in the Administration screen to display a list of all examinations carried out. Double click on the required Exam or click on the required exam and click the View button to activate.

Note : The Exam list is initially displayed with the most recent by date at the top. The order in which Exams are displayed can be altered by clicking on the appropriate Exam information headers, e.g., click on Patient to display Patient Surnames in ascending alphabetical order ("A" at the top), click again to reverse the order ("Z" at the top).

E-Mail Exam

To...

Cc...

Attach: C:\Program Files\Skidmore Medical\DopStudio\Data\dops_044506014513\dops_044506014513_image.jpg

Subject: DopStudio Report

Send! Cancel

E-mail selected Patient report

Select the Patient Report that you wish to send by clicking on it.

Click on the Send button in the Administration screen, enter the recipients e-mail address, Subject header and any accompanying text.

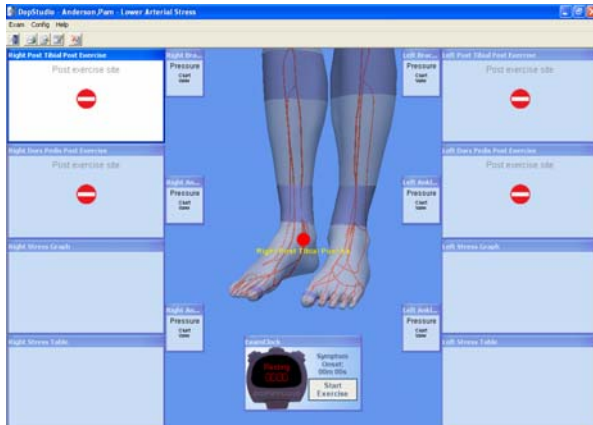
Click the Send! button to e-mail the selected report as an attachment and place it in the outbox of your e-mail software.

24. LOWER ARTERIAL STRESS TEST

Enter the programme by first selecting Lower Arterial Stress from the protocol window. It is assumed that the User is fully acquainted with the Lower Arterial report package before using this protocol and has entered all the Patient information.

Patient at rest

Measure the pressure at rest at the desired sites.



Start Exercise

Start the exercise period and start the Stop Watch by clicking the Start Exercise button.



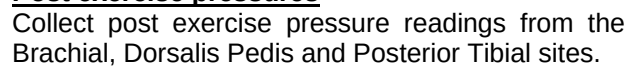
Symptom onset

As soon as the Patient complains of symptoms depress the Symptom Onset button.

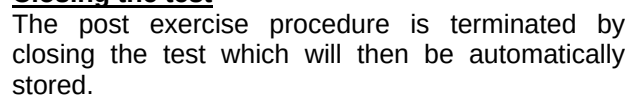


Continue exercise at the discretion of the Patient depressing the Stop Exercise button when the exercise has ceased.

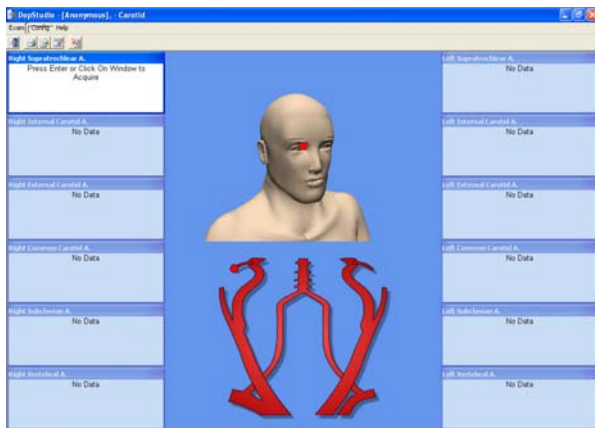
Select and record waveforms before taking any post exercise pressures.



The resultant stress graphs, both left and right, will be updated automatically in real time and right clicking on these graph allows the option of pressure or ABI to displayed.



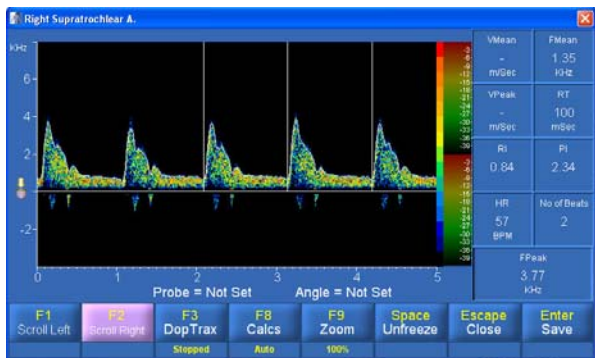
This section should enable the User to become acquainted with the Vicorder Carotid report package. It is assumed the User has previously entered all Patient information. Enter the programme by first selecting Carotid from the protocol window.



Carotid Report Page

Entering the Carotid protocol will bring up the Carotid screen.

Saved data may be replayed by right clicking over the data and selecting Play Audio.



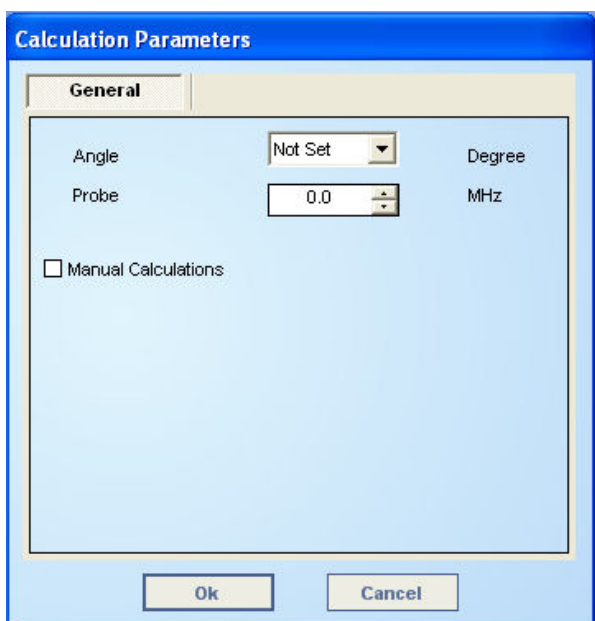
Acquire Screen

Clicking on the highlighted box or Enter will bring up the acquire screen. After collecting the required data and Freezing the F1 and F2 scroll keys will allow the trace to be scrolled to a particular point of interest, the audio for that section may then be replayed by clicking on F3 DopTrax.

Enter will save the data in the selected site.

Escape will close the window without saving any data.

The function of the other "F" keys is described in Section 11 Doppler Measurement.



Calculation Parameters

Clicking F8 Calcs will bring up the Calculation Parameters screen which will enable the Probe insonation angle and frequency to be entered.

Exam Notes

Exam Date : 04/01/2006 01:45	Weight : 95.25kg
First Name : Dick	Height : 1.52m
Last Name : Jones	ID : jon3394554-3353
Date Of Birth : 12/10/1957	Reviewed By : [Default],
Age : 48	Examined By : [Default],
Sex : M	Ordered By :

Existing conditions :

Doctors Summary :

Ok Cancel

Exam Notes Reporting page

From the Carotid reporting page click on the Exam Notes icon to bring up the notes boxes.

Close Current Exam

Clicking on the Close Current Exam icon will automatically save and close the current exam.

26. GENERIC PROTOCOL EDITOR

In order to learn how to programme your own Generic Test a tutorial example will be used.

Let us consider producing a simple protocol for the Carotid Artery examination.

Sites required :

three on the right side and

1. Right Common Carotid

3. Right External Carotid

5. Right Internal Carotid

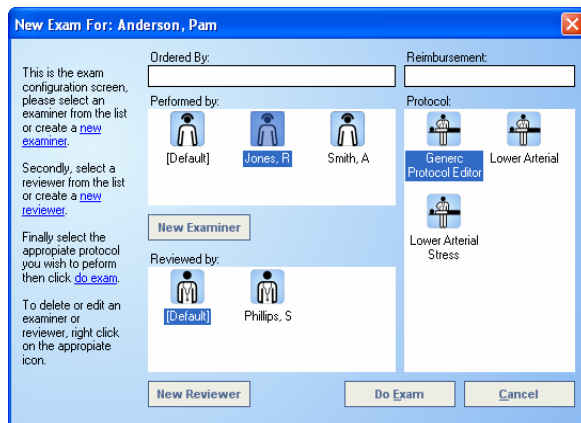
three on the left side, namely :

2. Left Common Carotid

4. Left External Carotid

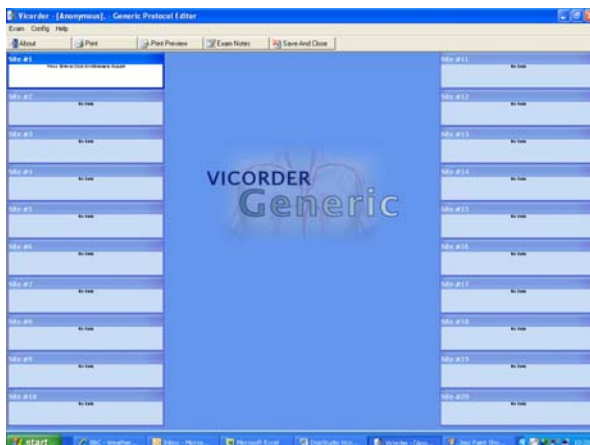
6. Left Internal Carotid

The measurement order will be as labelled above and displayed Calculations will be RI and Peak Frequency for each Site.



Step 1

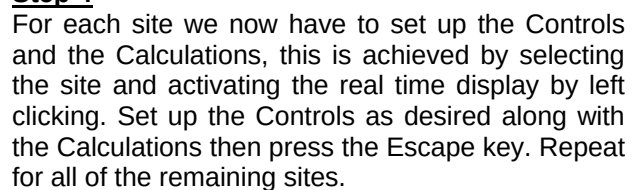
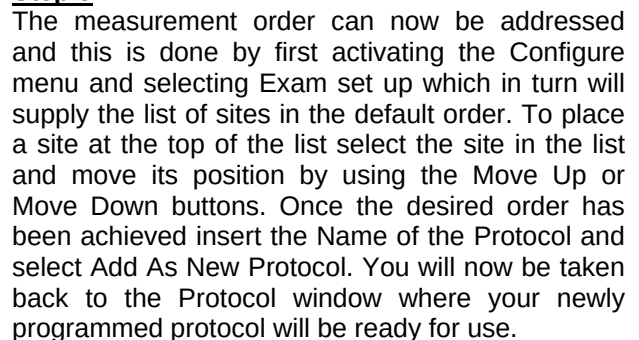
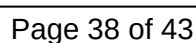
Select and click on Generic Protocol Editor.



Step 2

The Generic Protocol Editor consists of 20 sites. (Please note the body map is always absent in the Generic mode). As we only require 3 sites on the right and 3 sites on the left we must remove the surplus sites, this done by right clicking on a site and then activating the Delete Site selection.

Now we have to Name each site accordingly and this is done by first right clicking on the selected box and then choosing the Edit Name option.



New Exam For: Anderson, Pam

This is the exam configuration screen, please select an examiner from the list or create a [new examiner](#).

Secondly, select a reviewer from the list or create a [new reviewer](#).

Finally select the appropriate protocol you wish to perform then click [do exam](#).

To delete or edit an examiner or reviewer, right click on the appropriate icon.

Ordered By:

Reimbursement:

Performed by:

[Default] Jones, R Smith, A

New Examiner

Reviewed by:

[Default] Phillips, S

New Reviewer

Protocol:

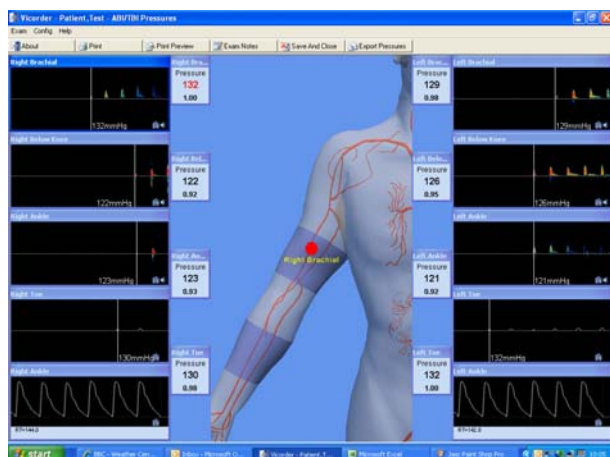
Carotid Artery Exam Generic Protocol Editor

Lower Arterial Lower Arterial Stress

Do Exam Cancel

Exam Screen

The New Exam screen will now appear as opposite.



Automatic ABI / TBI indices may be obtained from three segments on each side of the body using either Doppler or PPG techniques plus a PVR recording for the ankle segments.

28. COMPLIANCE INFORMATION

Quality System	Designed and manufactured at our Bristol facility, which is approved by SGS UK Ltd. to the following Standards :	
	ISO 9001:2000	Certificate number GB06/67764
	ISO 13485:2003	Certificate number GB06/67766
	ISO 13485:2003	Certificate number CA06/3801 (for Canadian CMDCAS)
CE mark		Certificate number GB06/67765
Declaration of Conformity	ISO/IEC 17050-1	Number DSVI/01 (Copy available on request)
Safety and essential performance	IEC 60601-1:2005 plus Corrigendum 1	Report number SM-TR/01 Issue 1.
EMC	EN 60601-1-2:2001 Clause 36	Certificate number EL4121/10832 Issue 1.
CE marking	93/42/EEC	Report number SM-COMP/01 Issue 1.
RoHS	2001/95/EC	The Vicorder, as a Medical Device, is currently exempt from the Directive however compliant components and methods are used throughout. No other materials of concern are used.
Disposal	2002/96/EC	WEEE for EU Countries, to be disposed of in accordance with the Directive. Elsewhere in accordance with local regulations. Otherwise with consideration for the environment.

EMC note

In order to maintain the same level of EMC performance of the Vicorder only cables in good order should be connected with all screens and grounds intact.

If difficulty with mutual interference is experienced when using the Vicorder try repositioning the unit or any adjacent equipment, moving leads or shortening them by coiling excess length.

The Vicorder is intended to be Serviced by return to Skidmore Medical Limited but if the case is opened by the User maintain its EMC integrity on closure by ensuring that all existing internal connections are maintained and all case securing screws are reinstated and fully tightened.

29. CLEANING, CALIBRATION AND SERVICE

Cleaning

- Cleaning of the Vicorder, its components and leads should only be undertaken by wiping with a soft cloth moistened with a mild soap or antiseptic solution.
- Do not immerse the Vicorder, its components or leads.
- Do not use alcohol, solvents or abrasive cleaners.
- The Vicorder, its components and leads are not intended to be sterilised.

Calibration

The Vicorder requires periodic calibration of its pressure channels to maintain optimum accuracy, Skidmore Medical recommend that this is carried out at 6 monthly intervals. The procedure can easily be accomplished at the point of use and should take no more than a few minutes. The Vicorder does not need to be opened and no adjustment tools are required, the calibration values are automatically stored in the Vicorder.

Required equipment :

A hand inflator connected to a Manometer and 2 way manifold. Both channels are calibrated in parallel.

Procedure :

1. Open the Vicorder software program and enter any pressure protocol.
2. Enter Calibration mode by typing Ctrl+C
3. Follow the on screen instructions. (Connect the hand inflator, Manometer and 2 way manifold when instructed to connect the calibration manifold)
4. On satisfactory completion exit the Calibration window, deflate by bleeding the hand inflator and disconnect the calibration manifold.

Service

There are no User adjustable or serviceable parts inside the Vicorder or its components. In the event of difficulty contact Skidmore Medical Limited, using one of the methods given in the Helpline Section 30, to be advised of our Servicing arrangements.

Please have available the Serial Number of your Vicorder and the version of software installed, available by clicking on the About box.

Contacting us

In the event of difficulty or query please contact :

Skidmore Medical Limited
1 The Old Estate Yard Office
North Stoke Lane
Upton Cheyney
Bristol
BS30 6NG
UK

Tel : +44 (0)1179 324 612
Fax : +44 (0)1179 323 943
e-mail : enquiries@skidmoremedical.com

Office hours : 07:30 to 15:30
(UK time) answerphone out of hours

Continuous improvement

Skidmore Medical Limited has a policy of continuous improvement to its products and we reserve the right to make changes without prior notice.

Feedback

We welcome your feedback, both positive and negative, on any aspect of this product or if you have any suggestions for improvement. Please feel free to contact us using one of the methods given above.

Environmental consideration

WEEE Directive, 2002/96/EC

At the end of the working life of the Vicorder please dispose of :

- via a locally approved recycling scheme or
- returning it to us at the address given above or
- with consideration for the environment.

