CARRS Cohort:
Proposed Measures
[Precision-CARRS]

MANUAL OF OPERATIONS:

ARTERIAL STIFFNESS TESTING

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1. Introduction

Arterial stiffening is associated with CVD risk factors, particularly age and hypertension, leading to arterial wall thickening and compensatory remodeling, adversely affecting the internal elastic properties of the vessel wall.[1-5] Carotid-femoral pulse wave velocity (PWV), an estimate of the speed of the pressure wave traveling along the aorta, is the current gold standard measure.[6] Higher PWV is independently predictive for future hypertension, HF, mortality, fatal and non-fatal coronary events, and stroke.[7-20] Increased pulsatile afterload during mid- and late-systole can be estimated as the augmentation index (AIx) and has adverse consequences on LV remodeling leading to LV hypertrophy and fibrosis.[21-26] Similarly, increased late systolic load impairs LV relaxation and systolic-diastolic coupling,[27] contributing to diastolic dysfunction,[28-31] and HFpEF.[18, 21, 32-40] Importantly, worsening arterial stiffness is associated with increased risk of incident HF[41] and improvement is associated with improved survival.[42] **Expected prevalence:** Age-specific 90th percentile reference values for PWV in healthy subjects are: <30 years: 7.1 m/s; 30 to 39 years: 8 m/s; 40 to 49 years: 8.6 m/s; 50 to 59 years: 10 m/s; 60 to 69 years: 13.1 m/s; and >70 years: 14.6 m/s.[43] As detailed in **Project 1**, studies in South Asians have suggested that PWV and AIx may be higher compared to other populations.[44-48] **Equipment:** SphygmoCor® PWV system (Atcor Medical, NSW, Australia).[49-53] **Duration of testing:** 15 minutes. **Technique: PWV:** Analyses will be performed in the sitting position in a quiet room after at least 15 minutes of rest. PWV measures the velocity of the blood pressure waveform between any two superficial artery sites. It is measured with a tonometer that records the pressure pulse waveform sequentially in the carotid and femoral arteries using the SphygmoCor PWV system attached to a laptop computer. Time delay (t) is measured between the feet of the flow waves recorded at these points. The distance (d) traveled by the pulse wave is measured over the body surface as the distance between the two recording sites minus that from the suprasternal notch to the carotid artery recording site. PWV is calculated as PWV=d/t. **AIx:** Aortic pulse (AP) waveform, augmentation index, and central aortic pressure will be derived at the radial artery by applanation tonometry. Because AIx is influenced by heart rate, an index normalized for heart rate of 75 bpm (AIx@75) will be used. Only high-quality recordings, defined as an in-device quality index >80% will be included. **Reproducibility:** In our laboratory, a coefficient of variation of 20.3% and 3.8% for AIx and PWV, respectively, were found on 2 separate measurements.[49-53]

2. Equipment

2.1. SphygmoCor®

In this study the vascular stiffness is measured using SphygmoCor™, Model SCOR-Vx with SPT-301B, which is a registered trademark of AtCor Medical Pty. Ltd. West Ryde, Sydney Australia.

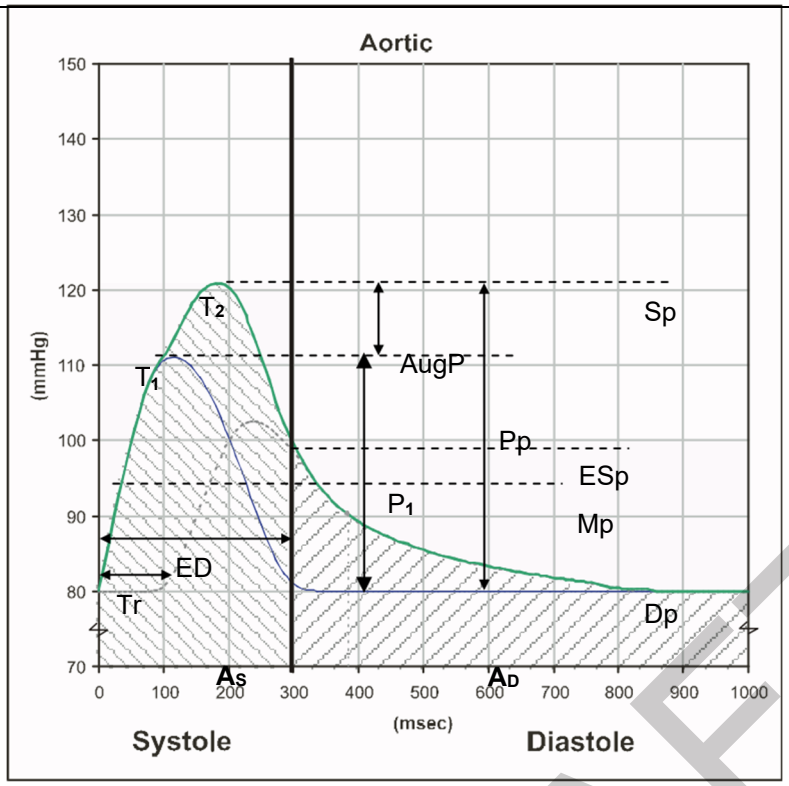
The picture below (see Figure 1) shows the components of the SphygmoCor® Aortic Blood Pressure Profile Analysis system. They are the SphygmoCor® software CD, the Electronic Module (EM), the Millar pressure Tonometer inside the EM, the Footswitch, the ECG cable,

the serial Cable, the electric Cable along with system documentation and manuals.

Figure 2. Sphygmocor system

2.2. Pulse Wave Analysis Principles

Radial artery pulse is the site for the study in adults (age 30-65 years). The Tonometer is used to obtain a steady pulse waveform. The SphygmoCor® Pulse Wave Analysis System (Model SCOR-Px using SphygmoCor® Software Version: 7.1.) uses applanation tonometry to non-invasively record a high fidelity peripheral artery blood pressure waveform. The entered brachial blood pressures (systolic and diastolic pressures) calibrate the averaged radial waveform.[11] The averaged aortic waveform is then calibrated based on this calibrated radial waveform. The SphygmoCor System extracts five time-relative points from the averaged waveform and from these points, further parameters related to the heart and arterial system are determined. Further, from this aortic BP waveform the total central pulse pressure (Pp) is separated into its two components: (1) the primary pulse pressure (PP) created by the forward wave resulting from the Left Ventricular (LV) ejection and (2) the backward reflected wave, a function of the large as well as peripheral small artery stiffness. The aortic BP waveform thus documents the components of ventricular/vascular interaction (see Figure 3). The transfer function which derives central pressures from peripheral pressures has been validated.[11-14]



Blue curve: forward wave; Dotted curve: backward wave; Green curve: resulting wave

SphygmoCor calculates this **aortic BP profile** from a non-invasive recording of the radial artery waveform, and then derives a range of clinically important **central cardiovascular parameters**.

■ Aortic systolic (Sp), mean (Mp), diastolic (Dp), and pulse pressure (Pp)

■ Augmented Pressure (mm Hg) and Augmentation Index *(= AugP/Pp, %)*

■ Ejection Duration (ms), ED %, time to return (Tr), time to 1st peak (T1), time to 2nd peak (T2)

■ LV Load *(=As, systolic area, TTI*), Ad (diastolic area, *DPTI*), SEVR *(= Ad/As, subendocardial vascular reserve)*

Figure 3 Pressure Wave Reflection at the Heart (from AtCor Medical, Inc.)

3. Measurement

3.1. Pulse Wave Analysis

Both the participant's and the operator's complete forearm should be resting on a firm surface (see Figure 4). The participant should be lying down on a bed with his/her arm along side his/her body, and the palm facing upwards. The operator finds the location of the strongest pulse at the right radial artery and places the tonometer between the two fingers and carefully adjusts it to stay perpendicular to the current point of contact with the skin directly over the point of the strongest pulse. The best results are obtained if the wrist is bent outward, in the "dorsiflex" position. This position pushes the artery towards the surface thus making it easier to access. The operator then presses the tonometer gently and steadily so that the waveform is displayed completely within the screen. If the trace is off the screen, on the top or bottom, it means that the operator is pressing too hard or not hard enough. Once the operator obtains a steady pulse waveform for 10 sec or two sweeps of the screen, he/she may press the space bar to freeze the

screen. Hint: once you get the final good wave, before you record it, lift the tonometer up while keeping your eyes on the optimal location, in order to erase the previous recordings from the system memory. It is important to set and use the quality control (QC) parameters available in the software to maintain quality data. **The minimum QC value is 85, i.e., "acceptable."**

Figure 4. Correct hand position

3.2. Pulse Wave Velocity

3.2.1. Principle

The velocity of the blood pressure pulse waveform is dependent on the stiffness of the artery along which the pulse is traveling. Serial measurement of pulse wave velocity in a section of artery will indicate the magnitude of change in arterial stiffness in that section of artery. The SphygmoCor® Vx Pulse Wave Velocity (PWV) System measures the velocity of the blood pressure waveform between any two superficial artery sites. The carotid and femoral pulses will be the sites of PWV measurement. The same pressure tonometer is used to record the pressure pulse waveforms simultaneously with an ECG signal, which provides an R-wave timing reference. The system uses applanation tonometry to non-invasively record high fidelity peripheral artery blood pressure waveforms consecutively at two carotid and femoral artery sites.

Pulse Wave Velocity (PWV) is calculated as follows:

PWV = distance (m.)/transit time (sec.)

PWV is simply the velocity of the pressure wave travelling through the arteries.

Aortic PWV:

- is a direct measure of arterial (aortic) stiffness
- is a parameter directly measured from real-time measurement of the time taken for the forward pressure waves to travel down the aorta.

The transit time between the arterial sites is determined by the difference in delays between the R wave on the ECG and a reference point on the waveform.

3.2.2. Procedure

The participant should be lying down on a bed with their arms alongside the body. To ensure a stable and artefact-free ECG, the electrodes must be positioned correctly. The electrodes may be placed on the periphery [left leg (LL), left arm (LA), right arm (RA)] or on the chest if required to obtain a stronger signal (see Figure 5). The SphygmoCor® system utilises a 3- lead ECG in the LEAD II configuration.

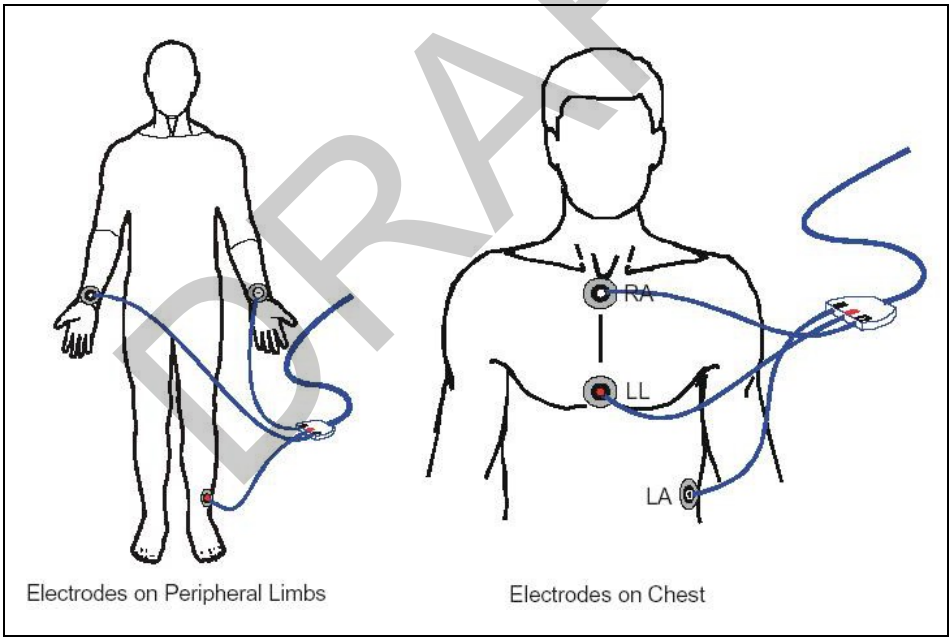


Figure 5. PWV electrodes position

The RAs will manually measure the following segments (mm):

- the distance from the suprasternal notch (notch at the top of the sternum) to the distal measurement site being used (usually radial or femoral),
- the distance from the suprasternal notch to the proximal (usually carotid) measurement site.

They will ensure there is a good ECG signal prior to performing the tonometry measurements. The R wave should be the tallest signal. If the T wave is taller than the R wave, the LA and LL leads should be reversed.

In PWV measurement, it is not essential to have a steady baseline in tonometer readings, BUT is still important to have waveform that is clear in the region of the 'foot of the wave' and consistent.

After the data for Site A has been captured, proceed with taking a reading at Site B
(Note: immediately after capturing data at Site A, you can elect to proceed with taking a reading at Site B, or to repeat the reading a Site A. Following the capture of data at Site B, you have the option of proceeding with the final calculation or repeating the reading at Site B).

Carotid measurement (site A):

1. Remove pillow if there is one. The participant's head should be tilted slightly to the back and to the side opposite to the side being interrogated.
2. The operator should feel for the position for the strongest pulse and place the tonometer directly on the top of the skin at this point.
3. The operator can be standing either behind the participant's head or to one side.

Femoral measurement (site B):

1. The femoral pulse is best felt by pressing directly backward at a point that is midway between the anterior superior iliac spine and the front of the pubic bone, and when the thigh is flexed at the hip joint and is moved away from the midline of the body and rotated away from the body.

4. Data management

All data collected of a quality index of ≥ 85 will be exported as text file and sent electronically to the data management core. The PWA variables exported are found in Table 1. A back up hard copy of the clinical screen and the detailed screen variable will be printed out and attached to the Sphygmocor form in the participant file. Quality index is not exportable and must be captured from the clinical screen printout.

Table 1. Exported PWA variables

LABEL	DEFINITION	LABEL	DEFINITION
C_AP	Central Augmented Pressure		
C_MPS	Central Mean Pressure of Systole		
Patient Number	Patient Number		
C_MPD	Central Mean Pressure of Diastole	SP	Entered Systolic Pressure
C_TTI	Central Tension Time Index	DP	Entered Diastolic Pressure
C_DTI	Central Diastolic Time Index		
C_SVI	Central Buckberg Sub-Endocardial Viability Ratio (SEVR)	MP	Entered Mean Pressure
C_PERIOD	Central Pulse Period	P_MAX_DPDT	Peripheral Pulse Maximum dP/dt
C_DD	Central Diastolic Duration	P_QC_PH	Peripheral Pulse Quality Control Pulse
C_ED_PERIOD	Central ED/Period %	P_QC_PHV	Peripheral Pulse Quality Control Pulse
C_DD_PERIOD	Period-ED/Period %	P_QC_PLV	Peripheral Pulse Quality Control Pulse
C_PH	Central Pulse Height	P_QC_DV	Peripheral Pulse Quality Control Diastolic
C_AGPH	Central Aug/PH %	P_SP	Peripheral Systolic Pressure
C_P1_HEIGHT	Central Pressure at T1 - Dp	P_DP	Peripheral Diastolic Pressure
C_SP	Central Systolic Pressure	P_MANP	Peripheral Mean Pressure
C_DP	Central Diastolic Pressure	P_T1	Peripheral T1
C_MEANP	Central Mean Pressure	P_T2	Peripheral T2
C_T1	Central T1	P_AI	Peripheral Augmentation Index
C_T2	Central T2	P_ESP	End Systolic Pressure
C_AI	Central Augmentation Index	P_P1	Peripheral P1
C_ESP	Central End Systolic Pressure	P_P2	Peripheral P2
C_P1	Central Pressure at T1	P_T1ED	Peripheral T1/ED %
C_P2	Central Pressure at T2	P_T2ED	Peripheral T2/ED %
C_T1ED	Central T1/ED %	P_QUALITY_T1	Peripheral Confidence Level of T1 (3-Very Weak/2-Weak/1-Strong/0-Very Strong)
Height		P_QUALITY_T2	Peripheral Confidence Level of T2 (3-Very Weak/2-Weak/1-Strong/0-Very Strong)
Height Variation			
C_T2ED	Central T2/ED %		
Length Variation			
C_QUALITY_T1	Central Confidence Level of T1 (3-Very Weak/2-Weak/1-Strong/0-Very Strong)		
Variation			
C_QUALITY_T2	Central Confidence Level of T2 (3-Very Weak/2-Weak/1-Strong/0-Very Strong)		
QUALITY_ED	Confidence Level of ED (3-Very Weak/2-Weak/1-Strong/0-Very Strong)		
ED	Adjusted Ejection Duration (ES)		
CalcED	Calculated Ejection Duration (ES)		

5. Quality control

To ensure the accuracy of the vascular stiffness / vascular stiffness measurements throughout the study, quality control measures are developed. These measures include:

1. Recruitment of the most qualified personnel
2. Standardized training by the Atcor Medical representative.
3. Observation of data collection by the supervisor.
4. Frequent staff meetings to provide feedback.
5. Editing of data by computer.
6. A quality assurance program administered by the Data Management Core.
7. Equipment maintenance program

5.1. Pulse Wave Analysis

5.1.1. Machine Setting

To assure quality data collection before each serial measurement, the sphygmocor configuration setting should be checked before EACH test:

a. Quality control: Minimum Pulse Height at 100, Maximum Pulse Height variation at 5 %. Maximum diastolic variation at 5 %.
b. Pressure sensitivity: set the upper limit at 4000.
c. Communications Port: select the appropriate communication from COM1 to COM4 or the USB Port.

5.1.2. Data collection

a. **The blood pressure** is measured just prior to performing the SphygmoCor assessment to allow the calibration of the radial pressure waveform.
b. **Quality control Indices**: the captured data quality control indices values, which are the average pulse height, the pulse height variation, and the diastolic pulse variation, displayed on the Clinical Report Screen, should appear in GREEN when they are within the limit set on the configuration setting. If the index falls outside the acceptable range, it will be displayed in RED (see Figure 6).

Figure 6. Quality index table

c. **Aortic Waveform criteria:** The following criteria should be applied to aortic waveform data (available on the Sphygmocor Clinical and Detailed Report Screens) as means of assuring data quality. **If any of these criteria should not be met, the recording should be repeated and strong consideration given to not retaining the data. However, if the attempts have lasted 20-30 minutes, and the indicators are still red, record the best measure obtained and make a note in the comments.**

T1 (detailed Screen): 80 msec < T1 < 150 msec

Augmentation Index (Clinical Screen): < 50%

Minimum Average Pulse Height (Clinical Screen): 100 units

Maximum Pulse Height Variation (Clinical Screen): 5%

Maximum Diastolic Variation (Clinical Screen): 5%

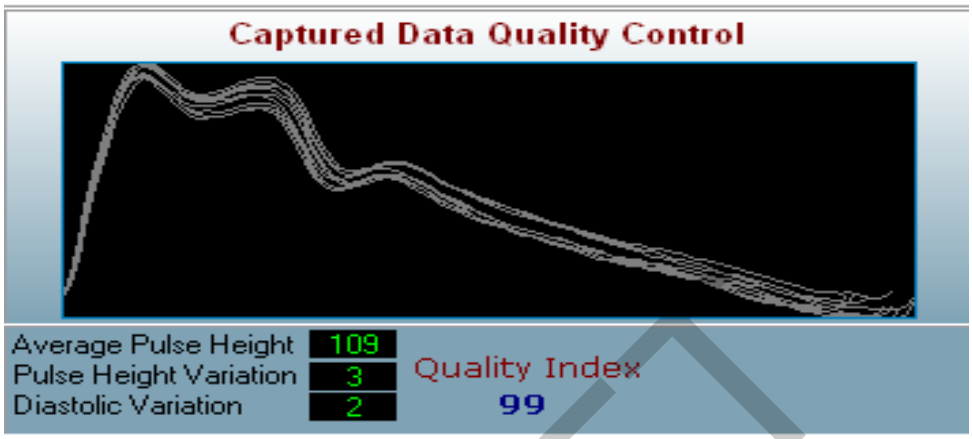
Minimum Quality Index (Clinical Screen): 85

Table 2. Guide used to determine if a measurement is of sufficient Quality Index

95 – 100 %	Excellent
90 – 94 %	Good
85 – 89 %	Acceptable
75 - 84 %	Borderline
< 74 %	Un-Acceptable

The Quality Index is a number calculated from the three Quality Control Indices (pulse height and height variation and pulse diastolic variation, with pulse height having the largest weight) and from how clear and distinctive the T1 is in the peripheral waveform. It is calculated by assigning a weight to each of these variables to give a combined number as a percentage. **This parameter is indicative of operator reproducibility**

d. **Pulse Overlay:** the variability of each individual overlayed pulse, which form an average pulse waveforms as displayed on the Clinical report screen, should be as little as possible.



e. Values of parameters determined from ejection duration when **ejection duration values** are outside the range of 200 – 400 milliseconds should be discarded.

f. Values of **parameters determined from P1 and T1** should be viewed with caution when T1 is outside the range 80 -150 milliseconds.

5.1.3. PWA parameters

The system outputs many variables as displayed in Table 1. SphygmoCor can calculate from the ascending aortic pressure waveform the following most useful cardiovascular data:

- **left ventricular load** As
- **central pulse pressure** Pp
- **systolic afterload** due to the state of the arteries AIx
- quality of **coronary artery perfusion pressure** Ad
- **ejection duration** (systolic vs diastolic dysfunction) ED
- index of **cardiac reserve** or **exercise tolerance** SEVR

SphygmoCor technology turns peripheral BP devices into powerful central cardiovascular diagnostic & monitoring tools.

5.2. *Pulse Wave velocity*

The quality control PWV measurement is based on observing the variation of the ECG R-wave and the foot of the waveform.
The system uses the foot of the waveform for locating the onset points used in calculating the time differences between the ECG and tonometer waveforms at each site.

- The SD (msec) in the statistical table should be **6**% of the mean time or below; this will be indicated in green.
- The SD of PWV should be 10% or less. A SD between 10 and 15 % could be a physiological variation; a SD above 20% is not acceptable, and in both instances the measurement should be repeated.

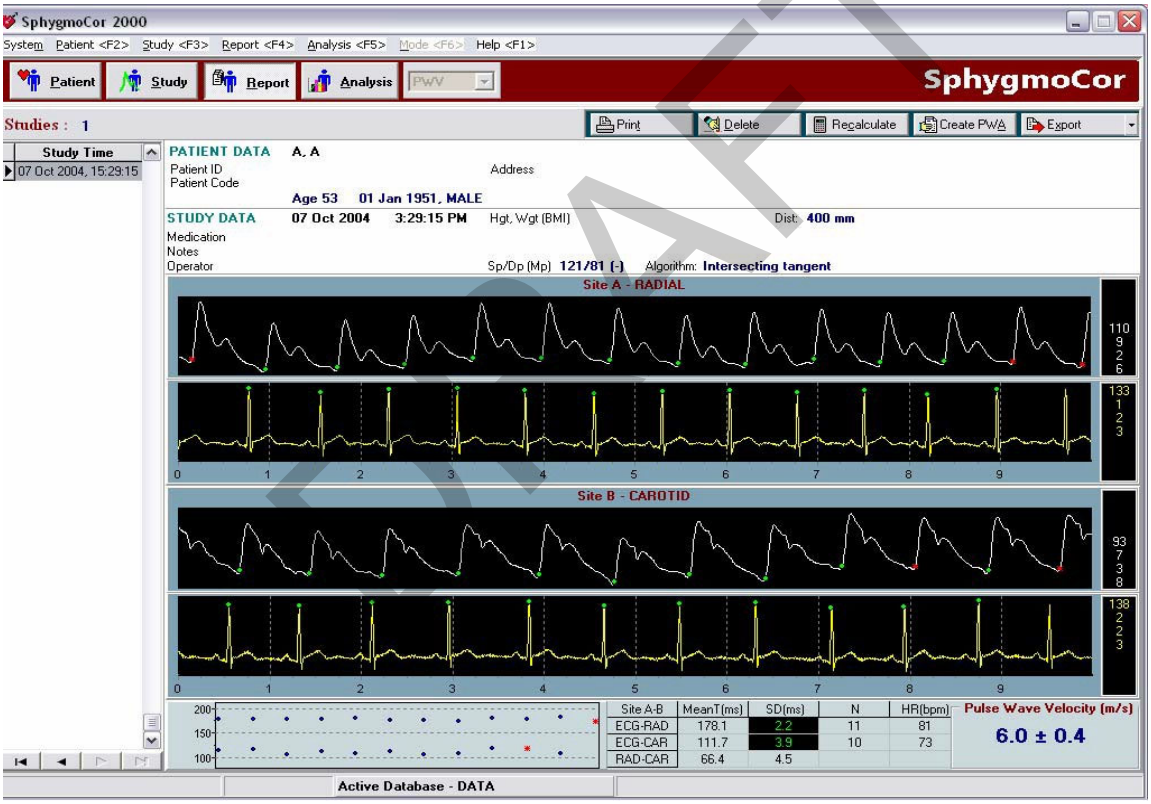


Figure 7. PWV strip

5.3. Standardized training by the Atcor personnel

The RAs received a standardized training from the AtCor representatives (see Appendix 1) with monthly feedback for questions and problems solving. After that the RAs practiced on their own pace to master their skills. A weekly self- assessment sheet graded from 5 (Excellent) to 1 (below Average) was filled by each RA and submitted to the Supervisor during the weekly meeting. A formal quality control reproducibility study was conducted in the Morehouse School of Medicine African-American Community volunteers. The study aims were to assess the within-person and the between-person variability and in the latter the contribution of the between-observer variability in the arterial stiffness measurements. A simple test and retest design whereby the three RAs examine the volunteers was used. Finally, the RA performance was assessed against the AtCor trainer's performance.

5.4. Equipment Maintenance

5.4.1.1. The Tonometer

The Tonometer (SPT-301B) tip is a delicate and sensitive device, and can be easily damaged if dropped or misused. Below are the guidelines to ensure the tonometer lifetime:

- The Tonometer should be kept in the white vest provided by the AtCor medical.
- When the transducer is not in direct use with the participant, protect the tonometer by placing the protective Tonometer Dome cover that was originally supplied with the unit.
- Do NOT use the Tonometer with any other instrumentation other than that supplied by the AtCor Medical. It is intended to be used in conjunction with the AtCor Medical Electronic Module, which has a floating (isolated) grounding system.
- Do NOT unplug the Tonometer from the Electronic Module unless to clean it. Multiple unplugging and plugging will damage or bend the Tonometer electrical pins.
- The Tonometer should be cleaned routinely **every month**, or when it becomes particularly dirty using Alconox® Powedered Precision Cleaner from ALCONOX, Inc. Clean between participants when using the femoral pulse to record pulse waves.
- Ensure to cover the Tonometer electric pins with the red cap supplied with the transductor to keep it from accidental wetting, which could cause corrosion or damage to circuitry. The caps should be saved and reused at each cleaning.

5.4.1.2. The Electronic Module

Precautions should be observed to reduce the risk of injury or damage to the unit:

- The Electronic Module will be placed onto a **stable** table. Caution will be followed to keep it from dropping.
- Do NOT apply heavy pressure to the module or subject it to strong impact. Excessive pressure or impact can damage electronic components or otherwise cause malfunctions.

  The electronic Module will be used and stored in a controlled room temperature of 15-30 °C (50-85°F). The unit will be kept from dirt, moist or dust exposition. It should not be exposed to direct sunlight, neither near a window nor left in the car nor taken outside in direct sun. This will overheat the unit and damage internal components.

- ❖ The unit will be placed away from apparel with strong magnetic fields such as radio, television sets, magnet or large electric motors.
- ❖ Any drink, coffee or liquid will not be put on the unit. Spilling liquids on or inside any components of the system can cause irreversible damage.
- ❖ Do NOT shake or drop the unit, sudden jolts can damage it.

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Appendix 1: QC criteria the RA must observe before and during the testing—to be completed by Supervisor

1. Check machine configuration setting before the test:

- Minimum Pulse Height at 100 units _____Yes _____No
- Maximum Pulse Height variation at 5 % _____Yes _____No
- Maximum diastolic variation at 5 % _____Yes _____No
- Pressure sensitivity upper limit set at **4000** _____Yes _____No

2. During the data collection

a. Measure BP just prior to performing the SphygmoCor assessment and **enter numbers** into the appropriate box. _____Yes _____No

b. **Quality control Indices** (Clinical Screen) **ALL** appear in GREEN.

c. Check the following Aortic Waveform criteria apply:

- T1 (detailed Screen): 80 < T1 < 133 msec _____Yes _____No
- Ejection duration (detailed Screen): 200<ED<400 msec_____Yes _____No
- Augmentation Index (Clinical Screen): < 50% _____Yes _____No

  Minimum Average Pulse Height (Clinical Screen): 100 units_____Yes_____No
- Maximum Pulse Height Variation (Clinical Screen): 5% _____Yes _____No
- Maximum Diastolic Variation (Clinical Screen): 5% _____Yes _____No
- Minimum Quality Index (Clinical Screen): 85% _____Yes _____No

Appendix 2: Check Procedures and Maintenance Instructions—MONTHLY or after mishandling or fall (damage suspicion) by the RA

Date:_____/_____/_____(mm/dd/yy)

Inspection:

Labels: Integrity: _____correct_____incorrect
Legibility : _____correct_____incorrect

Sphygmocor:

Power supply cord

	Loose connector*	yes	no
	Cracked	yes	no
	Broken	yes	no

*When there are loose components, the system rattles

ECG cable:

	Cracks	yes	no
	Break	yes	no
	Loose connection	yes	no
Serial cables	Cracks	yes	no
	Break	yes	no
	Loose Connection	yes	no

Tonometer:

	Cracks	yes	no
	Deformation (electric pins)	yes	no
	Corrosion (electric pins)	yes	no
	Loose Connection	yes	no
	Signal defect	yes	no

Appendix 3: Yearly check unless concerns about accuracy and safety (RA & RC) Date:

_____/_____/_____(dd/mm/yy)

Reason: _____systematic annual check

_____concern about accuracy

_____concern about safety

Tonometer

Sensitivity	_____correct	_____incorrect
Connection	_____ correct	_____incorrect
Sensor tip	_____ correct	_____ Incorrect
Signal defect	_____ Yes	_____ No

Comments:

Appendix 4: Tonometer cleaning procedure - monthly cleaning

Date :_____/_____/_____(mm/dd/yy) Operator:_____

Detergent used : _____

_____

1. unplug the sphygmocor from electric power
2. Unscrew the white protector vest using the tool provided with the device and slide it out of the probe.
3. cautiously wipe the tip of the milar transducer with an alcohol prep or a solution of pre-prepared alconox.
4. Wipe the tip with a dry gauze.
5. Replace the white vest and the protective cap.

Appendix 5: Vascular stiffness form

PRECISION CARRS Study ARTERIAL Stiffness Test

Visit 1

Screening No ☐☐☐☐ Subject ID ☐☐☐☐ Pt Initials ☐☐ Visit Date ☐☐/☐☐/☐☐

Start Time ☐☐:☐☐ am ☐ Pm ☐ End Time ☐☐:☐☐ am ☐ Pm ☐ RA Initials ☐☐

Blood Pressure: Systolic ☐☐☐ Diastolic ☐☐☐

Pulse Wave Analysis

Central Clinical Parameters	
Aortic SBP	
Aortic DBP	
Aortic PP	
Aortic Augmentation (AP)	
Augmentation Index (Aix)@75	
Ejection Duration (%)	
SEVR (%)	
Tr (m/s)	

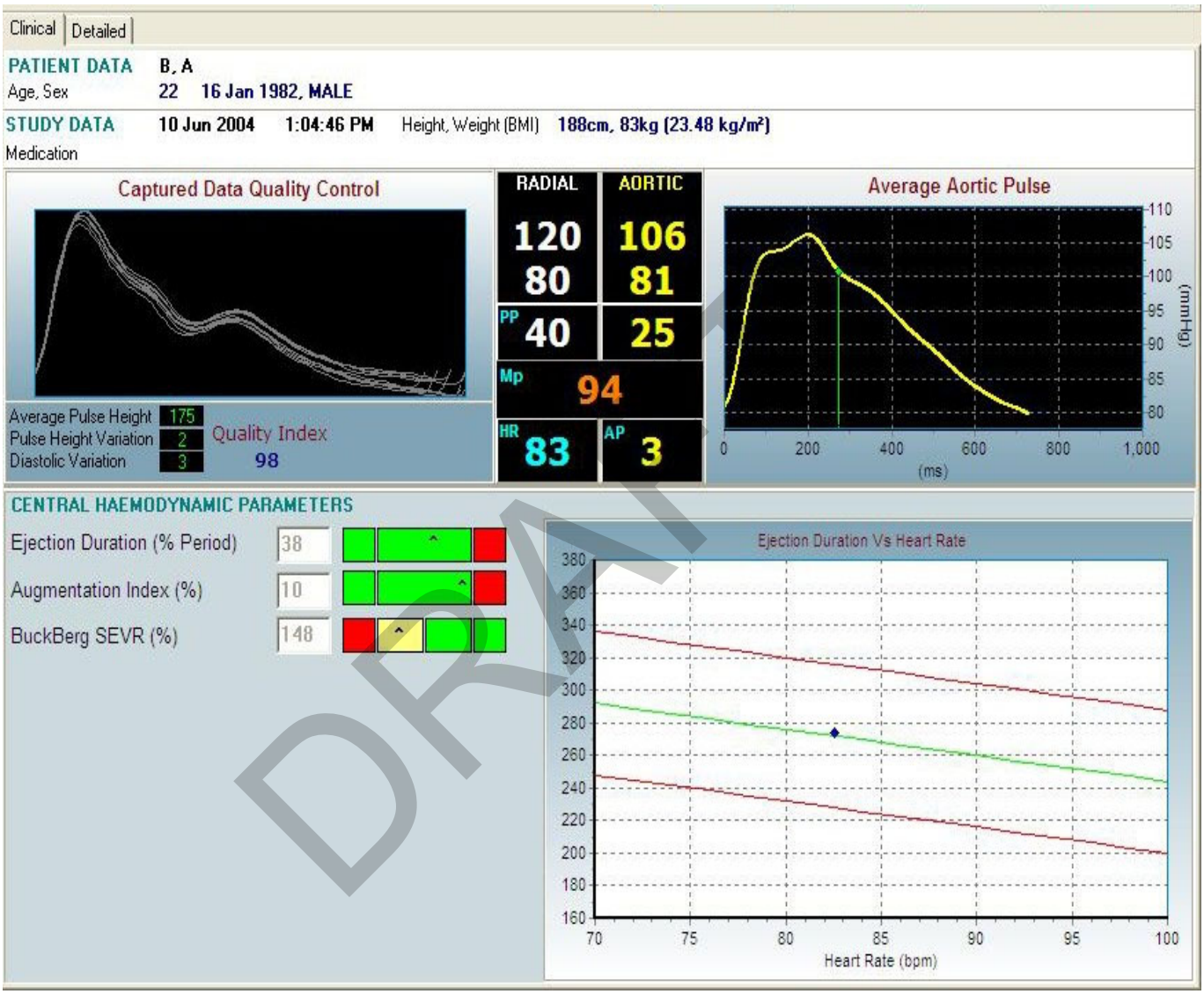
Pulse Wave Velocity

Pulse Wave Velocity Calculation				
SITE A-B	Mean T (m/s)	SD (m/s)	N	HR (bpm)
ECG-CAR				
ECG-FEM				
CAR-FEM				

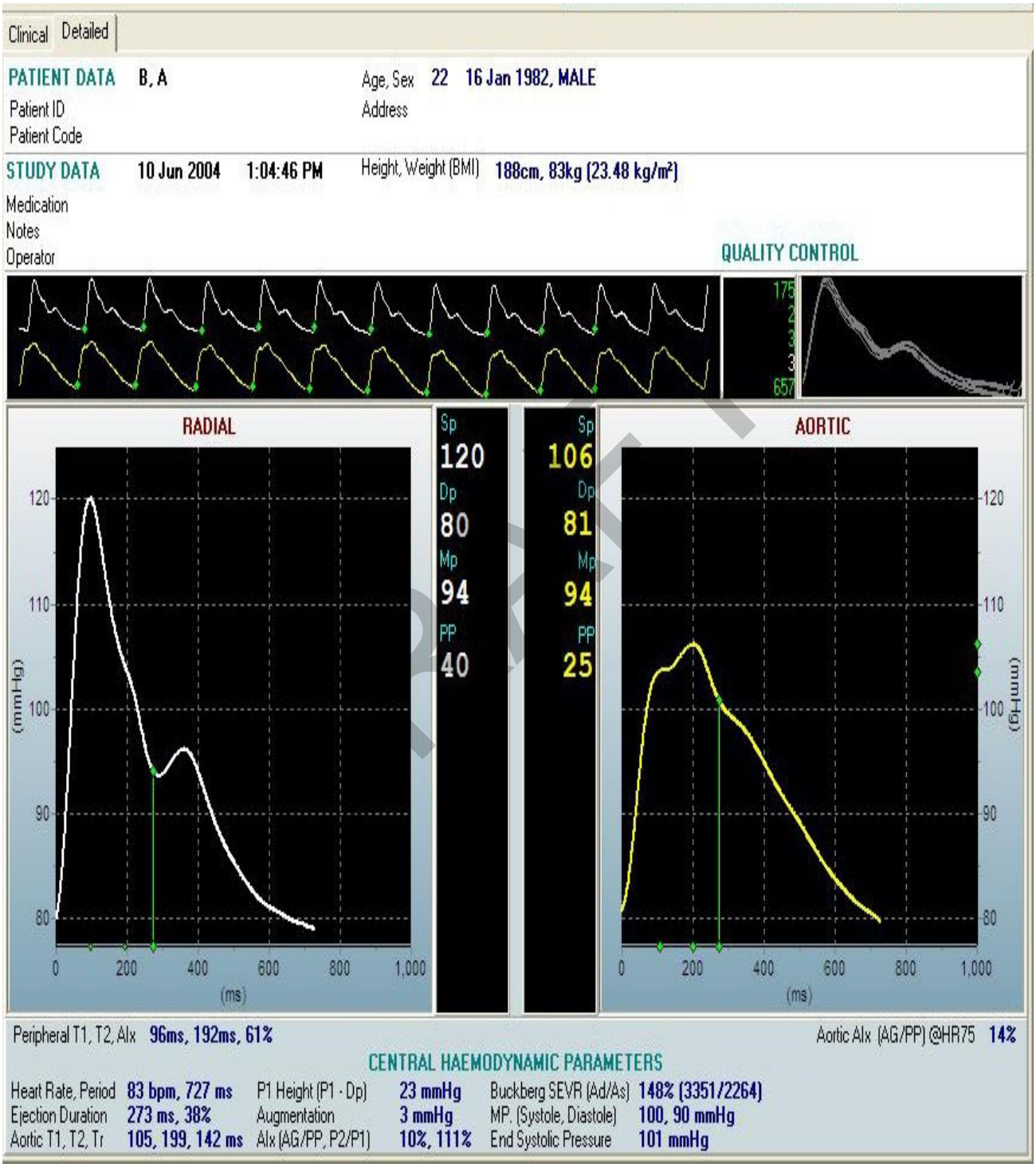
PWV(m/s)	
PWV ERR(±)	

Comments:

Appendix 6: Example of a clinical screen results



Appendix 7: Sphygmocor detailed screen



Appendix 8: Sphygmocor manufacturer operating manual

SphygmoCor
AT THE HEART OF CARDIOVASCULAR MANAGEMENT

Pulse Wave Analysis System SCOR-Px

Software Guide

AtCor MEDICAL

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SphygmoCor® Pulse Wave Analysis System Model SCOR-Px

Printed in Australia.

Rev: 8.1/1-PSOG

SphygmoCor® Software Version: 7

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DISCLAIMER

This manual has been validated and reviewed for accuracy. The instructions and descriptions it contains are accurate for the AtCor Medical product models at the time of this manual's production. However, succeeding models and manuals are subject to change without notice. AtCor Medical assumes no liability for damages incurred directly or indirectly from errors, omissions or discrepancies between the product and the manual.

This Manual is produced on the assumption that the operator is an experienced user of the Windows 9x/ME, Windows 2000/NT or Windows XP operating Systems.

If the operator is not familiar with Windows operations, please refer to the On-line Help of Windows or the Windows User Manual.

TRADEMARKS

REGULATORY APPROVALS

EC Declaration of Conformity

AtCor Medical Pty Ltd, West Ryde (Sydney), Australia

Herewith declares that the product

SphygmoCor Px Pulse Wave Analysis System

Model SCOR-Px

Described hereafter has been classified as Class IIa (Annex IX Rule 10) and is in conformity with the Annex I essential requirements and provisions of Council Directive 93/42/EEC Annex II.

CE 0120

Signature:  Date: 16/7/01

Place: Sydney, Australia

The SphygmoCor System is designed, tested and approved to the following standards:

- IEC601-1 (EN60601-1) Medical electrical equipment with Amendments 1 & 2

  Part 1: General requirements for safety (the International Electro-Medical Safety Standard for medical equipment)

- IEC601-1-2 (EN60601-1-2) Medical electrical equipment

  Part 1: General requirements for safety

  Collateral Standard: Electromagnetic compatibility - Requirements and tests that also requires approval to:

  - CISPR11 Emission standard
  - IEC 801-2 "Immunity to Electro Static Discharge" standard
  - IEC 801-3 "Radiated Immunity" standard
  - IEC 801-4 "Immunity to Fast Transients" standard
  - IEC 801-5 "Surge Immunity Test" standard

WARNINGS

Before use, operators should ensure that there are no conditions present that would impair accuracy of blood pressure measurement in the radial artery. The radial pulse should be identical in both arms, within the perception of the examining physician, and arterial pressure by cuff sphygmomanometry should be within 10 mmHg systolic prior to use. Since peripheral vasodilatation as in reaction hyperaemia, caused by arterial obstruction, alters brachial wave transmission, at least two minutes should elapse after use of the cuff sphygmomanometer before radial pressure waveform recordings are taken. The system is not applicable in generalised constriction or localised spasm of muscular conduit arteries such as seen immediately after hypothermic cardiopulmonary bypass surgery or accompanying Raynaud's phenomena or intense cold.

- The SphygmoCor process should not be used in persons with significant aortic valve stenosis (gradient >60mmHg)
- Values of parameters determined from ejection duration when ejection duration values are outside the range 200-400 msec should be disregarded.
- Values of parameters determined from P1 and T1 be viewed with caution when T1 is outside the range 80-133 msec.

CAUTION

U.S. Federal law limits sale of this device by or on the order of a physician

Contents

1. Introduction

The SphygmoCor® Px Pulse Wave Analysis (PWA) System is a sophisticated system for estimating the ascending aortic blood pressure waveform and central aortic haemodynamic indices from a peripheral blood pressure waveform measurement.

SphygmoCor provides a non-invasive cardiovascular profile with information such as:

- stiffness of arteries
- susceptibility to myocardial ischaemia
- risk stratification of marginal hypertensives
- cardiovascular risk of Type II Diabetic patients

You can more accurately identify those patients at risk of heart attack and stroke. With an assessment of risk factors, you can plan an effective and highly pro-active management regimen.

The system uses a Tonometer, connected to an electronics module, to non-invasively record a patient's peripheral artery blood pressure waveform at the radial or carotid* artery. From these measurements, the SphygmoCor software is able to estimate the calibrated ascending aortic blood pressure waveform, and a range of indices relating to ventricular-vascular interaction.

The SphygmoCor software maintains databases of patient measurements, and provides reporting and data analysis. Using the system, it is possible to clearly identify any changes to patient's condition, as well as the effects of short and long term drug therapy.

*Carotid artery measurements are not validated for clinical purposes in the USA only.

1.1 ABOUT THIS MANUAL

This manual is a guide to the operation of the SphygmoCor 2000 software. The manual is intended for the day-to-day use by the SphygmoCor operator, to take measurements using the system, and as an introduction to using the SphygmoCor software.

For details on the SphygmoCor System installation, for use and maintenance of the Tonometer and Electronics Module, and for use of the comprehensive analysis features available within the system, please refer to the SphygmoCor Operator's Manual.

This operator's guide accompanies Version 7 of the SphygmoCor 2000 Software. You can click the About option under the system Help menu to see the following screen, which shows you the version of the software you are running.

1.2 MANUAL CONTENTS

This guide contains the following sections:

Starting the Software

This section describes how to start the SphygmoCor software from your Windows 9x/ME, Windows NT/2000 or Windows XP operating system, and how to find your way around once it has started.

Taking a Measurement

This section is an overview to taking a measurement using the system. It describes all you need to get started with taking a measurement.

Working with the Patient Screen

In this section the features of the Patient screen are described more fully. The section includes how to search for existing patients, and how to add and edit patient details.

Working with the Study Screen

This section describes the procedure for taking a measurement from a patient. Measurements are taken from the Study screen.

Working with the Clinical & Detailed Report Screens

These sections describe the on-screen reporting that is available in the system, and how to print and export results.

Working with the Analysis Screen

This section describes the facilities in the system for performing analyses over a number of studies, for a chosen patient.

Advanced Topics

This section covers other procedures you may to need know about, such as what to do if the system tells you the database is empty, importing & exporting data and batch printing.

1.3 CONVENTIONS

This manual uses the following formats to describe, identify, and highlight terms and operating procedures.

Abbreviations

On first appearance, and whenever necessary for clarity, abbreviations are enclosed in parentheses following their definition. For example: Read Only Memory (ROM).

Messages Notes

Messages Notes are used in this manual to bring additional information to your attention. The message is identified as shown below.

NOTES

If, you see this, it means it is additional information.

The SphygmoCor Software also includes an online Help System. By pressing the F1 key at most stages in the System, you can get explanations of commands and screen messages.

Mouse Operation

Using the mouse cursor you can perform most software operations described in this manual. Various mouse functions perform specific tasks in the software. The mouse functions are described below:

Click - Press the primary mouse button (usually the left mouse button) with your finger once then release.

Right Click - Press the secondary mouse button (usually the right mouse button) with your finger once then release.

Double Click - Refers to quickly clicking the primary mouse button (usually the left mouse button) twice.

Drag - Press the mouse button while the cursor is on an object and while holding the button down move the mouse cursor to where you want the object moved then release the mouse button.

Keyboard Operation

The keyboard keys are used in the text to describe many software operations. A distinctive typeface identifies the key symbols as they appear on the keyboard. For example, ENTER identifies the Enter key.

Some operations require you to simultaneously use two or more keys. We identify such operations by the key symbols separated by a dash sign (-). For example, Ctrl-C means you must hold down Ctrl and at the same time press C**.** If three keys are used, hold down the first two and at the same time press the third.

Most Controls on the screen (buttons, menus, combo boxes etc.) can be activated by keyboard. A line appears underneath the letter that will activate that button. Press Alt & that key to activate.

For Example: 

To print, press Alt-T

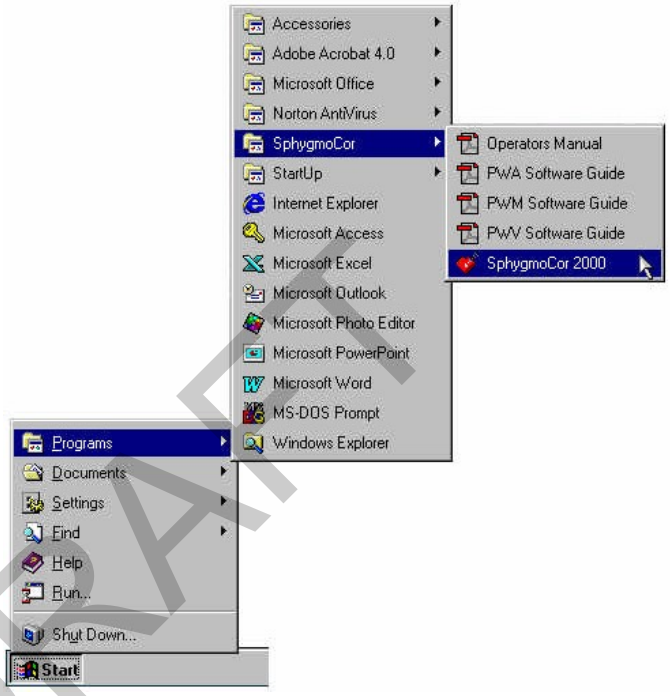
Display

When procedures require an action such as clicking an icon, button or entering text, the icon's name or the text you are to type in is represented in this type face: ENTER.

2. Starting the Software

See the Operator's Manual for Software Installation instructions.

You can start the SphygmoCor 2000 software from the Windows Start menu, by clicking and holding down the Start button, then navigating your mouse to the SphygmoCor 2000 program.



Alternatively, if you have a shortcut to the SphygmoCor 2000 software on your Windows desktop, just double-click the icon:

The SphygmoCor 2000 software displays a splash screen while it is loading and preparing itself for use. The Patient screen then appears.

COMMUNICATIONS ERROR

If a communications error message appears it is usually because either:

(a) The electronics module is not connected to the computer

(b) The electronics module is not switched on.

Click YES if you wish to attempt detecting the module again.

> Note that if the module is not detected on it's second attempt a message window will appear prompting you if you wish to change the configuration settings. If you click YES the SphygmoCor Configuration Window will appear, allowing you to change the computer communications port to which the electronics module is connected. See Section 9.1 for more on using the configuration window.

Click NO or CANCEL or press the Esc key to ignore the communications error message and continue working with the SphygmoCor system.

SOFTWARE UPGRADE

For upgrade versions you must have installed in the target computer a previous installation of the Version 5 SphygmoCor software. The system serial number of the existing V5 Software must correspond to the system serial number on the Upgrade Installation CD or the installation will be aborted.

If your computer does not have the previous installation then you may install the version 5 software from the disk that was supplied with your original system or if you have an earlier version of SphygmoCor you may request a Version 5 upgrade disk from AtCor Medical free of charge.

DATABASE UPGRADE

When a window appears at startup with a message that the Patient database is empty, you may import/upgrade from your earlier Version 5 SphygmoCor software**.** You may, however decide to use an empty patient database instead. To import a database click on Import Database**,** see Section 9.2. Note that you will not be able to use any measurements recorded in this new database in your earlier version of SphygmoCor**.**

To start using an empty database, click on Enter The System then you will need to create a new Patient. See Section 4.3.

If your system is not an upgrade proceed to using an empty database.

IMPORTANT NOTE

If you create any new patients you will not be able to import a database into the default database unless it is empty. You may, however import into another database, see the Database Manager in section 9.5.

2.1 THE MENU AND THE TOOL-BAR BUTTONS

When SphygmoCor has started, the Patient screen appears. At the top of the screen are the system menu and the tool-bar buttons, and these are displayed whenever the program is running.

Menu Bar	The menu bar gives you access to all the major areas of the program. When you click and hold down the mouse on the System and the Help menu options, further sub-menu options appear below them. For all the other menu options, when you click the option the relevant screen appears immediately Note that you can also use the function keys F1 to F5 to perform common functions, as shown on the menu bar.
Tool Bar Buttons	The tool-bar buttons allow quick access to all the major screens of the program.

2.2 THE STATUS BAR

The SphygmoCor status bar is always displayed at the bottom of the screen.

Active Database	This shows the name of the Patient database you are currently using.
Mode	When using the Patient screen, this shows whether you are currently in Edit mode or in Browse mode. See Section 4.1 for more on modes in the Patient screen.
Function	When using the Patient screen, this shows what function you are currently performing. See Section 4 for more on this.

3. Taking a Measurement

This section takes you step-by-step through the procedures necessary to take a measurement from a patient. See Sections 4, 5, 6, 7, and 8 for further details on each of the major screens in the program.

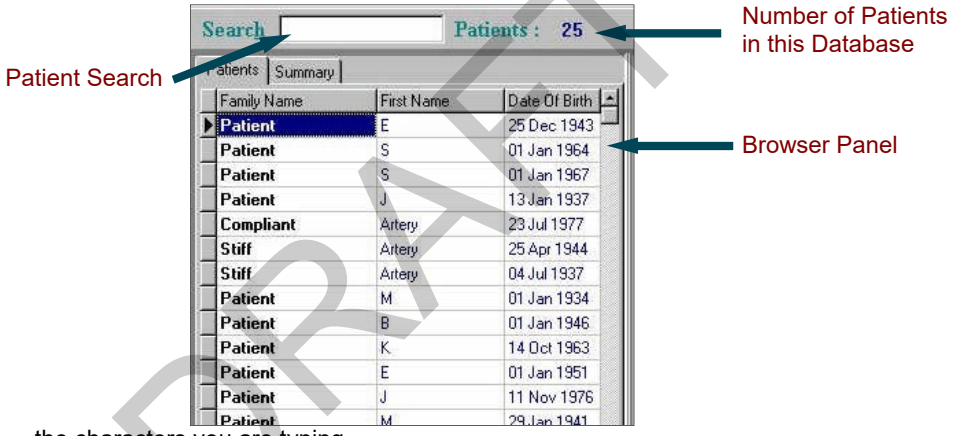
3.1 SELECT THE PATIENT

To take a measurement (also called making a Study) you must first choose a patient on the Patient Screen. Either select an existing patient, or add new patient details to the system.

3.1.1 BROWSE FOR AN EXISTING PATIENT

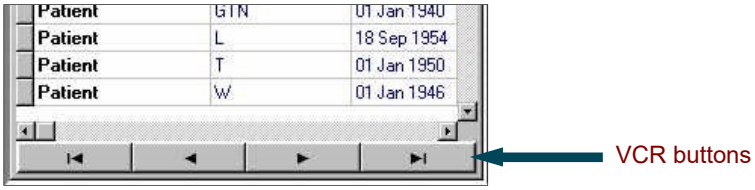
The Patient Screen has a browser panel on the left hand side. Use the browser panel to choose a patient. Choose a patient by one of the following means:

- Place the cursor in the Patient Search field and enter the patient's family name. As you do so the system selects the patient in the browser whose name best matches the characters you are typing.



- Click on any row in the browser to select that patient. When a patient is selected, the arrowhead symbol appears to the left of that patient in the panel, and the patient name is highlighted.

Use the VCR buttons at the bottom of the browser panel to select the patient. For more details on using this method, see Section 4.2.3.



3.1.2 CREATE A NEW PATIENT RECORD

Use this option if the patient is not already in the database, and you want to add details about the new patient.

Step 1 Click the Create New button on the Patient tool-bar:

Step 2 Enter the patient details into the Patient Edit panel. Only the fields Last Name, First Name, Date of Birth and Sex are mandatory. For more on editing patient details, and the Patient Edit panel, see Section 4.

Step 3 Click the Update button to add the details of the new patient to the database, or the Reject button to discard the details you have entered.

3.2 PERFORM THE STUDY

To perform the Study (take the measurement) for the selected patient, open the Study Screen. You can do this by clicking the Study tool-bar button or pressing F3. (Refer to the Menu Bar)

Alternatively, you can double-click any patient in the browser panel of the Patient Screen to move directly to the Study Screen, with that patient selected.

Step 4 Select the artery, by clicking either the Carotid* or the Radial check box.

Step 5 Enter the Diastolic pressure reading, taken using your sphygmomanometer or blood pressure meter.

Step 6 Enter *either* the Systolic pressure reading *or* the Mean pressure reading, taken using your sphygmomanometer or blood pressure meter.

Step 7 If required, enter the Medication, Notes and Operator details, and values for patient Height and Weight. All of these items are optional.

Step 8 To proceed to capture data click the Capture Data button at the top right of the Study Screen. The data capture now commences. Alternatively, you can also press the Enter key or Alt-U to start the data capture.

*Carotid artery measurements are not validated for clinical purposes in the USA only.

Step 9 On the Data Capture screen you will see a horizontal trace in the Signal Detail Area. When you obtain a waveform reading using the Tonometer probe, the waveform is shown in the Signal Detail Area. The entire 10- second waveform that will be processed by SphygmoCor is shown in the Signal for Processing Area.

SIGNAL DETAIL AREA

This area is refreshed and automatically re-scaled every five seconds. When a signal is detected the software will auto scale to zoom and fit the captured waveform within the window limits.

SIGNAL FOR PROCESSING AREA

This area of the Capture Screen shows the last 10 seconds of the actual waveform that will be captured by SphygmoCor for processing.

Step 10 When you are satisfied that you have a good reading, press the Space bar on the computer keyboard, or click the OK button at the top of the screen. You have up to 2 seconds between removing the Tonometer and pressing the space bar as the system removes the last 2 seconds of data recorded.

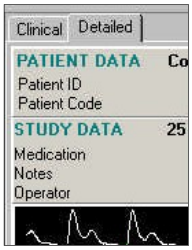
For more information on the data capture procedures see Section 5.2.

3.3 EXAMINE THE REPORT

After you have completed the data capture, a "calculation" icon appears while the measurements are being calculated. Then the Report Screen opens. The report you see relates to the measurement you have just taken. You should check data as explained in the following sections on the Report screen. See also Caveats and Limitations (Appendix 10.1).

3.3.1 CHECK THE PATIENT AND STUDY DATA

Check that the Patient data and the Study data are correct.



IF THE PATIENT DATA IS INCORRECT

Click the Patient tool-bar button to return to the Patient Screen and update Patient details.

IF THE STUDY DATA IS INCORRECT

Click the Recalculate tool-bar button to open the SphygmoCor Recalculate Report window. This window allows you to change any of the details you entered in the Study Screen, before you performed the data capture.

3.3.2 CHECK THE QUALITY CONTROL

Check the Quality Control area of the screen to ensure that the measurement is within the limits of the current quality control settings.

QUALITY CONTROL SETTINGS

These settings can be changed in the SphygmoCor Configuration window. For more on using the configuration window see Section 9.1.

The Quality Control area of the Report screen shows the raw and the processed recorded waveforms, the Quality Control indices and the Over-layed recorded data.

Step 11 Check that the indices are displayed in GREEN, to indicate that they are within the quality limits. If they displayed in RED, then the values are outside the limits. For more on the meaning of each of the numbers shown in this area, see Sections 6.2 & 7.1.

Step 12 Check that the over-layed recorded data is visually coherent. That is, the waveform pulses should overlay with minimal spread.

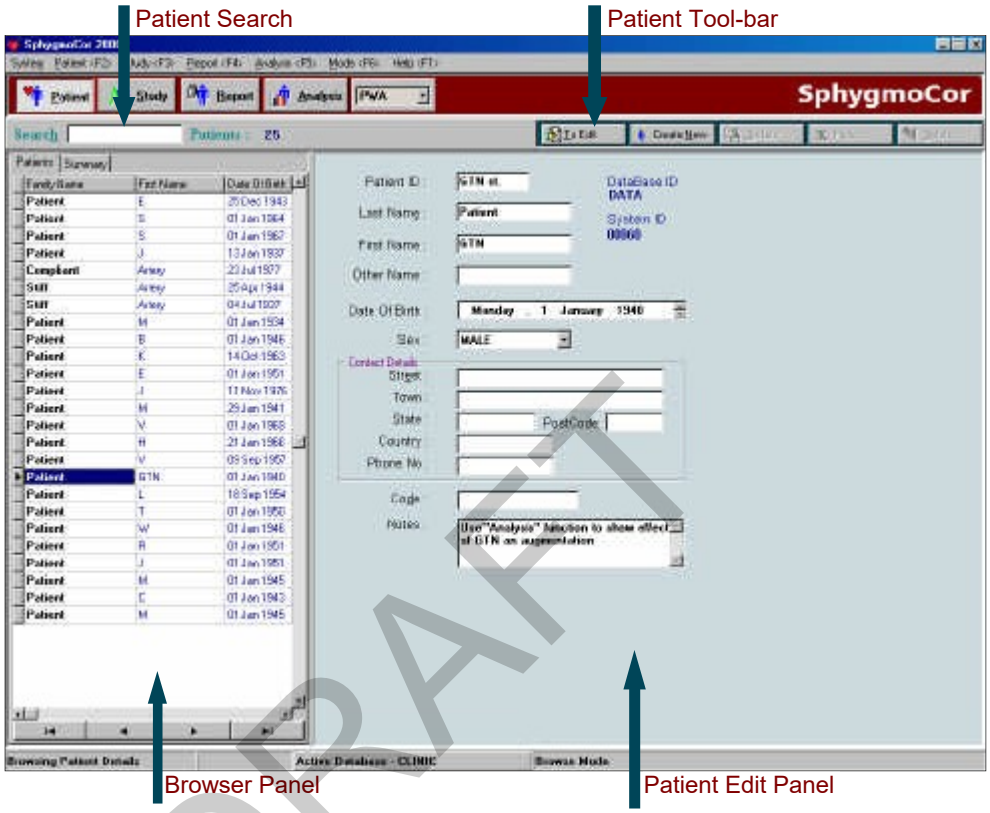
If you decide that the report does not meet the Quality Control settings, you should do one of the following:

- Perform the Study again. First delete the Study by clicking the Delete tool-bar on the right hand side of the Report screen. Then click the Study tool-bar button (or press F3) to return to the Study Screen.
- Check that you entered information correctly on the Study Screen. You can click the Recalculate tool-bar button on the Report Screen to display the SphygmoCor Recalculate Report screen, and change any of the details you entered for the Study.

- Check that the Quality Control limits are in fact acceptable. See Section 9.1 for details on how to do this.

4. Working with the Patient Screen

In this section the features of the Patient Screen are described in detail. The section explains how to search for existing patients, and how to add and edit patient details.



4.1 MODES

When working in the Patient Screen, there are two different modes you can work with:

- Browse Mode is used when you want to find an existing patient in the database.
- Edit Mode is used when you want to create a new patient record, or update the details held for an existing patient.

To switch between the two modes, use the first button on the patient tool-bar as follows:

- When in Browse Mode (which is the default mode), click the To Edit tool-bar button to enter the Edit Mode:

- When in Edit Mode, click the To Browse tool-bar button to return to the Browse Mode:

4.2 BROWSING FOR PATIENTS

The Browser panel on the left-hand side of the Patient Screen allows you to browse through the database and find an existing patient. There are several ways you can use the Browser Panel.

4.2.1 USING PATIENT SEARCH

Enter characters into the Patient Search field at the top of the Browser Panel. As you do so the system selects the patient in the browser whose name best matches the characters you are typing. The system shows which patient is selected by placing an arrow-head to the left of the selected patient:

When a patient is selected, the full details of the patient appear in the Patient Edit Panel.

4.2.2 SELECTING A PATIENT IN THE BROWSER

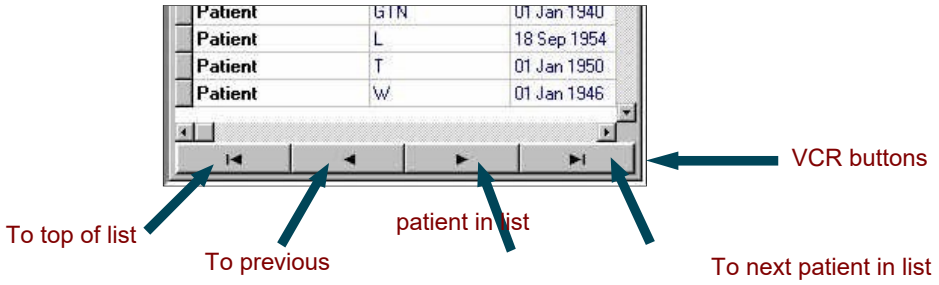
You can select a patient by clicking on the row in the browser where you see the patient details you are interested in. The arrowhead symbol appears to the left of the patient you clicked on.

NOTE:

If you cannot see all the browser columns, use the horizontal scroll bar at the bottom of the browser panel to move the hidden columns into view.

4.2.3 USING THE VCR CONTROLS

You can use the VCR-style controls at the bottom of the Browser panel to find a patient.

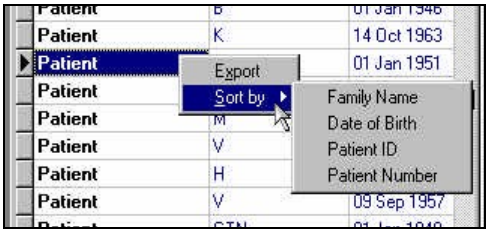


To bottom of list

Use the buttons as shown in the above picture. Note that by default, patients are sorted by Family Name in the browser. You can change the sort order of patients in the browser if you want to - see Section 4.2.4 for how to do this.

4.2.4 RIGHT-CLICK OPTIONS IN THE BROWSER

When you click the right hand mouse button when the cursor is on a selected patient, a small menu of options appears:



- Click the Export option to export the patient and study details to a file. See Section 9.6

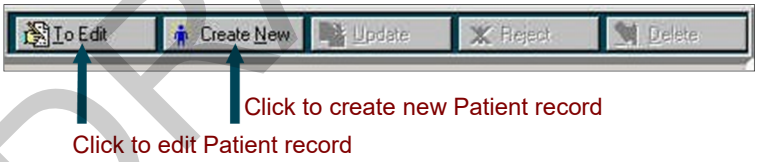
- Move the mouse over the Sort by option to see a list of columns by which you can choose to sort the browser panel contents.

  Click on any one of the options to sort the browser panel by the column of that name.

4.3 CREATING AND EDITING PATIENTS

When you are in the Browse Mode and you want to create a new patient, or edit the details for an existing patient, do the following:

Step 1 Click either the To Edit or the Create New button on the Patient tool-bar:



Symbols displayed in the Browser

While you are editing a record, the arrowhead symbol in the first column of the browser changes to the I-beam symbol to show that you are editing. The function displayed on the left of the status bar also reminds you that you are Editing the Patient Details.

While you are creating a new record, the arrowhead symbol in the first column of the browser changes to the asterisk symbol to show that you are inserting information into a new row of the browser. The function displayed on the left of the status bar also reminds you that you are Inserting New Patient Details.

Step 2 In the Edit panel, fill in the individual fields for the patient. The fields are as follows:

Patient ID	(Optional.)	An identification number for the patient
Last Name	(Mandatory.)	The last name of the patient.
First Name	(Mandatory.)	The first name of the patient.
Other Name	(Optional.)	Any other name, such as a middle name, for the patient.
Date of Birth	(Mandatory.)	The patient's date of birth.

Entering the Date of Birth

The Date of Birth field has four components to it: the Day of the Week, the Day Number of the Month, the Month Name and the Year. Click on any one of these four components to select it, in order to change that component. Then use the spin control to increase or decrease the displayed value for that component.

For the numeric components (Day Number and Year) you can also enter the required numbers directly, using the keyboard, when these components are selected.

Sex	(Mandatory.)	The sex of the patient, selected by clicking the down-pointing arrowhead and selecting either MALE or FEMALE.
Street	(Optional.)	The street number and name in which the patient lives.
Town	(Optional.)	The town or suburb in which the patient lives.
State	(Optional.)	The State or Province in which the patient lives.
Post Code	(Optional.)	The Post Code or Zip code for the patient.
Country	(Optional.)	The Country of residence of the patient.
Phone No	(Optional.)	The Telephone Number of the patient.
Code	(Optional.)	A Code, to a maximum of 15 characters, which can be used to help in categorising patients.
Notes	(Optional.)	Any Notes about the patient

Step 3 When you have entered all the details for the patient, click the Update button to save the details in the patient database, or click the Reject button to discard the details you have entered.

Click to update the Patient record

Step 4 You can now click the To Browse button on the patient tool-bar to return to the browse mode; or you can remain in Edit mode and make further changes to the current patient record, or to another patient record.

Moving to another Patient, in Edit Mode

When you move to another patient record while in Edit Mode (by clicking on another patient in the browser), you can begin editing the new patient's details immediately. The arrowhead symbol in the browser changes to the I-beam symbol to show that the new patient record is now being edited. Any changes you made to the *original* patient record are automatically saved.

4.4 DELETING PATIENTS

To delete an existing patient:

Step 1 Select the patient using the browser.

Step 2 Click the Delete button on the patient tool-bar. A message appears asking if you are sure you want to delete the patient **and all the associated patient study data.**

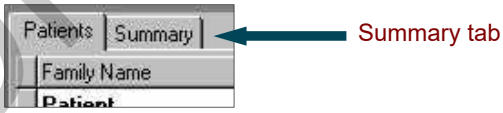
Step 3 Click Yes if you are sure about proceeding with the deletion or No or Cancel if you are not sure about proceeding.

CAUTION

Deleted data cannot be retrieved later.

4.5 PATIENT SUMMARY

The browser also has a Summary tab, which shows information about the currently selected patient. Click the Summary tab to see this information.



The Summary tab shows the number of studies performed on the selected patient, the dates of the first and the latest study, and the total number of days since the last study was performed, for the selected patient.

Click the Patients tab to return to the Patient Browser.

4.6 MOVING TO THE STUDY SCREEN

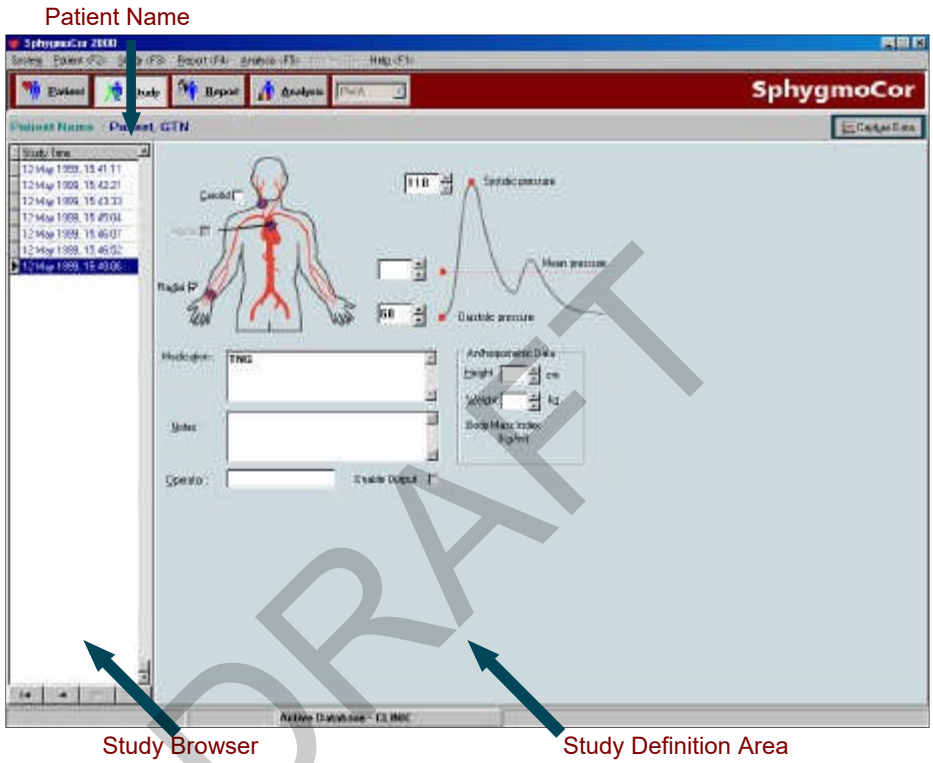
When in the Patient Screen, you can select a patient and then move to the Study Screen by one of the following methods:

- Click the Study tool-bar button.
- Press F3.
- Double-click a patient in the patient browser.

The study that you perform in the Study Screen is recorded against the patient that you selected in the Patient Screen.

5. Working with the Study Screen

This section describes in detail the procedure for taking a measurement from a patient. Measurements are taken in the Study Screen.



WARNING

Before use, operators should ensure that there are no conditions present that would impair accuracy of blood pressure measurement in the radial artery. The radial pulse should be identical in both arms, within the perception of the examining physician, and arterial pressure by cuff sphygmomanometry should be within 10 mmHg systolic prior to use. Since peripheral vasodilatation as in reaction hyperaemia, caused by arterial obstruction, alters brachial wave transmission, at least two minutes should elapse after use of the cuff sphygmomanometer before radial pressure waveform recordings are taken. The system is not applicable in generalised constriction or localised spasm of muscular conduit arteries such as seen immediately after hypothermic cardiopulmonary bypass surgery or accompanying Raynaud's phenomena or intense cold.

The Study Screen has the following key areas:

Patient Name	Check the name to ensure that you are performing the study for the correct person

Study Browser	Use the browser to examine previous studies made for this patient. The arrowhead symbol identifies which study is currently selected. Details of this selected study are shown in the Study definition area.
Study Definition Area	This area of the screen shows the fields that you fill in prior to performing a study. You can display and edit these fields, for existing study records.

5.1 ENTERING THE STUDY FIELDS

The fields in the Study Definition Area are as follows. When you enter data into these fields, you are specifying the data for the study you are about to perform.

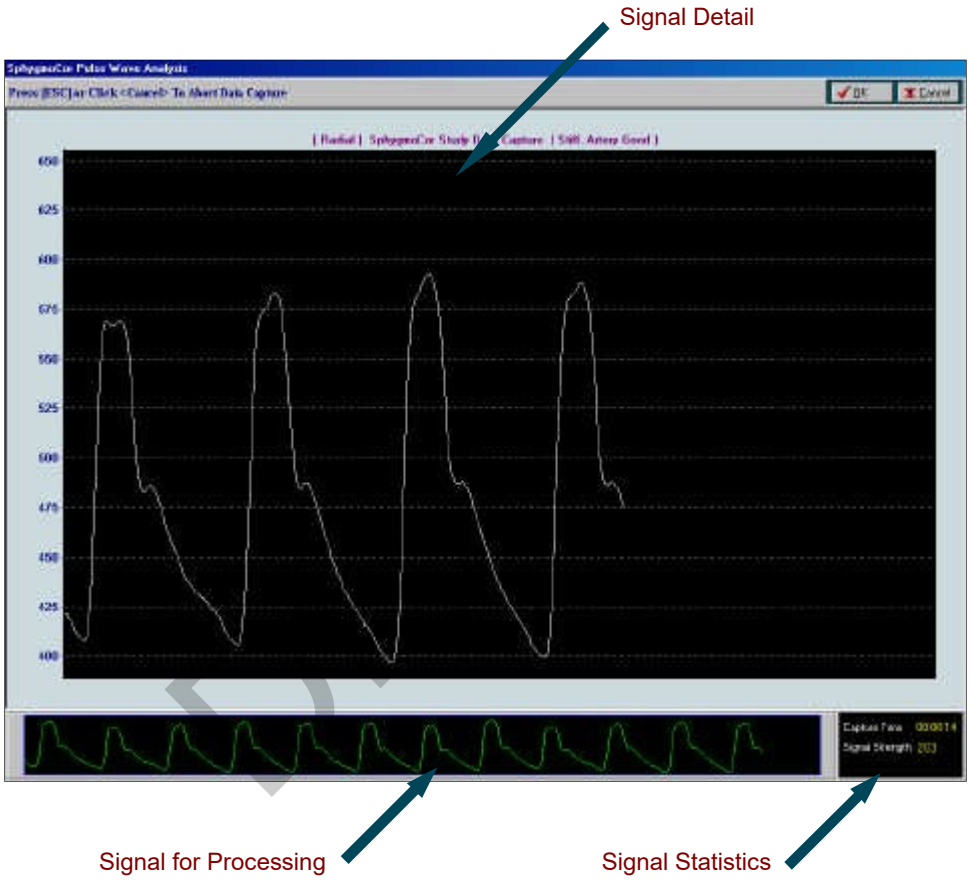
Carotid*		Pick the carotid artery as the site for the study, by clicking this check box.
Radial		Pick the radial artery as the site for the study, by clicking this check box.
Aortic**		Pick the Aortic site for the study, by clicking this check box.
Diastolic pressure		Enter the Diastolic pressure you have just measured using your sphygmomanometer or blood pressure meter. You can use the “up/down keys” to enter the value, or enter the numbers directly from the keyboard. 
Systolic pressure		Enter *either* the Systolic pressure reading *or* the Mean pressure reading, taken using your sphygmomanometer or blood pressure meter. 
Mean pressure		In the case of a carotid study enter the Mean pressure you have just measured using your sphygmomanometer or blood pressure meter, instead of the systolic pressure. 
Medication	(Optional)	Enter details of any Medication, if applicable.
Notes	(Optional)	Enter any notes relating to the study.
Operator	(Optional)	Enter the name or reference of the operator performing the study.
Height	(Optional)	Enter the height of the patient.
Weight	(Optional)	Enter the weight of the patient.
Enable Output (Optional)		Enable data output to the Electronics Module during data capture, by clicking this check box.

* Carotid artery measurements are not validated for clinical purposes in the USA only.
** When this check box is selected, no processing is done to the captured waveform, this feature is not enabled in this version of software

5.2 PERFORMING THE DATA CAPTURE

To perform the Data Capture:

Step 1 Click the Capture Data button at the top right of the Study Screen or press Enter or Alt-U. The Data Capture Screen then opens:



NOTE ON COMMUNICATIONS ERROR

If, at this stage, a communications error message appears, this is usually because either

(a) The electronics module is not connected to the computer

(b) The electronics module is not switched on.

Click OK to close the message box.

You will then need to change the communications port settings in the Configuration Settings Window, see section 9.1.

Step 2 On the Data Capture Screen, you will see a horizontal trace in the Signal Detail area. When you obtain a waveform reading using the tonometer, the waveform

is shown in the Signal Detail area. The entire waveform that will be processed by SphygmoCor is shown in the Signal for Processing area.

Step 3 Using the Tonometer, obtain a waveform from the chosen artery. The waveform is displayed in the Signal Detail area of the screen. You can use the display in this area to check that the signal is of sufficient strength, and that the individual pulses look similar.

Step 4 If you press too hard or too soft with the Tonometer, the signal level will either pass the maximum height of the Signal Detail Area or a low-level signal will be seen. The next time the screen is refreshed the auto-scale function will place the signal in the centre of the screen to full scale of the pulse height. Ensure that the signal being captured is steady on a consistent scale.

NOTE ON TONOMETER SENSITIVITY

If the Tonometer is too sensitive and your signal is continuously passing the maximum height on the Signal Detail Area even though you are applying slight pressure, you will need to increase the Pressure Sensitivity Upper Limit in the Configuration Settings Window, see section 9.1.

SIGNAL DETAIL AREA

This area is refreshed and automatically re-scaled every five seconds. When the horizontal grid lines appear farther apart, the signal strength is better. Use this area to enable you to obtain the strongest possible waveform measurement from the patient. Adjust the way you position the Tonometer while you examine the strength of the waveform on the screen.

Note that the spaces between the horizontal grid lines are always 25 units. These units (that is, the vertical axis units) are raw signal units, and are not calibrated pressure units.

SIGNAL FOR PROCESSING AREA

This area of the Capture Screen shows the actual waveform that will be captured by SphygmoCor. Make sure that you can see the bottom and the top of each wave pulse in this area, and that the wave pulses consistently fill the window. In other words, there should be a consistent pulse height on a horizontal base line.

Step 5 When you are satisfied that you have a good reading, press the Space Bar on the computer keyboard, or click the OK button at the top of the screen.

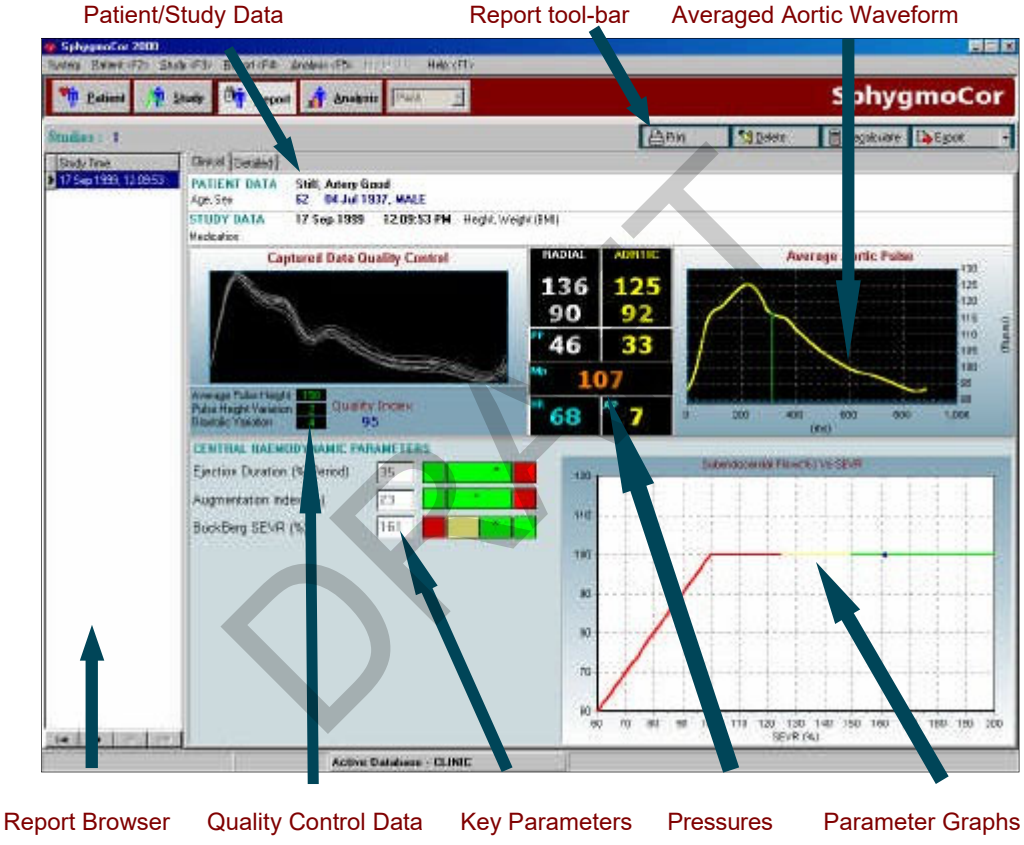
CHECKING THE SIGNAL STATISTICS

The Signal Statistics area shows you the following:

Capture Time	The length of time over which you have been capturing a signal.
Signal Strength	The strength of the signal you are capturing. This is the difference between the signal maximum and the signal minimum. The value you see here is automatically updated every 5 seconds. Although you should set your own standards for minimum signal strength, a value of no less than 100 is recommended by AtCor Medical.

6. Working with the Clinical Report Screen

This section describes the on-screen clinical reporting that is available in the system, and how to print and export results.



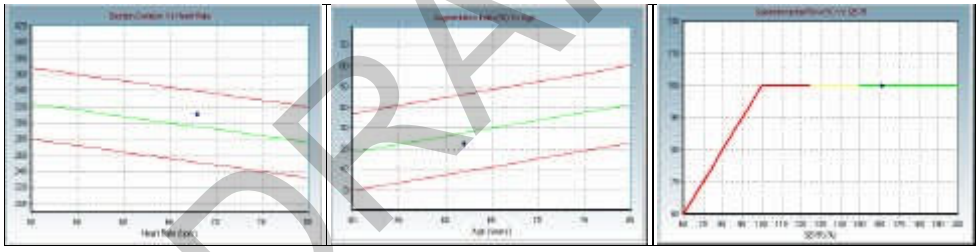
The Clinical Report Screen has the following key areas:

Report Tool-bar	Use this tool-bar to perform functions relating to the report which is currently being displayed. See Section 6.3 for more on these options.
Patient/Study Data	This section summarises information about the patient and the study you have just performed. Check this section to ensure that the details you have entered for the patient and the study are correct. If the study data is not correct, click the Recalculate button on the Report Tool-bar to open the SphygmoCor Recalculate Report window. This window lets you change any of the study fields you originally entered in the Study Screen.
Quality Control Data	Check this area to ensure that the measurement conforms to the quality control settings. See Section 6.2 for more on this area.
Report Browser	Use the Report Browser to examine other studies for the same patient. Notice that the current study (the one you have just performed) is the bottom study in the Browser Panel.
Averaged Aortic Waveform (Derived)	This section shows the derived Averaged Aortic Waveform. This reading is obtained by applying mathematical transforms to the Peripheral Pulse Waveform.
Key Parameters	This section shows three key parameters which can be used for clinical cardiovascular evaluation: • Ejection Duration (% of Period) • Augmentation Index (%) • Buckberg Sub-Endocardial Viability Ratio (SEVR %) The red, yellow and green bars to the right of the parameters indicate the position of that parameter within the population ranges for that measurement. If the arrow (^) is in the green area this indicates that the parameter is within the population range. See the relevant sections in the Clinical User Guide for more information.
Pressures	This area displays the peripheral and central pressures. (SP/DP, MP, PP), heart rate (HR) and augmentation pressure (AP).
Parameter Graphs	This area displays the population statistical comparison graphs associated with each parameter indicating the patient's position in the population range. See section 6.1 to select the different parameters.

6.1 PARAMETER GRAPHS

To display a particular parameter graph, simply move and click the mouse cursor on the parameter text label.

Graphs for the 3 key parameters:



Ejection Duration vs HR **Aug. Index vs Age** **Buckberg SEVR**

The green line indicates the population means and the red line indicates 90% confidence interval. Refer to the Clinical User Guide for more information on clinical ranges and the population data.

WARNING

In consequence of the above:

a) The SphygmoCor process should not be used in persons with significant aortic valve stenosis (gradient >60mmHg),

b) Values of parameters determined from ejection duration when ejection duration values are outside the range 200-400msec should be disregarded.

c) Values of parameters determined from P_1 and T_1 be viewed with caution when T_1 is outside the range 80-133 msec.

6.2 QUALITY CONTROL

The Quality Control Area of the Clinical Report Screen shows the captured peripheral waveforms over-layed on one graph, the Quality Control Indices and the Quality Index.

Check the quality control values to ensure that the measurement is within the limits of the current quality control settings.

Check that the indices are displayed in **GREEN**, this indicates that they are within the quality limits. If they are displayed in **RED**, then the values are outside the limits. The Quality Control values of the Report Screens show information to help you ensure that the measurement you have recorded is of sufficient quality.

6.2.1 QUALITY CONTROL INDICES

Where the figures appear in **GREEN**, they are within the limits set using the Configuration Settings. Where the figures are in **RED**, they are outside these limits.

- The Average Pulse Height is the average of the heights of all the pulses.
- The Pulse Height Variation is the amount of variation present in the pulse heights.
- The Diastolic Variation is the amount of variation present in the diastolic point of the pulse wave and indicates how constant the baseline pressure was during the measurement.
- Quality Index is a number calculated from the three indices above.

WARNING

If the Pulse Hight Variation or Diastolic Variation is outside the limits (ie. displayed in red) the operator should examine the radial artery waveform trace to ensure no transients occurred during the averaging period that would make the averaging process invalid.

6.2.2 OVERLAYED RECORDED DATA

This area displays a visual guide to how well the individual pulses can be overlayed to form an averaged pulse. There should be as little variability in the pulses as possible.

It is recommended to also examine each individual pulse in the waveform for shape consistency especially around the Sp peak.

6.2.3 QUALITY INDEX

The Quality Index is an indicator of overall quality of the captured signal. It is calculated by assigning a weighting to each of the Quality Control Indices and then adding them to give a number as a percentage.

Below is a guide that should be used to determine if a measurement is of sufficient quality:

95 – 100 %	Excellent
90 – 94 %	Good
85 – 89 %	Acceptable
75 – 84 %	Borderline
< 74 %	Un-Acceptable

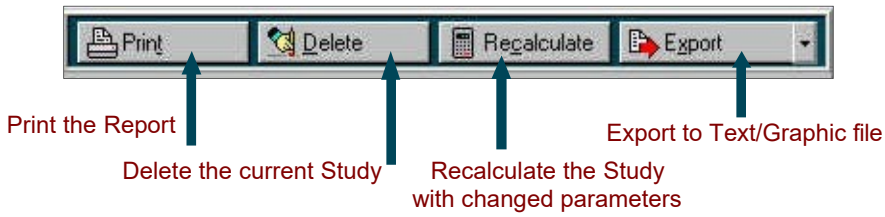
The table should be used as a guide to eliminate any reports that are not of acceptable quality. Measurements that are un-acceptable should be repeated.

NOTE:

Ensure you consider all the quality control data when making an assessment of data quality. Do not discard any measurements on the basis of the Quality Index alone. Visually inspect the waveform data to make a final decision. For example, some patients may have a low pulse pressure that will produce a low Quality Index, but if the waveform is consistent ie. individual pulses contain the same pulse shape, then it may still be acceptable.

6.3 REPORT TOOL-BAR BUTTONS

The tool-bar buttons are used as follows:



Print the Report	Use this option to print the clinical SphygmoCor Evaluation Report. This is a summary report providing information concerning the study, on a single A4 page.
Delete the current Study	Use this option to delete the study. Note that the study that is deleted is the one currently highlighted in the Report Browser. Take care that you are deleting the Study you intended to delete.
Export to Text/Graphic file	Use this option to export the study values to a text or graphics file. Select As Text to import the data into a spreadsheet program. Select As Graphic to save the report as a JPG graphic file to import into your word processor or presentation software. See section 9.6.3 for more information on exporting. Use the drop down menu to access the export type. 
Recalculate the Study	Use this option to open the SphygmoCor Recalculate Report window. This window lets you change any of the study fields you originally entered in the Study Screen.

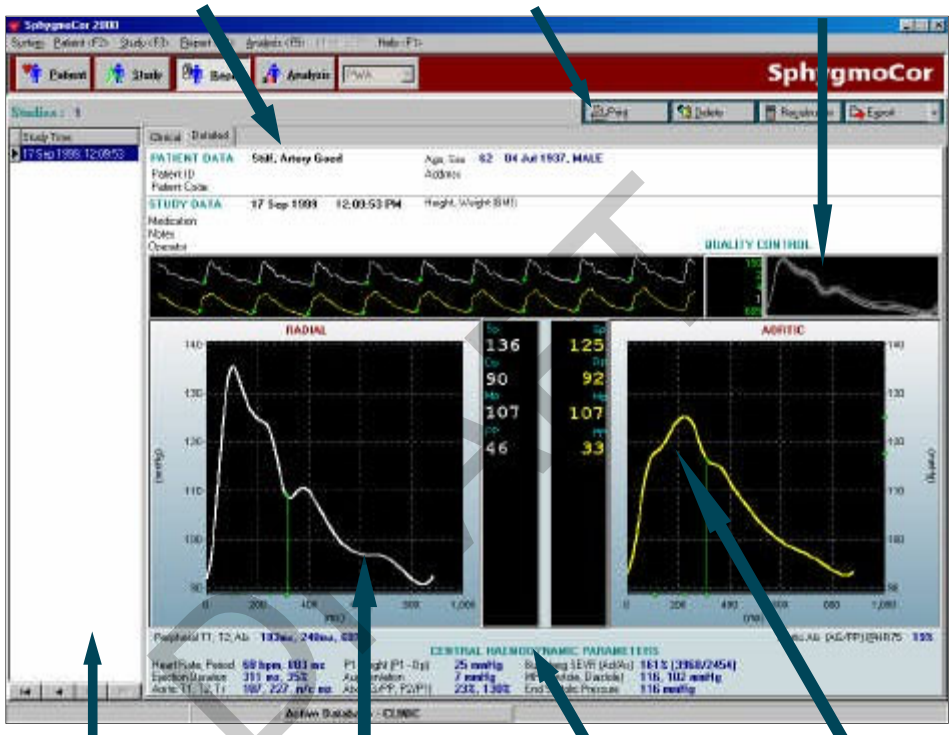
NOTE

As with interpretation of an electrocardiogram, the numerical values given need to be checked visually in deciding acceptability. See Caveats And Limitations (Appendix 10.1).

The accuracy of the derived parameters is within AAMI-SP10 standards for pressure values, or equivalent for timing values.

7. Working with the Detailed Report Screen

This section describes the on-screen reporting that is available in the system, and how to print and export results.



The Report Screen has the following key areas:

Report Tool-bar	Use this tool-bar to perform functions relating to the report which is currently being displayed. See Section 7.2 for more on these options.
Patient/Study Data	This section summarises information about the patient and the study you have just performed. Check this section to ensure that the details you have entered for the patient and the study are correct. If the study data is not correct, click the Recalculate button on the Report Tool-bar to open the SphygmoCor Recalculate Report window. This window lets you change any of the study fields you originally entered in the Study Screen.

Quality Control	Check this area to ensure that the measurement conforms to the quality control settings. See Section 7.1 for more on this area.
Report Browser	Use the Report Browser to examine other studies for the same patient. Notice that the current study (the one you have just performed) is the bottom study in the browser panel.

Peripheral Waveform	This section shows the peripheral waveform, obtained by taking an average of all the pulse waves that were captured in the reading. The waveform shown here is calibrated according to the pressure values you entered in the Study Screen.
Aortic Waveform (Derived)	This section shows the derived Aortic waveform. This reading is obtained by applying mathematical transforms to the Peripheral reading.
Parameters	This section lists the derived haemodynamic parameters that will be written to the SphygmoCor database for this study. See the Operator's Manual for more information on the parameters. The typeface of some parameters are used as indicators of the confidence level of that particular calculation or feature extraction: **Bold** - Strong or Very Strong Normal - Weak or Very Weak "n/c" - Not Calculated

WARNING

In consequence of the above:

a) The SphygmoCor process should not be used in persons with significant aortic valve stenosis (gradient >60mmHg),

b) Values of parameters determined from ejection duration when ejection duration values are outside the range 200-400msec should be disregarded.

c) Values of parameters determined from P_1 and T_1 be viewed with caution when T_1 is outside the range 80-133 msec.

7.1 QUALITY CONTROL

The Quality Control section of the Report Screen shows information to help you ensure that the measurement you have recorded is of sufficient quality.

7.1.1 RECORDED AND PROCESSED WAVES

This section shows you the peripheral waveform (in white) and the processed waveform (in yellow). Ensure that the beat-to-beat pulses in each waveform are similar, and that there is no marked drift of the signals outside the boundary of the window in which they are displayed.

7.1.2 OVERLAYED RECORDED DATA

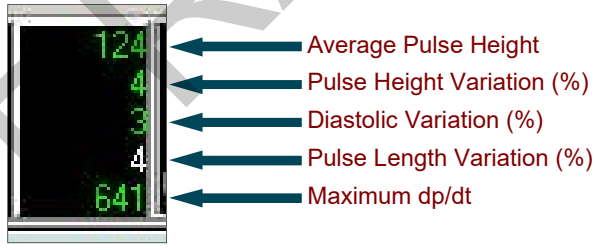
This section gives you a visual guide to how well the individual pulses can be overlayed to form an averaged pulse. There should be as little variability in the pulses as possible.

WARNING

If the Pulse Hight Variation or Diastolic Variation is outside the limits (ie. displayed in red) the operator should examine the radial artery waveform trace to ensure no transients occurred during the averaging period that would make the averaging process invalid.

7.1.3 QUALITY CONTROL INDICES

These are as follows:

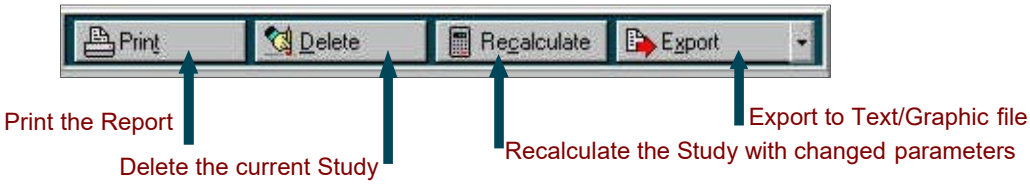


Where the figures appear in **GREEN**, they are within the limits set using the Configuration Settings. See Section 9.1 for more on the Configuration Settings. Where the figures are in **RED**, they are outside these limits.

- The Average Pulse Height is the average of the heights of all the pulses.
- The Pulse Height Variation is the amount of variation present in the pulse heights.
- The Diastolic Variation is the amount of variation present in the diastolic point of the pulse wave and indicates how constant the baseline pressure was during the measurement.
- The Pulse Length Variation is the amount of variation in the length of the measured pulses. The Pulse Length Variation in white has no limit setting associated with it, because variations in pulse length are not data-acquisition related.

- The Maximum dp/dt is the maximum value of the first derivative, or the maximum rate of rise of the peripheral waveform. See Caveats And Limitations (Appendix 10.1).

7.2 REPORT TOOL-BAR BUTTONS



The tool-bar buttons are used as follows:

Print the Report	Use this option to print the detailed SphygmoCor Evaluation Report. This is a summary report providing information concerning the study, on a single A4 page.
Delete the current Study	Use this option to delete the study. Note that the study that is deleted is the one currently highlighted in the Report Browser. Take care that you are deleting the study you intended to delete.
Export to Text/Graphic file	Use this option to export the study values to a text or graphics file. Select As Text to import the data into a spreadsheet program. Select As Graphic to save the report as a JPG graphic file to import into your word processor or presentation software. See section 9.6 for more information on exporting. Use the drop down menu to access the export type. 
Recalculate the Study	Use this option to open the SphygmoCor Recalculate Report window. This window lets you change any of the study fields you originally entered in the Study Screen.

7.3 UNDERSTANDING THE MEASUREMENTS

The measurements on the Report Screen enable you to see at a glance some of the important values for the study. These are shown in the picture below.

The measurements are shown on the Report Screen for the peripheral measurement (Radial or Carotid) and for the calculated measurement (Aortic).

In all these cases, the measurements are as follows:

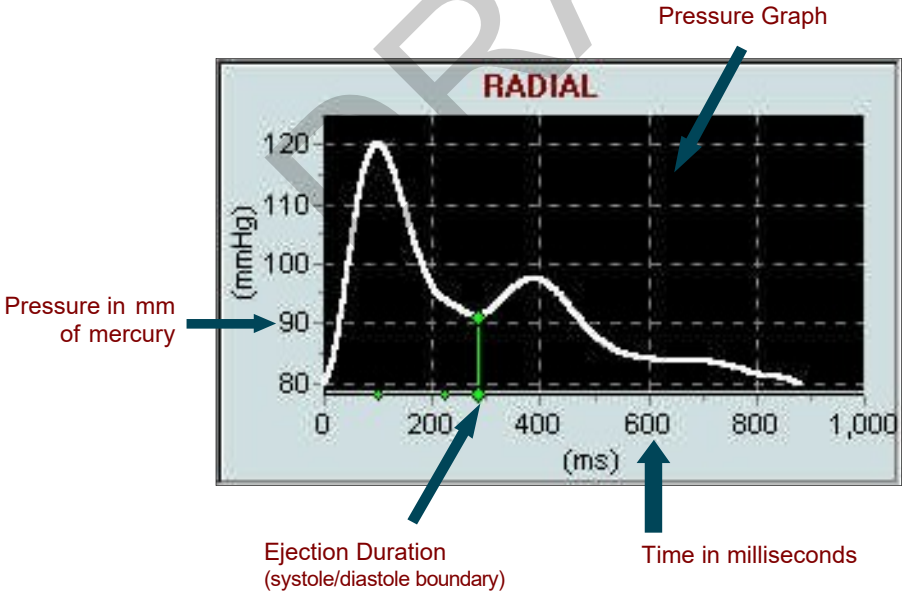
Systolic Pressure (Sp)

Diastolic Pressure (Dp)

True Mean Pressure (Mp)
(calculated by integration of the peripheral artery waveform)

Pulse Pressure (PP) = Sp - Dp

The graphs of peripheral and aortic pressure allow you to examine the results in further detail.



NOTE

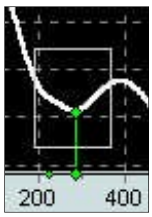
As with interpretation of an electrocardiogram, the numerical values given need to be checked visually in deciding acceptability. See Caveats And Limitations (Appendix 10.1).

The accuracy of the derived parameters is within AAMI-SP10 standards for pressure values, or equivalent for timing values.

You can zoom in on any part of the graph. To zoom in:

Step 1 Move the cursor over the graph you are interested in. The cursor changes to a cross hair.

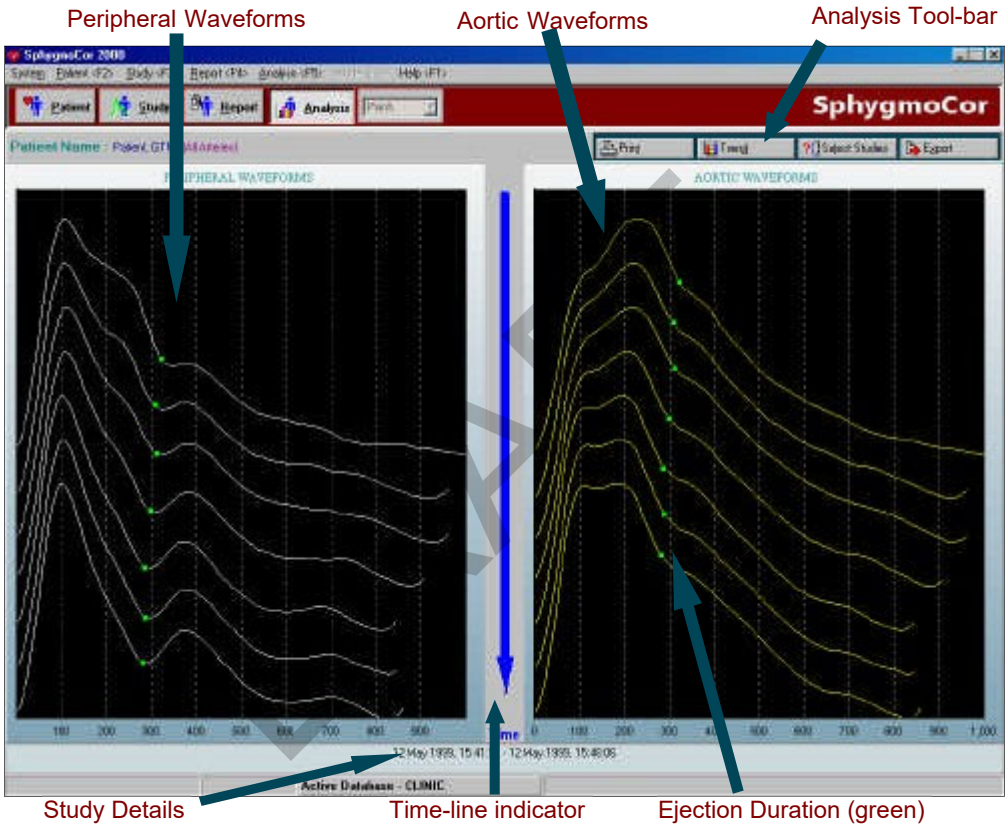
Step 2 Click and hold down the mouse button while you drag *down toward the right* to form a rectangular border for the area you want to zoom in on. This border is shown in the picture below.



Step 3 Release the mouse button. The graph zooms to the area you marked. To zoom out again, repeat the procedure for zooming in, except that you *drag up toward the left.* The graph automatically zooms out to its default full size.

8. Working with the Analysis Screen

The Analysis Screen is designed to allow you to view multiple Studies, over time, for a patient. This enables you to perform both long-term and short-term analyses for a patient.

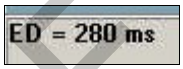
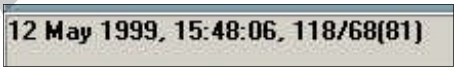


For example, you may want to examine drug effects over time. You could do this by making a control study, followed by periodic studies at regular intervals, after administering the drug. The Analysis Screen could then be used to examine qualitative changes both in the shape of the aortic waveforms, and in the ejection duration, over the course of the study.

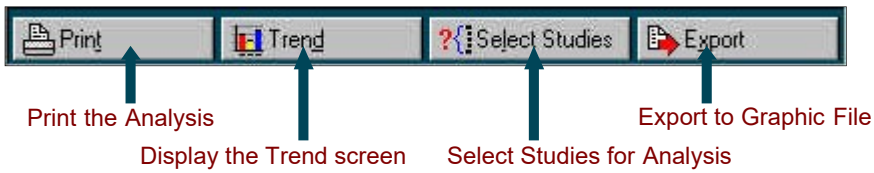
In the above example a patient takes a sublingual capsule of Nitroglycerin. SphygmoCor studies are performed as a control, and then every 30 seconds for 3 minutes, to derive calibrated aortic pressure waveforms. Observe the dramatic reduction in aortic systolic peak pressure due to arterial vasodilation (reduction in aortic pressure augmentation, or “afterload”).

SphygmoCor shows you important central effects of cardiovascular drugs that are not visible when using a cuff sphygmomanometer.

The Analysis screen has the following key areas:

Peripheral Waveforms	This area shows the peripheral waveforms for the patient, in time sequence. The first waveform (oldest) is at the top of the screen; the last waveform (most recent) is at the bottom of the screen.
Aortic Waveforms	This area shows the aortic waveforms for the patient, in time sequence. The first waveform (oldest) is at the top of the screen; the last waveform (most recent) is at the bottom of the screen.
Analysis Tool-bar	This tool-bar enables you to perform functions related to the Analysis Screen.
Study Details	This summary line shows you: • When the cursor is placed over the green ejection duration symbol, the ejection duration for the study is displayed:  • When the cursor is placed over any other part of the waveform, information about the Study (Date and Time of the Study, Systolic and Diastolic pressure, and Mean pressure) is displayed: 
Time-line indicator	This area is a visual reminder of the time sequence of the analysis information - with the earliest study at the top and the latest study at the bottom.
Ejection Duration	The value of the Ejection Duration is usually shown in green on the waveforms. Ejection Duration is measured in milliseconds (ms).

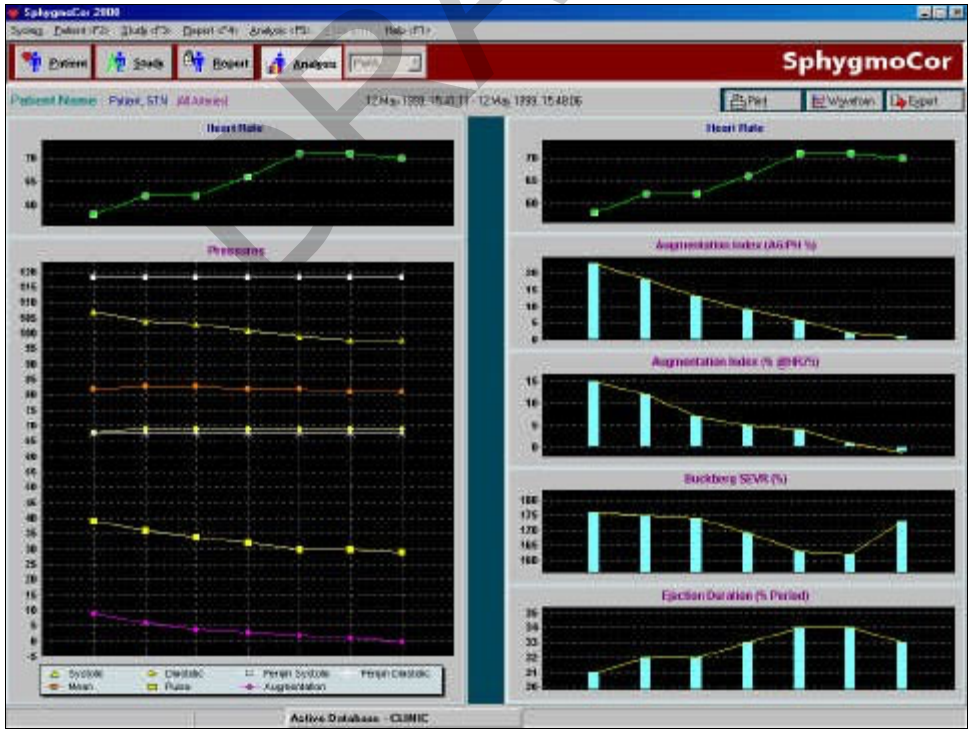
8.1 ANALYSIS TOOL-BAR BUTTONS



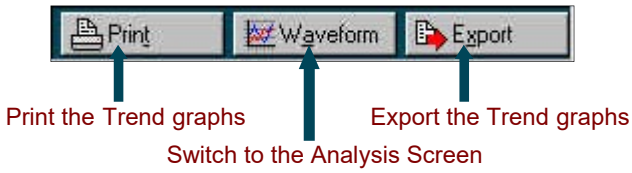
Print	Use this option to print the SphygmoCor Patient Analysis Report. This is a summary report providing information about all the Studies in the Analysis, on a single A4 page.
Trend	Use this option to switch to the Trend Screen. See section 8.2.
Select Studies	Use this option to determine which Studies are to be included in the Analysis. For more on how to do this, see Section 8.3.
Export	Use this option to export the analysis as a JPG graphic file to import into your word processor or presentation software. See section 9.6 for more information on exporting.

8.2 THE TREND SCREEN

The Trend Screen shows the trends for all the major measures in a study, over the course of the Analysis. The horizontal axes of the trend graphs show the separate studies in the Analysis. An example of a Trend Screen is shown below.



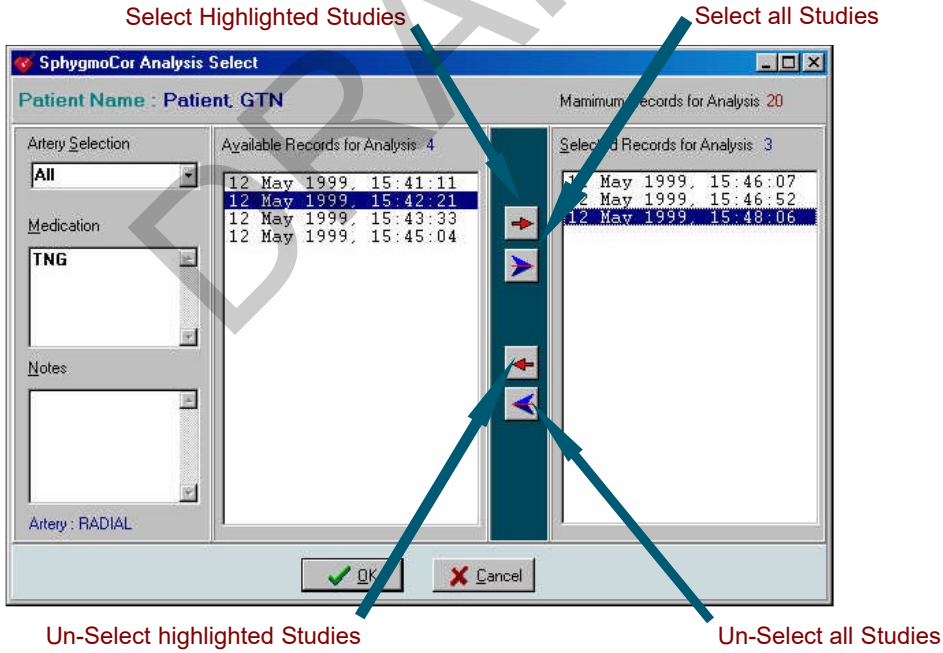
When you are in the Trend Screen:



- Click the Print tool-bar button to print the SphygmoCor Patient Trend Analysis Report.
- This is a summary report showing the trends in all the studies in the Analysis, on a single A4 page.
- Click the Waveform tool-bar button to return to the main (waveform) Analysis Screen.
- Click the Export tool-bar button to export the trend analysis as a JPG graphic file to import into your word processor or presentation software.

8.3 SELECTING STUDIES FOR ANALYSIS

You can decide which studies are to be included in any Analysis. You do this by clicking the Select Studies tool-bar button on the Analysis Screen. The SphygmoCor Analysis Select window then opens. This window is shown below.



Using this window, you can select the Studies to be included. The following points relate to using this window:

- In the Available Records for Analysis panel, select the Studies you want to include by clicking on them to highlight them. If you want to highlight more than one Study, use the

normal Windows conventions for highlighting multiple items in a list

HIGHLIGHTING MULTIPLE ITEMS

Hold down the Ctrl key while you click items, to highlight any number of items in the list.

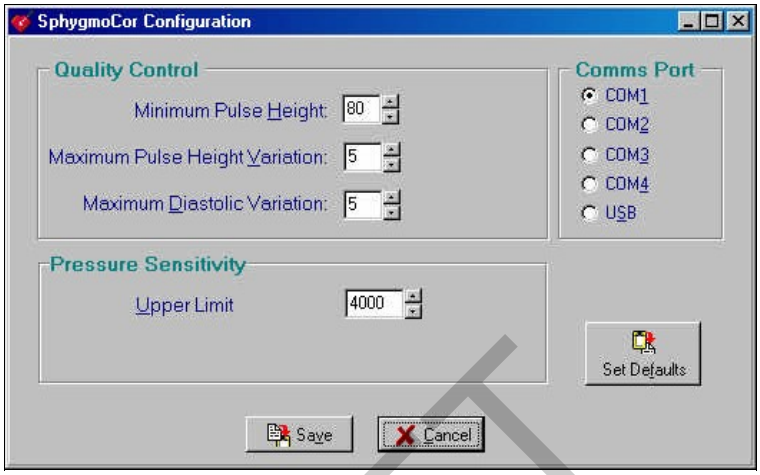
After clicking a first item, hold down the Shift key while you click a second item, to highlight *all items* between the first item you clicked and this second item.

You can also use the mouse to drag across multiple items, to select that group of items.

- When you have highlighted multiple items, click the Select Highlighted Studies arrow button to copy the highlighted items to the Selected Records for Analysis panel.
- Alternatively, click the Select all Studies arrow button to copy *all* the Studies to the Selected Records for Analysis panel.
- You can also highlight multiple items in the Selected Records for Analysis panel, then un-select them all (remove them from this panel) by clicking the Un-Select highlighted Studies arrow button.
- You can remove *all* items from the Selected Records for Analysis panel by clicking the Un-Select all Studies arrow button
- Whenever you click on an item in the Available Records for Analysis panel, any Medication or Notes about that item are displayed in the Medication and Notes fields.
- You can select Studies for just one of the two peripheral artery sites, by using the Artery selection pull-down. Alternatively, you can leave this pull-down set to All. Changing this setting causes the Available Records for Analysis panel to change to match the selection you made in the Artery selection pull-down.
- When you have completed your selection of Studies, click the OK button to return to the Analysis Screen. The Analysis Screen now changes to show only those studies that you selected in the SphygmoCor Analysis Select window.

9. Advanced Topics

9.1 CONFIGURATION SETTINGS



The SphygmoCor Configuration window is used to set the Quality Control values for the system, and to select the correct Comms Port for the Electronics Module communication. To access the window, click the Settings option under the File menu.

The following is an explanation of the settings:

- Enter the Minimum Pulse Height allowable, by entering the value from the keyboard, or using the spin control. Pulse heights smaller than this value are shown in the Quality Control section of the Report screen in red.

- Enter the Maximum Pulse Height Variation allowable, by entering the value from the keyboard, or using the spin control. Pulse height variations greater than this value are shown in the Quality Control section of the Report screen in red.

- Enter the Maximum Diastolic Variation allowable, by entering the value from the keyboard, or using the spin control. Diastolic variations greater than this value are shown in the Quality Control section of the Report screen in red.

- Enter the Pressure Sensitivity - Upper Limit to allow greater range of signal scale for very sensitive Tonometers when capturing the waveforms. If the pulse signal is being clipped while capturing you may need to increase this value to allow the auto-scale to increase the full-scale range.

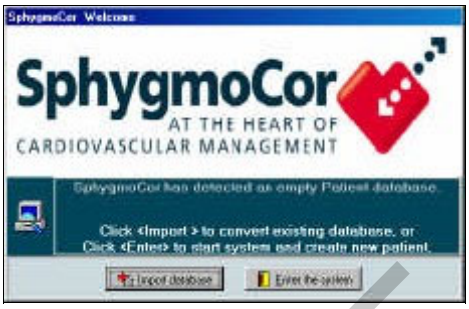
- Alternatively, to use the AtCor Medical default values click the Set Defaults button.

- To set the Comms. Port, select one of the radio buttons for COM1 to COM4. Select the USB option for the EM3 Electronics Module Only. If you are using a Serial to USB adaptor: select the corresponding COM port. (See the Operator's Manual for USB Adaptor Installation and COM Settings).

- When you have completed the changes in this window, click the Save button to save the changes and close the window.

9.2 STARTING SPHYGMOCOR WITH AN EMPTY DATABASE

When you start SphygmoCor and there are no patient records in the database, the following display appears:



This message also appears after you have just created a new database, using the Database Manager option in the System menu. See Section 9.5 for more on using this option.

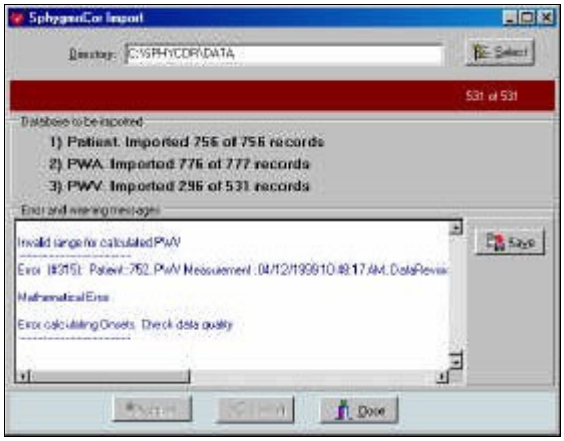
If you click the Enter the system button, SphygmoCor starts with an empty patient database. If you use this option, you will need to create a patient before you can perform a Study. See Section 3.1.2.

Alternatively, if you click the Import database button, SphygmoCor allows you to import your database records held in a Version 5.xx SphygmoCor database. See Section 9.3 for more on importing databases.

9.3 IMPORTING A DATABASE

When there are no patient records in the currently selected database, you can use the Import Database option to load records from a previous version (Ver 5.xx) of SphygmoCor. This option is available from the System menu in the Patient Screen (when the database is empty), and from the start-up window described in Section 9.2.

The picture below shows an example of the SphygmoCor Import window, which has been used to import records. In this example, the database held in directory C:\SPHYCOR\DATA has been imported, resulting in 756 Patient records being added to the current database, and 776 of 777 Measurement records (Study records) being added. Note that there were



conversion errors in a number of the Study records, and these errors are shown in the Error and Warning messages section of the window which can be also saved to a text file by clicking Save.

To import a database:

Step 1 Choose the directory to import from, (Location of previous V5.xx database files; usually C:\SPHYCOR\DATA) by clicking the Select button and finding the Windows folder in which the data is stored.

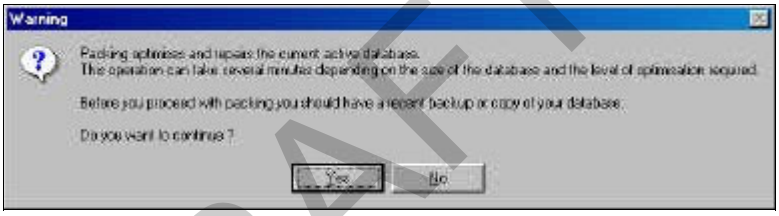
Step 2 Click the Import button to commence the import operation.

Step 3 When the import has finished, you may save the errors and warnings displayed by clicking the Save button, then click the Close button.

9.4 PACKING A DATABASE

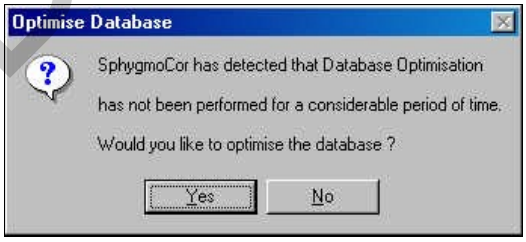
This menu option is available from the System menu, when you are in the Patient Screen. It optimises and repairs the current active database.

Before you attempt to pack the current database, you should always create a backup first. SphygmoCor will remind you to do so whenever you endeavour to pack a database, with the following warning:



Once you are certain the database has been backed up, click the Yes button. The database will then be packed.

If a database has not been packed for 90 days or more, the following reminder will be displayed each time you start SphygmoCor:

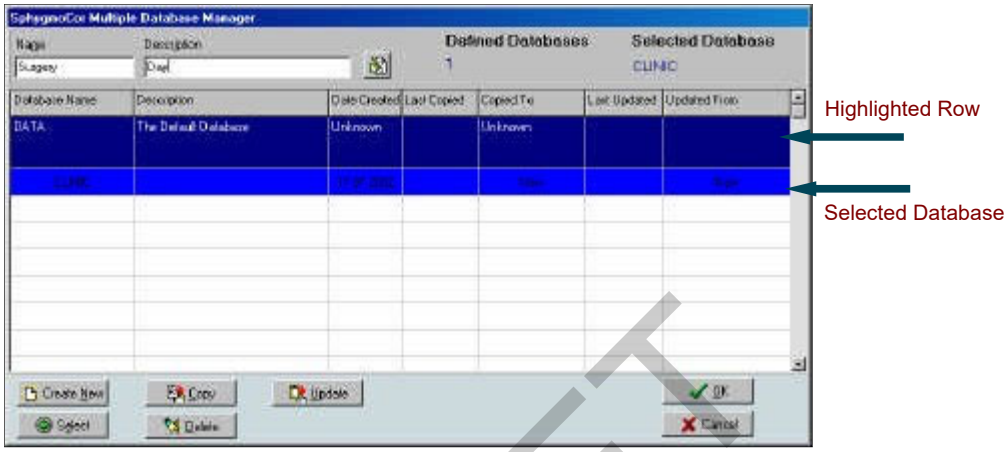


9.5 THE DATABASE MANAGER

This menu option is available from the System menu, when you are in the Patient Screen. It enables you to change between different SphygmoCor databases, to create new databases, and to copy databases.

You could use this option, for example, when you are involved in multiple Studies, and you want these Studies to be stored in separate databases. Another situation in which you might want to use separate databases is when there are several operators using the one SphygmoCor system. A SphygmoCor system can have a maximum of twenty databases.

To use the Database Manager option, select the Database Manager menu option from the System menu. The SphygmoCor Multiple Database Manager window opens. This window is shown below.



SELECTING DATABASES

When you are working in the SphygmoCor Multiple Database Manager, the currently selected database is always highlighted in light blue. This selected database is the one that will be opened in SphygmoCor as the current database after pressing OK.

To navigate within the Multiple Database Manager screen, you can click to highlight a row that you are interested in. The options that you can perform on that row are Select, Copy, Delete and Update.

As well as using these options, you can click Create New to create a new SphygmoCor database. All of these options are described below.

9.5.1 CREATING A NEW DATABASE

To create a new SphygmoCor database:

Step 1 Enter the name of the database you want in the Name field. Do not use any spaces in the Name field.

Step 2 Enter a description of the database in the Description field.

These fields are positioned at the top of the SphygmoCor Multiple Database Manager screen, as shown below:

Step 3 Click the Create New button to create the new database.

Note that only after the Name and Description fields are entered will the Create New button become active.

When the new database is created, it then automatically becomes selected.

9.5.2 SELECTING A DATABASE

When you select a database, you are requesting the system to use it for all the SphygmoCor data storage operations. When you create a new database, the new database becomes selected automatically. You can also select any one of the databases shown in the Multiple Database Manager screen by doing the following:

Step 1 Highlight the row showing the database you want to select.

Step 2 Click the Select button. 

The database shown in this row now becomes selected. Note that you can also select a database just by double-clicking the row showing the database.

When a database is selected and OK button is pressed, the current database is closed and the newly selected database is opened for use.

9.5.3 CHANGING A DATABASE DESCRIPTION

Only when a database is selected can you change its description (in the Description field).

To change the description of the selected database:

Step 1 Enter the new description in the Description field.

Step 2 Click the Change Button.

9.5.4 COPYING A DATABASE

Copying a database is a method to backup or transfer databases from one computer to another.

To Copy the selected database:

Step 1 Select the database you want to copy.

Step 2 Click the Copy button 

. The Copy To dialog window opens.

Step 3 Select the Windows folder that you want to copy the database to, and click the Ok button. The selected database is then copied to the folder you selected.

9.5.5 DELETING A DATABASE

CAUTION

Before deleting a database, the database must have been previously copied and no subsequent operations performed on the database ie. adding, deleting records. As a precaution, the system will not let you delete a database if you have not first copied it.

To Delete a SphygmoCor database:

Step 1 Select the database you want to delete.

Step 2 Click the Delete button 

. A confirmation dialog window opens.

Step 3 Click Yes in the confirmation window to proceed with the deletion or No otherwise.

Step 4 A second confirmation window opens, ensuring that you do not inadvertently delete a database. Click Yes in the confirmation window to proceed with the deletion or No otherwise. The database is now deleted.

THE ACTIVE DATABASE

You cannot delete the active database. If you try to delete the database that is currently active – that is, active at the time you entered the Multiple Database Manager screen, the following message appears.

DATABASE BACK UP

SphygmoCor ensures that you have backed up the database you are about to delete. It prevents you from deleting a database that has been active since it was last copied. If any database operations have been performed on a database since it was last copied (such as adding a measurement or deleting a patient) then the following message appears if you try to delete that database.


Warning Multiple Database Manager (#811)
Cannot Delete the Database Set CLINIC.
Database Operation has been performed since last copied.
OK

9.5.6 UPDATING A DATABASE

Use this option to restore a database to the contents it had at the time that it was last copied.

CAUTION

The database is changed to make it identical to the last copy that was taken of it. This means that any records added to the database after it was last copied are lost. Using the option makes the database revert to its state at the time it was last copied.

Updating a database is a method to restoring backed up databases that were previously copied (backed up) as per section 9.5.4.

To update a selected database:

Step 1 Click the Update button 

. The Update From dialog box opens.

Step 2 Select the Windows folder that you want to update from. The folder must be the same folder as the one holding the selected database.

Step 3 Click Ok in the Update From dialog. The update then occurs.

NOTE

The database you are updating from must be one to which you previously copied the selected database.

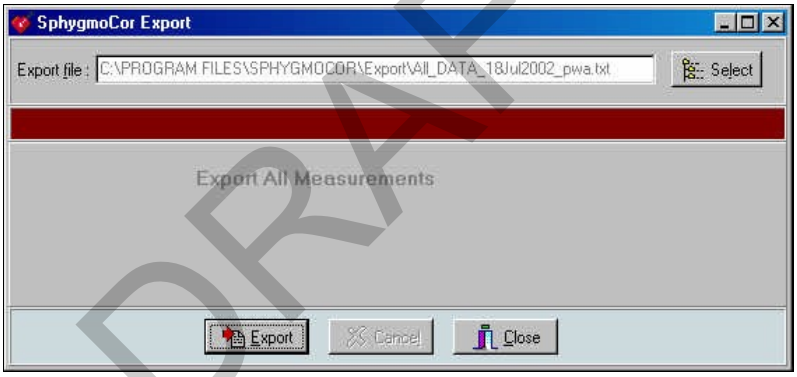
9.6 EXPORTING DATA

You can export data from the SphygmoCor system for use in other programs. Data is exported in a Tab-delimited text file format. This format is easy to import into spreadsheet applications, such as Microsoft® Excel.

You can export data from the SphygmoCor system in the following ways:

- All measurements in the database.
- All measurements for a patient.
- A single measurement for a patient.
- A single analysis for a patient.

Whenever you export data, the following Export window is displayed:



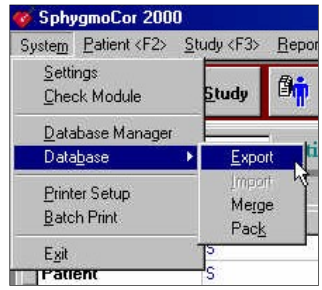
This window allows you to specify where the data will be exported to, in the Windows folder structure. The comment in the central section of the window changes according to which of the export operations are being performed.

9.6.1 EXPORT ALL MEASUREMENTS IN THE DATABASE

Step 1 Click the Export option on the System>Database menu. You must be in the Patient screen to do this. The Export window opens, as is shown above.

Step 2 Use the Select button to choose the Windows folder and/or file name to which you want all the measurements exported.

Step 3 Click the Export button. A progress bar shows you



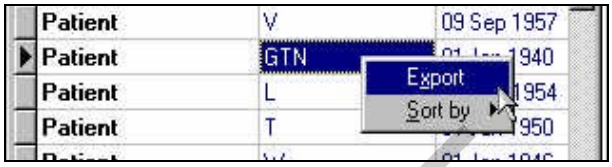
how much of the export has been completed. At the end of the operation, a status message appears in the Export window:

Step 4 Click the Close button to close the Export window.

9.6.2 EXPORT ALL MEASUREMENTS FOR A PATIENT

This option enables you to export all the Measurements for one Patient. Note that the Waveform data is not exported with this option. Access this option from the Patient Screen.

Step 1 Right-click the Patient for whom you want to export measurements. The Patient menu opens:



Step 2 Click the Export option on the Patient menu. The Export window opens. Notice that the default text file name in the Export window is prefixed with the name of the patient:

Step 3 Use the Select button to choose the Windows folder and/or file name to which you want all the measurements exported.

Step 4 Click the Export button. A progress bar shows you how much of the export has been completed. At the end of the operation, a status message appears in the Export window:

Step 5 Click the Close button to close the Export window.

9.6.3 EXPORT A SINGLE REPORT FOR A PATIENT

This option enables you to export a single report for a Patient. Access this option from the Report Screen. The option enables you to export the data:

As Text: All of the waveform data points and parameters in the Measurement are exported for further analysis or graphing. The data points can be graphed in spreadsheet programs such as Microsoft® Excel or SPSS.

As Graphic The report as displayed on screen is saved as a JPG file for importing later into a document or presentation.

Step 1 Open the Report Screen and select the Measurement you want to export.

Step 2 Click the Export button at the top right of the Report Screen.

If you select As Text then the Export window opens.

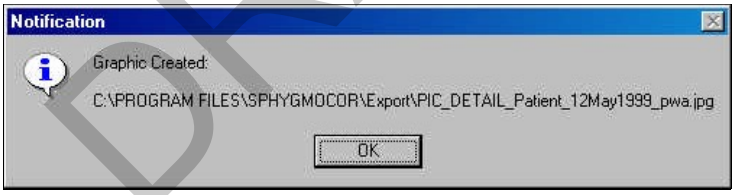
Notice that the default text file name in the Export window is prefixed with the name of the Patient and the date of the Measurement:

Step 3 Use the Select button to choose the Windows folder and/or file name to which you want the measurement exported.

Step 4 Click the Export button. A progress bar shows you how much of the export has been completed. At the end of the operation, a status message appears in the Export window:

Step 5 Click the Close button to close the Export window.

If you select As Graphic then the JPG file is exported and a Notification message appears with the file location.

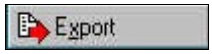


9.6.4 EXPORT A SINGLE ANALYSIS FOR A PATIENT

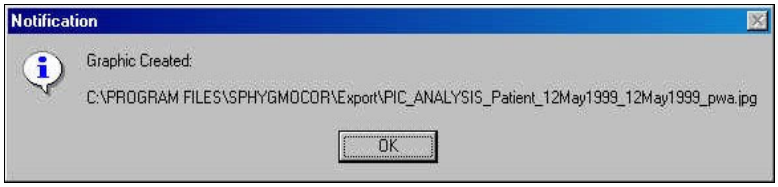
This option enables you to export a single analysis for a Patient. Access this option from the Analysis Screen. The option enables you to export the analysis as displayed on screen as a JPG file for importing later into a document or presentation.

Step 1 Open the Analysis Screen and select the Measurement you want to export.

Step 2 Click the Export button at the top right of the Analysis Screen.



The JPG file is exported and a Notification message appears with the file location.


Notification
Graphic Created:
C:\PROGRAM FILES\SPHYGMOCOR\Export\PIC_ANALYSIS_Patient_12May1999_12May1999_pwa.jpg
OK

9.6.5 EXPORTED FIELDS

Below is a list of the fields that are exported when a complete database export is performed:

System ID	System Serial Identification Number
Database ID	Database Identification
Patient Number	Patient Number
Surname	Entered Patient's Surname
First Name	Entered Patient's First Name
Sex	Entered Patient's Sex
Date Of Birth	Entered Patient's Date of Birth
Patient ID	Entered Patient' Identification
Patient Code	Entered Patient Code
SP	Entered Systolic Pressure
DP	Entered Diastolic Pressure
MP	Entered Mean Pressure
DATA_REV	Math's Data Revision
DATETIME	Date & Time of Study
MEDICATION	Entered Medication
NOTES	Entered Notes
OPERATOR	Entered Operator
HEIGHT	Entered Height
WEIGHT	Entered Weight
BODY_MASS_INDEX	Body Mass Index
SAMPLE_RATE	Raw Data Sample Rate
SUB_TYPE	Entered Artery
P_MAX_DPDT	Peripheral Pulse Maximum dP/dt
P_QC_PH	Peripheral Pulse Quality Control Pulse Height
P_QC_PHV	Peripheral Pulse Quality Control Pulse Height Variation
P_QC_PLV	Peripheral Pulse Quality Control Pulse Length Variation
P_QC_DV	Peripheral Pulse Quality Control Diastolic Variation
P_SP	Peripheral Systolic Pressure
P_DP	Peripheral Diastolic Pressure
P_MEANP	Peripheral Mean Pressure
P_T1	Peripheral T_1
P_T2	Peripheral T_2
P_AI	Peripheral Augmentation Index
P_ESP	End Systolic Pressure
P_P1	Peripheral P_1
P_P2	Peripheral P_2
P_T1ED	Peripheral T1/ED %
P_T2ED	Peripheral T2/ED %
P_QUALITY_T1	Peripheral Confidence Level of T1 (3-Very Weak/2-Weak/1-Strong/0-Very Strong)
P_QUALITY_T2	Peripheral Confidence Level of T2 (3-Very Weak/2-Weak/1-Strong/0-Very Strong)

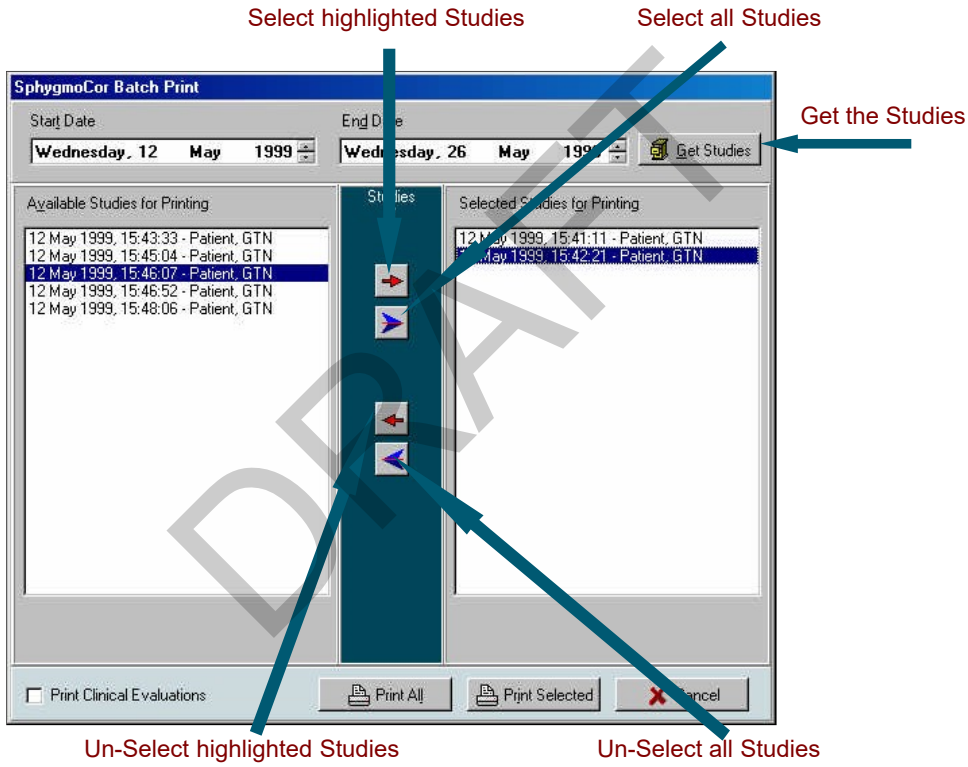
C_AP	Central Augmented Pressure
C_MPS	Central Mean Pressure of Systole
C_MPD	Central Mean Pressure of Diastole
C_TTI	Central Tension Time Index
C_DTI	Central Diastolic Time Index
C_SVI	Central Buckberg Sub-Endocardial Viability Ratio (SEVR)
HR	Heart Rate
C_PERIOD	Central Pulse Period
C_DD	Central Diastolic Duration
C_ED_PERIOD	Central ED/Period %
C_DD_PERIOD	Period-ED/Period %
C_PH	Central Pulse Height
C_AGPH	Central Aug/PH %
C_P1_HEIGHT	Central Pressure at T1 - Dp
C_SP	Central Systolic Pressure
C_DP	Central Diastolic Pressure
C_MEANP	Central Mean Pressure
C_T1	Central T1
C_T2	Central T2
C_AI	Central Augmentation Index
C_ESP	Central End Systolic Pressure
C_P1	Central Pressure at T1
C_P2	Central Pressure at T2
C_T1ED	Central T1/ED %
C_T2ED	Central T2/ED %
C_QUALITY_T1	Central Confidence Level of T1 (3-Very Weak/2-Weak/1-Strong/0-Very Strong)
C_QUALITY_T2	Central Confidence Level of T2 (3-Very Weak/2-Weak/1-Strong/0-Very Strong)
QUALITY_ED	Confidence Level of ED (3-Very Weak/2-Weak/1-Strong/0-Very Strong)
ED	Adjusted Ejection Duration (ES)
CalcED	Calculated Ejection Duration (ES)

9.7 BATCH PRINTING

The Batch Print option is available from the System menu, when you are in the Patient Screen. It enables you to print a selection of reports over a chosen time interval (maximum of 14 days). You may use this report at the end of the week, for example, to print the Studies that have happened during the week.

The report that is produced for each Study is the SphygmoCor Evaluation Report.

The Batch Print window is shown below.



9.7.1 SELECTING STUDIES FOR BATCH PRINT

You can display a group of Studies for a chosen period in the Available Records to be Printed window. To do this:

Step 1 Enter either the start date or the end date of the period, using the Start Date or End Date fields.

Step 2 Click the Get Studies button. The Available Records to be Printed window now shows the Studies that fall in this period. See the next Section for more on further selecting studies from this window.

Step 3 Either make a further selection from the displayed Studies, as described in the

next section, or alternatively click the Print All button to print all the records displayed in the Available Records to be Printed panel.

9.7.2 SELECTING STUDIES FOR PRINTING

You can apply a further selection to Studies that are displayed in the Available Records to be Printed panel. Do this as follows:

Step 1 In the Available Records to be Printed panel, select the records you want to print by clicking on them to highlight them. If you want to highlight more than one record, use the normal Windows conventions for highlighting multiple items in a list

HIGHLIGHTING MULTIPLE ITEMS

Hold down the Ctrl key while you click items, to highlight any number of items in the list.

After clicking a first item, hold down the Shift key while you click a second item, to highlight all items between the first item you clicked and this second item.

You can also use the mouse to drag across multiple items, to select that group of items.

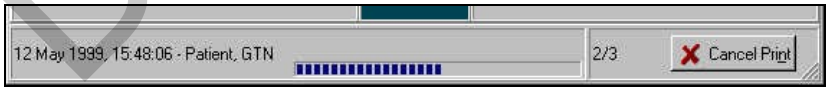
Step 2 When you have highlighted multiple records, click the Select Highlighted Studies arrow button to copy the highlighted items to the Records to be Printed panel.

Step 3 Alternatively, click the Select all Studies arrow button to copy *all* the Studies to the Records to be Printed panel.

Step 4 You can also highlight multiple items in the Records to be Printed panel, then un-select them all (remove them from this panel) by clicking the Un- Select highlighted Studies arrow button.

Step 5 You can remove *all* items from the Records to be Printed panel by clicking the Un-Select all Studies arrow button

Step 6 When you have completed your selection of Studies, click the Print Selected button to commence the Batch Print. The status of the Batch print is shown on the bottom of the Batch Print window:



Note that, alternatively, you can click the Print All button to print all the records displayed in the Available Records to be Printed panel.

9.7.3 SELECTING REPORT TYPE

By default the report format that is batch printed is the Detailed Evaluation Report that is identical to the Detailed Report Screen.

Alternatively, you may print the Clinical Evaluation Report by selecting the check box labelled Print Clinical Evaluation as shown below. The report that is printed is identical to the Clinical Report Screen.

9.8 PATIENT LISTING

Using the Patient Listing feature you may obtain a list of patients in the current database with database statistics. To print a list of patients:

Step 1 Go to the Patient Screen (F2).

Step 2 Select Patient Listing by clicking on the Patient menu then Listing, or by pressing F2, as shown below.

Step 3 A confirmation window will appear to confirm if you would like to proceed with the listing. Answer Yes or No.

NOTE

For large databases the listing may take some time to complete. Ensure that the printer is ready and you are prepared to wait for the Listing.

Step 4 If you answer Yes the patient listing will prepare a preview of the report.

Step 5 Click on the printer button on the tool-bar at the top to print.

9.9 ADJUSTING END OF SYSTOLE

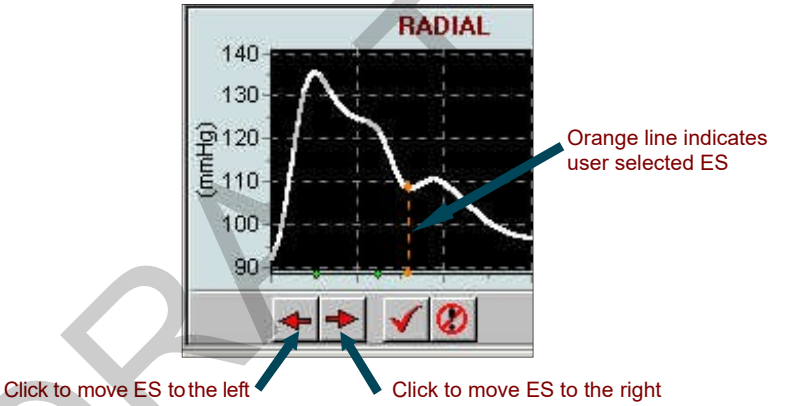
The Feature Extraction Software in SphygmoCor estimates the location of the end of systole. The operator can manually change this estimate and reprocess the calculated parameters.

To adjust the location of End of Systole:

Step 1 Select the particular Patient Report.

Step 2 On the Detailed Report screen move the mouse cursor to the text Ejection Duration at the bottom of the screen. When the cursor changes to a hand, double click on the text.

Step 3 Adjustment arrows will appear below the Peripheral Waveform allowing you to move the location of End of Systole (ES) either left or right. The ES on the Aortic Waveform will be moved also.



- Click  to move ES to the left by 2 msec.
- Click  to move ES to the right by 2 msec.

If ES is moved to another point other than the calculated point the ES line colour will change to orange, indicating that it is an user selected ES point.

Step 4 When you are satisfied of the location of ES press the accept button to confirm the selection. The related parameters will be re-calculated as you move ES.

Once the user has selected a point, that ES will be used throughout the reports and in the database and will be indicated as such by an orange colour or a dashed line.

To cancel the selection press the reject button and ES will be set back to the position prior to the adjustment.

NOTE:

At any point you may set the ES to the calculated value by clicking the recalculate button and performing a re-calculation. See section 7.2

10. Appendix

10.1 CAVEATS AND LIMITATIONS

The SphygmoCor Reports display the derived aortic pressure waveform (beat by beat and as an ensemble-averaged wave), together with the measured radial waveform (beat by beat and ensemble-averaged) from which the aortic wave was generated (as shown in the Report Screen).

As with interpretation of an electrocardiogram, the numerical values given need to be checked visually, according to quality of data entry and to physiological principles. As an aid to deciding acceptability, the SphygmoCor report contains the following features: -

1. The train of waves to be analysed is shown together with the reference point (wavefoot) for ensemble averaging. The waves selected are overlaid in relation to the reference point, and the variation in pulse height, diastolic pressure, and pulse length variation is calculated and displayed. These should correspond to respective variations (normally less than 6% through one respiratory cycle). Also shown are internal calibration and dP/dT maximum, for reference. Low dP/dT maximum (less than 300mmHg/sec) indicates likelihood of stenosis of an artery between aorta and radial, or artefact.

2. On the ensemble-averaged radial and aortic waves, time and pressure markers are shown to indicate where physiologically important landmarks have been identified, as follows:

   a) Ejection duration is calculated from the wavefoot to the incisura (which marks the end of ventricular ejection, and is identified by a vertical flagged line). This should immediately precede an inflection on the radial pulse and normally corresponds to a slight inflection on the synthesised aortic pulse. Ejection duration is inversely related to heart rate and normally varies from 250-350msec. Values < 200msec and > 400msec are unreliable. They should be rejected.

   b) Time T_2 is identified by a marker (triangle on the time axis), and corresponds to the secondary systolic peak or shoulder that is caused by wave reflection. The pressure at this time interval is identified by a marker on the aortic pressure axis (triangle on the pressure axis). As for ejection duration (ED), visual inspection is required to ensure that T_2 is greater than T_1 and less than ED.

   c) Time T_1 is identified by a marker (triangle on the time axis) and the pressure (P_1) at this point is also identified by a marker (triangle on the pressure axis). This time is meant to identify the peak of the pressure wave generated by ventricular ejection, in the absence of wave reflection. The time should correspond to the peak of flow in the aorta, and so should be between 80-133msec. T_1 times of < 80msec and > 133 msec are suspect and so then are P_1 and other indices determined from T_1 (augmented pressure, augmentation index). If there is a distinct inflection on the aortic synthesised waveform corresponding to the T_1 flag, and if T_1 is in the range of 80-133 msec, the calculation can be regarded as reliable. However if there is no distinct inflection, peak or shoulder on the synthesised aortic waveform within this time band, then the values of P_1, augmentation pressure and augmentation index can not be calculated reliably.

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Precision CARRS Study Arterial Stiffness Test

Visit 1

Screening No Subject ID Pt Initials Visit Date / /

Start Time : am Pm End Time : am Pm RA Initials

Blood Pressure: Systolic Diastolic

Pulse Wave Analysis

Central Clinical Parameters	
Aortic SBP	
Aortic DBP	
Aortic PP	
Aortic Augmentation (AP)	
Augmentation Index (Aix)@75	
Ejection Duration (%)	
SEVR (%)	
Tr (m/s)	

Pulse Wave Velocity

Pulse Wave Velocity Calculation				
SITE A-B	Mean T (m/s)	SD (m/s)	N	HR (bpm)
ECG-CAR				
ECG-FEM				
CAR-FEM				

PWV(m/s)	
PWV ERR(±)	

Comments:

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