SphygmoCor
AT THE HEART OF
CARDIOVASCULAR MANAGEMENT

SphygmoCor Service Manual

AtCor
MEDICAL

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SphygmoCor® Pulse Wave Analysis System Model SCOR-Px
Pulse Wave Velocity System Model SCOR-Vx
Heart Rate Variability System Model SCOR-Hx

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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 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

"SphygmoCor®" is a registered trademark of AtCor Medical Pty Ltd.

Millar, IBM, IBM PC, Microsoft, Windows, Excel, SPSS are PCMCIA are the registered trademarks of their respective holders.

CAUTION

Federal law restricts this device to sale by or on the order of a physician

Declaration of Conformity

Manufacturer: AtCor Medical Pty Ltd
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Product:	**SphygmoCor**
	Cardiovascular Management System (CvMS)
Description:	The SphygmoCor CvMS consists of the following modes: Central Pressure Analysis (PWA), Pulse Wave Velocity (PWV), Pulse Wave Monitoring (PWM) and Heart Rate Variability (HRV).
Standards Applied:	**IEC 60601-1** **IEC 60601-1-2**
Classification:	**IIa** Annex IX Rule 10
Conformity Assessment Route:	**Annex II** (excluding Section 4), 93/42/EEC

We herewith declare that the above mentioned products meet the transposition into national law of the provisions of Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

J. Abram
John Abram
Manager, Regulatory Affairs and Quality Assurance
AtCor Medical Pty Ltd
Sydney

14/10/2009
Date

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

☐ IEC60601-1 (EN60601-1) Medical electrical equipment with Amendments 1 & 2
Part 1: General requirements for safety (the International Electro-Medical Safety Standard for medical equipment)

☐ IEC60601-1 -2 (EN60601-1-2) Medical electrical equipment
Part 1: General requirements for safety, Collateral Standard: Electromagnetic compatibility

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 should be viewed with caution when T1 is outside the range 80-133 msec.

- The tonometer is fragile. Dropping or striking any probe can cause it to malfunction. Handle the tonometer with care. If a tonometer should be dropped, inspect it carefully for chips and cracks, and make a test scan on a known object.

- This device is not intended for foetal use.

- Do not expose tonometer to extreme heat.

CAUTION

- Federal law restricts this device to sale by or on the order of a physician

- The console must not be disconnected from the computer while the system is running.

- Applying excessive pressure to the tonometer will cause discomfort for the patient.

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1. Introduction

This Service Manual describes the SphygmoCor system with its three modes of pulse waveform analysis (PWA), pulse waveform velocity (PWV) and heart rate variability (HRV). This is a brief outline of the entire system and its three modes.

The user can select any of the three modes (if available) at any time by clicking on the button for that function at the left side of the opening Patient data screen.

After entering the patient information in the Patient data screen, the operator move to the Study screen by clicking the Study button on the top left of the screen. Clicking the capture button on the top right of the Study screen, the capture screen will appear and the operator will start a measurement. Finishing the measurement will produce a report appearing in the Report screen.

The operator can perform more than one measurement on the same patient. It is possible to copy and delete saved examinations one at a time.

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 your patient's condition, as well as to monitor the effects of short and long term drug therapy.

The printing system has been designed to use the default printer and provide access to the control functions available from the printer drivers.

There are no field-serviceable components in the system, and all preventive maintenance can be performed by the end user. Service action is limited to identifying components for replacement or upgrade. A spare parts list is shown on 12.

2. General Description

2.1 SPHYGMOCOR PWA

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

SphygmoCor PWA is diagnostic tool for the clinical assessment of central blood pressure. The peripheral pressure pulse waveform contains information in addition to the maximum and minimal values (systolic and diastolic pressures). The SphygmoCor Px System can derive the central aortic pressure waveform from the peripheral pressure waveform recorded at the radial or carotid* arteries.

The SphygmoCor Px System uses mathematical transforms to derive the central aortic pressure pulse waveform and then calculates a range of central indices of ventricular-vascular interaction, which are displayed both graphically and numerically.

This information enables you to 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 provide a range of indices relating to ventricular-vascular interaction.

2.2 SPHYGMOCOR PWV

The velocity of the blood pressure pulse waveform is dependent on the stiffness of the artery along which the pulse is travelling. 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 System measures the velocity of the blood pressure waveform between any two superficial artery sites. A pressure Tonometer is used to transcutaneously record the pressure pulse waveforms in the underlying artery. The pressure pulse waveform is recorded simultaneously with an ECG signal, which provides an R-wave timing reference. Pressure pulse recordings are performed consecutively at the two superficial artery sites. Often the carotid and femoral artery sites are used so the pulse wave velocity can be measured in a section of artery that includes the aorta.

Thee SphygmoCor Vx software processes each set of pressure pulse and ECG waveform data to calculate the mean time difference (□t) between the R-wave and the pressure wave - on a beat-by-beat basis. The Pulse Wave Velocity (PWV) is then calculated using the mean time difference and the arterial path length between the two recording sites. The SphygmoCor® Vx Pulse Wave Velocity (PWV) System is a system for estimating the pulse wave velocity between two superficial artery sites.

The system uses a Tonometer and 3 ECG leads, connected to an electronics module, to non-invasively record a patient's peripheral artery pressure wave and ECG waveform. From these measurements, the SphygmoCor software is able to then estimate the pulse wave velocity between the two artery sites.

2.3 SPHYGMOCOR HRV

The SphygmoCor® Heart Rate Variability (HRV) System is a system for assessing non-invasively the Autonomic Nervous System (ANS) based on Heart Rate Variability (HRV)

analysis. HRV analysis is based on measuring variability in intervals between R waves - “R To R intervals”

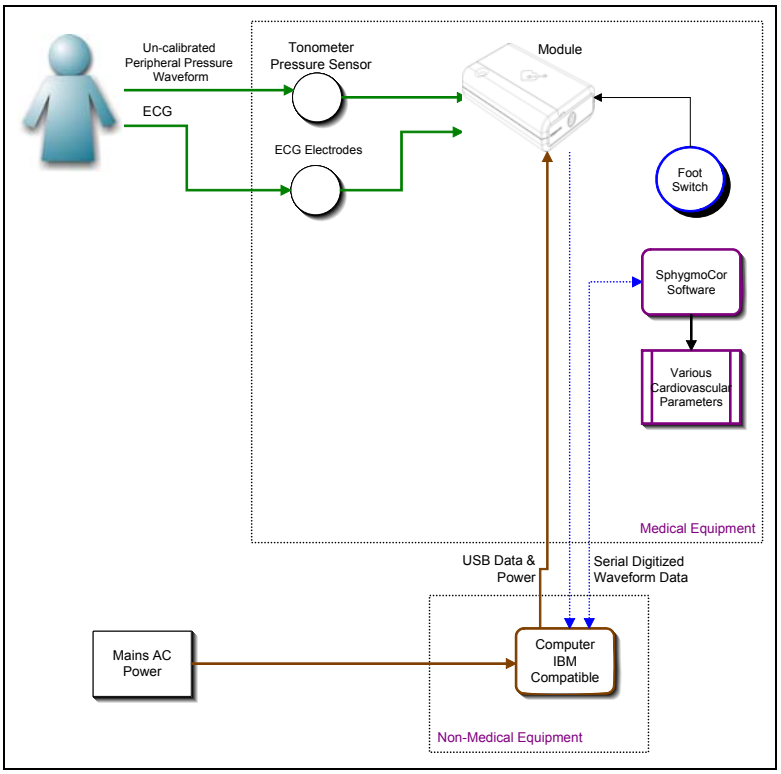
SphygmoCor HRV assesses sympathetic and parasympathetic autonomic function by providing stable and evoked measures of HRV:

- HRV measurement in Supine Resting State
- HRV measurement after Valsalva Manoeuvre
- HRV measurement after Stand Manoeuvre

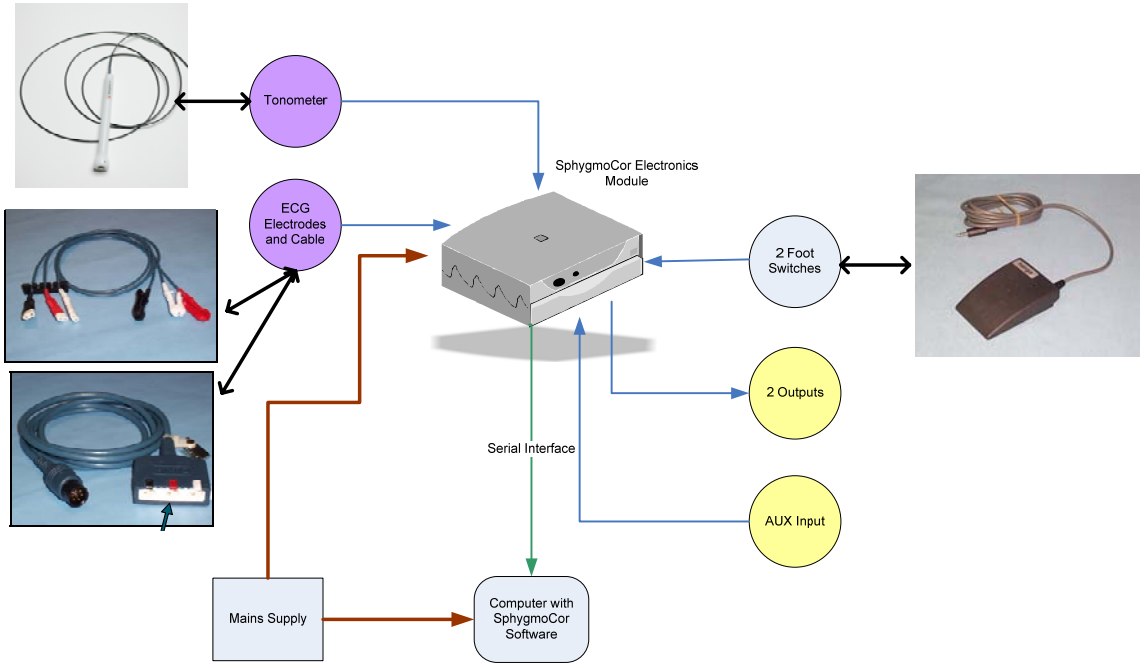
The system uses 3-lead ECG connected to an electronics module, to non-invasively record a patient's continuous ECG waveform. From these measurements, the SphygmoCor software is able to calculate parameters (spectral and temporal) related to ANS.

2.4 SYSTEM SPECIFICATION

2.4.1 SYSEM BLOCK DIAGRAM – CVMS-XXX SYSTEMS (EM3 MODULE)



2.4.2 SYSEM BLOCK DIAGRAM – SCOR-XXX SYSTEMS (MM3 MODULE)



2.4.3 PRODUCT CONFIGURATIONS

Module Name	Power Source	Supports PWA	Supports PWV	Supports HRV	Supports PWM
MM2	110V / 240V AC	✓			
MM3	110V / 240V AC	✓	✓	✓	✓
EM3	USB	✓	✓	✓	

2.4.4 MAXIMUM INTENDED DESIGN LIFE

The Maximum Intended Design Life of the Electronics Module is 5 Years.
The Maximum Intended Design Life of the Tonometer is 3 Years.

2.4.5 PHYSICAL AND ENVIRONMENTAL SPECIFICATIONS

Operating Ambient temperature:	**+15°C to 30°C (59°F to 86°F)**		
Operating Relative humidity:	20% to 80%		
Storage Ambient temperature:	+10°C to 50°C (50°F to 122°F)		
Storage Relative humidity:	20% to 90%		
Power Supply	Supply Voltage	MM2 module	220-240 VAC, (±10%) 50/60Hz 100-110 VAC, (±10%) 50/60 Hz
		MM3 module	100-250 VAC (±10%) 50/60 Hz
		EM3 module	USB +5VDC
	Power Consumption	MM2 module	12VA
		MM3 module	72VA
		EM3 module	500 mA Max
	Protective Class	MM2/MM3 module	IEC Class II
		EM3 module	IEC Class I, II or Internally powered (Depends on computer that module is connected to)
	Applied Parts	MM2/MM3 module	Type CF
		EM3 module	Type CF (ECG) Type BF (Tonometer)
	Power Connector	MM2/MM3 module	IEC 320 (Type 14) Appliance Inlet (No Earth)
		EM3 module	Via USB Type A Connector
Physical Specifications	Enclosure Material	MM2/MM3 module	ABS-Plastic
		EM3 module	PC-ABS
	Weight (Module & Tonometer)	MM2 module	1.5 kg (3.3 lbs)
		MM3 module	2.5 kg (5.5 lbs)
		EM3 module	0.8 kg (1.8 lbs)
	Dimensions	MM2/MM3 module	30.5 (l) x 26.1 (w) x 13.5 (h) cm 12" (l) x 10.3" (w) x 5.3" (h)
		EM3 module	16.0 (l) x 26.4 (w) x 5.8 (h) cm 6.2" (l) x 10.4" (w) x 2.3" (h)

2.4.6 INPUT SIGNAL SPECIFICATIONS

Input	Specification	
Tonometer	Diffused semiconductor whetstone bridge sensor	
	Sensitivity	5 µV/V/mmHg
	Contact Pressure Range	0 – 300 mmHg
	Calibration	Un-calibrated (Calibrate manually with sphygmomanometer)
	Reference Pressure	Atmosphere
	Bandwidth	DC – 40 Hz
	Sampling Rate	128 Hz
	Gain & Offset Adjust	Auto
	Signal Range, Accuracy	10mV, ±5%
ECG (MM3 and EM3 only)	Type	3-Lead (Lead II)
	Bandwidth	0.67 – 40 Hz (Device does not support extended low frequency response)
	Sampling Rate	PWV: 128 Hz HRV: 1024 Hz
	Gain & Offset Adjust	Auto
	Signal Range, Accuracy	±5mV, ±20%
	Heart Rate Range	30 BPM to 200 BPM
	Heart Rate Accuracy	±10 %
Auxiliary Input (MM3 Only)	Connector	BNC
	Signal Range	-5 to +5 V
	Frequency Range	DC – 40Hz
	Sampling Rate	128 Hz
	Calibration	Calibrated (User adjustable V/mmHg) or Un-calibrated (Tonometer Input)
	Gain & Offset Adjust	Auto
	Minimum Signal Level	50mV
	Allowable Pressure Range	30 – 250 mmHg
	Input Signal Accuracy	± 1% (30 – 50 mmHg) ± 3% (50 – 250 mmHg)
	Input Impedance	> 720 kΩ
Footswitch (MM3 and EM3 only)	Type	Micro-switch
	IP Rating	IPX8-1.0m

2.4.7 OUTPUT SIGNAL SPECIFICATIONS

Output	Specification	
Output 1 & 2 (MM3 Only)	Connector	BNC
	Signal Range	-5 to +5 V
	Frequency Range	DC – 30Hz
	Calibration	Calibrated (User adjustable V/mmHg) or Un-calibrated (Tonometer Input)
	Gain & Offset Adjust	Auto
	Pressure Range	30 – 250 mmHg
	Output Signal Accuracy	± 1% (30 – 50 mmHg) ± 3% (50 – 250 mmHg)
	Output Impedance	> 100 kΩ

2.4.8 PC INTERFACE SPECIFICATIONS

	Specification
Minimum Computer Requirements.	PC or notebook computer with: ▪ Pentium Processor P4 or greater ▪ 1 GB RAM ▪ 1024 x 768 256-colour XGA display ▪ 60GB initial free hard disc space ▪ CD-ROM drive ▪ Windows standard printer drivers ▪ Dedicated USB Port or Serial Port ▪ Windows 2000, XP (Prof) or Vista (Business)
Communication Interface	USB 1.1 serial interface USB Type B Female connector Serial Port

2.5 PRODUCT CODES & SPARE PARTS LIST

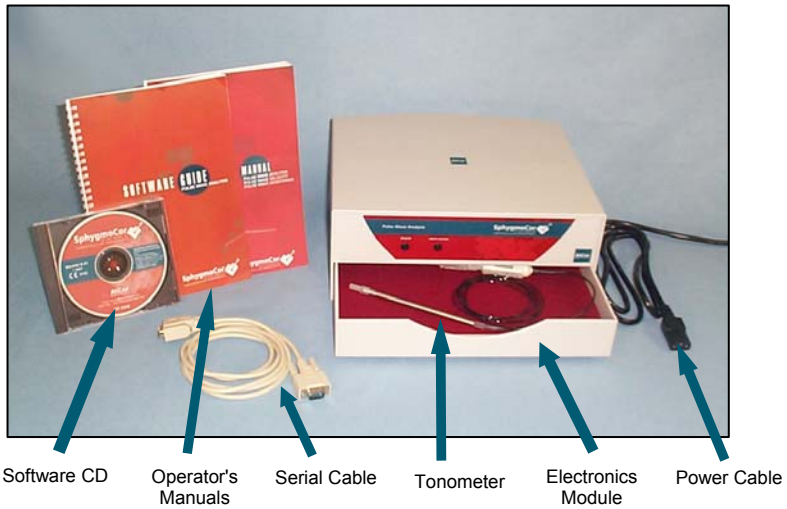
AtCor Medical reserves the right to modify the design and specifications contained within without prior notice. The product or component pictures shown in this manual may vary compared to the system supplied to you.

Product Code:	CvMS-CP	CvMS-CPV CvMS-CVPH	SCOR-Px	SCOR-PVx SCOR-PHx SCOR-PVHx	Atcor Medical Part Number
Item					
AtCor/Millar Tonometer SPT-304	✓	✓	In Module Tray	In Module Tray	T-02
SphygmoCor Electronics Module MM3			✓	✓	MM3
SphygmoCor Electronics Module EM3	✓	✓			EM3
Software CD-ROM (Includes Software Guides)	✓	✓	✓	✓	
Operator's Manual	✓	✓	✓	✓	1-00418 (MM3) 1-00601 (EM3)
Concise Software Guide	✓	✓	✓	✓	1-00561
USB-Serial Converter Cable			✓	✓	USB-COM
USB Cable - 2m	✓	✓			1-00600
Serial Cable			✓	✓	1-00011
ECG Cable (Conmed D8314II-06)	✓	✓	-	✓	1-00500
ECG Leads (Conmed DL24-03II)	✓	✓	-	✓	1-00501
Footswitch	✓	✓	✓	✓	F-01
Spare Tonometer Dome	✓	✓	✓	✓	1-00542

These items above may be purchased separately.

The picture below shows the contents of the SphygmoCor **"SCOR-XXX"** systems.

Note that items shown vary depending on the configuration you purchase. Specifications and features are subject to change without prior notice.



The picture below shows the contents of the SphygmoCor **"CvMS-XXX"** systems.

3. Software Installation

Refer to SphygmoCor Operator's Manual.

4. Hardware Installation

Refer to SphygmoCor Operator's Manual.

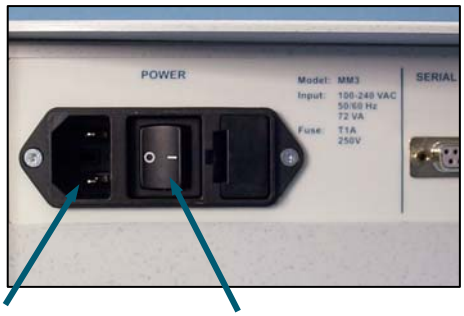
5. Operating Instructions

5.1 GENERAL - SCOR-XXX SYSTEMS (MM3 MODULE)

Step 1

Turn on the MM3 Electronics Module.

By switching the on/off switch adjacent to the power supply socket at the rear from "O" to "|". The green **POWER** light on the front panel of the module will illuminate to show power is connected to the Electronics Module. Each of the Input & Output indicators will turn on then off in sequence while the Module initialises, then the **READY** light will show orange indicating that initialisation has completed. See pictures below.



Power Cable Inlet

Power Switch

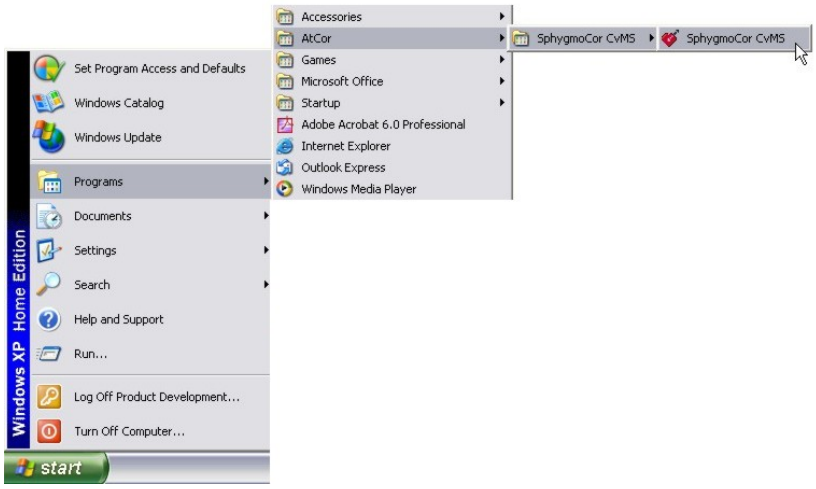
Front Panel Indicators

Step 2

After the **READY** light becomes orange ensure that the Tonometer is connected (see section **Error! Reference source not found.**), and then turn your computer on.

Note that the **READY** light will change to Green when it first communicates with the SphygmoCor Software.

Step 3 You can start the SphygmoCor CvMS software from the Windows Start menu, by clicking and holding down the Start button, then navigating your mouse to the SphygmoCor CvMS program.



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

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

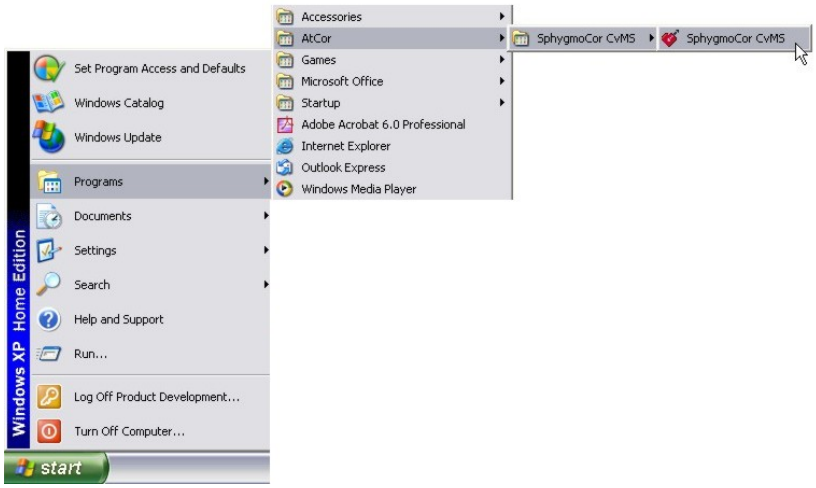
☐ See the SphygmoCor Px *Software Guide* for software operations.

□ See the *Concise Software Guide* or corresponding *Software operators guide* for software operations.

5.2 GENERAL - CVMS-XXX SYSTEMS (EM3 MODULE)

Step 1 Ensure the Electronics Module is connected to the computer and the green Power and orange Standby indicators are on.

Step 2 You can start the SphygmoCor CvMS software from the Windows Start menu, by clicking and holding down the Start button, then navigating your mouse to the SphygmoCor CvMS program.



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

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

- ☐ See the *Concise Software Guide* or corresponding *Software operators guide* for software operations.

5.3 PULSE WAVE ANALYSIS (PWA)

See the SphygmoCor Concise Software Guide for basic software operation or the Px Software Operator's Guide for advanced software operations including capturing good quality blood pressure waveforms. This is an essential part of using the System and takes some skill and experience.

5.3.1 RECORDING A PRESSURE WAVEFORM

After entering the Data Capture Screen a horizontal trace moving left to right across the bottom of the screen should appear. The main window displays the last 5 seconds of data; the bottom trace window displays the last 10 seconds of data.

The Tonometer is now active, as indicated by:

- the illuminated green light labelled **TONOMETER** on the **MM3** Electronics Module or by the illuminated blue light labelled  on the front of the **EM3** Electronics Module.

- the real-time signal now being displayed from left to right along the horizontal axis on the bottom of the screen.

When there is no pressure applied to the Tonometer, this real-time signal is zero and you will see a line being drawn across the horizontal axis of the screen. Gently press the end of the Tonometer until a waveform signal appears on the screen above the horizontal axis. This confirms that the Tonometer is now active.

CAUTION:

The Tonometer is a very expensive and delicate device. Treat it with great care and always ensure it is placed in the module tray when not in direct use.

Place the Tonometer on the artery and compress it gently (see picture below). Once you have received a consistent pressure waveform displayed between the upper and lower display limits, hold steady for at least 10 seconds (about 2 screens), and then click CAPTURE or press the SPACE BAR to capture data.

The objective is to get a pulse waveform that has:

- a steady vertical waveform position,
- constant pulse height
- consistent waveform profiles for two complete screens. (at least 10 seconds)
- QUALITY OF DATA = QUALITY OF RESULTS

WARNING: Do not use the SphygmoCor System on patients with aortic valve stenosis.

WARNING: Do not use the SphygmoCor System on patients with arrhythmia.

The last two seconds of displayed pulse waveform is discarded when data is captured. This allows the user up to two seconds between removing the Tonometer from the artery and pressing the Space Bar to capture the waveform. The recording will now be processed and a report will be shown. See the SphygmoCor Px *Software Guide* for more information.

The best results are obtained if the wrist is bent outward, in the "dorsiflex" position. This position pushes the artery towards the surfaces thus making it easier to access. When using the 'dorsiflex' position, the wrist should be supported by using a small cushion or the operator's hand (see picture below).

Press 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, the operator is pressing too hard or not hard enough respectively.

Adjust the Tonometer slightly backwards and forwards across the artery. As you move away from the centre of the artery the pulse waveform will become smaller. Eventually the signal will cease to have any pulsatile pattern and a "noisy" signal will result. Small movements in the patient's arm and in your hand holding the Tonometer cause this noise.

Once you have obtained a good waveform, you will notice that it is **consistent**, **large** and **moving across the screen in a steady vertical position**. Ten seconds of high quality waveforms, two sweeps of the screen, must be captured before pressing Space to capture and analyse the recorded waveform.

In summary, the steps for obtaining a waveform are:

Step 3	Find the artery using your index finger
Step 4	Use the Tonometer to obtain a steady pulse waveform. It is important to set and use the quality control parameters available to maintain quality.
Step 5	Press the Space Bar when you have two screens of good quality waveform. Note that the last two seconds of measurement data is discarded to allow for the delay between taking the Tonometer off the skin and pressing the Space Bar to capture data.

5.3.2 BLOOD PRESSURE CALIBRATION

When entering the systolic or mean and diastolic pressures take note of the following:

If the peripheral artery is **Radial**,

Calibrate the radial pressure waveform by entering systolic and diastolic blood pressures (either measured at brachial, or at the radial artery). The averaged aortic waveform is then calibrated based on this calibrated radial waveform.

Enter the patient's current Sphygmomanometer systolic and diastolic pressures into these two data fields. These pressures should be obtained by your standard method. For best results, take the blood pressure immediately before the study is conducted.

If the peripheral artery is **Carotid**,

The entered blood pressures systolic and diastolic (or mean and diastolic pressures) calibrate the averaged aortic waveform. The averaged carotid waveform is then calibrated based on the calibrated aortic waveform.

OR, Calibrate an averaged carotid by entering the:

- aortic blood pressures (systolic and diastolic pressures) obtained from a previous radial study.
- mean and diastolic pressures from, for example, a sphygmomanometer measurement.

An assumption can be made that the mean and diastolic pressures are the same throughout the arterial system. Thus the mean and diastolic pressure at the brachial artery (the sphygmomanometer measurement site) is assumed to be the same as the mean and diastolic pressure in the carotid artery.

Refer to the PWA Software Operator's Guide for further information on the use of the Carotid artery for measurements.

NOTE: The following checks are placed on these entered pressures. Pressures must be between 30 and 250 mmHg inclusive and the systolic pressure must be greater than the mean pressure that must be greater than the diastolic pressure. In mathematical terms,

$$30 \leq DP < MP < SP \leq 250.$$

5.4 PULSE WAVE VELOCITY (PWV)

☐ See the SphygmoCor Vx *Software Guide* for software operations.

CAUTION – DEFIBRILLATOR USE

This system may not be used in conjunction with the use of a defibrillator under any circumstances. However, should a defibrillator be used with this device, it is strongly recommended that the use of the device is stopped. AtCor Medical should be contacted for further advice.

IMPORTANT:

Do not connect these ECG Cables & Leads to any other ECG device. These cables are specifically designed for AtCor Medical Equipment only. Likewise only use ECG cables supplied by AtCor Medical on this module; do not use any other ECG cables with the AtCor Medical equipment.

Verification of ECG Signal Quality

Due to 50 or 60Hz mains power cables in typical operation environments, the ECG signal is subject to mains artefacts. Control circuitry in the ECG pre-amplifier will eliminate mains artefacts if good electrical contact to the skin is made through the diagnostic ECG pads. The presence of mains artefact indicates a problem with electrode application and the inability to obtain good electrical contacts to the skin. The Left Leg (Red) electrode is the most sensitive electrode and is usually the source of mains artefacts. To minimise these artefacts ensure that the ECG cable is coiled and kept close to the patient.

IMPORTANT:

When using the system ensure it is keep at a good distance from equipment that may emit excessive noise (e.g. MRI, X-ray) and hence affect the quality of the ECG signal.

5.5 HEART RATE VARIABILITY (HRV)

☐ See the SphygmoCor Hx *Software Guide* for software operations.

CAUTION – DEFIBRILLATOR USE

This system may not be used in conjunction with the use of a defibrillator under any circumstances. However, should a defibrillator be used with this device, it is strongly recommended that the use of the device is stopped. AtCor Medical should be contacted for further advice.

5.5.1 PATIENT PROCEDURES

Warnings

☐ SphygmoCor HRV should not be used for patients who demonstrate erratic, accelerated or mechanically controlled irregular heart rhythms.

☐ Patients in certain physiological states with the following conditions and/or implanted devices are specifically excluded:

- Atrio-ventricular block, 2nd or 3rd degree
- Pacemakers
- Sinoatrial depolarisation of <40 or >160 beats per minute
- Atrial fibrillation or flutter
- Mentally disoriented or unaware patients who are unable to follow instructions

☐ Patients who have Proliferate Retinopathy with systolic blood pressure of 160mmHg or higher or who have had laser treatment for Retinopathy in the past 3 months should not be made to perform the Valsalva manoeuvre. This may cause retinal rapture.

☐ Use of Medication may affect Heart Rate and should be taken into consideration when interpreting results.

Electrodes

CAUTION – ECG ELECTRODES

Electrodes with dissimilar metals should not be used with this device. The difference in potentials will cause polarisation and hence diminish ECG waveform quality. We recommend the use of disposable electrodes to minimise the effects of large offset potentials due to polarization. We do not recommend the use of bulb type electrodes.

Ensure when using disposable electrodes that they are used from a new packet. Old and dried electrodes will provide poor ECG signals. Check the quality of the electrodes before using them.

CAUTION - LINE TRANSIENTS

The device will detect and then reject irregular rhythms generated from line transients. Ensure correct electrode and cable placements to minimise the effect of line transients.

NOTE:

Ensure when using disposable electrodes that they are used from a new packet. Old and dried electrodes will provide poor ECG signals. Check the quality of the electrodes before using them.

IMPORTANT:

Do not connect these ECG Cables & Leads to any other ECG device. These cables are specifically designed for AtCor Medical Equipment only. Likewise only use ECG cables supplied by AtCor Medical on this module; do not use any other ECG cables with the AtCor Medical equipment.

Verification of ECG Signal Quality

Due to 50 or 60Hz mains power cables in typical operation environments, the ECG signal is subject to mains artefacts. Control circuitry in the ECG pre-amplifier will eliminate mains artefacts if good electrical contact to the skin is made through the diagnostic ECG pads. The presence of mains artefact indicates a problem with electrode application and the inability to obtain good electrical contacts to the skin. The Left Leg (Red) electrode is the most sensitive electrode and is usually the source of mains artefacts. To minimise these artefacts ensure that the ECG cable is coiled and kept close to the patient.

IMPORTANT:

When using the system ensure it is kept at a good distance from equipment that may emit excessive noise (e.g. MRI, X-ray) and hence affect the quality of the ECG signal.

6. Maintenance

The SphygmoCor System does not require any calibration or maintenance service. For faults and repairs refer to qualified service personnel as instructed by AtCor Medical. The device does not contain any serviceable or reusable parts. Disassembly of the device by unauthorised personnel voids any warranty conditions.

7. Cleaning & Disinfection

The SphygmoCor product is considered a “non-critical” device. Therefore a low-level disinfection method has been validated to assist users to disinfect the tonometer, which is the only patient contacting component of the SphygmoCor system (see below).

7.1 DISINFECTION INSTRUCTIONS

Tonometer disinfection
Use a 70% Isopropyl Alcohol (IPA) impregnated wipe or spray for low-level disinfection. Allow a contact time of at least 5 minutes.

CAUTION

Do not immerse the tonometer in IPA or any liquid as this could damage the tonometer electronics.

Do not use coarse cloths for wiping the tonometer as this will damage the sensitive transducer.

7.2 CLEANING INSTRUCTIONS

The best choice for cleaning is a neutral or near-neutral pH detergent solution, as these solutions generally provide the best material compatibility profile and good soil removal. Gently wipe the enclosure and cables with a soft cloth and detergent.

CAUTION

Ensure detergent does not ingress into any electronic components of the system (module, tonometer or cables) by not over spraying or allowing detergent solution to ‘run’.

8. Trouble Shooting

8.1 TROUBLE SHOOTING GUIDE

Symptom	Problem	Identfication	Action
Module does not turn on	Module not plugged in and/or power not turned on	Visual check	Connect module to power
	Fuse is blown	Remove cover at rear and make a visual check	Replace Fuse (IF FUSE BLOWS AGAIN, RETURN TO ATCOR)
	LED is faulty	System works as normal, but no LED to signify power is on.	Return to AtCor
	Module hardware fault	None of the above	Return to AtCor
Software cannot find module.	Module not plugged in to computer	Visual check	Plug it in
	Serial/USB cable faulty	Test with a different cable	Replace cable
	Incorrect com port used	Check system settings in SCOR software	Adjust system settings to correct port if available. Refer to Operator's manual.
	No spare coms port	No where for cable at the rear of the computer	Use splitter box, use parallel port, or use USB adaptor
	Com port conflict	Check if other com software is installed, e.g. fax, modem.	Advice customer to remove other software
	PC hardware faulty	Test with a different module	Advice customer to arrange repair.
	Module hardware fault	None of the above	Return to AtCor
Incorrect tonometer signal	Tonometer is faulty	Test with a different Tonometer	Request for a replacement (3 months warrantee from time of installation)
	Tonometer socket pins are damaged.	Compare with diagram	Customer is responsible. Advice for repair/ replacement.
	Module hardware fault	None of the above	Return to AtCor
Incorrect ECG signal	Incorrectly applied ECG pads/cables		Clean skin and re-apply the ECG pads and check the cables are connected correctly
	ECG cable are faulty	Test with different cables	Replace cables
	ECG leads are faulty	Test with different leads	Replace leads
	Module hardware fault	None of the above	Return to AtCor

8.2 FAQ HARDWARE PROBLEMS

For updated FAQ's visit: www.atcormedical.com

What type of computer do I need?

The computer to be used with the system must meet the specifications as per Section 2.4 **PC Interface Specifications**

Can I install the system on a Mac?

No, the system is not compatible with Mac computers.

My computer doesn't have a serial port available. Can I still use the system?

The system can use a USB port using the AtCor provided and recommended USB adaptor and driver if there is no serial port available.

How does the probe work? Is it a doppler probe?

The probe is a pressure tonometer. It measures the pressure wave via applanation tonometry. Applanation tonometry is the process of flattening (but not occluding) the artery against underlying bone. Applanating the artery allows for accurate recording of the intra-arterial pressure without penetrating the skin or blood vessels.

How sensitive is the probe?

The probe has been validated against intra-arterial pressure recording and shown to be very accurate, particularly across the higher frequency components (Kelly et al, J Vasc Med Biol Vol1 No3 1989). The probe is therefore able to detect even slight changes in the radial pressure waveform.

How durable is the probe? What maintenance is required?

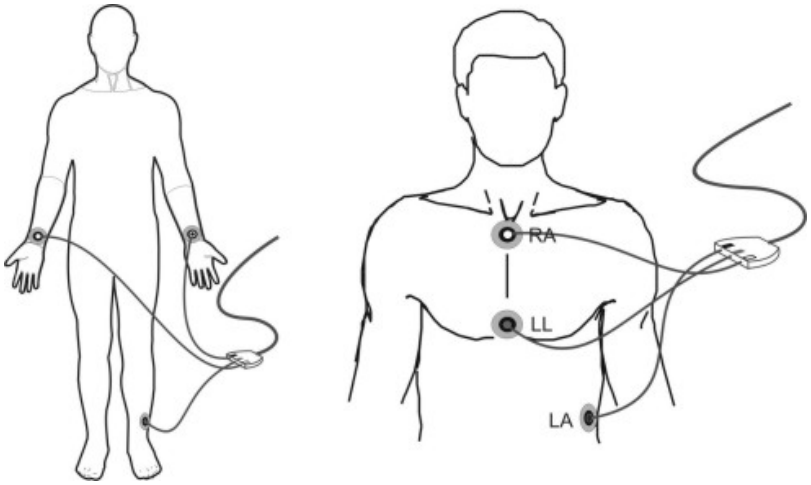
The probe is very durable and has a long life span, provided care is taken with it's use. The probe doesn't require any maintenance; however it can be disinfected if required (see section 7).

When the software is loading an error message pops up saying "Electronics Module Not Found"

This is usually because the electronics module is not switched on, or isn't connected to the computer, or has been assigned the incorrect communications Port. Check that the "Power" light is on and that the cables are properly connected, then click "Yes". In the event the incorrect Com Port has been assigned please refer to the operators manual for instructions.

The ECG recording is quite poor, how can I improve it?

Ensure that the ECG pads you are using have not dried out. Try cleaning the skin and repositioning the electrodes. The system uses the Lead II ECG configuration, make sure that each pad is placed in the correct location and attached to the correct lead, as displayed in the following figure.



8.3 FAQ SYSTEM & SOFTWARE PROBLEMS

How does the system work?

The SphygmoCor System uses a pressure probe to record the pressure wave at the radial artery, which is then calibrated with the brachial blood pressure. The system then derives the pressure wave at the ascending aorta utilising a generalised transfer function. The generalised transfer function essentially describes the properties of the brachial artery and the effect it will have on the pressure wave as it travels along it. By applying this transfer function, to the calibrated radial pressure wave, it allows the derivation of the calibrated aortic pressure wave.

Has the system been validated? Is it reproducible?

The SphygmoCor System has been validated against invasive recordings of the aortic pressure wave. The latest validation paper showed the derivation of the central pressures to be accurate to within 1mmHg. All reproducibility papers have shown the system to be very reproducible. The validation and reproducibility papers are listed in the publications section of AtCor website.

Does the system come with a computer?

The SphygmoCor System does not come with a computer. It can be installed on any PC or laptop that meets the minimum computer requirements.

Can I purchase the Vx system on it's own?

No, the Pulse Wave Velocity system (Vx) is sold as an add-on to the Pulse Wave Analysis System (Px).

Are you experiencing difficulty taking a tonometer reading?

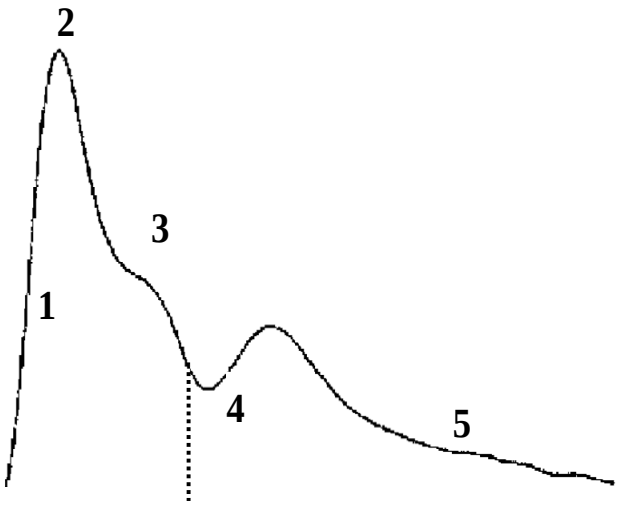
1. The patient's arm needs to be stable. Ensure that the arm is rested either on a table or bed, and the wrist is supported and slightly flexed (either with a small rolled-up towel, or the operator's hand).
2. Make sure that the wrist is flat and not being held on an angle.
3. The operator's entire arm should also be supported. Elbow should be resting on the table or bed, and the hand should be resting on the patient's thumb.
4. The tonometer should be held perpendicular to the wrist.
5. Hold the tonometer close to the tip, similar to holding a pen.
6. Place the probe over the area with the strongest pulse, which is generally closer to the bony section of the wrist.

How do I know if I have taken a good reading?

You should always check the Quality Control Section of the report. The following key quality control parameters are given: Average Pulse Height - is the average height of all the pulses, and hence a measure of pulse strength. Ideally, this number should be greater than 100, but numbers greater than 80 are considered acceptable. Pulse Height Variation - is the amount of variation there is in the pulse heights (expressed as a percentage). The variation should be no greater than 5%. Diastolic Variation - amount of variation in the diastolic portion of the pulse wave. This value should also be no greater than 5%. If these values are within the respective quality control limits, they will appear in green. If they are outside the limits, they will appear in red. On the "Clinical Report", you will also find the Operator Index. The Operator Index is a number out of 100 that is derived from the above quality control parameters. If the number is over 85, the reading is acceptable. If it is between 75-85, it is borderline. If it is less than 75, the reading is unacceptable.

Features of the Radial Artery Pressure Waveform that Identify a Good Quality Waveform

Certain features of the radial artery pressure waveform may vary in position, but overall waveform shape will remain the same. For example, the effects of aging are seen in the waveform of a middle-aged person as an increase in amplitude of the second systolic shoulder and a decrease in amplitude of the pressure waveform during diastole. The discussion and illustration below provide guidance for review of the radial waveform to assure good data quality.



1. A sharp, nearly linear initial upstroke of the pressure waveform for at least 80 msec. “Bumps” or noise in the upstroke will be incorrectly interpreted by the analysis software as the end of the initial pressure wave.
2. A peak (in some cases an inflection point or shoulder) at between 80 and 150 msec.
3. A late systolic shoulder between the first peak and incisura. The location of this shoulder will differ depending on the age and disease. In older persons this shoulder may, in fact, be a second peak. In very young people, this may not be detectable.
4. The incisura, marked on the sample waveform at left by a vertical dotted line, will be located after the late systolic shoulder and immediately before an inflection of the radial pressure waveform.
5. The pressure through diastole should smoothly decrease to approximately the same pressure as at the beginning of the waveform. It should nowhere be flat.

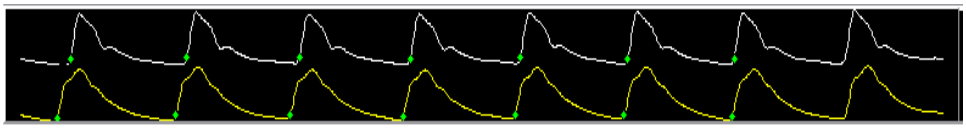
Waveform Criteria

The following criteria should be applied to waveform data available on the SphygmoCor Clinical and Detailed Report Screens as a means of assuring data quality. If any of these criteria are not met (regardless of the system's quality control parameters), the recording should be repeated and strong consideration given to not retaining the data.

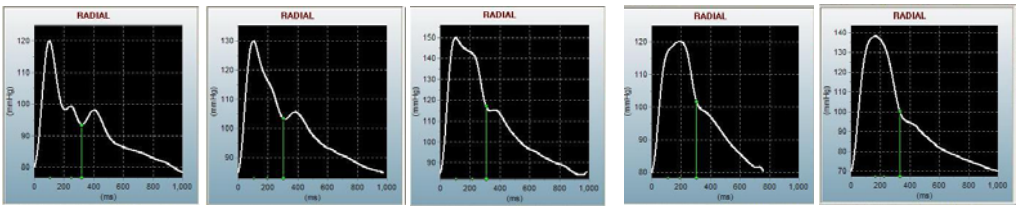
T1 (Detailed Screen):	80 ms < T1 < 150 ms
Minimum Average Pulse Height (Clinical Screen):	100 units
Maximum Pulse Height Variation (Clinical Screen):	5%
Maximum Diastolic Variation (Clinical Screen):	5%
MinimumOperator Index (Clinical Screen):	80
Augmentation Index (Clinical Screen):	<50%

Examples of typical, good quality radial waveforms

The detailed screen shows the 10 second of recorded and analysed waveforms (see Figure below). These can be examined to assess overall consistency of the waveforms. The series of waveforms should have consistent peaks and troughs, and the contour of the waveform, in particular the peak pressure and shoulder, should be identical.



Captured raw peripheral (top), displayed with the derived aortic waveform (bottom).

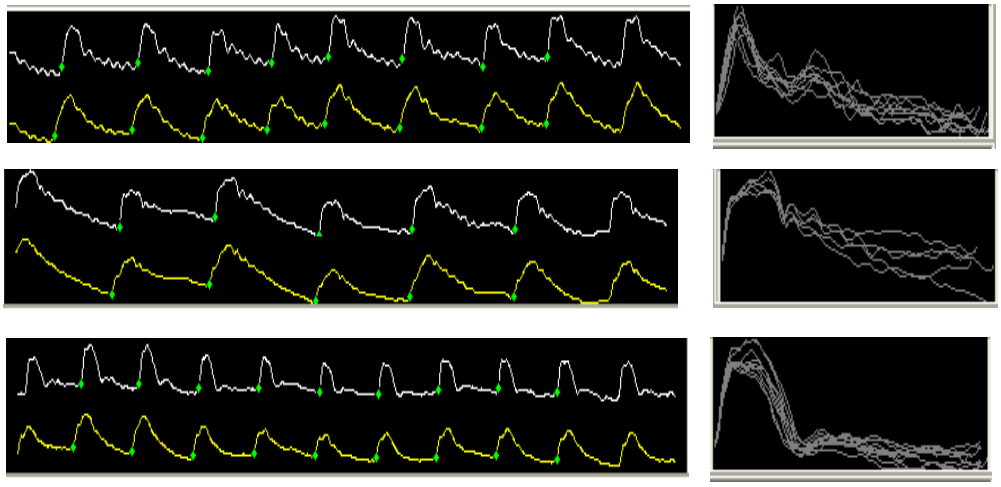


20 year old 30 year old 40 year old 50 year old 70 year old

Radial waveforms of people with different vascular ages (note that chronological age may differ substantially from vascular age):

Examples of poor raw waveform data

The captured waveforms and their respective waveform overlay show some common examples of poor quality waveforms. When the raw waveform signal appears as in the first two examples below, it is due to the tonometer not being directly on top of the radial artery and the tonometer needs to be readjusted. Variation in the peaks and troughs of the waveforms, as shown in the third example, indicates that a change in pressure was applied to the tonometer and the operator should aim to hold the tonometer steadier (However, this may also represent an unavoidable respiratory artifact). In addition, the diastolic portion of the waveform is flat, indicating that the hold-down pressure is too high and the artery is being occluded. In each instance the measurements should be repeated.



I don't understand why the reading hasn't met quality control.

If a reading hasn't satisfied quality control, it is either because the probe wasn't directly on the artery, or there was too much variation in the downward pressure applied with the tonometer. This can be determined by looking at the pulse overlay in the quality control section. When the probe is positioned directly on top of the artery the waveforms will all have the same shape, and be very "smooth". If the probe is on the side of the artery, there will be a lot more variation between each waveform and the signal will be more "noisy". If every waveform in the pulse overly has the same shape, but there is a wide spread, it indicates that the probe was directly on the artery, but the downward pressure on the probe was varied during recording.

There are 4 algorithms available for pulse wave velocity. What is the algorithm for, and which one should I use?

These algorithms are used to determine the point at which diastole ends and systole begins. A technical sheet with further information on these algorithms can be found in the AtCor website. If you do not have a preference for the algorithm to be used, we recommend using "3. Intersecting Tangents" as this is the algorithm the system uses for pulse wave analysis

How do I know if my PWV recording satisfies quality control?

The pulse wave velocity (m/s) of the measurement is presented with the standard deviation (PWV +/- SD). The standard deviation should be equal to or less than 10% of the velocity eg. If the PWV = 8.0m/s, the SD should be < 0.8. Also, the standard deviations of the mean timing data from ECG to Site A and ECG to Site B should be equal to or less than 6% of the mean time. These values can be found in the table at the bottom of the report screen, and appear in green if they are equal to or less than 6%, and red if they are greater than 6%. More information can be found here.

Why is my PWA report labeled with a “Note”?

The PWA report may have an additional ‘’Note’ labeled to it for three reasons:
1. Peripheral and Central T1 (time to the first peak) are outside the physiological range (80 to 150 msec).
2. The ratio between Peripheral T1 and Central T1 is more than 70%, which is called 'Correspondence of Aortic and Peripheral T1’.
3. Low Operator Index.

Why is my PWA report labelled as “Inconclusive” when I have a high Operator Index?

The high Operator Index indicates that the pressure waveforms captured over the 10 second period are consistent and do not vary considerably from beat to beat, however this does not provide a reflection of physiological features of the waveform. The timing of the first peak observed in the waveforms (Peripheral and Central T1) are physiological features of the waveform and the SphygmoCor software will indicate when these are detected outside the physiological range. Hence it is possible to have an Inconclusive label on a highly reproducible set of waveforms.

Should a report be discarded if it is labeled ‘Inconclusive’?

If the report is labeled ‘Inconclusive’ it is advisable to repeat the measurement. If on repeated measurements the ‘Inconclusive’ label is still present for the same reason (as mentioned above); care should be taken when analysing the results.

Why can repeated measurements of AIx (Augmentation Index) on the same subject vary?

AIx, like blood pressure varies through the day, and can be affected by coffee, cigarettes, heavy meals and activity. These conditions will change your heart rate and blood pressure and consequently your AIx (though may not be permanently altered). To ensure reproducible and accurate measurements, all subjects therefore should be measured under similar conditions. It is important to take SphygmoCor measurements when the subject is relaxed (either lying or sitting down) and has abstained from coffee, cigarettes, heavy meals or exercise prior to the measurement, unless these are the conditions specific to the study. All subjects have to be under similar conditions when measured, to insure reproducible and accurate measurements.

Is it possible to measure PWV in patients with a pacemaker and, if so, will it affect the quality of the measurement?

It is possible to measure PWV on most patients with a pacemaker. The main determinant will be the quality and morphology of the ECG signal. If the ECG signal displays a square wave (due to the Pacemaker itself) then this will affect the QRS detection, which is essential for measuring PWV with SphygmoCor. In these instances, care should be taken when analysing the results. Not all pacemakers have the square pulse, however, and in these instances good quality PWV measurements should be possible.

What does the ‘out of range dp/dt’ message mean? And should I disregard reports that produce such a message?

Max dp/dt is the highest slope during early systole. The SphygmoCor software measures this on the radial pressure waveform and will display the message ‘out of range dp/dt’ when this value is very low or very high. There are a number of reasons that a high or low Max dp/dt may be observed one of which is height of the pulse in mVolts in the raw recording, as opposed to being associated with Pulse Pressure. That is, the max dp/dt may be out of range due to technical reasons rather than physiological reasons.

When the message of ‘out of range dp/dt’ is observed, care should be taken when analysing the results from the measurement. Duplicate measurements are always recommended particularly in instances when measurements have cautionary messages displayed.

When performing a carotid to femoral PWV measurement, why do we subtract the carotid-sternum distance from the sternum-femoralis distance to get the total distance traveled by the pulse?

"The proximal and distal pulse waves may be recorded from two different arterial sites, where pulse waves propagate in opposite directions, such as for the carotid-femoral PWV measurement. In fact, the pulse wave generated by the left ventricle contraction is propagated throughout the aorta, iliac and femoral arteries in the opposite direction than through the carotid artery. In this case, evaluating the covered distance by superficial measurement ... presents some margin of error."[1]

In other words, using the superficially measured carotid to femoral distance to calculate PWV will produce an error because of the opposite direction of the pulse propagation of both arterial sites. To compensate for that, you need to subtract the carotid-sternum distance from the sternum-femoralis distance and use the result as the distance for calculating PWV.

1: Asmar R, "Arterial Stiffness and Pulse Wave Velocity: Clinical Applications", 1999 Editions scientifiques et medicals Elsevier SAS, 1999 Paris.

9. Technical sheets

Please refer to www.atcormedical.com for the latest Technical Notes which may help you to resolve and clarify any potential SphygmoCor issues before contacting technical support.

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