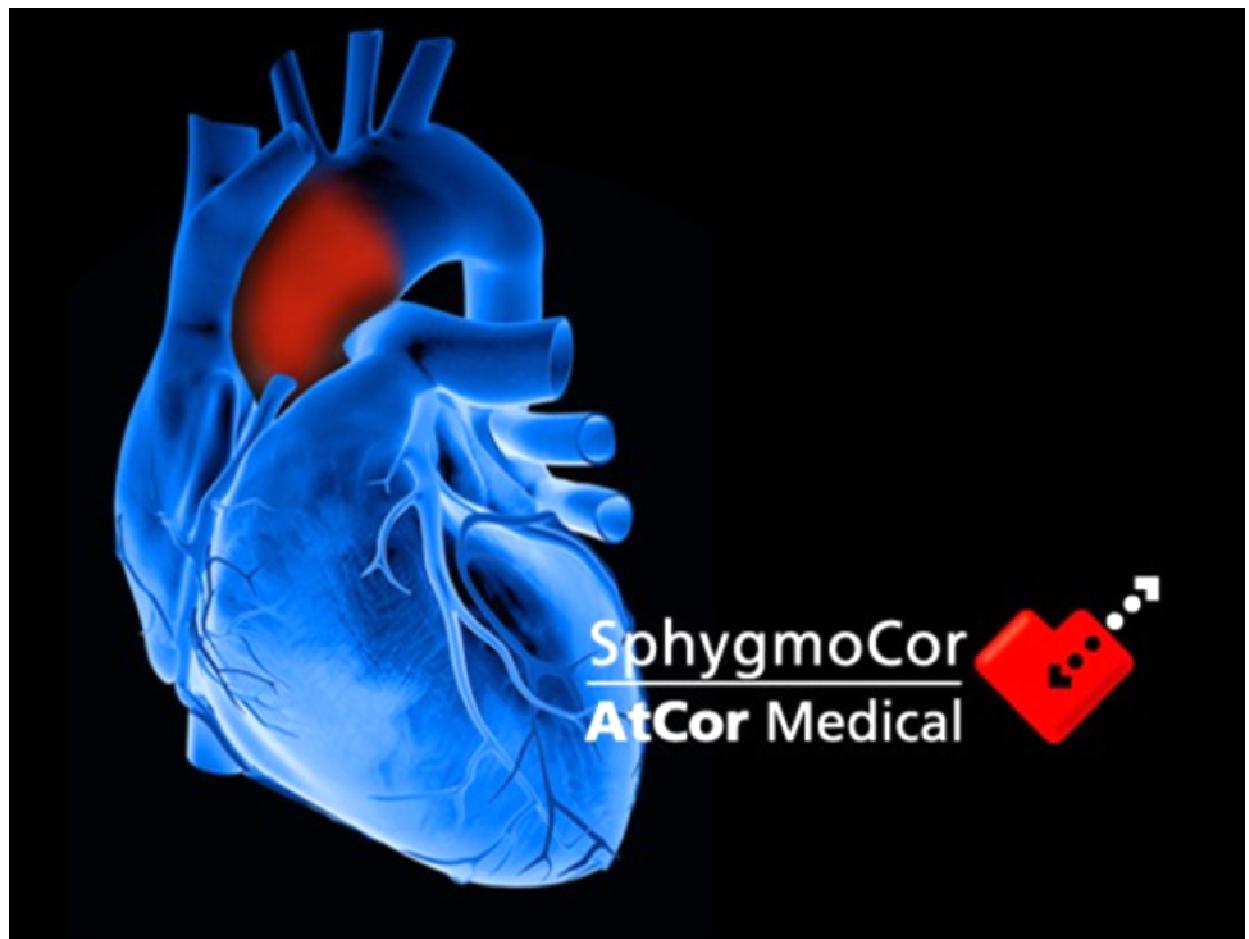


# *SphygmoCor® System*

## *Clinical Software Operators Manual*



## *Copyright*

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**SphygmoCor®**

Model: **CvMS** – Central Blood Pressure Assessment System

Software Version: 9

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DCN: 101159

Rev: 1.1

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## *Disclaimer*

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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 (Professional) / Windows Vista (Business) / Windows 7 (Professional) 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

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

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

## Disposal

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According to the Official Journal of the European Union WEEE Directive 2002/96/EC that requires the proper disposal of electrical and electronic equipment. This device should be disposed of separately, not as unsorted municipal waste. To dispose of your device, you should use appropriate collection, reuse and recycling systems available in your region. The use of these collection, reuse and recycling systems is designed to reduce pressure on natural resources and prevent hazardous substances from damaging the environment.

If you need information on these disposal systems, please contact your local waste administration. The crossed-bin symbol invites you to use these disposal systems. If you require information on collection and disposal of your AtCor Medical device please contact AtCor Medical Head Office or local distributor.



## Regulatory

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### CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

# SphygmoCor System

## Quick Start Guide

### Quick Start Guide

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This Quick Start Guide will briefly explain how to install the **SphygmoCor System**, its accessories and software, and successfully obtain a central blood pressure assessment.

For detailed instructions for use, please consult the manual following the Quick Start Guide.

#### Step 1 *Unpacking the SphygmoCor System*

---

Open the carton and carefully un-pack the **SphygmoCor System**. Inspect the contents of the system, including all accessories and documentation.

Check to ensure you have received the following items with your SphygmoCor System:

- SphygmoCor Electronics Module EM3
- Tonometer (SPT-304)
- Software CD-Rom (Includes software guides) \*
- USB cable \*
- Footswitch \*
- ECG electrodes, cable and leads\*

\* located in cardboard accessories box (situated directly beneath the electronics module) in the shipping carton.

#### Step 2 *Software Installation*

---

The **SphygmoCor Software Suite** CD-ROM supplied with the system contains the installation software to install the SphygmoCor software on your computer.

***Complete the software installation prior to connecting the module to your computer.***

- Step 1 Turn your computer on. Insert the **SphygmoCor Software Suite** CD-ROM into the CD-ROM drive of your computer.
- Step 2 A Micromedia Flash Player screen should automatically appear. Select **Install SphygmoCor Software [Start Here]** to begin the installation process.
- Step 3 When the Software License Agreement screen appears, read the terms of agreement and select **I Agree** to continue the installation.
- Step 4 On the Welcome screen, click **Next** to continue.
- Step 5 On the Choose Destination location screen, click **Next** to accept the suggested destination folder (C:\AtCor\SphygmoCor CvMS V9\). To change the location, enter an alternative folder name location.
- Step 6 The Select Program Manager Group screen will appear. The default folder name ‘SphygmoCor CvMS V9’ will appear. Click **Next** to continue. The Start Installation screen will appear. Click **Next** to copy the software to your computer.
- Step 7 Disconnect Module screen will appear. Ensure the module is not connected to the computer. Click **OK**.
- Step 8 The Installing screen will appear showing the files being copied and installed on your computer.
- Step 9 When the software installation is finished, the Installation Complete screen will appear. Click **Finish** to exit the set-up process.

### **Step 3 *Hardware Installation***

---

The tonometer is connected to the electronics module and can be accessed by opening the tonometer compartment door.

- Connect the footswitch, if desired, by inserting the connector on the end of the footswitch into the footswitch socket on the rear of the electronics module.
- Connect the electronics module to your computer using the USB cable supplied with your system. The electronics module is powered through the USB cable when connected to your computer. The USB driver should already be installed and an information balloon will appear in the taskbar of your computer screen indicating new hardware has been found and is ready to use.

**You are now ready to start using your SphygmoCor system.**

### **Step 4 *Operating Instructions***

---

- Step 1 Open the SphygmoCor software via the shortcut on your Windows desktop by double-clicking on the  icon.
- Step 2 Click **Patient** to activate the Patient Screen. To enter a new patient into the database, click the **New** button in the patient search area, and then click on the **Yes** button to confirm you would like to enter a new patient. Enter Patient details such as Last Name, First Name, DOB and Sex. Click on the **Save** button to advance to the next step.
- Step 3 Click the **PWA** or **PWV** button to perform measurement. If only one of these modes is available, there is no need to click on the button, simply proceed to the study screen.

#### **Central Blood Pressure Measurement Using Pulse Wave Analysis (PWA)**

- Step 1 Click on the **Study** button to enter study parameters. Enter the brachial pressure taken from a calibrated sphygmomanometer and any other details you wish to include.
- Step 2 Click on the **Capture Data** button to proceed with a measurement. Palpate the patient's radial artery to identify the strongest pulse point. Place the tonometer over the strongest pulse point. Gently press the tonometer down until you see a consistent pressure waveform displayed on the data capture screen. If Auto Capture is enabled (see Note below), the system will automatically save the measurement. To manually save the measurement for analysis, press the **spacebar** on your keyboard (or step on the footswitch, if used).

**Note:** When Capture Guide is enabled (default setting), Guidance Bars are displayed in red, yellow or green (green indicating within quality control parameters) and the waveform will automatically become green when 11 seconds of waveform data meets all quality control parameters. The waveforms will automatically be captured for analysis and a report will be generated.

- Step 3 If a repeat measurement is required with the same study parameters, click on the **Repeat** button to go return to the Capture Data screen and repeat the measurement as outlined in Step 4 above.
- Step 4 To perform a measurement on a new patient, click on the **Patient** button and return to Step 2 above.

#### **Arterial Stiffness Measurement Using Pulse Wave Velocity (PWV)**

- Step 1 Click on the **Study** button to enter study parameters.

- Step 2** Enter brachial pressure taken from a calibrated sphygmomanometer and the distance measured for the distal and proximal sites from the supra-sternal notch. Medication, Notes, and Operator fields may be entered, if desired.
- Step 3** Attach the three ECG electrodes and leads to the patient in a modified Lead II configuration or using the patient's limbs as indicated on the cables.
- Step 4** Click on the Capture button to proceed with the measurement. The PWV measurement is taken in two steps: A tonometry reading at Site A (carotid artery) followed by a tonometry reading at Site B (femoral artery).
1. Ensure the ECG signal is of acceptable quality.
  2. Place the tonometer on the carotid artery and gently press the tonometer down until you receive a consistent pressure waveform displayed on the data capture screen. When you have a minimum of 13 seconds of consistent waveforms, click the OK button or (press on the footswitch, if used).
  3. Place the tonometer on the femoral artery and gently press the tonometer down until you receive a consistent pressure waveform displayed on the capture screen. When you have a minimum of 13 seconds of consistent waveforms, click the OK button (or press the on the footswitch, if used).
- Step 5** The report(s) can now be reviewed. To perform a measurement on a new patient, click on the **Study** button and repeat this procedure or use the **Search** feature to search for an existing patient.

#### ***Shut Down***

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- Step 1** The software automatically saves all reports. To close the software, click on **System** from the main menu, and then click on **Exit**.
- Step 2** Place the tonometer in the module tray for storage.

## **Contents**

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Electrical Safety Warnings .....	9
<b>1 Introduction.....</b>	<b>12</b>
The SphygmoCor System – Central Blood Pressure Assessment (PWA) .....	12
The SphygmoCor System— Arterial Stiffness Assessment (PWV) .....	12
<b>2 Setting up the SphygmoCor System.....</b>	<b>12</b>
2.1 Unpacking the SphygmoCor System.....	12
2.2 Intended Use.....	12
2.3 Software Installation .....	13
2.4 Hardware Installation .....	14
2.4.1 Connector Symbols.....	14
2.4.2 Indicators.....	15
<b>3 Using the SphygmoCor System.....</b>	<b>16</b>
3.1 Overview .....	16
3.1.1 Central Blood Pressure Assessment Flowchart (PWA Mode).....	16
3.1.2 Arterial Stiffness Measurement Flowchart (PWV Mode) .....	17
3.2 Setting Up the Electronics Module and Starting the Software.....	18
3.3 Patient Entry - Select or Enter a New Patient.....	20
3.3.1 Create a New Patient Entry .....	20
3.3.2 Selecting an Existing Patient from the Database.....	21
3.4 Conducting a Pulse Wave Analysis (PWA) Measurement .....	22
3.4.1 Entering Study Details .....	22
3.4.2 Recording a Pressure Waveform (Data Capture).....	23
3.4.3 Reviewing the Patient Report .....	25
3.4.4 Analysis of Multiple Studies .....	26
3.5 Conducting an Arterial Stiffness Measurement in PWV mode .....	28
3.5.1 Entering Study Details .....	28
3.5.2 Recording Pressure and ECG Waveforms .....	30
3.5.3 Examining the Patient Report .....	31
3.5.4 Analysis of Multiple Studies .....	33
<b>4 Advanced Features .....</b>	<b>34</b>
4.1 SphygmoCor Configuration Settings .....	34
4.2 Database Manager .....	34
4.2.1 Create a New Database.....	34
4.2.2 Change the Description of an Existing Database .....	35
4.2.3 Copying a Database .....	35
4.2.4 Updating a Database .....	36
4.2.5 Deleting a Database .....	36
4.2.6 Database Optimisation (packing a database).....	36
<b>5 Appendix .....</b>	<b>37</b>
5.1 Warranty .....	37
5.2 Product Support.....	37
5.3 Maintenance .....	37
5.4 References.....	40
5.5 Troubleshooting Guide .....	41
5.6 Specifications.....	42

5.7	Disclosures and Limitations .....	45
5.8	Electromagnetic Compatibility (EMC) Warnings & Declarations .....	45
5.9	European Declaration of Conformity .....	48

## Electrical Safety Warnings

As a result of the approval of the **SphygmoCor System** to IEC60601-1 the following warnings are applicable:

- ❑ IEC60601-1-1 compliance is the responsibility of the end user. To ensure compliance to IEC60601-1-1 the **SphygmoCor System** must meet the following conditions:
  1. The PC and peripherals (e.g. USB hubs) must comply with IEC60950 or equivalent, and must not be located within 1.5m (approx. 6ft) from the patient.
- AND
- 2. The enclosure leakage current from any device within the patient environment, including any parts of equipment which extend into that environment, is not more than 0.1mA in normal condition and 0.5mA in the single fault condition of interrupting an earth conductor in any single power supply cord (for the U.S.A. the single fault limit is reduced to 0.3mA).
- ❑ The required low enclosure leakage current may be achieved by powering the PC and peripherals from an isolation transformer. It is not recommended the system be connected to other non-isolated monitoring equipment or communication networks. In this event it is the end user's responsibility to ensure compliance with IEC60601-1 and IEC60601-1-1.

### IEC60601-1-1 SAFETY WARNINGS

1. Ensure that only the SphygmoCor Electronics Module, Tonometer, ECG Cables and footswitch are within the Patient environment. The computer and other devices shall be outside the patient environment.
2. When using the SphygmoCor Electronics Module, do not connect the power cable of the computer to multiple portable socket-outlets or power boards which are connected to other devices. Do not place the multiple portable socket-outlet or power board on the floor while the SphygmoCor System is in use.
3. Do not connect any peripheral devices (eg. Printer, externally powered USB hubs) to the computer while using the SphygmoCor System as they may breach the patient isolation requirements of IEC60601-1 & IEC60601-1-1.
4. When using an isolation transformer and a multiple portable socket-outlet or power board to connect to the computer and the SphygmoCor System do not connect any other devices or equipment to the multiple portable socket-outlet or power board.
5. When using the SphygmoCor System, the operator should not touch the computer and the patient at the same time. The operator can capture the measurement using the footswitch, if connected.
6. Do not connect or use any cables or sensors other than those specified for use with the SphygmoCor System.
7. Do not disassemble the SphygmoCor Electronics Module. The SphygmoCor Electronics Module contains no serviceable parts. Servicing shall be performed by qualified service personnel.
8. Only use accessories supplied, or specified for use, with this system.

## Contraindications

### General

- Do not use mobile/cellular phones or other transmitting devices within 10 metres (30 feet) of the SphygmoCor System
- The SphygmoCor System should not be used for patients with erratic, accelerated or mechanically-controlled irregular heart rhythms, including patients with arrhythmias.
- The SphygmoCor System should only be used with an AtCor Medical supplied Tonometer
- Do not use the Tonometer on moist or wet skin
- Do not use the SphygmoCor System on patients with aortic valve stenosis
- Any interpretations made from the SphygmoCor System measurements should be made in conjunction with all other available medical history and diagnostic test information about a patient
- Since peripheral vasodilatation 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.
- Note additional warnings printed on the Electronics Module

## **Central Blood Pressure (PWA)**

- Tonometry should not be used on a patient's arm if there is an active or inactive fistula
- 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 Reynaud's phenomena or intense cold
- The SphygmoCor system should not be used on persons with significant aortic valve stenosis (gradient >60mmHg)

## **Pulse Wave Velocity (PWV) - (ECG)**

- SphygmoCor PWV should not be used for patients with the following conditions :
  - Atrio-ventricular block, 2<sup>nd</sup> or 3<sup>rd</sup> degree
  - Sinoatrial depolarisation of <40 or >160 beats per minute
  - Atrial fibrillation or flutter
  - Mentally disoriented or unaware patients who are unable to follow instructions
- Use of medications affecting heart rate should be taken into consideration when interpreting results
- Certain precautions should be observed to reduce the risk of personal injury or damage to the unit. Be certain to read the general precautions and basic system care below and to note the cautions included in the text of the manual.

### **WARNING – ECG ELECTRODES**

When placing ECG electrodes on the patient ensure that they are free of moisture or away from liquids.

### **WARNING - PACEMAKER PATIENTS**

SphygmoCor PWV should not be used for patients with pacemakers..

### **CAUTION – DO NOT USE AS A HEART RATE MONITOR**

This system is not a Heart Rate Monitor. Do not use the ECG functions of this device for heart rate monitoring purposes. Ensure the device is used as per the intended purpose as described in this manual.

### **CAUTION – DEFIBRILLATOR USE**

This system may not be used in conjunction with the use of an external 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.

### **CAUTION – ELECTROSURGICAL EQUIPMENT USE**

This system may not be used in conjunction with the use of any electrosurgical equipment under any circumstances.

## **USA Privacy Rule**

This AtCor Medical product stores, displays and exports patient health information which could affect HIPAA compliance. It is the responsibility of the health care organisation that is subject to the Privacy Rule to ensure compliance with HIPAA regulations. AtCor Medical does not make any claim with respect to compliance with HIPAA for its products. The Privacy Rule (also known as Standards for Privacy of Individually Identifiable Health Information) is contained in Title 45 of the Code of Federal Regulations, Part 160 and Subparts A and E of Part 164.

## **Cybersecurity**

If the PC used with the SphygmoCor System is connected to a network or the internet, the provider of services is responsible for ensuring the security of the information.

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## 1 Introduction

---

Following is a brief overview of the SphygmoCor System, focusing on the Central Blood Pressure measurements (PWA mode) and Pulse Wave Velocity measurements (PWV mode).

### The SphygmoCor System – Central Blood Pressure Assessment (PWA)

The SphygmoCor System is a non-invasive diagnostic tool for the clinical assessment of central blood pressure. The SphygmoCor System can derive the central aortic pressure waveform using a pressure waveform recorded at the radial artery. Analysis of the waveform provides key parameters including central arterial pressures and indices of arterial stiffness which are also compared to population reference range values. Measurements are performed by placing a pressure transducer (tonometer) over the radial artery and recording 11 seconds of quality radial waveforms.

### The SphygmoCor System— Arterial Stiffness Assessment (PWV)

The SphygmoCor System also measures the pulse wave velocity of the blood pressure waveform travelling between any two arterial sites that can be measured non-invasively. The velocity of the blood pressure pulse waveform is dependent on the stiffness of the artery along which the pulse is travelling. Measurements are normally performed by recording pressure waveforms at the carotid artery followed by the femoral artery, with an ECG signal recorded simultaneously.

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## 2 Setting up the SphygmoCor System

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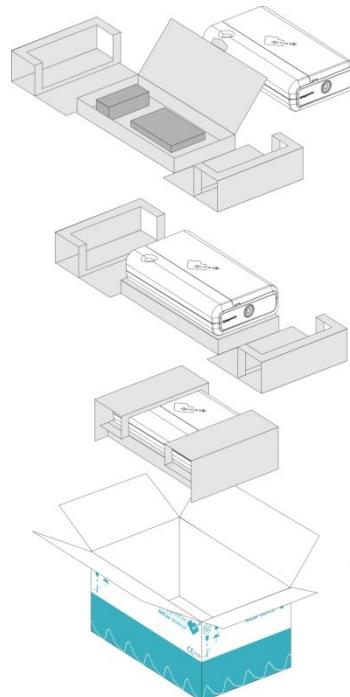
### 2.1 Unpacking the SphygmoCor System

Open the carton and carefully unpack the SphygmoCor System. Inspect the contents of your system, including all accessories and documentation.

Check to ensure you have received the following items with your SphygmoCor System:

- SphygmoCor Electronics Module EM3
- Tonometer (SPT-304)
- Software CD-Rom (Includes software guides)\*
- USB cable\*
- Footswitch \*
- ECG electrodes, cable and leads\*

\* located in cardboard accessories box (situated directly beneath the electronics module) in the shipping carton.



### 2.2 Intended Use

The SphygmoCor System provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. The SphygmoCor System is used with a tonometer placed over a radial artery calibrated with a standard cuff blood pressure measurement. It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

The SphygmoCor Pulse Wave Velocity (PWV) option is intended for use in obtaining PWV measurements.

## Intended Patient Population

The SphygmoCor System is intended to be used on adult patients only.

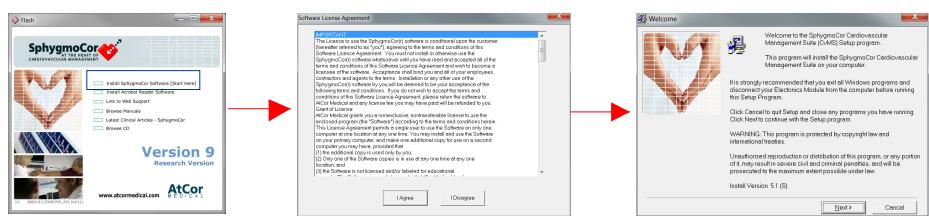
## Intended Environment

The SphygmoCor System is intended to be used in a Clinical Environment.

### 2.3 Software Installation

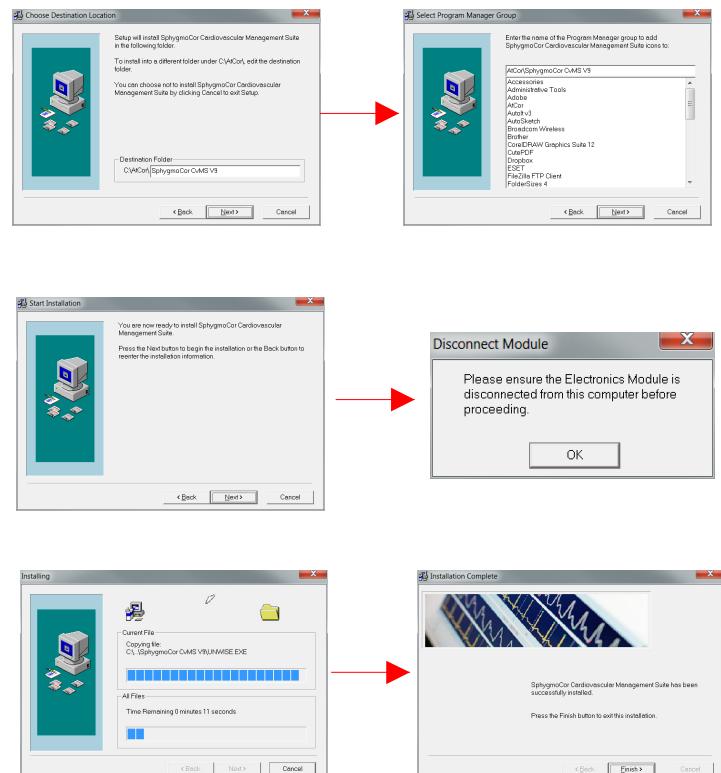
#### The SphygmoCor Software Suite

CD-ROM supplied with your system contains the software needed to install the SphygmoCor software on your computer. Complete the software installation prior to connecting the module to your computer.



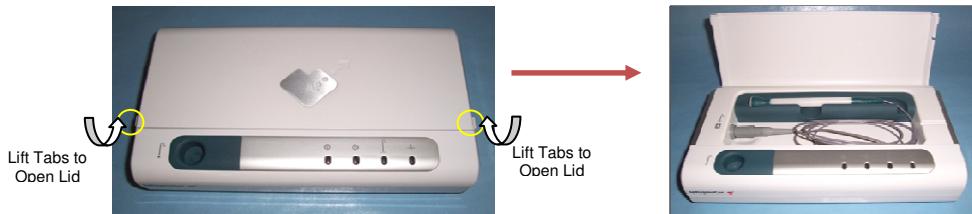
Turn your computer on. Locate the **SphygmoCor Software Suite** CD-ROM in the accessories box and insert the disk into the CD-ROM drive of your computer.

- A Micromedia Flash Player screen should automatically appear. Select **Install SphygmoCor Software [Start Here]** to begin the installation process.
- When the Software License Agreement screen appears, read the Terms of the Agreement and select **I Agree** to continue the installation.
- On the Welcome screen, click **Next** to continue.
- On the Choose Destination location screen, click **Next** to accept the suggested destination folder. The default location is **C:\AtCor\SphygmoCor CvMS V9\**. To change the location, enter an alternative folder name after the **C:\AtCor\** directory.
- The Select Program Manager Group screen will appear. The default folder name is **SphygmoCor CvMS V9**. Click **Next** to continue.
- The Start Installation screen will appear. Click **Next** to copy the software to your computer.
- Disconnect Module screen will appear. Ensure the module is not connected to the computer. Click **OK**.
- The Installing screen will appear showing the files being copied and installed on your computer.
- When the software installation is finished, the Installation Complete screen will appear. Click **Finish** to exit the set-up process.

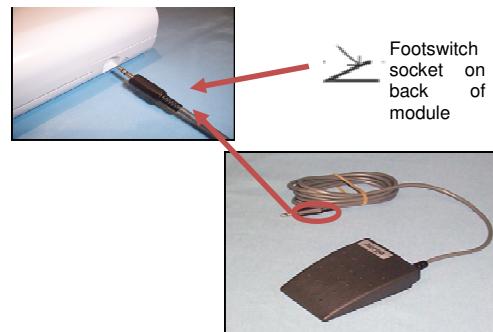


## 2.4 Hardware Installation

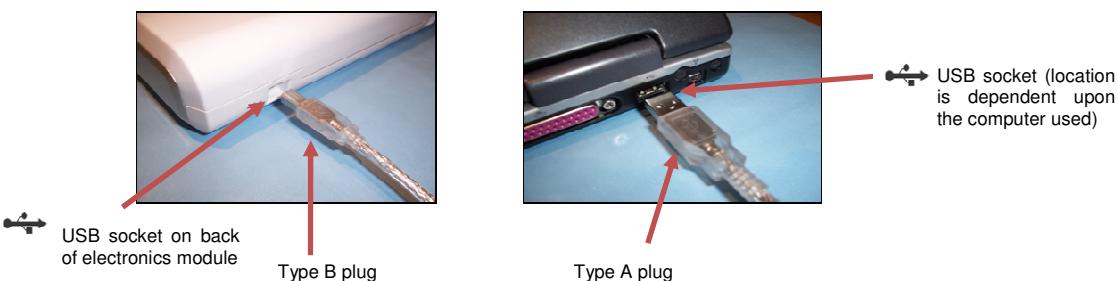
The tonometer is connected to the SphygmoCor electronics module and can be accessed by opening the tonometer compartment door.



Connect the footswitch (if desired) by inserting the connector on the end of the footswitch into the footswitch socket on the rear of the SphygmoCor electronics module.



Connect the SphygmoCor electronics module to your computer using the USB cable supplied with your system. The electronics module is powered through the USB cable when connected to your computer. The USB driver should already be installed. An information balloon will appear at the bottom of your computer screen indicating new hardware has been found and is ready to use.



**You are now ready to start using your SphygmoCor system.**

### 2.4.1 Connector Symbols

	<b>USB Socket</b> This socket provides power to the SphygmoCor electronics module and the means for the device to communicate to the computer.
	<b>Footswitch Socket</b> This socket is the connection for the footswitch provided with

	your SphygmoCor System.
	<p><b>ECG Cable Socket</b></p> <p>This socket is used to connect the ECG Cable to the SphygmoCor electronics module.</p>
	<p><b>Tonometer Socket</b></p> <p>This socket is used to connect the tonometer to the SphygmoCor electronics module. Note that the tonometer resides in the module tray connected to the device.</p>

#### 2.4.2 Indicators

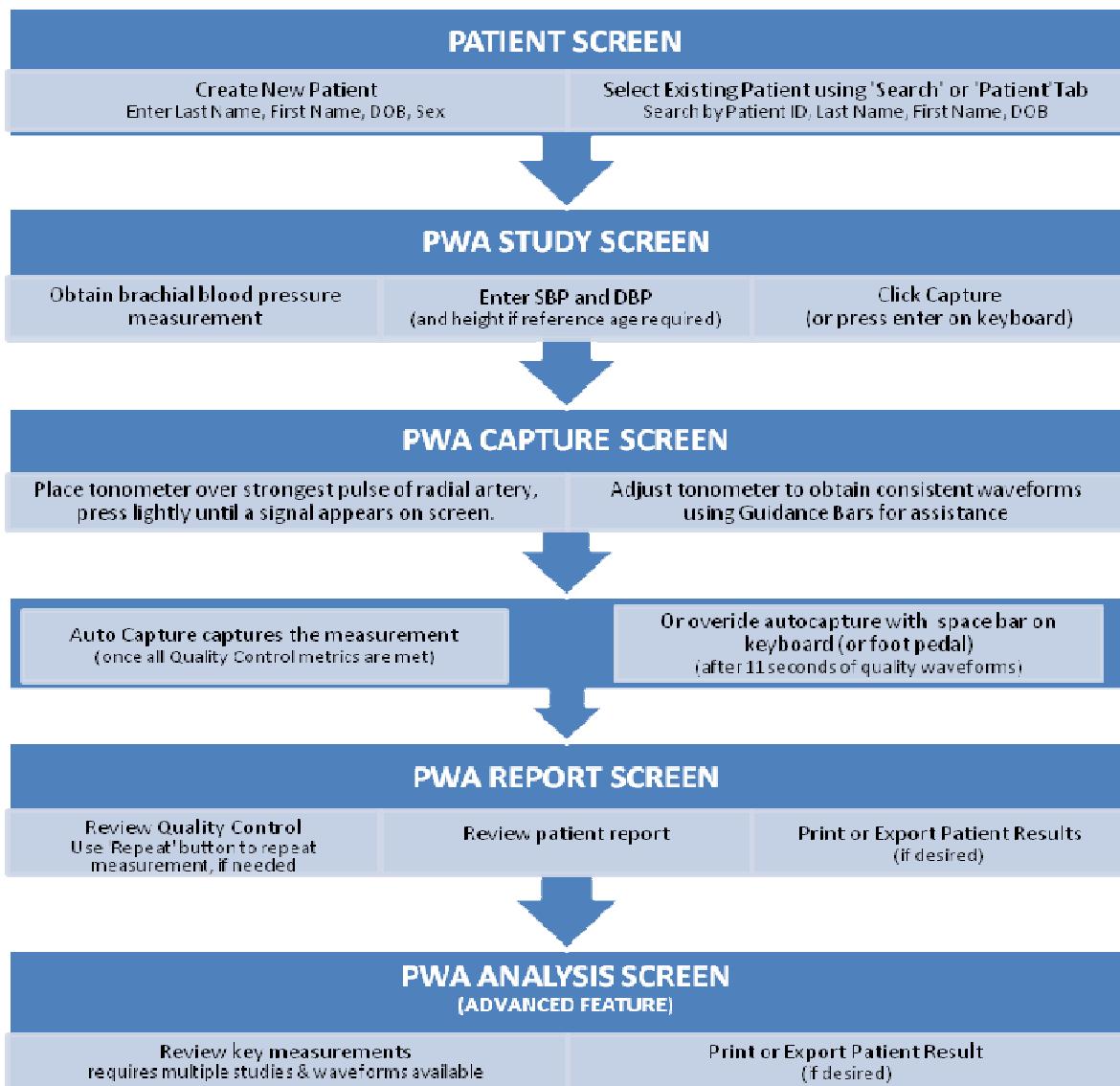
	<p><b>Power</b></p> <p>This indicator displays the status of the power to the electronics module. When the USB cable is connected, the green indicator will illuminate.</p>						
	<p><b>Standby/Ready</b></p> <p>This indicator displays the activity status of the electronics module. When the electronics module is powered on, this indicator will illuminate orange. Upon first communication with the SphygmoCor software the Standby/Ready indicator illuminates green. If the electronics module detects any errors, the indicator will illuminate red.</p> <p>Summary of Indictor activity:</p> <table style="margin-left: 20px;"> <tr> <td>Module power on (Orange):</td> <td></td> </tr> <tr> <td>Communication established with SphygmoCor Software (Green):</td> <td></td> </tr> <tr> <td>Error Condition (Red):</td> <td></td> </tr> </table>	Module power on (Orange):		Communication established with SphygmoCor Software (Green):		Error Condition (Red):	
Module power on (Orange):							
Communication established with SphygmoCor Software (Green):							
Error Condition (Red):							
	<p><b>ECG Active</b></p> <p>This indicator displays activity of the <b>ECG</b> input. When the <b>ECG</b> input is on and transferring data, this indicator illuminates <b>blue</b>.</p>						
	<p><b>Tonometer Active</b></p> <p>This indicator shows activity of the <b>Tonometer</b> input. When the <b>ECG</b> input is on and transferring data, this indicator illuminates <b>blue</b>.</p>						

### 3 Using the SphygmoCor System

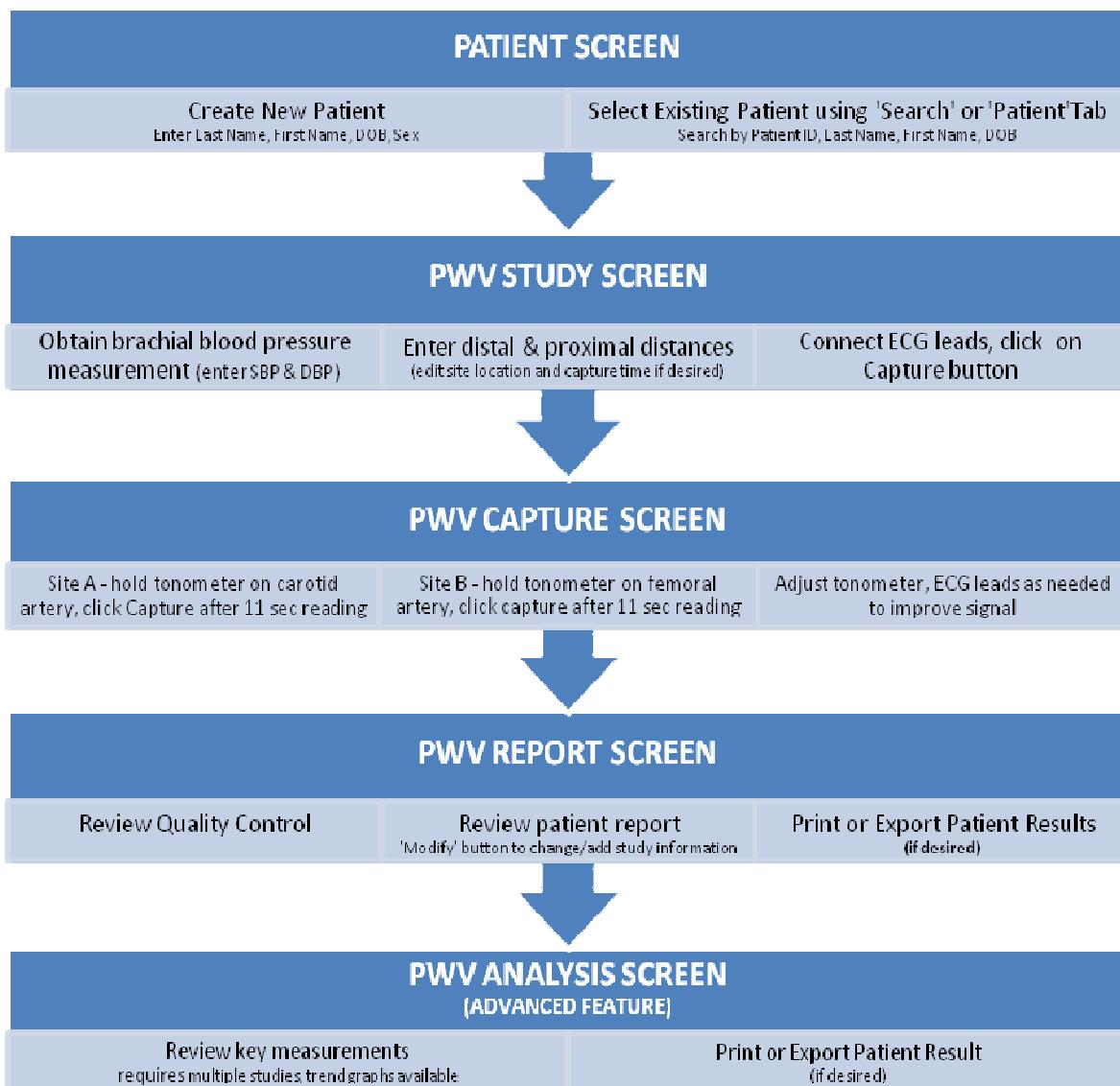
#### 3.1 Overview

The following flowcharts provide an overview of the steps required to conduct a central pressure measurement (PWA mode) or an arterial stiffness measurement (PWV mode).

##### 3.1.1 Central Blood Pressure Assessment Flowchart (PWA Mode)



### 3.1.2 Arterial Stiffness Measurement Flowchart (PWV Mode)



### 3.2 Setting Up the Electronics Module and Starting the Software

Ensure the SphygmoCor electronics module is connected to the computer and the green and orange **Standby Indicators** are illuminated.



You may wish to remove the tonometer and store it in the temporary storage holder in front of the device for ease of access when you are performing assessments.



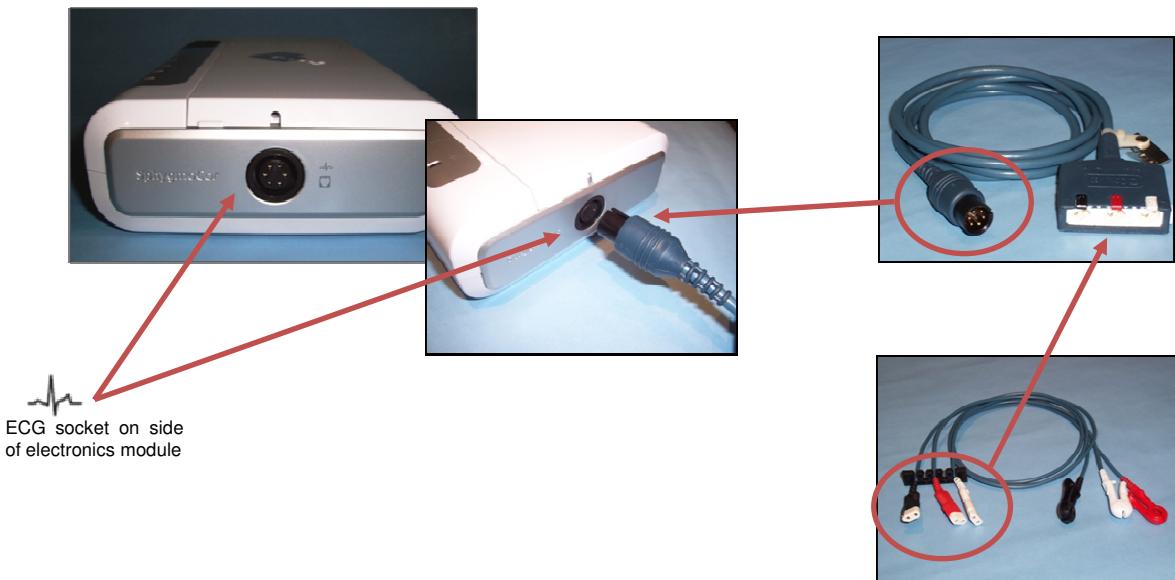
Tonometer storage inside  
SphygmoCor tray  
(recommended when not in  
use).



Temporary storage for  
tonometer.

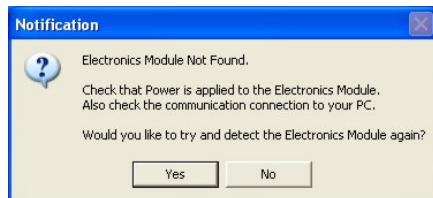
**Note:** The tip of the tonometer is delicate and can be easily damaged if dropped or misused. When the tonometer is not in direct use, protect it by placing it inside the storage tray under the cover or in the temporary storage holder on top of the device. The tonometer should be cleaned routinely with 70% Isopropyl alcohol. Do not immerse the tonometer in any liquid or use coarse cloths for wiping the tonometer as this will cause damage.

For PWV measurements, connect the ECG cable on the right side of the SphygmoCor electronics module by aligning and fitting the ECG connector until it is fully inserted into the socket panel. Connect the lead wires to the matching ports (red, black or white) on the end of the ECG cable. Ensure each wire is clicked into place.



Open the SphygmoCor software using the shortcut on your Windows desktop by double-clicking on the SphygmoCor icon. Alternatively, start the software from Windows **Start** menu, by clicking once on the **Start** button on the Windows taskbar, then navigate your mouse to the SphygmoCor program as follows: select **All Programs>AtCor> SphygmoCor CvMS V9>** **SphygmoCor CvMS V9.**

If a Notification window appears stating the electronics module not found, check the USB connection to the PC and on the electronics module and click **Yes** to have the software get a connection with the electronics module.



If the software still cannot communicate with the electronics module a Warning window will appear. If you require the software to communicate with the electronics module rather than work offline click **Yes**.



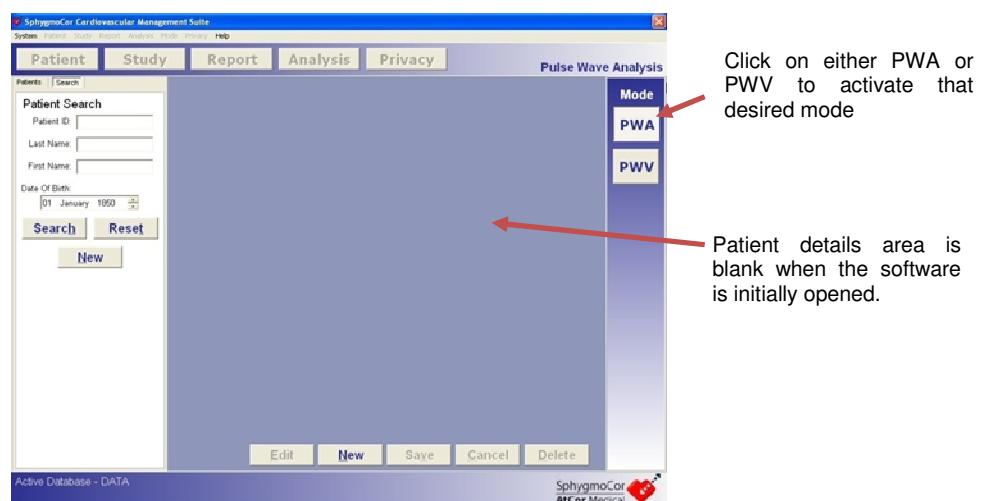
The SphygmoCor Configuration window will appear to allow you to select the Comms port. Refer to Section 4.1 for more information on the SphygmoCor configuration settings.

Alternatively you can click **No** and when the software opens select **System** then **Find module** from the main menu. This will activate the software to search all of the communications ports on the computer to locate the electronics module. A note will appear at the bottom of the screen to indicate the module has been found.

**NOTE:**

THE FIND MODULE PROCEDURE SHOULD ONLY BE USED THE FIRST TIME YOU CONNECT YOUR ELECTRONICS MODULE. ONCE THE MODULE HAS BEEN SUCCESSFULLY LOCATED YOU CAN SELECT SYSTEM THEN CHECK MODULE TO TEST IF COMMUNICATIONS ARE ESTABLISHED. IF THE MESSAGE APPEARS "MODULE NOT FOUND", THEN REFER TO THE TROUBLESHOOTING SECTION 5.5.

A blank patient screen will appear. The patient details area will become active after you search for a patient or click on the **Patient** tab (Refer to Section 3.3 Patient Entry - Select or Enter a New Patient).



If both PWA and PWV modes are available, the software will default to PWA mode upon opening.

**To begin taking a measurement**, refer to Section 3.3 Patient Entry - Select or Enter a New Patient.

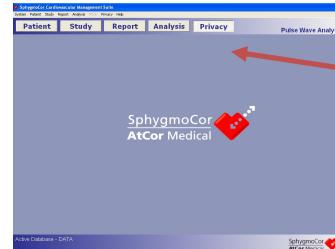
**To change the active database**, refer to Section 4.2. This section explains how to navigate between different SphygmoCor databases and how to copy databases.

**Database Warning:** Do not open the SphygmoCor database with any other program as it may corrupt your data. All database interactions should be performed using the SphygmoCor software. For further advice, contact AtCor Medical Product Support [www.atcormedical.com/support.html].

**To change the configuration settings**, such as units of measurement (imperial or metric), enable Guidance Bars and/or Auto Capture on the capture screen or enable Augmentation Index and/or Augmentation Index @ HR75 on the clinical report, proceed to Section 4.1. This section also enables you to enter the tonometer serial number and specify the Communications Port the tonometer is connected to (on your computer).



**The Privacy Screen** is available for use at any time (except during data capture) when it is undesirable to have patient details visible on the screen. Click on the **Privacy** button and all details will be shielded from view. To turn the Privacy Screen off, click on any of the other screen buttons as desired.



### 3.3 Patient Entry - Select or Enter a New Patient

To create a new patient entry or select a previously entered patient, open the Patient screen by clicking on the **Patient** button (or pressing **F2** on your keyboard function keys).

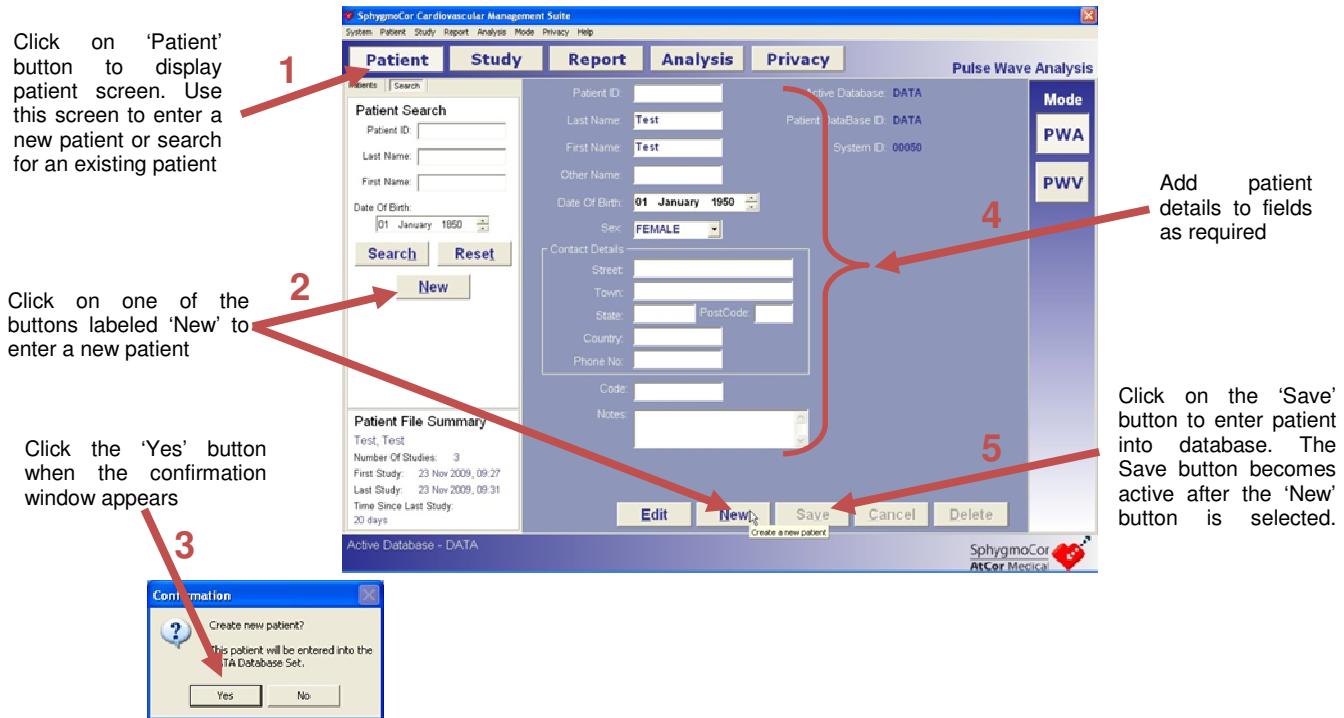
The process for entering or searching for a patient is identical for both PWA and PWV measurements. If your patient has had a PWA measurement and you are about to perform a PWV measurement, there is no need to enter the patient details again; simply search for the patient following the instructions below and proceed with the measurement.

#### 3.3.1 Create a New Patient Entry

To create a new patient entry, click on either of the **New** buttons

- When the confirmation message regarding creating a new patient appears, click the **Yes** button.
- Enter the patient details as required **Last Name, First Name, Date of Birth, and Sex must be entered to proceed, all other fields are optional**. Use the mouse or the **Tab** key on your keyboard to move between the fields.
- Click on the **Save** button when finished to add the details of the patient to the database.

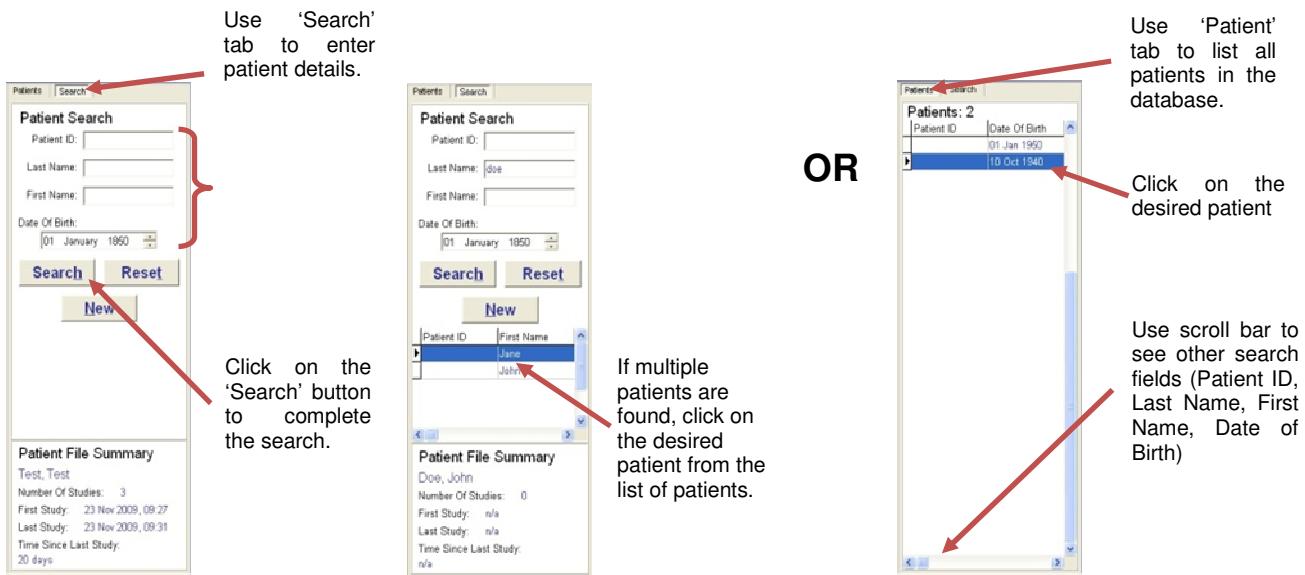
**Note: Before creating a new patient entry, confirm that the patient's information has not been previously entered into the database as separate patient entries cannot be merged.**



### 3.3.2 Selecting an Existing Patient from the Database

To identify previously entered patients within the database, you may use either the **Search** or **Patient** tabs

- Using the **Search** tab, enter the known patient details into any or all of the search fields (Patient ID, First Name, Family Name and/or Date of Birth). Click on the **Search** button. The Search screen requires the patient's complete name, ie, partial spelling of the name will not yield any results,
  - If only one (1) patient is found, the patient will automatically be selected and the details will appear on the main portion of the patient screen.
  - If multiple patients are found from the search criteria, a list of patients will appear and you should select the correct patient by clicking on the corresponding row containing the patient's information.
- Using the **Patient** tab, you can select a specific patient by clicking on the row relating to that patient. Note that the list of patients contains all patients in the database and may therefore be very long.
  - Use the scroll bar at the bottom of the search field to bring the other list headings into view (Patient ID, First Name, Family Name, and Date of Birth).
  - Right-Click on the patient list, select Sort By and then Patient ID, Date of Birth, First Name or Family Name to sort the list in alphabetical or numerical order.



### 3.4 Conducting a Pulse Wave Analysis (PWA) Measurement

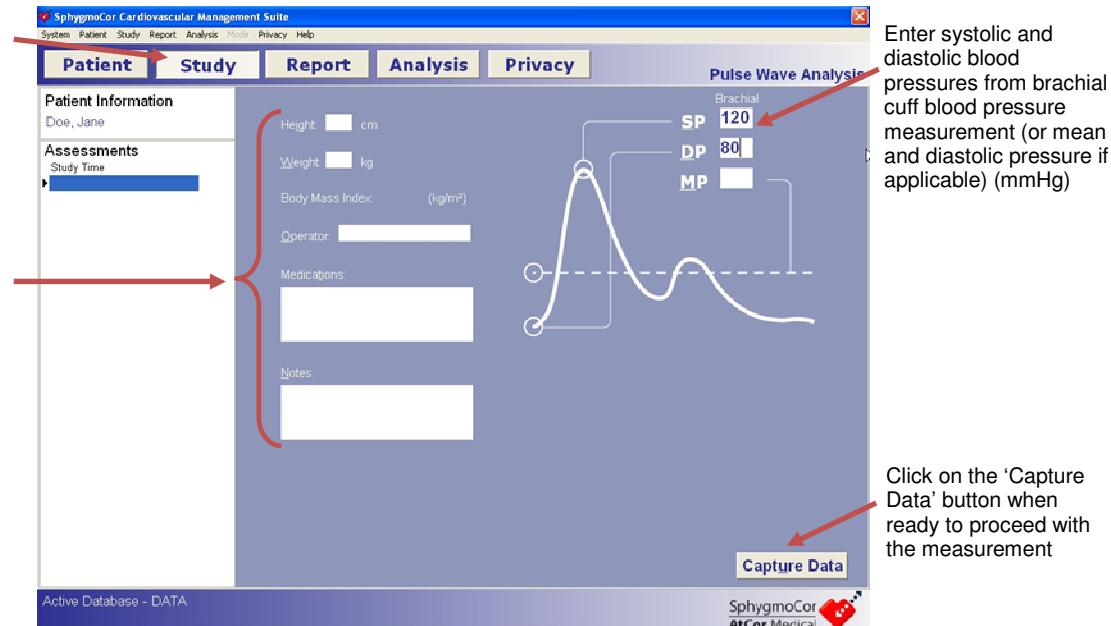
#### 3.4.1 Entering Study Details

Open the Study Screen by clicking on the **Study** button (or pressing the **F3** button on your keyboard). This screen will allow you to enter the study details and to proceed to the '**Capture Data**' screen.

- A brachial blood pressure measurement should be taken using either a manual or automatic sphygmomanometer. The patient should be sitting or lying comfortably and allowed to rest approximately 5 minutes prior to taking the brachial blood pressure measurement to ensure stable haemodynamics. At least 2 minutes should elapse between taking the patient's brachial blood pressure and recording a pressure waveform using the tonometer.
- Enter the diastolic and systolic blood pressure values (or mean and diastolic pressure, if applicable) obtained from the brachial blood pressure measurement in the corresponding fields on the Study Screen.
- Enter information in the Medication, Notes, and Operator fields, if required. If the SphygmoCor Reference Age calculation is desired, Height must also be entered.

Click on the **Capture Data** button to proceed.

Click on 'Study' button to enter study details



### 3.4.2 Recording a Pressure Waveform (Data Capture)

After entering the Data Capture Screen, a horizontal tracing will move across the screen. The main window displays the last 5 seconds of data and the bottom window displays the last 11 seconds of data.

#### Placement of the Tonometer

Placement of the tonometer is important to ensure quality waveforms:

- Remove the tonometer from either the tonometer storage tray or the temporary holder on the top of the electronics module. Hold the tonometer base gently but firmly between your thumb and the fingers.
- Locate the patient's radial artery with your index finger, and identify the strongest pulse point.

Note: The best results are obtained if the patient's wrist is in a slight dorsiflex position. You may wish to support the patient's wrist using your opposite hand or by placing a small pillow or rolled towel under the patient's wrist for support.

- When taking the measurement, ensure that your elbow and wrist are supported on a flat surface and your hand presses gently but firmly against the patient's wrist to provide stability and minimize movement.



- Gently place the tonometer over the strongest pulse point of the patient's radial artery until a waveform signal appears on the screen. If too much pressure is applied, the tracing will run across the top screen as a straight line. If you press too lightly, the tracing will run along the bottom of the screen.
- While holding the tonometer steadily over the patient's radial artery, the waveform signal should automatically resize with optimal placement. Watch the Capture Screen and make minor adjustments until waveforms uniform in shape and height travel horizontally at the same level across the screen. Pressing the spacebar after 11 seconds of consistent waveforms are visible in the bottom screen will 'capture' the data and save it to the patient's record,
  - When Guidance Bars are enabled, red, green or yellow bars will appear on the screen at the top, bottom and sides of the waveforms travelling across the screen.
  - The Guidance Bars indicate the amount of variation of the waveforms: red indicates too much variation, yellow indicates moderate variation and green indicates an acceptable level of variation. Messages will appear at the bottom of the screen indicating the area of variation to guide in adjusting the position of the tonometer. Adjust the tonometer slightly medially or laterally over the artery to obtain a clear, strong signal.
  - With Guidance Bars enabled, all 3 bars will turn green when a quality waveform has been identified by the software. The waveform tracing will change from white to green, indicating that quality criteria have been met, and data can be captured or saved.



## Waveform Capture

Waveform capture can be performed either automatically or manually.

- If Auto Capture is enabled (default setting), the software will automatically capture the waveform when all of the quality parameters are met (if Guidance Bars are enabled, all 3 Guidance Bars will also become green in colour) Alternatively, the space bar can be pressed at any time to override the Auto Capture feature and capture the waveform.
- If Auto Capture is disabled, data capture can be completed by manually pressing the spacebar on the computer keyboard when at least 11 seconds of quality waveforms are observed (if Guidance Bars are enabled, all 3 Guidance Bars will become green in colour).

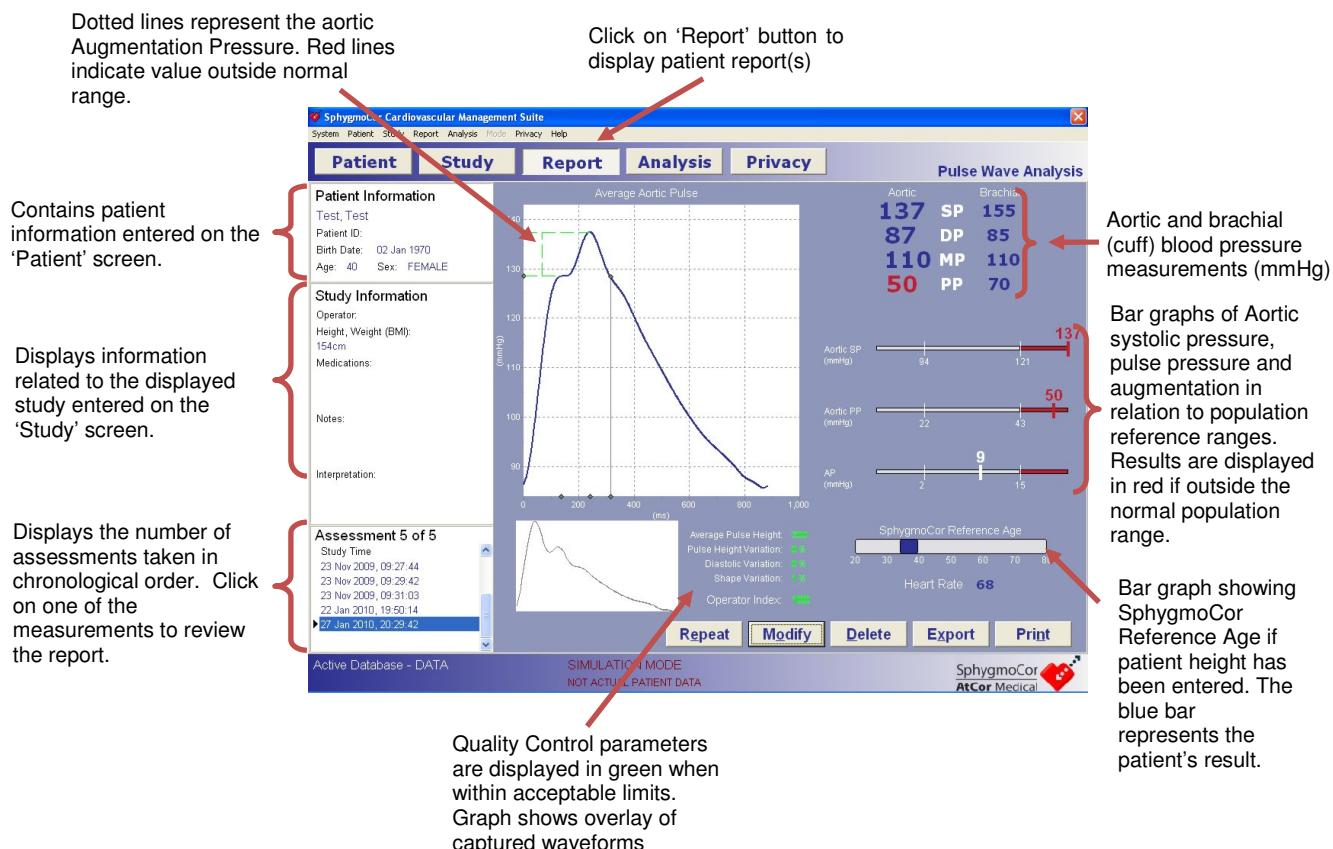
**Note:** Guidance Bars and Auto Capture are part of the Capture Guide feature in the software. The default setting on the software includes enabling of both Auto Capture and Guidance Bars. These features can be enabled or disabled from the System menu (Section 34.4.1 SphygmoCor Configuration Settings)

### 3.4.3 Reviewing the Patient Report

After data capture is completed, the Report screen will automatically be displayed. All reports are automatically saved and can be viewed at any time by selecting the patient from the 'Patient' screen and selecting the **Report** button.

The most recent report is displayed. If the patient has had more than one measurement, clicking on any measurement allows viewing of the corresponding report.

The report displays both quality control parameters and the results of the measurement. The quality control parameters should be assessed prior to reviewing the report. The parameters will appear in green if they fall within the acceptable limits and in red if they are outside acceptable limits. If any of the Quality Control parameters appear in red, the assessment should be repeated. The patient's results are presented both numerically and graphically.



### Quality Control Parameters

The Quality Control parameters are used to identify a valid, reproducible waveform. Any PWA measurements not considered of sufficient quality, based on the following criteria, should be repeated:

- Operator Index – composite quality control parameter ( $\geq 80$  acceptable, 75-79 is considered a borderline measurement and  $\leq 74$  is considered unacceptable).
- Quality Indices – reflect the degree of variation outside of acceptable limits (average pulse height  $\geq 80$ , pulse height variation  $\leq 5$ , diastolic variation  $\leq 5$  and shape variation  $\leq 4$ ).
- The graph showing the overlay of captured waveforms should have minimal variation between each waveform.

Ensure you consider all the quality control data when making an assessment of data quality. Do not discard any measurements on the basis of one value alone.

### Report Screen

The patient's report provides a number of key clinical parameters and highlights results that are considered to be outside normal limits and may indicate an increased risk of cardiovascular disease.

- Aortic and brachial blood pressure measurements are shown for Systolic Pressure, Diastolic Pressure, Mean Pressure and Pulse Pressure. The Aortic Pulse Pressure will be displayed in red if the value is  $\geq 50$  mmHg, as central pulse pressure  $\geq 50$  mm Hg has been shown to predict adverse cardiovascular disease outcomes<sup>1</sup>.
- The patient's aortic Systolic, Pulse and Augmentation Pressures are displayed on bar graphs. The patient's Augmentation Index and/or Augmentation Index @HR75 values are optional report settings (refer to Configuration settings in Section 4.1)
- The bar graphs indicate the normal range for individuals of the same age and gender as the patient.<sup>2</sup> When the patient's measurement is outside of the normal reference range (the red section of the graph), the value on the graph will be displayed in red.
- The SphygmoCor Reference Age for the patient is displayed on a bar graph as a blue band. This value will only be calculated and displayed when the patient is over 18 years old, the patient's height has been entered, and Augmentation Pressure has been calculated.<sup>2</sup> The blue bar represents the age range for the patient based on SphygmoCor aortic pressure parameters.
- The aortic Augmentation Pressure is indicated by the dashed lines on the aortic waveform. These dashed lines become red when the value is outside the normal range.

### Repeat, Modify, Export and Print Features

Additional features are available after reviewing the patient report.

- To repeat a measurement using the same study settings, click the '**Repeat**' button to return to the Capture screen and use the tonometer to repeat the measurement.

#### CAUTION

When performing a repeated PWA measurement via the 'repeat' button in the report screen, ensure that no change has been made which would affect the patient's blood pressure. If a change has been made, then re-measure the blood pressure and enter it in the study screen.

- Study details can be modified including changing the cuff blood pressure values or adding additional information, such as notes, medication, height and weight as well as adding an interpretation. To use this feature, click the modify button and enter or change the desired parameters as necessary, then click the '**Modify**' button.
- The Report screen can be exported as a text or graphic file (i.e., jpeg format) by right-clicking on the '**Export**' button and selecting '**As Text**' or '**As Graphic**'. Click on Select to choose the drive and folder on your computer to which you wish the file to be saved, and click '**Export**'.
- To print a report, click on the '**Print**' button. To print several reports at once, click on the '**Patient**' button, then select System>Batch Print from the main menu. To search for reports to print, select a start and end date within a 2 week window and click on '**Get Studies**'. A number of available studies will appear. If you wish to print all of the studies, click on the '**Print All**' button. Alternatively, you may either select individual reports by clicking on that study and pressing the  button or to select all studies for printing, press the  button, and then click on '**Print Selected**'.

### 3.4.4 Analysis of Multiple Studies

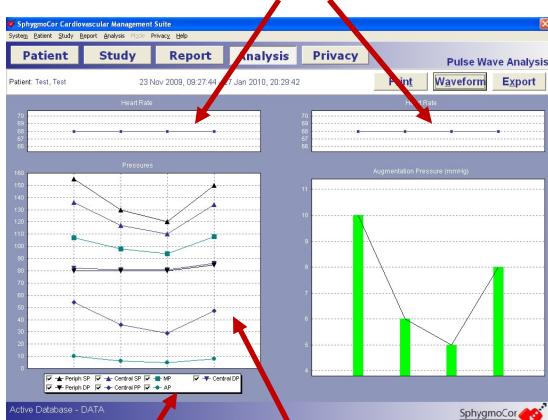
<sup>1</sup> Roman MJ, Devereux RB, Kizer JR, et al. High central pulse pressure is independently associated with adverse outcome. The Strong Heart Study. J Am Coll Cardiol 2009;54:1730-4.

<sup>2</sup> McEnery C, Yasmin, Hall I, Qasem A, Wilkinson I, Cockcroft J, Normal Vascular Aging: Differential Effects on Wave Reflection and Aortic Pulse Wave Velocity: The Anglo-Cardiff Collaborative Trial (ACCT), J Am Coll Cardiol 2005;46:1753– 60.

The **Analysis** screen is designed to allow you to view and compare multiple measurements for a patient. This enables you to perform both long-term and short-term analysis for a patient for whom more than one study exists. – a minimum of 2 measurements is required. When you have 2 or more measurements for a specific patient, click the **Analysis** button to view a report for these measurements.

- The Trend report is the default setting and can also be viewed by clicking on the **Trend** button. The Trend report shows the aortic and brachial blood pressure measurements for Systolic Pressure, Diastolic Pressure, Mean Pressure and Pulse Pressure against time (i.e., Study date and time). Check or uncheck the pressure boxes to show or remove the various pressures from the graph. The Augmentation Pressure is shown in a separate graph over time (i.e., Study date and time).
- The Waveform report can be viewed by clicking on the **Waveform** button. Both peripheral and aortic waveforms are shown in study date and time order. To select specific waveforms to view on the graph, click on the **Select** button and select or deselect the measurements by clicking on a particular study and using the arrow buttons to select one or select all. Click the **OK** button to return to the waveform screen.

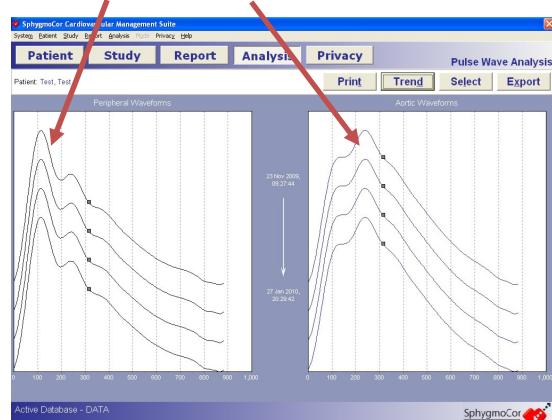
Right-click anywhere in the graph to display the study time and date. Left-click anywhere in the graph to display the heart rate value.



Check or uncheck boxes to display or remove pressures from graph.

Click anywhere in the graph to display the pressure value for all time points. Click on a single time point to display pressure values for that pressure (i.e., Peripheral SP)

Position the cursor over the curves to display the study time and date below the graph.



- The Report screen can be exported as a graphic (i.e., jpeg format) by clicking on the **Export** button. Click on **Select** to choose the drive and folder on your computer that you wish the file to be saved to and click **Export**.
- To print a report, click on the **Print** button.

### 3.5 Conducting an Arterial Stiffness Measurement in PWV mode

#### 3.5.1 Entering Study Details

Open the Study Screen by clicking on the “Study” button (or pressing the F3 button on your keyboard). This screen will allow you to enter the study details and to proceed to ‘Capture data’.

The patient should be resting supine with their arms by their side. Attach the three ECG electrodes and leads to the patient in a modified Lead II configuration or using the limbs as indicated on the lead wires.

#### WARNINGS

SphygmoCor PWV 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

Use of medication affecting heart rate and should be taken into consideration when interpreting results.

#### 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.

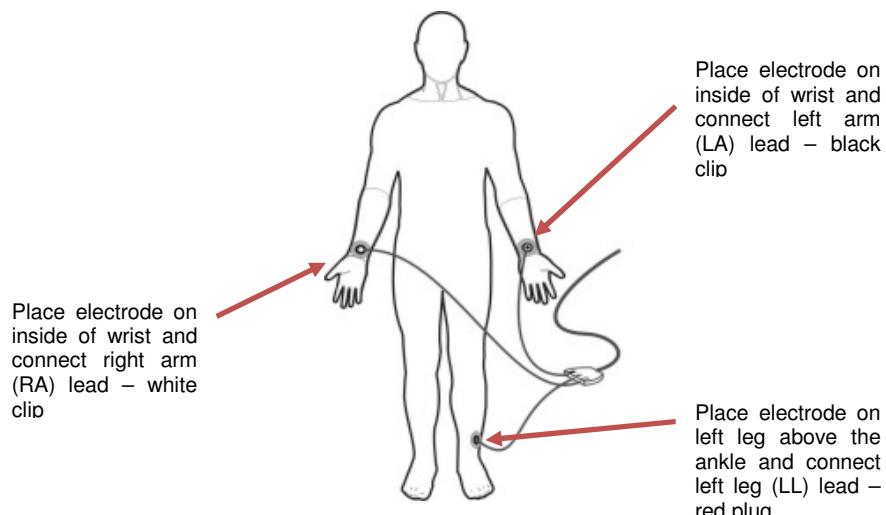
#### IMPORTANT

The SphygmoCor ECG cables and leads are designed for use with the SphygmoCor electronics module and should not be used with any other ECG device. Only ECG cables supplied by AtCor Medical should be used with the SphygmoCor electronics module; do not use any other ECG cables with SphygmoCor electronics module.

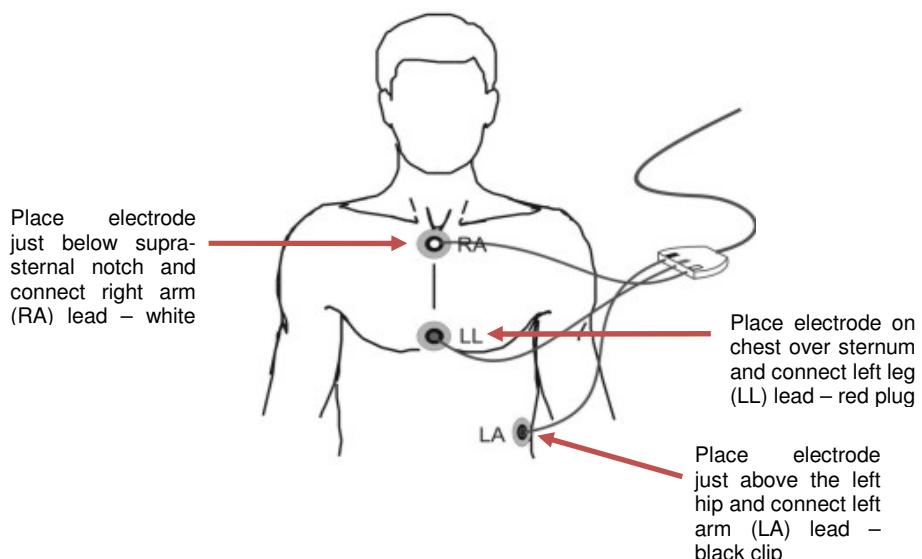
To maintain a clear, noise-free ECG signal, avoid exposure to other medical equipment emitting excessive noise (eg, MRI scanner, X-ray equipment, etc.).

- For optimal ECG lead application, prepare the patient’s skin by wiping with an alcohol wipe. Before applying the electrodes you may need to shave the area if excess hair prevents the electrodes from adhering to the patient’s skin.

- Remove the tape from the back of the electrode and apply the electrode to the skin in either peripheral or chest location as required and attach the leads as shown in the following diagram.



**Peripheral Limb Configuration**



**Chest (modified Lead II) Configuration**

Allow the patient to rest for approximately 5 minutes before taking a brachial blood pressure measurement to ensure heart rate and blood pressure are stable.

Enter the diastolic and systolic blood pressure values (or mean and diastolic values if available) obtained from the cuff sphygmomanometer or automatic blood pressure device.

Enter additional information into the study screen as desired.

**Note:** Multiple methods exist for measuring the distance between the aorta and femoral artery for non-invasive pulse wave velocity. It is recommended that the measurement be taken in a direct line between the supra-sternal notch and the carotid artery for site A, and then the supra-sternal notch and the femoral artery for Site B. The use of callipers is recommended in obese patients and in pregnant women. In some instances, you may need to position the tonometer in a different location than was used for the initial measurements. In this instance, you can re-measure the proximal or distal distance and enter the new measurements after the reading has been performed.

Click on the **Capture Data** button to proceed.

### 3.5.2 Recording Pressure and ECG Waveforms

After entering the Data Capture Screen, a horizontal tracing will move across the screen in both the ECG and waveform windows. The main window displays the last 5 seconds of data and the bottom window displays the last 12 seconds of data.

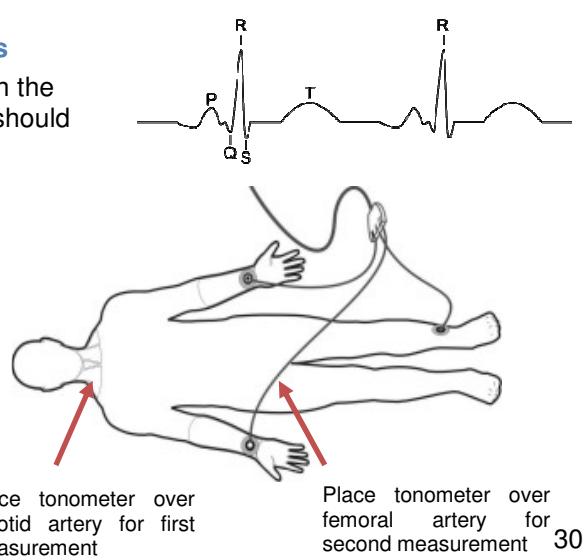
The PWV measurement is taken in two steps: a tonometry reading at Site A (typically, at the carotid artery), followed by a subsequent tonometry reading at Site B (typically, at the femoral artery) with an ECG signal simultaneously recorded.

#### ECG and Tonometer Placement and Capturing the Waveforms

Ensure that the ECG signal is free of noise and that the R-wave on the ECG tracing is the highest amplitude at each cardiac pulse. You should make any adjustments necessary to your ECG electrode placement to ensure a quality signal.

The carotid measurement should be taken first.

- With the patient in a supine position, the patient's head should be tilted slightly posterior and rotated laterally. This is best achieved in the absence of a pillow.
- Palpate to locate the strongest pulse point along the carotid artery and place the tonometer directly over the skin at this point.



Place tonometer over carotid artery for first measurement

Place tonometer over femoral artery for second measurement 30

- Ensure your forearm is resting on a stable surface to promote sufficient pressure and a consistent measurement.
- When you have a minimum of 12 seconds of quality waveforms, click the 'OK' button (or depress the footswitch, if used) to capture the carotid measurement.
- A confirmation window appears to confirm readiness to proceed to Site B (femoral artery). If the carotid measurement is acceptable, click the 'Yes' button, otherwise click the 'No' button to repeat taking a carotid measurement.

The femoral measurement is taken after the carotid measurement has been captured.

- The patient should be in a supine position with the patient's leg rotated laterally to expose the femoral artery. Palpate to locate the strongest femoral pulse.
- Place the tonometer directly on top of the skin and press down over the strongest pulse point to ensure a clear waveform signal.
- When you have a minimum of 12 seconds of quality waveforms, click the 'OK' button (or press on the footswitch, if used) to capture the femoral measurement.

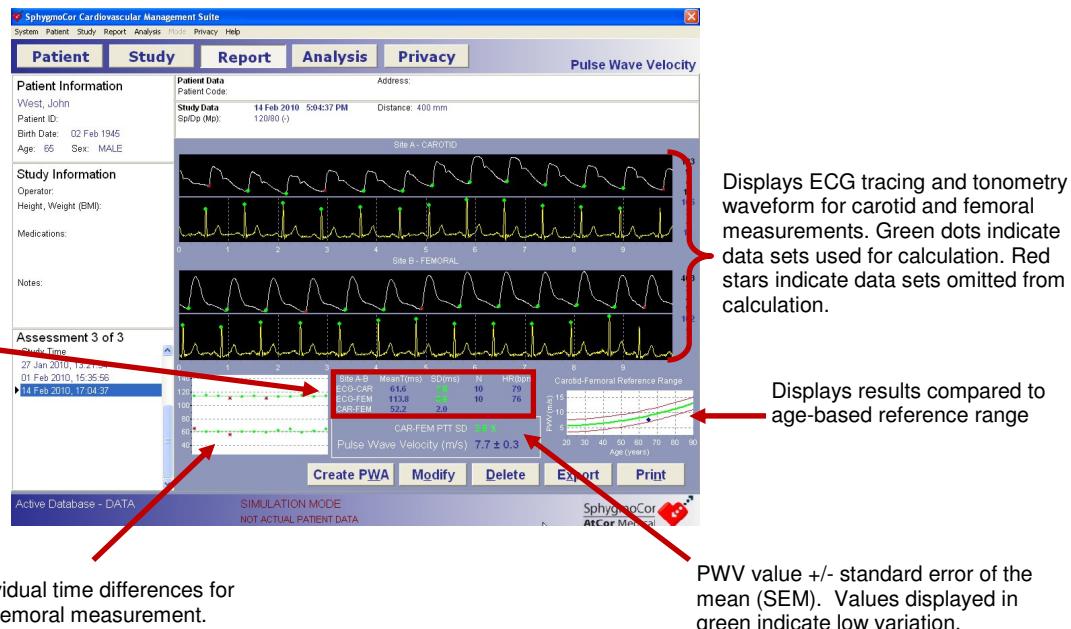


### 3.5.3 Examining the Patient Report

After you have completed data capture for Site B (femoral artery), the Report screen will automatically be displayed. All reports are automatically saved and can be viewed at any time by selecting the patient from the 'Patient' screen, then selecting the **Report** button.

The most recent report is displayed. If the patient has had more than one measurement, clicking on any measurement allows viewing of the corresponding report.

The report displays both quality control parameters and the results of the measurement. The quality control parameters should be assessed prior to reviewing the report.



## Review Quality Control Parameters

Review the Quality Control parameters on the report. Measurements not considered to be of sufficient quality (i.e., noted by red values) should be repeated.

- Confirm that the R-wave is clearly defined and has the highest amplitude of the ECG signal.
- Confirm that the foot of the pressure waveform (i.e., the initial upstroke) is clearly identifiable.
- SD values displayed in green indicate an acceptable level of variation. Values in red indicate a high level of variation; in this instance, the measurements should be repeated.
- The difference in heart rate between Site A and Site B measurements should not be more than 5 beats per minutes (bpm).

## Review Patient's Results

The patient's results are presented in two ways on the PWV report:

- The pulse wave velocity value is displayed as  $PWV \pm SEM^3$  in m/s<sup>4</sup>. In general, higher pulse wave velocity values are associated with stiffer arterial blood vessels.
- The patient's pulse wave velocity value is also displayed graphically against a normal population reference range, with the dot representing the patient's value and the area within the red lines representing the normal range.

Note: Normal Range values are based on measurements calculated by subtracting the sternal notch-carotid measurement from the sternal notch to femoral measurement.

## Create PWA, Modify, Delete, Export and Print

- The carotid waveforms (and radial, if performed) of a particular measurement can be used to create a PWA report. To do so, click on the **Create PWA** button. A confirmation window will appear; click on the **Yes** button to generate the PWA report. A second confirmation window will appear for the Carotid waveforms; click on the **Yes** button to use the carotid transfer function or the **No** button for the waveform to have no processing applied. The PWA report can be viewed by clicking on the **Patient** button to return to the patient screen, and then clicking on the **PWA** button to return to PWA mode. Click on the **Report** button to go to the report screen, and select the study using the date and time stamp of the PWV measurement. Refer to Section 3.4.3 for information on examining a PWA report, review the Quality Control parameters.

<sup>3</sup> SEM represents standard error of the mean

<sup>4</sup> m/s represents meters per second

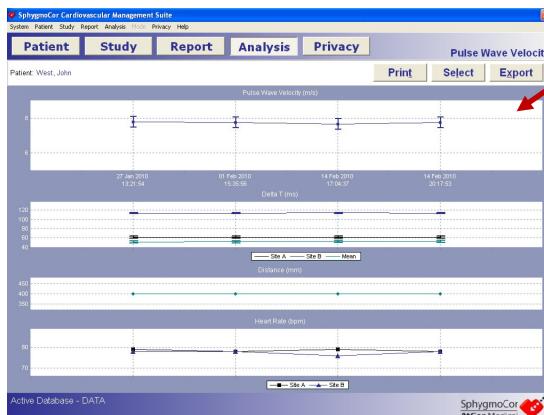
Note: For the correct calibration of the Carotid Waveform, the SphygmoCor software requires the mean arterial pressure (MAP) and diastolic blood pressure (DBP) values, not the SBP and DBP values. Use the **Modify** button to delete the SBP value and add the MAP value. A typical method for calculating the MAP is to add diastolic pressure and 1/3rd of pulse pressure.

- Study details can be modified by clicking on the **Modify** button. Brachial blood pressure values, notes, medications, height, weight, carotid-femoral measurements, and site location can be modified.
- The Report screen can be exported as a text or graphic file (i.e., jpeg format) by right-clicking on the **Export** button and selecting 'As Text' or 'As Graphic.' Click on the **Select** button to select the drive and folder on your computer to which the files should be exported, then click on the **Export** button.
- To print a report, click on the **Print** button. To print a number of reports at a time, click on the **Patient** button to return to the Patient screen, then select **System** then **Batch Print** from the main menu. To search for reports to print, select a start and end date within a two- week period, then click on the **Get Studies** button. To print all of the available studies, click on the **Print All** button. Alternatively, individual reports may be selected by clicking on a specific study and pressing the button. To select all studies for printing, press the button, and then click on the **Print Selected** button.

### 3.5.4 Analysis of Multiple Studies

The **Analysis** screen is designed to enable viewing and comparison of multiple studies for a patient. At least two (2) studies are required to use the Analysis feature. To view multiple studies, click the **Analysis** button.

- The values for PWV, Delta T, Distance and Heart Rate are all shown in separate graphs over time. To select specific study measurements to view on the graph, click on the **Select** button and select or deselect the measurements by clicking on a particular study. The **arrow** buttons may also be used to select one or all studies. Click the **OK** button to return to the Trend screen.



Click anywhere within the graph to display the value for all time points. Click on a single time point to display values for a specific study time and date.

- The Report screen can be exported as a graphic (i.e., jpeg format) by clicking on the **Export** button. Click on **Select** to choose the drive and folder to which the files should be saved, then click **Export**.
- To print a report, click on the **Print** button.

## 4 Advanced Features

### 4.1 SphygmoCor Configuration Settings

The SphygmoCor Configuration window allows you to make modifications to report settings, eg, change units of measurement from imperial to metric or enable/disable Capture Guide settings.

To change the configuration settings, select **System** and then **Settings** from the drop-down menu. This screen can only be accessed from the Patient or Study screens.

- The Quality Control parameters set the limits for displaying the corresponding values on the report screen in red (outside the limits) or green (within the limits). The factory set default settings are recommended to ensure acceptable quality waveforms. Changes to these settings will not affect the Operator Index, an indicator of overall quality.
- The default setting for Pressure Sensitivity is set at the upper limit. The factory set default settings should not require modification.



### 4.2 Database Manager

Database Manager allows you to create new databases, change between different SphygmoCor databases, and to copy databases. Separate databases may be used for multiple clinics or studies.

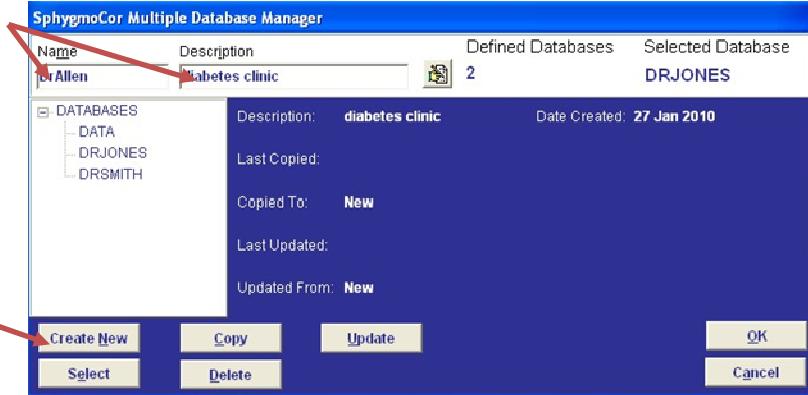
- From the Patient Screen, click on System to reveal the options menu, and then select **Database Manager**. The SphygmoCor Multiple Database Manager window will appear. The Database Manager screen is only available from the Patient Screen.
- To select another database, click on the name of the database, then click on the **Select** button. Click **OK** to open the database. Confirm that the name of the desired database is displayed on the bottom of the screen.

**Database Warning:** Do not open the SphygmoCor database with any other program to maintain data integrity. To prevent data corruption, all database interactions should be performed using the SphygmoCor software. For further advice contact AtCor Medical Product Support at [www.atcormedical.com/support.html](http://www.atcormedical.com/support.html)

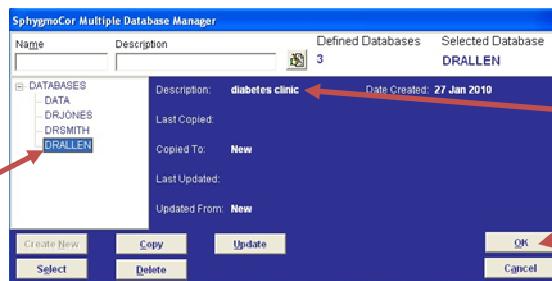
#### 4.2.1 Create a New Database

- Enter the name of the database in the Name field (spaces are not allowed). Enter a description of the database in the Description field, then click the **Create New** button to create the new database. The new database will automatically be selected.

Enter name for the new database and a description of the database.



Click on Create New button. The button will become active as soon as the name and description fields are completed.



The new database appears in the list and is automatically selected.

The description for the new database will appear here.

Click the OK button to activate the database.

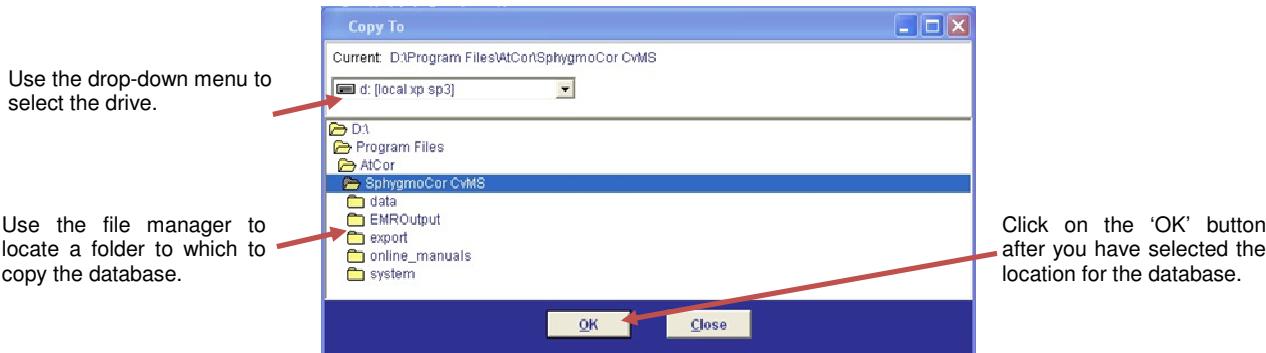
#### 4.2.2 Change the Description of an Existing Database

Click on the name of the database you wish to change, click the Select button. Enter a new description in the Description field, and click on the button. This button becomes active once you press the Select button.

#### 4.2.3 Copying a Database

You may wish to use this feature as a method of backing up your database or to transfer databases between computers.

Click on the name of the database you wish to copy, and click the Select button. When the Copy To window appears, select the drive and folder to which the database is to be copied, then click the OK button.



**Caution:** When copying a database, use caution when selecting the location to prevent copying over an existing database. If this occurs, the database will be corrupted, and the records will not be recoverable.

#### 4.2.4 Updating a Database

Use this feature to restore a database to the most recent copy. You should use this method if you are restoring a back-up copy of a database.

Click on the name of the database you wish to update, and click the **Select** button. Click the **Update** button. When the **Update From** window appears, select the drive and folder where the saved (copied) database is located. Click the **OK** button.

**Caution:** This feature overwrites the current database with the backup copy of the database. Any records added to the database since the last back up will be lost and are not recoverable.

#### 4.2.5 Deleting a Database

This feature is used to permanently delete a database. All data will be permanently removed.

**Caution:** As a precaution, the SphygmoCor software will not allow a database to be deleted without a saved copy.

Copy the database following the steps listed in Section 4.2.3. You will not be able to proceed until this has been performed.

Click on the name of the database you wish to delete, then click the **Select** button. Click the **Delete** button. When the Confirmation window appears, click the **Yes** button. A second Confirmation window will appear, click the **Yes** button to proceed with deleting the database. The database is now deleted.

#### Warning Messages

Active Database: You cannot delete the active database, i.e., the database that was active when opening the Multiple Database Manager window. If you attempt to delete the active database, a Warning message will appear indicating that you cannot delete the active database. If you wish to delete the currently active database, you must close it and open a different database before proceeding.

Database Backup: The SphygmoCor software prevents you from deleting a database that has had activity since it was last copied. If any database operations have been performed, such as adding or deleting a patient or measurement and a database deletion is attempted, a Warning message will appear indicating that the database cannot be deleted. If you still wish to delete this database, first make a copy of the database and then proceed with deleting the required database.

#### 4.2.6 Database Optimisation (packing a database)

You can perform a database optimisation at any time. If a database optimisation has not been performed recently, the software will prompt you to perform one. Database optimisation stores all your SphygmoCor files in the same part of your hard disk, freeing up memory space for other programs to run.

**Warning:** It is essential that a back-up of all databases is performed prior to performing a database optimisation. Failure to do this may result in complete loss of data.

If a back-up copy of the database has not been performed, follow the steps in section 4.2.3 to make a copy.

To perform the database optimisation, click on the **Patient** button to return to the patient screen. Select **System>Database>Pack** from the Main Menu. A warning message will appear reminding you to make a copy of the database. If you have already done so, click on the **Yes** button. The Patient screen will become active once the database optimisation has finished.

The software will automatically generate a reminder prompting database optimisation. If you have not performed a back-up of your databases, then click on **No** and perform a backup. If you have recently performed a back-up and no additional data has been added to the database, then click **Yes** to continue.

The database optimisation only optimises the active database. If you have multiple databases for the SphygmoCor System, each database will need to be opened and optimized individually following the steps listed above.

## 5 Appendix

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### 5.1 Warranty

The SphygmoCor® System, excluding the tonometer, is supplied with a full parts and labour warranty. The length of this warranty varies based on statutory requirements in each country – contact your distributor to determine the warranty for your device. Any parts that fail during this warranty period will be repaired or replaced without charge, at the discretion of AtCor Medical. This excludes any damage to the instrument arising from operational wear and tear, or from misuse.

The tonometer has a 120-day parts and labour warranty.

Service and technical support for the SphygmoCor system will be provided by AtCor Medical technical support.

### 5.2 Product Support

If you have any questions about the operation of your SphygmoCor System, first consult the Operator's Manuals

If you have additional questions after reviewing the manual, contact your local AtCor Medical distributor or contact AtCor Medical Technical Support at:

Telephone: +61 (0)2 9874 8761

Faxsimile: +61 (0)2 9874 9022

Email: [support@atcormedical.com](mailto:support@atcormedical.com)

Website: [www.atcormedical.com/support.html](http://www.atcormedical.com/support.html)

FAQ: [www.atcormedical.com/faq.html](http://www.atcormedical.com/faq.html)

Please provide your *System Serial Number* to your Product Support Representative. This serial number can be found by opening the SphygmoCor software and selecting Help>About from the Main Menu. A window will appear and will contain the System Serial Number. This window also contains the Version of software and the installed options.

When contacting by telephone, please have your SphygmoCor System nearby as well as a copy of the Operator's Manual and any other relevant documentation. You should be prepared to give the following information, if applicable:

- System serial number and version of SphygmoCor Software (to locate this information, see above)
- The error number and exact wording of any messages that appear. The error number will appear in the corner of the error message window.
- The sequence of events preceding the issue and any action taken as a result.
- .

### 5.3 Maintenance

The SphygmoCor System does not require any regular maintenance service. For 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.

#### Basic System Care

##### Stability

Place the SphygmoCor electronics module gently onto a stable bench or cart. Dropping the unit can cause damage and result in the unit not operating correctly.

- . For optimal use, the SphygmoCor System should be placed in a location that allows for easy access to the patient's anatomy as well as sufficient room to support the operator's arm position on a stable surface.

## **Pressure or impact damage**

Do not apply heavy pressure to the electronics module or subject it to strong impact. Excessive pressure or impact can damage electronic components or result in system malfunction.

## **Temperature**

The area in which the SphygmoCor System is used or stored should have an ambient temperature of 15-30°C (50-85°F) and relative humidity of 20-80%.

**WARNING:** Do not expose the unit to dirt, moisture or dust. Exposing the unit to dust or moisture could cause it to fail. Do not place the unit in direct sunlight. Exposure of this nature could result in damage to the internal components.

## **Magnetic fields**

Magnets, television sets, radios, large electric motors or any other source of strong magnetic fields will effect the operation or may cause the SphygmoCor System to fail.

**WARNING:** Do not place any components near strong magnetic fields.

## **Liquids**

Liquids on or inside any components of the SphygmoCor System can cause irreversible damage.

**WARNING:** Do not spill liquids on any component.

## **Weight**

Weight applied to the top of the electronics module may cause the casing to crack and other parts to be damaged.

**WARNING:** Do not place any objects on top of the electronics module.

## **Movement**

Always store the tonometer in the tonometers tray of the electronics module to prevent damage from unexpected movement. Use caution when moving the SphygmoCor System to prevent damage to the unit and components.

**WARNING:** Do not shake or drop the unit.

## **Shutting down**

Do NOT switch the PC off until the SphygmoCor software and Windows have been exited. Wait 4 seconds after turning the computer OFF before turning it on again.

**WARNING:** Exit the SphygmoCor software prior to shutting down your computer.

## **Cleaning Instructions**

To clean the SphygmoCor electronics module, first unplug the electronics module from the computer. Using a damp cloth with mild detergent, gently wipe the equipment. If you are unsure of using a particular cleaning agent, please contact AtCor Medical. Ensure excess liquids or cleaning agents are wiped immediately from the equipment. For further instructions on cleaning of the Tonometer, refer to Tonometer Cleaning & Disinfection section in this manual.

## **Notebook Batteries**

When using the SphygmoCor System with a notebook computer powered by rechargeable batteries, ensure that the batteries are fully charged. Do not use the system on low battery power. If the notebook is abruptly shutdown, the SphygmoCor database may be corrupted. Consult the notebook manufacturer's user documentation regarding the safety and maintenance of the notebook rechargeable battery.

## **USB CONNECTION**

The SphygmoCor electronics module is powered by the PC's USB Port. Ensure that the PC can supply the required 500mA USB power. Care should be taken when using USB hubs or multiple USB devices as they may limit the power supplied to the SphygmoCor system which may affect the functionality of the electronics module. When using a

notebook computer with the SphygmoCor System, ensure that the computer has sufficient battery power as low battery power may affect functionality of the electronics module.

### Tonometer Care

The tip of the tonometer is a delicate and sensitive device and can be easily damaged if dropped or misused. Follow the guidelines below to ensure optimal tonometer use.

- When not in direct use with the patient, protect the tonometer by placing it in the module tray or in the temporary storage holder in the front of the module.



Tonometer stored temporarily



Tonometer stored in module tray

- Do NOT use the tonometer with any other instrumentation other than those supplied by AtCor Medical.
- The tonometer is intended to be used in conjunction with the SphygmoCor electronics module only, which has a floating (isolated) grounding system.
- The tonometer should be cleaned routinely between uses using 70% isopropyl alcohol.

### Disinfection Instructions

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

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 Isopropyl alcohol or any liquid as this could damage the tonometer electronics.

Do not use coarse cloths for wiping the tonometer as this will damage the sensitivity of the transducer tip.

### 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**

To prevent damage, do not spray detergent directly on any of the components. Ensure detergent does not ingress into any electronic components of the system by not over-spraying or allowing detergent to 'run'.

#### 5.4 References

Refer to our website [www.atcormedical.com/publications.html](http://www.atcormedical.com/publications.html) for a current list of SphygmoCor publications.

## 5.5 Troubleshooting Guide

### Overview

**ATTENTION:** If any error messages indicate "database corruption" or "database access error," contact AtCor Medical Technical Support immediately.

See Section **Error! Reference source not found.** for Product Support contact details.

The built-in error checking and error pop-up windows solve most of the errors encountered within the **SphygmoCor CvMS Software**. Some errors described in this chapter of the Troubleshooting Guide may require the operator to contact AtCor Medical Technical Support. If the procedure or action required by the user is not clear, contact AtCor Medical Technical Support for assistance.

### SphygmoCor Electronics Module

#### Condition 1: The Electronics Module cannot be detected.

This error may appear at two places in the software:

- a) At the start of the software.
- b) Upon entry into the Capture Screen.

Check the following items:

- The Electronics Module is connected to the USB port of your computer.
- The Power light is on. (if it is off see "When the power light is off")
- The correct communications port is selected in the configuration settings. Refer to Section 4.1.

#### Condition 2: When the POWER light is off.

Check the following items:

- The Electronics Module is connected to the USB port of your computer and the computer is on.
- Disconnect the USB cable from the Electronics Module, wait 2-3 seconds, and reconnect. At this time check that the Electronics Module runs through the initialisation sequence:  
Standby indicator should change from Red → Green → Orange
- Ensure that the USB drivers have been installed on the computer

#### Condition 3: The Ready indicator on the front of the Electronics Modules is red.

This indicates that the Electronics Module has an internal fault or is in an error state. Cycle the power to the electronics module by disconnecting and reconnecting the USB cable to check if the module resets.

If the error persists, contact AtCor Medical Technical Support.

### Software Screens

Any software errors will be displayed in pop-up windows within the software. If you require further explanation of any pop-up window, contact AtCor Medical Technical Support for assistance.

### Pulse Capture Screen

#### The Tonometer fails to respond.

Ensure that the tonometer is connected to the connector in the tray of the Electronics Module.

**Note:** Care is required when connecting the Tonometer. Pins inside the connector can be easily bent or broken off. See section 0 for Tonometer care.

## 5.6 Specifications

### Product Configuration

Product	Inputs
Central Blood Pressure (PWA)	<ul style="list-style-type: none"> <li>Tonometer</li> </ul>
Pulse Wave Velocity (PWV)	<ul style="list-style-type: none"> <li>Tonometer</li> <li>ECG</li> </ul>

### 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 (USB powered):	Supply Voltage	USB +5VDC
	Power Consumption	500 mA Max
	Protective Class	IEC Class I, II or Internally powered (depending upon computer connection).
	Applied Parts	Type CF (ECG) Type BF (Tonometer)
Physical Specifications	Power Connector	Via USB Type A Connector
	Enclosure Material	PC-ABS
	Weight (Module & Tonometer)	0.8 kg (1.8 lbs)
	Dimensions	16.0 (l) x 26.4 (w) x 5.8 (h) cm 6.2" (l) x 10.4" (w) x 2.3" (h)

### 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	Type	3-Lead (modified Lead II)
	Bandwidth	0.67 – 40 Hz (Device does not support extended low frequency response)
	Sampling Rate	PWV: 128 Hz
	Gain & Offset Adjust	Auto
	Signal Range, Accuracy	±5mV, ±20%
	Heart Rate Range	30 BPM to 200 BPM
	Heart Rate Accuracy	±10 %
Footswitch	Type	Micro-switch
	IP Rating	IPX8-1.0m

### 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.

### PC Interface Specifications

	Specification
Minimum Computer Requirements.	PC or notebook computer with: <ul style="list-style-type: none"> <li>Intel Pentium Processor P4 or greater</li> <li>1 GB RAM</li> <li>1024 x 768 256-colour XGA display</li> <li>60GB initial free hard disc space</li> <li>CD-ROM drive</li> <li>Windows standard printer drivers</li> <li>Dedicated USB port</li> <li>Windows XP (Professional), Windows Vista (Business) &amp; Windows 7 (Professional)</li> </ul> The SphygmoCor® System is not supported on Windows NT/95/98/ME/2000.

Communication Interface	USB 1.1 serial interface USB Type B Female connector
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### AAMI EC13:2002 ECG Performance Specifications (as per clause 4.1.2.1)

Section	Performance Specification
a) Electrosurgery protection	This device is not protected from electrosurgical equipment
b) Active noise suppression	<p>This device does not contain a detection circuitry for respiration sensing or leads-off sensing. It does incorporate Active noise suppression to compensate for common mode signals from the Right Arm and Left Arm ECG connection.</p> <p>This compensating current is inversely proportional to the common mode signal. The compensation current amplitude is approximately the common mode voltage divided by a 540k series resistance.</p> <p>Medical safety leakage current is limited by isolated power supplies and series resistances in each ECG lead.</p>
c) Tall T-Wave rejection capability	Maximum T Wave amplitude is 1.5 mV
d) Heart rate averaging	The average heart rate is calculated for the whole record with standard deviation and a plot of beat to beat R to R values. The updating rate for Heart rate display is 5 seconds.
e) Heart rate meter accuracy and response to irregular rhythm	Not applicable as measurements of PWV and HRV are invalid for irregular ECG rhythms.
f) Response time of heart rate meter to change in heart rate	This device does not have a beat to beat heart rate meter, therefore the testing required to measure the response time of a step change in heart rate is not applicable. The displayed heart rate will update the averaged heart rate every 5 seconds.
g) Time to Alarm for tachycardia	The device does not incorporate any alarms for tachycardia. Measurements of PWV and HRV are invalid if tachycardia occurs.
h) Pacemaker pulse rejection	<p><b>WARNING - PACEMAKER PATIENTS.</b> This device may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Caution should be taken when evaluating results when these occur. Keep pacemaker patients under close surveillance.</p> <p>This device does not have any pace maker noise rejection capability.</p>
i) Audible alarm	This device is not fitted with any audible alarms
j) Visual alarm	This device is not fitted with any visible alarms for the purpose of Heart Rate monitoring.
k) Battery power	This device does not require any batteries
l) Telemetry	This device does not contain any telemetry functions
m) Line isolation monitor 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.
n) Non-permanent ECG waveform display	Time-base and aspect ratio are adjusted automatically in the software. The full time-base of the ECG screen is 5 seconds.
o) Electrode polarization	Use of disposable electrodes to minimise the effects of large offset potentials due to polarization is recommended. Use of bulb type electrodes is not recommended.
p) Auxiliary output	This device does not contain any auxiliary output facilities.
q) Alarm silencing	This device is not fitted with any audible alarms
r) Battery disposal	This device does not require any batteries

### Component Checklist

Check to ensure you have all the following items in your SphygmoCor System:

	Central Blood Pressure Assessment (PWA)	Arterial Stiffness Assessment (PWV)
Item		
Tonometer (SPT-304)	✓ (In Module Tray)	✓ (In Module Tray)
SphygmoCor Electronics Module EM3	✓	✓
Software CD-ROM (Includes Software Guides)	✓	✓
Operator's Manual	✓	✓
Concise Software Guide	✓	✓
USB Cable (2m)	✓	✓
ECG Cable (Conmed D8314II-06) (2m)	-	✓
ECG Leads (Conmed DL24-03II) (0.5m)	-	✓
ECG Electrodes	-	✓
Footswitch (Herga) (2m)	✓	✓

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.

The following optional items may be purchased separately and may be supplied in a separate shipping container:

- Notebook Computer plus accessories
- Spare Tonometer

## Classification of SphygmoCor System

The SphygmoCor System is classified as follows:

- Classification of the system may be Class I, Class II or internally powered depending on the computer to which the system is connected. If the computer provides protection against shock via a protective earth, then the system (as defined in IEC60601-1-1) is Class I. If the computer provides protection against shock via double insulation, then the classification is Class II. If the computer is a notebook and is battery powered, then the classification is internally powered.
- Type CF (ECG Input) & BF (Tonometer Input) Equipment
- Ordinary Equipment
- This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

The following symbols, listed below with their meanings, are used throughout this manual as well as on the equipment:



Attention - consult accompanying documentation.



Type CF Applied Part (ECG Input)



Type BF Applied Part (Tonometer Input)

## Standards

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

IEC60601-1:1998 ; EN60601-1 ; AS/NZS 3200.1.0 Medical electrical equipment with Amendments 1 & 2  
 Part 1: General requirements for safety (the International Electro-Medical Safety Standard for medical equipment)

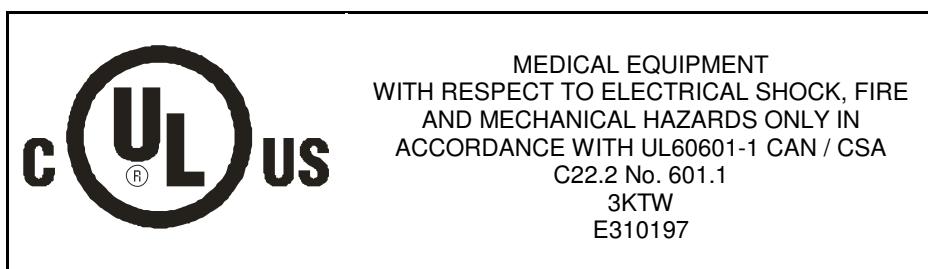
IEC60601-1-2:2000 & A1:2004; EN60601-1-2 ; AS/NZS 3200.1.2 Medical electrical equipment

Part 1: General requirements for safety;

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

- Emissions - CISPR11
- Immunity - Electrostatic Discharge (ESD) (IEC 61000-4-2)
- Immunity - Radiated RF Electromagnetic Fields (IEC 61000-4-3)
- Immunity - Electrical Fast Transient (EFT) Bursts (IEC 61000-4-4)
- Immunity - Surges (IEC 61000-4-5)
- Immunity - Conducted RF (IEC 61000-4-6)
- Immunity - Voltage Dips, Interruptions, Variations (IEC 61000-4-11)
- Immunity - Magnetic Fields (IEC61000-4-8)

AAMI EC13:2002 Cardiac monitors, heart rate meters, and alarms (Substantial compliance)



## 5.7 Disclosures 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, pulse length variation and shape deviation 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 and should be rejected.
  - b) Time T<sub>2</sub> is identified by a marker (diamond 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 (diamond on the pressure axis). For ejection duration (ED), visual inspection is required to ensure that T<sub>2</sub> is greater than T<sub>1</sub> and less than ED.
  - c) Time T<sub>1</sub> is identified by a marker (diamond on the time axis) and the pressure (P<sub>1</sub>) at this point is also identified by a marker (diamond 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 should be between 80-150msec. T<sub>1</sub> times of < 80msec and > 150 msec are suspect and consequently, P<sub>1</sub> and other indices determined from T<sub>1</sub> (augmented pressure, augmentation index) would be suspect. If there is a distinct inflection on the aortic synthesised waveform corresponding to the T<sub>1</sub> flag, and if T<sub>1</sub> is in the range of 80-150 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<sub>1</sub>, augmentation pressure and augmentation index can not be calculated reliably.

## Report Parameter Warnings

Before use, operators should ensure that there are no conditions present that would impair accuracy of blood pressure waveform 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 reactive 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 system should not be used on persons with significant aortic valve stenosis (gradient >60mmHg).
- Values of parameters determined from ejection duration when ejection duration values are outside the range 200-450 msec should be disregarded.
- Values of parameters determined from P<sub>1</sub> and T<sub>1</sub> should be viewed with caution when T<sub>1</sub> is outside the range 80-150 msec (AtCor Medical recommends repeating the measurement and where T<sub>1</sub> is consistently outside the range; strong consideration should be given for not retaining the data).

## 5.8 Electromagnetic Compatibility (EMC) Warnings & Declarations

- The SphygmoCor System requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual
- Portable and mobile RF communications equipment can affect the SphygmoCor System
- Operation of the SphygmoCor System during capture below the minimum digital unit signal amplitude (Pulse Height) specified below may cause inaccurate results.
  - PWA Capture – Pressure Pulse Height: 80
  - PWV Capture – Pressure Pulse Height: 80
    - ECG Pulse Height: 80
- Use of tonometers, accessories, and cables other than those specified or supplied by AtCor Medical may effect EMC compliance of the SphygmoCor System.

## WARNING

**THE SPHYGMOCOR SYSTEM IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS ONLY. THE SPHYGMOCOR SYSTEM MAY CAUSE RADIO INTERFERENCE OR MAY DISRUPT THE OPERATION OF NEARBY EQUIPMENT. IT MAY BE NECESSARY TO TAKE MITIGATION MEASURES, SUCH AS REORIENTING OR RELOCATING THE SPHYGMOCOR SYSTEM OR SHIELDING THE LOCATION.**

declaration - electromagnetic emissions (201)		
The SphygmoCor System is intended for use in the electromagnetic environment specified below. The customer or the user of the SphygmoCor System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The SphygmoCor System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

declaration - electromagnetic immunity (202)			
The SphygmoCor System is intended for use in the electromagnetic environment specified below. The customer or the user of the SphygmoCor System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines* ±1 kV for input/output lines (* tested on power supply of computer that device was attached to)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth (tested on power supply of computer that device was attached to)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0.5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	$U_T = 240V$ Complies at 0 % $U_T$  $U_T = 240V$ Complies at 40 % $U_T$  $U_T = 240V$ Complies at 70 % $U_T$  $U_T = 240V$ Complies at 0 % $U_T$ (tested on power supply of computer that device was attached to)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SphygmoCor System requires continued operation during power mains interruptions, it is recommended that the SphygmoCor System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	No effect at 3 A/m (50/60 Hz) (tested on power supply of computer that device was attached to)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity (204)			
The SphygmoCor System is intended for use in the electromagnetic environment specified below. The customer or the user of the SphygmoCor System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Complies at 3 Vrms modulation of 2Hz	Portable and mobile RF communications equipment should be used no closer to any part of the SphygmoCor System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance $d = 1.166\sqrt{P}$

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	80% AM  Complies at 3 V/m modulation of 2Hz 80% AM	$d = 1.166\sqrt{P}$ 80 MHz to 800 MHz  $d = 2.333\sqrt{P}$ 800 MHz to 2,5 MHz  where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SphygmoCor System is used exceeds the applicable RF compliance level above, the SphygmoCor System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SphygmoCor System.  <sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V <sub>i</sub> ] V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the SphygmoCor System (206)			
Rated maximum output power $P$ of transmitter in watts	Separation distance according to frequency of transmitter in metres		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.66	11.66	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## 5.9 European Declaration of Conformity

# Declaration of Conformity

Manufacturer: AtCor Medical Pty Ltd  
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European Representative: Advena Ltd  
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Notified Body: SGS United Kingdom Ltd  
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Weston-Super-Mare, BS22 0WA  
United Kingdom



<b>Product:</b>	<b>SphygmoCor</b>
	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:	<b>IEC EN 60601-1</b> <b>IEC EN 60601-1-2</b> <b>IEC EN 60601-1-4</b> <b>IEC EN 62366</b> <b>IEC EN 62304</b>
Classification:	<b>Class IIa</b> Rule 10 of Annex IX
Conformity Assessment Route:	<b>Annex II</b> (excluding Section 4), 93/42/EEC
Products covered:	Serial number of first system shipped under annex II

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC, all prior amendments and as transposed into national laws. All supporting documentation is retained under the premises of the manufacturer.

John Abram  
Manager, Regulatory Affairs and Quality Assurance  
AtCor Medical Pty Ltd  
Sydney, NSW, Australia

Date

17th March, 2010

DCN 100776 – Rev 5.0

## *Index*

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### **A**

Arrhythmia.....	9
Auto Capture .....	20

---

### **B**

Batch Print for PWV.....	33
--------------------------	----

---

### **C**

Carotid measurement for PWV .....	30
CD-ROM.....	43
Central Blood Pressure .....	12
CF Equipment .....	44
Communications port.....	41
configuration settings.....	20
Copyright .....	2

---

### **D**

Database	
Change the description of .....	35
Copying a database .....	35
Copying a database - caution .....	35
Create a new database.....	34
Deleting a database.....	36
Updating a database .....	36
Updating a database - caution .....	36
Warning.....	20, 34
Database .....	41
Warnings .....	36
Database access error.....	41
Database corruption .....	41
Database Manager.....	34
database optimisation .....	36
Detecting Module .....	41
Disclaimer .....	2
Disposal .....	3

---

### **E**

ECG Cables Checklist.....	12
ECG Electrodes.....	28
Checklist .....	12
ECG Leads Checklist .....	12
Electronics Module	
Checklist .....	12
Checklist: .....	43
Connector Symbols .....	14
Floating (isolated) ground .....	39
Indicators.....	15
Trouble Shooting .....	41
Error checking .....	41

---

Errors .....	41
European Authorised Representative.....	2

---

### **F**

Femoral Measurement for PWV .....	31
Flowchart .....	16
Footswitch .....	5, 14
Footswitch Checklist .....	12

---

### **G**

Guidance Bars .....	20
---------------------	----

---

### **H**

Hardware Installation .....	14
Head Office .....	2

---

### **I**

Introduction	
Central Blood Pressure .....	12
Pulse Wave Velocity .....	12, 43

---

### **N**

Notebook	
Batteries .....	38
Optional Accessory .....	44

---

### **O**

Operating Instructions	
Preparation ECG Electrodes.....	28
Operator Index.....	25
Operator's Manual .....	43

---

### **P**

Packing a database.....	See Database optimisation
Patient	
Create New Patient Entry .....	20
Search For Existing Patient .....	21
Power light.....	41
Precautions .....	10
Pressure Sensitivity .....	34
Print for PWV .....	33
Privacy Screen .....	20
Pulse Wave Velocity.....	12

---

**Q**

Quality Control	
for PWV .....	32
Setting Limits.....	34

---

**R**

Regulatory	
AAMI EC13 2002.....	44
AS/NZS 3200.1.0.....	44
AS/NZS 3200.1.2.....	44
EN60601-1 .....	44
EN60601-1-2.....	44
General requirements for safety .....	44
IEC60601-1 1998 .....	44
IEC60601-1 .....	9
IEC60601-1-1.....	9, 44
IEC60601-1-2 2000 & A1 2004 .....	44
UL Approval.....	44
Regulatory Approvals.....	6

---

**S**

Safety	
Mobile/Cellular Phones.....	9
Setting Up & Installation Components .....	43
Software	
Checklist .....	12
Installation.....	13
Software CD-ROM.....	43
Software License Agreement.....	13
Software Screens .....	41
SphygmoCor Classification.....	44
SphygmoCor Reference Age .....	26
Standby Indicators.....	18
Stenosis.....	9, 10, 45
System Care .....	37
Liquids .....	38
Magnetic fields.....	38
Movement.....	38

---

Pressure or Impact Damage .....	38
Stability.....	37
Temperature.....	38
Weight .....	38
System Serial Number.....	37

---

**T**

Tonometer .....	18
Installation.....	14
Placement for PWA .....	23
Warranty.....	37
Tonometer .....	39
Checklist .....	12
Checklist: .....	43
cleaning and basic care.....	18
Compartment .....	14
Storage .....	6
Temporary Storage Holder .....	5, 18, 20, 26, 37
Trademarks .....	3
Trouble Shooting.....	41
Electronics Module .....	41
Overview.....	41

**U**

USA Agent .....	2
USA Privacy Rule .....	10
USB	
Component Checklist.....	43
Connection .....	14
Warning .....	38
USB Cable	
Checklist .....	12

---

**W**

Warning Safety Leakage Currents .....	9
Warnings .....	9
Warranty.....	37



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