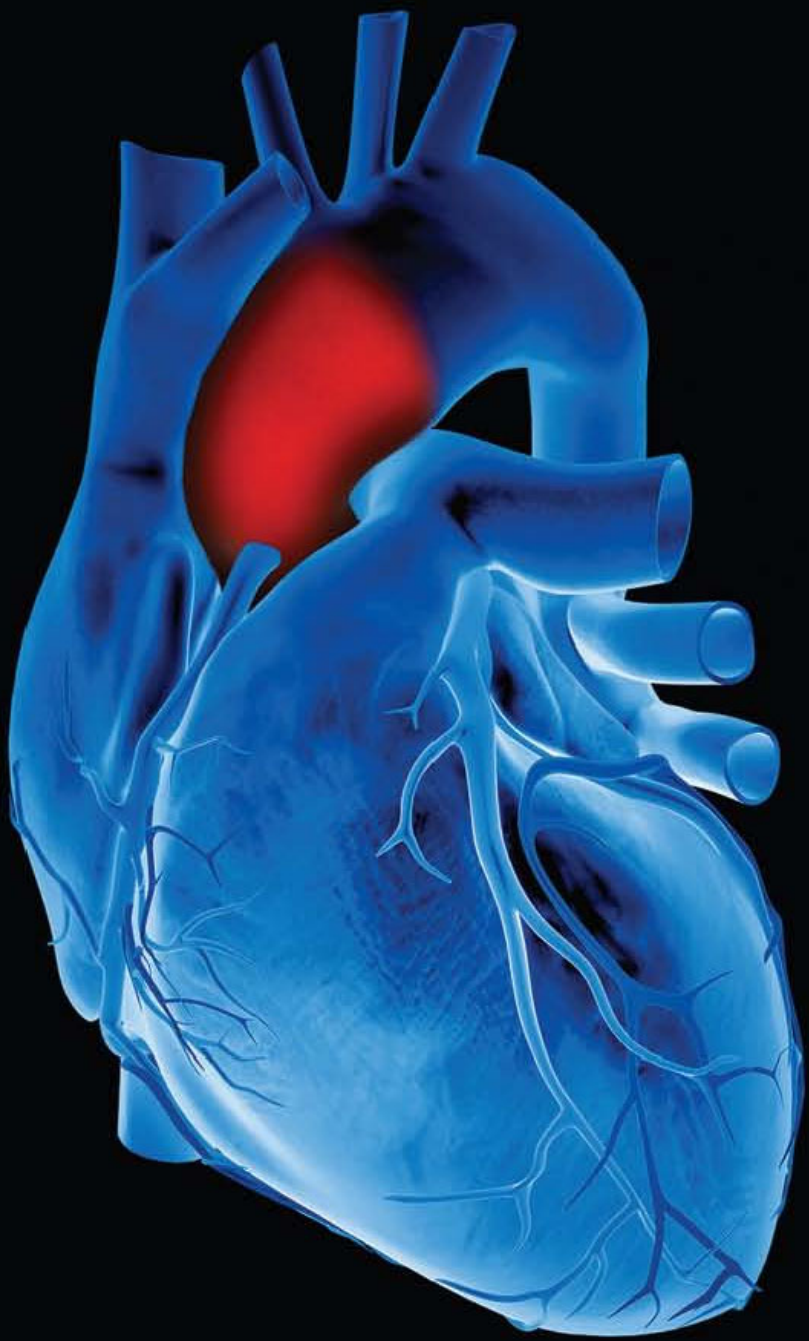
SphygmoCor XCEL

SIMPLY THE GOLD STANDARD

OPERATOR'S MANUAL
SphygmoCor XCEL System v1



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Copyright

SphygmoCor® XCEL

Pulse Wave Analysis Measurement

Pulse Wave Velocity Measurement

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Disclaimer

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

This Manual is produced on the assumption that the operator is an experienced user of Windows 10 or Windows 11 Operating Systems.

If the operator is not familiar with the Windows environment, please refer to the Windows User Manual or Windows Online Help.

Trademarks

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

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Caution
Federal (USA) law restricts this device to sale by or on the order of a physician

Introduction

The SphygmoCor XCEL Central Blood Pressure Measurement System

The SphygmoCor XCEL System is a non-invasive diagnostic tool for the clinical assessment of central blood pressure. The SphygmoCor XCEL System derives the central aortic pressure waveform from cuff pulsations recorded at the brachial artery. Analysis of the waveform provides key parameters including central systolic pressure, central pulse pressure and indices of arterial stiffness such as augmentation pressure and augmentation index. Increased central systolic pressure and augmentation index have been shown to be markers of cardiovascular risk.

The SphygmoCor XCEL Pulse Wave Velocity Measurement System

The SphygmoCor XCEL System also measures the pulse wave velocity of the arterial pulse waveform travelling through the descending aorta to the femoral artery. The aortic pulse wave velocity is detected from carotid and femoral arterial pulses measured non-invasively and simultaneously. The carotid pulse is measured using the tonometer while the femoral pulse is measured through pulsations in a cuff placed around the thigh. Higher carotid to femoral pulse wave velocity indicates a stiffer aorta, which is an indicator of target organ damage.

Indications for Use

The SphygmoCor® XCEL System provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a brachial cuff. 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.

Additionally, the SphygmoCor® XCEL System automatically measures Systolic blood pressure and Diastolic blood pressure.

The SphygmoCor® XCEL Pulse Wave Velocity (PWV) option is intended to obtain PWV measurements. The PWV option is used on adult patients only.

Intended purpose of accessories used to capture blood pulse or waveforms

Tonometer: The tonometer is used for obtaining a waveform from the carotid artery when performing a PWV measurement. The tonometer is intended for multiple use.
Cuff: The cuff is used for obtaining a waveform from the femoral artery when performing a PWV measurement, and to obtain a waveform from the brachial artery when performing a PWA measurement. The cuff is intended for multiple use.

Intended Patient Population

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

Do not use on neonates.

Safety and effectiveness in children under the age of 18 years of age and neonates have not been established.

Intended Environment

The SphygmoCor® XCEL System is intended to be used in a Clinical or Research environment.

The SphygmoCor XCEL System is intended to be used temporarily as a cardiovascular diagnostic tool. It is not intended to be used as a continuous monitoring device in hospital or emergency vehicle, and is not applicable to be classified as a defibrillation-proof applied part.

The SphygmoCor XCEL system is not intended for use during patient transport outside of a healthcare facility.

Contraindications

- The SphygmoCor XCEL System should not be used for patients with erratic, accelerated or mechanically controlled irregular heart rhythms, including patients with arrhythmias.
- Do not use the SphygmoCor XCEL System on patients with carotid or aortic valve stenosis.
- The device should not be used on patients with peripheral artery disease PAD or leg artery disease since an applied cuff pressure on the leg of these subjects may be harmful.
- On hypotensive patients, the device should be used with caution.
- 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.
- Any interpretations made from the SphygmoCor XCEL System measurements should be made in conjunction with all other available medical history and diagnostic test information about a patient.
- Do not use the cuff over a wound as this may cause further injury.
- Do not place the cuff on any limb being used for intravenous access or where an arterio-venous (A-V) shunt is present, or any area where circulation is compromised or has potential to be compromised and could result in injury to the patient
- It is advisable for patients with mastectomy not to perform measurement with the cuff on the side of mastectomy as it may cause harmful injury to the patient.
- The user need to check that application of the cuff do not result in prolonged impairment of patient blood circulation

Warnings

- Do not use mobile/cellular phones or other transmitting devices within 10 meters (30 feet) of the SphygmoCor XCEL System.
- Use only with the tonometer, cuffs and air hose supplied by AtCor Medical. Different tonometers, hoses and cuffs have not been validated with SphygmoCor XCEL and measurements with non-validated components may not be accurate,
- Do not use the Tonometer on moist or wet skin.
- Do not put objects on top of the SphygmoCor XCEL device that can obstruct access to the Stop Button.
- Continuous CUFF pressure due to connection tubing kinking, result in continuous disruption blood flow may cause harmful injury to the patient.
- Too frequent cuff PWA measurements can cause injury to the patient due to blood flow interference
- Do not modify this equipment without authorisation of the manufacturer.
- Temperature of tonometer and cuff may rise above 41 degrees Celsius if operating device at maximum operating ambient temperature.
- To disconnect from the supply mains, the power adaptor needs to be unplugged from the mains socket. Ensure the device is positioned such that the power adaptor plug (supply mains side) is not obstructed during use
- Note: additional warnings printed on the SphygmoCor XCEL device and at the end of the Manual.

SphygmoCor XCEL PWA Quick Start Guide

This Quick Start Guide is based on default software options for SphygmoCor XCEL. Changing from default settings may result in different menu options.

1. Software Installation

Note: Make sure that the SphygmoCor XCEL device is NOT connected during the software installation.

For instructions on how to download and install the software, refer to sections *Software Download* and *Software Installation*.

2. Hardware Setup

a) Connect the power supply to the SphygmoCor XCEL device, and plug in the power supply cable into a mains socket.

Warning: Do not connect any power supply to the SphygmoCor XCEL device other than the one provided by AtCor.

b) Connect the SphygmoCor XCEL device to your PC using the USB cable.

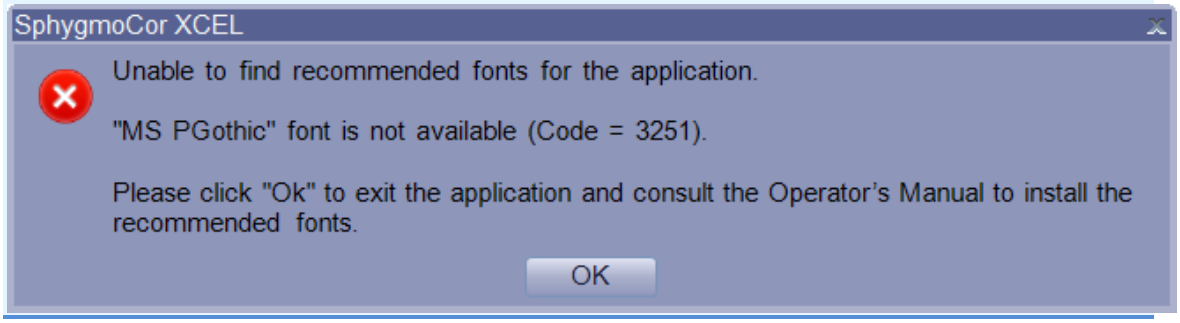
c) Connect the brachial cuff to the SphygmoCor XCEL device.

d) Switch on the SphygmoCor XCEL device.

e) Fit the cuff to the patient

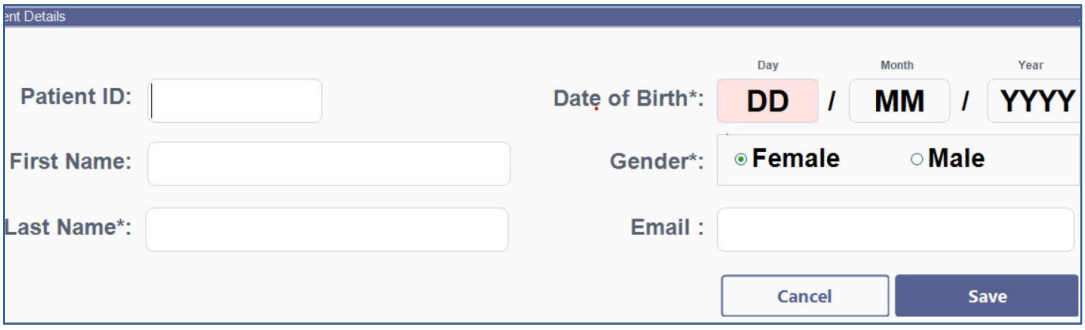
f) Start the SphygmoCor XCEL software by double-clicking on the SphygmoCor XCEL software icon on the desktop.

Note: If the following error (Code=3251) appears after starting the SphygmoCor XCEL software, refer to *Installing Recommended Fonts on Different Versions of Windows* section in the *Appendix* 1.



3. Creating a Patient Record

a) Click **New** to add a new patient record.



b) Enter all mandatory data, indicated by the * symbol next to the field.

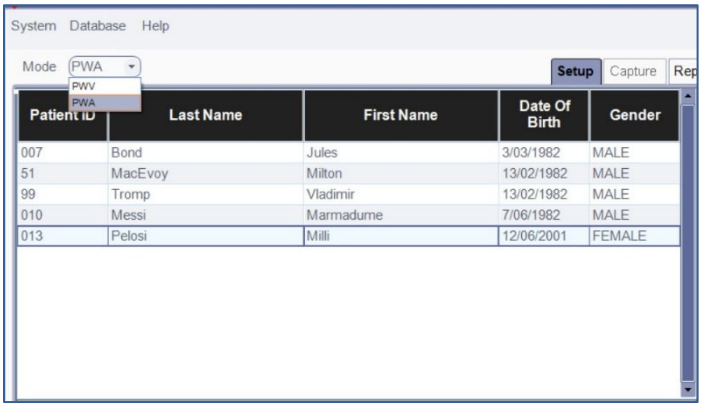
Note: Before creating a new patient entry, check whether the patient already exists in the database. Separate patient entries cannot be merged.

c) Click **Save**.

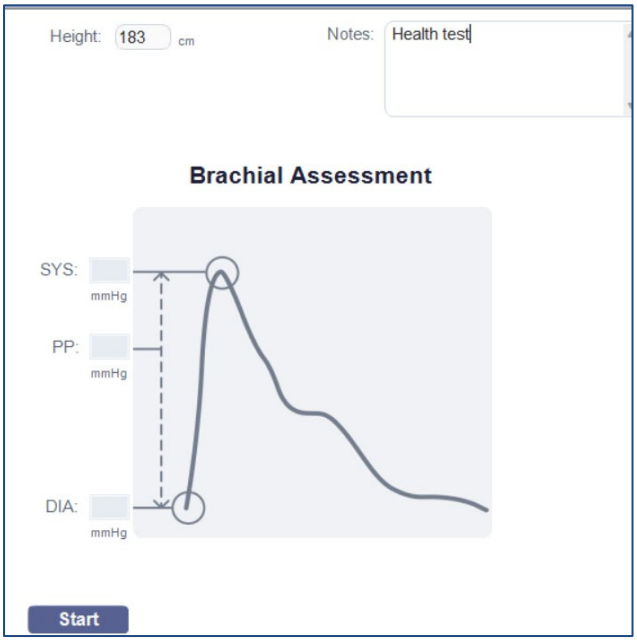
4. Recording a PWA Measurement

Note: Minimise the patient's limb movement while capturing data. Movement may prevent the capture from being completed or may reduce the quality of the measurement.

a) Select PWA (this is only necessary if you also have a license for PWV).

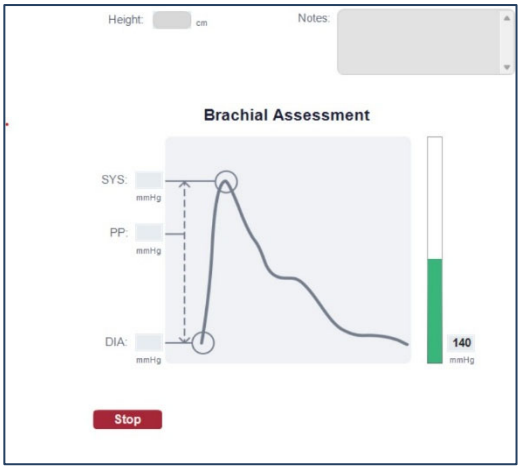


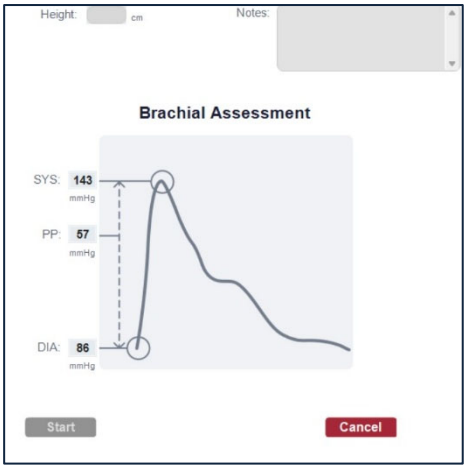
b) Select the patient (search for the record if necessary)



c) Click **Start**.

The cuff is inflated to measure patient's brachial systolic pressure (SYS), diastolic pressure (DIA) and pulse pressure (PP) which will be displayed. During a BP assessment, the pressure is shown both with a bar, and a numerical value on the right side of the screen.





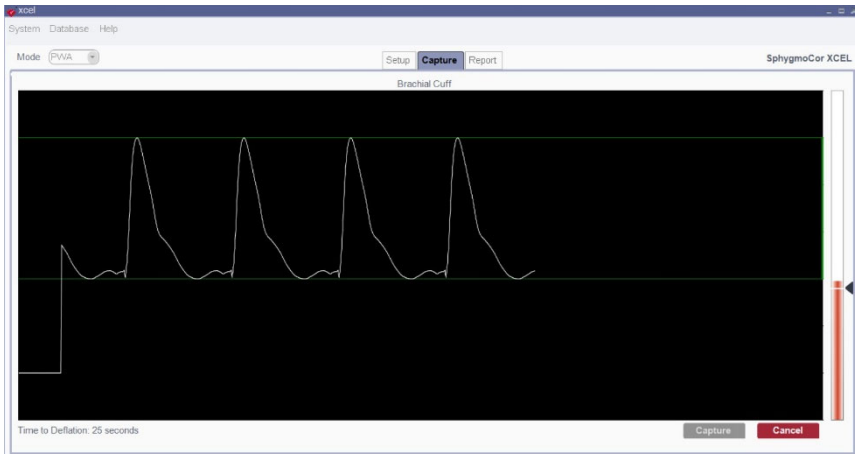
Note: If the multiple brachial BP assessments option is selected in the Brachial BP setting, the last displayed brachial SYS, DIA and PP will be the average values of the successfully completed assessments.

Five seconds after the cuff deflation, the PWA measurement starts automatically.

Note: When using the multiple brachial BP assessments option, there may be occasions where not all Brachial BP assessments were performed successfully. On these occasions, the user can either start the PWA measurement manually by clicking the Capture button or can start a new multiple Brachial BP assessment by clicking the Start button.



The cuff is inflated and the capture screen is displayed, showing the captured cuff waveform.



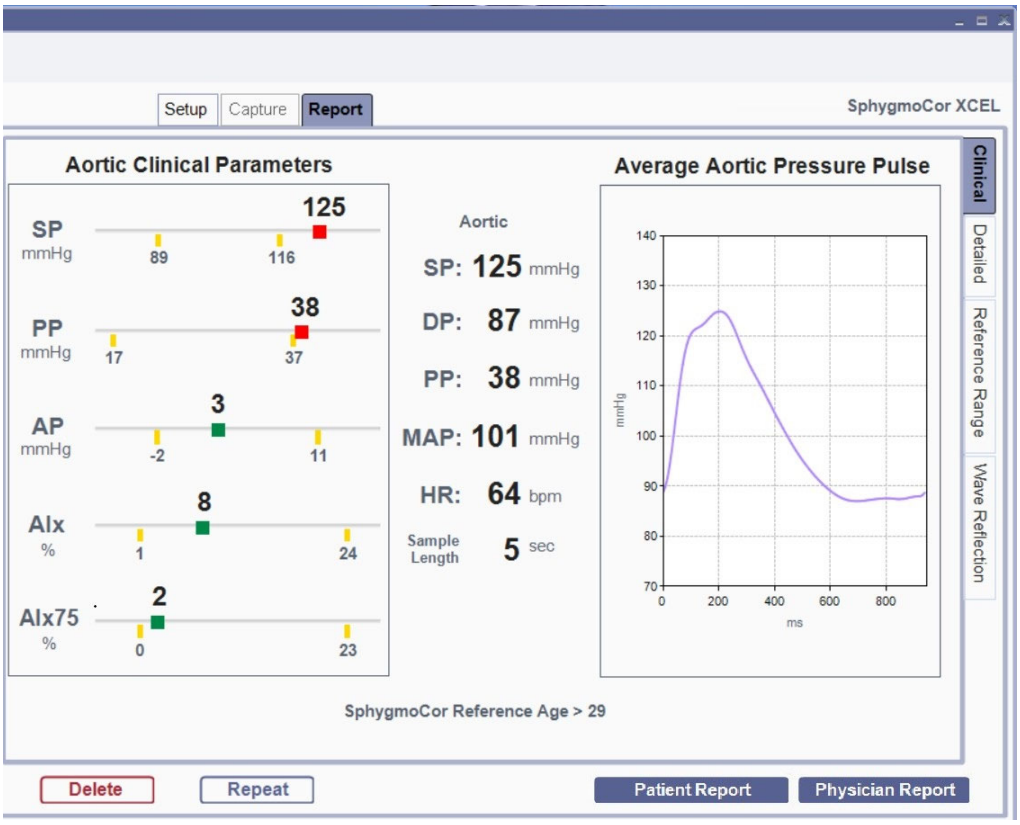
The cuff can be deflated at any time by clicking the **Cancel** button on the screen, manually pressing the **Stop** button on top of the SphygmoCor XCEL device, or turning off the SphygmoCor XCEL device.

Note: SphygmoCor XCEL inflates the cuff before each reading, then deflates the cuff.

d) After 5 seconds the recorded cuff waveform will be automatically captured and a report screen will be displayed showing the central aortic pressure waveform and parameters.

Refer to the *Using the Guidance Bars* section on *page 25* for explanation of the bars in the capture screen.

Note: If the report screen does not display after 20 seconds of recorded brachial cuff pulses, click the **Capture** button to produce a report.



Refer to
Reviewing the PWA Report section on *page* 27 for an explanation of the Report screen displayed parameters.

e) Click **Physician Report** for a single-page summary report, or click **Patient Report** for a multi-page Patient Report. The Patient Report may not be available in some regions.

f) Click **Repeat** to repeat the measurement on the same subject.

g) Click **Delete** to delete the report.

SphygmoCor XCEL PWV Quick Start Guide

This Quick Start Guide is based on default software options for SphygmoCor XCEL. Changing from default settings may result in different menu options.

1. Software Installation

Note: Make sure that the SphygmoCor XCEL device is NOT connected during the software installation.

For instructions on how to download and install the software, refer to sections *Software Download and Software Installation*.

2. Hardware Setup

a) Connect the power supply to the SphygmoCor XCEL device and plug in the power supply cable into a mains socket.

> **Warning**: Do not connect any power supply to the SphygmoCor XCEL device other than the one provided by AtCor.

b) Connect the SphygmoCor XCEL device to your PC using the USB cable.

c) Switch on the SphygmoCor XCEL device.

d) Fit the cuff on the patient's upper thigh.

e) Start the SphygmoCor XCEL software.

3. Creating a Patient Record

a) Click **New** to add a new patient record.



b) Enter all mandatory data, indicated by the * symbol next to the field.

> **Note:** Before creating a new patient entry, check whether the patient already exists in the database. Separate patient entries cannot be merged.

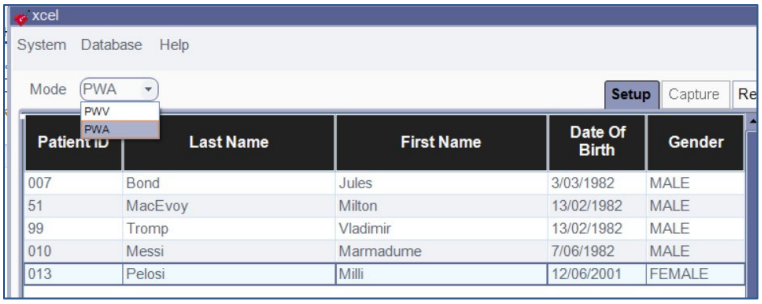
c) Click **Save**.

4. Recording a PWV Measurement

> **Note**: Minimise the patient's limb movement while capturing data. Movement may prevent the capture from being completed or reduce quality of the measurement.

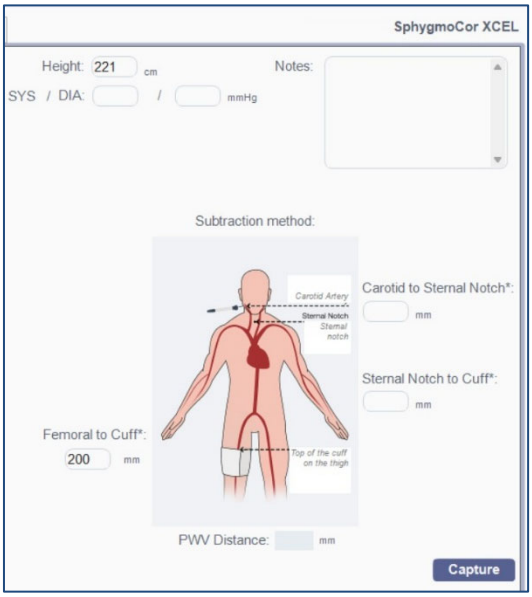
a) Go to the setup screen.

b) Select **Mode - PWV**.



c) Select the patient's record.

d) Enter the distance in millimetres from the patient's carotid artery to their sternal notch (*Carotid to Sternal Notch*) and also the distance from their sternal notch to the top edge of the femoral cuff (*Sternal Notch to Cuff)*.



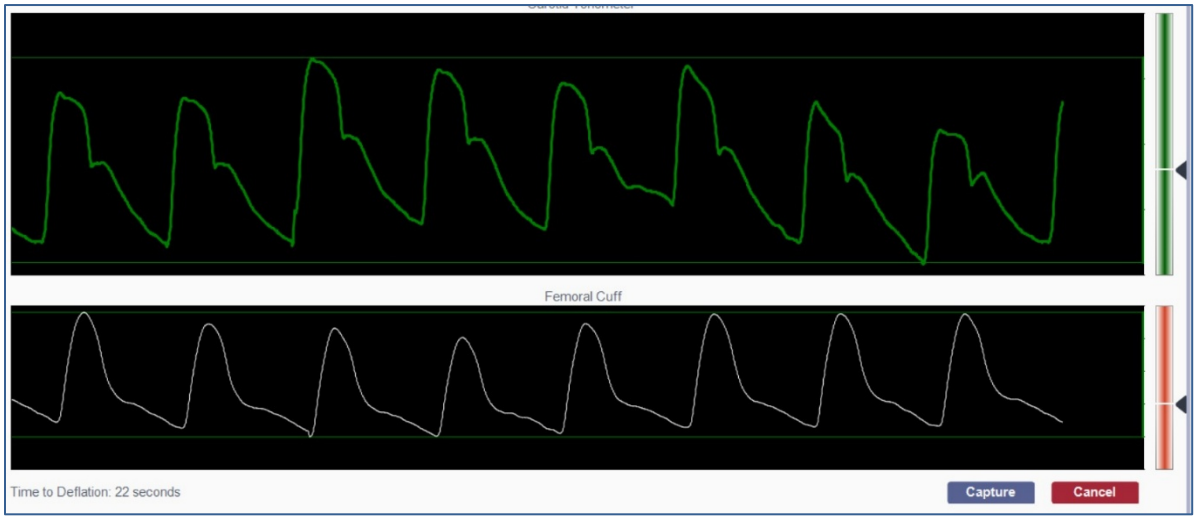
Note: The femoral to cuff distance value is set to 200mm by default. To improve the accuracy of the PWV reading, measure the distance from the top edge of the cuff to the femoral artery (near the groin) and use this value instead of the default.

Refer to

PWV Settings section on *page 74* for details on distance measurements.

e) Click **Capture**.

f) The cuff will be inflated to capture femoral waveform, and the carotid signal should be measured using the tonometer. When both signals are of "good" quality, both signals turn green and a PWV Report is produced.



The cuff can be deflated at any time by clicking the **Cancel** button on the screen, manually depressing the **Stop** button on top of the SphygmoCor XCEL device or by turning off the SphygmoCor XCEL device.

Note: SphygmoCor XCEL inflates the cuff before each reading, then deflates the cuff.

g) After 10 seconds of simultaneous valid carotid tonometer signal and femoral cuff signal, a Report screen will appear showing both signals and the calculated pulse wave velocity (PWV) and pulse transit time.

Refer to *Reviewing the PWV Report* section on *page 54* for an explanation of the parameters displayed in the Report screen.

Note: If the Report screen does not appear for over 20 seconds of continuous simultaneous recording of carotid and femoral pulses, click the **Capture** button to produce a report.



h) Click **Physician Report** for a single-page report, or **Patient Report** for a multi-page Patient Report. The Patient Report may not be available in some regions.

i) Click **Repeat** to repeat the measurement on the same subject.

j) Click **Delete** to delete the report.

Recording a PWA Measurement

Components and Accessories for PWA

	**SphygmoCor XCEL device** – the SphygmoCor microprocessor-controlled module for data capture and analysis. Refer to *SphygmoCor XCEL Device Status Indications* for an explanation of the panel indicators.

	**Brachial cuff** – a pneumatic cuff with a tube connection to the SphygmoCor XCEL device Part numbers: 1-00889 - Cuff PWA Adult Large 31-40cm 1-00890 - Cuff PWA Adult 23-33cm 1-00891 - Cuff PWA Adult Extra Large 38-50cm
	**Cuff Hose-** 1.5m cuff hose with connectors at both ends. Part number: 1-00865 - Cuff Hose 1.5m
	**Power supply** – an AC power adaptor for the SphygmoCor XCEL device. Always use the power supply provided by AtCor Medical Part number: 1-011910877 - Medical Power Adaptor (Mean Well – PN GSM36B15-R7B)
	**USB cable (2m)** - connects the SphygmoCor XCEL device to a PC or laptop. Part number: 1-00858 - USB Cable 2m

	**Tray (optional)** – provides storage of cuffs, as well as a mounting platform for the SphygmoCor XCEL device (The storage tray is an optional component supplied by AtCor Medical). Part number: 1-00896 - EM4 Storage Tray

Connection of Components

Warning: Do not connect any power supply to the SphygmoCor XCEL device other than the power supply provided by AtCor Medical.

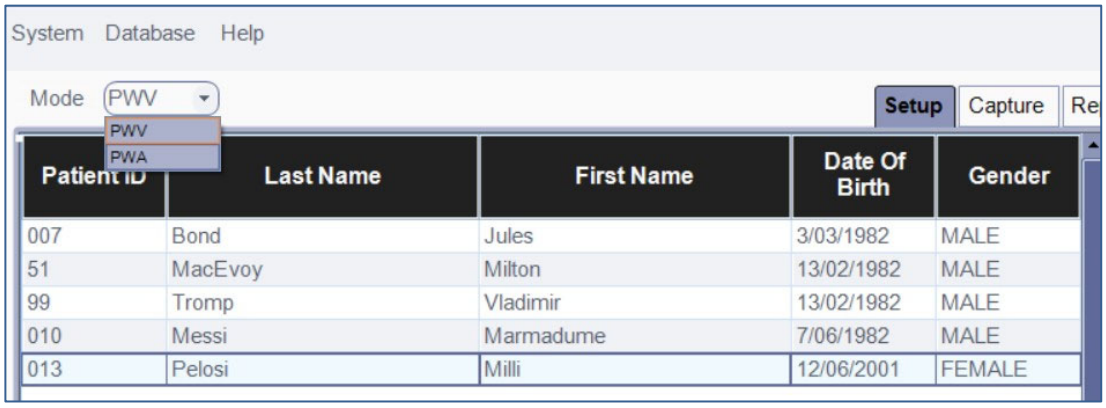
1. Connect the power supply to the SphygmoCor XCEL device and plug the power supply cable into an AC power outlet.
2. Connect the SphygmoCor XCEL device to the PC using the USB cable.
3. Connect the brachial cuff to the SphygmoCor XCEL device.
4. Power on the SphygmoCor XCEL device.

Note: Avoid compression or restriction of the connection tubing.

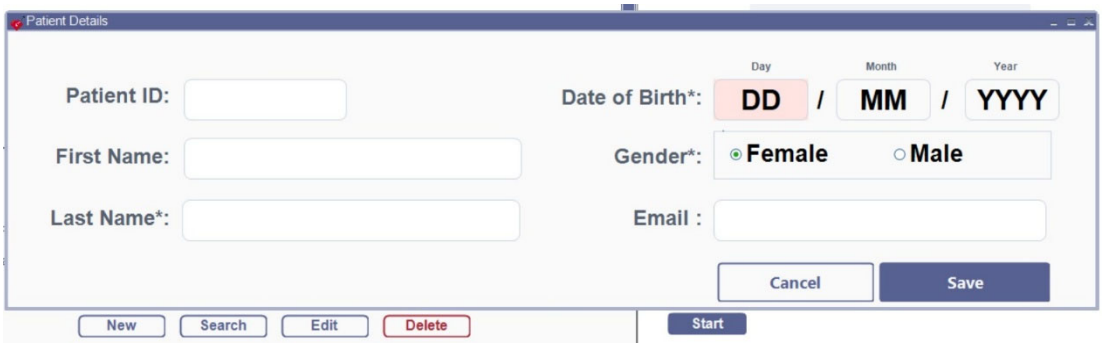
Start a Measurement

Note: The patient's limb movement should be minimised while capturing data as movement may prevent the capture from being completed or may reduce the quality of the measurement.

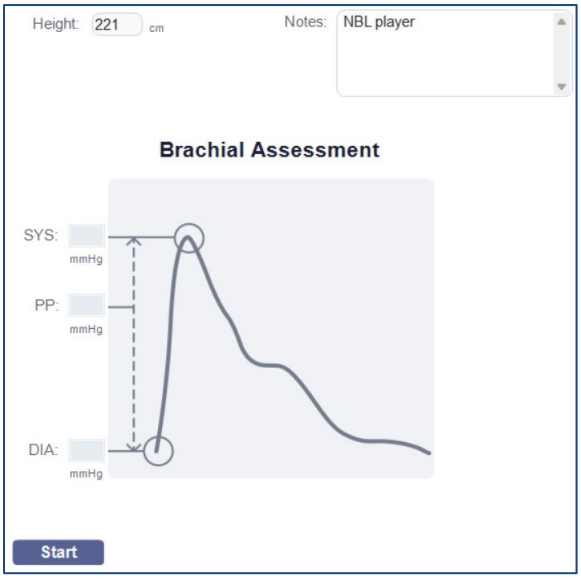
1. Select PWA (this is only necessary if you also have a license for PWV).



2. Select the patient (by searching Patient ID, Name or Date of Birth, if necessary). If the patient does not exist in the database, create a new patient record by clicking **New** and entering the patient details. Mandatory fields are indicated by *.

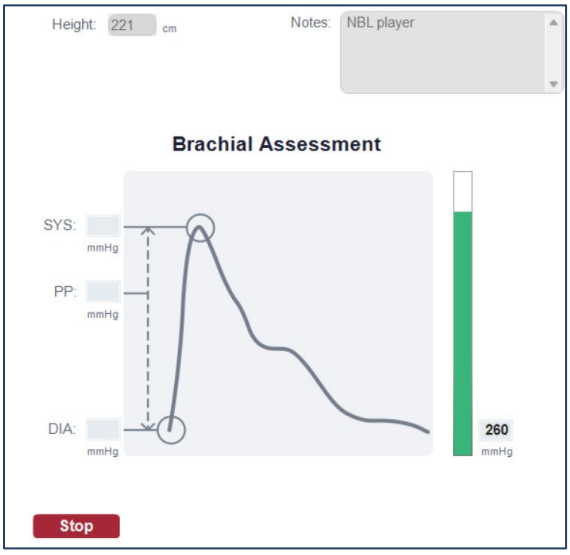


3. To determine the patient's SphygmoCor reference age, an estimate of the arterial age of the patient, enter the height of the patient in the height entry box.

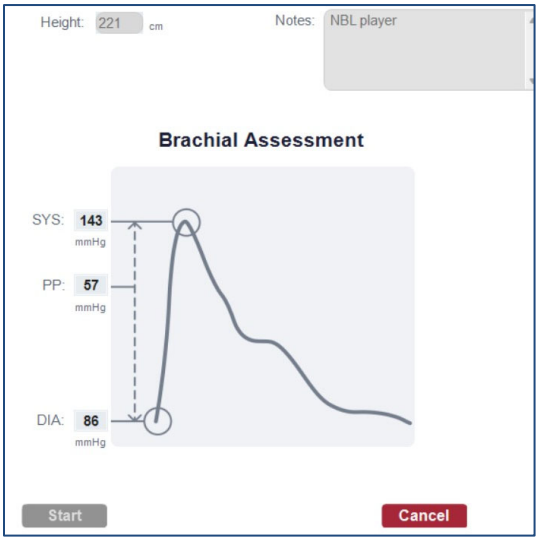


4. Click **Start**.

The cuff is inflated on the right of the screen, to measure brachial systolic and diastolic pressure. During a BP assessment, the pressure is shown both with a bar, and a numerical value on the right side of the screen.



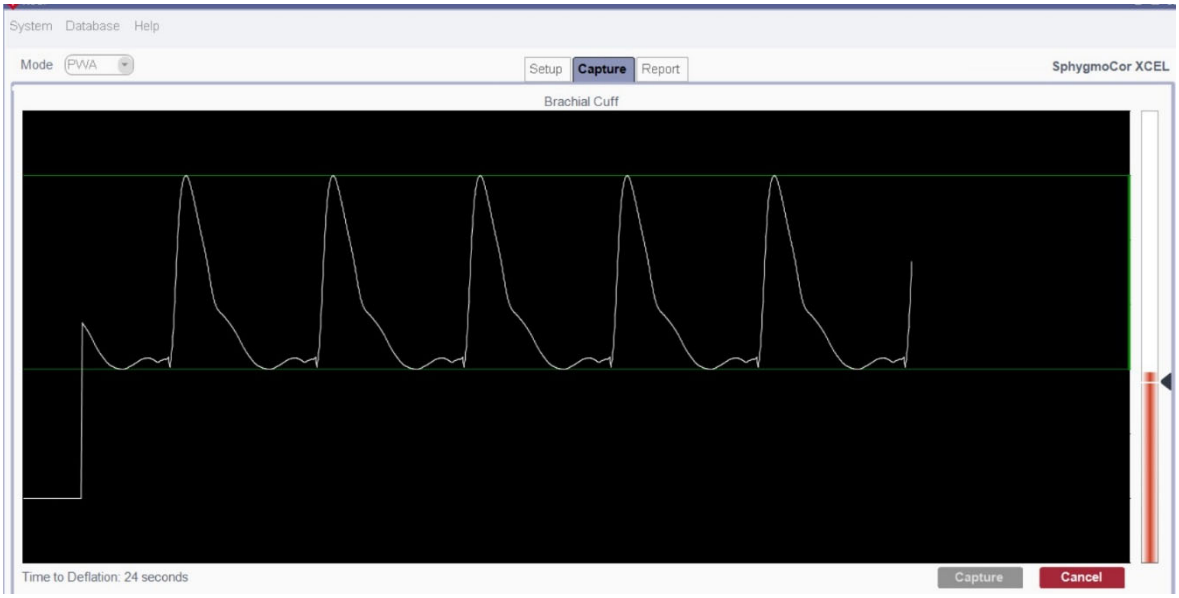
Brachial Systolic Pressure (SYS), Brachial Pulse Pressure (PP) and Brachial Diastolic Pressure (DIA) are displayed. If multiple Brachial blood pressure measurements are selected to calibrate the waveform, the Brachial BP measurement will be repeated and average values for brachial SYS, PP and DIA will be displayed.



After determining the Brachial Systolic and Diastolic pressure, the cuff will deflate. Five seconds later, the cuff will inflate again and automatically capture the PWA waveform.

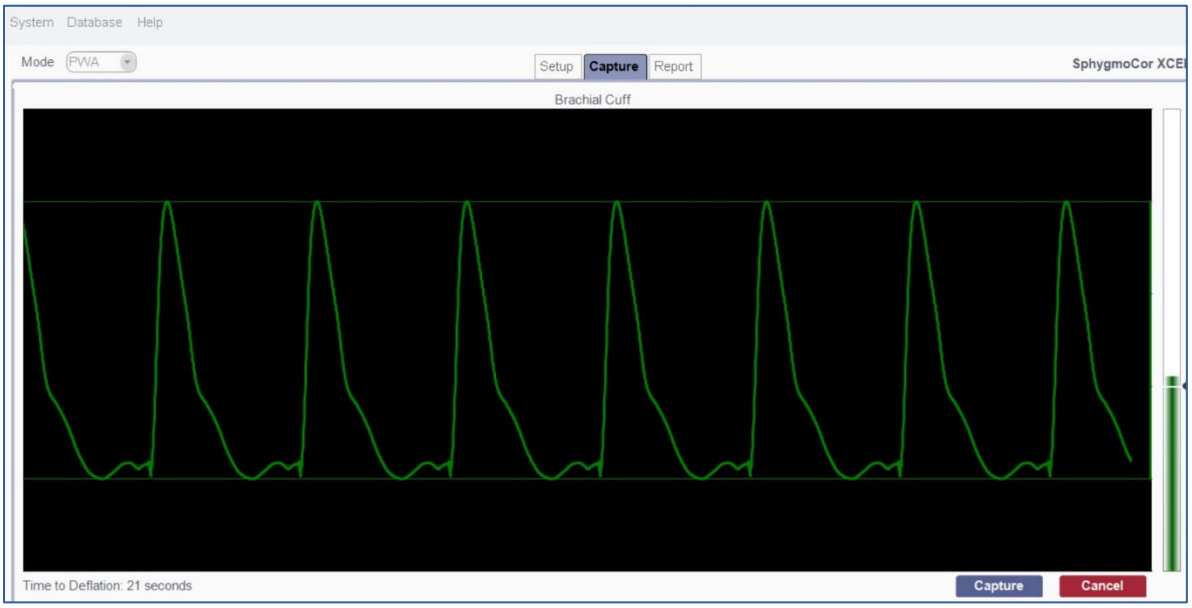
Note: During PWA waveform capture, the cuff can be deflated at any time by clicking the **Cancel** button on the screen, manually depressing the **Stop** button on top of the SphygmoCor XCEL device or turning off the SphygmoCor XCEL device.

The Capture screen displays the brachial waveform being collected from the cuff. The colour of the waveform along with vertical bar on the side becomes green when the waveform is consistent for capture. When the waveform colour and the side bar become green, the waveform will be automatically captured and the software will advance to the report screen. The waveform may also be captured manually by clicking the capture button at the bottom of the screen.

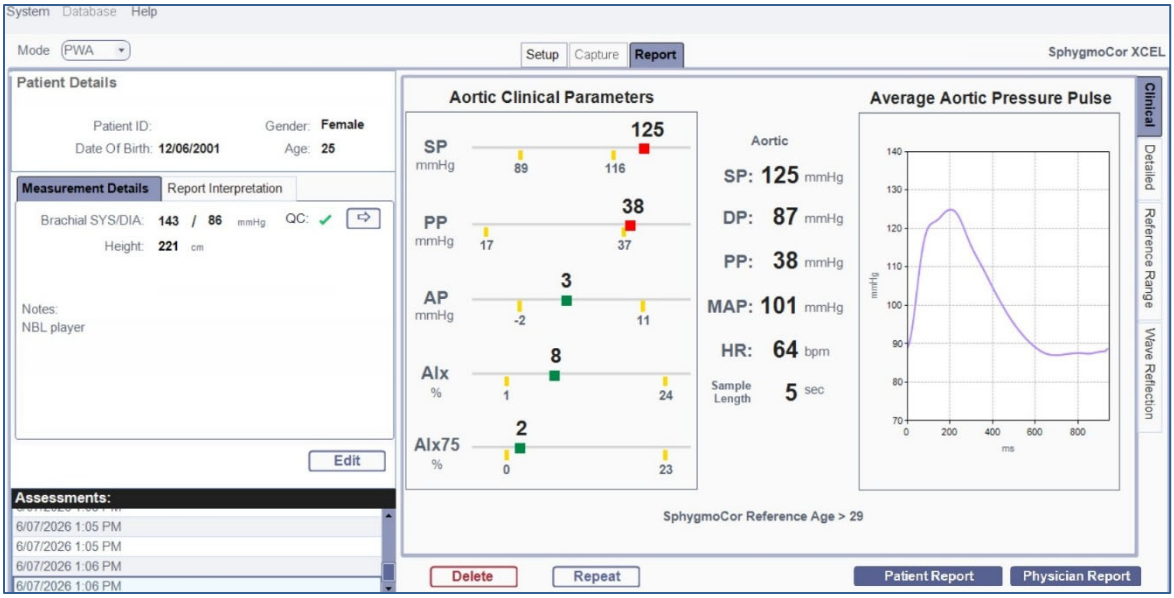


5. If the Auto Capture feature is disabled, waveforms are captured by clicking the **Capture** button when it is enabled. The **Capture** button is enabled when the software detects a sufficient number of pulses to produce a valid report.

Note: For best results, click the **Capture** button when the waveform colour and corresponding vertical bar are green, as shown in the following screen shot.



A report screen is then displayed, showing Average Aortic Pressure Pulse, aortic pressure waveform parameters and the Aortic Clinical Parameters plotted in reference to the normal range based on the patient's age and gender.



Refer to
Reviewing the PWA Report for a detailed explanation of this report and the Aortic pressure and arterial stiffness parameters.

6. Click **Physician Report** for a single-page report, or click **Patient Report** for a multi-page Patient Report. The Patient Report may not be available in some regions.
7. Click **Repeat** to repeat the measurement on the same subject.
8. Click **Delete** to delete the report.

Automatic versus Manual 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. Alternatively, the keyboard 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 the **Capture** button is enabled, indicating enough pulses have been recorded to produce a valid report.

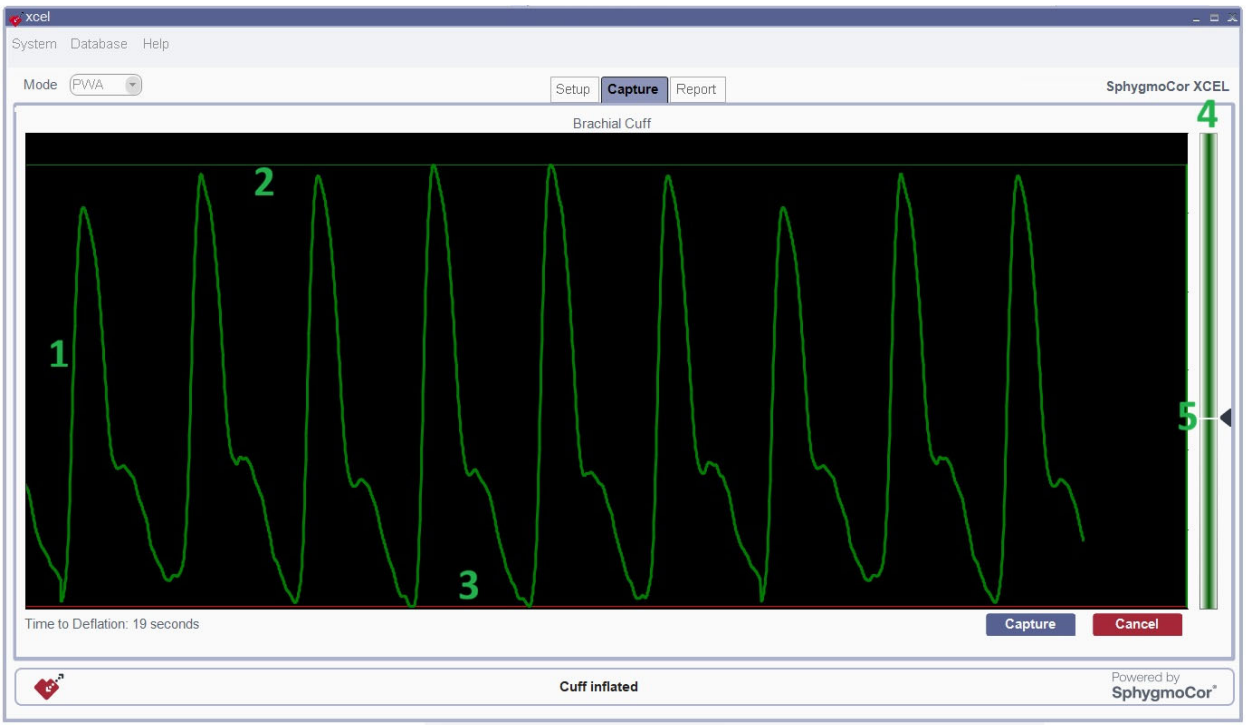
Using the Guidance Bars

When preparing to capture waveforms, the SphygmoCor XCEL System provides feedback that will help determine if the waveforms from the brachial cuff are consistent enough to provide an accurate central blood pressure (CBP) measurement.

There are multiple visual indications that provide feedback, as shown in the following diagram.

All of these visual signals are colour-coded, with some providing feedback based on each pulse, and some on the entire recorded waveform for the duration of the capture time.

If Auto Capture is enabled, the data is captured automatically when the waveform colour changes to green, indicating an acceptable quality waveform has been captured for the duration of the capture time. A report of calculated CBP and arterial stiffness indices is produced. The waveform can also be captured manually by clicking the **Capture** button, regardless of the waveform colour.



(1) Waveform – the waveform changes colour according to quality of the overall recording during capture time. The waveform colour is initially white, changes to green if the quality of the overall recording during the capture time is acceptable and the recording has at least the minimum number of quality pulses. The minimum number of pulses recorded can vary according to the data capture period selected in the PWA settings.

(2) Top Guidance Bar – a Guidance Bar is displayed at the top of the waveform and indicates reliability of the pulse peaks. It updates on a beat-by-beat basis. The colour changes from red to green as the waveform peaks become more consistent.

(3) Bottom Guidance Bar – a Guidance Bar is displayed at the bottom of the waveform and indicates reliability of the pulse troughs. The colour changes from red to green as the waveform troughs become more consistent.

(4) Bar graph – this graph indicates signal amplitude, measured on a beat-by-beat basis. The amplitude must be above the **threshold mark (5)** to ensure a reliable signal.

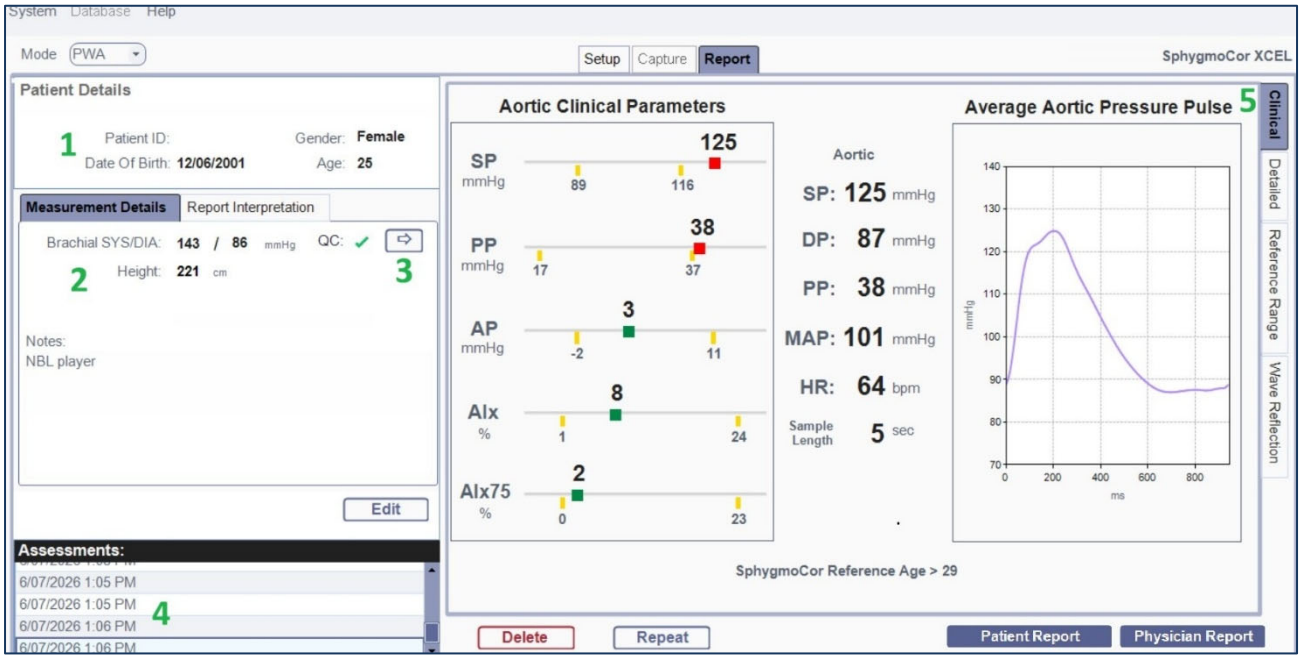
The waveform colour is synchronised with the bar graph colour:

- when the waveform is green, the bar graph is green
- when the waveform is white, the bar graph is red

Note: Guidance Bars and Auto Capture are part of the Capture Guide feature in the software. Both features are enabled as the default setting. These features can be enabled or disabled from the System menu (refer to

PWV Settings, *PWA Settings*, and *Brachial BP Settings*).

Reviewing the PWA Report



(1) **Patient Details** – Patient's personal data including Patient ID, Gender, Date of Birth and Age.

(2) **Measurement Details** –

a) Brachial SYS/DIA: Measured brachial systolic (SYS) and diastolic (DIA) blood pressure.

b) Height: Patient's height.

c) Notes: The notes entered by the operator for the measurement.

d) Quality Control (QC) Indicator: An indicator of the quality of the recorded signal. The QC indicator will appear as a green tick if the recorded signal is a "good" quality signal and as a red cross if the recorded signal is "bad" quality due to noise or patient movement. If the QC indicator displays a red cross, the assessment should be repeated. Click the arrow button ⇦ next to the **QC indicator** to show the Quality Control Report. Refer to *Quality Control Report (QC)* section for more information.

(3) **Report Interpretation** – Interpretation for a report entered by the operator.

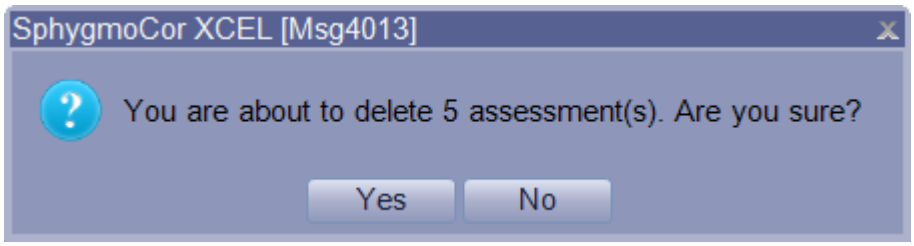
(4) **Assessments** – Chronologically ordered list of measurements where each measurement is stamped with the date and time of the measurement. If the patient has more than one assessment, clicking on any assessment allows viewing of the corresponding report. A different assessment can be selected by pressing the arrow key or the tab key on the keyboard.

(5) **Report Types** – Choose a tab for the report type (Clinical, Detailed, Reference Range, and Wave Reflection) from the right side of the screen. Refer to *PWA Report* Types section for more information.

Deleting Reports

Each measurement is automatically saved in the database. Reports can be deleted, if desired, as follows:

1. Click on the assessment to be deleted. Click **Delete** and the following message will be displayed.



2. Click **Yes** to delete the assessment.

Note: Reports can be deleted at any time, not only at the time of creation.

Repeat the measurement

Click the **Repeat** button, which will only be enabled at the last assessment. This will perform another measurement on the same patient and create another assessment for the patient.

Print the Report

The **Print** buttons provide a choice of printed reports.

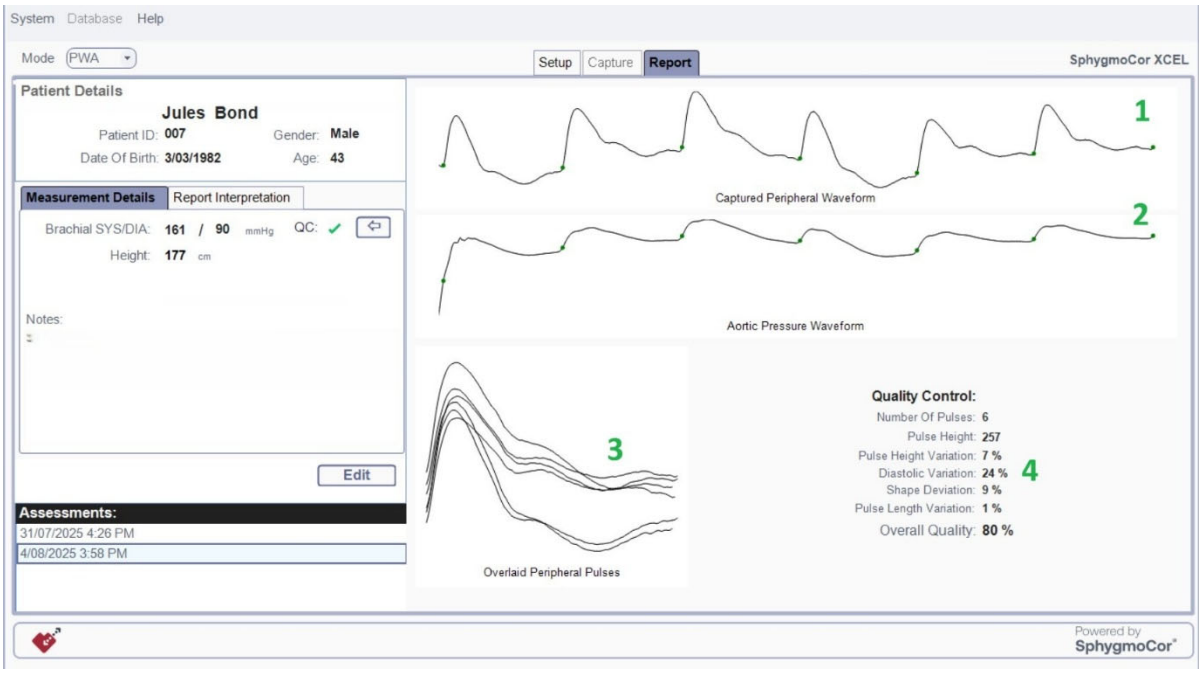


Physician Report – a single-page PWA Report of the report type selected (**5**).

Patient Report – a multi-page report that provides an explanation of the different PWA parameters. This report may not be available in some regions.

Quality Control Report (QC)

A QC Report of the captured waveform is shown by clicking ⇨ next to the **QC indicator** in the **Report** page. The QC Report includes the following information:



(1) Captured peripheral (brachial) waveform chart.

(2) Derived aortic pressure waveform chart.

(3) Overlaid peripheral (brachial) pulses.

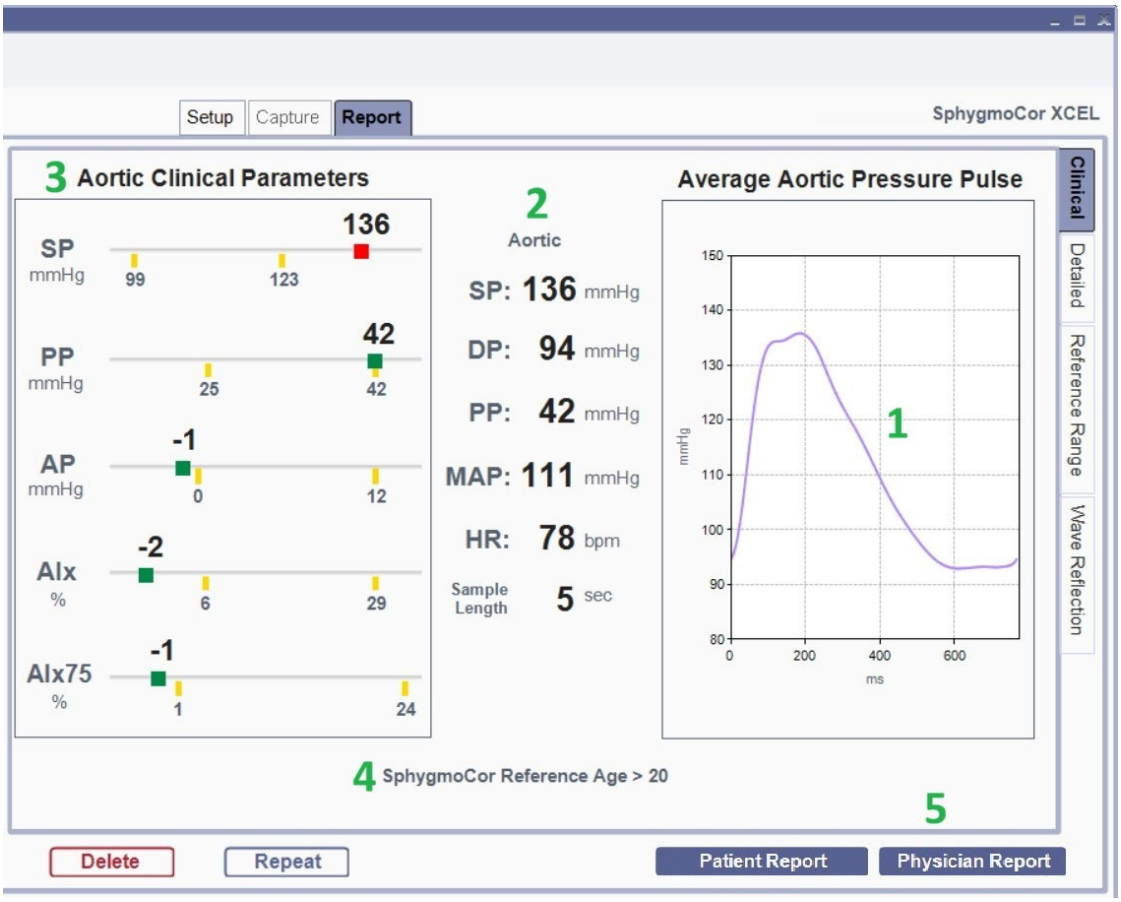
(4) Quality Control – Quality control indices quantifying the quality of the captured peripheral (brachial) waveforms listed as following:

- **Number of Pulses:** The number of pulses considered in the calculation.
- **Pulse Height:** The average pulse height of all the individual pulses in digital units.
- **Pulse Height Variation:** The average pulse height variation (in %) of all individual pulses from the average pulse.
- **Diastolic Variation:** The average diastolic or baseline variation (in %) of all individual pulses from the average pulse.
- **Shape Deviation:** The average waveform shape variation (in %) of individual pulses from the average pulse.
- **Pulse Length Variation:** The average pulse length variation (in %) of individual pulses from the average pulse.
- **Overall Quality:** A parameter quantifying the captured peripheral (brachial) waveform quality based on the Quality Control indices. For an Overall Quality value above or equal to 75%, the QC will be a green tick ✓ and for an Overall Quality value below 75%, the QC will be a red cross X.

PWA Report Types

Clinical

To view the Clinical Report, click the **Clinical** tab on the right side of the Report page. The Clinical Report contains the following information:



(1) **Average Central Aortic Pulse** – A graphical representation of the derived average aortic pressure pulse. The shape of the aortic pressure pulse is a result of the ventricular ejection and physical properties of the arterial system. The waveform shape changes with changes in arterial stiffness.

(2) **Aortic Parameters** – A summary representation of the derived average central pressure waveform parameters: **SP (Aortic Systolic pressure)** is the highest pressure value recorded in a pulse, **DP (Aortic Diastolic pressure)** is the lowest pressure value recorded in a pulse, **PP (Aortic Pulse Pressure)** is the height of the aortic pressure pulse, **MAP (Mean Arterial Pressure)** is the average pressure in a pulse and **HR (Heart Rate)** is the number of heart beats per minutes.

(3) **Aortic Clinical Parameters** – A bar graph representing the aortic clinical parameters in reference to a healthy population range based on the patient's age and gender:

- **SP:** Aortic Systolic Pressure (mmHg) is the maximum aortic pressure during cardiac ejection. A high aortic SP indicates high cardiovascular load. High arterial stiffness increases the reflected pressure wave in the arterial system, which augments or increases Aortic Systolic Pressure.
- **PP:** Aortic Pulse Pressure (mmHg) is the height of the aortic pressure pulse. PP can also be described as the difference between the maximum and minimum of the aortic pressure pulse, or the Aortic Systolic pressure minus the Aortic Diastolic pressure. High aortic PP has been shown to predict cardiovascular events[1].
- **AP:** Aortic Augmented Pressure (mmHg) is the difference between the two aortic pressure peaks during ejection (systole). AP is a measure of wave reflected back from lower body. The value of AP is affected by both the magnitude and speed of the reflected wave, which is an indicator of arterial stiffness. With aging, the arteries become stiffer, consequently, wave reflection increases, leading to increased Aortic Augmented Pressure and resulting in increased risk of cardiovascular disease or organ damage[2].
- **AIx:** Augmentation Index (%) is the ratio of AP to PP. Studies have shown that patients with diabetes tend to have high AIx, indicating stiffer arteries and higher risk of organ damage[3].
- **AIx 75:** The AIx is normalised for a heart rate of 75 beats per minute. AIx75 enables comparison of reports from patients with different heart rates, and enables comparison of arterial stiffness between visits of the same patient.

(4) **SphygmoCor Reference Age** – Estimated arterial age based on the average aortic pressure parameters of a healthy population. The patient's height must be entered on the set up screen, or the message "SphygmoCor XCEL reference age not calculated" will appear.

(5) **Printing a PWA Patient Report**
– Click **Patient Report**

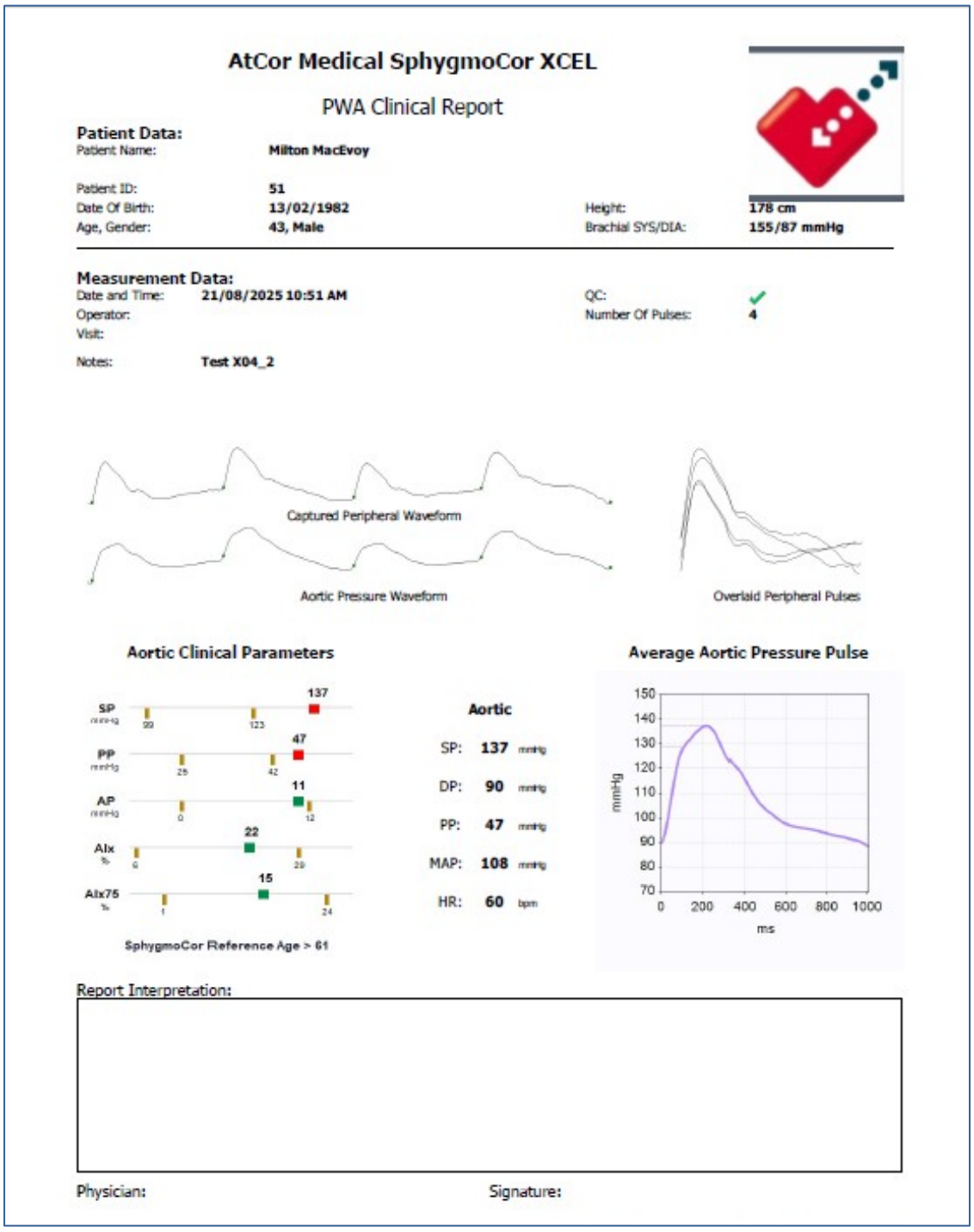
Printing a single-page PWA Report (Clinical)
– Click **Physician Report**

[1]Roman MJ, Devereux RB, Kizer JR, *et al*. High central pulse pressure is independently associated with adverse outcome. The Strong Heart Study. J Am CollCardiol 2009;54:1730-4.

[2] Chirinos et al Aortic Pressure Augmentation Predicts Adverse Cardiovascular Events in Patients With Established Coronary Artery Disease, Hypertension. 2005;45:980-985

[3] London et al Arterial Wave Reflections and Survival in End-Stage Renal Failure, Hypertension. 2001;38:434-438.

Printed single-page PWA Clinical Report Example:



AtCor Medical SphygmoCor XCEL

PWA Clinical Report

Patient Data:

Patient Name: **Milton MacEvoy**

Patient ID: **51**
Date Of Birth: **13/02/1982**
Age, Gender: **43, Male**
Height: **178 cm**
Brachial SYS/DIA: **155/87 mmHg**

Measurement Data:

Date and Time: **21/08/2025 10:51 AM**
Operator:
Visit:
QC: ✔
Number Of Pulses: **4**

Notes: **Test X04_2**

Captured Peripheral Waveform

Aortic Pressure Waveform

Overlaid Peripheral Pulses

Aortic Clinical Parameters

SP 137 (99 – 123)
PP 47 (25 – 42)
AP 11 (0 – 12)
AIx 22 (0 – 29)
AIx75 15 (1 – 24)

SphygmoCor Reference Age > 61

Aortic

SP: **137** mmHg
DP: **90** mmHg
PP: **47** mmHg
MAP: **108** mmHg
HR: **60** bpm

Average Aortic Pressure Pulse

mmHg: 150, 140, 130, 120, 110, 100, 90, 80, 70
ms: 0, 200, 400, 600, 800, 1000

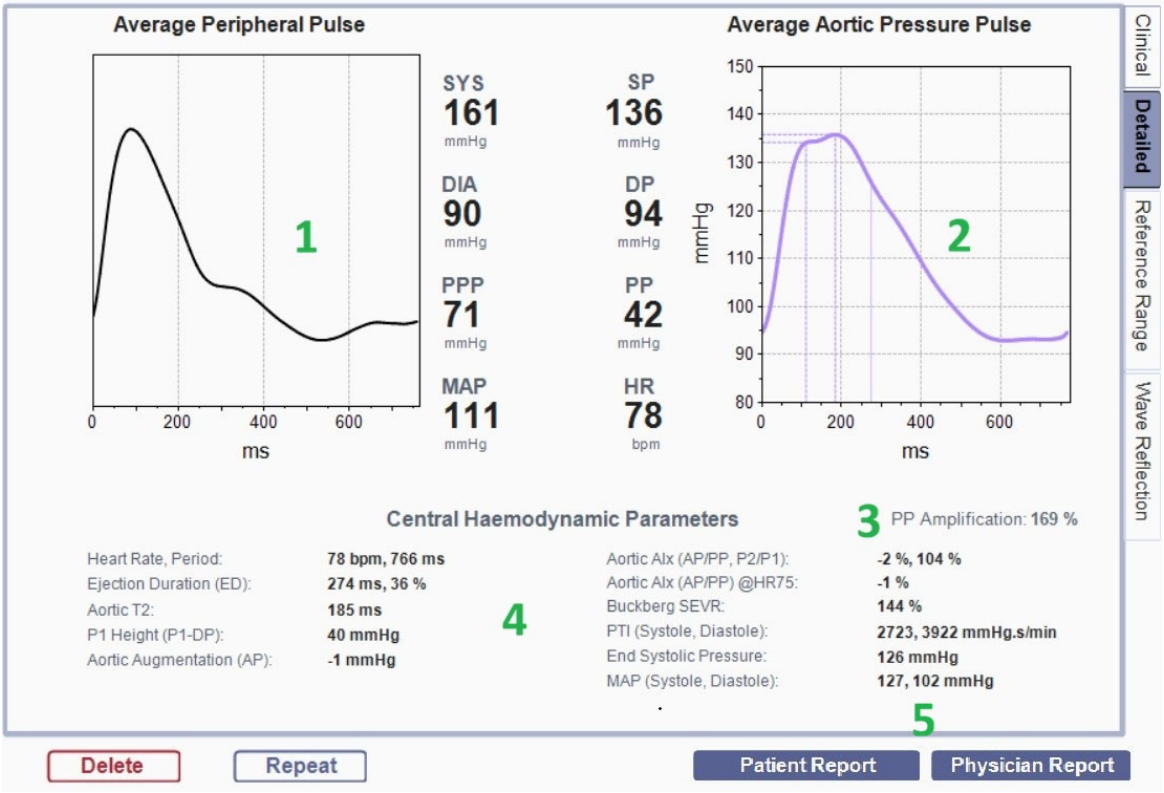
Report Interpretation:

Physician:

Signature:

Detailed

To view the Detailed Report, click the **Detailed** tab on the right side of the Report page. The Detailed Report contains the following information:



(1) **Average Peripheral Pulse-Brachial** – Graphical representations of the average of all brachial pressure pulses in the captured brachial waveform. A Summary Report of average peripheral pulse parameters is represented on the right side of the chart and includes:

- SYS (Peripheral Systolic Pressure in mmHg): Measured brachial systolic pressure or the highest pressure value in the average peripheral pulse.
- DIA (Peripheral Diastolic Pressure in mmHg): Measured brachial diastolic pressure or the lowest pressure value in the average peripheral pulse.
- PPP (Peripheral Pulse Pressure in mmHg): The height of the average peripheral pulse.
- MAP (Mean Arterial Pressure in mmHg): The mean pressure of the average peripheral pulse.

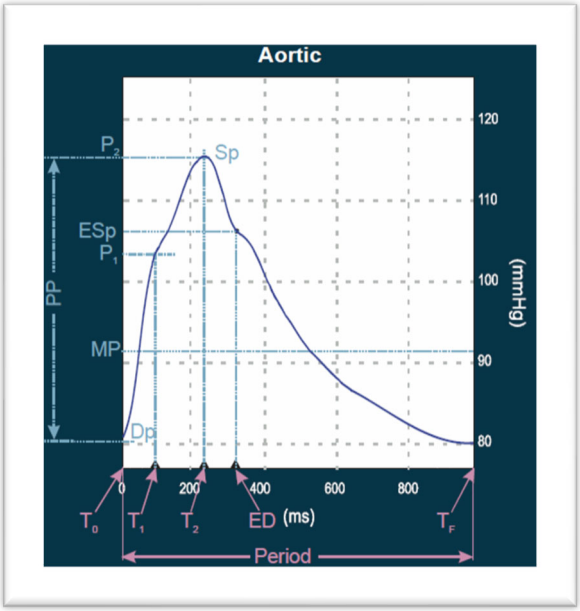
(2) **Average Aortic Pressure Pulse** – Graphical representations of the average of all aortic pressure pulses in the derived aortic pressure waveform. A Summary Report of the average aortic pressure pulse parameters is represented on the left side of the chart and includes:

- SP (Aortic Systolic Pressure in mmHg): The highest pressure value in the average aortic pulse.

- DP (Aortic Diastolic Pressure in mmHg): The lowest pressure value in the average aortic pulse.
- PP (Aortic Pulse Pressure in mmHg): The height of the average aortic pulse.
- HR (Average Heart Rate in bpm): The average number of heart beats per minute.

(3) **PP Amplification (PPP/PP) %** – The amplification of the peripheral pulse pressure (PPP) with respect to the aortic pulse pressure (PP).

(4) **Central Haemodynamic Parameters** – Central haemodynamic parameters calculated from **Average Aortic Pressure Pulse.**



- **Heart Rate, Period (HR, T_F)** – Heart Rate in beats per minutes (bpm) is the patient's average heart rate over the capture time. Period in millisecond (ms) is the length of an averaged derived central pulse.
- **Ejection Duration (ED)** – Ejection Duration is the period of time in milliseconds and in percentage to the full cardiac period from the start of the pulse for which the aortic valve is open (T_0) to the closure of the aortic valve (ED), End of Systole.
- **Aortic T2** (in millisecond) – Aortic T2 is the duration from the start of the pulse to the 2nd systolic peak (P2).
- **P1 Height (P1-DP) (P1H)** – **P1** Height in mmHg is the Primary wave Pressure at T1 which is the difference between the minimum pressure and the pressure at the first systolic peak (P1).
- **Aortic Augmentation (AP)** – The augmented pressure (AP) in mmHg is the difference between the first systolic peak pressure (P1) and second systolic peak pressure (P2).
- **Aortic AIx (AP/PP, P2/P1)** – Aortic Augmentation Index calculated using two different ratios (in %):

  - **AIx (AP/PP)** – The ratio of the augmented pressure (AP) to the pulse pressure (PP).

- **AIx (P2/P1)** – The ratio of the reflected peak (second systolic peak pressure P2) to the primary peak (first systolic peak pressure P1)

- **Aortic AIx (AP/PP) @HR75 in %** – Aortic Augmentation Index (AIx (AP/PP)) adjusted to a standard heart rate of 75 beats per minute.
- **Buckberg SEVR (SEVR %)** – Buckberg SEVR ratio also known as the subendocardial viability ratio, is the ratio of the **Diastolic Area** to the **Systolic Area** of the pressure pulse reflecting cardiac blood supply to organ's demand ratio.

- **PTI (Systole, Diastole) in mmHg.s/min** – **Pressure** Time Index (PTI) is the area under the pressure pulse. PTI (Systole) is area under the pressure pulse during systole per minute. This area is related to the work of the heart and oxygen consumption. PTI (Diastole) is the area under the pressure pulse during diastole per minute. PTI (Diastole) is associated with the pressure and time for coronary perfusion, and so is related to the energy supply of the heart.
- **End Systolic Pressure (ESP) in mmHg** – **The** pressure at the end of systole.
- **MAP (Systole, Diastole) in mmHg-** Mean Arterial Pressure during systole is the mean pressure between T_0 to ED and mean arterial pressure during diastole is the mean pressure between the ED and the end of the averaged pulse (T_F).

(5) **Printing a PWA Patient Report**

– Click **Patient Report**

Printing a single-page PWA Report (Detailed)

– Click **Physician Report**

Printed single-page PWA Detailed Report Example:

AtCor Medical SphygmoCor XCEL

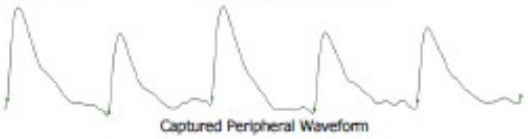
PWA Detailed Report

Patient Data:

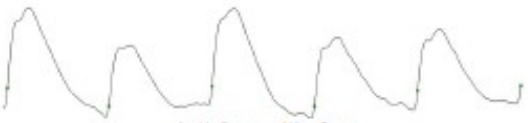
Patient Name:	**Vladimir Tromp**		
Patient ID:	**99**		
Date Of Birth:	**13/02/1982**	Height:	**178 cm**
Age, Gender:	**43, Male**	Brachial SYS/DIA:	**170/94 mmHg**

Measurement Data: QC: ✓

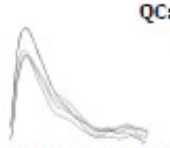
Date and Time: **22/08/2025 2:59 PM**



Captured Peripheral Waveform



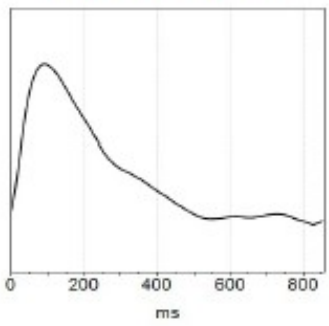
Aortic Pressure Waveform



Overlaid Peripheral Pulses

Number Of Pulses:	**5**
Pulse Height:	**259**
Pulse Height Variation:	**9 %**
Diastolic Variation:	**10 %**
Shape Deviation:	**2 %**
Pulse Length Variation:	**1 %**
Overall Quality:	**90 %**

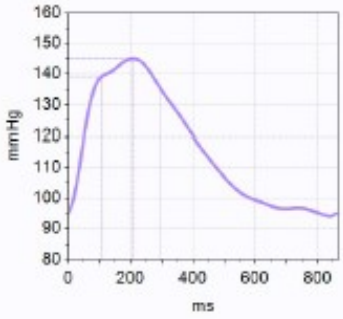
Average Peripheral Pulse



SYS	**170** mmHg
DIA	**94** mmHg
PPP	**76** mmHg
MAP	**116** mmHg

Average Aortic Pressure Pulse

SP	**145** mmHg
DP	**95** mmHg
PP	**50** mmHg
HR	**70** bpm



PP Amplification: **153 %**

Central Haemodynamic Parameters

Heart Rate, Period:	**70 bpm, 859 ms**	Aortic AIx (AP/PP, P2/P1):	**12 %, 113 %**
Ejection Duration (ED):	**297 ms, 35 %**	Aortic AIx (AP/PP) @HR75:	**10 %**
Aortic T2:	**209 ms**	Buckberg SEVR:	**150 %**
P1 Height (P1-DP):	**44 mmHg**	PTI (Systole, Diastole):	**2777, 4174 mmHg.s/min**
Aortic Augmentation (AP):	**6 mmHg**	End Systolic Pressure:	**135 mmHg**
		MAP (Systole, Diastole):	**134, 106 mmHg**

Reference Range

To view the Reference Range Report, click the **Reference Range** tab on the right side of the Report page. The Reference Range Report contains the following information:



The population reference data [4] graphs associated with each parameter are represented indicating the patient's position relative to the reference population data. On each graph, the green line indicates the reference population mean and the red lines indicate the 90% confidence interval on either side of that mean. The reference range for the Central Systolic Pressure (SP), Central Augmented Pressure (AP), Central Pulse Pressure (PP) and Central Augmentation Index (AIx) are plotted by age (years). The Ejection Duration (ED %) and SEVR (%) are plotted by Heart Rate (bpm).

[4] London et al Arterial Wave Reflections and Survival in End-Stage Renal Failure, Hypertension. 2001;38:434-438.
The Anglo-Cardiff Collaborative Trial (ACCT), Am Coll Cardiol 2005;46:1753– 60

(1) **Central Systolic Pressure (SP)** – Central Systolic Pressure (SP) is the highest blood pressure measured during an average heartbeat at the heart (not at the arm). This graph shows the patient's central systolic pressure value by patient's age relative to the reference population central systolic pressure from 20-90 years old.

(2) **Central Augmented Pressure (AP)** – Central Augmented Pressure (AP) is the additional pressure measured at the heart due to the stiffness of the arteries. The lower AP is indicator of less stiff arteries. This graph shows the patient's central augmented pressure value by patient's age relative to the reference population central augmented pressure from 20-90 years old.

(3) **Central Pulse Pressure (PP)** – Central Pulse Pressure (PP) is the difference between central systolic pressure (SP) and central diastolic pressure. It represents the change in pressure in central aortic artery. This graph shows the central pulse pressure value by patient's age relative to the reference population central pulse pressure from 20-90 years old.

(4) **Central Augmentation Index (AIx)** – Central Augmentation Index (AIx) is the amount of augmented pressure (AP) in reference to central pulse pressure (PP). Central Augmentation Index is another measure of arterial stiffness. The lower AIx is an indicator of less stiff arteries. This graph shows the central augmentation index value by patient's age relative to the reference population central augmentation index from 20-90 years old.

(5) **Ejection Duration (ED %)** – The Ejection Duration (ED %) is the duration of the ventricular ejection. It is the period of time from the start of the pulse for which the aortic valve is open to the closure of aortic valve (incisura), end of systole. This graph shows the ejection duration value by patient's heart rate relative to the reference population ejection duration with heart the rate range of 40-100 beats/min.

(6) **SEVR (%)** – The Sub-endocardial Viability Ratio (SEVR %) is the ratio of cardiac blood supply to organ's demand. This graph shows the SEVR value by the patient's heart rate relative to the reference population SEVR with the heart rate range of 40-100 beats/min.

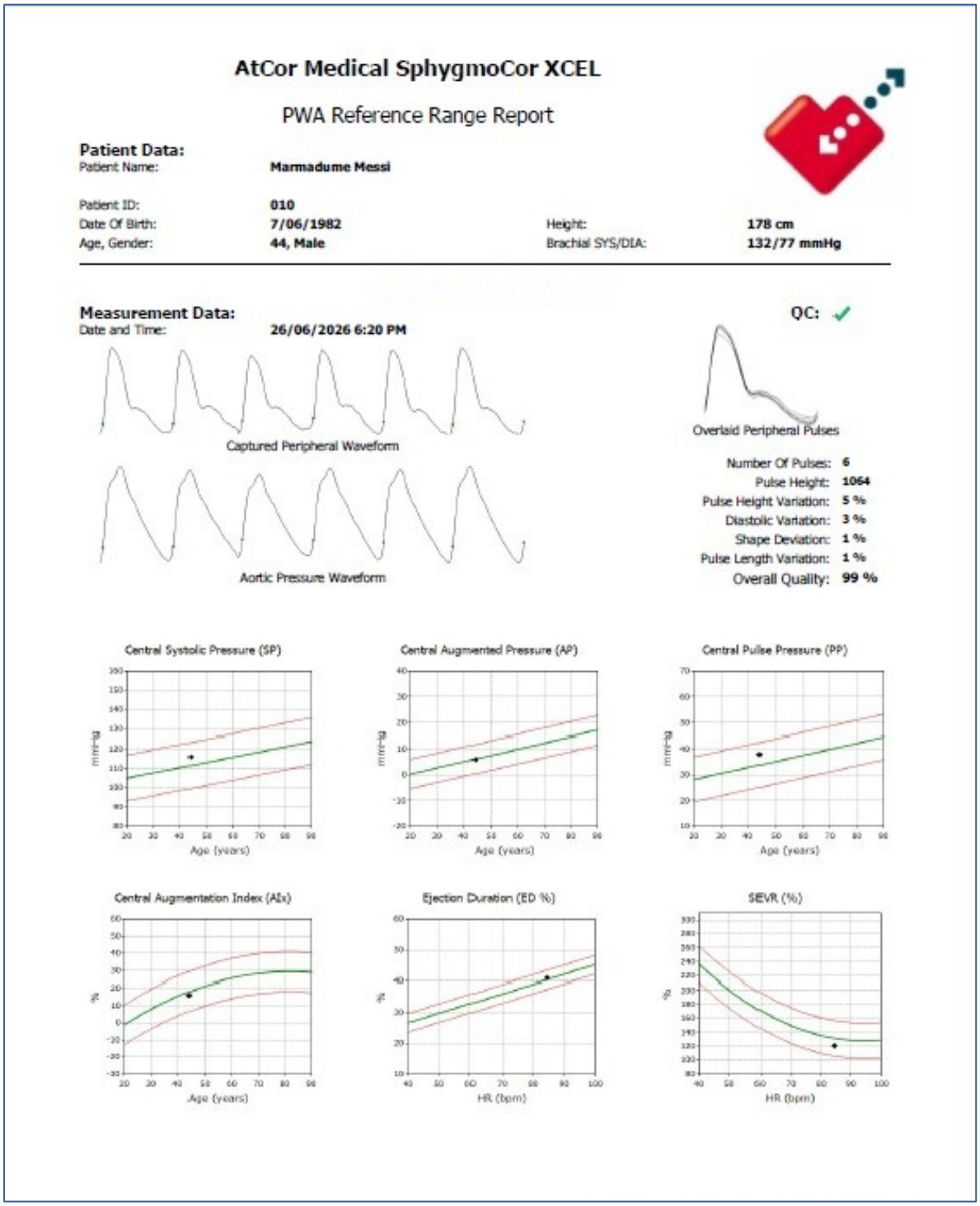
(7) **Printing a PWA Patient Report**

– Click **Patient Report**

Printing a single-page PWA Report (Reference Range)

– Click **Physician Report**

Printed single-page PWA Reference Range Report Example:



AtCor Medical SphygmoCor XCEL

PWA Reference Range Report

Patient Data:

Patient Name: **Marmadume Messi**

Patient ID: **010**
Date Of Birth: **7/06/1982**
Age, Gender: **44, Male**
Height: **178 cm**
Brachial SYS/DIA: **132/77 mmHg**

Measurement Data:

Date and Time: **26/06/2026 6:20 PM**

QC: ✓

Captured Peripheral Waveform

Aortic Pressure Waveform

Overlaid Peripheral Pulses

Number Of Pulses: **6**
Pulse Height: **1064**
Pulse Height Variation: **5 %**
Diastolic Variation: **3 %**
Shape Deviation: **1 %**
Pulse Length Variation: **1 %**
Overall Quality: **99 %**

Central Systolic Pressure (SP)

Central Augmented Pressure (AP)

Central Pulse Pressure (PP)

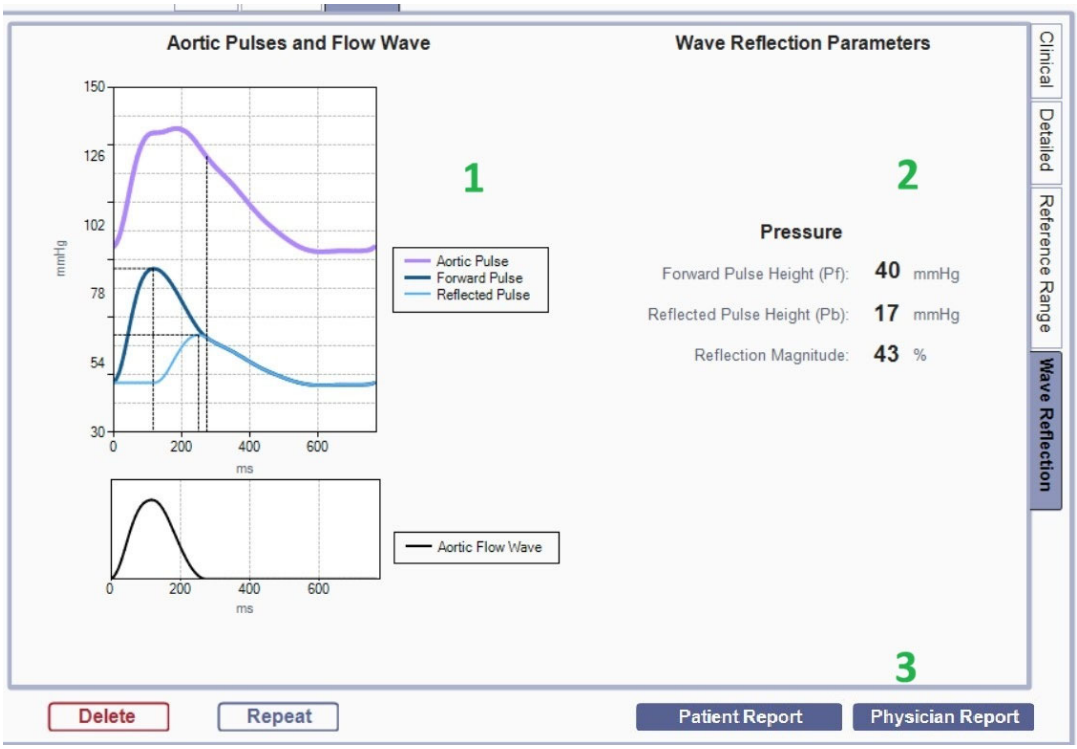
Central Augmentation Index (AIx)

Ejection Duration (ED %)

SEVR (%)

Wave Reflection

To view the Wave Reflection Report, click the **Wave Reflection** tab on the right side of the Report page. The Wave Reflection Report contains a graphical representation of the aortic pulse including forward and reflected pulses and a flow wave as well as wave reflection parameters.



(1) **Aortic Pulses and Flow Wave** – The central aortic pressure waveform is shown in blue. This waveform is the sum of two pressure waveforms: the pulse wave generated by cardiac ejection is called Forward Pulse shown in green and the pulse wave reflected from the arteries back to the heart is called Reflected Pulse shown in orange. Aortic flow wave resulting from the separation of forward and reflected pulses is also shown in black.

(2) **Wave Reflection Parameters** – The parameters of the reflected waveform.

- **Forward Pulse Height (Pf):** The height of forward pulse wave.
- **Reflected Pulse Height (Pb):** The height of reflected pulse wave.
- **Reflection Magnitude:** The ratio of Reflected Pulse Height to Forward Pulse Height in percentage.

(3) **Printing a PWA Patient Report**
– Click **Patient Report**

Printing a single-page PWA Report (Wave Reflection)
– Click **Physician Report**

Printed single-page PWA Wave Reflection Report Example:

AtCor Medical SphygmoCor XCEL

PWA Wave Reflection Report

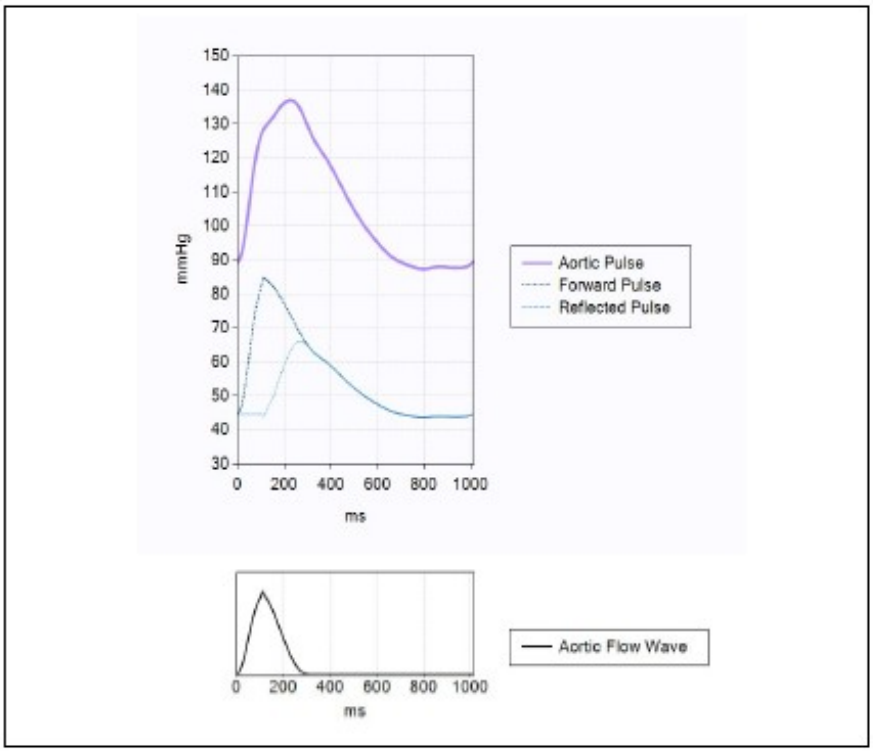
Patient Data:

Patient Name:	**Milli Pelosi**		
Patient ID:	**013**		
Date Of Birth:	**12/06/2001**	Height:	**221 cm**
Age, Gender:	**25, Female**	Brachial SYS/DIA:	**155/87 mmHg**

Measurement Data:

Date and Time: **8/07/2026 12:16 PM**

Aortic Pulses and Flow Wave



Wave Reflection Parameters

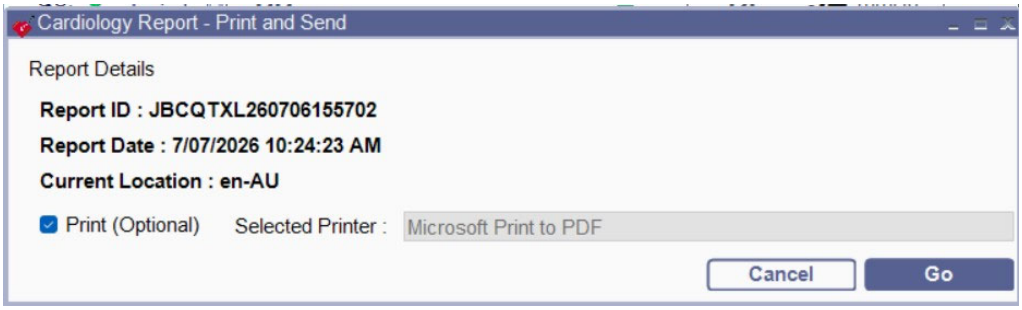
Forward Pulse Height (Pf):	**40**	mmHg
Reflected Pulse Height (Pb):	**21**	mmHg
Reflection Magnitude:	**52**	%

Patient Report

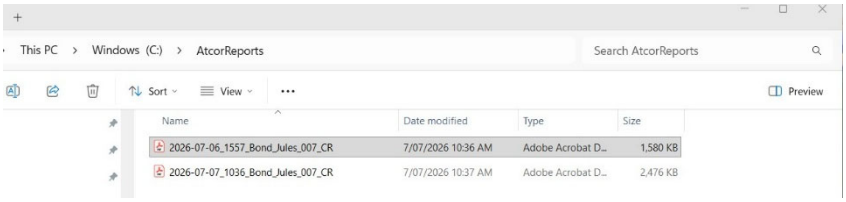
To print the multipage Patient Report, click the Patient Report button from any of the report tabs (Clinical, Detailed, Reference Range, or Wave Reflection).



Tick the box “Print (Optional)”.
When printing, the default printer will be used. To change the default printer, open the Windows Printer & Scanners menu under the Settings menu, and select the desired printer.
Press Go.



The report will be stored in the selected folder in the **System → Settings → Interface → Saved Reports Folder** setting. This should be set prior to creating a report.



Printed Patient Report Example

SphygmoCor®
Cardiovascular Risk Report

General Details

Name **Jules Bond** DOB **3rd March 1982 (44 yrs)** Sex **Male** Date of Report **06 July 2026**

Cardiovascular Risk Profile - Arterial Intelligence™

Low Cardiovascular Risk All measurements are within the normal range.	Intermediate Cardiovascular Risk 1 or more measurements are above the normal range.	High Cardiovascular Risk 1 or more measurements are above thresholds.
☐ Central Blood Pressure (SYS) is within or below normal range for your age.	☐ Central Blood Pressure (SYS) is above normal range for your age.	☑ Central Blood Pressure (SYS) is above a threshold of >130 mmHg.
☑ Central Pulse Pressure is within or below normal range for your age.	☐ Central Pulse Pressure is above normal range for your age.	☐ Central Pulse Pressure is above a threshold of >50 mmHg.
☑ Augmentation Pressure and Augmentation Index are within or below normal range for your age.	☐ Augmentation Pressure or Augmentation Index are above normal range for your age.	☐ Augmentation Pressure is >10 mmHg above normal or Augmentation Index is >10% above the normal range for your age.
☑ Pulse Pressure Amplification is ≥130%[1].		☐ Pulse Pressure Amplification is <130%[1].

Results & Clinical Trial Evidence

*For informational use only

Measurement	Central Blood Pressure[2]	Central Pulse Pressure[2]	Pulse Pressure Amplification[1]	Augmentation Pressure	Augmentation Index[2]
Threshold	>130 mmHg	>50 mmHg	<130 %[1]	Each 10 mmHg increase in AP	Each 10 % increase in AIx
Risk of CV Events[3]	3 times increased risk of CV events	2-3 times increased risk of CV events	2-3 times increased risk of CV events	Increases the risk of CV events by 30%	Increases the risk of CV events by 35-40%

A 4-mmHg reduction in central pressure can lower CV risk by 20%. Beyond lifestyle changes, reductions in arterial stiffness have been shown with ACE-inhibitors, calcium channel blockers, statins, PCSK9 inhibitors, and SGLT2 inhibitors.

Cardiovascular Risk Treatment Considerations

Coronary Artery Disease and Atherosclerosis Detection
- Coronary artery calcium score
- Coronary CT Angiography (CCTA)
- Artificial intelligence coronary plaque phenotyping (e.g., Cleerly)
- Carotid artery ultrasound

Advanced Cholesterol and Metabolic Profiling
- Lipid particle size, Lp(a)
- hsCRP, ApoB
- Insulin resistance, HbA1c
- Homocysteine, testosterone, and estrogen

1. Huang QF, An DW, Aparicio LS, et al. An outcome-driven threshold for pulse pressure amplification. Hypertens Res. 2024;47(9):2478-2488. doi:10.1038/s41440-024-01779-4. **5,204 patients followed for 4 years.** The threshold presented is intended solely for informational purposes and should not be used to guide clinical decisions or actions.
2. Vlachopoulos C, Aznaouridis K, O'Rourke MF, Safar ME, Baou K, Stefanadis C. Prediction of cardiovascular events and all-cause mortality with central haemodynamics: a systematic review and meta-analysis. Eur Heart J. 2010;31(15):1865-1871. doi:10.1093/eurheartj/ehq024. **5,648 patients followed for 4 years.**
3. CV events are defined as a myocardial infarction, coronary revascularization, stroke, heart failure, or CV mortality.

Viewing PWA Reports

Measurements from previous sessions can be displayed at any time.

1. Select the **Report** tab.
2. Select the session from the **Assessments** list.
3. Select one of the four report types (Clinical, Detailed, Reference Range, Wave Reflection) from the right side of the screen.

Analysis of Multiple PWA Reports for the Same Patient

The Analysis feature can be used to compare multiple measurements for a selected patient. At least 2 assessments are required to use this feature, and a maximum of 30 measurements can be compared.

1. Select **PWA**.
2. Click **Report**.
3. Select the first assessment for comparison (click the corresponding date under the Assessment heading).
4. Press **Ctrl** and select another assessment. You can also select multiple assessments with the left mouse button, by holding and dragging to select as desired. Check the Analysis screen to make sure the assessments included for analysis are the same as your desired assessments. The number of blue dots on Central SP graph shows the number of assessments included in the analysis, with the the date and time of assessment is noted on the x axis.

   Note: To select a new set of assessments for analysis, click once on any of the assessment in the Assessment section and follow the same procedure from step 3

5. The selected assessments are plotted.



6. (Optional) Click **Print** to print a copy of the Analysis Report.
7. Select the **Setup** tab to exit the assessment screen, or click on any assessment to return to the report screen.

Techniques for Obtaining Quality PWA Measurements

Control Conditions

When performing a SphygmoCor XCEL measurement, it is recommended that the patient:

- Abstain from alcohol for at least 6 hours prior to the measurement.
- Abstain from tobacco and caffeine for at least 4 hours prior to the measurement.
- Fast for at least 6 hours prior to the measurement, however, if this cannot be achieved, a light meal before the measurement is allowed.
- Rest (seated or supine position) comfortably, for at least 5 minutes prior to the measurement.
- Has their back and arm supported during the measurement.
- Be as relaxed as possible and not talk during the measurement
- When possible, subsequent measurements should be obtained at the same time of the day so as to account for the diurnal blood pressure effect.

Note: Blood pressure can be affected by the measurement site, the position of the patient (standing, sitting, lying down), exercise, or the patient's physiological condition.

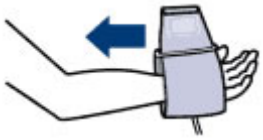
Cuff Placement

1. Select a cuff that is an appropriate size for the patient’s limb.

Each cuff has a size range marked on the inside. Brachial cuffs also have an index mark on the end. When wrapped around the patient's arm the index mark must fall within the marked range. If it is outside this range, select a different cuff.

2. Place the cuff on the upper arm, centred on the brachial artery. Palpate the brachial artery if necessary in order to locate accurately the artery.

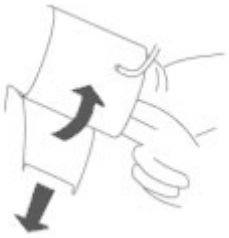
   The cuff should be placed on bare arm. Remove tight, bulky clothing from the upper arm to prevent constriction



3. Hold the cuff open with the tube pointing downward. Slide the cuff onto the upper arm.



4. Position the cuff with the artery marker over the brachial artery and aligned with the patient's small finger. The cuff should be as high as possible on the arm.



5. Fasten the cuff so it is snug, but not too tight. Two fingers should fit between the patient's arm and the cuff.
6. Position the arm to ensure that the cuff (i.e., middle of the cuff) and the heart are at the same level.

Note: Avoid compression or restriction of the connection tubing

Recording a PWV Measurement

Components and Accessories for PWV

 	**SphygmoCor XCEL device** – the SphygmoCor microprocessor-controlled module for waveform capture and analysis. Refer to *SphygmoCor XCEL Device Status Indications* for an explanation of the panel indicators.
	**Tonometer** – the non-invasive pressure sensing device for measuring carotid pressure. Part number: T-03C - SphygmoCor Tonometer, XCEL
	**Femoral cuff** (light blue) – a large, thin pneumatic cuff with a connector for the SphygmoCor XCEL device Part number: 1-00897 - PWV Cuff Adult 1-00898 - PWV Cuff Large Adult

	**Cuff Hose-** 2m cuff hose with connectors at both ends Part number: 1-00864 - Cuff Hose 2m
	**Power supply** – an AC power adaptor for the SphygmoCor XCEL device. Always use the power supply provided by AtCor Medical with your SphygmoCor XCEL device. Part number: 1-01191 - Medical Power Adaptor (Mean Well – PN GSM36B15-R7B)
	**USB cable**: connects SphygmoCor XCEL device to PC or laptop. Part number: 1-00858 - USB Cable 2m

	**Tray (optional)** – provides storage of cuffs and tonometer, as well as a mounting platform for the SphygmoCor XCEL device (The storage tray is an optional component supplied by AtCor Medical.) Part number: 1-00896 - EM4 Storage Tray

Connection of Components

Warning: Do not connect any power supply to the SphygmoCor XCEL device other than the power supply provided by AtCor.

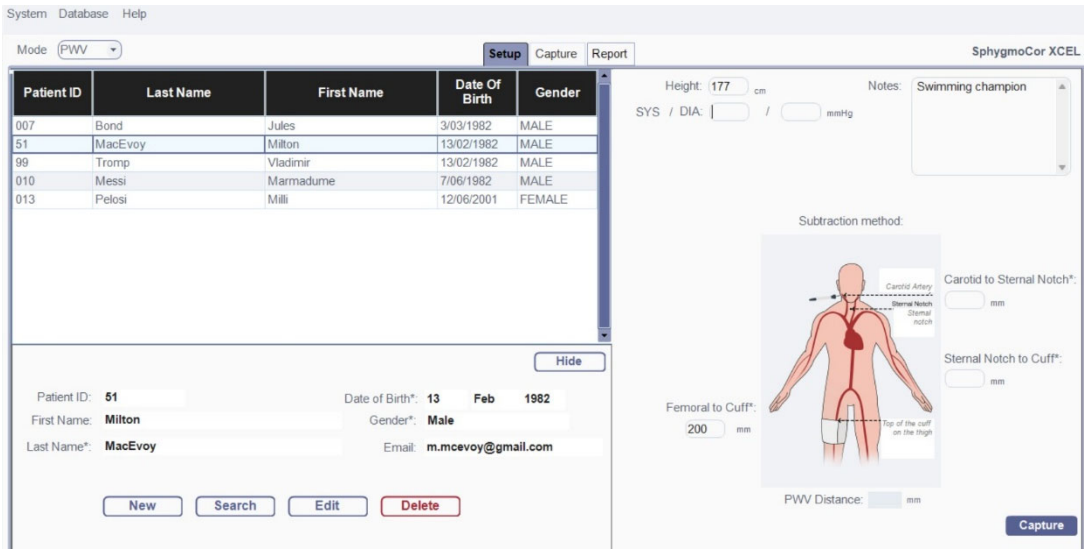
1. Connect the power supply to the SphygmoCor XCEL device and plug in the power supply cable to an AC power outlet.
2. Connect the SphygmoCor XCEL device to the PC using the USB cable.
3. Connect the tonometer to the SphygmoCor XCEL device.
4. Connect the femoral cuff to the SphygmoCor XCEL device.
5. Power on the SphygmoCor XCEL device.

Note: To disconnect the tonometer, gently push back the connector plug and the connector will automatically release away from the module. DO NOT twist the Tonometer connector.

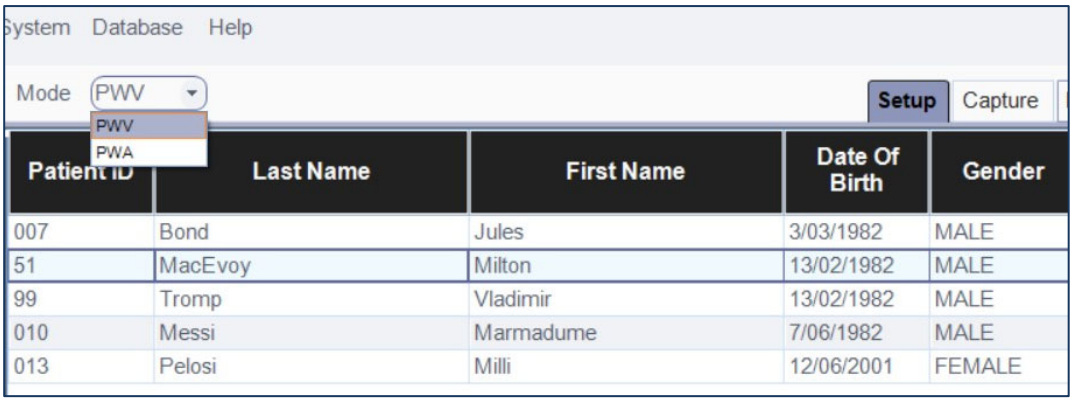
Start the Measurement

Note: The patient's limb movement should be minimised while capturing data as movement may prevent the capture from being completed or reduce quality of the measurement.

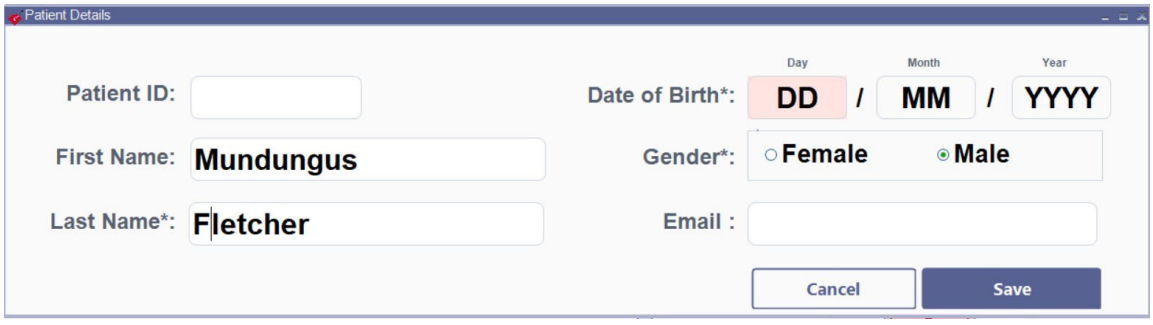
1. Select the Setup screen.



2. Select **PWV** mode. (Only required if you have a license for PWA as well).



Select the patient (by searching Patient ID, Name or Date of Birth, if necessary). If the patient does not exist in the database, create a new patient record by clicking **New** and entering the patient details. Mandatory fields are indicated by *.



3. If the patient's measurement is to be compared to the European General population, the brachial systolic and diastolic pressures should be entered. The brachial pressure obtained from a PWA measurement may be used (if applicable) or from a measurement using a validated sphygmomanometer.
4. Position the femoral cuff around the patient's thigh, as high as possible.

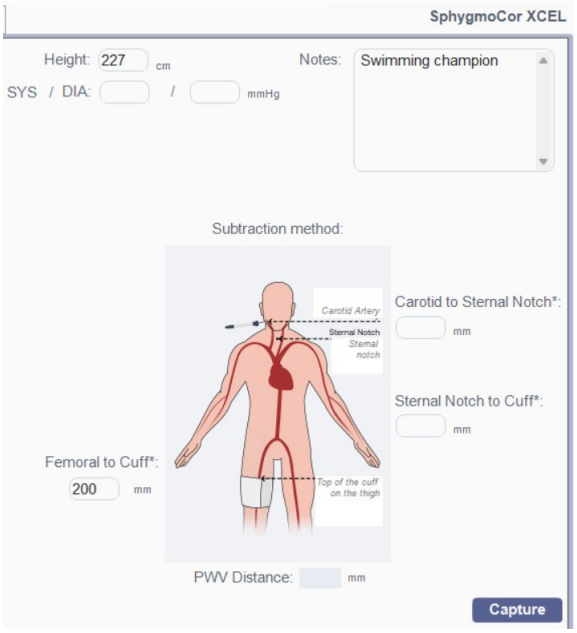
5. Measure the PWV Distance

Note: The default setting for the femoral to cuff distance is 200mm. To improve the accuracy of the PWV reading, measure the distance from the top edge of the cuff to the femoral artery, and enter this distance in place of the default. The default setting of 200mm can be changed in the PWV settings menu.

To determine the PWV Distance using the **subtraction method**:

First, measure the *Sternal Notch to Cuff* (top edge of the cuff to the sternal notch) distance in mm using a tape measure, and enter this value into the box marked "**Sternal notch to cuff**". Typical values are between 400 and 700 mm. Next, measure the distance between the *Carotid and the Sternal Notch* in mm, and enter this value in the box marked **"Carotid to Sternal notch".**

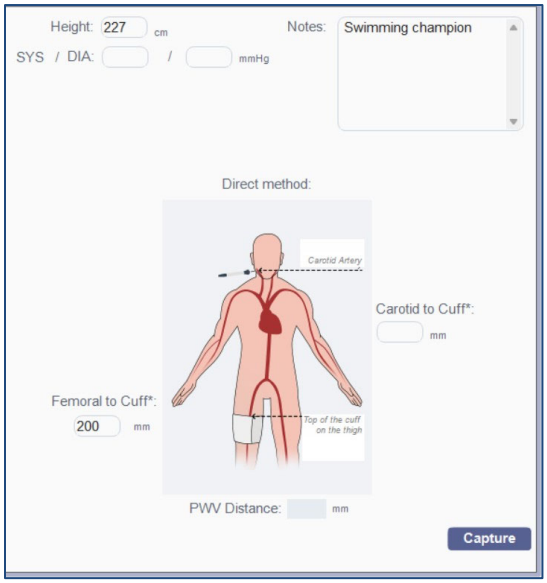
Enter the measured **"Femoral to cuff distance"**, if applicable. The PWV distance that will be used in the calculation will be displayed below the diagram.



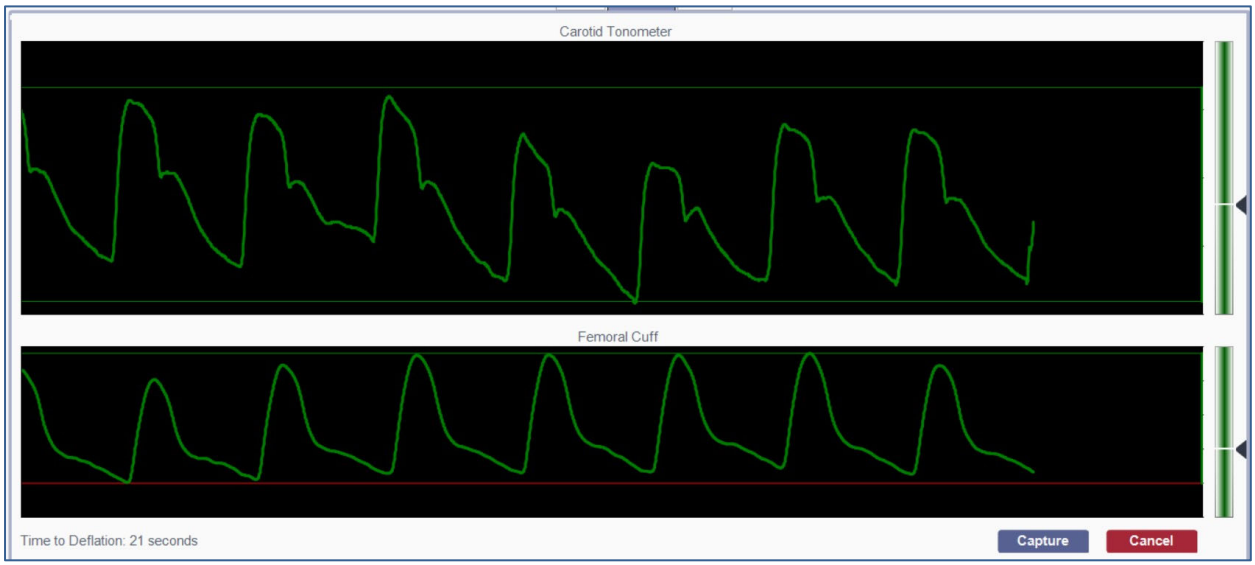
An alternative method of determining the PWV distance is the **direct method**:

Measure the *Carotid to Cuff* (top edge of the cuff to the carotid artery) distance in mm using a tape measure, and enter this value into the box marked "**Carotid to Cuff"**. Typical values are between 500 and 800 mm.

Enter the measured "**Femoral to Cuff distance"** if you do not want to use the default value. The PWV distance that will be used in the calculation will be displayed below the diagram.



6. Locate the patient's carotid pulse and position the tip of the tonometer on it. Once the SphygmoCor XCEL system detects a regular carotid pulse, the femoral cuff will be inflated. As soon as the detection period for both the carotid and femoral pulses is complete, the waveforms will turn green and a report will be generated for this measurement. The cuff will then deflate.



Note: The tonometer provides un-calibrated pressure pulse signals. The carotid waveforms displayed are only for qualitative purposes.

If **Cuff/Tonometer Sync** mode is turned off (selected in the PWV settings menu), measure the carotid signal using the tonometer. When the signal quality is valid (the waveform signal colour changes to green), click **Capture** to inflate the femoral cuff and obtain both the carotid and

femoral waveforms. The **Capture** button is enabled when there are sufficient signals from the carotid and femoral arterial sites.

Note: For best results, click the Capture button when both waveforms are green.

Once capture is complete, the PWV Report screen is automatically displayed.

Reviewing the PWV Report



Report data

(1) **Pulse Wave Velocity** – displays femoral and carotid arterial pulses that were recorded during the measurement. The carotid waveform is displayed in blue femoral waveform is displayed in black.

Each waveform has status markers indicating the start of each pulse. A green marker indicates that the pulse was used in the PWV calculation. A red marker indicates that the pulse was not used in the PWV calculation.

(2) **Healthy Population graph** – this shows the patient's overall result in the context of other healthy people of the same age (using data obtained by the University of Cambridge, UK[5]).

[5] McEniery et al Normal Vascular Aging: Differential Effects on Wave Reflection and Aortic Pulse Wave Velocity: The Anglo-Cardiff Collaborative Trial (ACCT), Am Coll Cardiol 2005;46:1753– 60

(3) **European General Population graph** – this shows the patient's overall results in the context of a general population that included -patients with diabetes[6].

(4) **Heart Rate** – average heart rate in beats per minute during the measurement.

(5) **Pulse Wave Velocity** – carotid femoral pulse wave velocity in meters/second (m/s), calculated as the distance divided by the pulse transit time. PWV is averaged over the reading.

(6) **Pulse Transit Time** – time for the pulse to travel from the central arteries to the femoral artery, in milliseconds. The time is measured from the foot (start) of each pulse. The Pulse transit time is averaged over the reading.

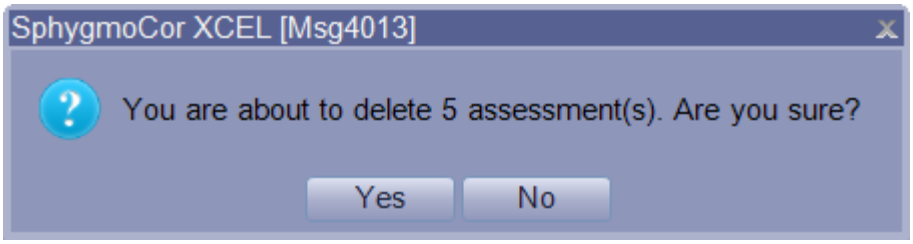
(7) **QC**– Quality Control of the PWV measurement. QC is an indicator of PWV pulse-to-pulse variability over the recording period. High PWV variability indicates a potentially inaccurate PWV measurement as the pulse transit time may not be accurate. An inaccurate measurement is marked with a red cross and the measurement should be repeated. Low PWV variability indicates a high-quality PWV measurement and is shown with a green tick (check mark). The QC indicator should be reviewed after every measurement.

(8) **Assessments** – after data capture is completed, the Report screen is automatically displayed. All measurements are automatically saved and can be viewed at any time by selecting the patient from the Patient screen and pressing the Report button. The most recent report is displayed. Each Measurement is stamped with the date and time of the measurement, with the oldest measurement listed first. If the patient has more than one assessment, clicking on any assessment allows viewing of the corresponding report. A different measurement can also be selected by pressing the arrow key or the tab key on the PC keyboard

Deleting Reports

Each measurement is automatically saved in the database. Reports can be deleted, if desired, as follows:

1. Click **Delete** to remove it from the database.



2. Click **Yes**.

Note: Reports can be deleted at any time.

[6] Boutouyrie et al, Determinants of pulse wave velocity in healthy people and in the presence of cardiovascular risk factors: 'establishing normal and reference values, European Heart Journal 2010 Oct;31(19):2338-50

Repeat the Measurement

Click the **Repeat** button, which will only be enabled at the last assessment, to perform another measurement on the same patient and create another assessment for the patient.

Return to Patient List

Click **Setup** (at the top of the screen) to return to the list of patients.

Viewing Multiple Reports with the Analysis Screen

Use Analysis to compare multiple sets of data for the selected patient.

1. Select **PWV** mode.
2. Click **Report**.
3. Select the first assessment (click on the date and time of the desired assessment).
4. Press **Shift** and select another assessment. If it is not adjacent to the first assessment, all of the assessments between these two are also selected.
5. The selected assessments are plotted on the screen.



6. (Optional) Click **Print** to print a copy of the PWV analysis Report.
7. Select the **Setup** tab to exit the assessment screen, or click on any assessment to return to the Report Screen.

Viewing PWV Reports

You can recall data from any previous session and display it as a report.

1. Select the **Report** tab.
2. Select the measurement from the **Assessments** list.

Printing PWV Reports

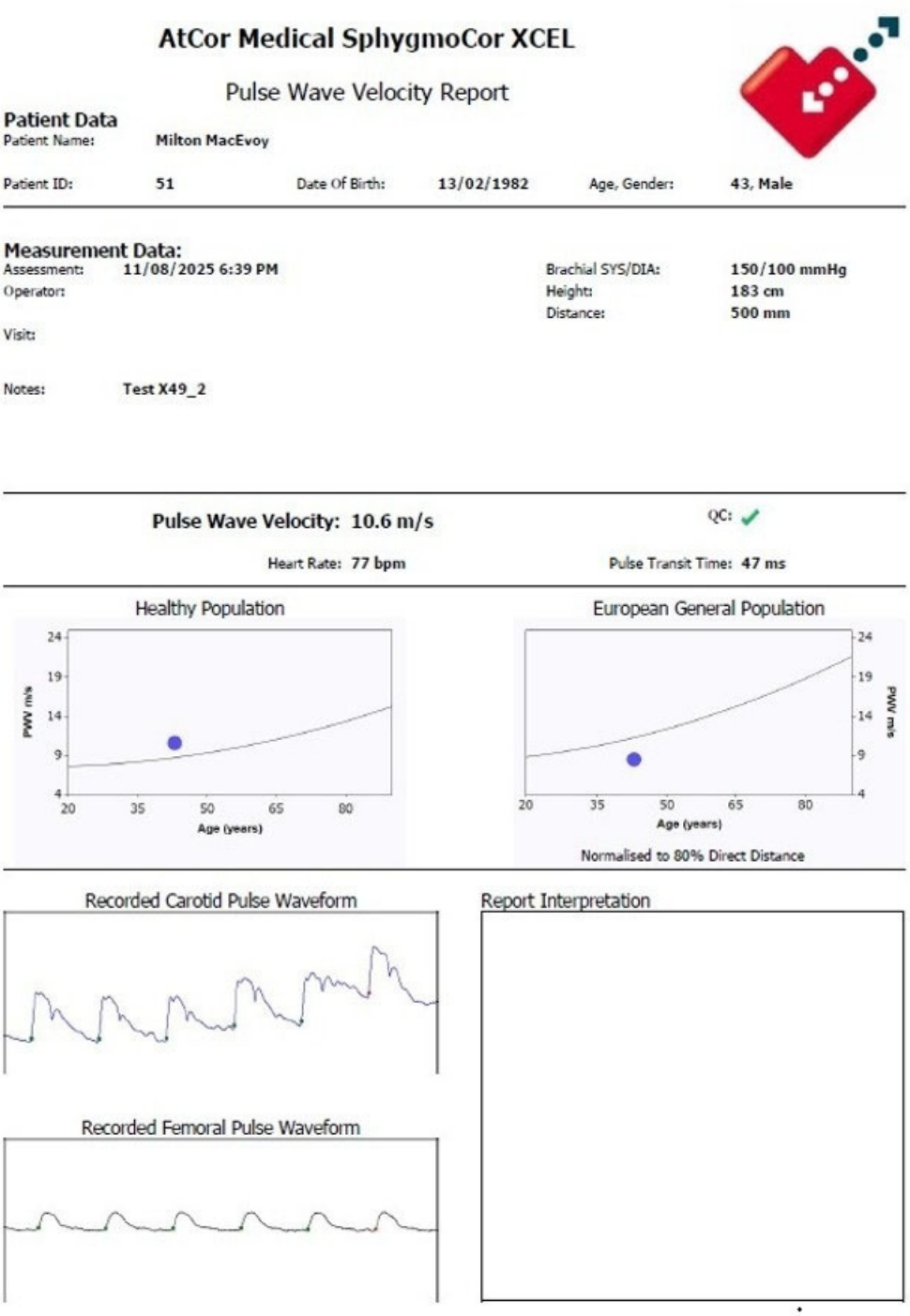
The below buttons provide a choice of printed reports.



Physician Report – print a single-page PWV Report.

Patient Report – produce a multi-page Report that provides an explanation of the different PWV parameters. This report may not be available in some regions.

Printed single page PWV Report Example



AtCor Medical SphygmoCor XCEL

Pulse Wave Velocity Report

Patient Data

Patient Name: **Milton MacEvoy**

Patient ID: **51** Date Of Birth: **13/02/1982** Age, Gender: **43, Male**

Measurement Data:

Assessment: **11/08/2025 6:39 PM**
Operator:
Visit:
Notes: **Test X49_2**

Brachial SYS/DIA: **150/100 mmHg**
Height: **183 cm**
Distance: **500 mm**

Pulse Wave Velocity: 10.6 m/s QC: ✔

Heart Rate: **77 bpm** Pulse Transit Time: **47 ms**

Healthy Population

European General Population

Normalised to 80% Direct Distance

Recorded Carotid Pulse Waveform

Recorded Femoral Pulse Waveform

Report Interpretation

AtCor Medical SphygmoCor XCEL

Pulse Wave Velocity Report

Patient Data

Patient Name: **Milton MacEvoy**

Patient ID: **51** Date Of Birth: **13/02/1982** Age, Gender: **43, Male**

Measurement Data:

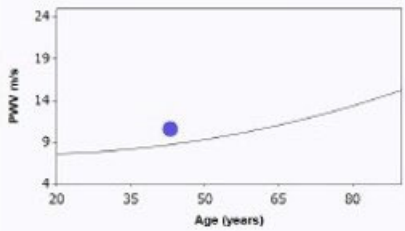
Assessment: **11/08/2025 6:39 PM**
Operator:
Visit:
Notes: **Test X49_2**

Brachial SYS/DIA: **150/100 mmHg**
Height: **183 cm**
Distance: **500 mm**

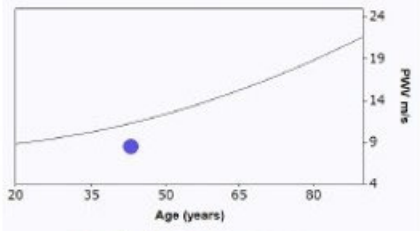
Pulse Wave Velocity: 10.6 m/s QC: ✔

Heart Rate: **77 bpm** Pulse Transit Time: **47 ms**

Healthy Population



European General Population

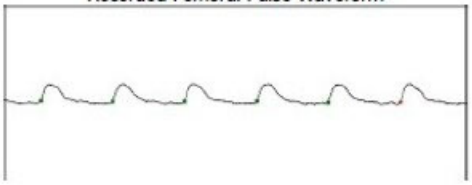


Normalised to 80% Direct Distance

Recorded Carotid Pulse Waveform



Recorded Femoral Pulse Waveform



Report Interpretation

Automatic versus Manual Waveform Capture

Carotid Waveform capture can be performed either automatically or manually.

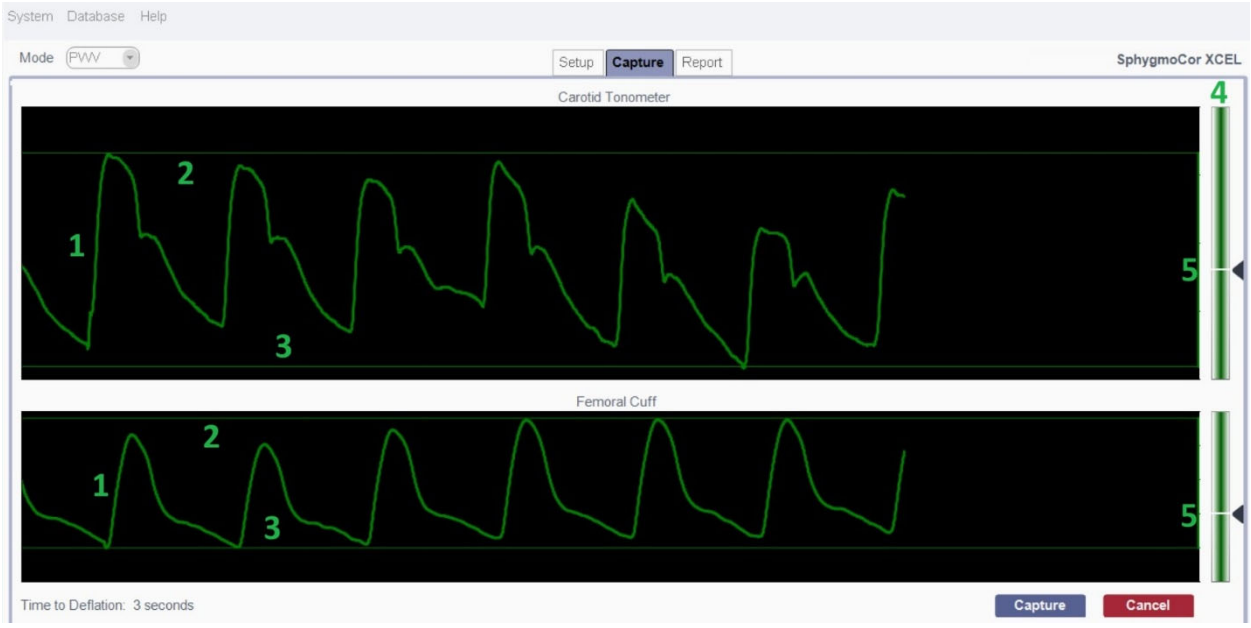
- If Auto Capture is enabled (default setting), the software will automatically capture the waveform when all of the quality parameters are met. Alternatively, the keyboard space bar can be pressed at any time to override the Auto Capture feature and capture the carotid waveform.
- If Auto Capture is disabled, data capture can be completed by manually pressing the spacebar on the computer keyboard when the minimum number of reliable pulses has been recorded and the capture button has become illuminated.

Using the Guidance Bars

SphygmoCor XCEL System provides feedback (guidance bars above and below the waveform) to aid in determining if the waveforms are consistent enough to provide an accurate PWV measurement.

As shown in the following diagram, there are multiple visual indications that provide feedback.

If Auto Capture is used (default setting), the data is captured automatically and calculation is performed to produce a report after the waveform colour changes to green. This indicates quality waveforms for the duration of the capture time. For PWV, both carotid tonometer and thigh cuff signals need to be green for the data to be automatically captured and a valid report produced. Data capture can be initiated at any time by clicking the **Capture** button, regardless of the waveform colour.



(1) Waveform – the waveform changes colour according to the quality of the overall recording during capture time. Initially, the waveform is white and changes to green if the quality of the overall recording during the capture time is acceptable and the recording has at least the

minimum number of quality pulses. This number varies according to the data capture duration selected in setup.

(2) Top guide bar – displayed at the top of the waveform, indicating reliability of the pulse peaks. It updates beat-by-beat. It is green if acceptable for data capture and red if not recommended for data capture. For the tonometer carotid signal only, it can also be yellow, indicating marginal data.

If the top guide bar of the tonometer signal is not green, apply more pressure to the tonometer. If that is not successful, try moving the tonometer slightly.

(3) Bottom guide bar – displayed at the bottom of the waveform, indicating reliability of the pulse troughs. It is green if acceptable for data capture and red if not recommended for data capture. For the tonometer only, it can also be yellow, indicating marginal data. Apply a consistent pressure on the tonometer to ensure that the signal remains green.

(4) Bar graphs – indicate signal amplitude, measured beat-by-beat. The amplitude must be above the threshold mark (**5)** to ensure a reliable signal.

The waveform colour is synchronised with the bar graph colour:

- when the waveform is green in colour, the bar graph is also green
- when waveform is white in colour, the bar graph is red in colour

Note: Guidance Bars and Auto Capture are part of the Capture Guide feature in the software. The default setting includes enabling of both Auto Capture and Guidance Bars. These features can be enabled or disabled from the System menu (refer to

PWV Settings)

Techniques for Obtaining Quality PWV Measurements

Fitting the femoral cuff

Correct fitting of the cuff helps to ensure a reliable reading. Use the following pictures as a guide.

Note: To ensure reliable readings, the thigh cuff should be placed over bare skin, or over thin clothing or material.

1. Place the cuff in position around the patient's upper thigh, with the tube on top of the leg and facing upwards (towards the patient's head).



2. Wrap the cuff firmly but not too tight.



3. Ensure the cuff fits neatly, as shown in this picture.



Control Conditions

When performing a SphygmoCor XCEL PWV measurement, it is recommended that the patient should:

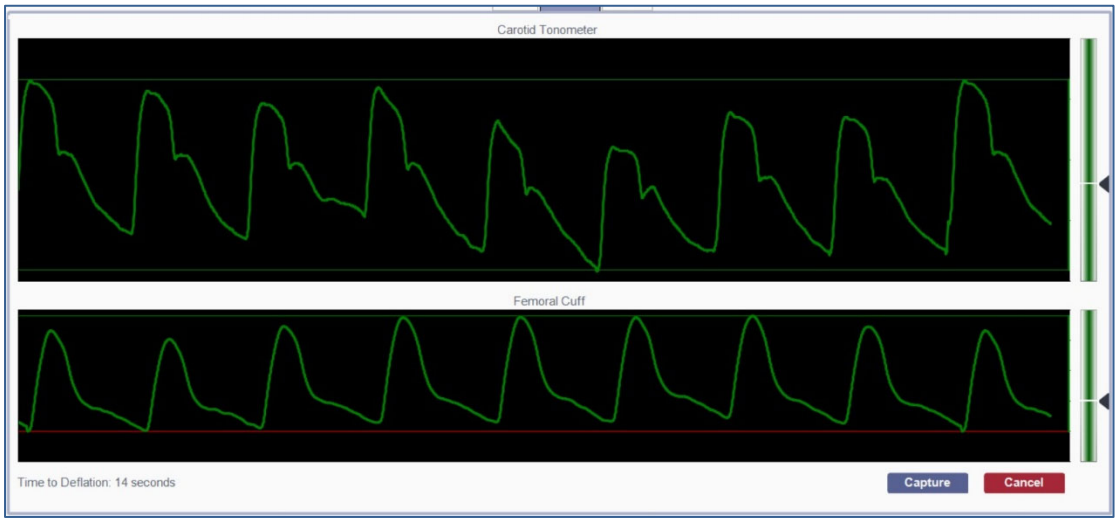
- Abstain from alcohol for at least 6 hours prior to the measurement.
- Abstain from tobacco and caffeine for at least 4 hours prior to the measurement.
- Fast for at least 6 hours prior to the measurement, however, if this cannot be achieved, a light meal before the measurement is allowed.
- Rest (seated or supine position) for at least 5 minutes prior to the measurement.
- Be as relaxed as possible and not talk during the measurement.
- When possible, subsequent measurements should be obtained at the same time of the day so as to account for the diurnal blood pressure effect.

Tonometer Technique

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 SphygmoCor XCEL device. Hold the tonometer base gently but firmly between the tip of the thumb and the fingers.
- Locate the patient's carotid artery by palpation, and identify the strongest pulse point.
- Press the tonometer gently but firmly against the patient's neck at the strongest pulse point.
- Maintain steady pressure with the tonometer.

- If the trace is flat at the top of the screen, reduce the pressure. If the trace is flat across the bottom of the screen, increase the pressure.
- While holding the tonometer steadily on the patient's neck, the waveform signal should automatically resize with optimal placement. Make minor adjustments until the waveforms are uniform in shape and height.
- When the 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. The following image shows an example of good signals.



System Installation and Setup

Unpacking

Carefully un-pack the SphygmoCor XCEL System.

Remove the SphygmoCor XCEL device from the packaging then remove the protective plastic film.

A smaller carton contains all the accessories included with the system.

Note: AtCor Medical strongly recommends that the SphygmoCor XCEL System is installed on a dedicated computer or notebook computer, because some 3rd party software applications may interfere with the operation of SphygmoCor XCEL software.

Software Download

The SphygmoCor XCEL software installer for XCEL 1.5 can be downloaded from the below website:

https://www.atcormedical.com

1- Navigate to the “XCEL V1.5 Software Installation Package” link, then click it.

2- The zipped file would have been downloaded.

3- Right click on the zip file and extract the files.

Software Installation

The SphygmoCor XCEL software installer contains all that is required to install the SphygmoCor XCEL software on a dedicated computer. Complete the software installation prior to connecting the module to the computer.

Run the downloaded .exe file, then follow the screen instructions.

Note: Administrator privileges are required for installation.

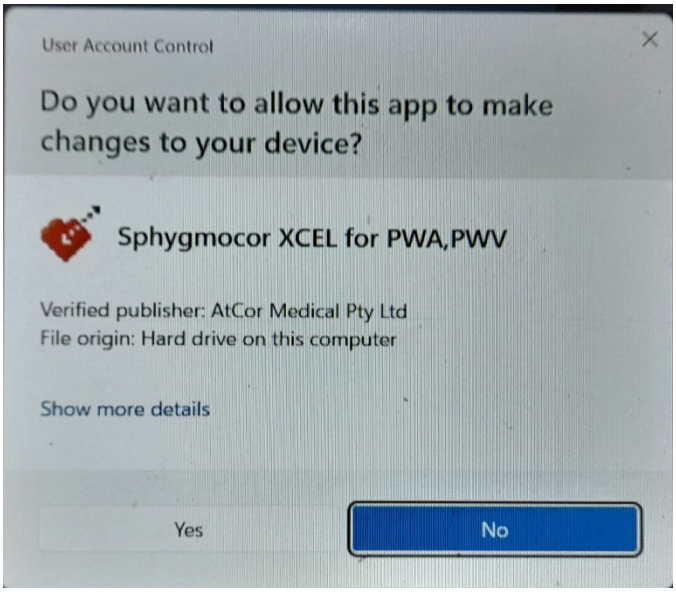
Note: It is recommended to connect the computer to the internet and download and install all Windows Updates before installing the software.

Note: XCEL 1.5 can be installed on computers that have a previous version of XCEL installed.

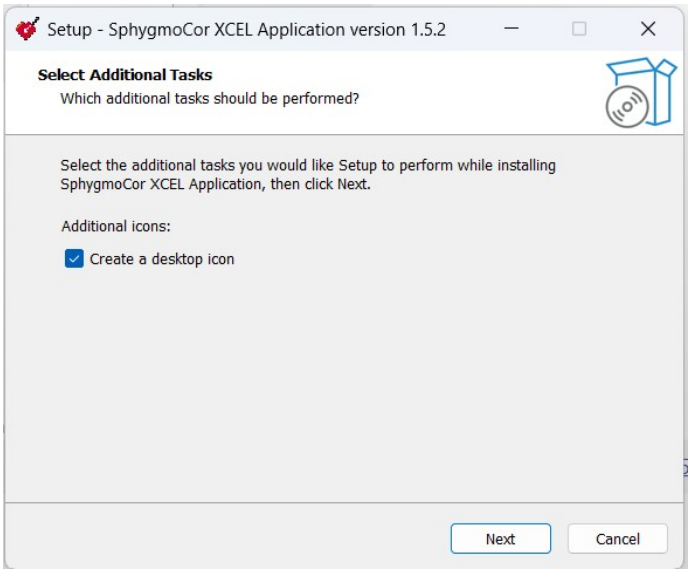
Standard Installation

1. Close all other programs

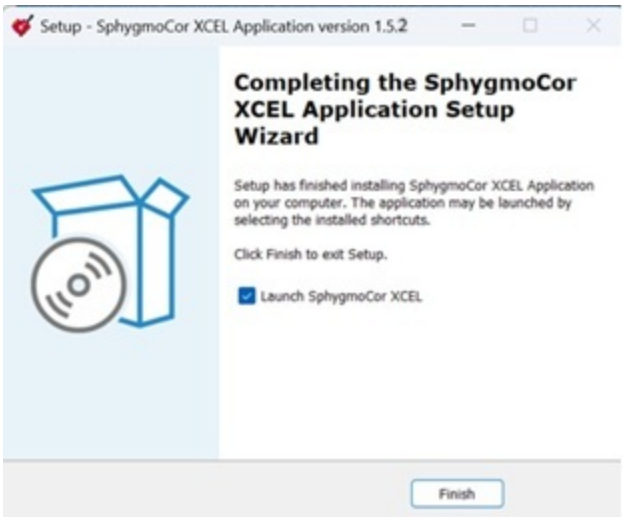
2. Run the downloaded .exe file to commence installation. Follow the screen instructions. Click **Yes** to continue



3. Option to create a desktop icon. Click **Next**.



4. Option to launch XCEL 1.5 when installation is completed. Click Finish to complete.



Click **Finish**.

Uninstallation

If you want to uninstall the SphygmoCor XCEL 1.5 software, uninstall from 'Add or remove programs' in Windows.

Note: It is recommended to back up your database before uninstallation.

Starting SphygmoCor XCEL software

1. Ensure the SphygmoCor XCEL device is set up as described in the PWA or PWV *Connecting Components* sections.
2. Connect the SphygmoCor XCEL device to the computer and power on the device by using the switch at the rear of the device. The green power and orange standby indicators shall illuminate.
3. Ensure the PC is connected to the internet and start the SphygmoCor XCEL software by either:
   - Selecting **Start → Program Files → Atcor Medical → SphygmoCor XCEL → double click "xcel.exe"**
   - Double-clicking the XCEL 1.5 software icon on the desktop, if the shortcut was created during the installation process.
4. Xcel 1.5 will check with the License Server if there is a valid subscription.
   If valid, Xcel shall show a subscription message at the bottom of the screen.



5. In the top menu, click **System, then Find Module**
6. The message *Electronic Module Found* would appear at the bottom of the screen indicating that the PC has identified the connection to the SphygmoCor XCEL device.



> **Note:** If the message does not appear, check the USB connection and confirm that the SphygmoCor XCEL device is powered ON, then repeat Step 5. If the problem persists, please contact AtCor Medical for technical support.

7. The SphygmoCor XCEL system is ready for use.

   The details of the licence can be checked from the menu **Help → Subscription**

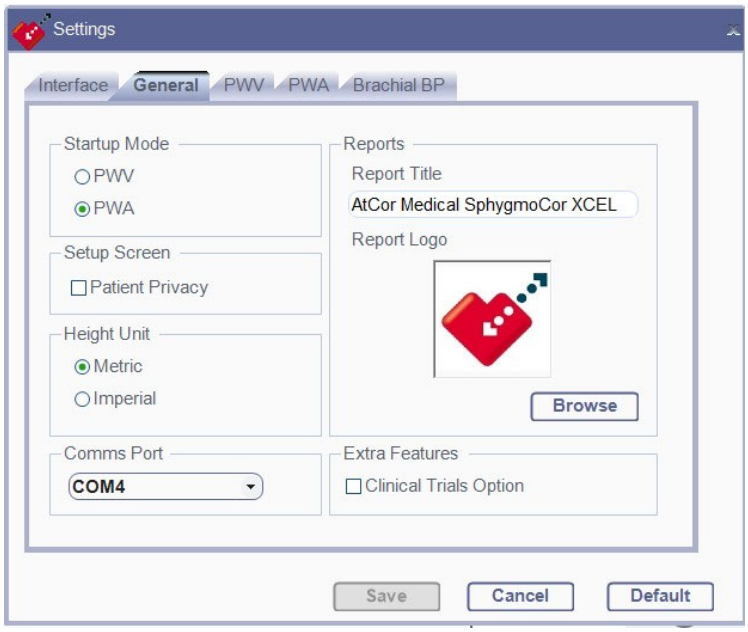


System Settings

The SphygmoCor XCEL System Settings enable the operator to configure many features and options in the software. The System Settings contains the following:

1. General Settings
2. PWV Settings
3. PWA Settings
4. Brachial BP Settings
5. Interface

General Settings



Startup Mode – PWV / PWA – this setting determines the default mode when the SphygmoCor XCEL software is started (if both modes are enabled in the software). Click on PWA or PWV to change the setting. The selected start up mode is marked with a green dot.

Setup Screen – Patient Privacy – these features offers the ability to temporarily hide the list of patients to maintain patient privacy. A check mark appears in the box when patient privacy has been selected.

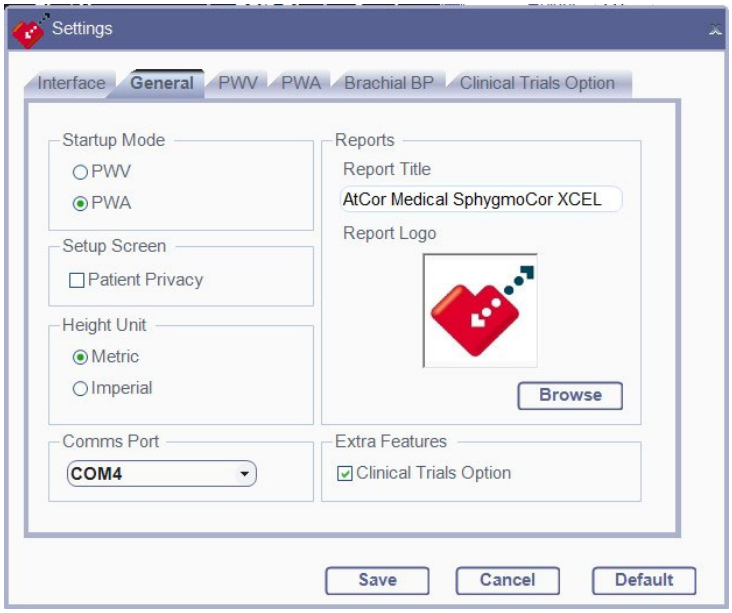
Height Units – SphygmoCor XCEL software can display height in either metric (cm) or imperial (feet/inches) measurements.

Comms Port – This setting identifies which communications (comms) port on the PC is connected to the module as well as enables simulation of SphygmoCor data for demonstration purposes. If Simulation is selected, the software will display demonstration data and *not* actual patient data. When obtaining a measurement on a patient, the communications port (eg, com3, com4, etc) should be displayed. The Simulation setting should only be chosen when demonstrating the software functionality *without* a patient.

Reports – Report Title, Report Logo – This section enables customization of the title on printed reports, e.g., hospital or clinic name, as well as incorporation of customised logo on the printed report. To modify the report name, move the cursor to the space under "Report Title" and enter the title you would like printed on reports. To use your organization's logo on reports, the logo must be in either .jpg or .bmp file format. Click "Browse" and select your logo. It is recommended to import a 512 × 512 pixel logo image for maximum resolution. The selected logo will be stored in the internal memory of SphygmoCor Xcel, until a different logo is selected.

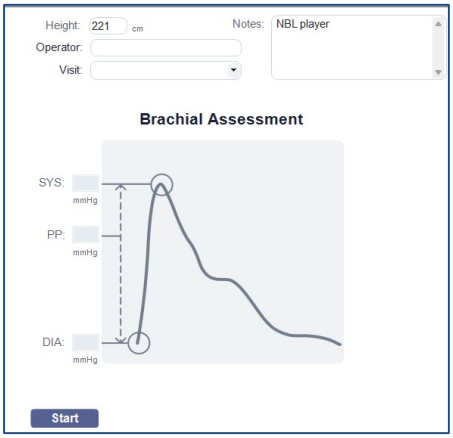
Extra Features – Clinical Trials Option – When Clinical Trials Option is selected, a **Clinical Trials Option** tab will appear in the settings allowing the appropriate personnel to define descriptions for individual visits of a clinical trial and to protect the settings by a password.

Note: Simulation Mode will not be enabled if the **Clinical Trials Option** has been selected.

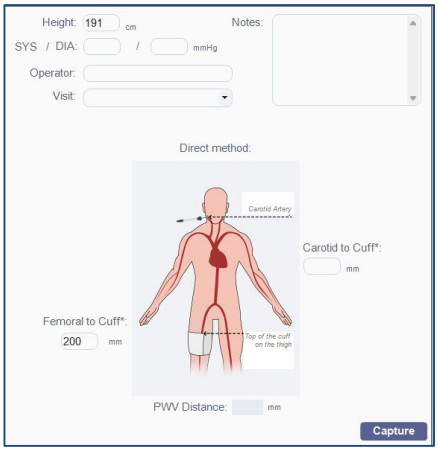


When the **Clinical Trials Option** is selected, two fields will appear in the PWA and PWV **Setup** and Report screens: **Operator** and **Visit.** Fill in with the operator's name and patient's visit description respectively.

PWA Setup



PWV Setup

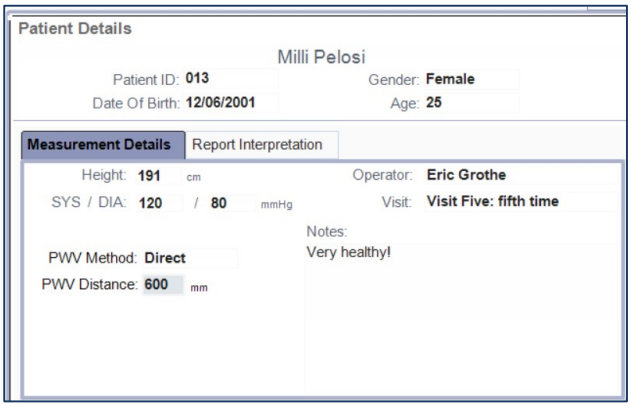


In the **Report** Screen, the operator's name and patient's visit description will appear in the *Measurement Details* section of PWA Report and PWV Report as following:

PWA Report

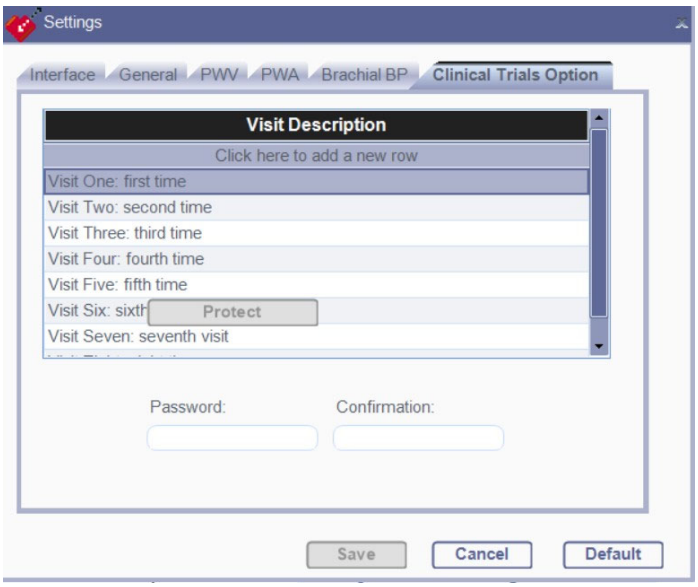


PWV Report



Click on the **Clinical Trials Option** heading tab in the Settings window to define visit descriptions and set the optional password to protect the settings:

a) **Visit Description** – Click on the first row to add a visit description. To edit a visit description, double click on the existing visit description. To delete a visit description, click on the visit description, and press **Delete** button on the keyboard.

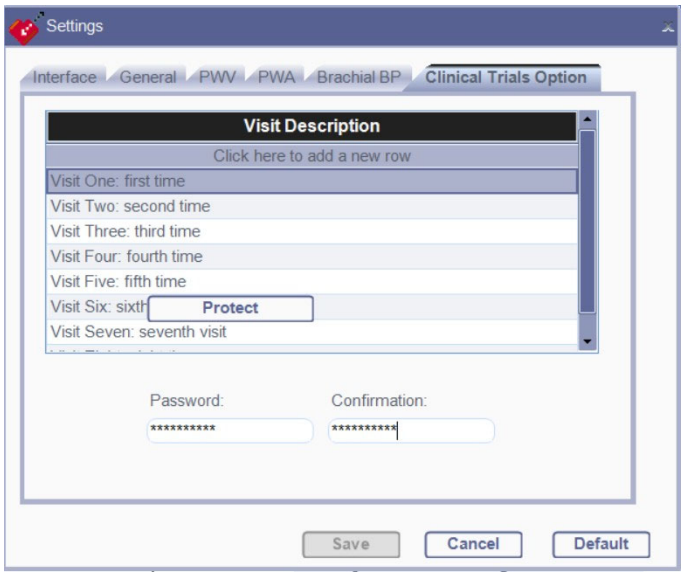


Note: In **Clinical Trials Option**, when a new patient is created, the patient ''Last Name" field is initially automatically populated with the text "Subject".

b) **Password** – The appropriate personnel can select a password to protect **Settings** from other users. The correct password is required to change any of the settings.

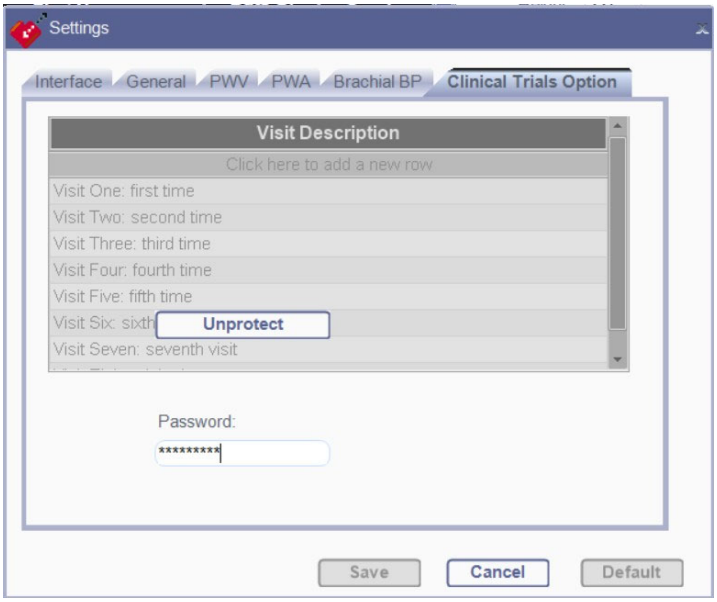
- **To Protect the Settings with a password:**

  1. Go to **System → Settings → General → Extra Features**
  2. Check **Clinical Trials Option** box in Extra Features (a new window will be opened)
  3. Go to **Clinical Trials Option.**
  4. Enter your password in the **Password** field.
  5. Re-enter the selected password in the **Confirmation** field.
  6. Click **Protect** to lock the settings.
  7. Click **Save** to save changes.



- **To Unprotect the Settings using the selected password:**

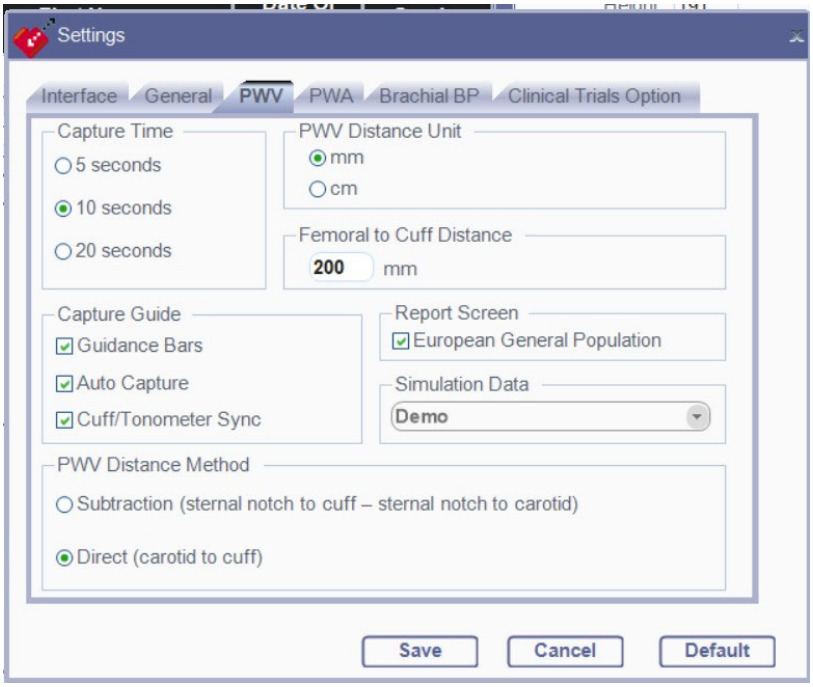
  1. Go to **System → Settings → Clinical Trials Option**
  2. Enter the password in the **Password** window**.**
  3. Click **Unprotect** to unlock the settings.
  4. Click **Save** to save changes.



Note: If the wrong password is entered, the **Invalid Password** warning will appear.

PWV Settings

These settings are only available if PWV software was purchased with the SphygmoCor XCEL System.



Capture Time – this setting refers to the length of time for which a stable reading must be available for a successful PWV measurement. The default setting is 10 seconds. For patients with a stable heart rate, the setting can be changed to five seconds. For patients with unstable heart rates, the 20 second capture may be required to obtain a valid measurement.

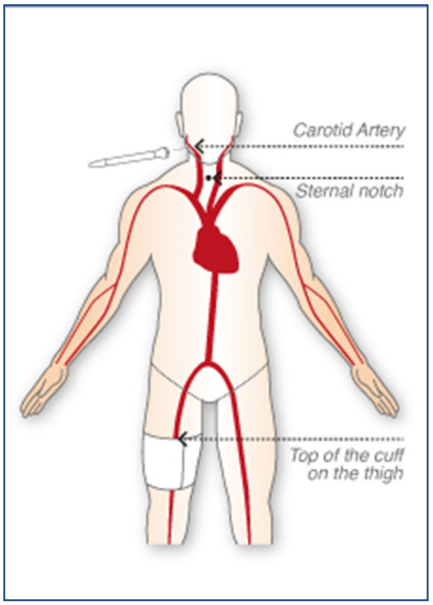
Capture Guide features

- Guidance Bars – this setting enables visual guides that give feedback of the signal quality from both tonometer and cuff while a measurement is in progress. Refer to *Using the Guidance Bars* for an explanation of how Guidance Bars can improve data capture. The default setting is Guidance Bars enabled.
- Auto Capture – this setting results in automatic capture of the recording as soon as reliable tonometer and cuff signals are detected simultaneously. If not selected, capture must be manually triggered by pressing the space bar (Manual capture can be achieved by pressing the space bar, even if Auto Capture is enabled). Default setting is that Auto capture is enabled.
- Cuff/Tonometer Sync mode – this setting causes the thigh cuff to inflate when a reliable carotid signal from the tonometer is detected. If disabled, the cuff inflation is triggered as soon as the capture starts. The default setting is disabled.

Simulation Data – this setting offers the ability to demonstrate PWV simulation mode (i.e., without a patient). The PWV data file contains both carotid tonometer and thigh cuff signals. Switching between real measured data and simulated data is controlled by the COM Port setting under *General Settings*. Actual patient data will not be obtained when the Simulation is enabled.

PWV Distance Method – this setting determines how the SphygmoCor XCEL System calculates the distance between the patient's carotid measurement site and the cuff. There are two commonly used methods supported by SphygmoCor XCEL.

- Direct method – the distance is measured directly from the carotid artery to the top edge of the femoral cuff.
- Subtraction method – distance is measured from the sternal notch to the top edge of the femoral (thigh) cuff (distal distance), and from the carotid artery to the sterna notch (proximal distance). The proximal distance is subtracted from distal distance to provide the aortic distance, which is used in the calculation of PWV. The subtraction method is the default setting.



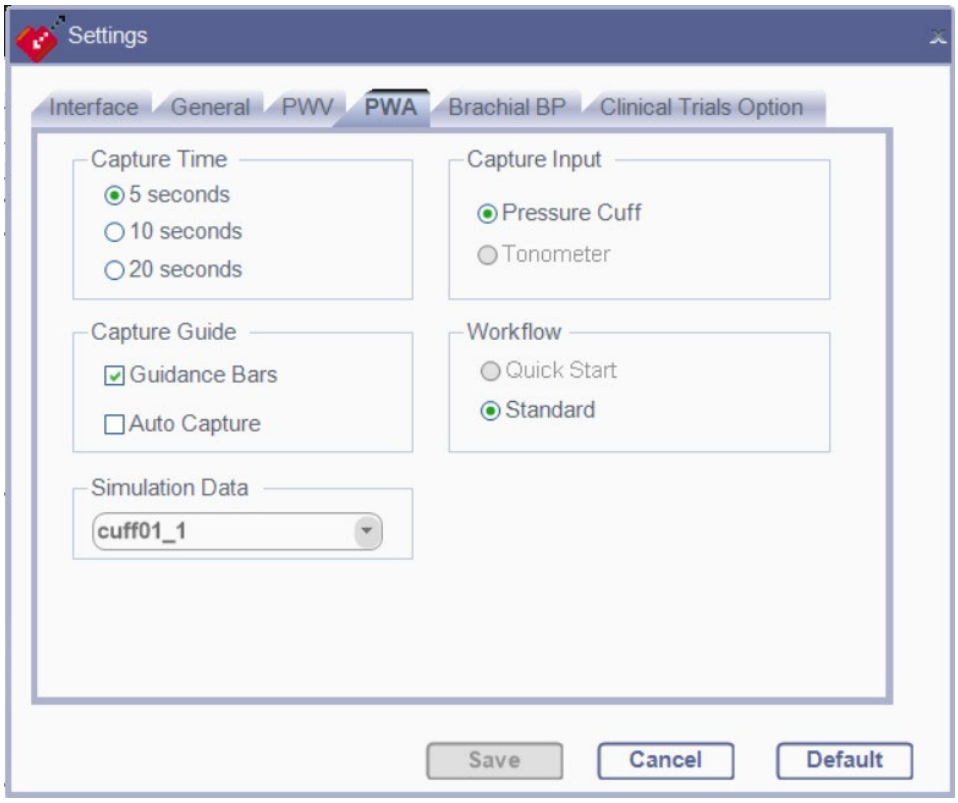
PWV Distance Unit – this setting offers use of either centimetres or millimetres as the PWV distance units. Millimetres (mm) are the default option.

Femoral to Cuff Distance – a default distance between the top of the cuff and the femoral artery of 200mm is used during PWV measurements (PWV Setup Screen). The value can be changed in the PWV Set up screen.

Report Screen – the PWV Report will include reference PWV values from the European General Population to be compared with the measured PWV if this option is selected. This reference population includes healthy subjects and subjects with cardiovascular risk factors. The default setting includes the European General Population data on the report.

PWA Settings

These settings are only available if PWA software was purchased with the SphygmoCor XCEL system.



Capture Time – this setting refers to the length of time for which waveforms will be collected for a successful PWA measurement. A higher capture time may be needed for patients with slow respiratory cycles and/or a highly variable heart rate. The default setting is 5 seconds but for patients with slow respiratory cycles and/or a highly variable heart rate, a higher capture time may be needed for a valid measurement.

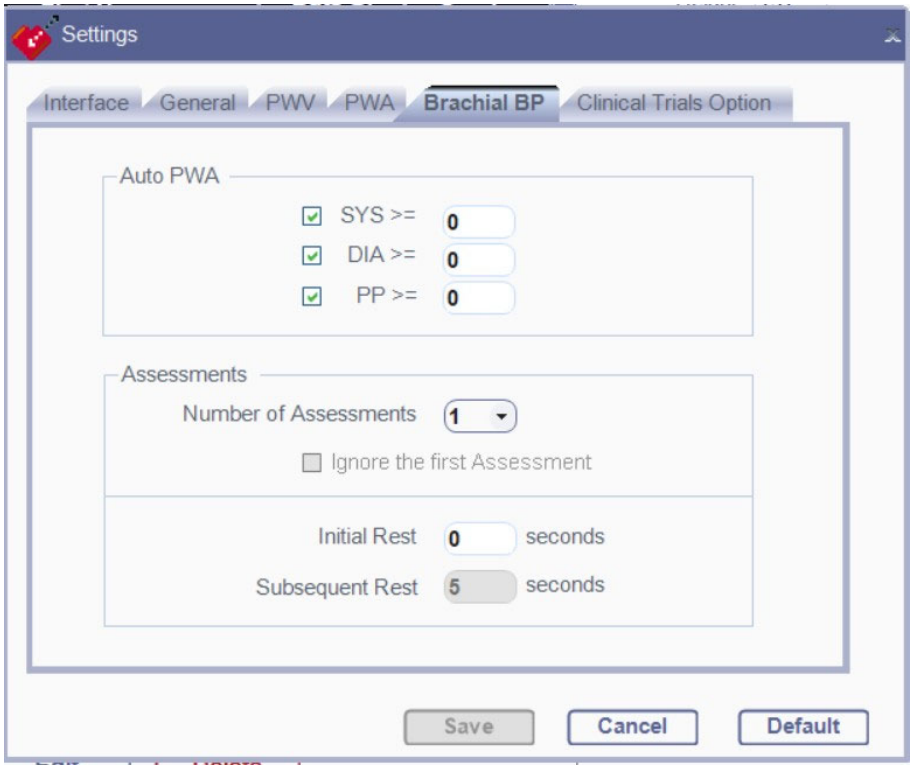
Capture Guide

- Guidance Bars – if selected, colour-coded Guide Bars are displayed, indicating the quality of recorded pulses. Refer to *Using the Guidance Bars* for an explanation of how Guidance Bars can improve data capture. The default setting is Guidance Bars enabled.
- Auto Capture – if selected, automatic capture of the recording will occur once reliable quality cuff signals are detected i.e., colour is green. If not selected, capture must be triggered manually by pressing the keyboard space bar. Refer to the *Automatic versus Manual Waveform Capture* section under PWA. The default setting is Auto Capture enabled.

Simulation Data – this setting offers the ability to demonstrate the PWA software using simulated data (i.e., actual patient data will not be captured when this Simulation is selected). Simulation must also be selected under *General Settings* in order to use the "Demo" setting.

Capture Input – this setting determines whether the signal is captured from the Pressure Cuff (i.e. brachial upper arm cuff) or radial artery tonometer. For SphygmoCor XCEL software version 1.5, Pressure Cuff is the only available option.

Brachial BP Settings



Auto PWA – this setting enables threshold values for brachial systolic, diastolic or pulse pressure (SP, DP and PP respectively). If the measured blood pressure is above the threshold, PWA waveform capture commences automatically. If the measured Brachial Blood pressure is below the threshold or all check boxes are not selected, the PWA waveform assessment will only be performed if **Capture** is clicked.

Note: It is recommended that the user click **Capture** as soon as the brachial BP measurement has ended and the brachial BP values are displayed. Also, it is recommended that the patient refrain from movement and remain in a stable position until the PWA measurement ends.

When enabled, this option can be used to screen patients with potential cardiovascular risk indicated by high brachial blood pressure. The default setting is 0 for each, thus the PWA waveform capture always starts automatically.

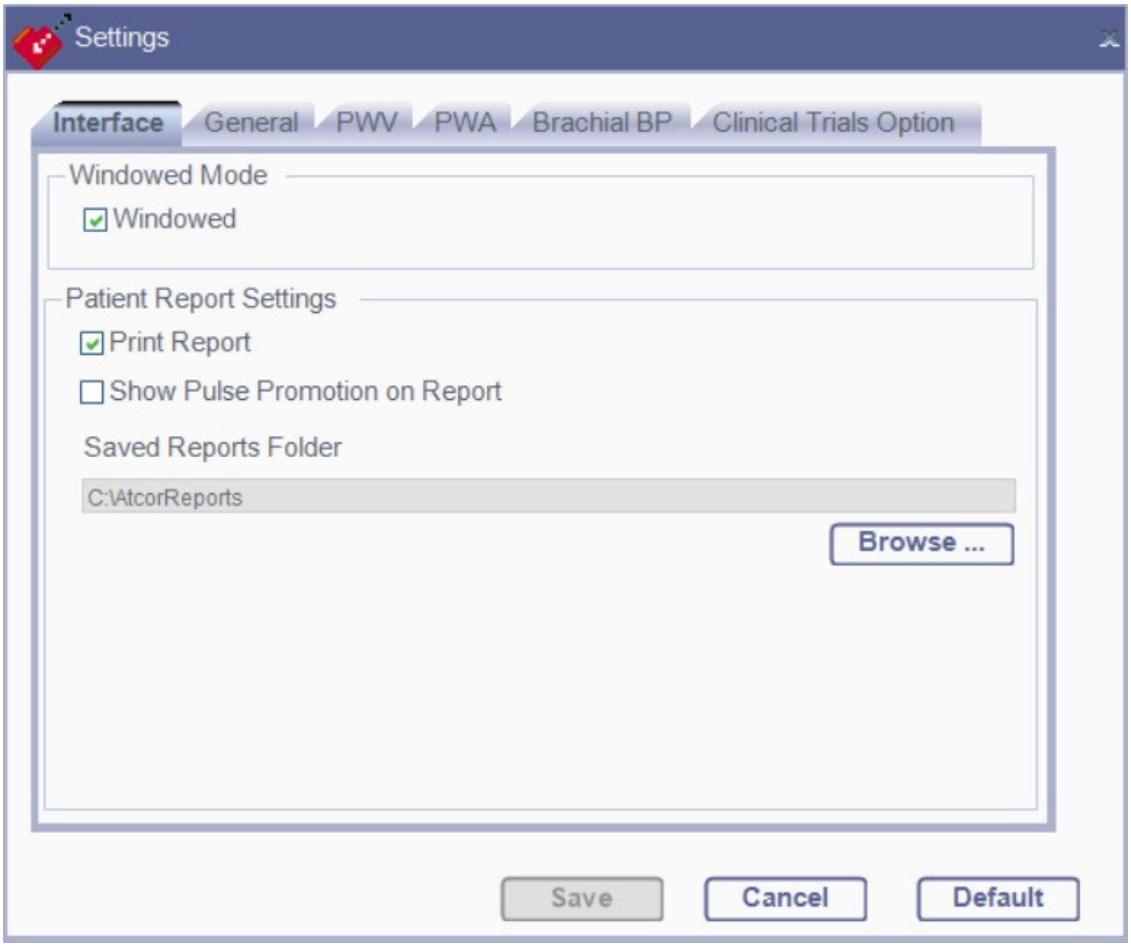
Number of assessments – this setting enables the captured waveform to be calibrated with multiple readings of brachial systolic and diastolic cuff pressure. The number of brachial assessments can be set from 1 to 5, with 1 being the default value. Studies have shown that the average of multiple measurements of brachial blood pressure may provide a more

accurate measure than one individual brachial blood pressure measurement.[7] The operator can also choose to ignore the first brachial BP measurement by ticking the **Ignore the First Assessment** checkbox.

Initial Rest – Allow the operator to choose the time to start the first brachial BP assessment after clicking the **Start** button. The default initial rest is 0 seconds.

Subsequent Rest – Allow the operator to choose the time between subsequent brachial BP assessments when the operator chooses more than one brachial BP assessment. The default (and minimum) subsequent rest is 5 seconds.

Interface



Windowed Mode – this setting determines if the XCEL window can be freely moved around in the screen (Windowed), or if its position is fixed.

Patient Report Settings – this setting sets a number of report related options:
- Setting the default Printing mode for a report.

[7] Vidt, DG et al. Taking Blood Pressure: Too Important to Leave to Humans? Cleve Clin J Med. 2010 Oct; 77(10):683-8

- Directory used to save the Patient Reports.
- Option to show promotional inserts in the Patient Report.

SphygmoCor XCEL Device Status Indications

Indicators on the SphygmoCor XCEL device indicate the device status, as shown in the following diagram and table.





Number	Name & Symbol	Colour and state	Status
1	Power ⏻	Off	Power is off
		Green	Power is on
2	Status	Yellow	Software is initializing
		Flashing Yellow	Software initialization failure

		Flashing Red or off	Device requires service (Return to manufacturer)
		Flashing Green	Communicating with PC
		Green	Operating normally (waiting)
3	Cuff	Blue	Active
		Off	Any other condition
4	Tonometer	Blue	Active
		Off	Any other condition
5	Stop	Red	STOP button had been pressed and the cuff is deflating.
		Off	Operating normally (cuff ready to inflate)
		Flashing Red	Safety cuff deflation by device

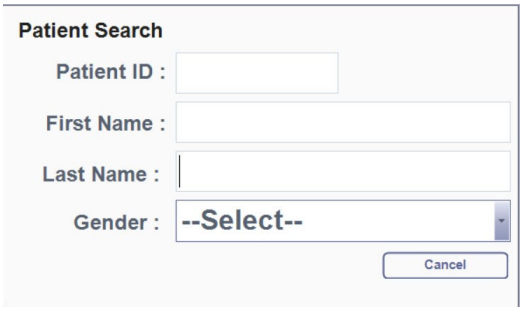
Creating and Managing Patient Records

Before creating a new patient entry, confirm that the patient's information has not already been entered by searching the patients list (database) as separate patient entries cannot be merged.

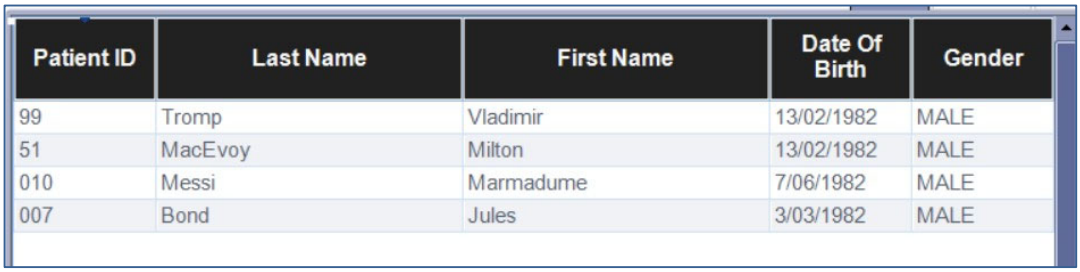
To locate a patient record

1. Click **Search**. The patient fields become white.
2. Enter the known patient details into any of the search fields (Patient ID, First Name, Last Name, and Gender).

   Example: enter **s** in the first name field.



Note: the software will begin searching as soon as data is entered in any searchable field. The set of results becomes smaller as more data is entered.



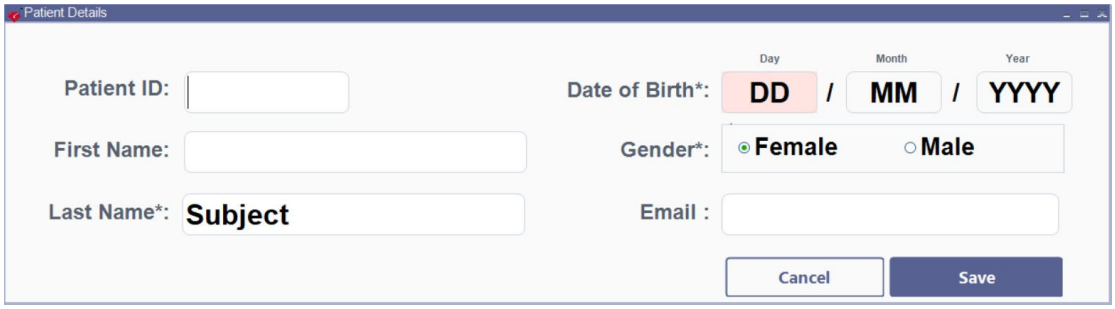
Patient ID	Last Name	First Name	Date Of Birth	Gender
99	Tromp	Vladimir	13/02/1982	MALE
51	MacEvoy	Milton	13/02/1982	MALE
010	Messi	Marmadume	7/06/1982	MALE
007	Bond	Jules	3/03/1982	MALE

3. Click any of the column headings to sort the list of results according to data in that column, such as Last Name. Click the heading again to sort in reverse order.
4. Click anywhere in the patient's record to select that patient.
5. Click **Cancel** to end the search and return to the full list of patients.

To create a new patient record:

1. Click **New**.

   The patient entry fields will become white, indicating the software is ready for new patient entry.

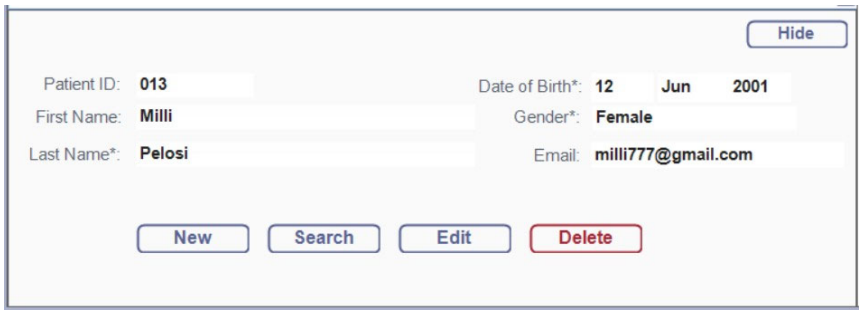


2. Enter all mandatory data, indicated by the * symbol. Other data may also be entered but is optional.
3. Click **Save**.

Editing an Existing Patient

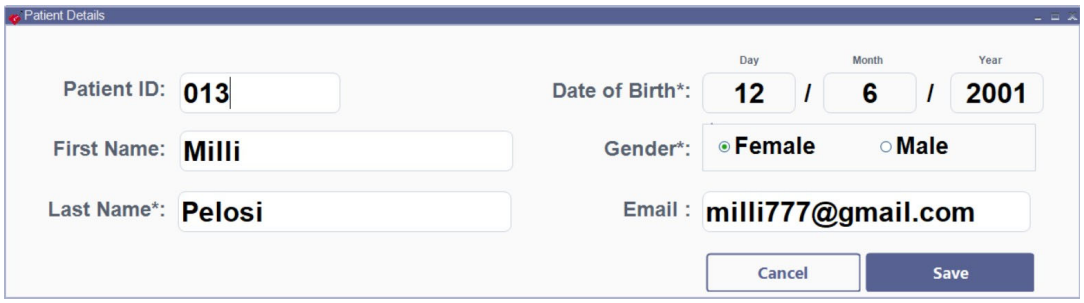
To edit a record:

1. Select the record (search, if necessary).



Initially, the record is read-only, which is shown by white text.

2. Click **Edit**.



The record details change to black, allowing for editing.

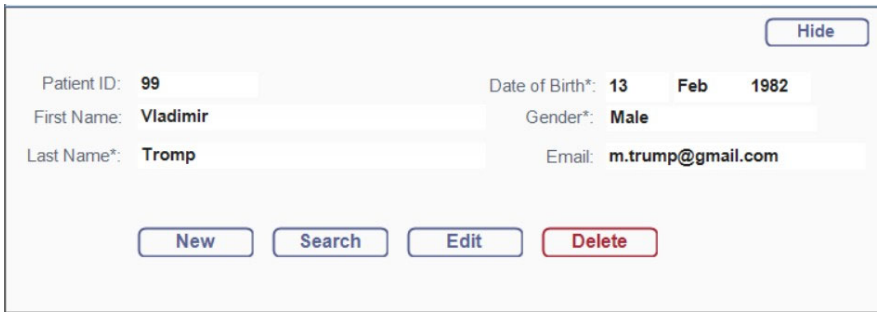
Note: Editing a patient's ID, First Name or Last Name is not case sensitive. If you want to change these fields by uppercase or lowercase, make sure to change the spelling first and save it. Then, modify the field to desired case and original spelling.

Deleting a Patient

Caution: Deleted data is permanently removed from the database and cannot be retrieved.

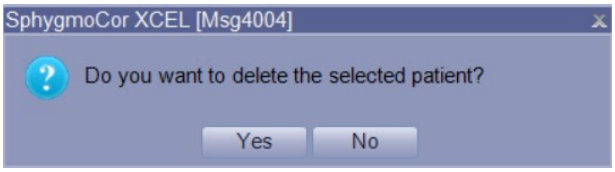
To delete a record:

1. Select the record (search, if necessary).



The record is read-only, unless edited.

2. Click **Delete**.



3. Select **Yes** from the confirmation pop-up window to confirm deletion.

Troubleshooting

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

The SphygmoCor XCEL Software conducts a series of internal tests with prompts to guide the user should an error occur. In most instances, errors can be resolved following these prompts. However, if the error is not resolved and the solution is not apparent, please contact AtCor Medical Technical Support for assistance.

SphygmoCor XCEL Device

Condition 1: The SphygmoCor XCEL device cannot be detected.

This error may appear at two places in the software:

- When the SphygmoCor XCEL software is started.
- Upon entry into the Capture Screen.

Check the following items:

- The SphygmoCor XCEL device is connected to your computer.
- The SphygmoCor XCEL device is plugged into an AC outlet and the power switch is toggled to the “on” position.
- The Power light is illuminated (if it is not illuminated, refer to Condition 2 “The POWER light is off” below)
- The correct communications port is selected in the configuration settings.

  From the **Setup** Screen, select **System** – **Find Module.**
- If using a USB Adaptor, ensure that appropriate USB adaptor drivers have been installed on the computer.

  If none of the above actions resolves the issue, please contact AtCor Medical Technical Support.

Condition 2: The POWER light is off.

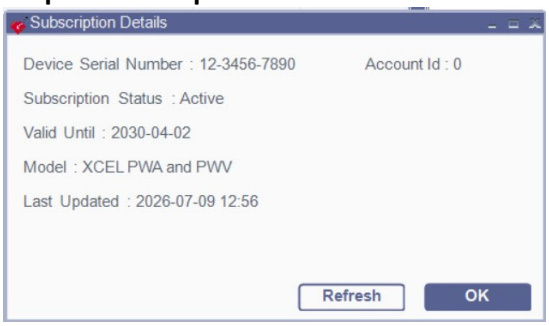
Check the following:

- The SphygmoCor XCEL device power cable is connected to an AC outlet and the toggle switch is in the “ON” position.
- If the above action does not resolve the issue, please contact AtCor Medical Technical Support.

Condition 3: Unexpected subscription status.

If your subscription is valid, or recently renewed, and the SphygmoCor XCEL software shows lapsed or expired, check the below:

- Check your device is online, then refresh the licence details from the menu.
  Help → Subscription



- If the above fails, please restart the Xcel application. If the problem is not resolved, please contact AtCor Medical Technical Support.

Software Screens

The user will be notified of software issues via pop-up windows with instructions to resolve the issue. If the screen freezes or you require further explanation of any pop-up window, please contact AtCor Medical Technical Support for assistance.

Capture Screen

The Tonometer fails to respond.

Ensure that the Tonometer is connected to the appropriate port at the rear of the SphygmoCor XCEL device.

Note: Use caution when connecting the Tonometer as pins inside the connector can be easily bent or broken.

Error Codes

The following is a list of possible errors that may be encountered.

Note: If any error occurred where the code is not listed in the following table, exit XCEL software, turn OFF/ON the device and then start XCEL software. If problem persists please contact AtCor Medical Technical support.

Error Code	Error Message	Action
1	Unable to continue Brachial Assessment due to weak oscillometric signal (Code = 1).	• Ensure use of correct cuff size, correct positioning and fit • Ensure that no obstructions (eg, clothing) are located between the cuff and the patient's arm • After completing these steps, attempt another measurement

Error Code	Error Message	Action
2	Unable to continue Brachial Assessment due to erratic oscillometric signal (Code = 2).	• Ensure that the patient's arm is stationary during the measurement • Ensure use of correct cuff size, correct positioning and fit • After completing these steps, attempt another measurement
3	Unable to continue Brachial Assessment due to exceeded retry count (Code = 3).	• Ensure that the patient's arm remains stationary during the measurement • Ensure use of correct cuff size, correct positioning and fit • Remove any obstructions between the cuff and the arm • After completing these steps, attempt another measurement
4	Unable to continue Brachial Assessment due to exceeded measurement time limit (Code = 4).	Before retrying the measurement: • Ensure that the patient's arm remains stationary during measurement • Ensure use of correct cuff size, correct positioning and fit • Remove any obstructions between the cuff and patient's arm • After completing the above steps, attempt another measurement
85	Unable to continue Brachial Assessment due to pneumatic blockage (Code = 85).	• Ensure that the hose is not bent or pinched • Ensure that the hose and cuff is not under the patient • Ensure use of correct cuff size, correct positioning and fit • After completing the above steps, attempt another measurement
87	Unable to continue Brachial Assessment due to inflate timeout (Code = 87).	• Ensure that the hose connections to the device and cuff are intact and tight • Ensure use of correct cuff size, correct positioning and fit • Ensure that the cuff is not leaking air • After completing the above steps, attempt another measurement
88	Unable to continue Brachial Assessment due to safety timeout (Code = 88).	• Turn the device OFF and then turn it ON • Ensure use of correct cuff size, correct positioning and fit • Ensure that the patient's arm is stationary during the measurement • After completing the above steps, attempt another measurement
89	Unable to continue Brachial Assessment due to cuff overpressure (Code = 89).	• Ensure use of correct cuff size, correct positioning and fit • Ensure that the hose is not bent or pinched • Ensure that the cuff and hose are not beneath patient • After completing the above steps, attempt another measurement

Error Code	Error Message	Action
90*	Unable to continue Brachial Assessment due to hardware problem (Code = 90).	• Turn the device OFF. • Ensure the data/power input are connected • Turn the device ON • After completing the above steps, attempt another measurement
103*	File “DatabaseUpgradeReport.csv” is in use by other application (code=103)	• Close the application
608*	Unable to backup database to <pathname> (Code = 608).	• Ensure the correct backup directory has been selected: C:\ProgramData\AtCor Medical\Backup\ No other directory shall be used because of restricted settings in SQL Server.
609*	Unable to restore database from <pathname> (Code = 609).	• Ensure the correct restore directory has been selected: C:\ProgramData\AtCor Medical\Backup\ No other directory shall be used because of restricted settings in SQL Server.
611*	Unable to migrate data due to database error (Code = 611).	• Restart the SphygmoCor XCEL software.
800*	Database server is not responding (Code = 800).	• Restart the computer • Contact Support
2046	Unable to continue Capture due to unsuccessful start of capture (Code = 2046).	• Ensure that the device is connected to the computer. • Ensure the cuff is connected to the device. • Ensure that there aren’t any tubing obstructions • Turn the device OFF and ON. • Attempt Capture again.
2047	Unable to continue Capture due to unsuccessful stop of capture (Code = 2047). "Press the STOP button on the module to deflate the cuff	• Ensure that the device is connected to the computer • Ensure that the cuff is connected to the device. • Ensure use of the correct cuff size and that it is correctly positioned • Turn the device OFF and ON. • Attempt Capture again.
2049 2050	Unable to continue Capture due to unsuccessful inflation of cuff (Code = 2049). (Code = 2050)	• Ensure the device is connected to the computer. • Ensure the cuff is connected to the device. • Ensure use of the correct cuff size and that it is correctly positioned • Turn the module OFF and ON. • Attempt Capture again.
2051 2053	Unable to continue Capture due to unsuccessful deflation of cuff (Code = 2051)	• Press the STOP button on the device to deflate the cuff.

Error Code	Error Message	Action
	(Code = 2053)	• Ensure that the device is connected to the computer. • Ensure that the cuff is connected to the device. • Ensure use of the correct cuff size and that it is correctly positioned • Turn the device OFF and ON. • Attempt Capture again
2058	Unable to continue Capture due to exceeding the maximum number of inflation/deflation cycle per measurement (Code = 2058).	• Ensure that the patient's limb with cuff is stationary during measurement. • Ensure use of correct cuff size, correct positioning and fit. • Ensure that there are no obstructions such as thick clothing between the cuff and arm. • For PWV mode: Ensure the tonometer is detecting pulses. • After completing the above steps, attempt Capture again.
2076	Unable to continue Capture due to invalid data from the Electronics Module (Code = 2076).	• Press the STOP button on the device. • Ensure that the device is connected to the computer. • In the Setup screen, click on the System and select Find Module. • Attempt Capture again.
2077 2078	Unable to continue Capture due to Communication error (Code=2077) (Code=2078)	• Press the STOP button on the device. • Turn the device OFF and ON. • Ensure that the device is connected to the computer. • Exit the XCEL software • Start the XCEL software • In the Setup screen, click on the System and select Find Module. • Attempt Capture again.
2079	Unable to continue Capture due to deflation of cuff (Code = 2079).	• Ensure that the patient's limb with cuff is stationary. • Ensure use of the correct cuff size and that it is correctly positioned. • Ensure that there are no obstructions between the cuff and arm. • After completing the above steps, attempt Capture again.
2080	Unable to continue Brachial Assessment due to brachial pressure being outside the normal range (Code=2080)	• Ensure systolic pressure is within the range 50 to 260 mmHg and diastolic pressure is within the range 40 to 200 mmHg. • Ensure use of correct cuff size, correct positioning and fit.

Error Code	Error Message	Action
		• Ensure that there are no obstructions between the cuff and arm. • After completing the above steps, repeat measurement.
2081*	Unable to continue Brachial Assessment due to timeout.	• Turn the module OFF/ON . • Click OK button. • Proceed with the measurement.
2090*	One of these messages related to "mismatch serial number" error will appear: (a) Unable to find the Electronics Module due to mismatch serial number, (b) Unable to start Brachial Assessment due to mismatch serial number (c) Unable to start Capture due to mismatch serial number	• In the Set Up screen, click System Key. • Enter the correct system key provided by AtCor Medical.
2091	One of these messages related to "incomplete calibration" error will appear: (a) Unable to find the Electronics Module due to incomplete calibration (b) Unable to start Brachial Assessment due to incomplete calibration (c) Unable to start Capture due to incomplete calibration	• Close SphygmoCor XCEL software. • The SphygmoCor XCEL Electronics Module need to be calibrated. Please refer to XCEL Calibration KIT or contact AtCor Medical for technical support.
3051*	Unable to generate PWV Report (Code= 3051).	• Ensure that the entered distance in mm is correct. • Ensure use of the correct cuff size and that it is correctly positioned. • Ensure waveform quality (use the guidance bar). • After completing the above steps, repeat PWV measurement.
3052*	Unable to generate PWV Report (Code= 3052).	• Ensure there is enough memory in the computer. • Ensure the user has read/write permission for the computer on which the SphygmoCor XCEL software installed. • Ensure the entered distance in mm is correct. • Ensure use of the correct cuff size and that it is correctly positioned. • Ensure waveform quality (use the guidance bar).

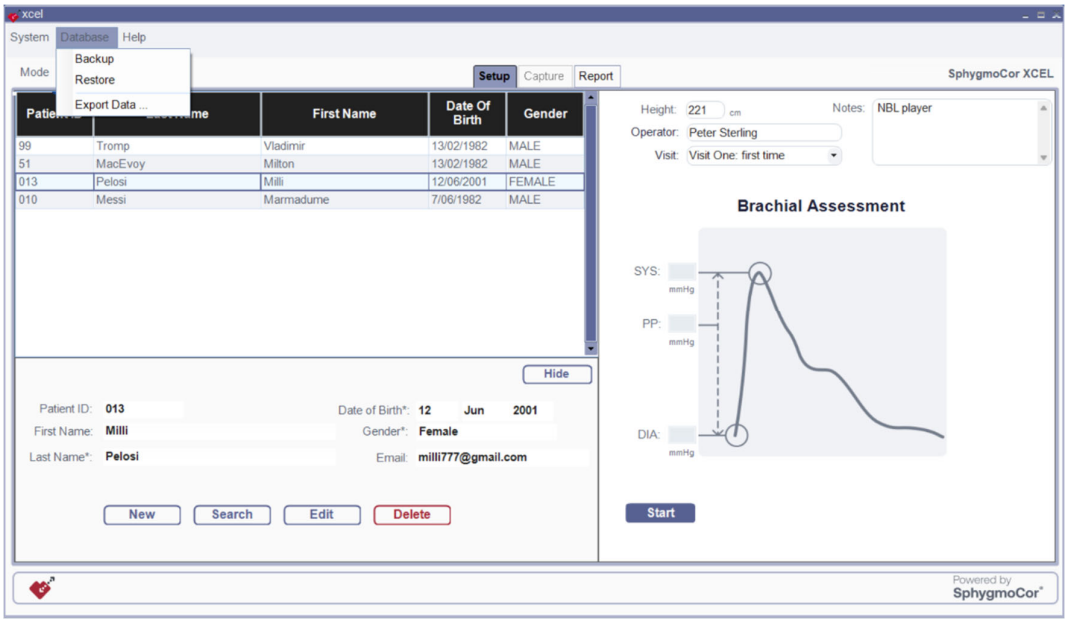
Error Code	Error Message	Action
		• After completing the above steps, repeat PWV measurement.
3053*	Unable to generate PWA Report (Code= 3053).	• Ensure use of correct cuff size, correct positioning and fit. • Ensure waveform quality (use the guidance bar). • After completing the above steps, repeat PWA measurement.
3054*	Unable to generate PWA Report (Code= 3054).	• Ensure there is enough memory in the computer. • Ensure that the user has read/write permission where the XCEL software installed. • Ensure use of correct cuff size, correct positioning and fit. • Ensure waveform quality (use the guidance bar). • After completing the above steps, repeat PWA measurement.
3060	Unable to start Capture (Code= 3060).	• Ensure that the device is connected to the computer. • Ensure that the cuff is connected to the device. • Ensure use of correct cuff size, correct positioning and fit. • Turn the device OFF and ON. • After completing the above steps, attempt Capture again.
3101*	Unable to complete the operation due to system error (Code=3101)	• Close SphygmoCor XCEL software. • Turn the device OFF and ON. • Open SphygmoCor XCEL software.
3125	Unable to calculate PWV (Code= 3125).	• Ensure that the entered distance in mm is correct.
3126*	Unable to find the Electronics Module (Code = 3126).	• Ensure the device is on. • Ensure the device is connected to the computer. • In the Setup screen, click **System** and select **Find Module**.
3128	Unable to continue due to unsupported screen resolution (Code =3128). It must be equal to or higher than 1366 by 768 pixels.	• Ensure the screen resolution is set to 1366 by 768 pixels or higher. • You may need to adjust the window display scaling level to 100% via Control Panel → Appearance and Personalization → Display
3136*	Unable to continue due to the incompatible database version (code=3136)	• Contact Support.
3216	Check that the Electronics Module is powered up and connected	• Then select Find Module from the System Menu, or restart the Application

*If the problem persist persists, please contact AtCor Medical Technical support.

Maintenance

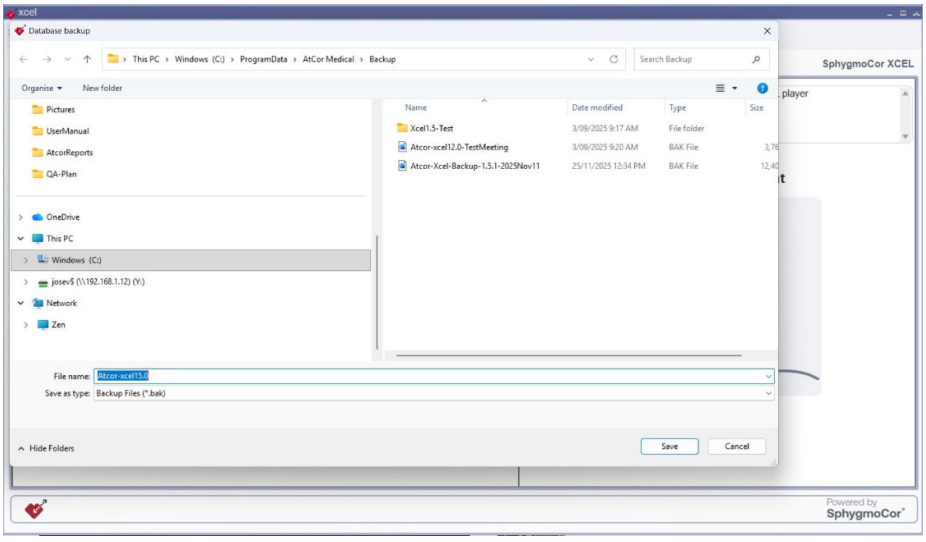
Database Manager

Database Manager allows you to backup and restore databases. You should backup the database regularly to protect against the possibility of losing important patient data. To access the Database Manager, click **Database** at the top of the screen.



Backup a Database

1. Select **Database - Backup**.



2. IMPORTANT!
   Do not change from the selected directory C:\ProgramData\AtCor Medical\Backup\

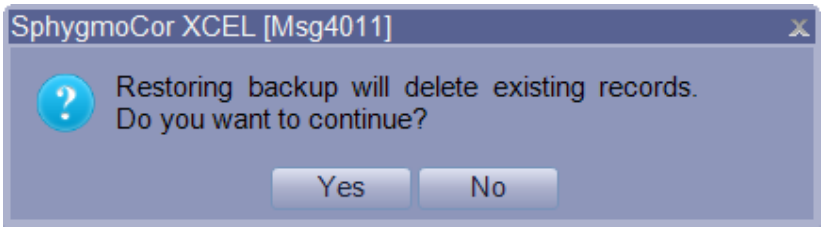
No other directory shall be used because of restricted settings in SQL Server.
Click **Save**.

Restore a Database

The user can restore a backup database to the existing database.
The Database – Restore feature is used if a database becomes corrupted, or needs to be installed onto another PC, or want to import a database from XCEL 1.3.
Ensure your current database is backed up before restoration, to avoid data loss.

Note: For multi-user SphygmoCor XCEL, the software should not be accessed by other users before Restore is complete.

1. Select **Database - Restore**.



2. Click **Yes** if you are certain that you want to replace your existing database with a backup database.
3. Navigate to the location of the backup file, which shall be C:\ProgramData\AtCor Medical\Backup\ and select the backup file.
   IMPORTANT! Do not attempt to restore from any other directory, because of restricted settings in SQL Server.
   Click **Open**. The restore will be completed automatically.

Note: To delete the existing database, copy the file **Database_BLANK.bak** in directory **C:\Program Files\Atcor Medical\SphygmoCor XCEL\Factory,** to directory C:\ProgramData\AtCor Medical\Backup\, and restore file **Database_BLANK.bak**.

Note: When restoring a SphygmoCor XCEL database from an Xcel 1.3, follow the below steps:
1. From XCEL 1.3, backup up the database.
2. Copy the backed up XCEL 1.3 database, to folder C:\ProgramData\AtCor Medical\Backup\
3. From XCEL 1.5, restore the database file in 2.

Export Data from the Database

XCEL 1.5 enables you to export the data, into .csv format.

1. Select **Database – Export Data...**



2. Select the directories to export the PWA and PWV data.



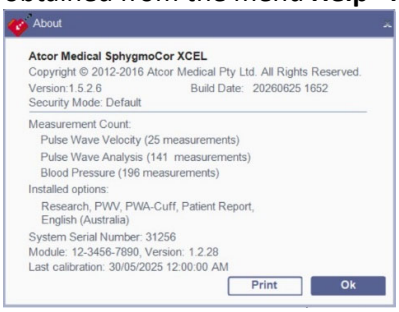
3. Click **Export**

The 2 files would be available in the selected directories. The data files will automatically include the export date as part of the file name, for easier archiving and recognition.

If the file name already exists, a warning message will appear.

Software Version

The software version of your XCEL 1.5 application, as well as other system details, can be obtained from the menu **Help - About**.



Basic System Care

Stability

Place the SphygmoCor XCEL device gently onto a stable surface. Dropping the unit can cause damage and result in the unit not operating correctly.

Choose a proper location that is free of clutter and away from high activity areas where the device could be accidentally dropped.

Pressure or impact damage

Do not apply heavy pressure to the SphygmoCor XCEL device or subject it to strong impact. Excessive pressure or impact can damage electronic components or otherwise cause malfunctions.

Temperature

The SphygmoCor XCEL System should be used and stored in ambient temperature and relative humidity within the range outlined in Technical Specifications.

Caution: 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 – prolonged sun or heat exposure may result in overheating and damage to internal components. If you place the unit near a window, leave it inside your car, or take it outside in direct sun, it may overheat and damage internal components.

Magnetic fields

Magnets, television sets, radios, large electric motors or any other source of strong magnetic fields such as MRI devices will affect the operation or may cause it to fail.

Caution: Do not place any components near strong magnetic fields.

Liquids

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

Caution: Do not spill liquids on any component.

Weight

Weight applied to the top of the SphygmoCor XCEL device may cause the unit enclosure to crack and other parts to be damaged.

Caution: Do not place any objects on top of the SphygmoCor XCEL device. Items on top of the SphygmoCor XCEL device may obscure or inadvertently activate the Stop Button.

Movement

Sudden jolts can cause damage to the unit or the tonometer if it is not stored properly.

Caution: Do not shake or drop the unit.

Shutting down

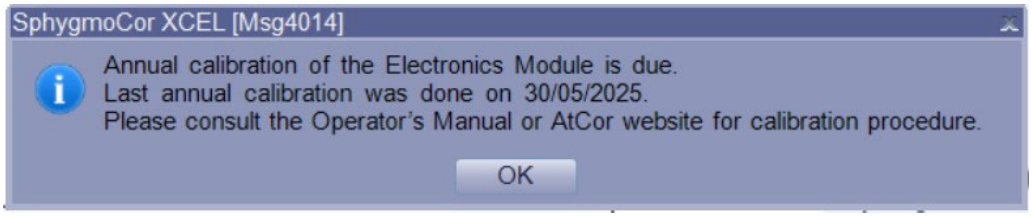
Do not power off the PC until the SphygmoCor XCEL software and Windows Operating System have been shut down. Wait 4 seconds after turning the computer OFF before turning it on again.

Caution: Exit the SphygmoCor XCEL software prior to shutting down the computer.

Equipment Calibration

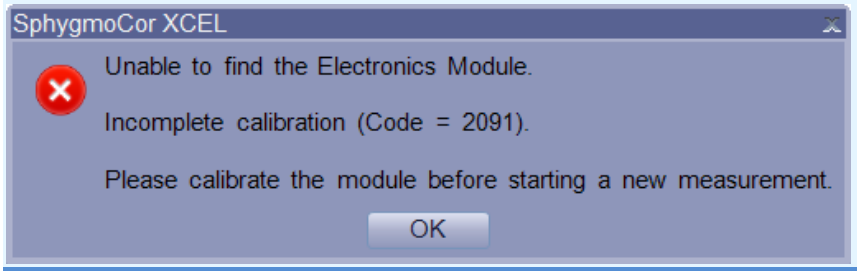
Warning: The SphygmoCor XCEL System requires calibration annually. Failure to do so, may result in the device being out of specification. This may result in inaccurate measurements.

When calibration is due the follow message will appear.



Calibration can be completed by the customer by using the XCEL Calibration Kit (purchased from AtCor Medical). Alternatively, Calibration can be completed by AtCor Medical by returning your SphygmoCor XCEL System to an AtCor Medical representative. Please contact your local AtCor Medical representative for further information.

Note: If a message appears indicating incomplete calibration, please refer to the SphygmoCor XCEL Calibration Kit instruction manual for recalibration or contact AtCor Medical for technical support.



For repairs, refer to qualified service personnel as instructed by AtCor Medical. The device does not contain any user-serviceable or reusable parts. Disassembly of the device by unauthorised personnel voids any warranty conditions.

Cleaning Instructions

To clean the SphygmoCor XCEL device, first unplug it from the computer and the power outlet. Using a damp cloth with mild detergent, gently wipe the equipment. Do not use other cleaning agents. Ensure excess liquids are wiped immediately from the equipment.

Caution: Do not spray cleaning agents or liquid directly on any components.

Notebook Batteries

Ensure when using the SphygmoCor XCEL System on notebook computers running on rechargeable batteries that the batteries are fully charged. Do not use the system on low battery power. If the notebook is abruptly shut down, the SphygmoCor database may be corrupted. Consult the notebook manufacturer's user documentation regarding the safety and maintenance of the notebook rechargeable battery.

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 tonometer lifetime is maintained.

When the tonometer is not in direct use with the patient, protect the tonometer by placing it in the storage holder in the tray or in the temporary storage holder on top of the SphygmoCor XCEL device.

Do not use this tonometer with any other instrumentation other than that supplied by AtCor Medical. Do not use a tonometer from any other supplier. The SphygmoCor XCEL tonometer is intended to be used in conjunction with the AtCor Medical SphygmoCor XCEL device only, which has a floating (isolated) grounding system.

Disinfection Instructions for Tonometer and Cuffs

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

For tonometer disinfection, use a 70% Isopropyl Alcohol (IPA) impregnated wipe or cloth for low-level disinfection. Allow a contact time of at least 5 minutes.

For cuff cleaning, refer to the cleaning instructions accompanied in the cuff packaging.

Caution: Do not immerse the tonometer in any liquid as this will damage the tonometer electronics. Do not use coarse cloths for wiping the tonometer as this will damage the sensitivity of the transducer.

PWV Thigh Cuff Care

Cleaning Cuffs: Removable covers on straight and contoured cuffs make cleaning easy. The cuff covers are made of Nylon and Velcro. Remove the bladder then wash the cuff cover in a washing machine on gentle cycle or by hand using mild soap . Open the top of the cuff and line dry only. When completely dry, reinsert the bladder. If bladder is contaminated, wash it in soapy water and rinse well without getting any liquid in the bladder or tubing.

Disinfecting Cuffs: Spray or wipe entire surfaces of cuff with disinfectant until wet. Allow the cuff to remain visibly wet for a minimum of 10 minutes to insure complete disinfection. Wipe dry with clean cloth. The following disinfectants have been tested for compatibility with Hokanson cuffs. The manufacturers do not claim effective disinfection on porous surfaces; we have been unable to find any disinfectants that claim disinfection on porous surfaces. Hydrogen peroxide, hydrogen peroxide with silver (Sanosil®), hydrogen peroxide, peroxyacetic acid, silver (Steriplex°"), silver with citric acid (PureGreen24Tm & SpectraSanTM 24), Octyl decyl dimethyl ammonium chloride with dioctyl dimethyl ammonium chloride with didecyl dimethyl ammonium chloride with dimethyl benzyl ammonium chloride (ProtexTM), 99% isopropyl alcohol, or T-SprayTM. Note: Some disinfectants may cause the cuff blue colour to bleed into cuff labelling. This does not affect the cuffs performance.

WARRANTY: Cuffs are guaranteed for one year from the date of purchase.

PWA Brachial Cuff Care

- Follow the application instructions for use to ensure the correct size cuff for the patient. Failure to do so will adversely affect the accuracy of the reading.
- Avoid contact with the cuff, other than that of the patient's limb, while measurement is in progress. Do not compress or pinch cuff tubing.
- Promptly remove cuff from patient when monitoring is not in progress
- During frequent or extended measurement, check cuff site and limb to ensure proper blood flow. Do not apply cuff where circulation may be compromised.

Cleaning instructions

The following cleaning methods have been applied 20 times to the cuff without any apparent negative effects.

The cuff may be sprayed with a mild disinfectant solution (e.g. Cidezyme® ENZOL®, or 10% bleach solution), rinsed with distilled water and line dry. Ensure that no liquid enters tubing.

OR

To machine wash the cuff, remove the bladder and fully engage the hook and the loop. Machine wash warm with a mild detergent (50 -130° F or 1 - 54° C) and line dry.

Reference Information

Refer to our website www.conneqthealth.com for a current list of SphygmoCor publications.

Electromagnetic Compatibility (EMC) Warnings & Declarations

- The SphygmoCor XCEL System needs 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 could affect the SphygmoCor XCEL System

- Use of tonometers, power supplies, accessories, and cables other than those specified or supplied by AtCor Medical may affect EMC compliance of the SphygmoCor XCEL System.

Warning: The SphygmoCor XCEL System is intended for use by healthcare professionals only. The SphygmoCor XCEL 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 XCEL System or shielding the location.

The ShygmoCor XCEL System has been tested, and complies with no deviations to the below immunity and emissions standards.

Electromagnetic Emissions		
Type	**Compliance to standard**	**Electromagnetic environment**
RF emissions (conducted and radiated)	CISPR11 Group 1 Class B	Clinical or Research
Harmonic distortion	IEC 61000-3-2 Class A	Clinical or Research
Voltage fluctuations and flicker	IEC 61000-3-3	Clinical or Research

Electromagnetic Immunity		
Type	**Compliance to standard**	**Test levels Clinical or Research environment**
Electrostatic Discharge	IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM @ 1kHz
Proximity Fields	IEC 61000-4-3	385MHz, 18Hz pulse, 27V/m, 3m distance 450MHz, 18Hz pulse, 28V/m, 3m distance 710MHz, 217Hz pulse, 9V/m, 3m distance 745MHz, 217Hz pulse, 9V/m, 3m distance 780MHz, 217Hz pulse, 9V/m, 3m distance 810MHz, 18Hz pulse, 28V/m, 3m distance 870MHz, 18Hz pulse, 28V/m, 3m distance 930MHz, 18Hz pulse, 28V/m, 3m distance 1720MHz, 217Hz pulse, 28V/m, 3m distance 1845MHz, 217Hz pulse, 28V/m, 3m distance 1970MHz, 217Hz pulse, 28V/m, 3m distance 2450MHz, 217Hz pulse, 28V/m, 3m distance 5240MHz, 217Hz pulse, 9V/m, 3m distance 5500MHz, 217Hz pulse, 9V/m, 3m distance 5785MHz, 217Hz pulse, 9V/m, 3m distance
Electrical fast transients/bursts (EFT)	IEC 61000-4-4	±2kV 100kHz repetition frequency
Surges	IEC 61000-4-5	Line to line ±0.5kV, ±1kV Line to earth ±0.5kV, ±1kV, ±2kV
Conducted disturbances	IEC 61000-4-6	3Vrms, 150kHz to 80MHz 6Vrms for ISM bands between 150kHz-80MHz at 80%AM at 1KHz modulation
Power Frequency Magnetic Fields	IEC61000-4-8	30A/m @ 50Hz and 60Hz
Voltage Interruptions	IEC61000-4-11	0%, 0°, 5 seconds @ 100V 0%, 0°, 5 seconds @ 240V

Voltage Dips	IEC61000-4-11	70%, 0°, 0.5 seconds @ 100V 0%, 0°, 1 cycle @ 100V 0%, 45°, 90°, 135°, 225°, 270°, 315°, @ ½ cycle @ 100V 70%, 0°, 0.5 seconds @ 240V 0%, 0°, 1 cycle @ 240V 0%, 45°, 90°, 135°, 225°, 270°, 315°, @ ½ cycle @ 240V

Important information required by the FCC

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

Technical Specifications

Physical and Environmental Specifications

Operating Ambient temperature:	+15°C to 40°C (59°F to 104°F)	
Operating Relative humidity:	15% to 95% non-condensing	
Storage Ambient temperature:	-20°C to 65°C (-4°F to 149°F)	
Transport Ambient temperature:	-20°C to 65°C (-4°F to 149°F)	
Storage Relative humidity:	20% to 90% non-condensing	
Transport Relative humidity:	20% to 90% non-condensing	
External Power supply	Input	100-240 VAC, 50-60Hz
	Output	15VDC at 2A
	Protective Class	IEC Class II, Double Insulated
	Power Connector	4 PIN DIN
Physical Specifications	Enclosure Material	Polycarbonate
	Weight	0.7 kg (1.5 lbs)
	Dimensions (EM4C)	9.9 (l) x 19 (w) x 17.2 (h) cm
	Dimensions (Tray)	30.5(l) x 16.7 (w) x 8.6 (h) cm
Measurement	NIBP	Oscillometric. Diastolic values correspond to Phase 5 Korotkoff sounds.
Range	NIBP, PWA	Sys: 50 - 260 mmHg Dia: 40 – 200 mmHg
	PWV	2 to 25 m/s
	Heart rate	30 - 220 beats per minute
	Display	0 - 300mmHg
Resolution	1 mmHg	
Tonometer	Uncalibrated pressure transducer	

Maximum Intended Design Life

The Maximum Intended Design Life of the SphygmoCor XCEL device is 5 Years.

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

Recommended Minimum Computer Requirements

Type	x86 PC
Processor	AMD64 compatible (ARM processors not supported)
Nominal Speed	2.4 GHz minimum
Memory	2GB RAM minimum
Hard Disk	Size 40 GB or larger
	2GB for Installation
	10GB for database
Accessories	USB port
Printer Drivers	User Provided
Communications	USB port
Operating Systems	Windows 10, version 22H2, English Windows 11, English

Classification of SphygmoCor System

The SphygmoCor XCEL System is classified as follows:

- Class II
- Double insulated
- Type BF Equipment
- This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- Continuous Equipment

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


Caution


Consult Operating Instructions


Double insulated


Type BF Applied Part


Date of Manufacture



Serial Number


Manufacturer



Tonometer



USB



Power Indicator



DC Power Inlet





Power On/Off



Cuff Indicator



Status Indicator



Emergency Stop

Standards

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

- IEC/EN 60601-1 ANSI/AAMI ES60601-1 CSA C22.2 No 60601.1 Medical electrical equipment -- Part 1: General requirements for safety.
- IEC 80601-2-30 Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.
- IEC 60601-1-2 Medical electrical equipment -- Part 1: General requirements for safety Section 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests.
- 47 CFR Part 15 – Radio Frequency Devices, Subpart B (Unintentional Radiators)

SphygmoCor XCEL Electronics Module, model number EM4X

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by Atcor Medical Pty. Ltd., would void the user's authority to operate the product.

Explanation of Parameters/Indices

The SphygmoCor PWA Report screens and printed reports contain key patient details, the averaged (derived) aortic waveform, and central hemodynamic parameters.

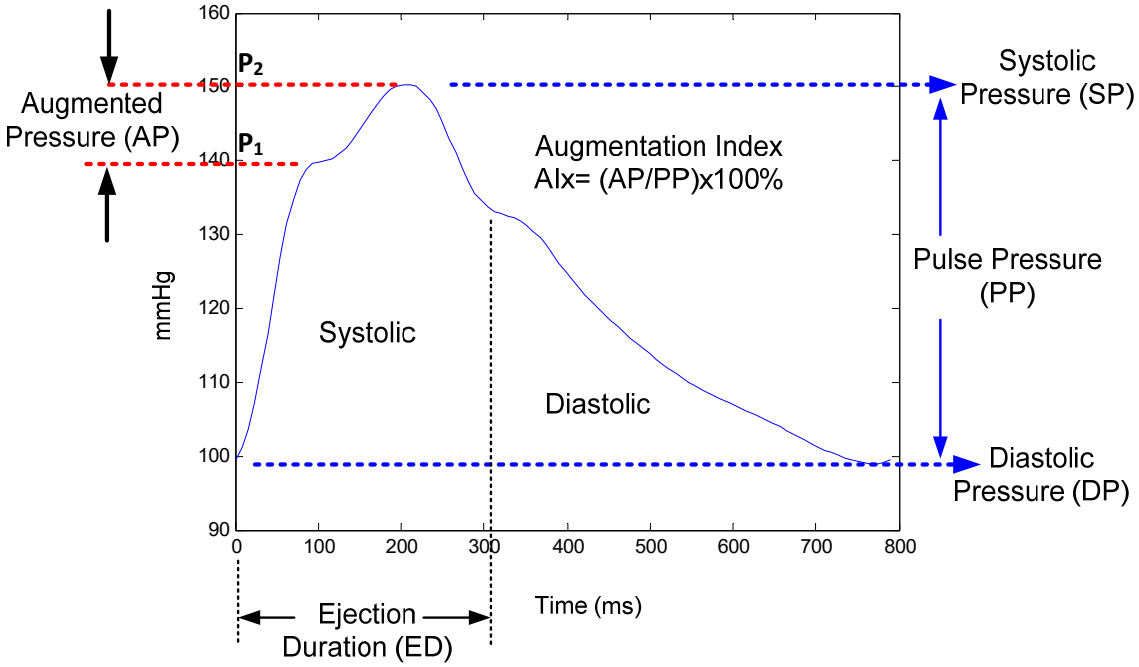
The following parameters apply to each averaged waveform:

Displayed Parameter Summary:

Calculated Parameters	Description	Abbreviation	Units
Peripheral Pulse Indices			
Heart Rate	Number of heart beats per minute	HR	Beats/min
Period	Cardiac pulse length in time	T_F	milliseconds
Ejection Duration	The ejection time in one pulse	ED	milliseconds
Brachial Systolic and Diastolic Pressure	The highest and lowest peripheral (brachial) pressure respectively in one cardiac pulse	SYS, DIA	mmHg
Pulse Pressure - Brachial	The difference between maximum and minimum peripheral pressure in one cardiac pulse. Pulse pressure represents the height of the pressure pulse.	PPP	mmHg
Central Aortic Indices			
Aortic Systolic and Diastolic Pressure	The highest and lowest central aortic pressure respectively in one cardiac pulse	SP, DP	mmHg
Aortic Pulse Pressure	The difference between maximum and minimum (SP, DP) central aortic pressure in one cardiac pulse. Pulse pressure represents the height of the pressure pulse.	PP	mmHg
Mean Pressure	Average pressure in a cardiac pulse	MP	mmHg
Augmentation Index at 75 BPM heart rate	AIx normalised to heart rate of 75 BPM	AIx@75	%

Features of the Arterial Pulse

The following diagram shows the central aortic pressure waveform.



Parameter	Description	Symbol	Units	Calculation	Sample from above graph
Systolic Pressure	The maximum pressure	SP	mmHg	Maximum Point on Chart	150 mmHg
Diastolic Pressure	The minimum Pressure	DP	mmHg	Minimum Point on Chart	100 mmHg
Pulse Pressure	The height of the pressure pulse	PP	mmHg	PP = SP – DP	= 150 – 100 mmHg = 50 mmHg
Augmentation Pressure	The difference in pressure between the two peaks during heart ejection (systolic). The first peak (P_1) is related to cardiac ejection and the second peak (P_2) is related to wave reflection due to arterial stiffness.	AP	mmHg	AP = $P_2 – P_1$	= 150-140 mmHg = 10 mmHg
Augmentation Index	The difference between the two peaks during heart ejection, relative to the pressure pulse height or pulse pressure (PP). AIx is defined as (AP/PP) x 100%. The measurement is an indication of arterial wave reflection which is due to arterial system elasticity.	AIx	%	AIx=(AP/PP)x100%	= (10/50)*100% = 20 %

Warranty

The SphygmoCor® XCEL 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 XCEL system will be provided by AtCor Medical technical support group. Contact your local distributor to organise the service.

Product Support

If you have additional questions after reviewing the manual, contact your local AtCor Medical representative / distributor. The details of your local representative / distributor can be found at www.atcormedical.com .

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

When contacting your local AtCor Medical representative / distributor, please have your SphygmoCor XCEL System nearby as well as copy of the Operator's Manual open on your PC. You should be prepared to give the following information, if applicable:

- System ID number
- The error number and exact wording of any messages that appear. The error number will appear in the corner of the error message window.
- Relevant details related to the issue, and activity that transpired prior to the problem occurrence.
- Any action that you took as a result of a warning/error/problem.
- The version of your SphygmoCor software.

Safety Warnings

Medical Equipment Systems Compliance Warnings

(IEC60601-1 Section 16 & IEC60601-1-1)

IEC60601-1-1 compliance is the responsibility of the end user. To ensure compliance to IEC60601-1 Section 16 & IEC60601-1-1, the SphygmoCor XCEL System must meet the following three conditions:

1. Ensure that only the SphygmoCor XCEL device, Tonometer, cuffs and hose are within reach of the patient. The computer and other devices should be at least 1.5m (6ft) away from the patient.
2. The PC and peripherals (e.g. USB hubs) must comply with IEC60950 or equivalent.
3. 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).
4. The required low enclosure leakage current may be achieved by powering the PC and peripherals from an isolation transformer. Connecting the SphygmoCor XCEL System to other non-isolated monitoring equipment or communication networks is not recommended. It is the end user's responsibility to ensure compliance with IEC60601-1 Section 16 and IEC60601-1-1.

General Safety Warnings

1. When using the SphygmoCor XCEL device, 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 XCEL System is in use.
2. Do not connect any peripheral devices (e.g. printer, externally powered USB hubs) to the computer while using the SphygmoCor XCEL System as they may breach the patient isolation requirements of IEC60601-1 & IEC60601-1-1.
3. When using an isolation transformer and a multiple portable socket-outlet or power board to connect to the computer and the SphygmoCor XCEL System, do not connect any other devices or equipment to the multiple portable socket-outlet or power board.
4. When using the SphygmoCor XCEL System, the operator should not touch the computer and the patient at the same time.
5. Do not connect or use any cables, cuffs, hose or tonometer other than those specified for use with the SphygmoCor XCEL System.
6. Do not disassemble the SphygmoCor XCEL device. The SphygmoCor XCEL device does not contain any serviceable parts. Servicing shall be performed by qualified service personnel.

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 organization 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 XCEL System is connected to a network or the internet, the provider of services is responsible for ensuring the security of the information.

Refer to Appendix 2 for details.

Disposal

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.

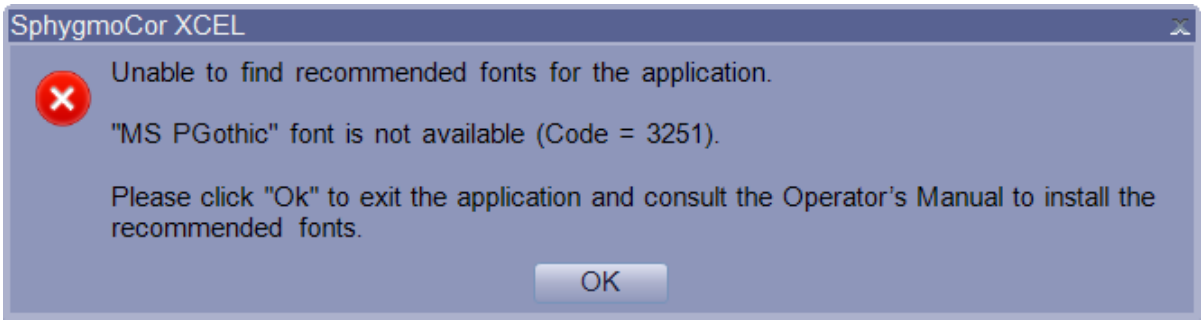
If you need information on these disposal systems, please contact your local waste administration. The crossed-bin symbol invites you to use these disposal systems. If you require information on collection and disposal of your AtCor Medical device please contact AtCor Medical Head Office or local distributor.



Appendix 1

Installing Recommended Fonts on Different Versions of Windows

The following error message (Code=3251) indicates the unavailability of one or more fonts in Windows. In this case, for example, the **recommended** font (MS PGothic) is not available, and the user needs to add this font to Windows.



To resolve this error, follow the instructions below depending on the operating system used.

Windows 10

1. Click the **Start** button.
2. In **Settings**, click **System**.
3. Click **Apps & features**.
4. Click on the link, **Manage optional features**.
5. Click on the "**+**" icon next to Add a feature.
6. Scroll to find your recommended font. Click on that item, then click on **Install**.
7. Click on the back arrow in the upper left corner of the window to see the font installation in progress.
8. When finished, click **Set optional feature history** to confirm installation was successful.
9. Restart Windows.

Windows 11

1. Click the **Windows** button.
2. Select **Settings**.
3. Select **Personalisation**.
4. Click on the link **Fonts**.
5. Follow screen instructions for 'Browse and install fonts', select the font, and install.
6. Restart Windows.

Appendix 2

Cybersecurity Information for Users

1. Cybersecurity Responsibilities of the User

To ensure safe and secure operation of the SphygmoCor XCEL system, users must:
- Use supported versions of Microsoft Windows 10 or 11 with current security patches
- Restrict access to the workstation hosting the system using strong user passwords
- Ensure the device is connected to a secure local area network managed by their IT department
- Disable public file sharing and enforce operating system-level access controls
- Apply all XCEL software updates

2. Software Update Capabilities

Software updates for the XCEL Desktop Application are provided manually. When available, an update will be:
- Announced via email directly to the customer
- Available for download from a secure server
- Published and signed by “AtCor Medical Pty. Ltd.”

Users are responsible for downloading and applying updates manually following provided instructions.

3. Use of Third-Party Components

The XCEL Desktop Application includes several third-party software libraries. A Software Bill of Materials (SBOM) is maintained by Atcor Medical and monitored for known vulnerabilities. If a high-severity vulnerability is identified in a used component, users will be notified.

4. Security Controls Built into the Product

The following security measures are built into the system:
- Software updates are digitally signed
- The application accepts no inbound network connections
- Data access is restricted by the operating system’s user-level permissions
- No remote execution or remote desktop interfaces are enabled by default

5. Network Requirements and Restrictions

The system does not require continuous internet access. It connects periodically to validate licensing. There are no incoming network services or open ports. The system is designed to be operated securely within a managed network environment.

6. Data Handling and Privacy

All data generated by the SphygmoCor XCEL system is stored on the installed database. It is the responsibility of the institution to:

- Manage encryption of backups if required
- Restrict physical and digital access to the workstation
- Comply with applicable data protection regulations (e.g. HIPAA, GDPR)

7. Vulnerability Disclosure Policy

AtCor Medical supports responsible disclosure. Security researchers or users who identify potential cybersecurity issues are encouraged to contact AtCor Medical via the official support channels for coordinated resolution.