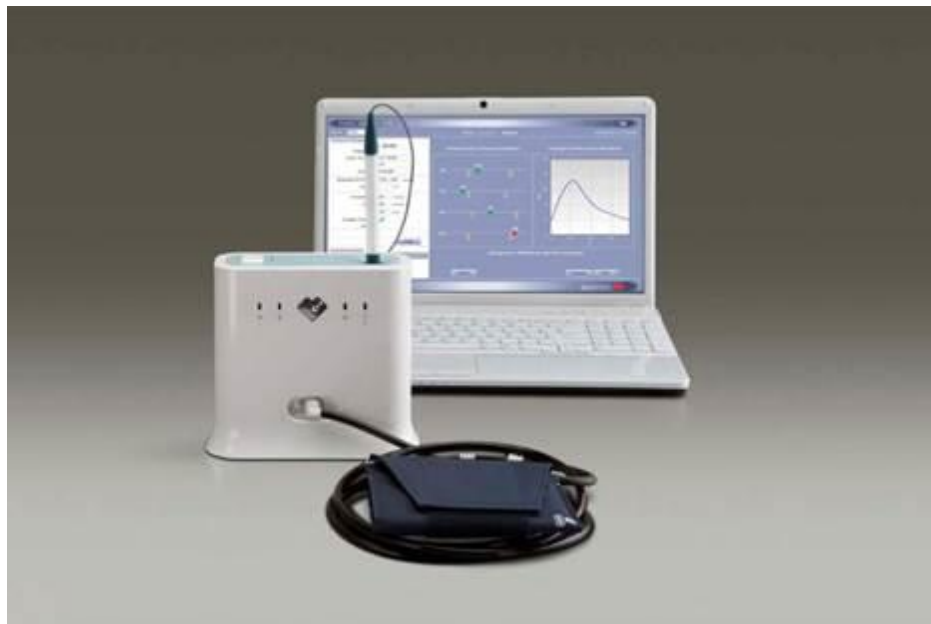




SIMPLY THE GOLD STANDARD

Service Manual

SphygmoCor XCEL System



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SphygmoCor® XCEL Service Manual

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DCN: 101397

Manual Revision: 4.0

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Disclaimer

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

This Manual is produced on the assumption that the operator is an experienced user of the Windows XP/ Windows 7/ Windows 8 operating Systems.

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

Trademarks

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

IBM, Microsoft, and Windows are the registered trademarks of their respective holders.

Caution

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

Cautions, Warnings and Contraindications

Please refer to the SphygmoCor XCEL Operator's Manual (DCN 101335) for the list of cautions, warnings and contraindications.

Troubleshooting SphygmoCor XCEL

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 does not resolve or 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 the USB drivers have been installed on the computer (refer to Step 4 in *Installation on the User Manual*).

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.

Note: If the Status Light is either flashing yellow, flashing red, or is off, then return the unit to the manufacturer.

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.

SphygmoCor XCEL Software

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.

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 Calibration due to weak oscillometric signal (Code = 1).	<ul style="list-style-type: none">• 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
2	Unable to continue Brachial Calibration due to erratic oscillometric signal (Code = 2).	<ul style="list-style-type: none">• 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 Calibration due to exceeded retry count (Code = 3).	<ul style="list-style-type: none">• 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 <p>After completing these steps, attempt another measurement</p>
4	Unable to continue Brachial Calibration due to exceeded measurement time limit (Code = 4).	<p>Before retrying the measurement:</p> <ul style="list-style-type: none">• Ensure that the patient's arm remains stationary during measurement

Error Code	Error Message	Action
		<ul style="list-style-type: none"> • Ensure use of correct cuff size, correct positioning and fit • Remove any obstructions between the cuff and patient's arm <p>After completing the above steps, attempt another measurement</p>
85	Unable to continue Brachial Calibration due to pneumatic blockage (Code = 85).	<ul style="list-style-type: none"> • 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 <p>After completing the above steps, attempt another measurement</p>
87	Unable to continue Brachial Calibration due to inflate timeout (Code = 87).	<ul style="list-style-type: none"> • 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 <p>After completing the above steps, attempt another measurement</p>
88	Unable to continue Brachial Calibration due to safety timeout (Code = 88).	<ul style="list-style-type: none"> • 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 <p>After completing the above steps, attempt another measurement</p>
89	Unable to continue Brachial Calibration due to cuff overpressure (Code = 89).	<ul style="list-style-type: none"> • 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 <p>After completing the above steps, attempt another measurement</p>
90*	Unable to continue Brachial Calibration due to hardware	<ul style="list-style-type: none"> • Turn the device OFF.

Error Code	Error Message	Action
	problem (Code = 90).	<ul style="list-style-type: none"> • Ensure the data/power input are connected • Turn the device ON <p>After completing the above steps, attempt another measurement</p>
103*	File "DatabaseUpgradeReport.csv" is in use by other application (code=103)	Close the application
608*	Unable to backup database to <pathname> (Code = 608).	<ul style="list-style-type: none"> • Select a different folder for backup (preferably at the local PC instead of the network), and then attempt to backup the database again
609*	Unable to restore database from <pathname> (Code = 609).	<ul style="list-style-type: none"> • Copy the backup file in a different folder (preferably at the local PC instead of the network) • Try to restore from the new location of the backup file.
611*	Unable to migrate data due to database error (Code = 611).	<ul style="list-style-type: none"> • Ensure that the PC can locate the SQL data server. • Restart the SphygmoCor XCEL software.
800*	Database server is not responding (Code = 800).	<ul style="list-style-type: none"> • Restart the computer • Insert the SphygmoCor XCEL installation DVD • Select Create Database and follow the instructions on the screen.
2046	Unable to continue Capture due to unsuccessful start of capture (Code = 2046).	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Ensure that the device is connected to the computer • Ensure that the cuff is connected to the device.

Error Code	Error Message	Action
	the cuff	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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) (Code = 2053)	<ul style="list-style-type: none"> • Press the STOP button on the device 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
2058	Unable to continue Capture due to exceeding the maximum number of inflation/deflation cycle per measurement (Code = 2058).	<ul style="list-style-type: none"> • 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).	<ul style="list-style-type: none"> • 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

Error Code	Error Message	Action
		select Find Module. <ul style="list-style-type: none"> Attempt Capture again.
2077 2078	Unable to continue Capture due to Communication error (Code=2077) (Code=2078)	<ul style="list-style-type: none"> 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).	<ul style="list-style-type: none"> 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 Calibration due to brachial pressure being outside the normal range (Code=2080)	<ul style="list-style-type: none"> 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 Ensure that there are no obstructions between the cuff and arm. After completing the above steps, repeat measurement.
2081*	Unable to continue Brachial Calibration 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:	In the Set Up screen, click System Key Enter the correct system key provided by AtCor Medical

Error Code	Error Message	Action
	<p>(a) Unable to find the Electronics Module due to mismatch serial number</p> <p>(b) Unable to start Brachial calibration due to mismatch serial number</p> <p>(c) Unable to start Capture due to mismatch serial number</p>	
2091	<p>One of these messages related to “incomplete calibration” error will appear:</p> <p>(a) Unable to find the Electronics Module due to incomplete calibration</p> <p>(b) Unable to start Brachial calibration due to incomplete calibration</p> <p>(c) Unable to start Capture due to incomplete calibration</p>	<p>Close SphygmoCor XCEL Software</p> <p>XCEL Electronics Module need to be calibrated. Please refer to SphygmoCor XCEL Calibration KIT or contact AtCor Medical for technical support.</p>
3051*	Unable to generate PWV Report (Code= 3051).	<ul style="list-style-type: none"> • 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).	<ul style="list-style-type: none"> • 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

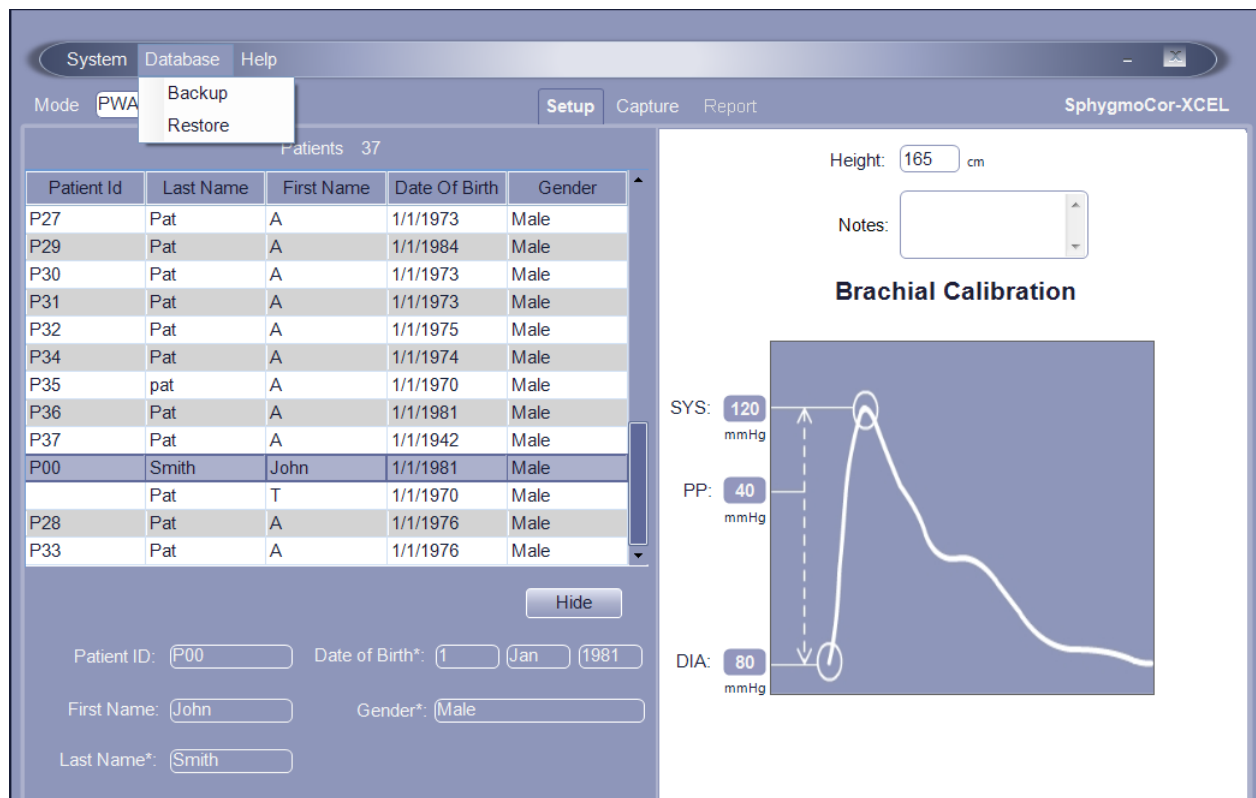
Error Code	Error Message	Action
		<p>it is correctly positioned</p> <ul style="list-style-type: none"> • Ensure waveform quality (use the guidance bar). • After completing the above steps, repeat PWV measurement
3053*	Unable to generate PWA Report (Code= 3053).	<ul style="list-style-type: none"> • Ensure 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).	<ul style="list-style-type: none"> • 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).	<ul style="list-style-type: none"> • 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)	<p>Close SphygmoCor XCEL software</p> <p>Turn the device OFF and ON.</p> <p>Open SphygmoCor XCEL software</p>
3125	Unable to calculate PWV (Code= 3125).	<ul style="list-style-type: none"> • Ensure that the entered distance in mm is correct.

Error Code	Error Message	Action
3126*	Unable to find the Electronics Module (Code = 3126).	<ul style="list-style-type: none"> Ensure the device is on. Ensure the device is connected to the computer. In the Setup screen, click System and select Find Module.
3136*	Unable to continue due to the incompatible database version (code=3136)	Upgrade SphygmoCor XCEL software

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

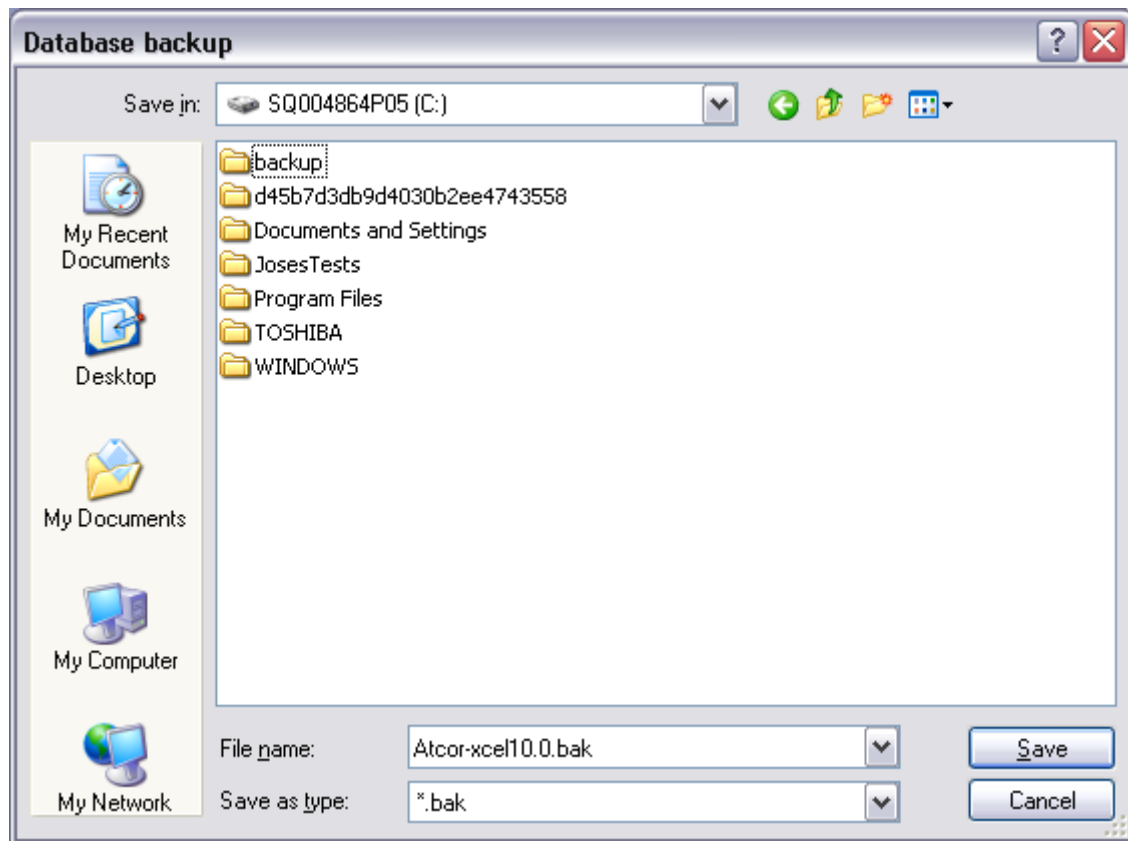
Database Manager

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. Choose a location to save your back up file and click **Save**.

The backup database must not be saved in any of the following locations:

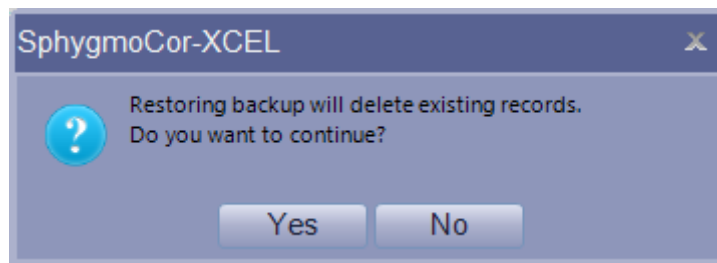
- C:\
- C:\Program Files
- C:\Documents and Settings
- Desktop
- My Documents
- Any network folder

Restore a Database

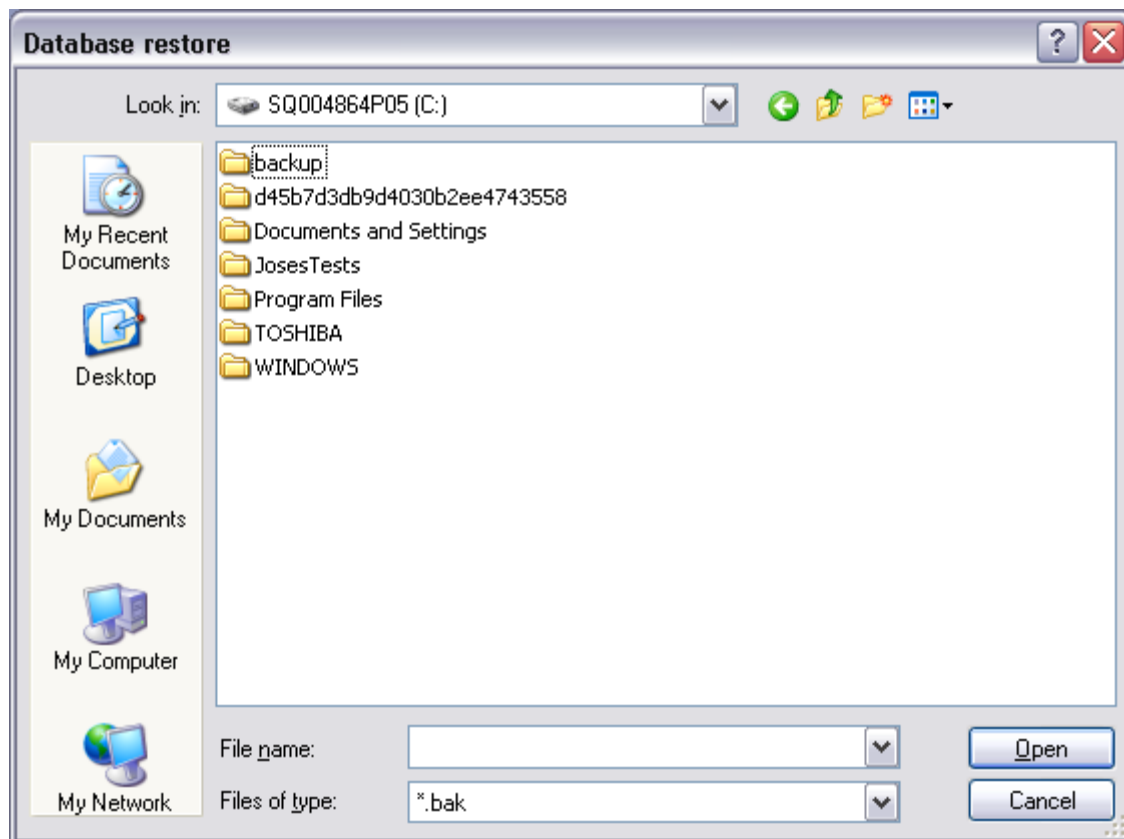
The Database – Restore feature is used if a database becomes corrupted or needs to be installed onto another PC.

Note: When the SphygmoCor XCEL is used by multiple users, SphygmoCor XCEL should not be accessed by other users before the database is restored.

1. Select **Database - Restore**.

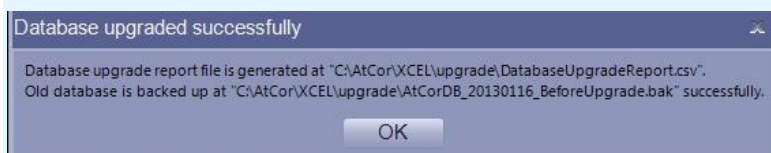


2. Click **Yes** if you are certain that you want to replace your existing database with a backup database.



Navigate to the location of the backup file and click Open. The restore will be completed automatically.

Note: When restoring the SphygmoCor XCEL database from an earlier version , a message will appear indicating that database upgrade report is generated and the earlier version XCEL database is backed up.



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 in the user manual.

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 isn't stored properly.

Caution: Do not shake or drop the unit.

Shutting down

Do not power the PC off until the SphygmoCor XCEL software and Windows software have been exited. 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

The SphygmoCor XCEL System should be checked annually for calibration. 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 unauthorized 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 shuts 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 (PureGreen24™ & SpectraSan™ 24), Octyl decyl dimethyl ammonium chloride with dioctyl dimethyl ammonium chloride with didecyl dimethyl ammonium chloride with dimethyl benzyl ammonium chloride (Protex™), 99% isopropyl alcohol, or T-Spray™. Note: Some disinfectants may cause the cuff blue color to bleed into cuff labeling. 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.

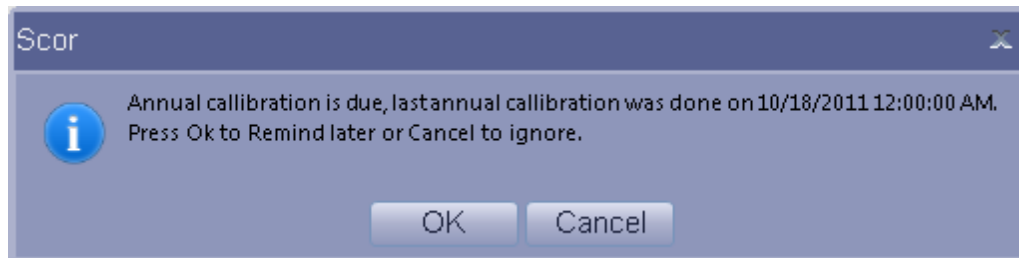
OR

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.

Calibrating SphygmoCor XCEL

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

When calibration is due, the following message will appear in the SphygmoCor XCEL application:



Note: The SphygmoCor XCEL device will continue to take measurements even though the calibration period has expired.

2 options are available for completing calibration:

- 1- Contact your distributor or AtCor Medical to arrange for your SphygmoCor XCEL to be returned for calibration.
- 2- Purchase a Calibration Kit. Contact your distributor or AtCor Medical for further information.

SphygmoCor XCEL Calibration Kit Operating Instructions

Intended Use

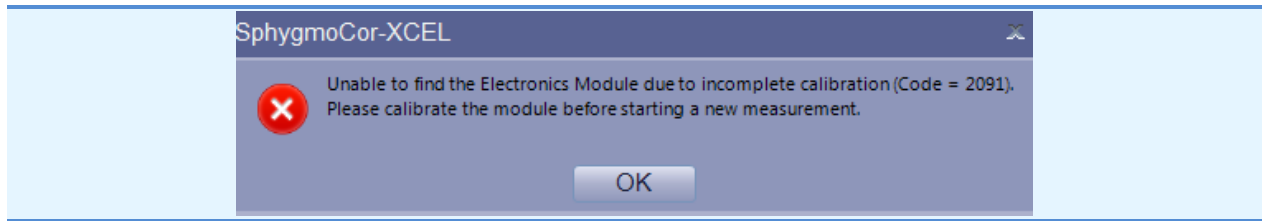
The SphygmoCor XCEL Calibration Kit calibrates the SphygmoCor XCEL Device by providing a rigid 1/2L volume and a pumping bulb to pressurise the pneumatic system. An external calibrated manometer (electronic manometer, Sphygmomanometer mercury column, or aneroid Sphygmomanometer) with indication in mmHg and resolution of 1mmHg shall be used with the SphygmoCor XCEL Calibration Kit. The SphygmoCor XCEL Calibration Kit is intended to be used by medical professionals and biomedical service personnel.

Warning: The aneroid Sphygmomanometer or manometer that will be used to calibrate the SphygmoCor XCEL, must be calibrated prior to calibrating the SphygmoCor XCEL device.

Basic Care

As per the relevant areas of the Basic System Care section for the SphygmoCor XCEL.

Note: If the following message appears in SphygmoCor XCEL application indicating incomplete or unsuccessful calibration, then refer to the Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.



WARRANTY: The SphygmoCor® XCEL Calibration Kit components are guaranteed for one year from the date of purchase

Calibration Kit Components

The Calibration Kit contains the following components:

- 1- Calibration Pneumatic kit



- 2- 1/8 " male to 1/8" male adapter



- 3- 3/16" male to 3/16" male adapter



- 4- 3/16" female to 1/8" male adapter



5- Calibration Kit Dongle

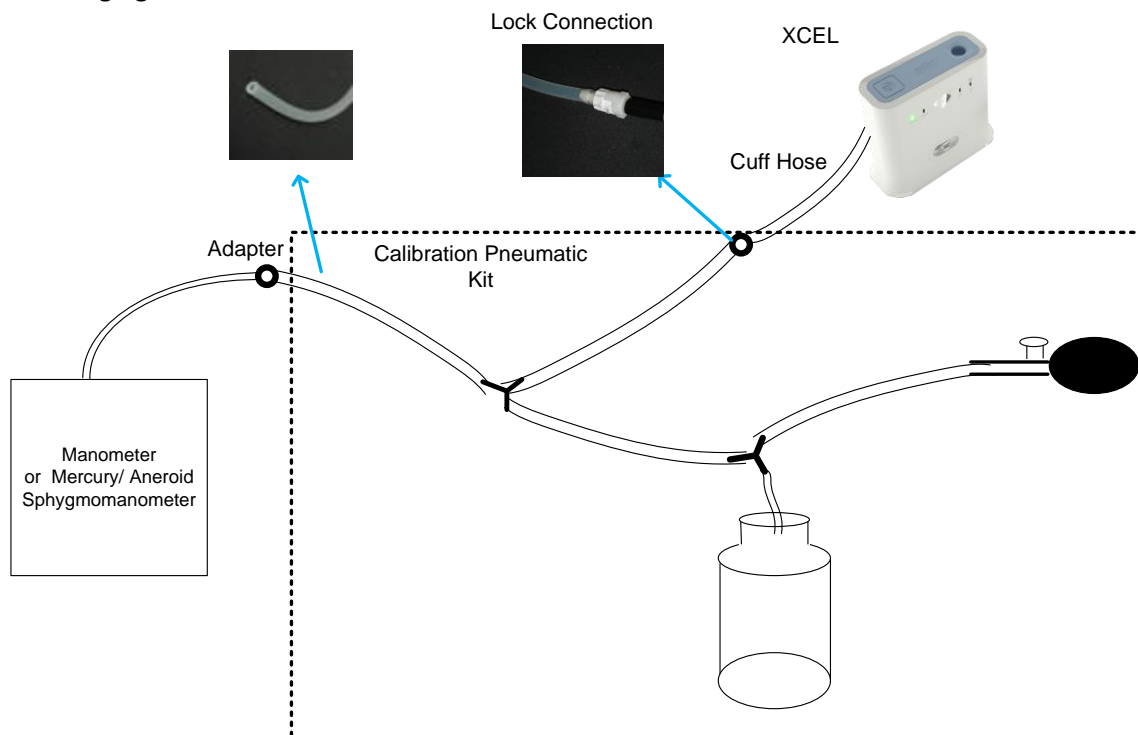


6- Calibration Installation CD



Calibration Setup

Connect the open ended tube of the Calibration Pneumatic Kit to a calibrated manometer (electronic or Sphygmomanometer mercury column or aneroid Sphygmomanometer, with reading in mmHg, and resolution of 1mmHg) using one of the adaptors provided. Connect the other tube of the Calibration Pneumatic Kit to the cuff hose of SphygmoCor XCEL using the lockable connection as illustrated in the following figure

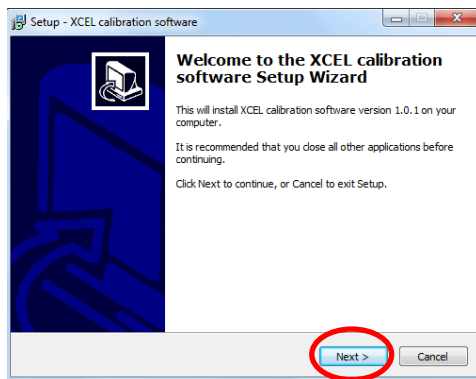


Installation of the SphygmoCor XCEL Calibration Software

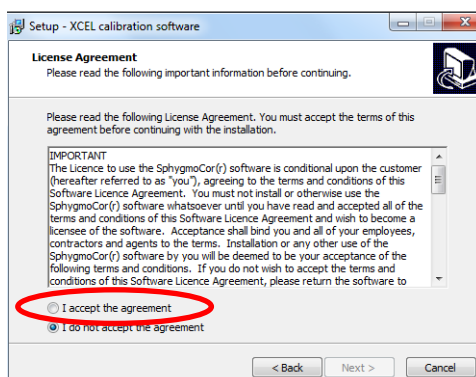
Minimum computer requirements to install the XCEL Calibration Software

Type	IBM Compatible PC
Processor	Intel or compatible
Nominal Speed	2GHz minimum
Memory	1GB RAM minimum
Hard Disk	2GB for Installation
Accessories	DVD drive
Printer Drivers	Standard
Communications	USB port
Operating Systems	Windows 7 Professional (32 and 64 bits) Windows 8 Professional (32 and 64 bits)

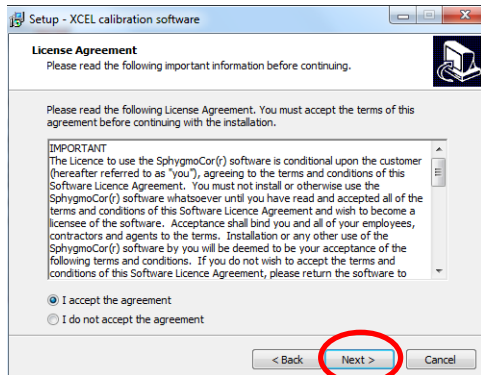
- 1- Insert the installation disk into the CD / DVD Drive and run setup.exe



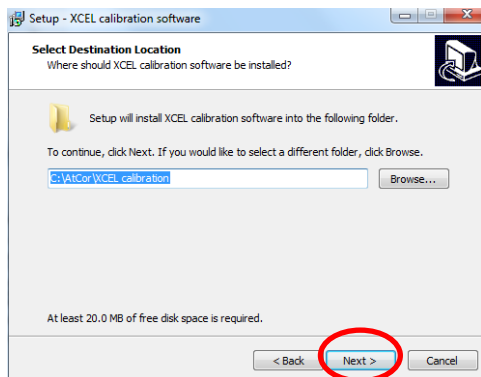
- 2- Click Next



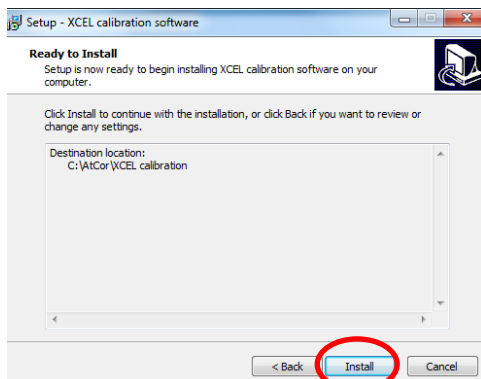
- 3- Select "I accept the agreement" if you agree with the terms and conditions.



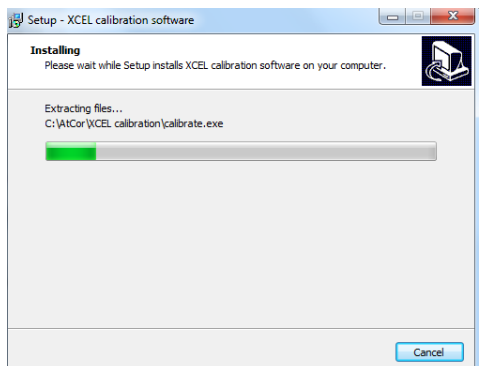
- 4- Click *Next* when the Next button is enabled.

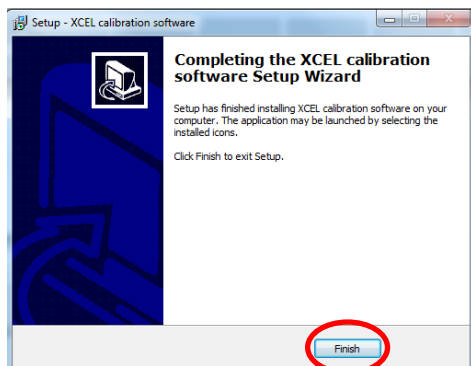


- 5- Click *Next* when this screen appears.



- 6- Click *Install* when this screen appears.





- 7- Click *Finish* when the installation is complete

SphygmoCor XCEL Calibration Steps

Note: If during the calibration process a message appears indicating incomplete or unsuccessful calibration, or the calibration did not complete as expected, then refer to the Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.

- 1- Turn the SphygmoCor XCEL device ON, and connect the USB cable to your computer.
- 2- Connect either the tonometer supplied with your SphygmoCor XCEL or the Calibration Kit Dongle to the SphygmoCor XCEL device.

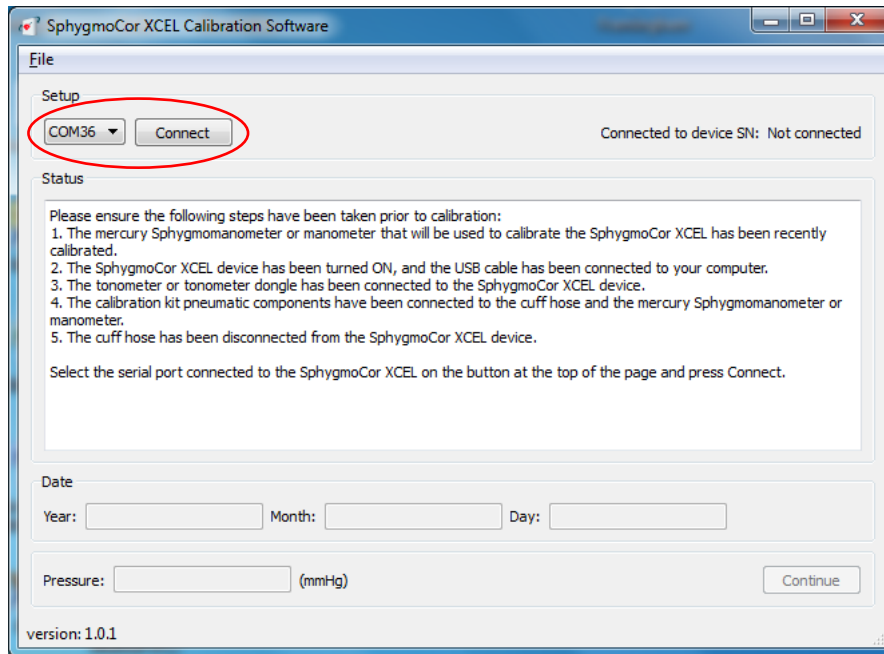
Note: To disconnect the Tonometer/Calibration Kit Dongle, gently push back the connector plug and the connector will automatically release away from the module. DO NOT twist the Tonometer/tonometer dongle connector.



- 3- Disconnect the cuff hose from the SphygmoCor XCEL device.



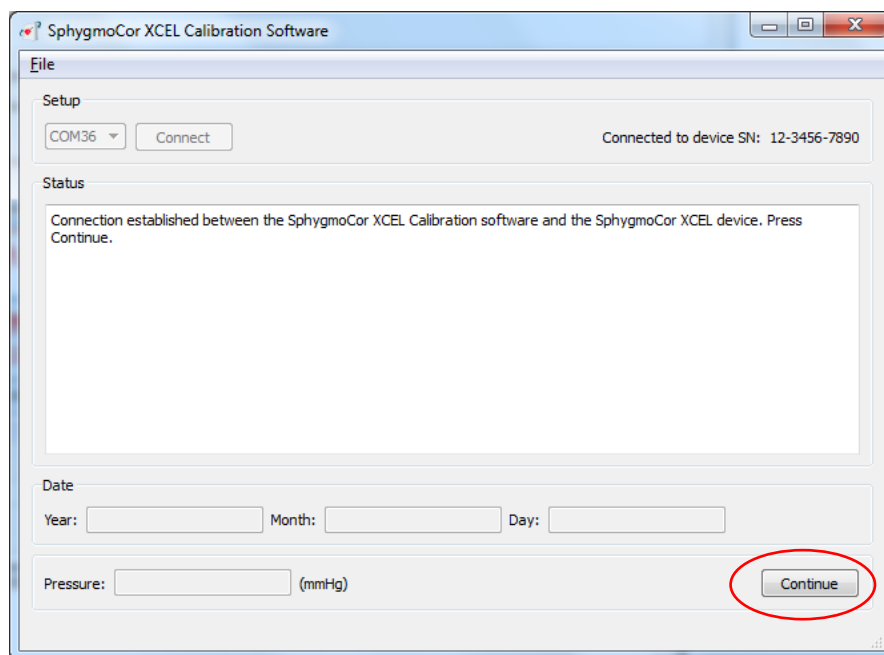
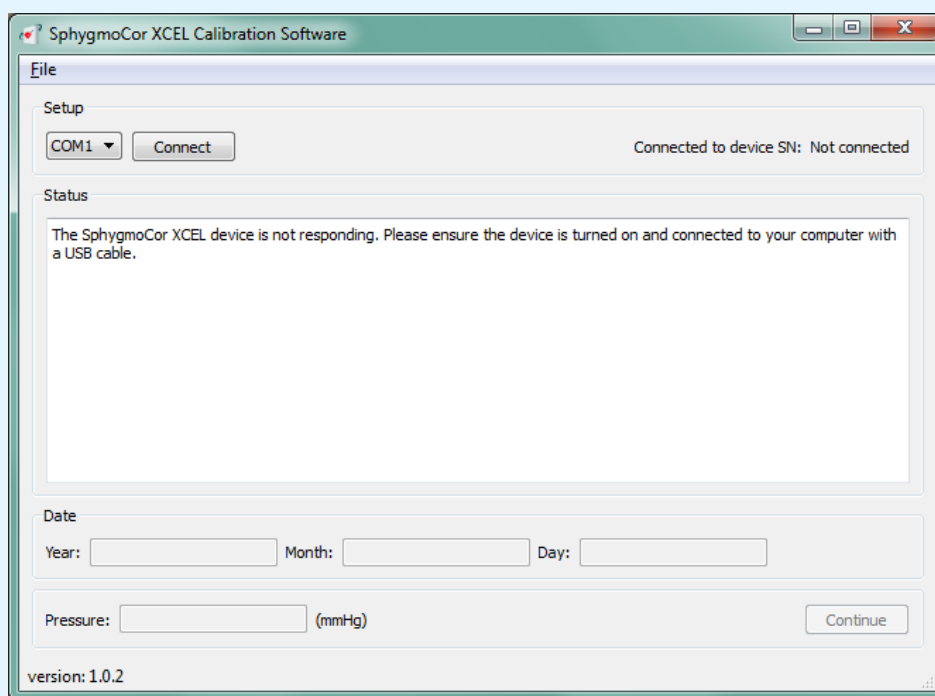
- 4- Run XCEL Calibration Software by selecting this icon.



- 5- Select the Com port number that is connected to the SphygmoCor XCEL device using the drop down menu and click *Connect*

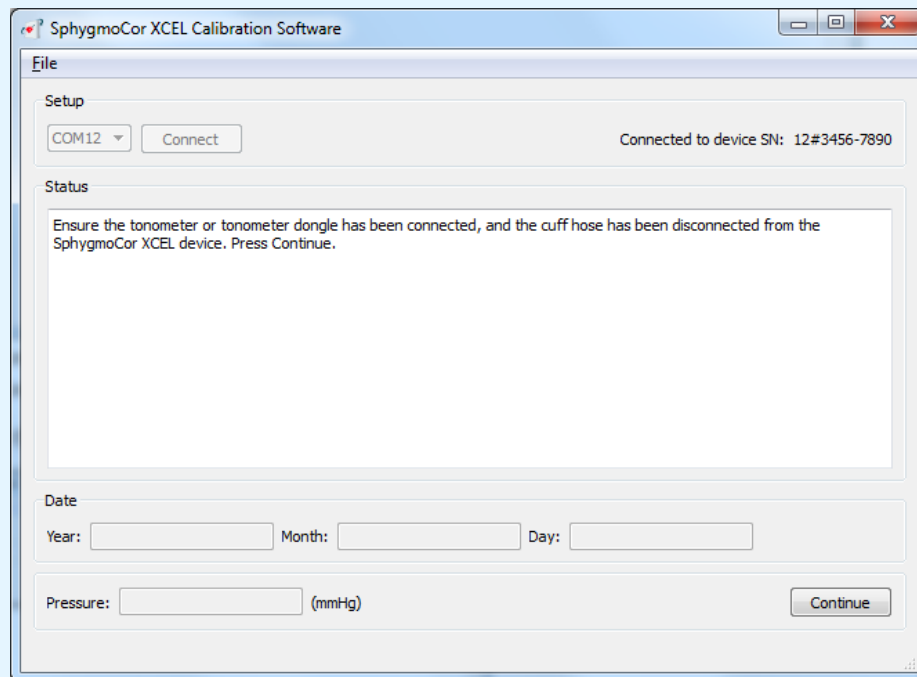
Note: To find the Com port that is connected to the SphygmoCor, please refer to the Finding Com Port Section in the Calibration Troubleshooting section.

Note: The following screen appears if the incorrect Com port has been selected. Please refer to the Finding Com Port Section in the Calibration Troubleshooting section.

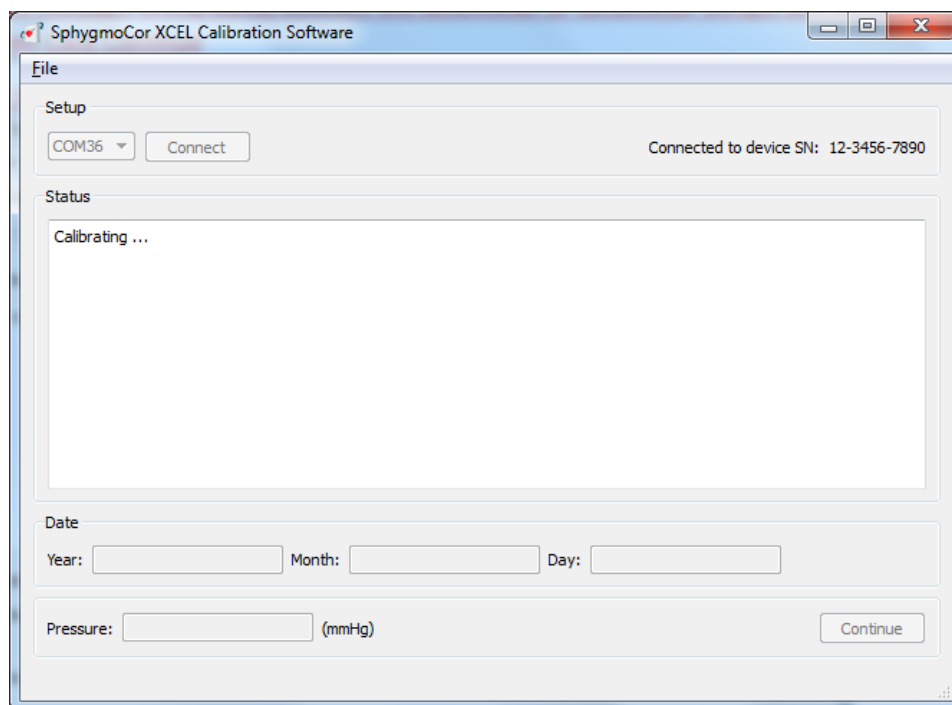


6- If successfully connected, click *Continue* in the bottom right hand corner

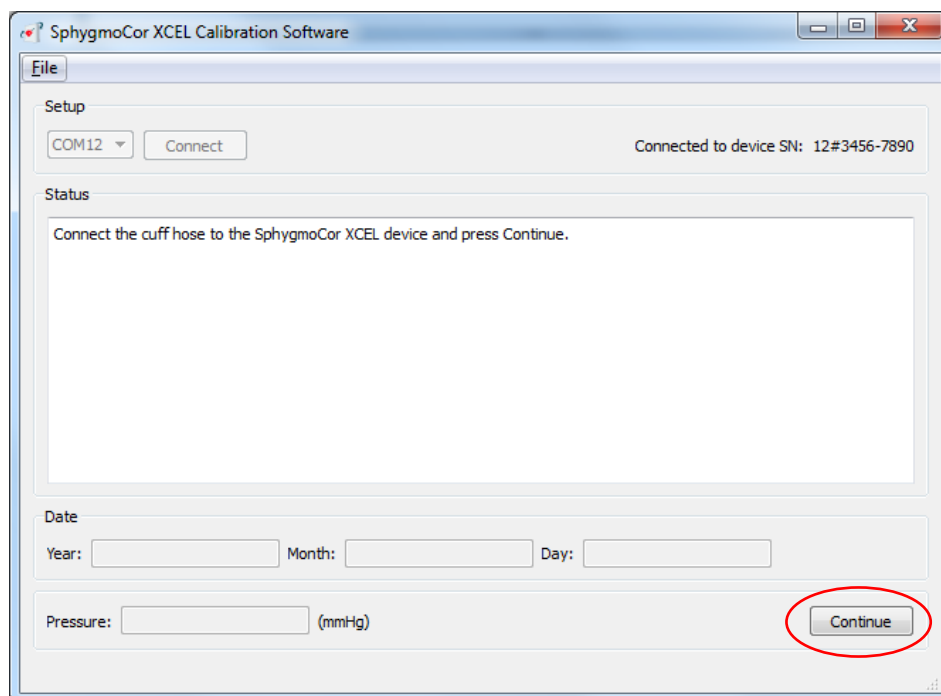
Note: The following screen appears if the tonometer or Calibration Kit Dongle is not connected, or if the cuff hose is connected to the SphygmoCor XCEL device.



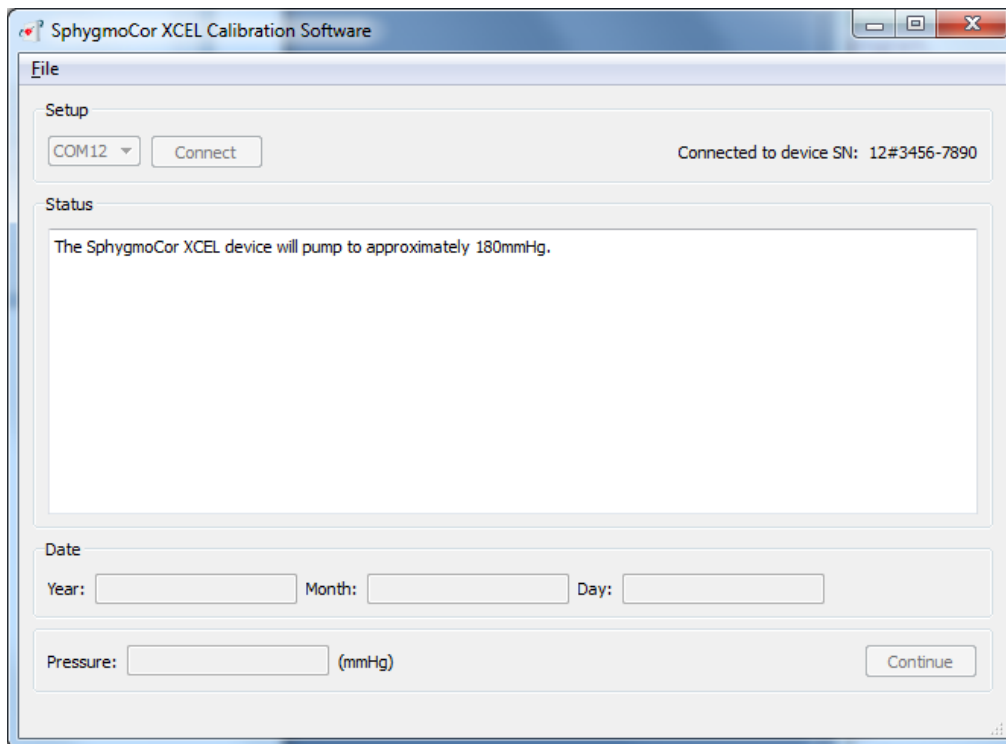
If this message is displayed, connect the tonometer or Calibration Kit Dongle and disconnect the cuff hose then click Continue



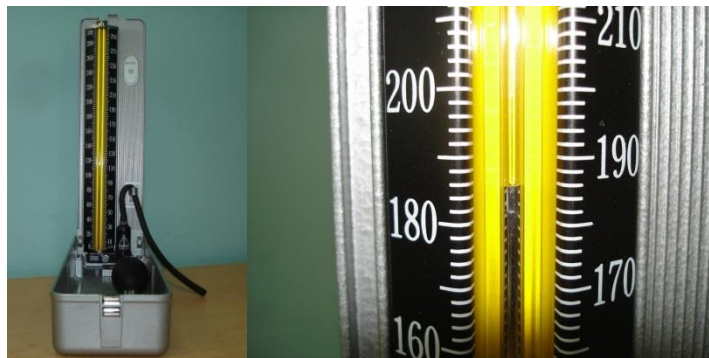
7- The software will display this message for a few seconds.



8- Connect the cuff hose on the SphygmoCor XCEL and click *Continue*



9- The software will display this message



10- Review the pressure displayed on the manometer or Sphygmomanometer

SphygmoCor XCEL Calibration Software

File

Setup

COM36 Connected to device SN: 12-3456-7890

Status

Read the pressure on the mercury Sphygmomanometer or manometer, enter it in the Pressure box, then press Continue when enabled.

Date

Year: Month: Day:

Pressure: (mmHg)

11- Enter the pressure value in whole numbers (no decimal points) and Click *Continue*

Note: The pressure value should be entered within 30 seconds; otherwise the following screen will appear:

SphygmoCor XCEL Calibration Software

File

Setup

COM12 Connected to device SN: 12#3456-7890

Status

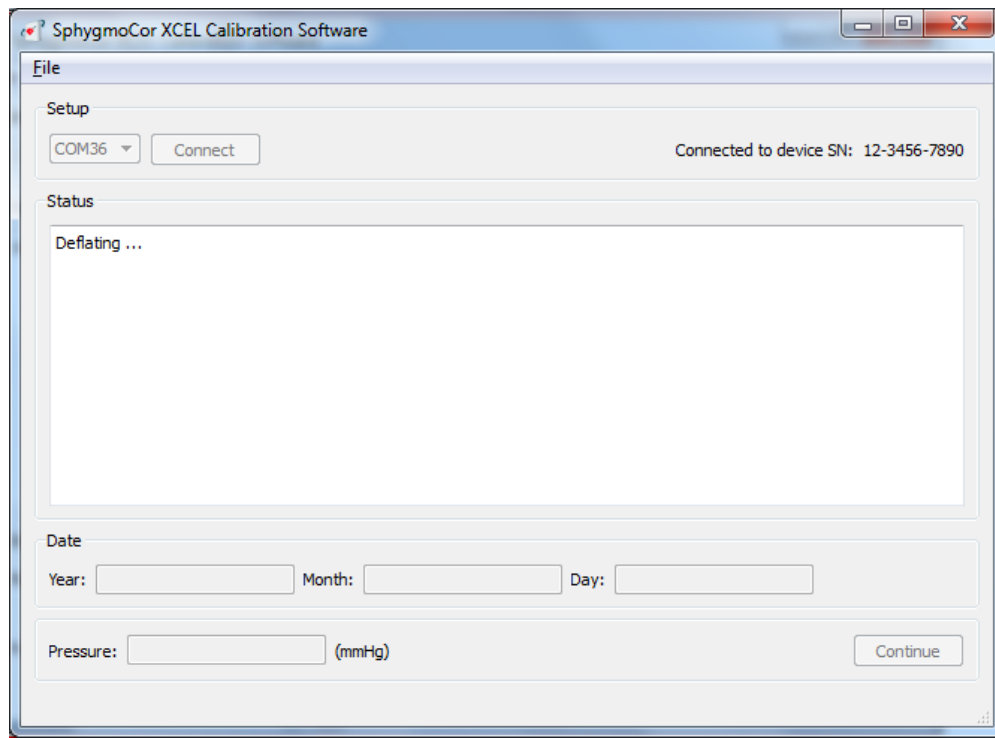
SphygmoCor XCEL calibration has not been completed.
Power off and on the SphygmoCor XCEL device.
Close this application and repeat the calibration procedure.

Date

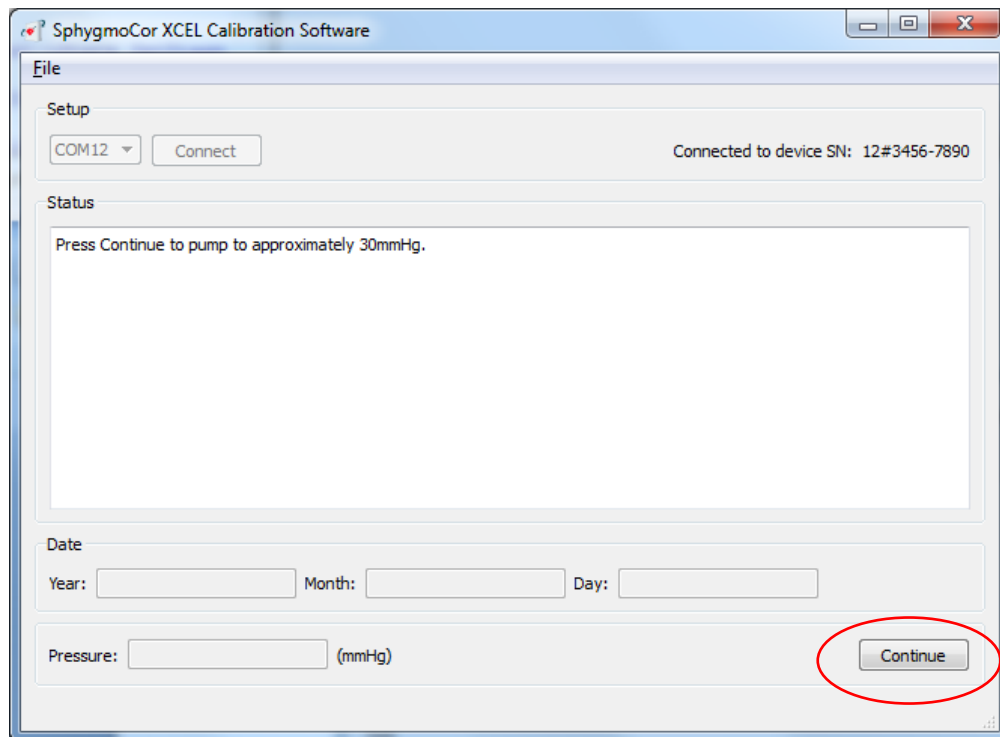
Year: Month: Day:

Pressure: (mmHg)

If this message appears, turn OFF and then ON the SphygmoCor XCEL device, close the SphygmoCor XCEL Calibration software, and repeat the calibration procedures from step 1. Please refer to Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.



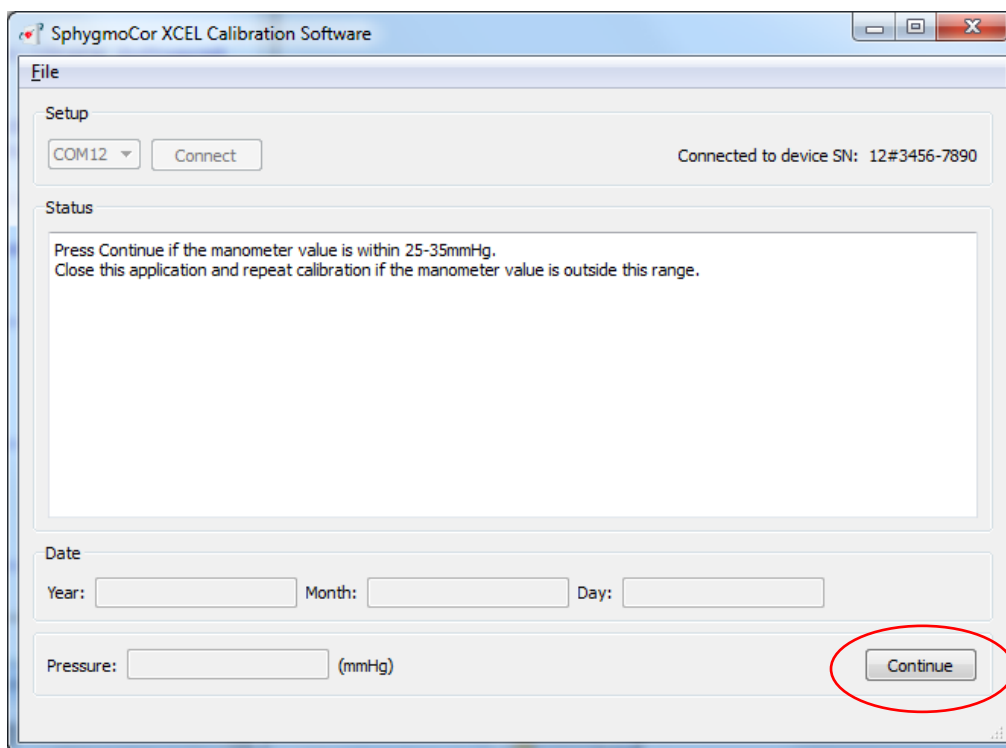
12- The software will display this message.



13- Click *Continue*

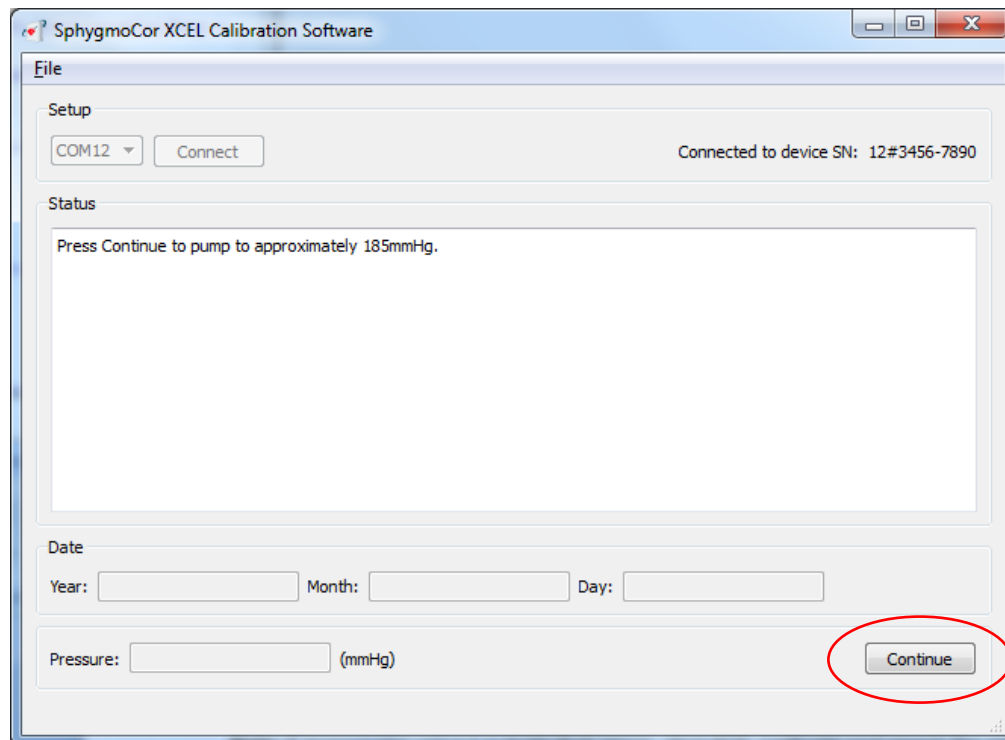


14- View the pressure displayed on the manometer or Sphygmomanometer



15- If the manometer readings is between 25-35 mmHg click *Continue*.

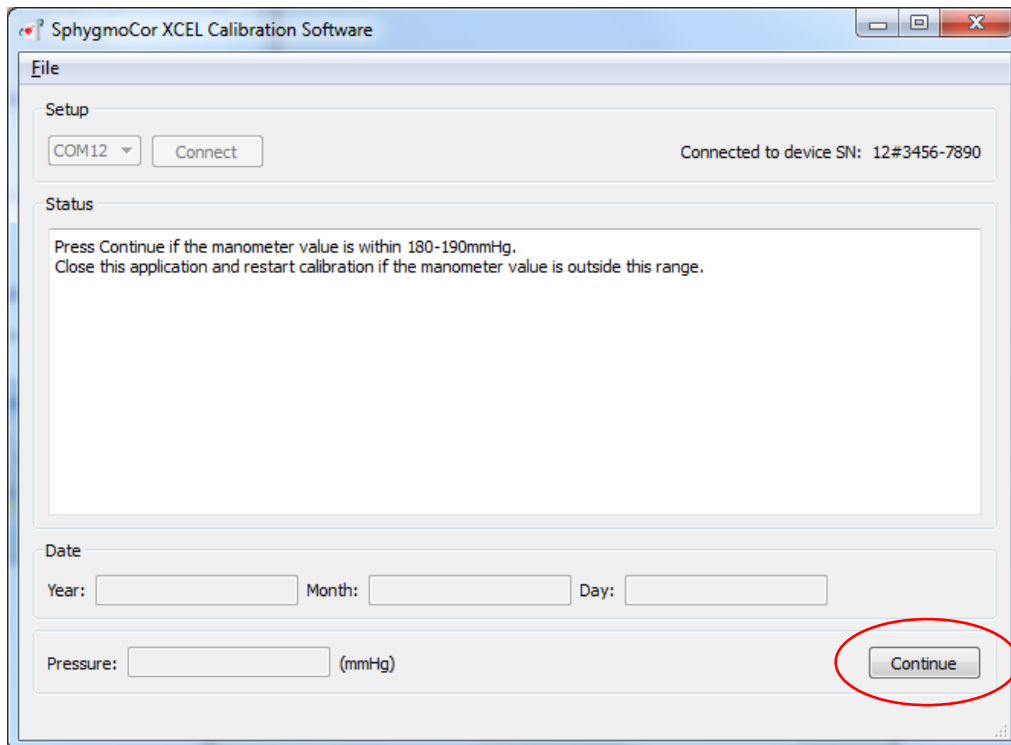
Note: If the manometer reading is not between 25-30 mmHg, close the SphygmoCor XCEL Calibration software and start the calibration procedures from Step 1. Please refer to Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.



16- Click *Continue*



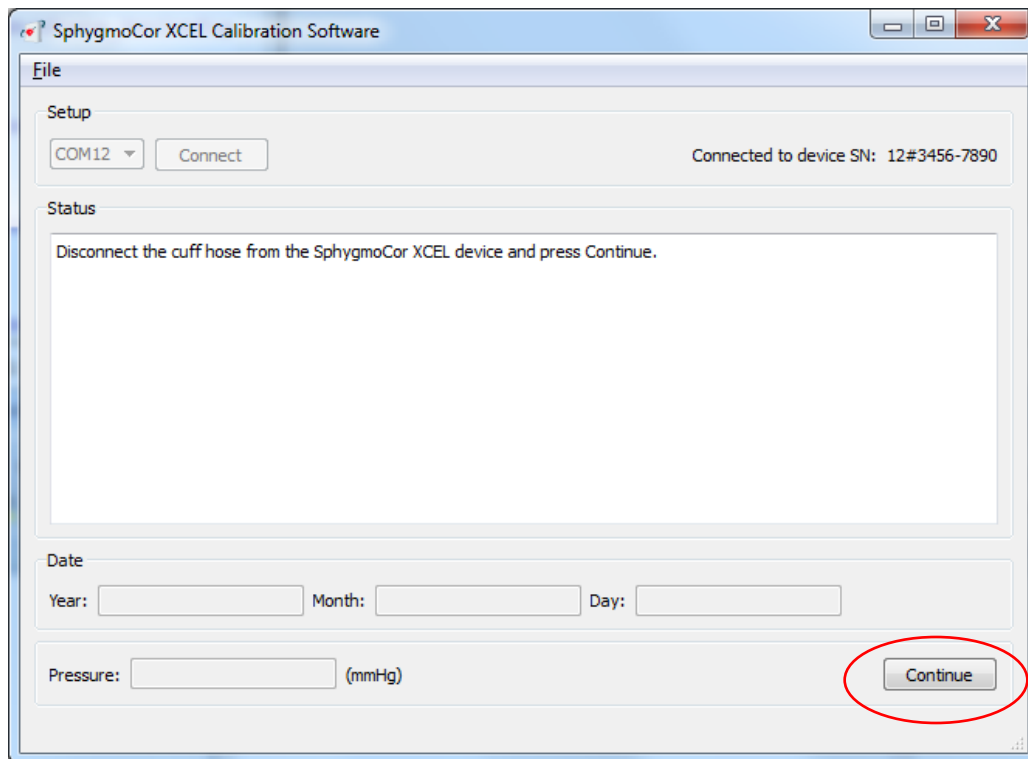
17- View the pressure displayed on the manometer or Sphygmomanometer



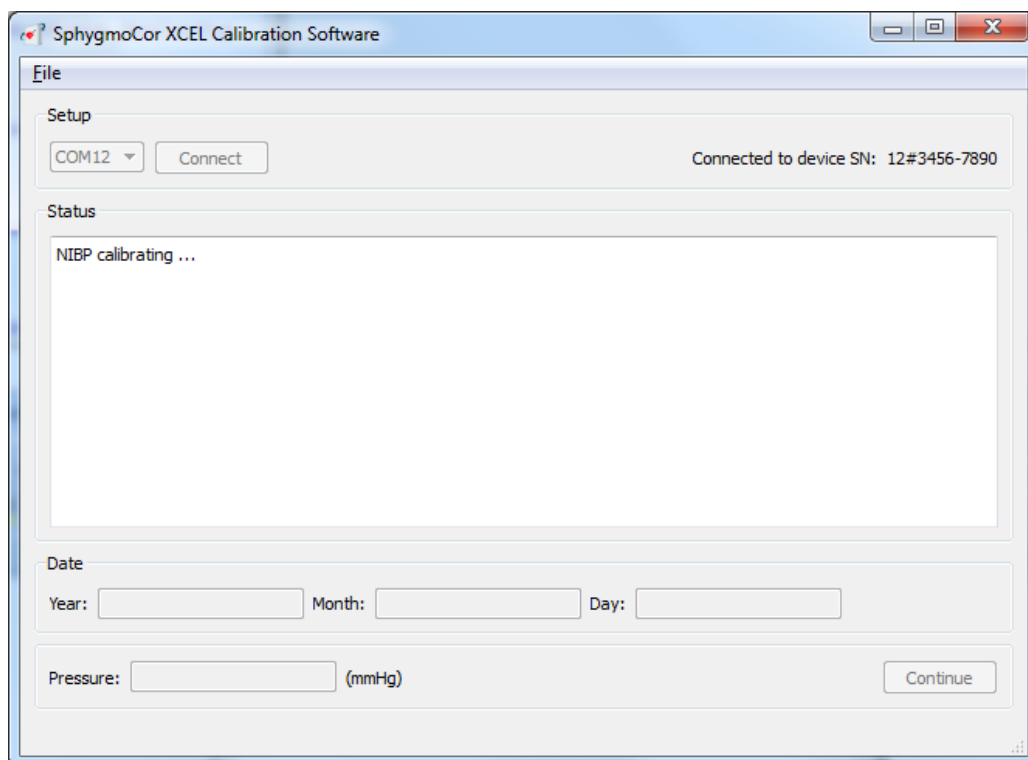
18- If the manometer reading is between 180-190 mmHg click *Continue*.

Note: If the manometer reading is not between 180-190 mmHg, close the SphygmoCor XCEL Calibration software and start the calibration procedures from Step 1. Please refer to Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.

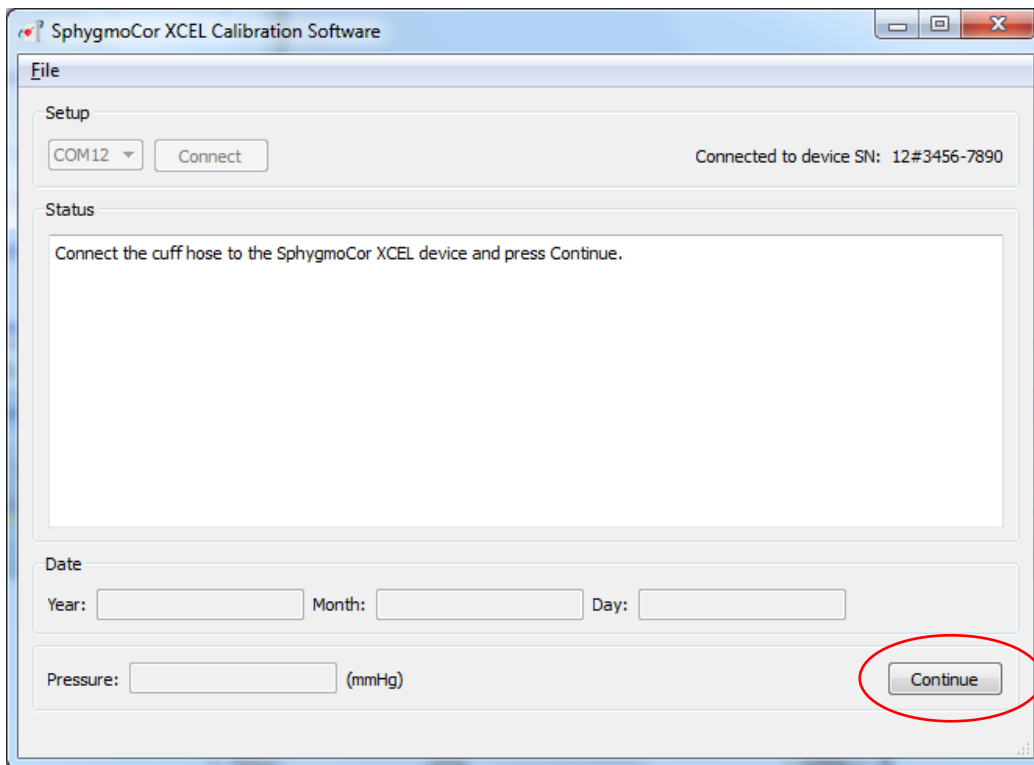
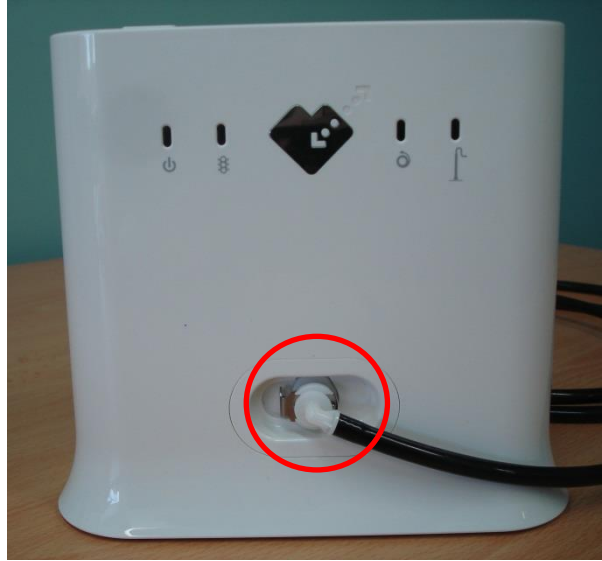




19- Disconnect the cuff hose on the SphygmoCor XCEL and click *Continue*



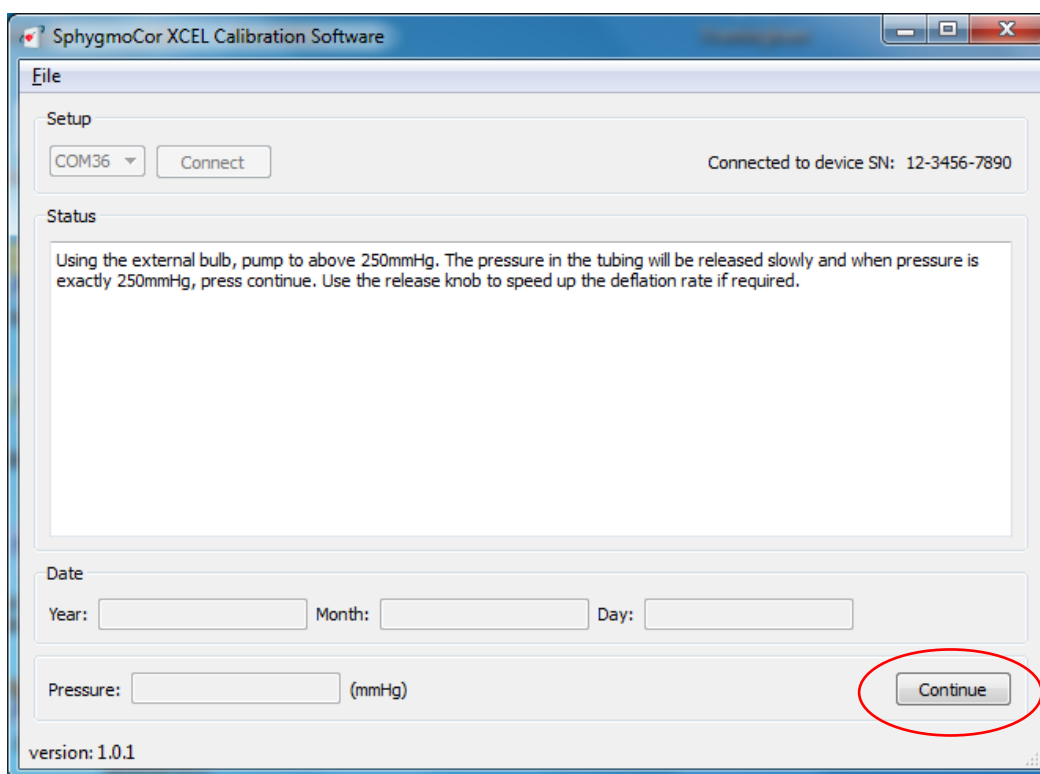
20- The software will show a message.



21- Connect the cuff hose on the SphygmoCor XCEL and click *Continue*

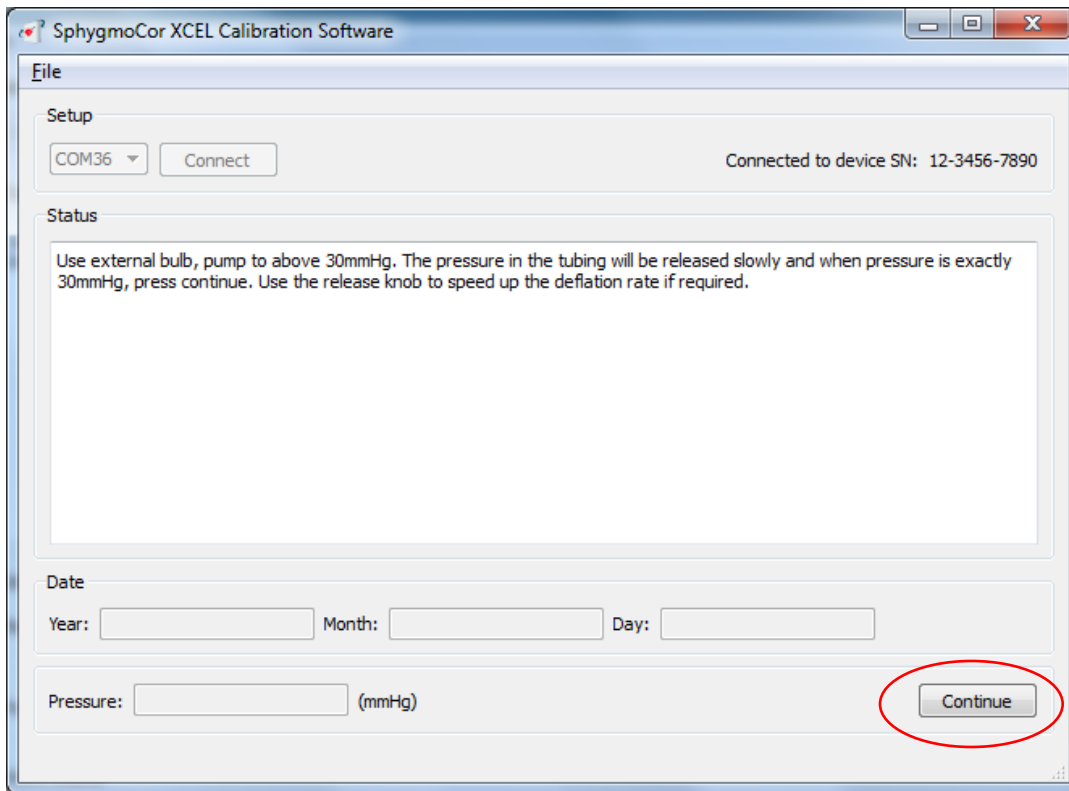


22- Using the bulb, pump until the pressure on the manometer is slightly above 250 mmHg.



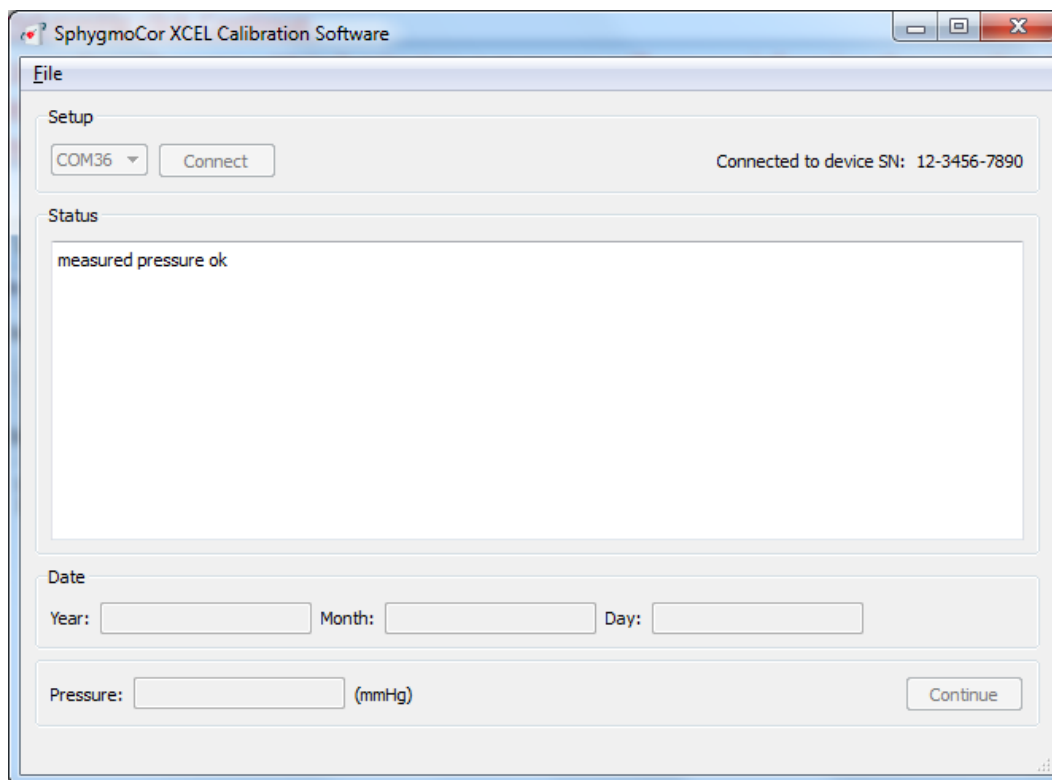
23- Release the pressure slightly using the release knob on the bulb. When the pressure drops to 250 mmHg click *Continue*.

Note: Once pumping starts ensure to click Continue within 3 minutes. If not, a message will appear informing that the calibration was unsuccessful. Then close the SphygmoCor XCEL Calibration Software, turn off/on the module and repeat the calibration procedures from Step 1. Please refer to Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.

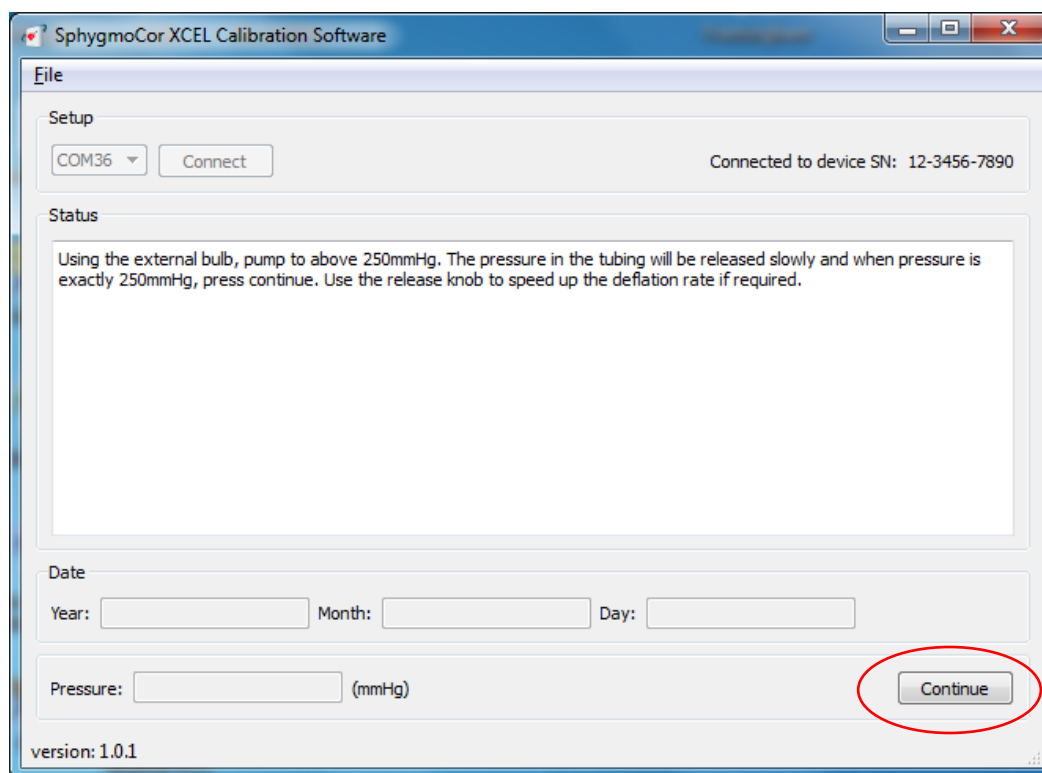


24- Using the bulb, pump until the pressure on the manometer is slightly above 30 mmHg. Release the pressure slightly using the release knob on the bulb. When the pressure drops back to 30 mmHg, click *Continue*.

Note: Once pumping starts ensure to click Continue within 3 minutes. If not, a message will appear informing that the calibration was unsuccessful. Then close the SphygmoCor XCEL Calibration Software, turn off/on the module and repeat the calibration procedures from Step 1. Please refer to Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.

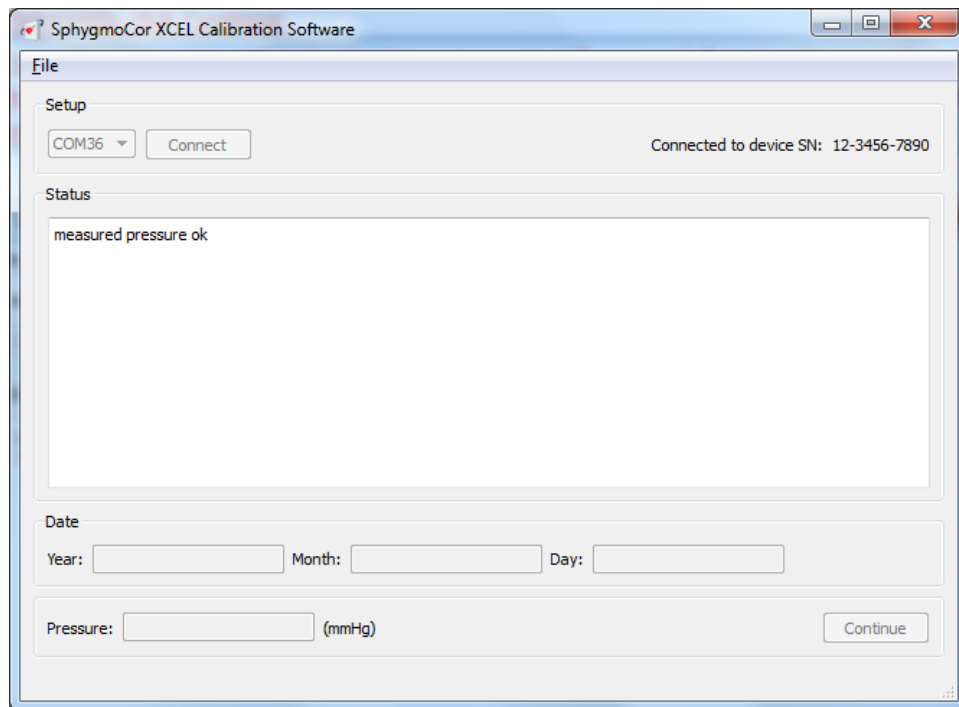


25- The software will display this message.



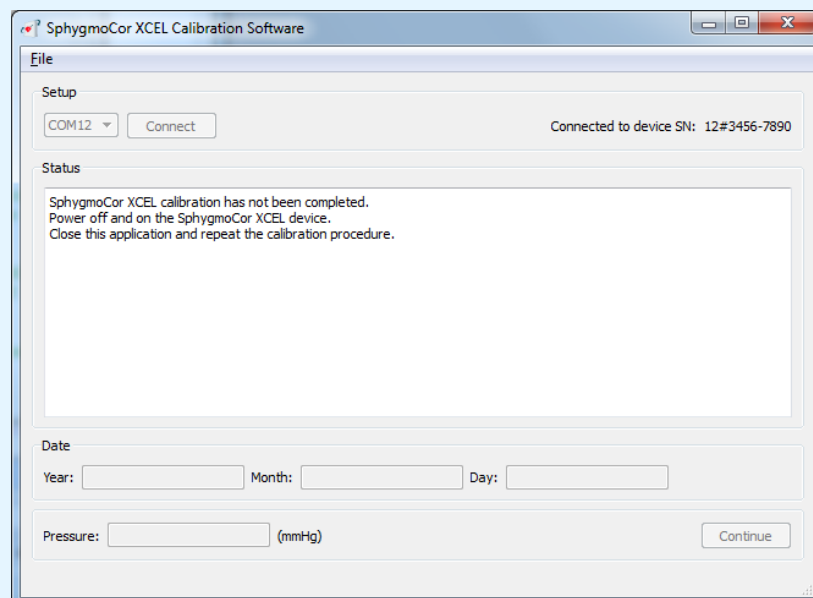
26- Using the bulb, pump until the pressure on the manometer is slightly above 250 mmHg. Release the pressure slightly using the release knob on the bulb. When the pressure drops back to 250 mmHg, click *Continue*.

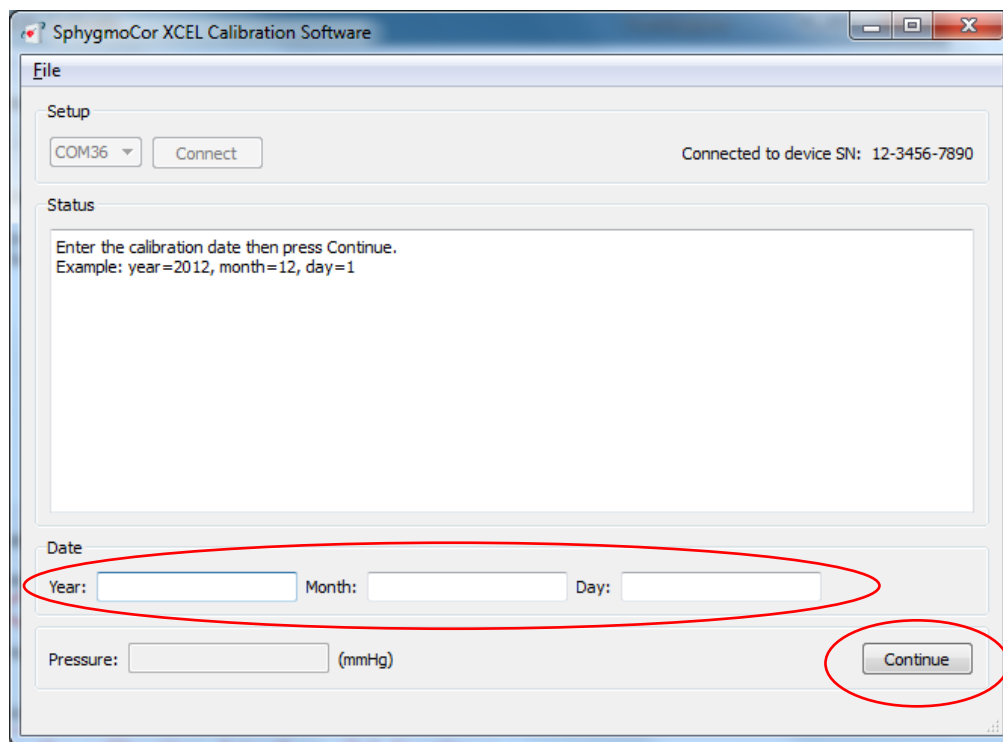
Note: Once pumping starts ensure to click Continue within 3 minutes. If not, a message will appear informing that the calibration was unsuccessful. Then close the SphygmoCor XCEL Calibration Software, turn off/on the module and repeat the calibration procedures from Step 1. Please refer to Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.



27- The software will display this message.

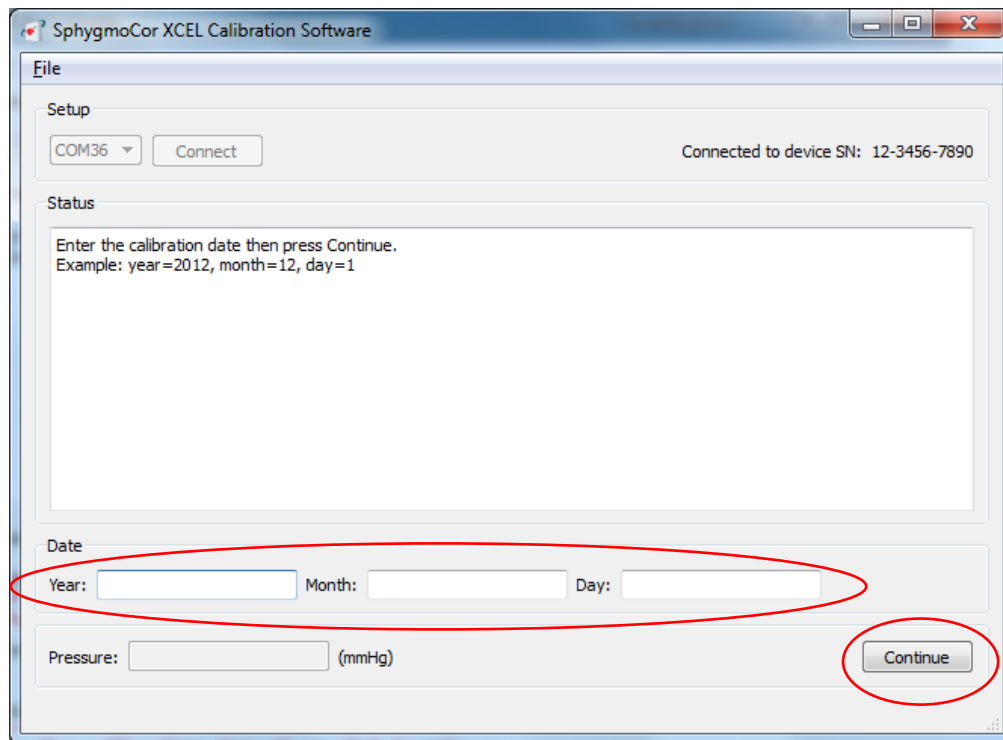
Note: If this message appears (calibration was unsuccessful), then turn OFF and ON the device and close the SphygmoCor® XCEL Calibration Software and repeat the calibration procedures from step 1. Please refer to Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.





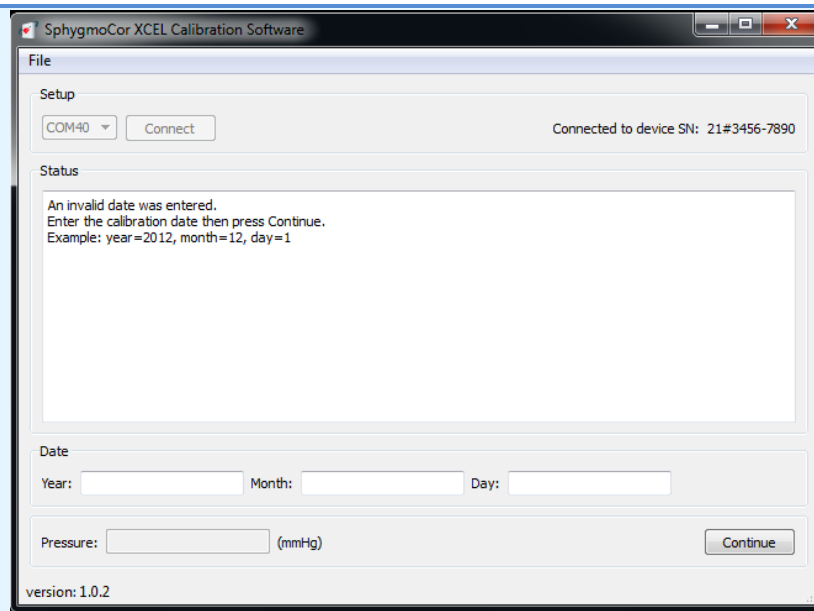
28- Upon successful calibration, enter the calibration date (year, month & date) then click *Continue*

If the Continue button is pressed without entering a date, close the SphygmoCor XCEL Calibration software, turn OFF and then ON the SphygmoCor XCEL device, and repeat the calibration procedures from step 1. Please refer to Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.

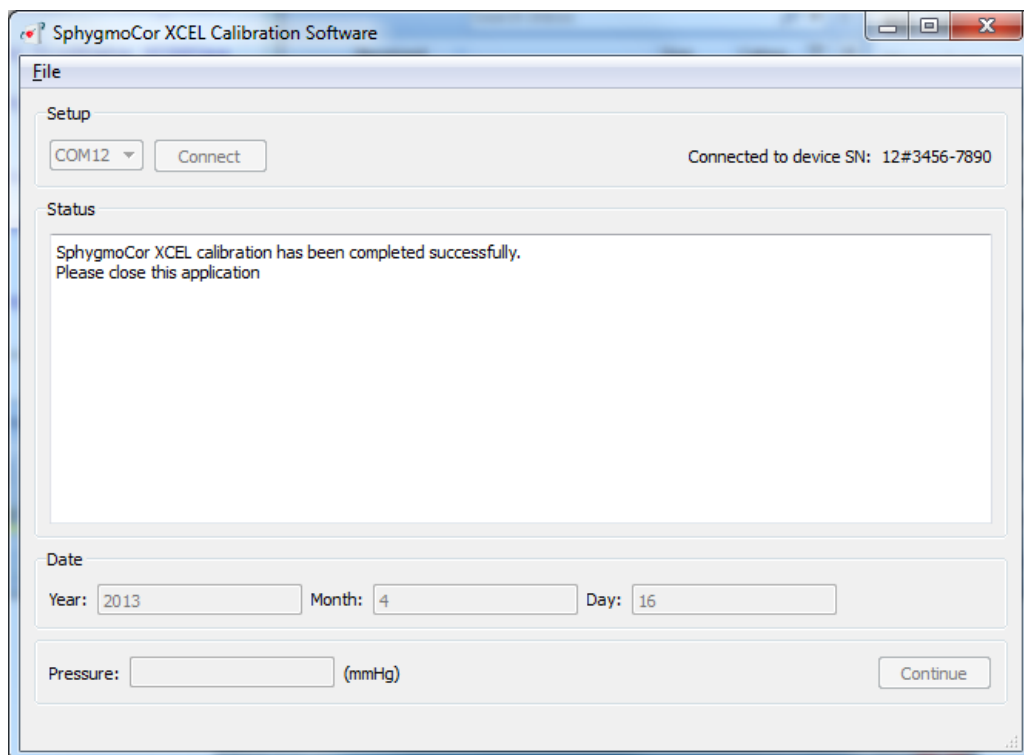


29- For verification purposes, the date is required to be entered for a second time. Enter the calibration date (year, month & date) then click *Continue*

If the *Continue* button is pressed without entering a date, close the SphygmoCor XCEL Calibration software, turn OFF and then ON the SphygmoCor XCEL device, and repeat the calibration procedures from step 1. Please refer to Restarting the Calibration Procedure Section in the Calibration Troubleshooting section.

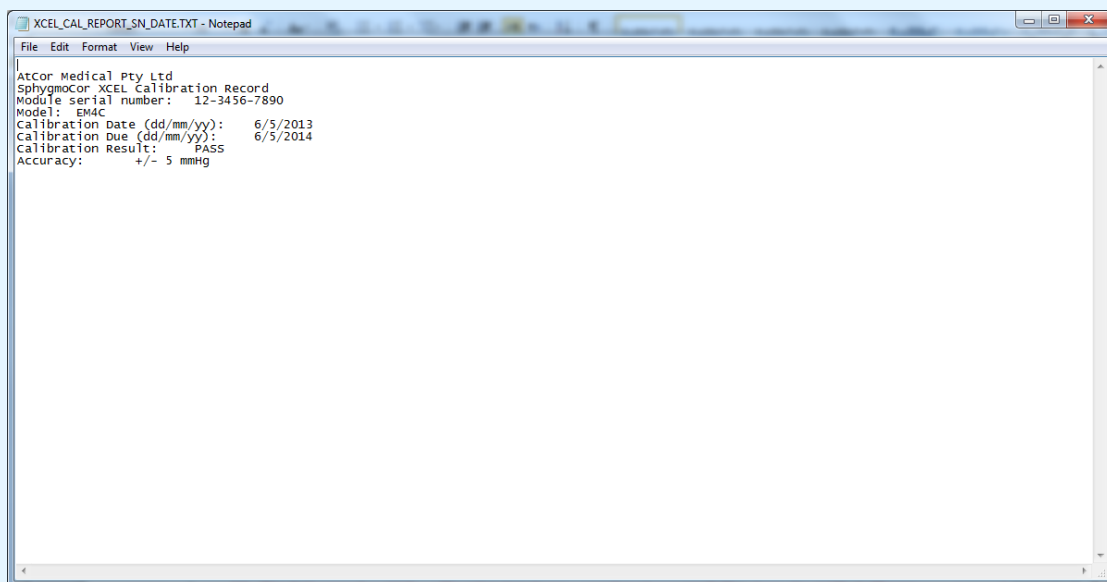


Note: If this message appears (incorrect date entered), enter the correct date and press *Continue*.



30- The SphygmoCor XCEL calibration has been completed successfully, close the XCEL Calibration Software

Note: Once the calibration has been completed successfully, a calibration summary report will be generated and saved as “XCEL_CAL_REPORT_SN_DATE.txt” in the same directory where the application was installed (default installation directory is “C:\AtCor\XCEL calibration\”, but this can be changed by the installer during the installation process).

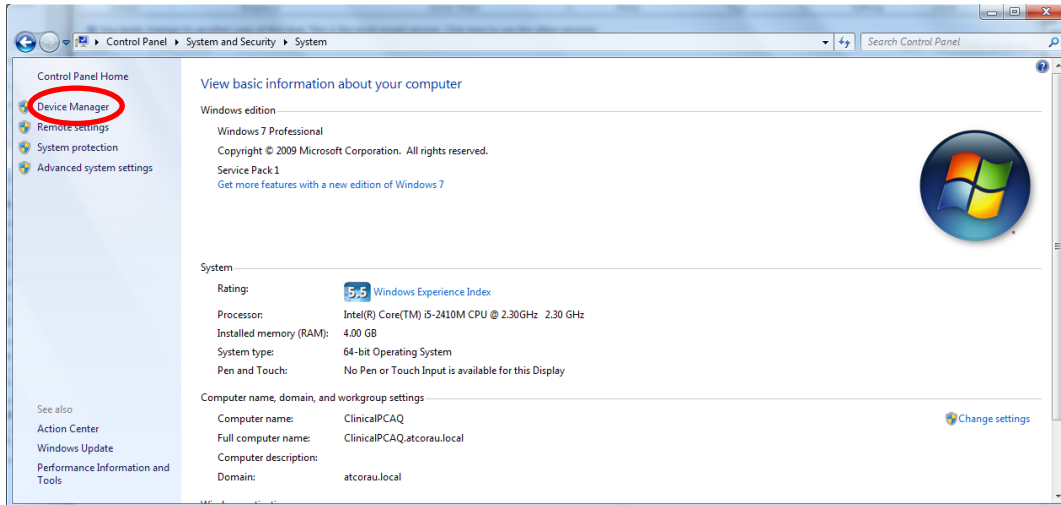


Calibration Troubleshooting

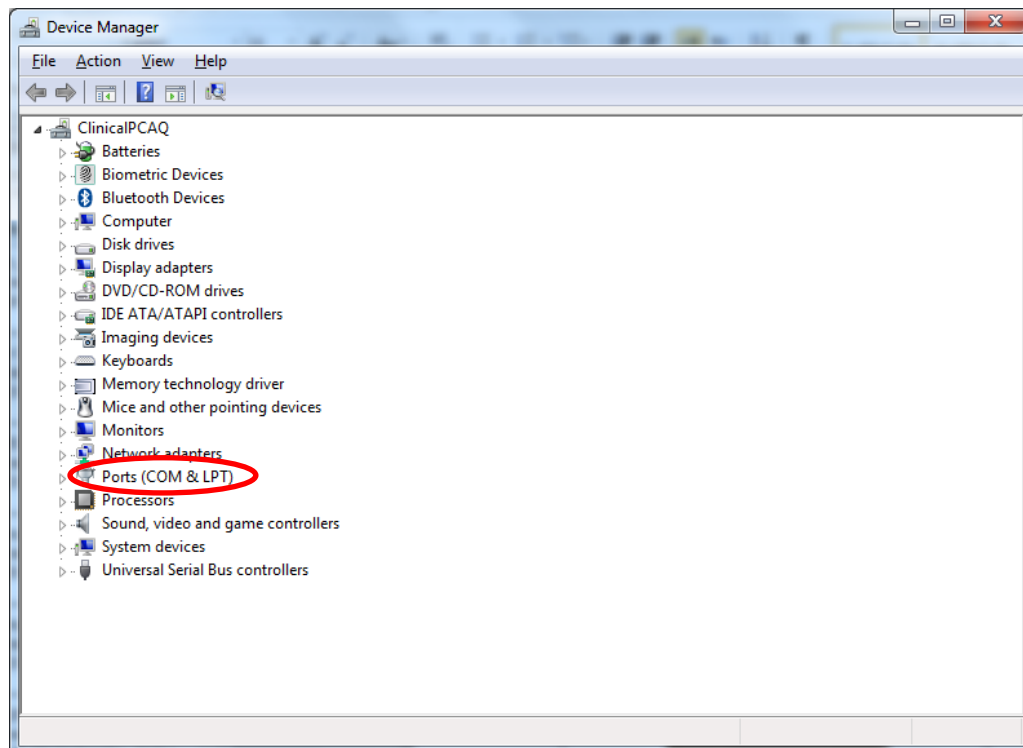
Finding Com Port

To find the com port that is connected to the SphygmoCor XCEL device, follow these steps:

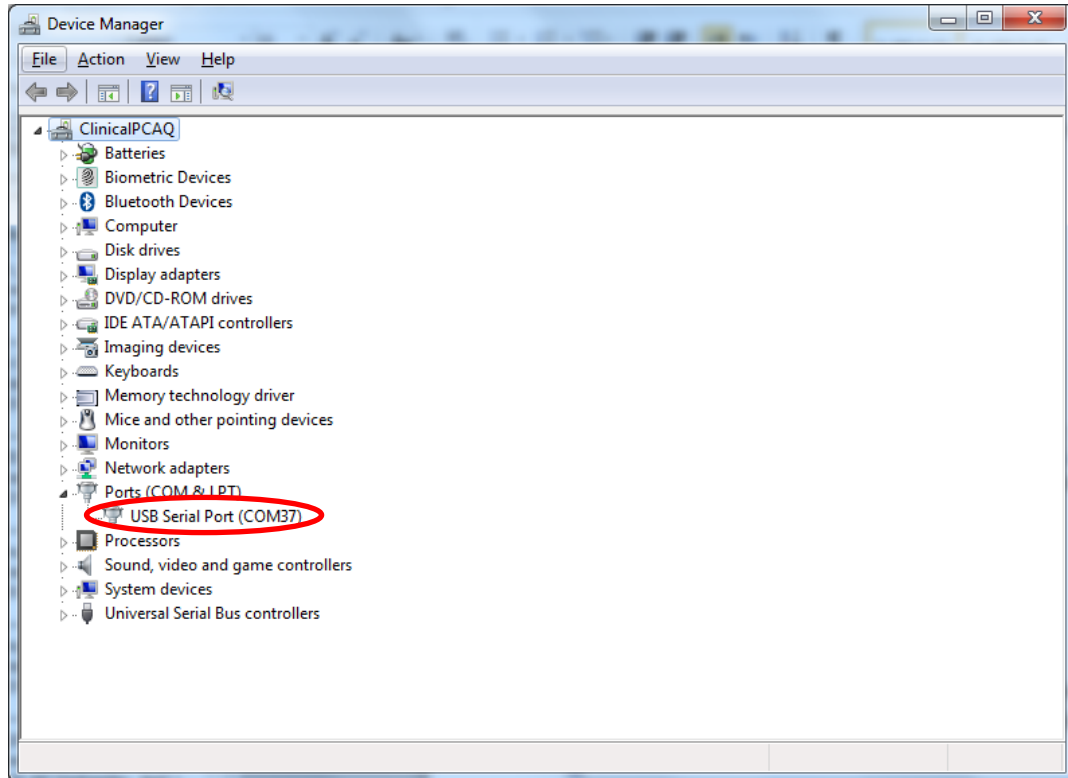
- 1- Connect the SphygmoCor XCEL device to the computer via the USB cable. Ensure your SphygmoCor Software is closed.
- 2- Navigate to Control Panel -> System and Security -> select System.



- 3- Select the Device Manager link on the left menu.



- 4- Expand the PORTS (COM & LPT) section.



- 5- The SphygmoCor XCEL will appear as 'USB Serial Port' and the COM Port number will be displayed next to 'USB Serial Port (COM##)'.
- 6- In the Calibration Kit software you will need to select the Com Port number (COM##) from the drop down list.

Restarting the Calibration Procedure





If calibration is not completed successfully, before restarting the calibration procedure, ensure the following:





1. That the Aneroid Sphygmomanometer or manometer that will be used to calibrate the SphygmoCor XCEL has been recently calibrated.
2. That the SphygmoCor XCEL Calibration software has been closed.
3. That the SphygmoCor XCEL device has been turned OFF/ON, and the USB cable has been connected to your computer.
4. That the tonometer or Calibration Kit dongle has been connected to the SphygmoCor XCEL device.
5. That the calibration kit pneumatic components have been connected to the cuff hose and the Sphygmomanometer or manometer.
6. That the cuff hose has been disconnected from the SphygmoCor XCEL device.

Note: If the restart calibration is not successful, please contact AtCor Medical for technical support.

Spare Parts List

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

	<p>Brachial cuff – a pneumatic cuff with a tube connection to the SphygmoCor XCEL device</p> <p>Part numbers:</p> <ul style="list-style-type: none"> • 1-00889 - Cuff PWA Adult Large 31-40cm • 1-00890 - Cuff PWA Adult 23-33cm • 1-00891 - Cuff PWA Adult Extra Large 38-50cm
	<p>Femoral cuff (light blue) – a large, thin pneumatic cuff with a connector for the SphygmoCor XCEL device</p> <p>Part numbers:</p> <ul style="list-style-type: none"> • 1-00897 - PWV Cuff Adult • 1-00898 - PWV Cuff Large Adult
	<p>For PWA Cuff Hose- 1.5m cuff hose</p> <p>Part number:</p> <ul style="list-style-type: none"> • 1-00865 - Cuff Hose 1.5m <p>For PWV Cuff Hose- 2m cuff hose</p> <p>Part Number:</p> <ul style="list-style-type: none"> • 1-00864 - Cuff Hose 2m
	<p>Power supply – an AC power adaptor for the SphygmoCor XCEL device. Always use the power supply provided</p> <p>Part number:</p> <p>1-00877 - Medical Power Adaptor</p> <p>(Meanwell – PN MES30B-4R6B)</p>

	<p>USB cable (2m) - connects the SphygmoCor XCEL device to a PC or laptop. Always use the USB cable provided</p> <p>Part Number:</p> <ul style="list-style-type: none"> 1-00858 – USB Cable 2m
	<p>Storage Tray – provides storage of cuffs, as well as a mounting platform for the SphygmoCor XCEL device.</p> <p>Part Number:</p> <ul style="list-style-type: none"> 1-00896 – EM4 Storage Tray
	<p>Tonometer – the non invasive pressure sensing device for measuring carotid pressure</p> <p>Part Number:</p> <ul style="list-style-type: none"> T-03C – SphygmoCor Tonometer, XCEL
	<p>Calibration Kit – for calibration of the SphygmoCor XCEL device.</p> <p>Part Number:</p> <ul style="list-style-type: none"> CK-01 – SphygmoCor XCEL Calibration Kit



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.

Minimum Computer Requirements







Type	IBM Compatible PC
Processor	Intel or compatible
Nominal Speed	2GHz minimum
Memory	2GB RAM minimum
Hard Disk	Size 40 GB
	2GB for Installation
	10GB for database
Accessories	DVD drive
Printer Drivers	Standard
Communications	USB port
Minimum Display Resolution	1024 x 768 pixels
Operating Systems	Windows XP Professional SP3 (32 bits), Windows 7 Professional, or Windows 8 Pro.

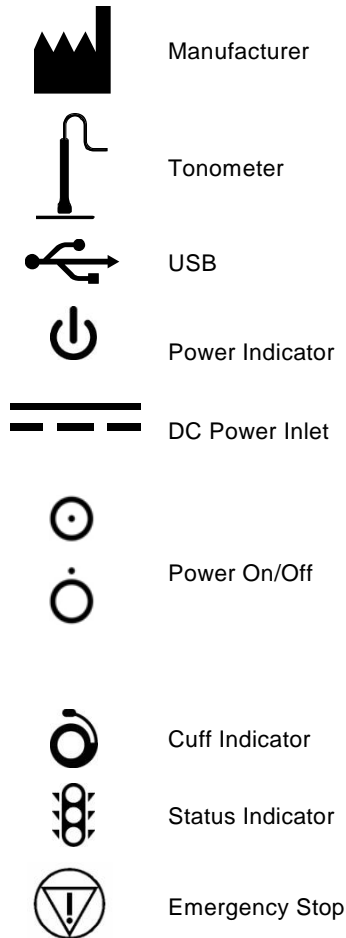
Classification of SphygmoCor System

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



Standards

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

- Medical electrical equipment -- Part 1: General requirements for safety
IEC/EN 60601-1:1988+A1+A2 (2nd Ed.), CSA C22.2 No 601.1-M90 (2003), UL 60601-1 (2003)
IEC/EN 60601-1:2005 (3rd Ed.), CSA C22.2 No 60601.1 (2008), ANSI/AAMI ES60601-1 (2005+A2)
- Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 80601-2-30:2009
- Medical electrical equipment -- Part 1: General requirements for safety Section 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-1-2:2007 This standard requires approval to:
Emissions- CISPR11
Immunity - Electrostatic Discharge (ESD) (IEC 61000-4-2)
Immunity - Radiated RF Electromagnetic Fields (IEC 61000-4-3)
Immunity - Electrical Fast Transient (EFT) Bursts (IEC 61000-4-4)
Immunity - Surges (IEC 61000-4-5)
Immunity - Conducted RF (IEC 61000-4-6)
Immunity - Voltage Dips, Interruptions, Variations (IEC 61000-4-11)
Immunity - Magnetic Fields (IEC61000-4-8)