User Manual

Thank you for purchasing the ARTSENS Plus PWV device. Before using it, make sure to read and understand the information in this manual. Follow all the safety instructions in the manual to use the device effectively. For more information, visit www.vascrisk.com and www.vascrisktech.in

This manual contains confidential and proprietary information owned by Vascrisk. It is intended exclusively for individuals involved in the operation and maintenance of the equipment outlined herein. The information in this manual should not be used, copied, or shared with third parties for purposes other than those directly related to operating and maintaining the specified equipment unless Vascrisk provides written permission. Reproducing, translating, printing, or converting any part of this manual into electronic or machine-readable form is strictly prohibited without Vascrisk's prior written consent. It's important to note that Vascrisk follows a policy of continuous product improvement, so specifications and features are subject to change without prior notice.

Disclaimer

The information provided in this manual is not a substitute for professional medical advice, and users are strongly encouraged to consult healthcare professionals for guidance on their reports. Unauthorized modifications to the device and use of non-standard accessories may void the warranty and compromise safety. Strict adherence to the specified schedule for regular maintenance is crucial to ensure the device's proper functioning, and users are responsible for complying with these guidelines. It is the user's responsibility to comply with local, state, and national regulations. The manufacturer and distributors are not liable for damages, injuries, or losses resulting from the use or misuse of the ARTSENS Plus PWV device. Users, by interacting with the ARTSENS Plus PWV device, acknowledge and agree to comply with the terms and conditions outlined in this manual. For any inquiries or clarifications, users are encouraged to contact the manufacturer's customer support.

Contact Details
Technical support is available on all weekdays from 9:00 am to 5:00 pm.

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Revision History

Version	Date	Description
1.0	17-05-2024	Initial Release

Table of Contents

1. Introduction

a. Device Description

ARTSENS Plus PWV device measures Aortic Pulse Wave Velocity (PWV), through the analysis of synchronously and non-invasively captured pulse wave information from carotid and femoral artery sites. The device is connected to the host computer for performing the measurement and displaying the results.

b. Intended Use

The ARTSENS Plus PWV, Pulse Wave Velocity (PWV) device is intended to obtain PWV measurements. The device enables visualization and measurement of anatomical structures and fluid, including blood flow.

It is to be used on those patients where information related to aortic PWV is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

The device is used on adults 18 years of age and older patients only.

i. Intended Patient Population

- ARTSENS Plus PWV device is intended to be used on adults only.
- ARTSENS Plus PWV device is not intended to be used on neonates. Safety and effectiveness in children below 18 years old have not been established.

ii. Intended Environment

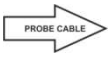
- The ARTSENS Plus PWV device is intended to be used in a clinical or research setting.
- The device is not intended to be used as a continuous monitoring device in a hospital or emergency vehicle and is not applicable to be classified as a defibrillation-proof applied part.
- The device is not intended for outdoor use and during individual transport.

iii. Contraindications

- ARTSENS Plus PWV device is not intended for use as a cardiovascular disease screening tool in the general patient population. It is intended to supplement, not substitute, the clinician’s decision-making process. It should be used in conjunction with knowledge of the patient’s history and other clinical findings.
- The device should not be used for patients with erratic, accelerated or mechanically controlled irregular heart rhythms, including patients with arrhythmias.
- The device should not be used on patients with carotid or aortic valve stenosis.
- The device should not be used on patients with peripheral artery disease or leg artery disease since an applied cuff pressure on the thigh of these subjects may be harmful.
- The device should not be used on hypotensive patients in the absence of directions by a clinician.
- The device should not be used on patients with generalized constriction or localized spasm of muscular conduit arteries such as seen immediately after hypothermic cardiopulmonary bypass surgery or accompanying Raynaud's phenomena or intense cold.
- The device should not be used on patients who have undergone mastectomy.
- The cuff should not be used on a wound as this may cause further injury.
- The cuff should not be placed 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 the potential to be compromised and could result in injury to the patient.

2. Equipment conventions

The following symbols are marked on the ARTSENS Plus PWV device and in this manual to convey key information.

Icon	conventions	Descriptions
	Power Port	Plug-in the Medical grade power adapter into the connector (Centre positive polarity)
	USB Port	Port to which the host is connected.
	Probe Port	Port to which ultrasound transducer probe is connected.
	Don’t insert hands	Operators should not insert hands into openings marked.
	Battery Charging status	Red indicates the device charging status. Red indication turns off when the device is fully charged.
	Host connection status	Amber indicates the host connection status.
	Measurement activity status	Green indicates if the measurement has started.
	Probe cable	Route the cable this way.
	Warranty void sticker	Tampering of this sticker will void the warranty.
	Temperature limit	Room Temperature: Operating range of device = 15 to 45 Deg. C.
	Humidity limit	Room Humidity: Operating range of device = 10 to 80% Relative Humidity.
	Keep dry	To indicate that the device needs to be protected from moisture and keep away from rain.
	Serial number	To indicate the manufacturer's serial number, on the device.
	Catalogue number	To identify the manufacturer's catalogue number on the device.
	Date of manufacture	To indicate the date on which the device was manufactured.
	Manufacturer	To identify the manufacturer of a product.
	Prescription use	Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. (refer Sec. 801.109 Prescription devices)
	Keep away from sunlight	To indicate that transport package shall not be exposed to sunlight.
	Refer to the instruction manual/booklet	Use the device only after reading the instructions for use.
	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	Recycle: Electronic Equipment	Separate collection for electrical and electronic equipment.
	This way up	To indicate that the packaging should be kept during storage / transit in this way.
	Fragile	Package are easily breakable and should be handled with care to prevent damage during transport and storage

Icon	conventions	Descriptions
	Do not roll	To indicate that the transport package shall not be rolled or turned over but shall remain in the upright position
	Do not Stack	To indicate that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.
	Handle with care	The packaging must be handled with care to avoid damaging its contents
	Tested OK	To indicate that a product has passed Quality Control inspection.
	QC Pass	To signify that a product has passed all required tests successfully.

3. Safety

Product or product container is **Not Made with Natural Rubber Latex**

a. Medical Ultrasound Safety

In the ARTSENS Plus PWV device, the ultrasound transducer probe consisting of a single ultrasound crystal operates at a set frequency of 5 MHz and there are no controls provided to the user that is capable of varying its acoustic output level. The table provided below compares the measured acoustic output levels from the device's probe against the FDA-approved acoustic output exposure levels for ultrasound devices used in vascular applications. The device has acoustic output exposure much lower than the approved levels.

Parameters	Reference Values	Actual Values
Attenuated Spatial peak temporal average intensity ($I_{SPTA,0.3}$)	720 mW/cm^2	11.04 mW/cm^2
Attenuated Spatial peak pulse average intensity ($I_{SPPA,0.3}$)	190 W/cm^2	79 W/cm2
Mechanical Index (MI)	1.9	0.672

b. Safety Standards

The ARTSENS Plus PWV device is in compliance with the safety standards outlined below,

Tests	Product standards
Medical devices — Symbols to be used with information to be supplied by the manufacturer	ISO 15223-1:2021
Medical devices — Information to be supplied by the manufacturer	ISO 20417:2021
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic compatibility - Requirements and tests.	IEC 60601-1-2:2014
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.	ISO 10993-5:2009
Biological evaluation of medical devices - Part 10: Tests for skin sensitization.	ISO 10993-10:2021
Biological evaluation of medical devices - Part 23: Tests for Irritation.	ISO 10993-23:2021
Medical electrical equipment - Part 1: General requirements for safety.	IEC-60601-1:2005+AMD1:2012+AMD2:2020 CSV
Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	IEC 60601-2-37:2015

c. Safety Instructions

- Before use, carefully inspect the device. Check the cable, housing, and connector for signs of damage such as cracks, chips, abrasions, or leaks. To ensure electrical safety, do not use the probe if there is any sign of damage.
- Use of accessories, probes, and cables other than those specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and may result in improper device operation.
- The probe is designed to remain sealed. Do not attempt to disassemble the probe.
- Keep the device within 1.5 meters of the patient to prevent stretching the probe wire, cuff, and hose pipe during use, reducing the risk of the device falling off the table when pulled.
- Avoid any tilting of the instrument while in operation, as it may result in the misalignment of internal components.
- Avoid inserting foreign objects into any of the openings on the instrument.
- Refrain from using the instrument in close proximity to radiating devices such as CT or MRI machines.
- Avoid using the instrument near RFID (Radio-Frequency Identification) and security systems like Metal Detectors and Electronic Article Surveillance (EAS) systems.
- Avoid using the instrument near diathermy, electrocautery, or electrosurgical units as high-frequency Electromagnetic fields or currents could cause malfunction or damage to the device.
- Do not wash the cuff in a washing machine or dishwasher (Refer Chapter 7 Section C– Cleaning and Disinfection).
- If there is any discomfort experienced by the patient during inflation of the cuff, immediately disconnect the cuff from the hosepipe, thereby releasing the pressure.
- If there is any discomfort experienced by the patient when the probe comes into contact with the skin, pause the measurement and carefully reposition it ensuring it is placed correctly and comfortably on patient's skin.
- Do not kink the air hose during use, which may cause the cuff to continually inflate resulting in patient discomfort.
- Operate the device in patient areas under these conditions: Room humidity should be between 10% and 80%, and room temperatures should range from 15°C to 45°C.
- Ensure there is a 5-minute gap before conducting the second assessment on the patient.
- Ensure the operator is familiar with IFU and video tutorials available at https://vascrisk.in/product-tutorial/ before utilizing the device on any patient.
- The device does not contain user-serviceable parts. Do not attempt to open or disassemble the device as this will void the warranty. Contact Support of Vascrisk (Refer Chapter 10 - Product support) if the device does not operate.

4. Unpacking the Device

As you unpack your ARTSENS Plus PWV device packaging, check to make sure that you have all the components. If there is a missing component, please contact your supplier.

Note: An ultrasound gel is required to use the Ultrasound Transducer probe given with the device. You may procure an Ultrasound Gel that is biocompatibility tested and use with the device.

Fig.1. Unboxing ARTSENS Plus Device

a. Instrumentation description

Fig.2. ARTSENS Plus Device

Part Name	Part Description
USB port	For connecting the host computer
Power Input	For connecting the power adapter input
Probe Compartment	Compartment to secure the probe
Cuff connection port	For connecting the cuff and hosepipe to the device
Serial number label	Device identification
System status indication	Red indicates charging status (If battery is not fully charged) Amber indicates the Host connection status Green indicates measurement activity
ARTSENS logo	Logo of ARTSENS Plus PWV device

b. Battery indication description

Icon	Battery Status	Description
	Unknown	Battery status not available
	1-25%, Mains not connected	Low
	26-50%, Mains not connected	Moderate
	51-90%, Mains not connected	Optimal
	91-100%, Mains not connected	Full
	91-100%, Mains connected	Full with mains connected

5. Device setup

a. Minimum Host Requirements

The host PC must meet the following minimum hardware requirements to ensure the proper functionality of the ARTSENS PLUS PWV device.

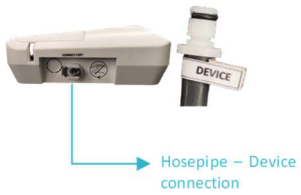
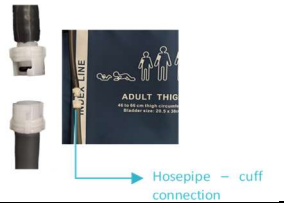
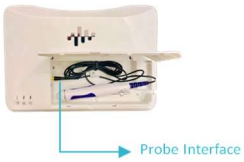
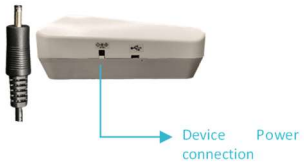
Software

OS Version	Windows 10 or above
OS Architecture	x64-bit

Hardware

Processor Family	at least Intel core i5
Processor Architecture	x64-bit
RAM	at least 8 GB
Internal storage	At least 128 GB, with a minimum of 1 GB available storage space for installation
Display resolution	1920 × 1080p
Connectivity	1 × USB type A 2.0

b. Device Interfaces

Fig.3.Device-Hosepipe connection 	Connect one end of the hosepipe to the Cuff connection port of the device. You would hear an audible 'click' sound when the hosepipe is connected securely. Remove and reconnect if this feedback is not heard.
Fig. 4. Hosepipe-cuff connection 	Connect the other end of the hosepipe with the cuff and gently twist to lock the connector. **Note: Connect the cuff to the device only after it is wrapped on the patient before the measurement.**
Fig. 5. USB connection 	Connect the device to the host computer using a USB cable through the USB port.
Fig.6. Device-Probe connection 	The Ultrasound transducer probe comes interfaced with the device at the probe port. Do not remove the probe from the connector.
Fig.7. Device power connection 	The power port on the ARTSENS Plus PWV device allows connecting the power adaptor to the device both for powering the device and charging the battery.

c. Components Connections

1. Connect the power adapter to the power port of the device. Plug another end of the adapter into an AC power outlet.

Note: This may not be required if the device has adequate battery backup left.

2. Ensure the host is powered while operation.
3. Connect hosepipe to the ARTSENS Plus PWV device.

Note: Push the connector of the hosepipe into cuff port available on the device. You should hear a "click" sound when the connector is locked.

4. Connect the thigh cuff to the hosepipe. The connector is a twist-to-lock type.

Note: Wrap the thigh cuff when the patient is in supine position.

5. Connect the micro-USB cable to the device and the other end to the host.

d. Software installation

Note: It is recommended to directly connect the device to the host without using the USB Hub. If there are no Type-A ports and only Type-C, then use a powered USB 2.0 Hub to ensure proper connectivity.

1. Connect the software installation drive to the host computer.
2. Open File Explorer and navigate to the USB drive to locate the software installation files.

3. Look for the file named "install.exe" and run the file.

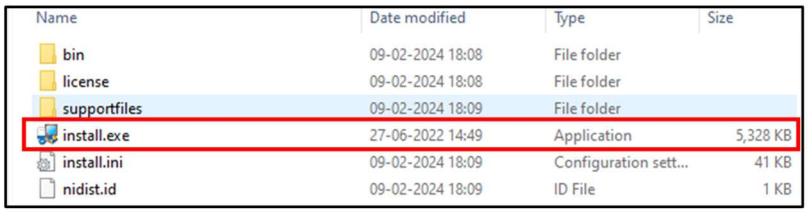


Fig.8. ARTSENS Plus Installation file

4. Pop-up appears as shown in fig.9. Click Yes.

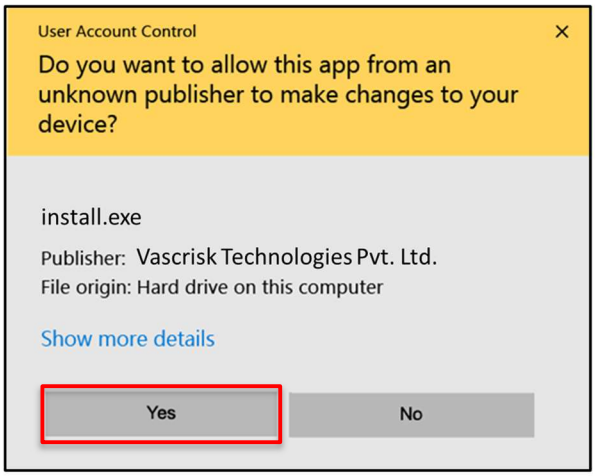


Fig.9. ARTSENS Plus Software installation

5. Review and agree to the terms and conditions of the license agreement displayed during the installation process.

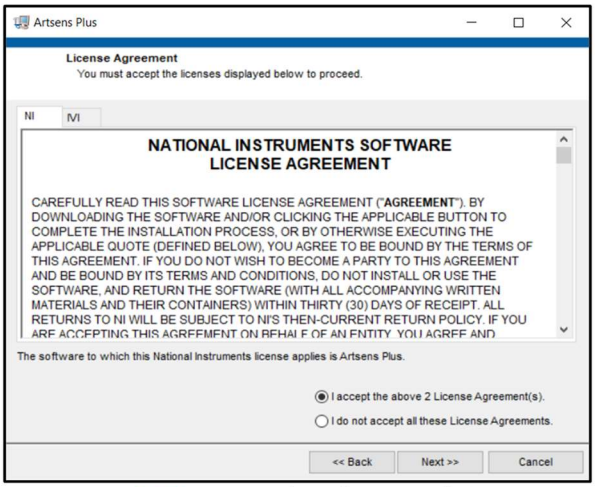


Fig.10. ARTSENS Plus Software installation

6. Follow the instructions provided by the installation wizard to install the software.
7. Wait for the installation to complete.
8. Respond to any on-screen prompts that appear during the installation, including granting necessary permissions for the software to install properly. Contact Healthcare facility IT administrator if any permissions are required. Contact the manufacturer if there are any problems or in need of additional support.
9. Once the installation is complete, Restart the system when prompted.

Note: If you encounter difficulties during the software installation, consider temporarily disabling the antivirus on your host system. Once the installation is complete, remember to re-enable the antivirus for continued protection.

Warning: Any attempt to modify or tamper with the software files is strictly prohibited to ensure the integrity and security of the application.

e. Software Start-up

1. Double-click on the ARTSENS Plus PWV application icon on the host device to open the software.
2. The software will automatically verify if the display parameters are optimal.

3. If the host PC meets the optimal display settings, the ARTSENS software will be launched after internal verification.
4. In case the host computer's display settings do not meet the specified criteria, follow the on-screen instruction changes as shown in fig. 11 and relaunch the software.

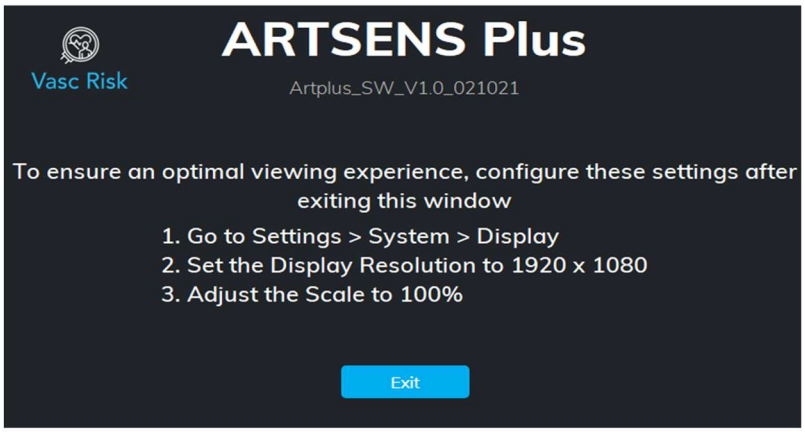


Fig.11. Check Display Parameters Page

f. Power ON self-test

1. ARTSENS Plus PWV software's start screen is displayed. Please wait as this may take a few minutes.
2. The instrument automatically performs a self-test i.e. sequence of hardware tests to ensure that the device modules are fully functional. The software screen displays the test sequence progress as shown in fig. 12.

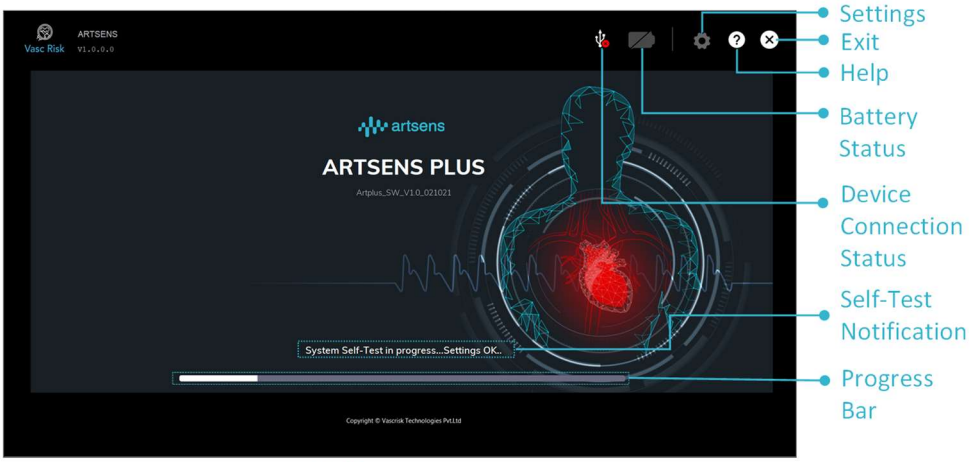


Fig.12. Self-test Progress

3. White progress bar indicates no error and "SELF-TEST SEQUENCE COMPLETE" message is displayed in status bar on test completion. The software will display the registration page if registration is not done. Once the software is registered, the software will display the home screen.

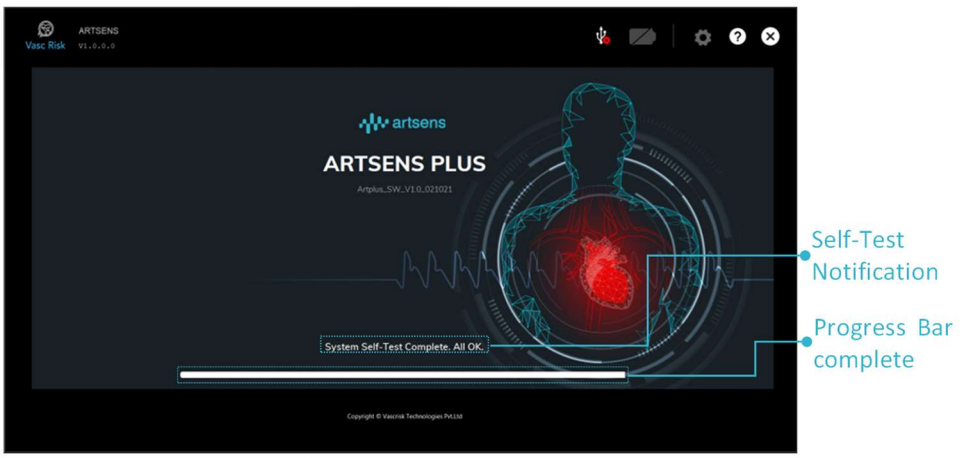


Fig.13. Self-test Complete

4. On contrary to above, red progress bar indicates error and the "SELF-TEST ERROR" message is displayed in the status bar as in fig. 14.

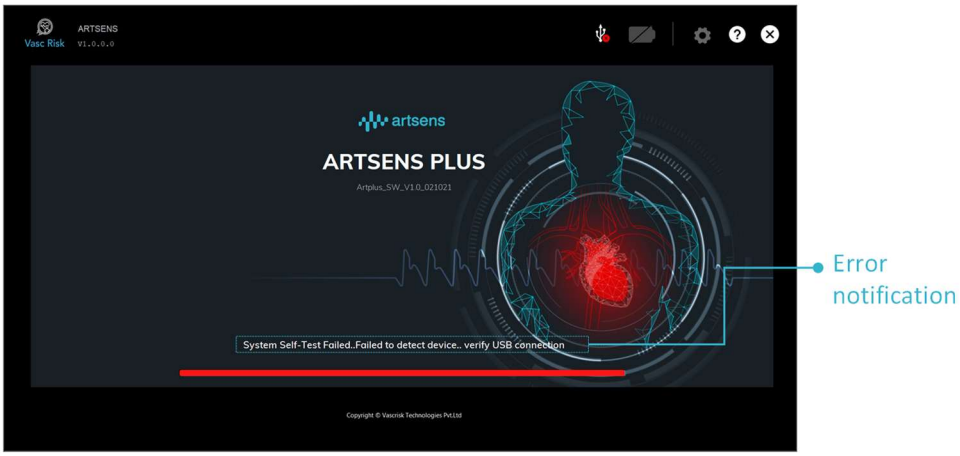


Fig.14. Self-test Failure

5. Refer Error Codes & Solutions (Chapter 7 section D - System Troubleshooting) for further instructions on troubleshooting and solving errors.

g. Online device registration

1. The device registration page, as shown in fig. 15, is displayed along with the necessary instructions.
2. Scan the QR code or visit vascrisktech.in/register-page

Note: Ensure the device remains connected throughout the entire registration process.

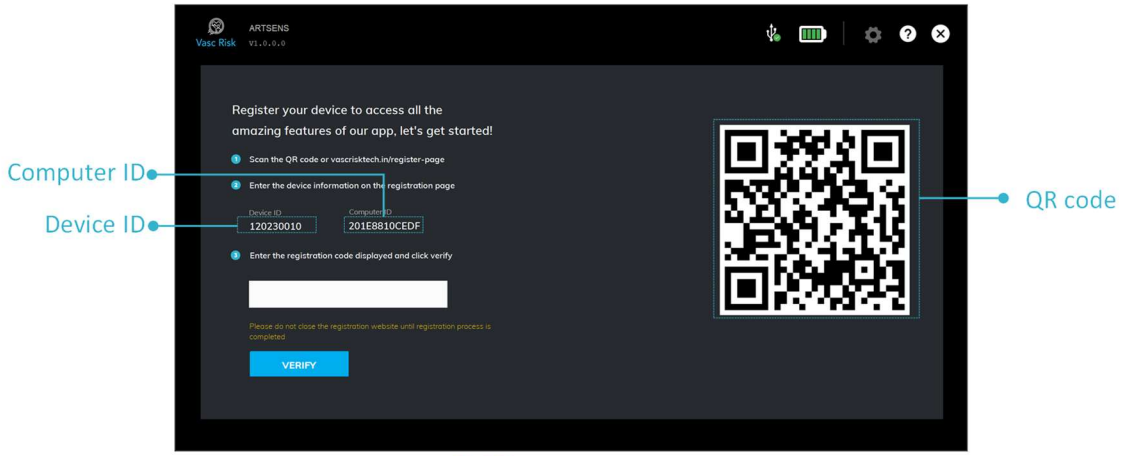


Fig.15. Device Registration Page

Note: Make sure to have a stable internet connection on the device where the link for registration is accessed.

3. Register either through your phone or the host PC.
4. Enter the necessary information on the website.
5. Enter the ARTSENS Plus PWV device ID and host's computer ID that is displayed on the ARTSENS Plus PWV software.

Note: The device ID and host ID (computer ID) are detected automatically. In the event of unsuccessful detection of any of them (as shown in fig. 16), exit and start again the software.

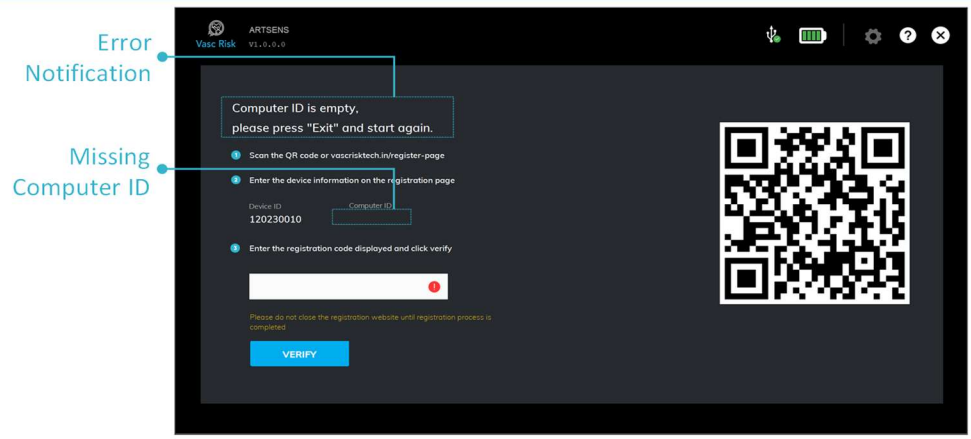


Fig.16. Device Registration Page

6. Read and agree to the terms and conditions stated in the license agreement.
7. Upon successful registration a six-digit registration code will be generated.

Warning: Do not close the window/ exit the registration page before completing the registration.

8. Enter the displayed registration code in the field provided and click “verify” as shown in fig. 17.

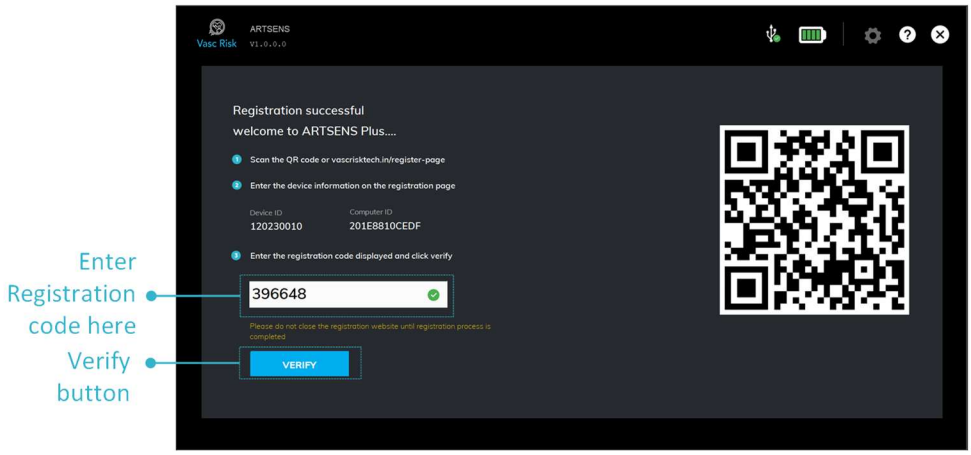


Fig.17. Device Registration Page

Note: Ensure the device remains connected throughout the entire registration process.

9. If the verification is successful, your registration is complete, and the Home page of the application will be displayed (as shown in fig. 18). If not, repeat the registration process from the beginning for a successful registration.

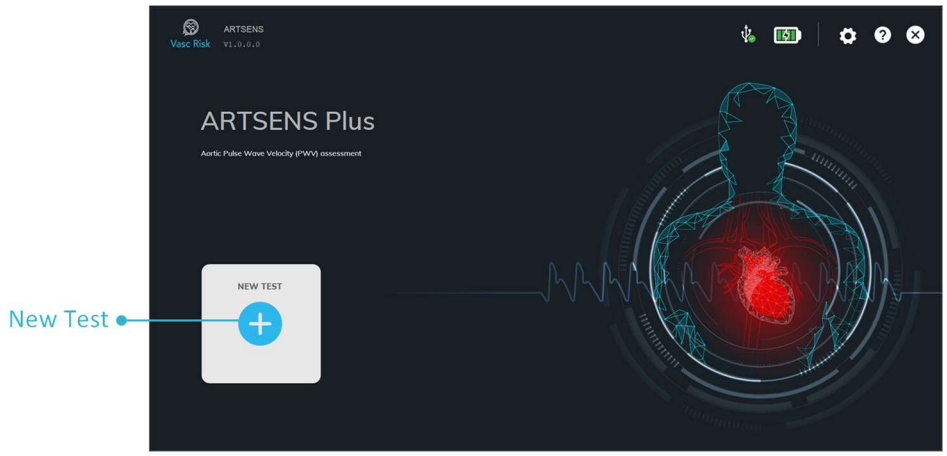


Fig.18. Home page

10. If the entered registration code is displayed as invalid, confirm whether the entered registration code is correct. If that’s correct confirm whether the entered device serial number and host ID on the online registration page are correct.

h. Settings Page

The software will have default settings to initiate the measurement. However, users can access and reconfigure these settings on the settings page. A click on the Home Page settings icon, navigates to a software and hardware Settings Page as shown in fig. 19.

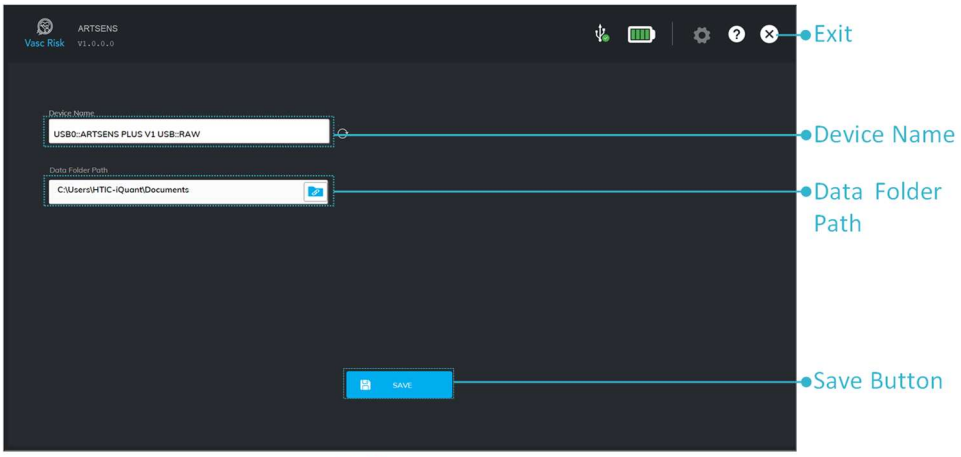


Fig.19. Settings Page

1. When the device is connected to the host, Software automatically detects the Device Name and when not connected, “No Device Found” message is displayed.
2. Connect the device and click Refresh icon next to the Device name. Now the software detects the Device name, and it is displayed.
3. Users have the option to change the Data Folder Path based on their preferences.
4. Select the Browse icon within the Data Folder Path section to modify the location. Click the Save button below to confirm the changes.

Note: Please refrain from closing the Settings page without specifying the data folder path.

6. Operating Guide

a. Measurement on new individual

A new measurement can be started from the Home page of the ARTSENS Plus PWV application.

Note: If the application is not running, double-clicking the ARTSENS Plus PWV application icon will take you to the Home page, provided the device registration was successfully finished prior.

1. Click on the "New Test" button located on the Home page, as depicted above in fig. 18.
2. Enter the patient information, as shown in fig. 20.

Note: In the event of using the on-screen keyboard, please press the scroll button to enter information in the 'Referred By' field.

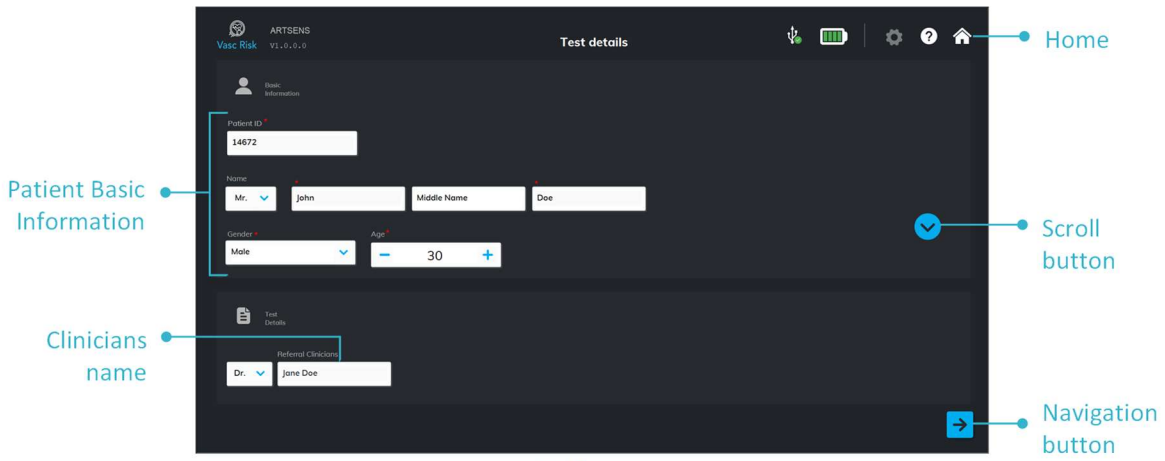


Fig.20. Test Details

Note: Operator should enter valid information in all the mandatory fields (marked with *) to proceed. A warning is prompted otherwise.

3. Click the "NEXT" button, that will take you to the Assessment Preparation page.
4. As instructed on the page, wrap the cuff firmly around the left thigh as shown in fig. 21.

Note: If the cuff is not wrapped properly or has a leak, an error message will appear. Physically check and ensure that the cuff connections and the wrapping are proper.

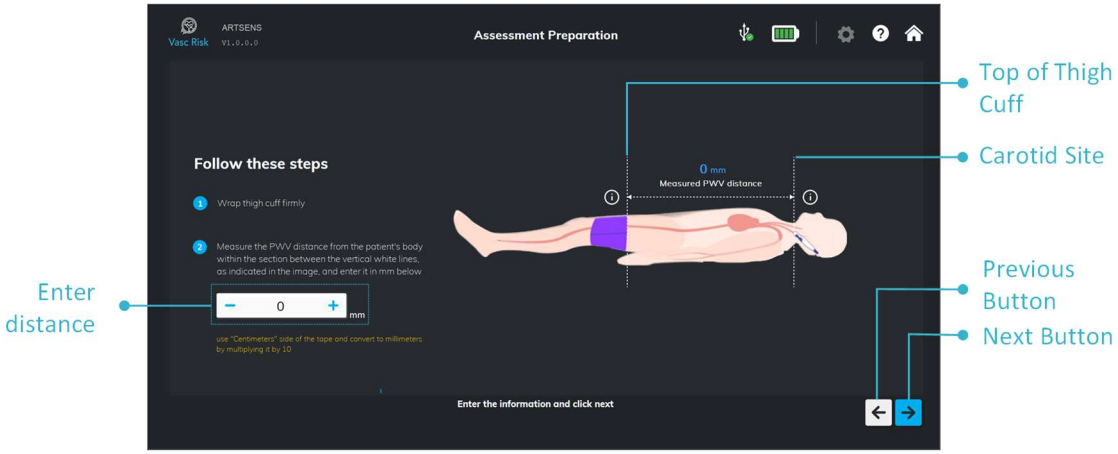


Fig.21. Assessment Preparation Page

Note: Make sure the cuff, hosepipe is not kinked while wrapping and refer to recommendations for measurement section for proper cuff wrapping. Make sure to perform carotid and femoral measurements on the left side of the body.

5. Join and lock the hosepipe to the port on the cuff. Ensure the connection is secure and no leakage.
6. Palpate the left side of the neck to identify carotid pulsations as shown in fig. 22.

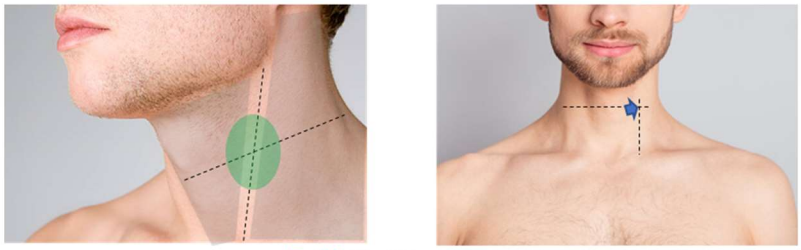


Fig.22. Ideal Measurement site

7. Measure the PWV distance from that point on neck to the top of the cuff and enter it (refer fig. 21). It needs to be measured above the patient's body using the Carotid Site and the Top of Thigh Cuff as landmarks for measurement and is measured in a straight line above the body. The PWV distance should not use patient contact where the individual contours of the patients' body can incorrectly increase PWV distance based on their own individual anatomical external body structure.

Note: Using the centimetre scale on the measuring tape, measure the PWV distance. Then, divide the result by 10 to convert it to millimetres and enter the distance into the software.

8. Click the next button located at the bottom of the page.
9. The software verifies the connectivity of the cuff and the probe. During the cuff check, the cuff inflates and deflates. After this, the Measurement page will be displayed, as shown in fig. 23.

Note: The operator should ask whether the patient is experiencing any discomfort during the measurement. If so, disconnect the cuff and remove the probe from contact.

Note: If the cuff is not wrapped properly or has a leak, an error message will pop up. Physically check and ensure that the cuff connections and the wrapping are proper. Click "NEXT".

Fig.23. Measurement Page

10. Ensure that the probe cable is routed properly through the slot marked in the probe compartment. Do not close the lid on the probe cable.

Note: Refer to the video tutorials provided for guidance on the proper positioning and orientation of the cuff and probe.

11. Put a drop of gel on the Ultrasound Transducer probe and position it where pulsations are felt.
12. Move and orient the probe until you locate the artery using the Carotid motion display.
13. Once the probe is correctly placed on the artery, the Carotid motion display will only display two vertically adjacent patterns with consistent movements opposite to each other as shown in fig. 24.

Fig.24. Measurement Page

14. The artery detection will be indicated with a translucent green colour bounding region around the artery wall.
15. The status of measurement will be displayed above the progress bar.
16. Once the probe is held steadily, you'll see the display of carotid and femoral pulse waveforms.
    A Quality bar shows the Ultrasound Transducer probe recording quality as shown in fig. 25.

Fig.25. Measurement Page

17. When the pulses are being captured, the progress bar commences to fill.
18. When the measurement is complete, the Progress bar fills up to its maximum and the Results page appears as shown in fig. 26.

Note: Progress bar is filled only when the femoral waveform is displayed in blue colour and usable quality pulses are captured. (Refer Chapter 6 Section C– Recommendations for measurements for ensuring good quality recordings.

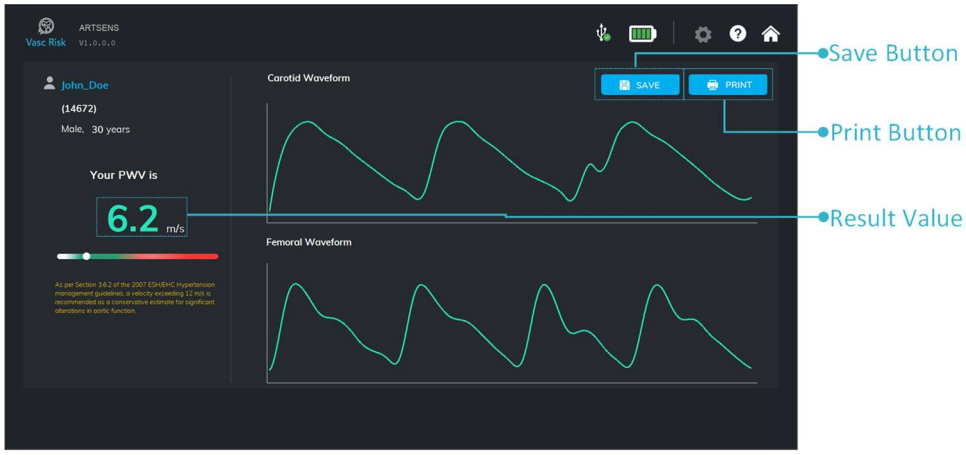


Fig.26. Result Page

Note: If the quality of the recorded measurement pulses is not satisfactory the software pop-ups the notification indicating the same. You may either exit and go to the home page or redo the measurement.

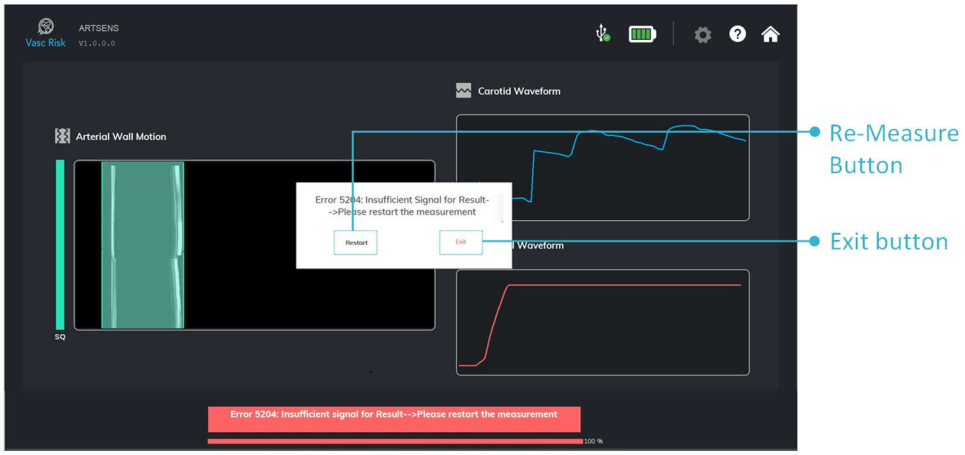


Fig.27. Insufficient signal error popup

b. Understanding your Pulse Wave Velocity test results

Aortic PWV is a metric of arterial stiffness, generally considered a regional parameter as opposed to local. Stiffness and consequently, PWV of the person may vary depending on the food intake, medication, health, stress, and exercise.
A higher PWV indicates higher stiffness. Although the relationship between aortic stiffness and cardiovascular events is continuous, a value greater than a threshold of 12 m/s has been suggested as a conservative estimate of significant alterations of aortic function in middle-aged hypertensives by 2007 ESH/ESC hypertension guidelines.

Hence users may use the device to track the increased PWV.

Note: The measurements from the ARTSENS Plus PWV device are not intended for screening cardiovascular risks or diseases in the general patient population. It is intended to supplement, not substitute, the physician's decision-making process. The readings should be used by a clinician in conjunction with knowledge of the user's history and other clinical findings.

The reference bar in the Results page shows the user's overall results with respect to the definition of normal versus impaired PWV provided in the ESH/ESC guidelines.

The circular marker on the bar indicates the user's measured PWV. The colour gradient in the bar transits from green to red

- Green zone represents normal.
- Red zone represents impaired.

Users are recommended to consult a physician or healthcare professional if the PWV value is in the red zone.

Note: Inaccurate results may occur,

- If the cuff is improperly wrapped.
- If the user has not sufficiently rested (at least for five minutes) before the measurement.
- If the carotid and femoral measurements are not performed on the same side of the body.
- The patient is experiencing stress due to
    - White coat hypertension manifests a momentary increase in blood pressure.
    - Hyperventilation, leading to substantial motion artifacts.

c. Recommendations for measurements

Probe
In fig. 22 ideal region for identifying the carotid artery and placing the Ultrasound transducer probe is marked.

- Palpate to feel the strongest pulses in the marked region to obtain optimum signal quality.
- Apply gentle pressure to keep the probe stable throughout the measurement.

Note: Avoid applying too much pressure. It may cause discomfort to the patient and may affect the carotid pulse wave capturing.

- If possible, rest your wrist against support to hold the probe stable if the measurement takes a longer time.

Cuff
In fig. 21 illustrates the correct way to wrap the thigh cuff.

- Wrap the cuff on the left leg in a way that its tube is facing downwards. In this manner, you will find that the Velcro is being wrapped over the inner side of the thigh.

Note: The cuff shouldn't be loose on the thigh. You may hold one end of the cuff on top of the thigh and use the other hand to wrap the cuff firmly clockwise.

- It is strongly recommended to always position the cuff around the center region of the thigh, as shown in fig. 21.
- Wrap the cuff on the thigh as high as possible.
- Care must be taken such that the hose pipe is not wrapped along with the cuff.

Measurement feedback
The GUI of the software application provides you several visual feedback that allows you to take the best possible measurements.

- On the measurement page (fig. 23), The Carotid motion display shows structures that are moving along the scan axis. Initially, as you are searching the artery there wouldn't be a characteristic pattern (fig. 24), But when you place a probe over the artery the Carotid motion display will show only two vertical adjacent patterns with consistent oscillations opposite to each other as shown in fig 25.
- There is a signal quality bar next to the motion display. The level of the bar indicates the quality of the carotid scans. It is recommended to place and orient the probe so that the bar at least fills 50%. The colour of the filling will change from white to green when good-quality signals are recorded.

Host computer

- Host computer should be plugged into mains power while performing the measurements. This is required to ensure the host does not automatically optimize the processing settings under the power saving mode that may affect the USB data transfer.

Note: If the host is a standalone system solely for working with ARTSENS Plus PWV device, it is recommended to change the power & sleep settings to "never" or above 30 minutes to ensure the display screen is not turned off during measurement.

7. Maintenance

a. Reuse Life Limits

Probe
The lifespan for the probe is 5 years. The reuse life of the probe extends until it either fails during the self-test procedure or exhibits any visible physical damage on its cables. It is recommended to regularly inspect the probe for any signs of wear and tear, such as fraying or exposed wiring, which may compromise its functionality and accuracy. If the probe fails the self-test or shows any visible damage, immediate discontinuation of use is advised, and the probe should be replaced promptly.

Cuff
The cuff's reuse life is defined by the manufacturer at 10000 cycles of operation. Velcro tapes of the cuff withstand a minimum of 1,000 open-close cycles without failure. The Cuff Bladder is capable of enduring at least 10,000 pressure cycles to inflate to 300 mmHg without compromising functionality. Regular maintenance and inspection of the cuff, including checking for tears or leaks, are necessary to maintain its integrity and accuracy. Upon reaching the specified limit cycles or upon detection of any visible damage, the cuff should be replaced promptly to maintain accuracy in measurements and user safety.

b. Basic system care

i. ARTSENS Plus PWV Device

Stability
Place the ARTSENS Plus PWV device on a flat surface. Mishandling or dropping the device may result in damage and improper functioning. Select an appropriate location that is stable and away from drop-prone areas to minimize the risk of accidental drops.

Pressure or impact damage
Avoid applying excessive pressure to the ARTSENS Plus PWV device and prevent it from being subjected to strong impacts. Doing so could harm its electronic components or lead to operational issues.

Temperature
Ensure that the ARTSENS Plus PWV device is operated and stored within the specified temperature and relative humidity range as detailed in the Technical Specifications.

Note: Ensure that the unit is shielded from dirt, moisture, and dust, as these elements could lead to operational failure. Prevent direct exposure of the unit to sunlight, as prolonged exposure to sun or heat can result in overheating and harm to internal components. Exercise caution when placing it near windows, leaving it inside a car, or taking it outdoors in direct sunlight to prevent overheating and internal damage.

Magnetic fields
Strong magnetic fields from devices like CT and MRI machines, or sources such as large electric motors, magnets, television sets and radios can interfere with the device's operation or potentially cause it to malfunction.

Liquids
Keep all components of the ARTSENS Plus PWV device away from contact with liquids, both inside and outside, as exposure to liquids can lead to permanent damage.

Note: Do not spill liquids on the device, its applied parts and accessories.

Weight
Applying weight to the top of the ARTSENS Plus PWV device may result in the unit's enclosure cracking and other parts getting damaged.

Note: Avoid placing any objects on the top of the device.

Movement
Sudden jolts lead damage to the unit or the ultrasound transducer probe if it is not stored correctly.

Note: Refrain from shaking or dropping the device.

Components

Only use the probe, cuff, and other components provided with this system. Do not substitute them with parts from other products or supplies.

ii. Ultrasound transducer Probe

The ultrasound transducer probe's tip is a fragile and sensitive component, susceptible to damage if mishandled or dropped. To preserve the probe's longevity, please adhere to the following guidelines.

- Handle the probe with care and be careful not to drop it on the floor.
- During the measurement procedure, hold on grips provided on the probe.
- Wipe off the gel from the tip of the probe after each measurement with a clean tissue or cloth.
- When the probe is not in direct use with the patient, protect the probe by placing it in the probe storage compartment given on the unit.
- The probe is intended to be used in conjunction with the ARTSENS Plus PWV device only.

iii. Device Battery

- Use the device only for its intended purpose. Avoid leaving it connected when not in use.
- When you're not actively using the device, unplug the USB cable and adapter to prevent unnecessary power drain.
- Pay attention to the battery status indicator displayed by the device. This will give you a clear idea of how much power is left and when you should recharge.
- If the device will not be used for an extended period, store it in a cool, dry place with the battery partially charged (at least 50%) to prevent deep discharge.
- Dust and debris can affect the performance of the device and its cooling system, potentially leading to increased power consumption. Regularly clean and maintain the device.
- Use power adapters or cables, use those provided with the device or ones that meet the device's specifications. Incompatible accessories may damage the battery and device.

Note: If the device is not in use after extended periods of storage, it may be necessary to charge the device before performing the measurement.

iv. Equipment Calibration

Note: The ARTSENS Plus PWV's OEM pressure module requires an annual calibration. Failure to do so, may result in a compromise of cuff control functionality.

When it's time for calibration, users will receive a reminder via their registered email. Calibration can be carried out by the nearest dealer upon returning your ARTSENS Plus PWV System, with associated charges. For additional details, please get in touch with your local representative. Detailed recalibration instructions, including packaging and service procedures, are available on the official product website: www.vascrisk.com. You may also contact our technical support team through the contact information listed on the website.

Warning: All first-time users and any users acquiring the device through second-hand sales or transfer must register the device at the time of setup through the official website, the details of which are used for recalibration reminders

c. Cleaning and Disinfection

Cleaning of ARTSENS Plus PWV device
Visually inspect the device for any visible dirt or foreign particles. To clean the device, first unplug it from the computer and the power outlet. Using a cloth damp with water, gently wipe the equipment. Do not use any cleaning agents.

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

Cleaning the ultrasound transducer probe
Examine the probe tip for any gel residue. Remove the ultrasound gel by wiping the probe with a paper towel. Wipe the probe and cable with a wet paper towel. Use a disposable, clean paper towel to wipe off the ultrasonic gel or other visible dirt on the surface of the probe.

Note: Do not use abrasive paper products when cleaning or wiping an ultrasound probe. The use of abrasive wipes can damage the soft surface. Avoid using alcohol to wipe the probe. If alcohol comes into contact with the transducer, wipe it off immediately.

Cleaning Cuffs
The cuff covers are made of Nylon and Velcro. Visually inspect the cuff for any visible dirt or debris. Gently wipe the cuff with a cloth dampened with water and a neutral pH detergent (example: Alconox Liquinox). Ensure there is no lint accumulated on the Velcro straps, as this may affect the cuff's ability to fasten securely and provide accurate measurements.

Disinfecting Cuffs and ultrasound Transducer Probe
As ARTSENS® Plus PWV is classified as a non-critical device and is not intended for contact with sterile tissue or mucous membranes, we have included low-level disinfection instructions based on widely accepted practices for reprocessing non-critical medical devices. Therefore, a low-level disinfection method has been provided to assist users to disinfect the ultrasound transducer and cuffs, which are the only patient-contacting components of the ARTSENS Plus PWV device.

For disinfecting the applied parts, use an EPA-registered, alcohol-free low-level disinfectant wipe, such as a quaternary ammonium-based wipe (e.g., Sani-Cloth® AF3). Wipe the entire surface and allow the disinfectant to remain for a minimum of 10 mins. Dry with a clean cloth, if needed.

Note: Some disinfectants may cause the cuff's blue colour to bleed into cuff labelling. This does not affect the cuff's performance.

Note: Do not immerse the ultrasound transducer probe in any liquid as this will damage the probe. Do not use coarse cloths for wiping the probe as this will damage the sensitivity of the transducer.

d. System Troubleshooting

The following is a list of possible errors that may be encountered when operating the ARTSENS Plus PWV. If any unlisted error(s) occur, exit ARTSENS Plus PWV software, reconnect ARTSENS Plus PWV device, and start the software. Contact authorized service personnel in case of a persistent problem.

Error Code	Description	Solution
5200	ARTSENS Plus PWV hardware not connected, please connect the hardware and try again	Reconnect all the components connection and check again.
5201	The internal hardware Module is busy	When Measurements are already in process, it may be 2nd instance of the ARTSENS PWV application running on the same PC.
5202	Cuff error - Please connect or Reconnect the Cuff	Check for leaks and reconnect the cuff.
5203	Connection for the ARTSENS Plus PWV hardware has been lost	Reconnect all the components connection and check again.
5204	Insufficient Signal for Result	Restart the measurement and check signal quality.
5205	Probe error - Please connect or Reconnect the Probe	Check if the Probe wire is kinked. Reconnect the Probe and check again. If problem persists, contact manufacturer.
5206	Cuff inflation error - Please restart measurement	Check for leaks. Check for proper wrapping and secure holding. Check if the Hose pipe is kinked. Lock the connectors properly. Reconnect the cuff and restart the measurement. If problem persists, contact manufacturer.
5300	Application error - Folder, please check the software is installed correctly	Uninstall the old software and reinstall by downloading from the website.
5301	Application error - Settings, please check the software is installed correctly	Uninstall the old software and reinstall by downloading from the website.
5000	Internal Software error, try to restart the application	Close all programs in your PC, restart your PC and open only the ARTSENS Plus PWV software.
5100	Setting file missing, reinstall the software	Reinstall Software. If problem persists, contact manufacturer.
5101	Settings file failed to Load-->Please check Whether values in Settings file is changed	Reinstall Software. If problem persists, contact manufacturer.
5102	Settings failed to save	Reinstall Software. If problem persists, contact manufacturer.

8. Warranty

Component	Warranty period from the date of purchase
ARTSENS Plus PWV device	12 months parts and labour warranty
Adult Cuff	12 months parts and labour warranty
Ultrasound Transducer Probe	4 months warranty

The warranty covers the items against any manufacturing defects and does not cover damages arising from operational wear and tear, or misuse.
Service and technical support for the ARTSENS Plus PWV device will be provided by the Vascrisk technical support group. Contact your local distributor to organize the service.

9. Cybersecurity

The ARTSENS Plus PWV device consists of the device embedded with firmware and software installed on the host PC. Operating as a closed system, it prohibits the installation of external components and restricts users from upgrading or modifying the device's firmware. The software operates on a host platform, the security of which lies within the user's responsibility. Importantly, both the device firmware and software lack features for detecting or reporting security events. To enhance security, it is advised to employ a strong user password to secure the host platform thereby preventing unauthorized activation of the device or access to personal information.

- Implement authenticated access on the desktop platform using user credentials and secure the host PC with a password or alternative means (e.g., biometric, pin code).

- Restrict physical access to the host platform and the ARTSENS Plus PWV device to authorized personnel only.
- Keep the software updated with the latest security patches.
- Install software exclusively from the installation drive provided by the manufacturer, refrain from installations via third-party links, DVDs, or cloud sources.

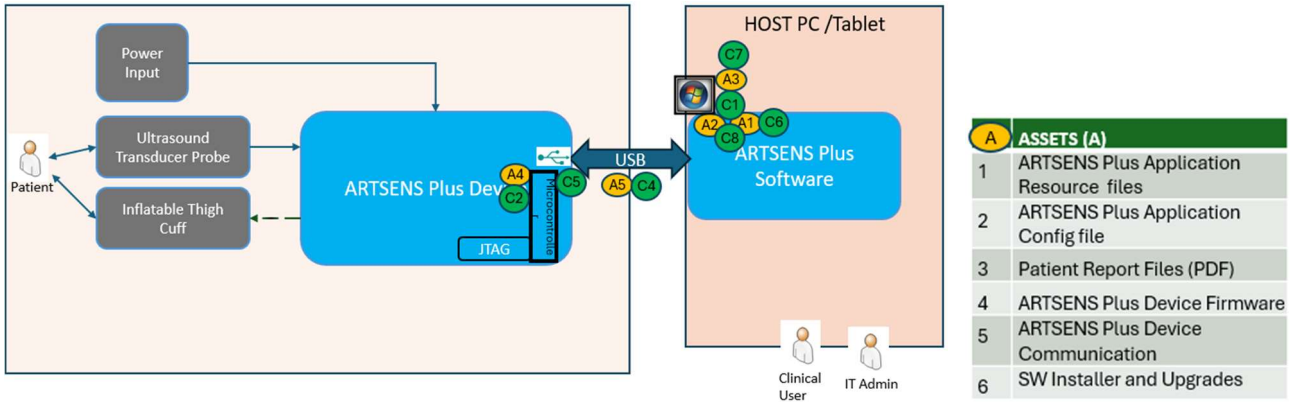
Note: It is strongly recommended to secure your host platform with a password or an equivalent security mechanism to prevent unauthorized activation of the device.

System security and IT Maintenance
From a security perspective, The ARTSENS Plus PWV device consists of a) ARTSENS Plus PWV device, which consists of embedded firmware b) ARTSENS Plus PWV software application installed on the host PC running Microsoft Windows OS. The computer to be utilized for this purpose is to be provided by the hospital.

The ARTSENS Plus PWV application is to be installed by hospital IT on the computer using the ARTSENS Plus PWV software USB installer provided with the device. Refrain from installations via third-party links, or cloud sources.

Restrict physical access to the host platform and the ARTSENS Plus PWV device to authorized personnel only.

The security asset view of the system is illustrated below.



A	ASSETS (A)
1	ARTSENS Plus Application Resource files
2	ARTSENS Plus Application Config file
3	Patient Report Files (PDF)
4	ARTSENS Plus Device Firmware
5	ARTSENS Plus Device Communication
6	SW Installer and Upgrades

Fig. 28. Security asset view of the system

Host PC Security and Configuration
The host PC does not need to be connected to the hospital internet or hospital domain for its intended use. However, Hospital IT may choose to do so for other organizational reasons. Hospital IT is responsible for configuring and maintaining the host PC as per the hospital's IT policies. Following considerations are to be accounted for this purpose:

- User accounts: Implement authenticated access on the desktop platform using user credentials and secure the host PC with a password or alternative means (e.g., biometric, pin code). Restrict administrative privileges such that changes to the ARTSENS Plus PWV Application resource files cannot be done by unauthorized users.

- Anti-virus: Windows's default antivirus - Microsoft Defender Antivirus – should be left turned on, or other hospital-preferred anti-virus software may be utilized.

Note: ARTSENS Plus PWV application functionality has only been tested with Microsoft Defender Antivirus. However, considering the low-safety risk of the device and the ARTSENS Plus PWV application technical implementation, other standard anti-virus solutions would be acceptable.

- Ports and Interfaces: ARTSENS Plus PWV device utilizes USB connection for device communication. It does not utilize any virtual or network port. Hospital IT may whitelist the port configuration of the host PC accordingly.
- Security Log: It is recommended to turn-on at least the following Windows OS security log events:
    - audit account management.
    - audit login events.

PHI and Audit Log
ARTSENS Plus PWV application does not save any Protected Health Information (PHI) or procedural data. Optionally, the user may print a report document in PDF format. The report document contains PHI.
ARTSENS Plus PWV application adds an entry to the Windows Audit Log every time a report document has been created. The log consists of following fields: a) date/time b) user ID of the user logged in to the OS c) changed data folder path.

Note: Instruct network administrator to enable OS audit log.

Report access and back-up
By default, the PDF report documents are saved locally in the documents folder. Location may be changed to any local or network path from the settings page of the ARTSENS Plus PWV Software. Hospital IT is advised to keep the location access privileged so that unauthorized users do not have access to the Report documents.

Configuration Recovery
In an event that the resource file(s) of the ARTSENS Plus PWV application is modified/corrupted, the application may fail to start. In such a scenario, the application can be reinstalled via the ARTSENS Plus PWV USB installer.

If the problem persists, contact Customer Support.

Software Updates and Patches
Hospital point-of-contact will be notified through the manufacturer's Sales and Support team whenever a software update or a patch is released. The information about the type of update and the method to obtain a manufacturer-authorized version will also be provided along with.

These updates may include enhancements, bug fixes, and security patches. Keep the software updated with the latest updates.

SBOM
Machine-readable Software Bill of Material (SBOM) for the ARTSENS Plus PWV system is provided in the Installation drive. After software installation, the SBOM is in the documents folder of PC.

Device Decommissioning
ARTSENS Plus PWV device does not contain any confidential information of significance. No specific steps are required for secure decommissioning.
Host PC may be decommissioned as per the hospital's policy after patient report data backup has been taken.

10. Product support

If you have additional questions after reviewing the manual, contact your local Vascrisk representative/distributor. The details of your local representative/distributor can be found at www.vascrisk.in
Please quote your device Serial Number to your Product Support Representative. This serial number can be found on the bottom of the device.
When contacting your local Vascrisk representative/distributor please have your ARTSENS Plus PWV System nearby as well as a copy of the Operator's Manual opened on your PC. You should be prepared to give the following information, whichever if applicable:

- Device Serial number (refer fig. 2)
- The error number and the exact wording of any messages that appear. The error code 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 ARTSENS Plus PWV software.

11. End of life Management – Disposal

Vascrisk is deeply invested in the preservation of the natural environment. Equipment may contain materials that pose a risk to the environment if proper disposal procedures are not followed. Recycle the ARTSENS Plus PWV and accessories at the end of their useful life and in accordance with local, state, provincial, and/or national regulations.

Prior to recycling, items should be clean and contaminant-free.

12. Reference information

Refer to our website https://artsens.tech/publications/ for a current list of ARTSENS publications.

13. Technical specifications

S. No	Parameter	Description
1	Product name	ARTSENS Plus PWV
2	Product version	V1
3	Product type	Medical device
4	Product Class	Class-II
5	**Standard Accessories**	
	Ultrasound transducer probe	1 x Single element Piezo ultrasonic Probe
	Thigh Cuff	1 x Adult cuff Standard size: 46-66cm thigh circumference
	Hosepipe	1 x 1/8" pipe; Length: 1.5m
	Micro USB cable	1 x Micro USB to USB type A cable; Length: 1m
	Measuring Tape	1 x 150cm, with 1mm resolution
6	**Physical Features**	
	Colour	White
	Dimensions	240 mm X 170 mm x 60 mm
	Weight	~1Kg
	Material	Acrylonitrile Butadiene Styrene (ABS) Plastic
	Thigh cuff material	Nylon
7	**Host Requirements**	
	Minimum System Specifications	Intel i5 Processor, 8GB RAM, Microsoft Windows 10 and above, 1 x USB2.0 port
	Minimum Display resolution	1080p
8	**Environmental Conditions**	
	Operating Environment	Indoor
	Operating Temperature (°C)	15°C to 45°C
	Storage Temperature (°C)	10°C to 60°C
	Relative Humidity (%)	10 to 80%, non-condensing
9	**Electrical Specifications**	
	Input DC Voltage (V)	9
	Input DC Current (A)	3.3
	Battery	7.2V, 5100 mAh Li-ion rechargeable battery
	Battery Backup	Up to 5 hours
10	**Power Adapter Specifications**	
	Type	2 MOPP Class II

S. No	Parameter	Description
	Input AC Voltage Range (V)	80 ~ 264Vac
	Input AC Frequency Range (Hz)	47 to 63
	Input AC Current Range	0.9A max
	Output DC Voltage(V)	9
	Output DC Current range (A)	3.3
	Rated Power (max)	36W
11	**Status Indication**	
	Status indication on device	Green indicates measurement activity status. Amber indicates the device ON status. Red indicates the battery charging status.
	Status indication on software	Device connectivity Battery level Mains power connection
	Error and warning	Error and warning codes will be indicated along with messages
	Software Features	Intuitive GUI
		Patient enrollment
		Synchronized carotid and femoral pulse acquisition
		Beat to beat calculation and processing of pulse waveforms with Quality checks
		Visual feedback of measurement
		Automated cuff control
		Report generation & printing
12	**Measurements Method**	
	Measurements supported	Aortic Pulse Wave Velocity (PWV)
	Measurement Specifications	Aortic PWV Range: 2 to 25 m/s
	Error in PWV	0.05 ± 0.5 m/s, validated as per ARTERY Society Guidelines
	Measuring sites	Left Carotid and femoral sites
	Physiological signals for PWV measurement	Pulse waves from carotid and femoral arteries
	Distance for PWV measurement	Direct method: 80% of Carotid-to-Thigh cuff distance
	Signal Acquisition	Simultaneous and time-synchronized recording
13	Applied Parts	
	Applied Parts	Ultrasound transducer probe, Thigh cuff
	Ultrasound transducer probe	Capture carotid artery pulsations Type: Broadband, focused piezo ultrasonic element. Centre frequency: 5 MHz Diameter: 5mm Spatial half angle < 1.3 degrees
	Cuff control	Pressure module
	Thigh cuff	Capture femoral artery pulsations
14	**Device connectors**	

S. No	Parameter	Description
	USB connection	Interfaced to Tablet/PC/Laptop via a Micro USB to USB type A cable.
	Carotid ultrasound transducer probe	Coaxial SMB connector
	Hosepipe-to-device	Hose Barb Valved In-line Coupling
	Cuff-to-Hosepipe	Fast and secure twist-to-connect coupling
15	**Standards**	
	Device symbols	ISO 15223-1:2021
	Device information	ISO 20417:2021
	Electromagnetic Compatibility	IEC 60601-1-2:2014
	Biocompatibility Test-Cytotoxicity	ISO 10993-5:2009
	Biocompatibility Test -Skin Sensitization	ISO 10993-10:2021
	Biocompatibility Test -Skin Irritation Test	ISO 10993-23:2021
	Electrical Safety	IEC 60601-1:2005+AMD1:2012+AMD2:2020
	Safety of Ultrasound diagnostic probe	IEC 60601-2-37:2015