Vitasigns



ProSeries 2 Blood Pressure Monitor

Quick Start Guide A complete user guide is available at vitasigns.com

VS47129-0200

Welcome to Vitasigns

Our mission is to empower you to live a healthy life. We're passionate about creating simple technology that helps you monitor your vital signs so you can achieve your health and fitness goals.

Our intelligent devices improve your health awareness by making it easy to measure, monitor, and track your weight, pulse rate, blood pressure, steps, activity, and more.

Every day – people just like you choose our products. We honor that choice by ensuring our products are the highest quality and by doing business responsibly.

Thank you for making Vitasings part of your life.

Table of Contents

| Safety Information1 |
|-------------------------------|
| ProSeries2 LCD Display5 |
| Getting Started |
| Monitor Components |
| Configuring the ProSeries2 |
| Prepare to Measure 10 |
| Measurement Tips |
| Taking a Measurement |
| Records Management |
| Maintenance |
| Vitasigns Application15 |
| Systolic & Diastolic Pressure |
| Standard Blood Pressure |
| Irregular Heartbeat Detector |
| Frequently Asked Questions |
| Troubleshooting |
| Specifications |
| Complied Standards |
| FCC Statement |
| EMC Guidance |



The **ProSeries2** measures systolic and diastolic blood pressure and pulse rate of an adult by using a pressurized cuff on the upper arm. The device is not intended for use on infants and children. The device is designed for home use only, and is not intended for ambulatory measurement - measurement recorded continuously throughout the day.

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the American National Standard, Manual, Electronic or automated sphygmomanometers.

If you suffer from disorder of heart rhythm (arrhythmia), only use this blood pressure monitor after consulting with your physician. In certain oscillometric cases, this measurement method may produce incorrect readings.

This Vitasigns measurement device is not intended to be a diagnostic device. Contact your physician immediately if prehypertensive or hypertensive values are indicated.



| Symbol | Description |
|------------|---|
| 8 | The Operation Guide Must be Read |
| F© | Complies with FCC Rules |
| *** | Manufacturer |
| SN | Serial Number |
| | Indoor Use Only |
| | Class II Equipment |
| * | Type BF Applied Parts |
| | Direct Current |
| F1 | T1A/250V ø3.6*10CCC |
| ~~ | Manufacturer Date |
| X | ENVIRONMENT PROTECTION - Wast electrical products should not be disposed of with house- hold waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice |

Caution

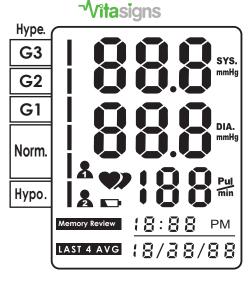
Read this user manual thoroughly before use. This device is designed and manufactured to operate within defined design limits. Misuse may result in harm. The following should be observed to best use and maintain your device:

- This device is intended for adult use only.
- This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on body extremities other than the wrist.
- Its sole functions are blood pressure and heart rate measurement.
- Monitoring blood pressure with this device does not equate to a medical diagnosis.
- This device allows you to monitor your blood pressure under the care of a physician.
- If you are taking medication, consult with your physician to determine the most appropriate time for your measurement. Never change a prescribed medication without your physician's consent.
- This device is not suitable for continuous monitoring during medical emergencies or operations.

Caution

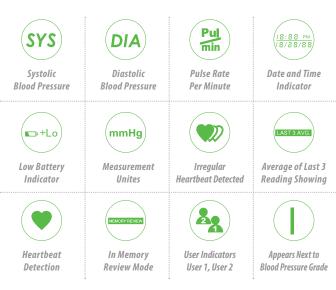


- If the pressure of the cuff exceeds 40 kPa (300 mmHg), the device will automatically deflate. Should the cuff not deflate when its pressure exceeds 40 kPa (300 mmHg), detach the cuff from the wrist and press START/STOP to stop inflation.
- Do not use the monitor under the conditions of strong electromagnetic field (e.g. medical radio frequency equipment) that radiates interference signal or electrical fast transient/burst signal.
- The device is not AP/APG equipment. It is not suitable for use in the presence of flammable gases (avoid oxygen, nitrous oxide).
- Keep the unit out of reach of infants or children. Inhalation or swallowing of the device's small pieces is dangerous or even fatal.
- Use only accessories and detachable parts specified and authorized by the manufacturer. Not doing so may cause damage to the unit or danger to you.





Important Symbols



Getting Started

Charging Your Pro Series 2

The Pro Series 2 Blood Pressure Monitor contains a built-in lithium-ion rechargeable battery. To charge the battery plug the provided USB cable into your Pro Series 2 and plug the other end of the cable into a computer or USB power adapter.

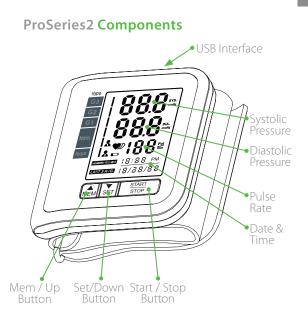
A full charge should last for one month, taking measurements





Caution

The battery of the ProSeries2 is built-in rechargeable lithium-ion battery, please do not disassemble. The battery can be charged up to 300 times under normal usage conditions. If the battery does not tharge or the blood pressure does not function properly please contact Vitasigns, info@vitasigns.com. If measuring twice times per day, the battery will last for about 30 days, if it was fully charged. Store and use the blood pressure monitor in a cool, dry and ventilated environment. Avoid direct contact with fire and the heat sources, as the can cause the battery to explode. Only use the Vitasigns authorized USB cable to charge your ProSeries2. The ProSeries 2 can not be used while charging. When the charging indicator disappears from the display charging is complete and you may unplug and use the ProSeries 2.



Configuring the ProSeries2

Setting the Time and Date

Before using your Pro Series 2 to take a Blood Pressure Measurement, you should set the date and time to ensure that measurement results store correctly.

Follow these simple steps to set the time, date, and unit:

- With the Pro Series 2 off, press and hold in the "Set" button for 3 seconds until the time appears on the display with the hour flashing.
- 3. Press the "Mem" button to change the number. Each press will increase the number by 1.
- 4. Press the "Set" button to confirm the change and move onto minutes.
- 5. Repeat this same process for minutes, month, day and year.
- Once you have confirmed the year, "dONE" will appear on the screen and the monitor will shut off automatically.

Selecting a User

- 1. With the Pro Series 2 off, press and hold in the "Mem" button for 3 seconds to enter the select user mode.
- 2. Press the "Mem" button to select between User 1 & 2.
- 3. Press the "Set" button to confirm your selection.

Preparing to Measure

Positioning the Cuff

- Remove your watch and/or jewelry from your left hand (if your physician has diagnosed you with poor circulation in your left wrist, use your right wrist).
- 2. If applicable, roll or push up your sleeve to expose your skin.
- 3. Fasten the cuff around your wrist, palm facing up, and fasten.
- Make sure the cuff is firmly against your skin, if the cuff is too loose, the measurement will not be accurate.
- 5. Sit comfortably on a chair. The center of the cuff should remain at the same level as your heart. Your legs should be relaxed with the feet facing outwards.

Measuring Tips

Tips for Measurina

- Sit comfortably on a chair, with your legs relaxed and your feet flat on the floor facing out with your back and arm supported.
- For meaningful comparisons try to take readings under the same conditions at the same times.
- 3. Relax for at least 5 minutes before taking a measurement.

Following these additional tips when taking a measurement to get a more accurate reading. Measurement taking under any of the following circumstances, may result in inaccurate readings.

















Wait at least 1 hour to measure after eating or drinking

Wait at least 20 minutes to measure after bathing or showering

Don't measure if you are in a very cold environment

Don't measure after drinking tea, coffee or smoking

Don't measure while talking or moving your hands to use the restroom and finaers

Don't measure when you need

Taking a Measurement

Measuring

After correctly positioning the cuff and selecting the user you are measuring for, press the "Start" button to activate and complete the measurement process.

Press the "Stop" button at anytime during the process to stop the measurement.

One completed, press the "Stop" button to turn off the monitor otherwise it will turn off automatically.





Caution

When using this device, please pay attention to the following situations which may interrupt blood flow and influence blood circulation, thus having the potential to cause injury to the patient: too frequent or consecutive measurements; the application of the CUFF and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; Inflating the cuff on the arm on the side of a mastectomy.

Do not apply the cuff over a wound, doing so may cause further injury. Do not inflate the cuff on the same limb which other monitoring equipment is applied around simultaneously, this could cause temporary loss of function of those simultaneously-used monitoring equipment. Don't limk the connection tube, to anything that can result in the cuff pressure continuously increasing which can prevent blood flow and result in harmful injury.

Recalling and Review Records

To recall or review your records, press the "Mem" button. The first thing you will see is the calculated average for the last three measurements taken for the selected user. Use the "Mem/Up" and "Set/Down" buttons to navigate through the measurement history.

Remember, the most recent measurement is always shown first.

Deleting Records

You can delete all the records on the Pro Series 2 by entering the recall records mode and then holding in the both the "Set" and "Mem" buttons for 3 seconds.

The display will show, "dEL d0NE" indicating that the memory has been cleared completely.

The monitor will shut down automatically when finished.

Remember, the average value of the latest three readings is always shown first.

Caution

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

ProSeries2 Maintenance

For best performance, please follow below instructions.



Store in a dry place and avoid direct sunlight.

Avoid getting the monitor Avoid dropping or shaking wet, clean with a dry cloth. the monitor



Avoid storing in dusty or Use a dry or slightly damp Do not wash the monitor intemperate environments cloth to remove dirt in water or submerge it

Caution

Please make sure the unit functions safely and it is in proper working conditions before use. Don't ser or maintain while the device is in use. If you have any problems with this device, such as setting up, maintaining or using, please contact Vitasigns (info@vitasigns.com). Do not open or repair the device yourself. Please report to Vitasigns if any unexpected operation or events occur.

Cleaning: Dusty environments may affect the performance of the unit. Please use a soft doth to remove any dirt from the device and cuff before and after use. Disposal: Degraded sensors may result in inaccurate measurement while loosened electrodes may cause the monitor's failure to power on. Please dispose of ACCESSORIE, Detachable parts, and ME EQUIPMENT according to local guidelines.



Vitasigns makes health awareness easy with intelligent devices that support Smart Routines for you and those you love.

Track your Blood Pressure and Pulse Rate as part of your Smart Routine for health awareness. Enter your readings into the Vitasigns App to store data, monitor progress, set, and achieve goals or even share your information with a personal trainer or physician. Download the Vitasigns App for free from the Apple App Store or Google Play.

www.vitasigns.com/app

Setting Up the Application

Downloading the App

The first step in setting up your Vitasigns Application is to download the Application from either the App Store or Google Play.

You can also visit vitasigns.com/app

Set Up Your Account

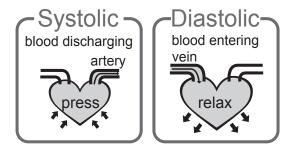
After you launch the App it's time to set up your Vitasigns account. To begin press the "Sign Up" button:

- 1. Enter your email address and create a password.
- 2. Enter your name and select your gender.
- 3. Select your birthday.
- 4. Enter your height and weight.
- 5. Select or take a photo of yourself to be used as your account avatar.
- Confirm that your information is correct and press the "OK" button.

You can use the Vitasigns App to track your progress on the Pro Series 2 Blood Pressure Monitor by manually entering your results after each measurement. Keeping an accurate account will let you track your progress and share your results with your family, friends, or medical professional.

Systolic & Diastolic Blood Pressure

What are systolic pressure and diastolic blood pressure? When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure.



When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.

Standard Blood Pressure

The chart below shows the standard blood pressure classifications published by the American Heart Association (AHA).

| Blood Pressure Category | Systolic mm Hg (upper #) | | Diastolic mm Hg (lower #) |
|--|-----------------------------|-----|------------------------------|
| Normal | less than 120 | and | less than 80 |
| Pr-hypertensive | 120-139 | or | 80-89 |
| High Blood Pressure Stage 1 (Hypertension) | 140-159 | or | 90-99 |
| High Blood Pressure Stage 2 (Hypertension) | 160 or higher | or | 100 or higher |
| Hypertensive Crisis (Emergency Care Needed) | Higher than 180 | or | Higher than 110 |

AHA Home Guideline for Upper Limits of Normal Blood Pressure are:

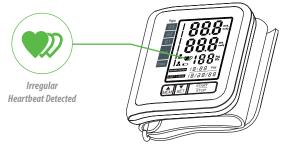


DIA 85 mm Hg

Please consult a physician if your measurement results fall outside the normal range.

Irregular Heartbeat Detection

This ProSeries2 Blood Pressure Monitor is equipped with an Irregular Heartbeat (IHB) Detector. During each measurement, it records your heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, the IHB symbol will display on the screen with the measurement result.



Caution

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. If the symbol appears often, you should seek medical advice. This device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

Frequently Asked Questions

Why does my blood pressure fluctuate?

There are multiple reasons behind fluctuations in your readings. The way you tie the cuff on, the position in which you sit, level of exercise and activity. Taking your readings at the same time and in the same position every day will help to reduce fluctuations.

Why is the reading I get at the doctor's different?

Blood pressure readings vary best on conditions as described above and just being in the hospital or the doctor's office can raise your blood pressure causing your reading to be higher.

Does it matter which wrist I use?

You can take a measurement on either wrist, though most medical professionals normally want to take your pressure on the left side. Whichever wrist you choose measure on it consistently as readings will vary between wrists.

Troubleshooting

| PROBLEM | SYMPTOM | CHECK THIS | REMEDY |
|------------------|---|--|--|
| No Power | Display is dim or will not light up. | Power are exhausted | Charge the Unit |
| Low Batteries | Low Battery Symbol displays | Low Battery | Charge the Unit |
| Error Message | E1 Shows | The cuff is not secure | Refasten the cuff and then measure again |
| | E2 Shows | The cuff is too tight | Refasten the cuff and then measure again |
| | E3 Shows | The pressure of the cuff is excessive | Relax for a moment then measure again |
| | E10 or E11 Shows | The monitor detected motion while measuring. | Movement can affect the measurement. Relax then measure again. |
| | E20 Shows | The measurement process does not detect the pulse signal. | Loosen clothing on the arm and them measure again. |
| | E21 Shows | Measure incorrectly | Relax for a moment and then measure again |
| | EExx,shows on the display. | A calibration error occurred. | Retake the measurement. If the problem persists, contact customer service for further assistance. Refer to the warranty for contact information and return instructions. |

Specifications

| Power supply | 3.7V 420mAH Built-in rechargeable lithium-ion battery, 5V / 1A USB |
|--|---|
| Display mode | Digital LCD V.A.46.5x36.5mm |
| Measurement mode | Oscillographic testing mode |
| Measurement range | Rated cuff pressure: 0kpa-40kpa (0mmHg-300mmHg) Measurement pressure: 5.3kPa-30.7kPa (40mmHg-230mmHg) pulse value:(40-199)beat/minute |
| Accuracy | Pressure: 41°F-104°F within±0.4kpa(3mmHg); pulse value:±5% |
| Normal working condition | Temperature: 41°F - 104°F (5°C to 40°C) Relative humidity ≤85% Atmospheric Pressure: 80kPa to 106kPa |
| Storage & transportation condition | Temperature:-4°F to 140°F (-20°C to 60°C) RH: 10% to 93% Atmospheric pressure: 50kPa to 106kPa |
| Measurement perimeter of the wrist | Approximately 5.3 in - 8.5 in (13.5 cm - 21.5 cm) |
| Net Weight | Approximately 0.24 pounds (110 grams) |
| External dimensions | Approx. 3.14 in x 2.85 in x 0.52 in (79.8×72.5×13.2mm) |
| Attachment | USB Cable and user manual |
| Mode of operation | Continuous operation |
| Degree of protection | Type BF applied part |
| Protection against ingress of water | IP22, It means the device could protected against solid foreign objects of 1.2.5 mm and greater, and against vertically falling water drops when ENCLOSURE titled up to 15°. |
| Software version | V01 |
| Device classification | Battery Powered Mode: Internally Powered ME Equipment AC Adapter Anarged Mode: Class II ME Equipment |

Complied Standards

| Risk Management | ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices |
|---------------------------------------|--|
| Labeling | ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements |
| User manual | EN 1041: 2008 Medical equipment manufacturers to provide information |
| General Requirements for Safety | IEC 60601-1: 2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| Electromagnetic compatibility | IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| Performance and clinical requirements | IEC 80601-2-30:2009 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers ANSI/AAMI SP10:2002/A2: 2008 Manual, electronic, or automated sphygmomanometers |
| Software life-cycle processes | IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes |

FCC Statement

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

EMC Guidance

- The Blood Pressure Monitor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS
- Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3,3 m away from the equipment.

(Note. As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m)

TWO-YEAR WARRANTY

This Vitasigns product is warranted to be free of manufacturer's defects in materials or workmanship for two years from the date of purchase. Damage or wear resulting from an accident, misuse, abuse, commercial use, or unauthorized adjustment and/or repair are not covered under this warranty.

Should this product require warranty service (or replacement at our discretion) please contact client service to obtain a Return Merchandise Authorization number (RMA) and return instructions, proof of purchase is required. Products returned without a Vitasigns generated RMA number will not be accepted and the sender will not receive a refund, replacement, or repaired product.

Witasigns

info@vitasigns.com | 1.888.824.2424 31 East MacArthur Crescent, Suite 111, Santa Ana, CA 92707 vitasigns.com

There are no express warranties except as listed above. This warranty gives you specific legal rights and you may have other rights which very from state to state.

PLEASE DO NOT RETURN PRODUCT TO A RETAILER. TO OBTAIN WARRANTY SERVICE OR REPAIR SIMPLY CONTACT US DIRECTLY. THANK YOU.