Vitasigns

ProSeries 1

Blood Pressure Monitor

Instruction Manual

VS45130-0200

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.

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Safety Information

The ***ProSeries1*** 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 pre-hypertensive or hypertensive values are indicated.

Safety Information

Symbol	Description
	The Operation Guide Must be Read
	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
	ENVIRONMENT PROTECTION - Wast electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice

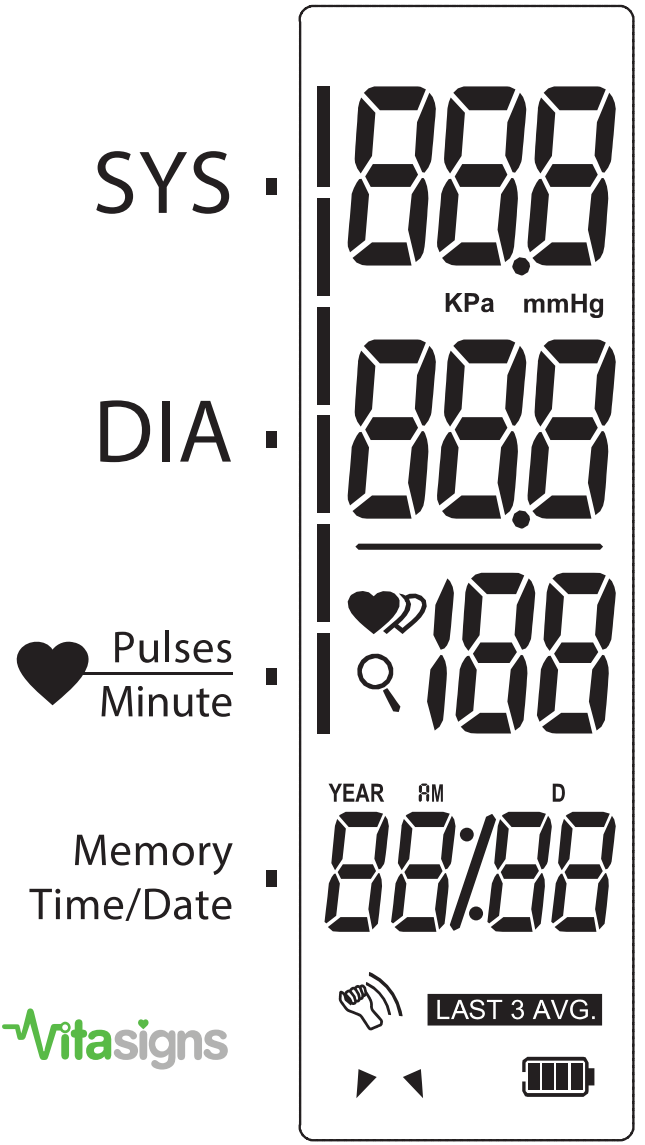
Caution

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.

Caution

- This device is not suitable for continuous monitoring during medical emergencies or operations.
- 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.


SYS
DIA
Pulses
Minute
Memory
Time/Date
KPa mmHg
YEAR
M
D
LAST 3 AVG.

Some Important **Symbols**

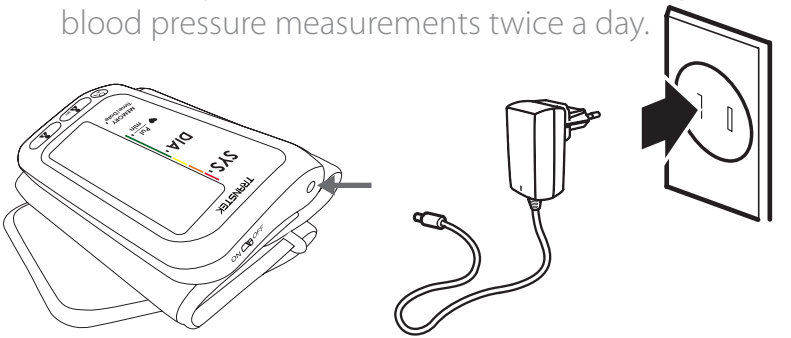
		
Systolic Blood Pressure	*Diastolic Blood Pressure*	*Pulse Rate Per Minute*
		
Battery Charge Indicator	*Measurement Unites*	*Irregular Heartbeat Detected*
		
Heartbeat Detection	*Memory Query*	*User Indicator Points to User*
		
Date and Time Indicator	*Shaking Indicator Stop Moving*	*Appears Next to Blood Pressure Grade*

Getting Started

Charging Your ProSeries1

The Pro Series 1 Blood Pressure Monitor contains a built-in Li-polymer rechargeable battery. To charge the battery simply insert the AC adapter into the power socket on the ProSeries1 and plug the other end of the adapter into an AC power outlet.

A full charge should last for one month taking blood pressure measurements twice a day.

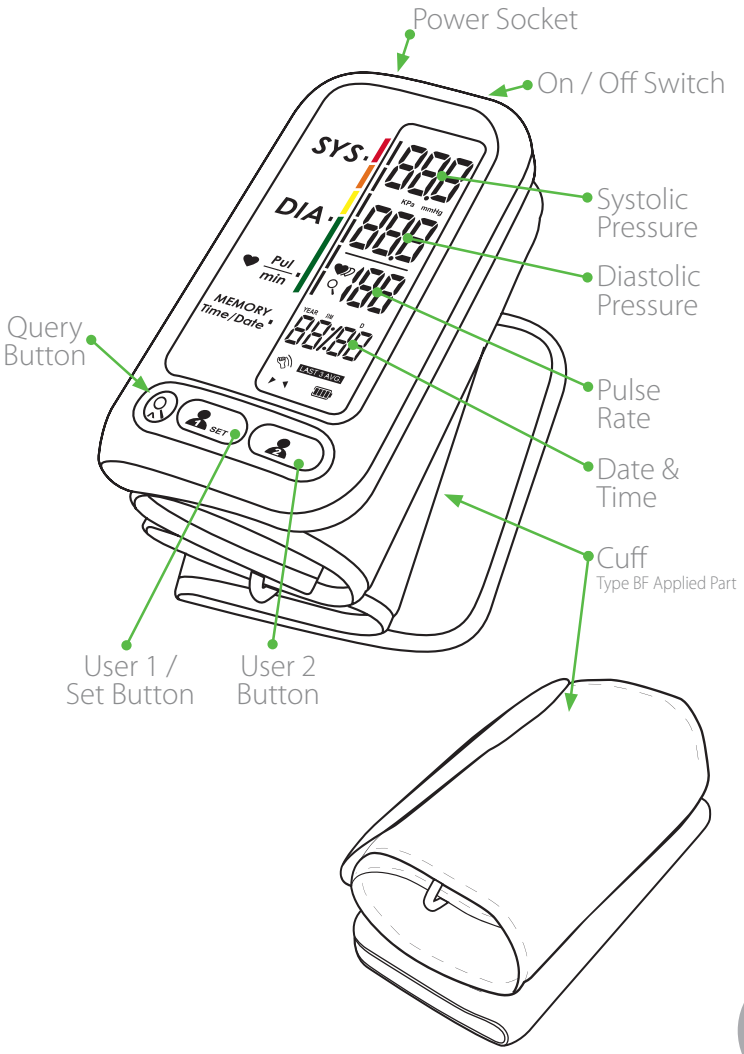


A full charge should last for one month taking blood pressure measurements twice a day.

Caution

The battery of ProSeries1 is a built-in rechargeable li-polymer battery, please do not disassemble. The battery can be charged up to 300 times under normal usage conditions. if the battery does not charge 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 AC Adaptor (6V/1A) to charge your ProSeries1. The ProSeries 1 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 1.

ProSeries1 Components



Configuring the ProSeries 1

Setting the Time, Date and Unit

Before using your Pro Series 1 to take a Blood Pressure Measurement, you should set the date and time to ensure that measurement results store correctly.

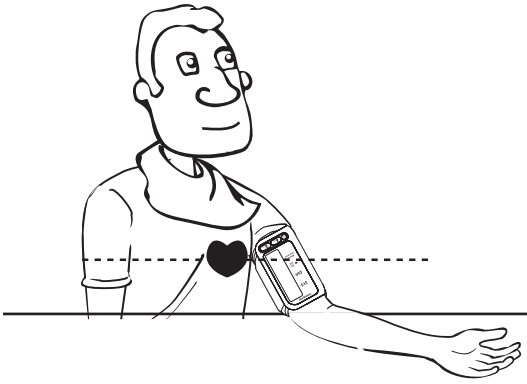
Follow these simple steps to set the time, date, and unit:

1. Turn the switch on the top of the ProSeries1 to "On."
2. Press and hold in the "User 1 / Set" button until the time appears on the display with the hour flashing.
3. Press the Query button (the one with the magnifying glass icon) to change the hour.
4. Press the "User 1 / Set" button to confirm the change and move onto minutes.
5. Repeat this process for minutes, month, day and year.
6. Once you have confirmed the year, "0.0" will appear on the display with "mmHg" above it. Press the "User 1 / Set" button to confirm that you are measuring in "mmHg." You can change the unit of measure to "kPa" by pressing the Query button.
7. Press the "User 1/Set" button to confirm completion. After you complete this process "dONE" will appear on the screen, and then the LCD will turn off.

Preparing to **Measure**

Positioning the Cuff

1. 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. The cuff needs to be placed on exposed skin.
3. Fasten the cuff around your upper left arm with your palm facing up, and fasten.
4. Make sure the cuff is firmly against your skin, if the cuff is too loose, the measurement will not be accurate.
5. For patients with Hypertension: the middle of the cuff should be at the level of your right atrium. Before starting a measurement please sit comfortably with your feet flat on the floor and your back and arms supported.

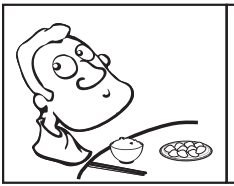


Measuring Tips

Tips for Measuring

1. Sit comfortably on a chair, with your legs relaxed and your feet flat on the floor facing out with your back and arm supported.
2. 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.

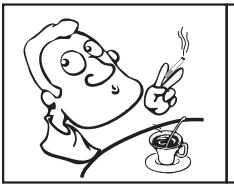
Following these additional tips when taking a measurement to get a more accurate reading. Measurement taking under any of the following circumstances, may result in inaccurate readings.



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 immediately after drinking tea, coffee or smoking

Don't measure while talking or moving your hands and fingers

Don't measure when you need to use the restroom

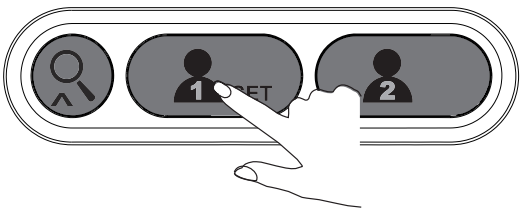
Taking a **Measurement**

Measuring

After correctly positioning the cuff and turning the monitor on, press User 1 or 2 button, depending on which you are using, to activate and complete the measurement process.

Press your User button again to stop the monitor at anytime during the process.

Once completed, your measurement will display for one minute before tuning off.



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 link the connection tube, to anything that can result in the cuff pressure continuously increasing which can prevent blood flow and result in harmful injury.

Records Management

Recalling and Review Records

To recall or review your records, press the Query button and then the User button that corresponds to your measurements.

Repeatedly pressing the Query button will scroll through all records saved for the selected user.

Remember, the most recent measurement is always shown first.

Deleting Records

You can delete all the records by entering the recall records mode and then holding in the Query button until the display reads, "dEL ALL."

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

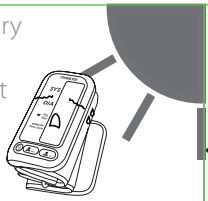
Caution

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.

ProSeries1 Maintenance

For best performance, please follow below instructions.

Store in a dry place and avoid direct sunlight.



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

Avoid dropping or shaking the monitor

Avoid storing in dusty or intemperate environments

Use a dry or slightly damp cloth to remove dirt

To do wash the monitor in water or submerge it

Caution

Please make sure the unit functions safely and it is in proper working conditions before use. Don't service 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 by 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 cloth 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 ACCESSORIES, detachable parts, and ME EQUIPMENT according to local guidelines.

OPTIONAL FREE APP

Vitasigns

Download on the App Store

ANDROID APP ON Google play

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:

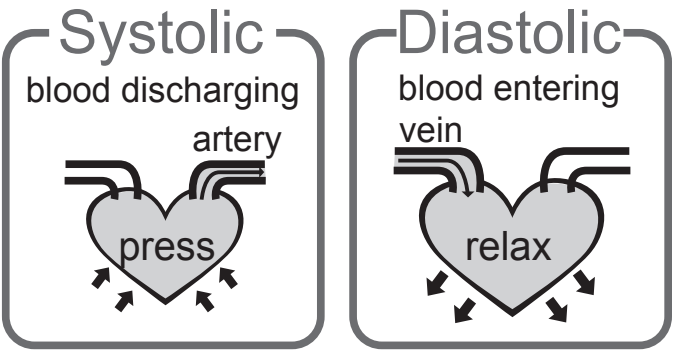
1. Enter your email address and create a password.
2. Enter your name and select your gender.
3. Select your birthday.
4. Enter your height and weight.
5. Select or take a photo of yourself to be used as your account avatar
6. Confirm that your information is correct and press the "OK" button.

You can use the Vitasigns App to track your progress on the ProSeries 1 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:

SYS	135 mm Hg	**DIA**	85 mm Hg

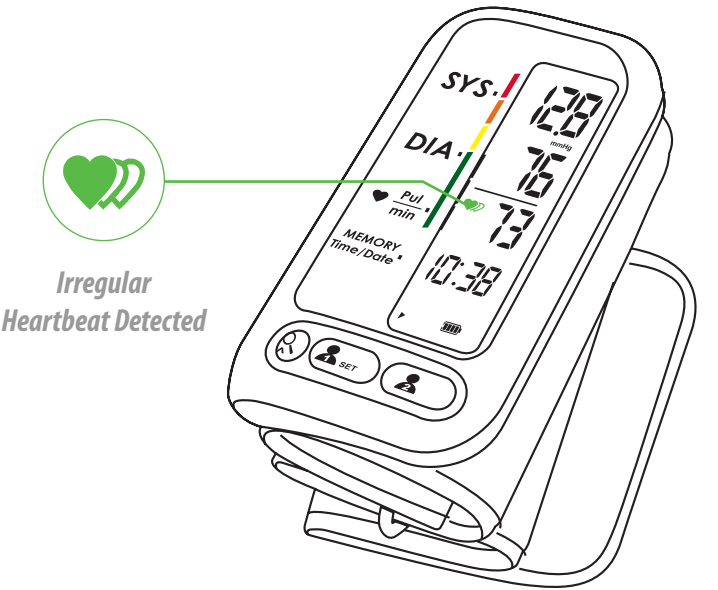
Please consult a physician if your measurement results fall outside the normal range.

Irregular Heartbeat Detector

This ProSeries1 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.



Irregular Heartbeat Detected

Frequent 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 arm I use?

You can take a measurement on either arm, 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 is 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 the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.

Specifications

Power supply	3.7V 1000mAH Built-in rechargeable li-polymer battery, 6V ⎓A AC Adaptor
Display mode	Blue LCD with White Backlight V.A.= 86.5mm(L) x24mm(W)
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 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 upper arm	Approximately 8.5 in - 13.5 in (22 cm - 32 cm)
Net Weight	Approximately 0.58 pounds (265 grams)
External dimensions	Approx. 5.11 in x 2.84 in x 1.16 in (130×72.2×29.4mm)
Attachment	AC Adaptor 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 12.5 mm and greater, and against vertically falling water drops when ENCLOSURE tilted up to 15°.
Software version	V01
Device classification	Battery Powered Mode: Internally Powered ME Equipment AC Adapter charged Mode: Class II ME Equipment

No Modification of this Equipment is Allowed

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

1. 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

2. 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.

Vitasigns

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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.