Baxter

Welch Allyn
Home
Blood Pressure Monitor
1500 Series

Instructions for use

For information about any Baxter product, contact Baxter Technical Support: baxter.com/contact-us.

For technical support, contact hrc_wah_technical_support@baxter.com.

777244, 80030493B
Revision date: 2025-12

This manual applies to # 901042 AUTOMATED BLOOD PRESSURE SYSTEM, REF RPM-BP100.

Distributed by Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153 USA

baxter.com

Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No. 105, Dongli Road,
Torch Development District, 528437
Zhongshan, Guangdong, China

Made in China

Baxter

Contents

Introduction

The **Welch Allyn Home** Blood Pressure Monitor 1500 Series is indicated for adult use in the home or domestic setting only.

The design provides you with two years of reliable service. Readings taken by the device are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This *Instructions for use* contains important safety and care information and provides step by step instructions for using the device. Read the manual thoroughly before using the device.

Indications for use

The Blood Pressure Monitor is a digital device intended for use in measuring blood pressure and pulse rate in adult patient populations with arm circumferences between 22 cm to 42 cm (approximately 8.75 to 16.5 inches).

It is intended for adult indoor use only.

MRI safety information

The Blood Pressure Monitor is MR Unsafe. Do not use it near a magnetic resonance imaging (MRI) scanner.

Symbols

Documentation symbols

	**WARNING** The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. The yellow in this symbol appears gray in a black-and-white document.
	**CAUTION** The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.
	Follow instructions/directions for use (IFU) -- mandatory action. The blue in this symbol appears black in a black-and-white document.
	Consult instructions for use or consult electronic instructions for use

Power symbols

	Direct current (DC)
	Power

Shipping, storing, and environment symbols

	Humidity limitation
	Separate collection of Electrical and Electronic Equipment. Do not dispose as unsorted municipal waste.
	Temperature limit
	Atmospheric pressure limitation
	Recyclable
	Stacking limit by number

Blood pressure device and cuff symbols

	Artery marker
	Range
	Index edge
	Limb circumference (minimum/ maximum)
	Lot code
	Not made with natural rubber latex
	Date of manufacture

Miscellaneous symbols

	Type BF applied part
	Serial number
	Reorder number
	Manufacturer
	Product identifier
	Non-ionizing electromagnetic radiation
	Unique device identifier
	Global Trade Item Number

	Class II equipment
	MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment.
IP22	Ingress protection: the device is protected against solid foreign objects of 12.5mm and greater and against vertically falling water drops when ENCLOSURE is tilted up to 15°
	**Bluetooth®**

About warnings and cautions

Caution statements can appear on the device, the packaging, the shipping container, or in this *Instructions for use*.

The device is safe for adults when used in accordance with the instructions and caution statements presented in this *Instructions for use*.

Before using the device, you must familiarize yourself with all cautions, with the steps to power up the device, and with the sections of this *Instructions for use* that pertain to your use of the device. In addition to reviewing the general cautions presented in the next section, you must also review the more specific cautions that appear throughout the manual in conjunction with setup/startup, operation, and maintenance tasks.

- Failure to understand and observe any warning statement in this manual could lead to injury or illness.
- Failure to understand and observe any caution statement in this manual could lead to damage to the equipment or other property, or loss of measurement data.

Warnings

WARNING Do not apply the cuff on an arm that has an intravenous drip or a blood transfusion attached.

WARNING Do not kink, fold, stretch, compress, or otherwise deform the tube during measuring, as the cuff pressure might continuously increase, which could prevent blood flow and result injury.

WARNING Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.

WARNING Do not apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.

WARNING Do not place the cuff on the arm of a person whose arteries or veins are undergoing medical treatment, i.e. intra-vascular access or intra-vascular therapy or an arteriovenous (A-V) shunt, which could disrupt blood circulation and cause injuries.

WARNING Do not place the cuff on the arm on the same side of a mastectomy (especially when lymph nodes have been removed). it is recommended to take measurements on the unaffected side.

WARNING Do not wrap the cuff on the same arm to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.

WARNING Please check (for example, by observation of the limb concerned) that the operation of the device does not result in prolonged impairment of patient blood circulation.

WARNING On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the arm (cuff pressure >300 mmHg or constant pressure >15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.

WARNING Do not use this device with high-frequency (HF) surgical equipment at the same time.

WARNING This device is not used in conjunction with oxygen rich environments, not intended for use with flammable anaesthetics, not intended for use in conjunction with flammable agents.

WARNING Excessive cuff tube lengths could cause strangulation if you don't manage them properly.

WARNING Do not touch output of the batteries/ adapter and the user simultaneously.

WARNING The power cord is considered the disconnect device for isolating this equipment from supply mains. Do not position the equipment so that it is difficult to reach or disconnect.

WARNING Do not use this device if you are allergic to polyester, nylon, or plastic.

WARNING Only use accessories approved by manufacturer. Using unapproved accessories might cause damage to the unit and injure users.

WARNING If you experience discomfort during a measurement, such as pain in the arm or other complaints,press the Power button immediately to release the air from the cuff.

WARNING Do not use the device while under maintenance, or being serviced.

WARNING Keep the device, cuff, and batteries away from children or pets as they may pose a risk of choking or strangulation if used improperly.

WARNING Sensor degradation or looseness may reduce performance of device or cause other problems.

WARNING Injury risk. Do not burn batteries. Batteries may leak or explode.

WARNING Injury risk. Do not connect the air tube to other medical equipment. This could cause air to be pumped into intravascular systems or high pressure, which could lead to serious injuries.

WARNING Injury risk. No modification to this equipment is allowed. Modifying the equipment could damage the unit or endanger the user.

WARNING Blood Pressure Monitor is intended to be operated by adults, including medical staffs and lay persons. Adult patients could also be intended users or operators. DO NOT self-diagnose the measurement results and start treatment by yourself. The measurement results given by this device is not a diagnosis. ALWAYS consult your doctor for evaluation of the results and treatment. * DO NOT adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure.

Cautions

CAUTION This device is intended for indoor, home/ temporary home use.

CAUTION This device is not intended for self-use in public areas.

CAUTION This device is portable, but it is not intended for use during patient transport.

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

CAUTION This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm, or for any purpose other than obtaining a blood pressure measurement.

CAUTION This device is for adults. Do not use this device on neonates or infants. Do not use it on children and adolescents unless otherwise instructed by a medical professional.

CAUTION Consult with your physician before using this monitor if you suffer from the following conditions: common arrhythmias such as premature ventricular beats or atrial fibrillation; peripheral arterial disease; pregnancy; preeclampsia; implantation with electrical devices; undergoing intravascular therapy; arteriovenous shunt or mastectomy. Please note that any of these conditions may affect measurement readings, in addition to patient motion, trembling or shivering.

CAUTION Do not use this device for diagnosis or treatment of any health problem or disease. Contact your physician if you have or suspect any medical problem. Do not change your medications without the advice of your physician or health care professional.

CAUTION If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.

CAUTION This device may be used only for the intended use described in this *Instructions for use*, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.

CAUTION Use the device under the environment which is provided in this *Instructions for use*. Otherwise, the performance and lifetime of the device will be impacted and reduced.

CAUTION The device may require up to 30 minutes to warm up/cool down from the minimum/ maximum storage temperature before it is ready for use.

CAUTION The blood pressure monitor, its adapter, and the cuff are suitable for use within the patient environment.

CAUTION Do not wash the cuff in a washing machine or dishwasher !

CAUTION The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.

CAUTION Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.

CAUTION Blood Pressure Monitor is intended for use by medical staffs and lay persons, and patient is also an intended user or operator.

CAUTION The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5 and ISO 10993-10. It will not cause any potential sensitization or irritation reaction.

CAUTION Before use, make sure the device functions safely and is in proper working condition.

CAUTION Report any unexpected operation or events to the manufacturer.

CAUTION Use a soft cloth to clean the entire unit. Do not use any abrasive or volatile cleaners. See the cleaning instructions presented later in this *Instructions for use*.

CAUTION Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorized service centers.

CAUTION It is recommended that the performance should be checked after repair, maintenance, and every two years of use, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg). Please contact manufacturer or distributor for authorized service personnel.

CAUTION Store your device, cuff and adapter in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.

CAUTION Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during storage.

CAUTION Dispose of accessories, detachable parts, and the device according to the local guidelines.

Notes

NOTE You can use this device to take your own measurement, no third-party operator is required.

NOTE Adapter is specified as a part of ME EQUIPMENT.

NOTE At the request of authorized service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by the manufacturer or distributor.

NOTE The service life of the cuff may vary by the frequency of washing, skin condition, and storage state.

NOTE Please report to the manufacturer and the competent authority of the Member State / the FDA in which you are established about any serious incident that has occurred in relation to this device.

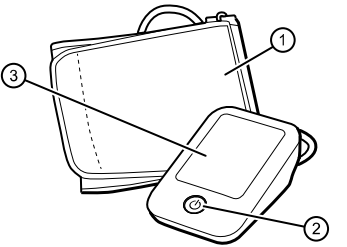
Contents list

The following items are in the device box:

- Blood pressure device
- D-Ring Standard Wide Cuff (22cm to 42cm / 8.75in to 16.5in)
- (4) AA alkaline batteries
- Instructions for use

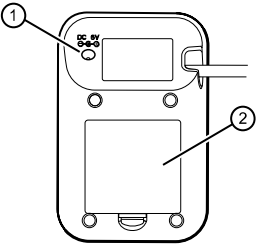
Controls and indicators

Device front



No.	Feature	Description
1	D-Ring blood pressure cuff	Apply to upper arm to take a blood pressure measurement
2	Power button	Powers on the device, starts and stops a blood pressure measurement, and — when pressed for 2 seconds — initiates a **Bluetooth** pairing
3	LCD Display	Displays blood pressure reading and other pertinent information regarding the reading

Device back



No.	Feature	Description
1	Direct current power connection	When used with an accessory power cord (not included), connects the device to a power outlet
2	Battery compartment (behind cover)	Houses 4 AA alkaline batteries

Power options

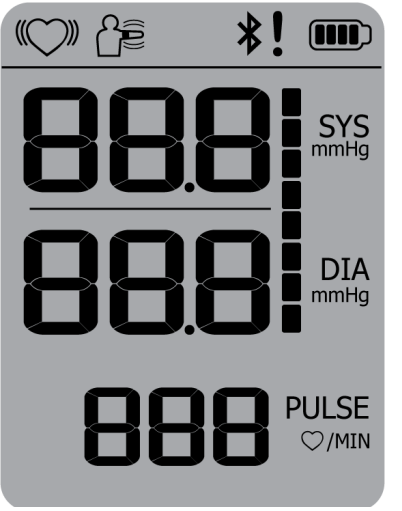
CAUTION To get optimal performance and protect your device, use only the correct batteries or the Baxter-approved power adapter.

The device is powered by one of two sources:

- 4 AA alkaline batteries
- AC adapter (6V ⎓ 1A) (not included)

Screen elements

The liquid crystal display (LCD) displays the following: systolic blood pressure (mmHg), diastolic blood pressure (mmHg), pulse rate (bpm), pulse (regular or irregular) while acquiring blood pressure measurements, excessive motion alert, **Bluetooth** connectivity status or data transmission error, and battery charge level.



Symbol	Description
SYS mmHg	Systolic blood pressure mmHg = measurement unit of the blood pressure
DIA mmHg	Diastolic blood pressure mmHg = measurement unit of the blood pressure
PULSE ♡/MIN	Pulse in beats per minute
	Irregular pulse Device is detecting an irregular pulse during measurement. See "Irregular pulse detector" elsewhere in this *Instructions for use*.
	Pulse Device is detecting a pulse during measurement.
	Full battery indicator Indicates the current battery charge
	Low battery indicator Indicates the current battery charge

Symbol	Description
	Calls attention to another indicator on the screen, such as a high reading, low reading, or data-transmission error.
	If the **Bluetooth** icon flashes, it indicates that the connection is starting.
	If a flashing box appears around the **Bluetooth** symbol, it indicates either that pairing has succeeded or that data is being transmitted.
	If the exclamation point (!) appears next to the **Bluetooth** symbol, it indicates a data-transmission error.
	Motion indicator Motion may result in an inaccurate measurement.
	High reading out of range Either SYS > 230mmHg or DIA > 130mmHg. The symbol may appear in either the SYS or DIA area of the screen.
	Low reading out of range Either SYS < 60mmHg or DIA <40mmHg. The symbol may appear in either the SYS or DIA area of the screen.

Measuring blood pressure

Overview

You are the intended operator of the device. You can measure your blood pressure and then save and send measurement data to a smartphone or tablet. You can also maintain your device and its accessories, and you can change the batteries under normal circumstances.

To measure your blood pressure, you need the following:

- Blood pressure device with batteries inserted
- Blood pressure cuff ("D-ring" style for easy, one-handed adjustment)
- Blood pressure air tube

To save and transfer blood pressure measurements, you also need a smartphone or tablet with **Bluetooth** wireless connectivity and the application or software to receive your data, such as the **Welch Allyn Home** application or another healthcare provider application.

Set up your equipment

Insert or replace the batteries

WARNING Injury risk. Do not burn batteries. Batteries may leak or explode.

CAUTION Remove the batteries if the device is not used regularly.

CAUTION Dispose of old batteries by following your local recycling guidelines.

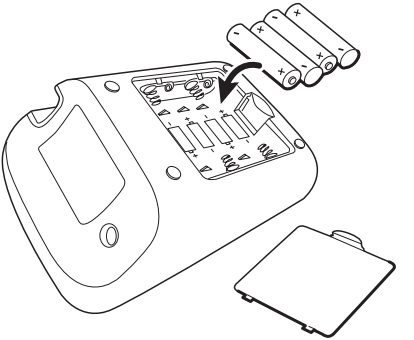
If you are not using AC power, you must install 4 AA alkaline batteries before using the device.

Replace the batteries when any of the following occurs:

- The battery charge indicator indicates a low charge.
- The display dims.
- The display does not light up.

1. Slide off the battery cover.

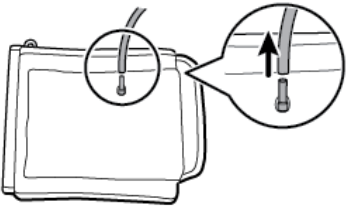
2. Install the batteries by matching the polarity as shown in the diagram.



3. Replace the cover.

Replace the cuff

1. Remove the old cuff by using your thumb and forefinger to slide the air hose off the connector on the cuff.



2. Use your thumb and forefinger to slide the air hose onto the connector on the new cuff.

Pair a smartphone, a tablet, or a communication hub with the device

Advanced **Bluetooth** 4.0 technology enables your smartphone, your tablet, or a communication hub to receive your personal health information from your blood pressure device. You have two alternatives to pair the blood pressure device with these devices:

- If you are using the **Welch Allyn Home** application, follow the pairing instructions presented in the application.
- Contact your remote monitoring solution provider or use the instructions that office provided to set up these communications devices.

With either alternative, you complete the same steps on the blood pressure device:

1. Confirm that smartphone, tablet, or communication hub is powered on and in discoverable mode (ready for pairing). **Bluetooth** wireless connectivity is only available for devices which support **Bluetooth** 4.0 technology.

2. Press and hold the power button on the blood pressure device for 2 seconds to power on the device and activate **Bluetooth** pairing. The **Bluetooth** symbol flashes while discovering the blood pressure device.

If successful, a steady  symbol surrounded by a dotted line appears on the LCD screen. If unsuccessful, the  appears.

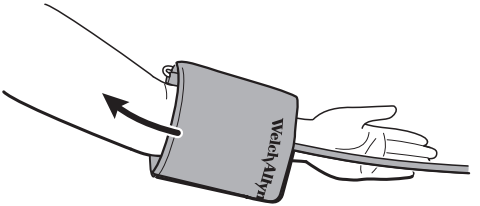
Position the blood pressure cuff

To achieve an accurate blood pressure reading, follow these steps to position the blood pressure cuff properly. Only use a cuff that has been approved by the manufacturer for this device model. Before use, please confirm if it fits your arm circumference.

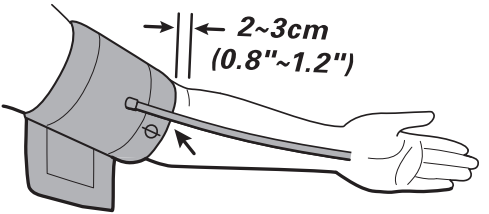
1. Remove any sleeves covering your upper arm.

NOTE The preferred site for taking a blood pressure measurement is your bare upper arm.

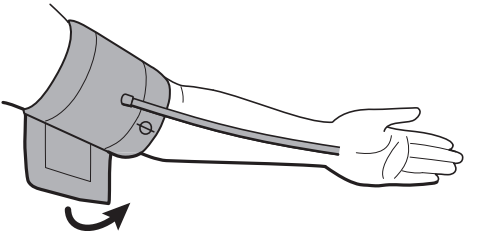
2. Place the cuff loosely over your arm so that the blood pressure tube extends down over your hand. It should appear on your arm as shown.



3. Open the cuff to resize it as needed and slide it over your bare upper arm. The bottom edge of the cuff should be 2 to 3 centimeters (0.8 to 1.2 inches) above the bend in your arm, and the tube and artery marker should appear on your arm as shown.



4. Keeping the artery marker and the tube in place, wrap the cuff snugly around your arm, but not too tight. If you can insert just two fingers between the cuff and your arm, the tightness is acceptable.



Start the measurement

1. Prepare yourself to take your blood pressure.
    a. Sit comfortably in a chair that supports your back.
    b. Keep legs uncrossed.
    c. Place feet flat on the floor.
    d. Support your arm on the flat surface.

e. Ensure the cuff is level with your heart (right atrium).

f. Rest for 5 minutes after sitting down and positioning the blood pressure cuff.

2. Verify that the cuff is positioned correctly with the tube running down the middle of your forearm.

3. Press the power button to power up the device and begin the blood pressure measurement.

   The cuff inflates and tightens around your arm until it completes the measurement. A vertical stack of segments appears onscreen to show increasing pressure in the cuff. The heart icon in the upper-left corner blinks to indicate your pulse rate until the measurement is complete.

NOTE If you press the power button to stop the measurement, dotted lines replace the SYS and DIA numbers onscreen.

When the inflation cycle is complete, systolic and diastolic measurements as well as your pulse rate appear onscreen.

4. Record your measurement results. Either record these measurements manually along with the time of measurement, or transfer them electronically to your connected device.

CAUTION The device that receives transferred measurements displays the most recent record first as record 1. Each new measurement becomes record 1, and all other records move down the list (for example, 2 becomes 3, and so on). You can store a maximum of 99 records. When you pass that limit, the oldest record drops from the list.

NOTE For a meaningful comparison, try to take measurements under consistent conditions. For example, take daily measurements at approximately the same time, on the same upper arm, or as directed by your physician.

Some points to remember about your blood pressure device:

- After 10 seconds of inactivity, the device powers down.
- If you press and release the power button, the device powers down.
- After successful transfer, the device powers off the **Bluetooth** radio, and the **Bluetooth** icon (and rectangle) disappear.

Blood pressure facts, pointers, and best practices

Helpful definitions

Systolic pressure When ventricles contract and pump blood out of your heart, the point at which blood pressure reaches its maximum value in the cycle.

Diastolic pressure When the ventricles relax, the point at which blood pressure reaches its minimum value in the cycle.

Pulse rate A measurement of the pulse rate, or the number of times the pulse beats per minute. As the heart pushes blood through the arteries, the arteries expand and contract with the flow of the blood.

Irregular pulse detector

An irregular pulse is detected when a pulse rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, the device records the pulse intervals and calculates the average. If any average is larger than or equal to 25%, the irregular pulse symbol appears on the display when the measurement results appear.

CAUTION The appearance of the irregular pulse icon indicates that a pulse irregularity consistent with an irregular pulse rate was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. The device does not replace a cardiac examination but detects pulse irregularities at an early stage.

Why does my blood pressure fluctuate throughout the day?

- Individual blood pressure varies multiple times every day because of weather, emotion, and activity.
- The way you position your cuff and your measurement posture can affect blood pressure. Try to take blood pressure measurements under similar conditions.

- Sometimes blood pressure on one arm is different from blood pressure on your other arm. Use the same arm for blood pressure measurements.
- Medication might affect your blood pressure.
- The "white coat effect" might cause your blood pressure to be higher in a hospital or doctor's office.

Factors that could cause inaccurate measurements

- Cuff position is poor
- Cuff is too loose or too tight
- Cuff is applied over clothing rather than on a bare upper arm
- Taking a measurement within 1 hour of eating or drinking
- Taking a measurement within 20 minutes of taking a bath
- Being in a cold environment
- Taking a measurement immediately after smoking or drinking caffeinated beverages
- Taking a measurement while talking or moving your fingers
- Taking a measurement when you need to urinate
- Taking measurements in rapid succession

Factors that promote accurate blood pressure measurements

- Proper cuff position on the upper arm
- Proper cuff tightness
- No clothing under the cuff or restricting circulation above the cuff
- Proper posture: feet flat on the floor, back straight, legs uncrossed, arm resting on a flat surface, upper arm at heart level
- Relaxing or sitting still for a few minutes after positioning the cuff and before taking a blood pressure measurement
- Sitting still during measurement
- Not talking during measurement
- Waiting at least 3 minutes between measurements

Maintenance

Maintain the device and cuff

The device does not require calibration.

To get the best performance from your device, follow the maintenance steps below.

- Store the unit in a dry place away from direct sunlight.
- Avoid shaking and dropping the device.
- Avoid operating the device in dusty and unstable temperature environments.

Cleaning

CAUTION Use a soft cloth to clean the entire unit. Do not use any abrasive or volatile cleaners.

1. Clean the device only when necessary with one of the following compatible cleaning agents:
    - 70% isopropyl alcohol
    - 10% chlorine bleach/90% water solution (standard bleach wipe)
2. If necessary, you may wipe the cuff with a soft, damp cloth.

Troubleshooting

This section includes a list of error messages and frequently asked questions for problems you may encounter with your device. If the device is not operating as you think it should, check here before arranging for service.

Problems and error messages

The device presents technical error messages and physiological error messages. Technical error messages occur when there is a device-related error. Physiological error messages occur when blood pressure measurements fall outside of set limits.

Technical error message conditions

Problem	Symptom	Root cause	Solution
No power	Display will not light up	Batteries are drained.	Replace with new batteries.
		Batteries are inserted incorrectly.	Insert the batteries correctly.
		AC adapter is inserted incorrectly.	Insert the AC adapter tightly.

Problem	Symptom	Root cause	Solution
Low batteries	The display indicates the "BAT-LO" message, pauses for 3 seconds. The battery icon shows empty (does not flash).	Batteries are low.	Replace with new batteries.
High power	The display indicates the "H BAt" message, pauses for 10 seconds, the device powers down.	The DC power is too high.	Make sure to insert the authorized AC adapter. Model: UE08WCP-060100SPA: input: 100-240V, 50-60Hz, 400mA; output: 6V, 1A Model: UES06WNCP-060100SPA: input: 100-240V, 50-60Hz, 200mA; output: 6V, 1A

Problem	Symptom	Root cause	Solution
Error messages	E 01 shows	The cuff is not secure.	Readjust the cuff, relax for a moment, and then measure again.
	E 02 shows	The cuff is very tight.	Refasten the cuff and then measure again.
	E 03 shows	There is too much pressure in the cuff.	Refasten the cuff and then measure again.
	E 10 or E 11 shows	The device detected motion while measuring.	Readjust the cuff, relax for a moment, and then measure again.
	E 20 shows	The measurement process does not detect a pulse signal.	Loosen the clothing on the arm and then measure again.
	E 21 shows	The measure-ment is incorrect.	Relax for a moment and then measure again.

Problem	Symptom	Root cause	Solution
	EEx (such as EE1, EE2, EE3...) shows	Hardware error	Measure again. If the problem persists, contact the retailer or Welch Allyn customer service at hrc_wah_technical_support@baxter.com for further assistance.
	0Ut shows	Pressure measure-ment out of range.	Switch the unit off to clear, then measure again.

Contact Baxter Technical Support for further assistance at: baxter.com/contact-us.

Physiological error message conditions

Symptom	Root cause	Solution
	High reading out of range. Either SYS >230mmHg or DIA >130mmHg. The symbol may appear in either the SYS or DIA area of the screen.	Press and hold the Power button to reestablish **Bluetooth** connectivity. Measure again. If the problem persists, contact your physician.
	Low reading out of range. Either SYS <60mmHg or DIA <40mmHg. The symbol may appear in either the SYS or DIA area of the screen.	Press and hold the Power button to reestablish **Bluetooth** connectivity. Measure again. If the problem persists, contact your physician.

Specifications

Item	Specification
Power supply Battery powered mode	6VDC 4*AA batteries
Power supply AC-adapter-powered mode (optional)	Model UE08WCP-060100SPA: input: 100-240 V, 50-60 Hz, 400 mA; output: 6 V, 1 A Model UES06WNCP-060100SPA: input: 100-240 V, 50-60 Hz, 200 mA; output: 6 V, 1 A
Battery's expected lifetime	About 750 single measurements
Display mode	Digital LCD V.A.68mm*90mm
Measurement model	Oscillometric testing mode
Measurement range	Rated cuff pressure: 0mmHg to 299mmHg (0kPa - 39.9kPa) Measurement pressure: SYS: 60 to 230mmHg DIA: 40 to 130mmHg Pulse value: (40 to 199)beat/ minute
Accuracy	Pressure: ±0.4kPa (3mmHg) Pulse value:±4%
Operating conditions	Temperature: 5 °C - 40 °C Relative humidity 15% - 90% RH Atmospheric pressure: 700 hPa - 1060 hPa
Storage and transportation conditions	Temperature: -20 °C - 60 °C Relative Humidity: ≤ 93% RH Atmospheric pressure: 500 hPa - 1060 hPa

Item	Specification	
Types of use or reuse	Single patient, multiple use	
Product's life expectancy	2 years	
Cuff's life expectancy	2 years or 15,000 measurements	
Circumference of the upper arm	Part Number	Cuff size
	Standard wide = BPACC-02	22cm to 42cm Approx. 8.75in to 16.5in
Net Weight	Approx. 284g (excluding the dry cells)	
External dimensions	Approx. 94mm *142mm*66mm	
Degree of protection	Type BF applied part	
Protection against ingress of water	IP22	
Software version	Version A01	

General radio compliance

Item	Specification
Bluetooth module no.	nRF51802
Radio frequency (RF) range	2402 MHz to 2480 MHz
Output power	0 dBm
Supply voltage	2.0 to 3.6V
Antenna gain	0.0 dBi

Item	Specification
Transmitting distance	10 meters (30 feet)

Device classification

Battery powered mode	Internally powered ME equipment
AC adaptor powered mode	Class II ME equipment

Federal Communication Commission (FCC) Interference Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions.

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

This equipment (FCC ID: OUT9TMB1591BS) has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may

cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures.

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Consult the dealer or an experienced radio/TV technician for help.

   Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Complied standards list

Item	Standard
Risk management	ISO/EN 14971 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1 Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements
User manual	EN 1041 Medical equipment manufacturers to provide information
General Requirements for Safety	IEC 60601-1+A1+A2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-11+A1 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	IEC/EN 60601-1-2+A1 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Item	Standard
Performance requirements and clinical investigation	IEC 80601-2-30 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers ISO81060-2 Non-invasive sphygmomanometers — Part 2: Clinical validation of automated measurement type
Software life-cycle processes	IEC/EN 62304: Medical device software - Software life cycle processes
Usability	IEC 62366-1+A1 Medical devices - Application of usability engineering to medical devices (IEC 62366) IEC 60601-1-6+A1+A2 Medical electrical equipment - Part 1 -6: General requirements for basic safety and essential performance - collateral standard: Usability
Small-bore connectors	IEC 80369-5 Small-Bore Connectors for Liquids and Gases in Healthcare Applications - Part 5: Connectors for Limb Cuff Inflation Applications

Warranty

Welch Allyn will warranty the blood pressure monitor to be free of defects in material and workmanship and to perform in accordance with manufacturer specifications for the period of two years from the date of purchase from Welch Allyn or its authorized distributors or agents.

The warranty period shall start on the date of purchase. The date of purchase is: 1) the invoiced ship date if the device was purchased directly from Welch Allyn, 2) the date specified during product registration, 3) the date of purchase of the product from a Welch Allyn authorized distributor as documented from a receipt from said distributor.

This warranty does not cover damage caused by: 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Welch Allyn, and 4) accidents.

The product warranty is also subject to the following terms and limitations.

- Accessories are not covered by the warranty.
- Shipping cost to return a device to a Welch Allyn service center is not included.
- A service notification number must be obtained from Welch Allyn prior to returning any products or accessories to Welch Allyn's designated service centers for repair. To obtain a service notification number, contact Welch Allyn Home Technical Support at: hrc_wah_technical_support@baxter.com.

Approved accessories

Item	Description
BPACC-02[a]	D-Ring Standard Wide Cuff (22-42cm)
RPM-BPACC-04	RPM BP AC Adapter. This adapter is an alternate power source for the blood pressure monitoring device.

a. RPM-BPACC-02 can also be used if the tubing supplied is removed from the cuff.

Essential performance

Accuracy of measuring blood pressure and pulse rate.

Measurement range	Systolic pressure: 60-230 mmHg Diastolic pressure: 40-130 mmHg Pulse: 40-199 beats/minute
Rated cuff pressure	0-299 mmHg (0-39.9 kPa)
Accuracy	Pressure: ±3 mmHg / 0.4 kPa Pulse: ±5%

EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.

WARNING Don't be near the active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

WARNING Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment TMB-1490-BHJ including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity.

Table 1 Guidance and manufacturer's declaration - electromagnetic emissions

Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Comply

Table 2 Guidance and manufacturer's declaration – electromagnetic Immunity

Immunity test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not Applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
Conduced RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 3 Guidance and manufacturer's declaration - electromagnetic Immunity

	Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**IEC 60601-1-2 Test Level (V/m)**	**Compliance level (V/m)**
Radiated RF IEC 61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM ± 5 k Hz deviation 1 kHz sine	2	0.3	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
	780							

Table 3 Guidance and manufacturer's declaration - electromagnetic Immunity

810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28

Table 3 Guidance and manufacturer's declaration - electromagnetic Immunity

	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9

Welch Allyn Home
Blood Pressure Monitor

777244, 80030493B
Revision date: 2025-12

Baxter