Welch Allyn Home™ Blood Pressure Monitor

Directions for use

901042 Automated Blood Pressure System

Software version A01

Welch Allyn Home

For information about any Welch Allyn product, contact Welch Allyn Technical Support: *hillrom.com*

#	749521 DIR 80025286 Ver. B Revised: 2019-08
REF	This manual applies to the 901042 Automated Blood Pressure System

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Welch Allyn® Home™

Contents

Introduction

The Welch Allyn Home™ blood pressure monitor is indicated for adult use in the home or domestic setting only.

The Welch Allyn Home blood pressure monitor features blood pressure measurement via SureBP® Technology, pulse rate measurement, and data management using *Bluetooth*® Smart technology.

SureBP Technology is an advanced blood pressure measurement technology that obtains a blood pressure reading during the inflation cycle (as the cuff pumps up). This technology allows for a faster, more comfortable reading. If on inflation, SureBP Technology is unable to determine a blood pressure due to excessive patient movement or any arrhythmia, it will inflate the cuff to a slightly higher pressure, then measure the blood pressure while deflating the cuff, providing an accurate reading with less chance of a reading failure.

The design provides you with two years of reliable service. Readings taken by the monitor are equivalent to those obtained

by a trained observer using the cuff and stethoscope auscultation method.

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

Indications for use

The Welch Allyn Home blood pressure monitor is a digital monitor intended for use in measuring blood pressure and heart rate in adult patient populations with arm circumferences between 15 cm to 54 cm (approximately 6 to 21 inches).

Contraindications

This device is contraindicated for any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator.

This blood pressure monitor is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

Symbols

Documentation symbols

	**Warning**: The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death.
	**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.
	Mandatory - Consult Directions for Use

Power symbols

	Direct current (DC)
	Stand-By

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

	SureBP technology logo
	Artery marker
	Range
	Index edge
	Limb circumference (Minimum/Maximum)
	Lot code
	Not made with natural rubber latex

Miscellaneous symbols

	Type BF applied part
	Serial Number
	Product Identifier
	Manufacturer
	Reorder Number
	Non-ionizing electromagnetic radiation
	Global Trade Item Number
	Class II 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 Welch Allyn Home blood pressure device, the packaging, the shipping container, or in this *Directions for use*.

The Welch Allyn Home blood pressure device is safe for adults when used in accordance with the instructions and caution statements presented in this *Directions 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 *Directions 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 and cautions

WARNING Injury risk. The device is not suitable for measuring the blood pressure of neonatal infants or children.

WARNING Injury risk. The device is not suitable for use on pregnant women, users with implanted electrical devices, users with preeclampsia, premature ventricular beats, atrial fibrillation, peripheral arterial disease, and users undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Consult your doctor prior to using the unit if you suffer from any of these illnesses or conditions.

WARNING Injury risk. Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.

WARNING Injury risk. Keep the unit out of reach of infants, children, or pets, since inhalation or swallowing of small parts is dangerous or even fatal.

WARNING Injury risk. The device is not intended to be a self-measurement station used in a public place or center. Use the device only in your home or temporary residence.

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

WARNING Injury risk. 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. Loosen and remove the cuff from your arm.

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

WARNING Injury risk. This unit is not suitable for continuous monitoring during medical emergencies or operations.

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

WARNING Injury risk. Do not kink the connection tube during use. The cuff pressure might continuously increase, which could prevent blood flow and result in injury.

WARNING Injury risk. Never apply the cuff over damaged skin. This can cause further injury.

WARNING Injury risk. If applying to someone else, do not touch output of the batteries/adapter and the user simultaneously.

WARNING Injury risk. Do not use the unit if you are allergic to polyester or synthetic materials.

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

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

WARNING Injury risk. Do not service or perform any maintenance while using the device.

WARNING Injury risk. Use only accessories approved by the manufacturer. Using unapproved accessories might cause damage to the unit and injure users.

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

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 arm or for functions other than obtaining a blood pressure measurement.

Caution 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 on the same arm at the same time.

Caution To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.

Caution The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. 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 Use the device in the environment described in this directions for use. Otherwise, you will compromise the device's performance and reduce its lifetime.

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

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 *Directions for use*.

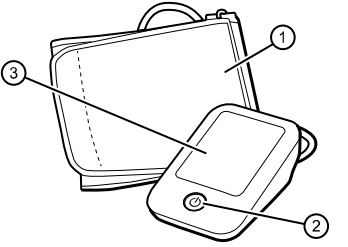
Contents list

The following items are in the device box:

- Blood Pressure Monitor
- D-Ring Standard Wide Cuff (22cm to 42cm) with air tube attached
- (4) AA alkaline batteries
- Directions for use
- Quick reference guide

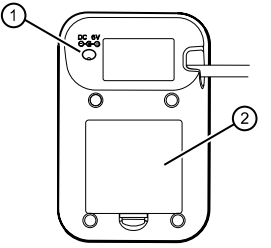
Controls and indicators

Monitor 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 monitor, 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

Monitor back



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

Power options

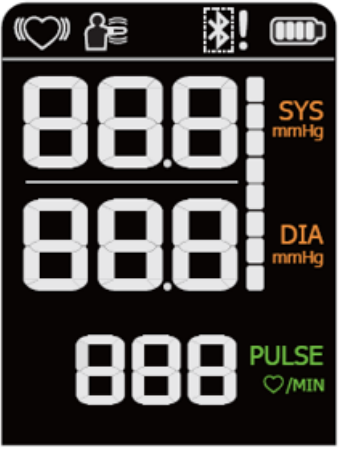
Caution To get optimal performance and protect your monitor, use only the correct batteries or the Welch Allyn-approved power adapter.

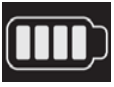
The monitor is powered by one of two sources:

- 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), heart beat (regular or irregular) while acquiring blood pressure measurements, excessive motion alert, *Bluetooth* connectivity status or data transmission error, alarm priority, and battery charge level.



Symbol	Description
	Systolic blood pressure mmHg = measurement unit of the blood pressure
	Diastolic blood pressure mmHg = measurement unit of the blood pressure
	Pulse in beats per minute
	Irregular heartbeat Monitor is detecting an irregular heartbeat during measurement
	Heart beat Monitor is detecting a heartbeat during measurement
	Battery indicator Indicates the current battery charge
	Battery indicator Indicates the current battery charge

Symbol	Description
	*Bluetooth* connectivity status or data transmission error
	Motion indicator Motion may result in an inaccurate measurement.
	Reading out of range Either SYS > 260mmHg or DIA > 220mmHg. The symbol may appear in either the SYS or DIA area of the screen. Alarm priority = Low (an! appears near the top of the screen)
	Reading out of range Either SYS < 50mmHg or DIA <25mmHg. The symbol may appear in either the SYS or DIA area of the screen. Alarm priority = Low (an! appears near the top 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 monitor 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.

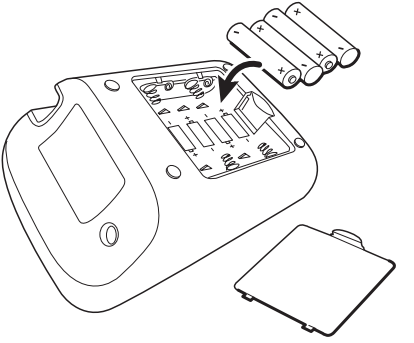
If you are not using AC power, you must install 4 AA alkaline batteries before using the device.

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.

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

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

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 monitor for 2 seconds to power on the device and activate *Bluetooth* pairing. The *Bluetooth* symbol flashes while discovering the monitor.

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

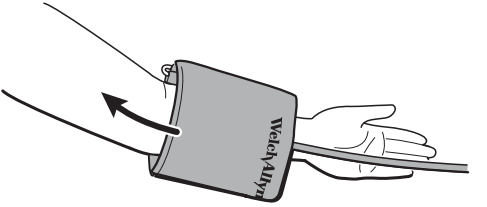
Position the blood pressure cuff

To achieve an accurate blood pressure reading, follow these steps to position the blood pressure cuff properly.

1. Remove any sleeves covering your upper arm.

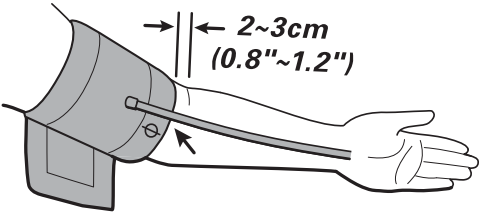
Note The preferred site for taking a blood pressure measurement is your bare upper arm.

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.

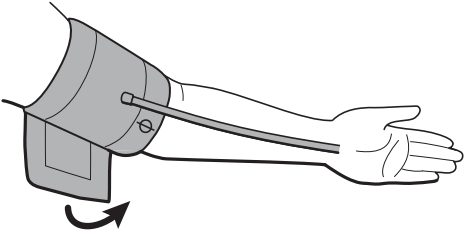


3. Open the cuff to resize it as needed and slide it over your bare upper arm. The bottom edge of the cuff should be 2 to 3 centimeters (0.8 to 1.2 inches) above the bend in your arm,

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 monitor 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.

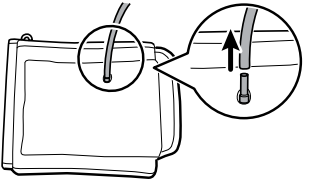
Some points to remember about your blood pressure device:

- 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.

Remove and attach a blood pressure cuff

Note The air tube remains connected to the blood pressure monitor at all times, but you can remove and attach blood pressure cuffs as follows.

1. To remove a connected cuff, gently pull the air tube connector away from the cuff connector.



2. To attach a cuff, gently press the cuff connector into the air tube.

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 heart rate, or the number of times the heart beats per minute. As the heart pushes blood through the arteries, the arteries

expand and contract with the flow of the blood.

Irregular heartbeat detector

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

⚠ 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. 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 monitor and cuff

The monitor does not require calibration.

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

- Store the unit in a dry place away from direct sunlight.
- Avoid shaking and dropping the monitor.
- Avoid operating the monitor 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 monitor 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 blood pressure monitor. 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 alarms and low-priority physiological alarms. Technical alarms occur when there is a device-related error. Physiological alarms occur when blood pressure measurements fall outside of set alarm limits.

Technical alarms

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.
Error messages	E 01 shows	The cuff is not secure, the cuff is too tight, or a leak is detected.	Readjust the cuff, have the patient relax for a moment, and then measure again. Inspect the connection tube for leaks or kinks.
	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 monitor detected motion while measuring	Readjust the cuff, relax for a moment, and then measure again

Problem	Symptom	Root cause	Solution
	EE or E 19 shows	Hardware error	Measure again. If the problem persists, contact the retailer or Welch Allyn customer service at *hillrom.com* for further assistance.

Visit *hillrom.com* for further assistance.

Physiological alarms

Symptom	Root cause	Solution
	Out of range. Either SYS >260mmHg or DIA >220mmHg. 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. Alarm priority = Low
	Out of range. Either SYS <50mmHg or DIA <25mmHg. 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. Alarm priority = Low

Specifications

Item	Specification
Power supply: Battery powered mode:	6VDC 4*AA batteries
Power supply: AC adapter powered mode:	Input: 100-240V, 50-60Hz, 400mA; Output: 6V, 1A
Power supply model number	UE08WCP-060100SPA
Display mode	Digital LCD V.A.68mm*90mm
Measurement model	Oscillometric testing mode
Measurement range	Rated cuff pressure: 0mmHg to 300mmHg (0kPa-40kPa) Measurement pressure: SYS: 50 to 260mmHg DIA: 25 to 220mmHg Pulse value: (40 to 199)beat/minute
Accuracy	Pressure: ±0.4kPa (3mmHg) Pulse value:±4%

Item	Specification	
Normal working conditions	Temperature: 5°C to 40°C Relative humidity 85% RH Atmospheric pressure: 86kPa to 106kPa	
Storage and transportation condition	Temperature:-20°C to 60°C Relative Humidity: 10% RH–93% RH Atmospheric Pressure: 50kPa to 106 kPa	
Circumference of the upper arm	Part Number	Cuff size
	D-Ring Extra Small Cuff BPACC-01	15–24cm
	D-Ring Standard Wide Cuff BPACC-02	22–42cm
	D-Ring Extra Large Cuff BPACC-03	40–54cm

Item	Specification
Net Weight	Approx. 283g (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.	AW51822
Radio Frequency (RF) Range	2402 MHz to 2480 MHz
Output Power	4.0 dBm
Supply Voltage	1.8V to 3.6V
Antenna Gain	0.0 dBi
Transmitting Distance	10 meters (30 feet)

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: OU9TMB1591-A) 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.

Industry Canada (IC) compliance

To ensure compliance with FCC and Industry Canada RF exposure requirements, this device must be

installed in a location where the antennas of the device will have a minimum distance of at least 20 cm from all persons. Using higher gain antennas and types of antennas not certified for use with this product is not allowed. The device shall not be co-located with another transmitter.

Pour s'assurer de la conformité des exigences aux expositions RF de la FCC et de l'Industry Canada, cet appareil doit être installé dans un emplacement où les antennes de l'appareil sont au moins à 20 cm de distance de toute personne. L'utilisation d'antennes et de types d'antennes à gain supérieur non garantis avec ce produit est interdite. L'appareil ne doit pas être installé à proximité d'un autre émetteur.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme aux normes RSS exemptes de licence de l'Industry

Canada. Son fonctionnement est soumis aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This radio transmitter (IC: 12725A-TMB1591A) has been approved by Industry Canada to operate with the antenna listed in the specification table.

Ce transmetteur de radio (IC: 12725A-TMB1591A) a été approuvé par l'Industry Canada pour fonctionner avec l'antenne répertoriée dans la table des spécifications.

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

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 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-11 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

Item	Standard
Electromagnetic compatibility	IEC/EN 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
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 ISO81060-2:2013 Non-invasive sphygmomanometers — Part 2: Clinical validation of automated measurement type
Software life-cycle processes	IEC/EN 62304+AC: Medical device software - Software life cycle processes

Item	Standard
Usability	IEC 62366 Medical devices - Application of usability engineering to medical devices (IEC 62366) IEC 60601-1-6 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 Technical Support at technicalsupport@hillrom.com.

Approved accessories

Item	Description
BPACC-01	D-Ring Extra Small Cuff (15–24cm)
BPACC-02	D-Ring Standard Wide Cuff (22-42cm)
BPACC-03	D-Ring Extra Large Cuff (40–54cm)
107041	ProBP 2000 adapter set. This adapter is an alternate power source for the blood pressure monitoring device.

Emissions and immunity information

Electromagnetic emissions		
The Welch Allyn Home Blood Pressure Monitor H-BP100SBP is intended for use in the electromagnetic environment specified below. The customer or user of the Welch Allyn Home Blood Pressure Monitor should assure that it is used in such an environment.		
	Caution 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=3,3m 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=3,3m at an IMMUNITY LEVEL of 3V/m).	
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Welch Allyn Home Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Electromagnetic emissions		
RF emissions CISPR 11	Class B	The Welch Allyn Home Blood Pressure Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

The Welch Allyn Home Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn Home Blood Pressure Monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ± 15kV air	±8 kV contact ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2kV line(s) to earth	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.

Electromagnetic immunity			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle	< 5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Welch Allyn Home Blood Pressure Monitor requires continued operation during power mains interruptions, it is recommended that the Welch Allyn Home Blood Pressure Monitor be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	< 5% U_T (>95% dip in U_T) for 5 seconds	< 5% U_T (>95% dip in U_T) for 5 seconds	
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m and 30 A/m	3A/m and 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the AC mains voltage prior to application of the test level.

Electromagnetic immunity			
The Welch Allyn Home Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn Home Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Welch Allyn Home Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms and 6 Vrms 150 kHz to 80 MHz	3 Vrms and 6 Vrms	$d = 1{,}2\sqrt{P}$

Electromagnetic immunity			
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz
	10 V/m 80 MHz to 2,6 GHz	10 V/m	$d = 2{,}3\sqrt{P}$ 800 MHz to 2,6 GHz where *P* is the maximum output power rating ofthe transmitter in watts (W) and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Electromagnetic immunity

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Welch Allyn Home Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Welch Allyn Home Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed,additional measures may be necessary, such as reorienting or relocating the Welch Allyn Home Blood Pressure Monitor.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Welch Allyn Home Blood Pressure Monitor

The Welch Allyn Home Blood Pressure Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Welch Allyn Home Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Welch Allyn Home Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,6 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Recommended separation distances between portable and mobile RF communications equipment and the Welch Allyn Home Blood Pressure Monitor
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Welch Allyn® Home™
Blood Pressure Monitor

Model: H-BP100SBP

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DIR 80025286 Ver. B