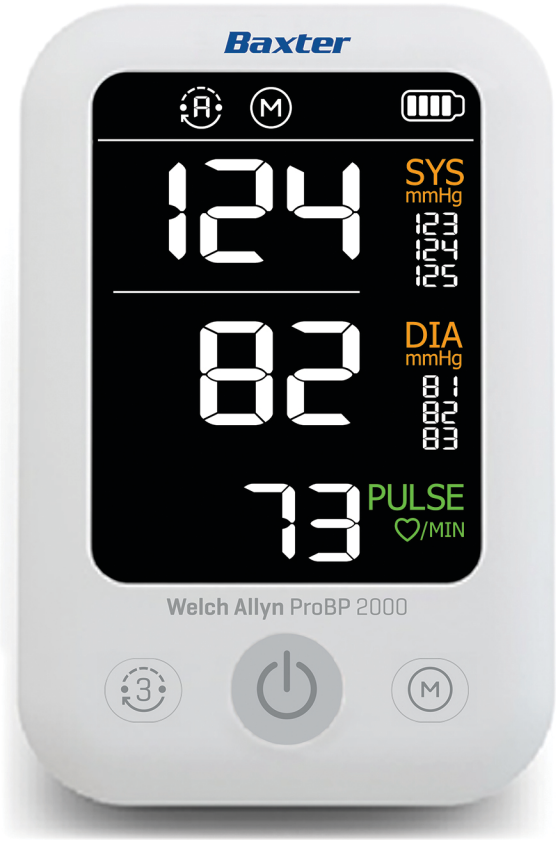
Welch Allyn
ProBP 2000
Digital Blood Pressure Device

Software version A01



Instructions for use

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

80030865 Ver. A

Revision date: 2025-07

This manual applies to # 901123 DIGITAL BLOOD PRESSURE DEVICE, REF 2000-A and 2000 PLUS-A.

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Made in China

Contents

Introduction

Readings taken by the **Welch Allyn ProBP** 2000 Digital Blood Pressure Device are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method. This device uses the Baxter **SureBP** algorithm to allow the device to capture blood pressure readings quickly (in about 20 seconds) while the cuff inflates, addressing patient comfort.

These instructions for use contain important safety and care information and provides step-by-step instructions for using the device. Read the manual thoroughly before using the device.

Device description

The **ProBP** 2000 Digital Blood Pressure Device provides timely and accurate blood pressure and pulse rate measurements to clinicians and medically qualified personnel.

Intended use/Indications for use

The **Welch Allyn ProBP** 2000 Digital Blood Pressure Device is intended for use in measuring blood pressure and pulse rate in patients at least 3 years of age or older with arm circumferences between 15 cm to 55 cm (approximately 5.9 to 21.7 inches).

The **Welch Allyn ProBP** 2000 device automatically measures systolic and diastolic pressure and pulse rate. The device is intended to be used by clinicians and medically qualified personnel.

Contraindications

This device is not intended for use on neonates, infants, or children under the age of 3 years. The effectiveness of this device has not been established in pregnant, including pre-eclamptic, patients.

MRI safety information

The **ProBP** 2000 Digital Blood Pressure Device is unsafe to use near an MRI (magnetic resonance imaging) scanner.

Symbols

For information on the origin of these symbols, see the Welch Allyn symbols glossary: bax.to/docs-wa-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 the instructions for use (IFU)—mandatory action. A copy of the IFU is available on this website. A printed copy of the IFU can be ordered from Baxter for delivery within 7 days. The blue in this symbol appears gray in a black-and-white document.

Power symbols

	Direct current (DC)
	Power on/display power-saving

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

Miscellaneous symbols

	Manufacturer
	Date of manufacture
	Type BF applied part
SN	Serial number
REF	Reorder number
LOT	Batch code
#	Product identifier

	Nonionizing electromagnetic radiation
	Unique device identifier
	Class II equipment
IPXX	Degree of protection provided by enclosure (IP code)
R_x ONLY	Prescription only or "For Use by or on the order of a licensed medical professional"
	MR Unsafe items should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned.
	SGS safety mark
	**SureBP** algorithm for measuring blood pressure
	One-button-press operation
	**Welch Allyn FlexiPort** blood-pressure-cuff technology

About warnings and cautions

Warning and caution statements can appear on the **ProBP** 2000 Digital Blood Pressure Device, on the packaging, on the shipping container, or in these instructions for use.

Warnings and cautions

WARNING Patient injury risk. The device is not suitable for measuring the blood pressure of neonatal infants or children under the age of 3 years.

WARNING Patient injury risk. The decision to use the device on pregnant or pre-eclamptic patients is at the discretion of the trained clinician using the equipment.

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

WARNING Patient injury risk. If the patient experiences 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 the patient's arm.

WARNING Patient 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 > 300 mmHg or constant pressure > 15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.

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

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

WARNING Patient injury risk. Do not place the cuff on the arm on the same side of a mastectomy. If necessary, use the femoral artery in the thigh to take a measurement.

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

WARNING Patient injury risk. Do not use the unit if the patient is allergic to polyester or synthetic materials.

WARNING Patient 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 Patient injury risk. The device has not been designed for use with high-frequency (HF) surgical equipment and does not protect against hazards to the patient.

WARNING Inaccurate measurement risk. Do not place the cuff where it can disturb proper circulation. Do not place the cuff on any area where circulation is compromised or on any extremity used for intravenous infusions. Do not use an SpO2 finger clip sensor and a blood pressure cuff simultaneously on the same limb. Doing so may cause a temporary loss of pulsatile flow, resulting in either no reading or an inaccurate SpO2 or pulse rate until the flow returns.

WARNING Inaccurate measurement risk. Do not use the device on patients who are on heart-lung machines.

WARNING Inaccurate measurement risk. Do not use the device on patients who are experiencing convulsions or tremors.

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

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

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.

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 The device is not intended for use during patient transport.

CAUTION This device is intended for noninvasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm or for purposes other than obtaining a blood pressure measurement.

CAUTION United States federal law restricts this device to sale, distribution, or use by or on the order of a physician or licensed healthcare professional.

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 Use the device in the environment described in these instructions 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 these instructions for use.

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

NOTE This device has not been evaluated for any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator.

NOTE This device is not intended for use in a home healthcare environment. It is intended for professional use in a clinical setting.

Device configurations

The **ProBP** 2000 device comes in multiple configurations. When you place an order, choose from the following REF numbers.

REF	Included accessories		Device information	
	FLEXIPORT adult cuff	**Power supply and AC-plug-adapter kit**	**Single blood pressure measurement**	**Blood pressure averaging[1] & last-measurement memory[2]**
2000-A	✓	—	✓	—
2000 PLUS-A	✓	✓	✓	✓

[1] You can press the ③ button to automatically take 3 blood pressure measurements and see the average. This average can give you a broader view of the patient's true blood pressure than a single measurement.

[2] After the measurements disappear from the screen, you can press the Ⓜ button to see the most recently completed measurements.

Box contents

Each **ProBP** 2000 device comes with the accessories that are included with the device's configuration and the following items:

- Startup guide

- 4 AA alkaline batteries

Power options

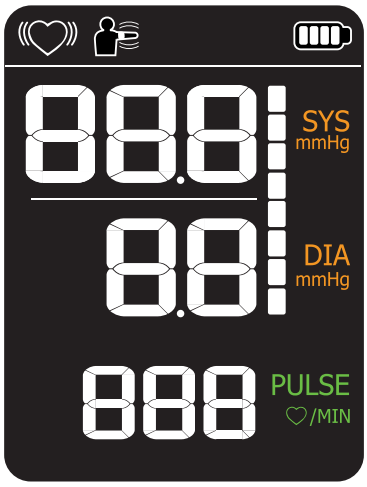
CAUTION To get optimal performance and protect your device, use only the correct batteries or the Baxter-approved AC plug adapter.

The device is powered by one of two sources:

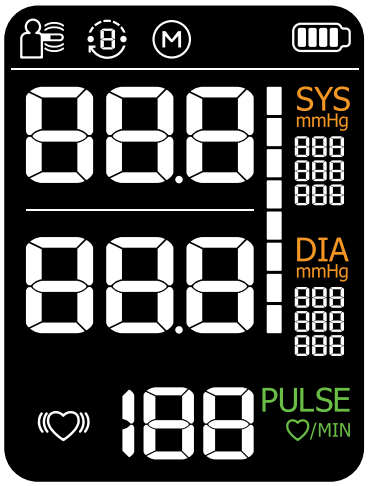
- 4 AA alkaline batteries
- AC: 6 V ⎓, 1 A (with plug adapter, optional)

Screen elements

The liquid crystal display (LCD) shows the following: systolic blood pressure (mmHg), diastolic blood pressure (mmHg), pulse rate in beats per minute (bpm), pulse being detected while blood pressure measurements are being acquired, motion alert, and battery-charge level.

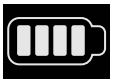


REF 2000-A



REF 2000 PLUS-A

Symbol	Description
SYS mmHg	Systolic blood pressure result mmHg = measurement unit *PLUS configuration only:* When an averaging program completes, each individual systolic blood pressure result appears below the SYS.
DIA mmHg	Diastolic blood pressure result mmHg = measurement unit *PLUS configuration only:* When an averaging program completes, each individual diastolic blood pressure result appears below the DIA.

Symbol	Description
	Pulse rate Beats per minute
	Pulse being detected The device is detecting a pulse during measurement.
	Full battery Indicates the current battery charge.
	Low battery Indicates the current battery charge.
	Motion Motion may result in an inaccurate measurement.
	High reading, out of range Either systolic >260 mmHg or diastolic >220 mmHg. HI may appear in either the SYS or DIA area of the screen. To clear this condition, press and hold the power button. Measure again.
	Low reading, out of range Either systolic <50 mmHg or diastolic <25 mmHg. LO may appear in either the SYS or DIA area of the screen. To clear this condition, press and hold the power button. Measure again. If the problem persists and battery charge is low, either replace the batteries or use the external power supply if you have one, and measure again.
	Averaging program is active (PLUS configuration only) Indicates which measurement of an averaging program is in process.
	Averaging-program result (PLUS configuration only) Indicates that the displayed blood pressure was derived from the averaging program.
	Result is from memory (PLUS configuration only) Indicates that the most recently completed blood pressure result is displayed.

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.

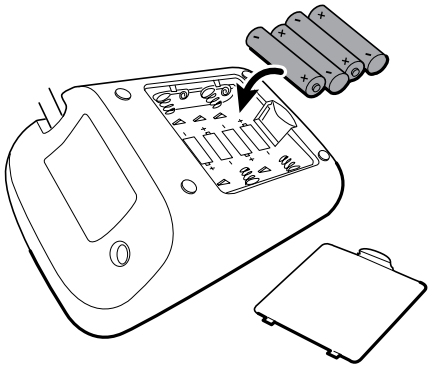
If you are not using AC power, you must insert 4 AA alkaline batteries before using the device.

Replace the batteries when any of the following occurs:

- BAt Lo appears for 3 seconds, and the low-battery icon appears: 
- The display dims.
- The display does not light up.

Insert the batteries as follows:

1. Slide off the battery cover.
2. Insert the batteries, matching the polarity as shown in the diagram.



3. Replace the cover.

About 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.

The blood pressure classification published by the World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:

Blood pressure (mmHg)	Level					
	Optimal	**Normal**	**High-normal**	**Mild**	**Moderate**	**Severe**
Systolic	<120	120–129	130–139	140–159	160–179	≥180
Diastolic	<80	80–84	85–89	90–99	100–109	≥110

CAUTION Only a physician can tell your normal blood pressure range. Contact a physician if your measuring results fall out of the range. Only a physician can tell whether your blood pressure value has reached a dangerous point.

Using the device

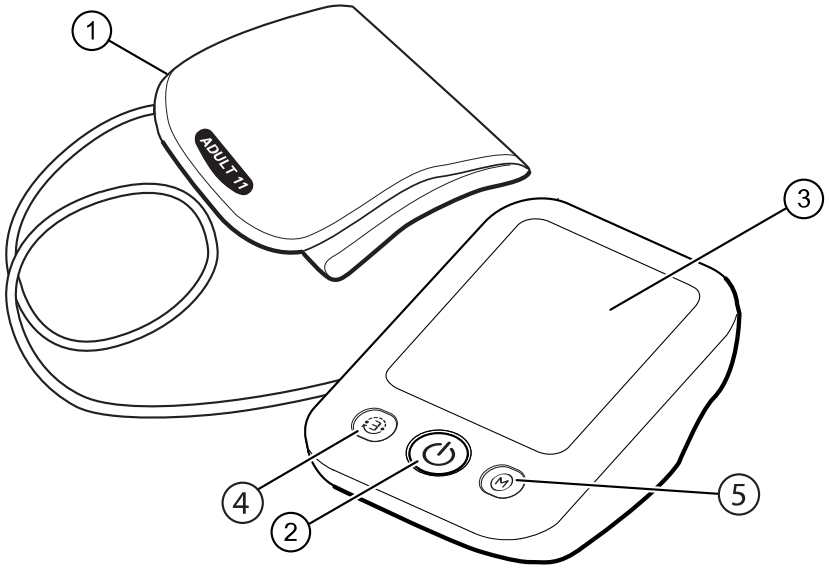
Position the blood pressure cuff on the patient

To achieve an accurate blood pressure reading, use a cuff that has been approved by the manufacturer for this device. Also properly position the cuff and prepare the patient by following these steps. For an illustrated guide, see bax.to/docs-bp-bestprac.

1. Place the cuff on a bare arm.
2. Confirm that the cuff is the proper size. If two cuff sizes fit, use the larger one.
3. Place the artery marker over the brachial artery.
4. Apply the cuff snugly, allowing room for no more than two fingers.
5. Allow the patient to sit quietly for five minutes.
6. Do not talk to the patient while taking the blood pressure.
7. Support the patient's back with feet on the floor during the measurement. Keep legs uncrossed.
8. Keep the upper arm at heart level and passively support the lower arm.
9. Keep the arm still during the measurement cycle.

Controls and indicators

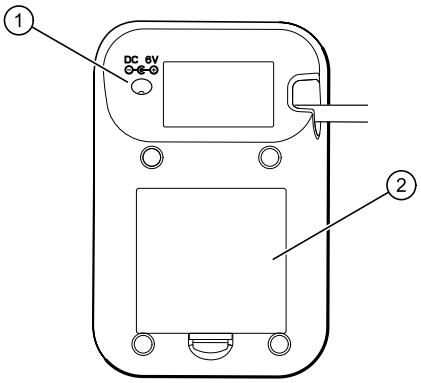
Device front



No.	Feature	Description
1	**FlexiPort** blood pressure cuff	Wraps around the patient's upper arm to take a blood pressure measurement.
2	Power button	Powers on the device and starts a blood pressure measurement.
3	Liquid crystal display (LCD)	Displays blood pressure readings and other pertinent information.

No.	Feature	Description
4	Averaging button (PLUS configuration only)	Powers on the device and starts an automatic program that averages 3 blood pressure measurements.
5	Memory button (PLUS configuration only)	Powers on the device and displays the most recently completed blood pressure results.

Device back



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

Take a blood pressure measurement

- Make sure that the **FlexiPort** cuff is connected to the device.
- Position the cuff properly on the patient.

1. Press ⏻.

   The screen lights up, and the measurement starts. While the device is taking the measurement, you can press this button again to stop it.

   When the measurement is completed, the blood pressure and pulse measurements appear.

2. (Optional) *PLUS configuration only:* Press the ③ button to automatically take 3 blood pressure measurements and see the average. This average can give you a broader view of the patient's true blood pressure than a single measurement.

   The screen lights up, and the first measurement starts, as indicated by a 1 on the screen. After the first measurement is completed, a 60-second countdown appears. When the countdown reaches zero, the device takes a second and third measurement in the same way. While the device is taking the measurements, you can press the same button again to stop it.

When all measurements are complete, the averaged blood pressure and pulse measurements appear along with the 3 individual blood pressure measurements.

NOTE *PLUS configuration only:* After the measurements disappear from the screen, you can press the Ⓜ button to see the most recently completed measurements.

Maintenance

Maintain the device

The device does not require calibration.

To get the best performance from your device, follow these practices:

- Store the device in a dry place away from direct sunlight.
- Avoid shaking and dropping the device.
- Avoid operating the device in dusty and unstable temperature environments.
- When storing the device, power cord, and accessories, observe the environmental storage conditions that are identified in the product specifications.

Clean and disinfect the device

Clean and disinfect the device only when necessary. For information on cleaning and disinfecting the **FlexiPort** cuff, see the cuff's instructions for use.

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

CAUTION Quaternary ammonium cleaning products are not recommended as they may cause the plastic to crack.

1. Remove visible soil.
2. Clean and disinfect the device with one of the following compatible agents:
    - 70% isopropyl alcohol
    - 10% chlorine bleach/90% water solution (standard bleach wipe)

For example, you can use wipes—approved by the Environmental Protection Agency (EPA) or equivalent international agency—that contain 70% isopropyl alcohol or 10% chlorine bleach. Follow the wipe manufacturer's directions for optimum results.

Disposing of electronic equipment

This product and its components must be disposed of according to local laws and regulations. Do not dispose of this product as unsorted municipal waste. For more specific disposal or compliance information, see bax.to/docs-weee, or contact Baxter Technical Support: baxter.com/contact-us.

Troubleshooting

This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure device. If the device is not operating as you think it should, check this section before contacting Baxter Technical Support: baxter.com/contact-us.

Problems and error messages

The device presents technical 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 messages and conditions

Condition	Cause	Remedy
Screen does not light up.	Batteries are drained.	Replace with new batteries.
	Batteries are inserted incorrectly.	Insert the batteries correctly.
	AC plug adapter is inserted incorrectly.	Insert the AC plug adapter tightly.
BAt Lo appears for 3 seconds, and the low-battery icon appears: 	Batteries are low.	Replace with new batteries.
BAt HI appears for 30 seconds. The device powers down.	The DC power is too high (over 7.5 V).	Insert the authorized AC plug adapter.
E01 appears.	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.
E03 appears.	There is too much pressure in the cuff.	Refasten the cuff and then measure again.
E10 or E11 appear.	The device detected motion while measuring.	Readjust the cuff, have the patient relax for a moment, keep the patient stationary, and then measure again.
EE or E19 appear.	Hardware error.	Measure again. If the problem persists, contact Baxter Technical Support: baxter.com/contact-us.

Physiological error messages and conditions

Condition	Cause	Remedy
 HI appears in either the SYS or DIA area of the screen.	High reading, out of range. Either systolic > 260 mmHg or diastolic >220 mmHg.	To clear this condition, press and hold the power button. Measure again. If the problem persists, contact Baxter Technical Support: baxter.com/contact-us.
 LO appears in either the SYS or DIA area of the screen.	Low reading, out of range. Either systolic <50 mmHg or diastolic <25 mmHg.	To clear this condition, press and hold the power button. Measure again. If the problem persists and battery charge is low, either replace the batteries or use the external power supply if you have one, and measure again. If the problem persists, contact Baxter Technical Support: baxter.com/contact-us.

Specifications

Item	Specification
Software version	A01
Power supplies and their AC-plug-adapter modes (optional)	Model UE08WCP-060100SPA: Input 100–240 V, 50–60 Hz, 400 mA. Output: 6 V, 1 A.
	Model UES06WNCP-060100SPA (the only approved power-supply option for the PLUS configuration): Input 100–240 V, 50–60 Hz, 200 mA. Output: 6 V, 1 A.
Battery-powered (DC) mode	6 V, 4 AA batteries
Battery's expected lifetime	About 750 single measurements or about 250 triple, averaged measurements (PLUS configuration only)
Display mode	Digital LCD, vertical alignment (VA), 68 mm x 90 mm
Measurement model	Oscillometric testing mode
Measurement range	Rated cuff pressure: 0–300 mmHg Measurement pressure: systolic 50–260 mmHg, diastolic 25–220 mmHg Pulse value: 40–199 beats per minute
Accuracy	Pressure: ±3 mmHg Pulse value: ±4%
Operating conditions	Temperature: 5–40 °C Relative humidity: 15–90% Atmospheric pressure: 70–106 kPa
Storage and transportation conditions	Temperature: -20–60 °C Relative humidity: 10–93% Atmospheric pressure: 50–106 kPa
Types of use or reuse	Multiple patient, multiple use
Product's life expectancy	5 years or 15,000 measurements, whichever comes first
External dimensions	Approx. 94 mm x 142 mm x 66 mm
Net weight, approximate (excluding batteries)	REF 2000-A: 335 g REF 2000 PLUS-A: 354 g
Degree of protection against electric shock	Type BF applied part

Item	Specification
Degree of protection against ingress	IP22: The device is protected against solid foreign objects of diameter 12.5 mm and greater and against vertically falling water drops when the enclosure is tilted up to 15°.

Transducer accuracy test

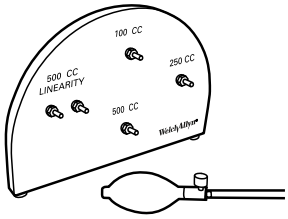
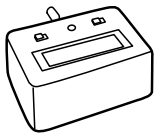
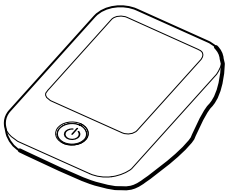
Required tools, equipment, and accessories

To complete the transducer accuracy test, you need the following tools and accessories:

- Scissors or other cutting device
- One 4-way hose-barb tee for the silicone-rubber tubing
- At least 81 cm (32") of silicone-rubber tubing (or equivalent) with 3.175 mm (0.125") inside diameter (ID)
    - ≥36 cm (14") from the hand bulb to the 4-way tee
    - ≥30 cm (12") from the test volume repair fixture to the 4-way tee
    - ≥15 cm (6") from pressure-meter simulator to the 4-way tee

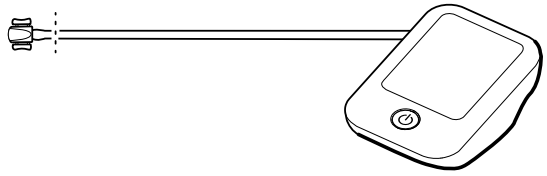
You also need the test equipment that's listed in the following table.

For further information or to order the test equipment, contact Baxter Technical Support: baxter.com/contact-us.

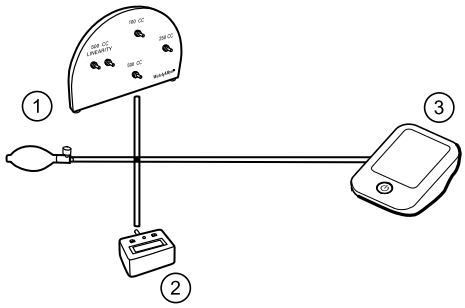
No.	Test equipment	Description
1		**Welch Allyn** Blood Pressure Test Volume Repair Fixture 407672 or equivalent with test manifold, bulb and valve, 4-way hose-barb tee, and 6.35-mm (0.25") OD silicone-rubber tubing
2		Pressure-meter simulator (with an accuracy of ±3 mmHg)
3		**ProBP** 2000 Digital Blood Pressure Device

Perform the transducer accuracy test

1. Use scissors or other cutting device to cut off the **FlexiPort** cuff's hose fitting from the end of the **ProBP** 2000 Digital Blood Pressure Device tubing.



2. Set up the test equipment.



   a. Connect the tubing from the **ProBP** 2000 device (item 3) to the 4-way tee.
   b. Connect the silicone-rubber tubing to the 4-way tee and the test manifold's 500-ml volume port (item 1).
   c. Connect the hand bulb (with bleed valve) to the silicone-rubber tubing and the 4-way tee.
   d. Connect the pressure-meter simulator (item 2) to the silicone-rubber tubing and the 4-way tee.
3. If using the optional AC plug adapter, disconnect the power supply from the **ProBP** 2000 device.
4. Put the **ProBP** 2000 device in internal mode:
   a. Open the battery door and remove one of the batteries.
   b. Press and release the power button. This ensures that all power has been removed from the device.
   c. Press and hold the power button while reinstalling the battery. When `tESt` appears on the screen, release the power button.
   d. Press the power button 3 times.
5. Turn on the pressure-meter simulator. Zero it if necessary.
6. Perform the transducer accuracy test using the hand bulb:
   a. Pressurize the device to 50 ± 3 mmHg. Allow 10 seconds for the pressure to stabilize.
   b. Pressurize the device to 150 ± 3 mmHg. Allow 10 seconds for the pressure to stabilize.
   c. Pressurize the device to 280 ± 3 mmHg. Allow 10 seconds for the pressure to stabilize.

   If the difference between the device and the reference manometer at any calibration point exceeds ±3 mmHg plus the stated accuracy of the reference manometer, contact Baxter Technical Support: baxter.com/contact-us.
7. Disassemble the test equipment. Slide the device tubing's end over the **FlexiPort** cuff's hose-fitting barb.
8. Open the battery door, and remove one of the batteries to power off the device.
9. Press and release the power button. This ensures that all power has been removed from the device. You can now turn on the device and use it in normal mode.

Standards and compliance

This device conforms to the following safety and performance standards.

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 information to be supplied by the manufacturer—Part 1: General requirements.
User manual	ISO/EN 20417 Medical devices—Information to be supplied by the manufacturer.
General requirements for safety	IEC/EN 60601-1+A1+A2 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance.
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 disturbances - Requirements and tests.
Performance requirements and clinical investigation	IEC/EN 80601-2-30 Medical electrical equipment—Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers. ISO 81060-2 Noninvasive sphygmomanometers—Part 2: Clinical validation of intermittent automated measurement type.
Software life cycle processes	IEC/EN 62304+A1 Medical device software—Software life cycle processes.
Usability	IEC/EN 62366-1+A1 Medical devices—Part 1: Application of usability engineering to medical devices. IEC/EN 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.

FCC interference statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the Federal Communication Commission (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. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio or TV technician for help.

Warranty

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

Welch Allyn will warranty the **FlexiPort** cuff to be free of defects in material and workmanship and to perform in accordance with manufacturer specifications for the period of three 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 Baxter service center is not included.
- A service notification number must be obtained from Baxter prior to returning any products or accessories to Baxter's designated service centers for repair. To obtain a service notification number, contact Baxter Technical Support: baxter.com/contact-us.

Approved accessories

You can use the device with the following applied parts and optional detachable components. For operating, cleaning, and disinfecting information as well as precautions, risks, etc., related to each item, see that item's instructions for use.

Applied parts: FLEXIPORT reusable cuffs

Item	Size (upper-arm circumference)
REUSE-09	Child (15–21 cm)
REUSE-10	Adult small (20–26 cm)
REUSE-11	Adult (25–34 cm)
REUSE-11L	Adult long (25–34cm)
REUSE-12	Adult large (32–43 cm)
REUSE-12L	Adult large, long (32–43 cm)
REUSE-13	Thigh (40-55 cm)

Optional detachable components

Item	Description
107201	Holster kit (holster and wall-mount bracket)
107195	Mobile stand with holster kit
107194	Basket with holster kit
107041	Power supply with AC plug adapters for US, EU, UK, and AU

EMC guidance and manufacturer’s declaration

EMC compliance

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

WARNING Patient injury risk. The device has not been designed for use with high-frequency (HF) surgical equipment and does not protect against hazards to the patient.

WARNING Do not 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 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION Do not use a mobile phone, or other devices that emit electromagnetic fields, near the unit. The unit can be affected by portable and mobile radio-frequency (RF) communications equipment, resulting in incorrect operation of the unit.

NOTE This unit has been thoroughly tested and inspected to assure proper performance and operation.

Technical description:

- All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.
- Guidance and manufacturer's declarations for electromagnetic emissions and immunity.

This device is intended for use in the electromagnetic environment specified in the emissions and immunity tables. The customer or user of the device should assure that it is used in such an environment.

Electromagnetic emissions

Emissions test	Compliance
RF emissions: CISPR 11	Group 1
RF emissions: CISPR 11	Class A
Harmonic emissions: IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions: IEC 61000-3-3	Complies

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 power supply lines ±1 kV signal input/output lines	±2 kV power supply lines ±1 kV signal input/output lines
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line-to-line ±0.5 kV, ±1 kV, ±2 kV line-to-earth	±0.5 kV, ±1 kV line-to-line ±0.5 kV, ±1 kV, ±2 kV line-to-earth
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°, 315° 0% U_T; 1 cycle 70% U_T; 25/30 cycles 0% U_T; 250/300 cycles	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T; 1 cycle 70% U_T; 25/30 cycles 0% U_T; 250/300 cycles
Power frequency magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz
Conducted RF IEC 61000-4-6	3 Vrms 0.15–80 MHz 6 Vrms in ISM and amateur radio bands 0.15–80 MHz	3 Vrms 0.15–80 MHz 6 Vrms in ISM and amateur radio bands 0.15–80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz–2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz–2.7 GHz 80% AM at 1 kHz

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

Test specifications for enclosure port immunity to proximity magnetic fields

Test frequency	Modulation[1]	Immunity test level (A/m)
134.2 kHz	Pulse modulation 2.1 kHz	65 (rms before modulation is applied)
13.56 MHz	Pulse modulation 50 kHz	7.5 (rms before modulation is applied)

Test frequency	Modulation[1]	Immunity test level (A/m)

[1] The carrier shall be modulated using a 50% duty cycle square wave signal.

Test specifications for enclosure port immunity to RF wireless communications equipment (IEC 61000-4-3)

Test freq. (MHz)	Modulation	Max. power (W)	Immunity test level (V/m)	Compliance level
385	Pulse modulation[1] 18 Hz	1.8	27	27
450	FM[2] ±5 kHz deviation: 1 kHz sine	2	28	28
710	Pulse modulation [1] 217 Hz	0.2	9	9
745				
780				
810	Pulse modulation [1] 18 Hz	2	28	28
870				
930				
1720	Pulse modulation [1] 217 Hz	2	28	28
1845				
1970				
2450	Pulse modulation [1] 217 Hz	2	28	28
5240	Pulse modulation [1] 217 Hz	0.2	9	9
5500				
5785				

NOTE Dwell time minimum 3 s.

[1] The carrier shall be modulated using a 50% duty cycle square wave signal.

[2] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because, while it does not represent actual modulation, it would be worst case.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