Welch Allyn ProBP™ 2000 Digital Blood Pressure Device

Instructions for use

Software Version A01

For information about any product, contact Hillrom Technical Support: hillrom.com/en-us/about-us/locations/.

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This manual applies to the # 901123 Digital Blood Pressure Device

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EC REP

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Made in China

Hillrom™

CE 0123

Contents

Introduction

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.

Intended use/Indications for use

The Welch Allyn ProBP 2000 Digital blood pressure device is intended for use in measuring blood pressure and heart 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 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.

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.
	Follow instructions/directions 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 Welch Allyn for delivery within 7 calendar days.

Power symbols

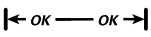
	Direct current
	Power

Shipping, storing, and environment symbols

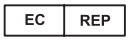
	Humidity limitation
	Separate collection of Electrical and Electronic Equipment. Do not dispose as unsorted municipal waste.
	Temperature limit
	Atmospheric pressure limitation
	Recyclable

	Stacking limit by number

Cuff symbols

	Artery marker
	Range
	Artery index marker
	Limb circumference (Minimum/Maximum)
	Lot Code
	Not made with natural rubber latex

Miscellaneous symbols

	Authorized Representative in the European Community
	Manufacturer
	Date of manufacture
	Type BF applied part
	Serial Number

REF	Reorder Number
LOT	Lot Code
#	Product Identifier
	Non-ionizing electromagnetic radiation
	Australian Communications and Media Authority (ACMA) Radio Compliance Mark (RCM)
GTIN	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°
R_x ONLY	Prescription only or "For Use by or on the order of a licensed medical professional"
	The product contains certain hazardous substances.
	Bluetooth

Note Your model might not contain all of these features.

About warnings and cautions

Warning and caution statements can appear on the Welch Allyn ProBP™ 2000 Digital Blood Pressure Device, the packaging, the shipping container, or in this *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.

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 >300mmHg or constant pressure >15mmHg 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 non-invasive 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 this *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 this *Instructions for use*.

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.

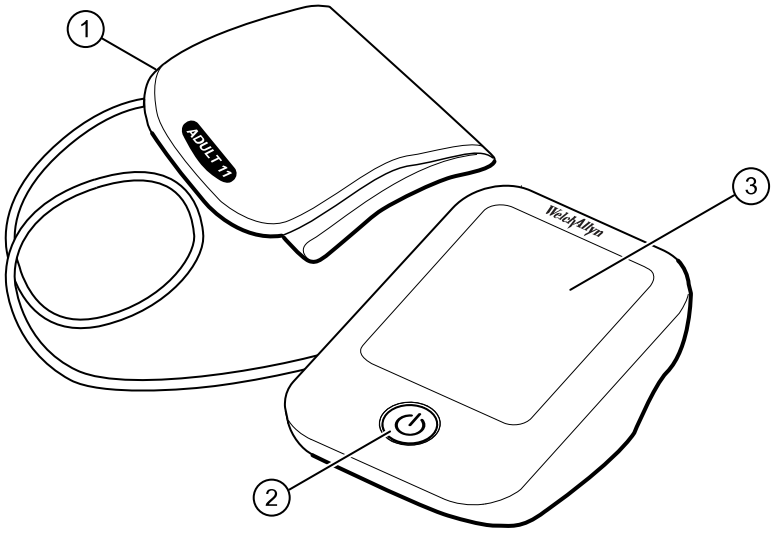
Contents list

The following items are in the box:

- Blood pressure device
- REUSE-11 Adult cuff (25–34cm)
- (4) AA alkaline batteries
- AC adapter (optional)

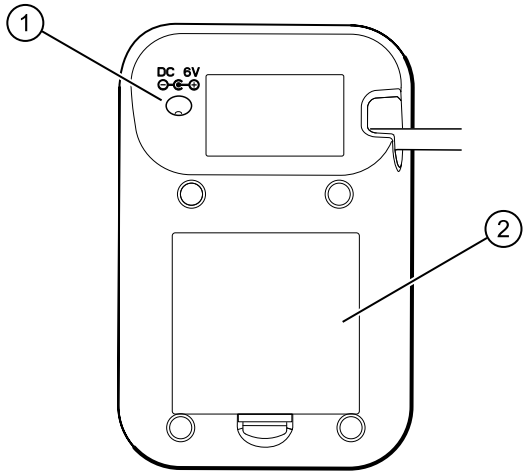
Controls and indicators

Device front



No.	Feature	Description
1	FlexiPort® blood pressure cuff	Apply to upper arm to take a blood pressure measurement
2	Power button	Powers on the blood pressure device and starts and stops a blood pressure measurement
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 (optional), connects the device to a power outlet
2	Battery compartment (behind cover)	Houses 4 AA alkaline batteries

Power options

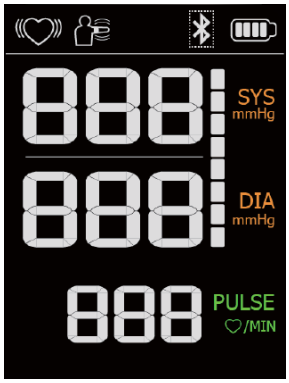
CAUTION To get optimal performance and protect your device, use only the correct batteries or the Welch Allyn-approved power adapter.

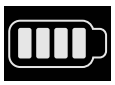
The device is powered by one of two sources:

- 4 AA alkaline batteries
- AC adapter (6v ⎓ 1A) (optional)

Screen elements

The liquid crystal display (LCD) displays the following: systolic blood pressure (mmHg), diastolic blood pressure (mmHg), pulse rate (bpm), heart beat while acquiring blood pressure measurements, excessive motion alert, alarm priority, and battery charge level.



Symbol	Description
SYS mmHg	Systolic blood pressure result mmHG = measurement unit of the blood pressure
DIA mmHg	Diastolic blood pressure result mmHG = measurement unit of the blood pressure
PULSE ♡/MIN	Pulse in beats per minute
	Heart beat Device is detecting a heartbeat during measurement
	Full battery indicator Indicates the current battery charge
	Low battery indicator Indicates the current battery charge
	Motion indicator Motion may result in an inaccurate measurement.

Symbol	Description
	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)

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.

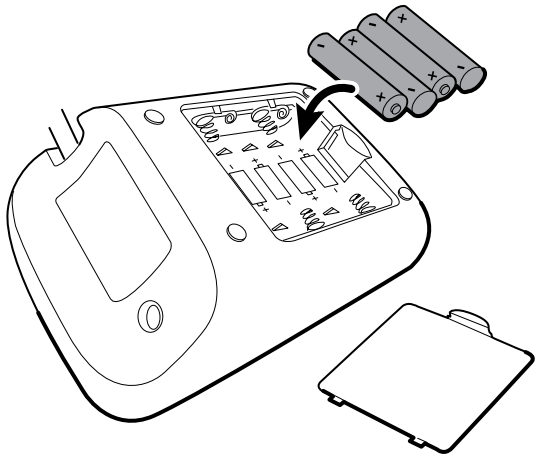
CAUTION Dispose of old batteries by following your local recycling guidelines.

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.

Position the blood pressure cuff on the patient

Before taking an NIBP measurement, follow these steps to properly attach the cuff to the patient. For information about obtaining blood pressure measurements, refer to Blood pressure guidelines at: https://www.welchallyn.com/probp2000.To achieve an accurate blood pressure reading, follow these steps to position the blood pressure cuff properly.

1. Place the cuff on a bare arm.
2. Use the proper size cuff. 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. Once the cuff is placed, 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.

Maintenance

Maintain the device

The device does not require calibration.

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

- 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.

Visible soil must be removed prior to cleaning and disinfection. The use of approved wipes (EPA or equivalent International Agency) containing 70% isopropyl alcohol or 10% chlorine bleach can be used to clean and disinfect the device. Follow the wipe manufacturer's directions for optimum results.

Cleaning

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.

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)

Storing the equipment

When storing the device, power cord, and accessories, observe the environmental storage conditions that are identified in the product specifications.

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 www.welchallyn.com/weee, or contact Hillrom Technical Support: hillrom.com/en-us/about-us/locations/.

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 here before contacting Hillrom Technical Support: hillrom.com/en-us/about-us/locations/.

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
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.	Readjust the cuff, have the patient 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, have the patient 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 patient's arm and then measure again
	E 21 shows	The measurement is incorrect	Have the patient relax for a moment and then measure again
Visit Hillrom Technical Support: hillrom.com/en-us/about-us/locations/ 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. Measure again. If the problem persists, contact Hillrom Technical Support: hillrom.com/en-us/about-us/locations/ for further assistance. 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. Measure again. If the problem persists, contact Hillrom Technical Support: hillrom.com/en-us/about-us/locations/ for further assistance. 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-06100SPA
Display mode	Digital LCD V.A. 68mm x 90mm
Measurement model	Oscillometric testing mode
Measurement range	Rated cuff pressure: 0mmHg to 300mmHg (0kPa to 40kPa) Measurement pressure: SYS: 50mmHg to 260m DIA: 25mmHg to 220mmHg Pulse value: (40 to 199) beats per minute
Accuracy	Pressure: ± 0.4kPa (3mmHg) Pulse value: ± 4%
Operating environment	Temperature: 5ºC to 40ºC Relative Humidity: ≤85% RH Atmospheric Pressure: 86kPa to 106kPa
Storage and transportation environment	Temperature: -20ºC to 60ºC Relative Humidity: 10% RH - 93% RH Atmospheric Pressure: 50kPa - 106kPa
Circumference of the upper arm	FlexiPort Part Number: Standard wide = REUSE-11 Cuff size: 25cm to 34cm
Net weight	Approx. 283g (Excluding the dry cells)
External dimensions	Approx. 94mm x 142mm x 66mm
Degree of protection	Type BF applied part
Protection against ingress of water	IP22

Item	Specification
Software version	Version A01

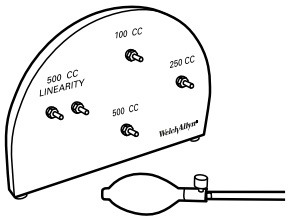
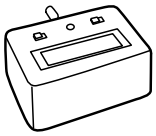
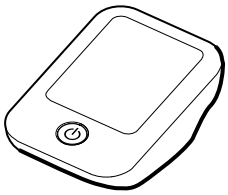
Transducer accuracy test

Required tools, equipment, and accessories

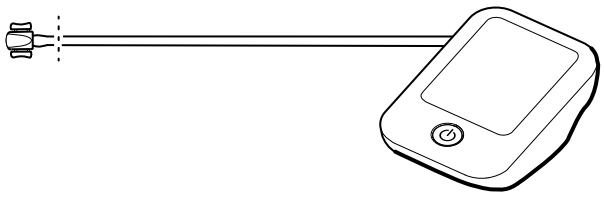
To complete the transducer accuracy test, the following tools and accessories are required:

- scissors or other cutting device
- one 4-way hose barb tee for 1/8 inch ID tubing
- a minimum of 32 inches of 1/4 inch (.25) OD and 1/8 inch (.125) ID silicone rubber tubing
  - approximately 14 inches from the hand bulb to the 4-way tee
  - approximately 12 inches from the test volume repair fixture to the 4-way tee
  - approximately 6 inches from pressure meter simulator to the 4-way tee

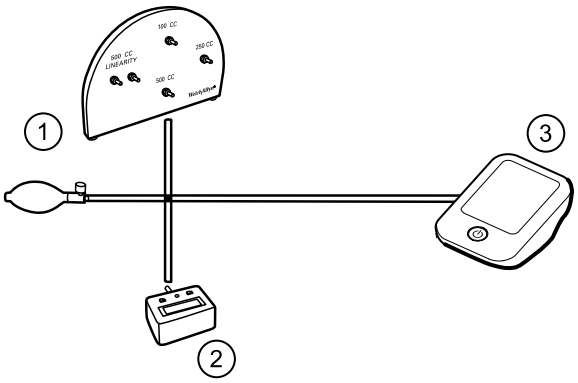
For the transducer accuracy test, the following equipment is required: (1) the test volume repair fixture with test manifold, bulb, and valve; (2) a pressure meter simulator; (3) the device with the Flexiport® connector removed. For further information or to order the test equipment, contact Hillrom Technical Support: hillrom.com/en-us/about-us/locations/. .

No.	Item
1 	Test volume repair fixture (Welch Allyn BP Test Volume Repair Fixture 407672 or equivalent with test manifold, bulb and valve, 4-way hose barb tee, and 1/4 inch [.25] OD silicone rubber tubing) **Note** For the transducer accuracy test, connect the test equipment shown below. Connect the manifold to the test volume repair fixture. The calibrated volume is 500 ml.
2 	Pressure meter simulator (with an accuracy of ± 3 mmHg)
3 	Device (ProBP™ 2000 Digital BP Device)

1. Use scissors or other cutting device to cut off the Flexiport® hose fitting from the end of the device tubing.



2. Set up the test equipment.



   a. Connect the device tubing to the 4-way tee.
   b. Connect the silicone rubber tubing to the 4-way tee and to the 500 ml volume port of the test manifold.
   c. Connect the hand bulb (with bleed valve) to the silicone rubber tubing and to the 4-way tee.
   d. Connect the pressure meter simulator to the silicone rubber tubing and to the 4-way tee.
3. If the optional AC power adapter is used, disconnect the power supply from the ProBP™ 2000 Digital BP Device.
4. Open the battery door and remove one of the batteries.

   Note Press the **Power** button to ensure that all power has been removed from the device.

5. Press and hold the **Power** button while reinstalling the battery.
6. When *tESt* appears on the screen, release the **Power** button.
7. Press the **Power** button 3 times.

   As the device enters internal mode, begin the Transducer accuracy test.
8. Turn on the pressure meter and zero if necessary.
9. Using the hand bulb, pressurize the device to 50 mmHg ± 3 mmHg and allow 10 seconds for the pressure to stabilize.
10. Using the hand bulb, pressurize the device to 150 mmHg ± 3 mmHg and allow 10 seconds for the pressure to stabilize.
11. Using the hand bulb, pressurize the device to 300 mmHg ± 3 mmHg and 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 Welch Allyn.

12. After the test completes, disassemble the test equipment and slide the end of the device tubing over the Flexiport® hose fitting barb.
13. Open the battery door and remove one of the batteries to power off the device.

Note Press the **Power** button to ensure that all power has been removed from the device. The device can now be powered on to begin using the device in normal mode.

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
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 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
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

General radio compliance

Item	Specification
Bluetooth module part number	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)

The wireless features of this device must be used in strict accordance with the manufacturer's instructions as described in the user documentation that comes with the product.

This device complies with Part 15 of the FCC rules and with the rules of the Canadian ICES-003 as described below.

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 d'interférences, et (2) l'appareil doit accepter toute interférence radioélectrique subie, même si l'interférence 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 le tableau 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.

European Union

Czech	Guangdong Transtek Medical Electronics Co., Ltd. tímto prohlašuje, že tento vysílač s nízkým výkonem je v souladu se základními požadavky a dalšími příslušnými ustanoveními směrnice 2014/53/ ES
Danish	Guangdong Transtek Medical Electronics Co., Ltd. erklærer herved, at denne lavt strøm transmitter er i overensstemmelse med de væsentlige krav og andre relevante bestemmelser i direktiv 2014/53/ EF

Dutch	Hierbij verklaart Guangdong Transtek Medical Electronics Co., Ltd. dat deze low power transmitter voldoet aan de essentiële eisen en andere relevante bepalingen van Richtlijn 2014/53/EG
English	Hereby, Guangdong Transtek Medical Electronics Co., Ltd. declares that this low power transmitter is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EC.
Estonian	Käesolevaga Guangdong Transtek Medical Electronics Co., Ltd. teatab, et see väikese võimsusega saatja on vastavus olulistele nõuetele ja teistele asjakohastele sätetele direktiivi 2014/53/ EÜ
Finnish	Näin ollen Guangdong Transtek Medical Electronics Co., Ltd. vakuuttaa, että tämä pienitehoinen lähetin on direktiivin 2014/53/EY olennaisten vaatimusten ja muiden asiaa koskevien säännösten mukainen
French	Par conséquent, Guangdong Transtek Medical Electronics Co., Ltd. déclare que cet émetteur de faible puissance est conforme aux exigences essentielles et autres dispositions pertinentes de la directive 2014/53/CE
German	Hiermit erklärt Grason-Stadler, dass dieser Niedrigleistungssender den grundlegenden Anforderungen und anderen relevanten Bestimmungen der Richtlinie 2014/53/EG entspricht
Greek	Με αυτό τον τρόπο, η Guangdong Transtek Medical Electronics Co., Ltd. δηλώνει ότι αυτός ο πομπός χαμηλής ισχύος είναι σύμφωνος με τις βασικές απαιτήσεις και άλλες σχετικές διατάξεις της οδηγίας 2014/53/ΕΚ
Hungarian	A Guangdong Transtek Medical Electronics Co., Ltd. ezúton kijelenti, hogy ez az alacsony teljesítményű adó megfelel a 2014/53/EK irányelv alapvető követelményeinek és egyéb vonatkozó rendelkezéseinek
Italian	In questo modo, Guangdong Transtek Medical Electronics Co., Ltd. dichiara che questo trasmettitore di bassa potenza è conforme ai requisiti essenziali e alle altre pertinenti disposizioni della direttiva 2014/53/CE.
Latvian	Ar šo, Guangdong Transtek Medical Electronics Co., Ltd. paziņo, ka šis mazjaudas raidītājs atbilst būtiskajām prasībām un citiem attiecīgiem noteikumiem Direktīvā 2014/53/EK
Lithuanian	Šiuo dokumentu Guangdong Transtek Medical Electronics Co., Ltd. deklaruoja, kad šis mažas energijos siųstuvas atitinka esminius reikalavimus ir kitas susijusias nuostatas Direktyva 2014/53/EB
Malti	Hawnhekk, Guangdong Transtek Medical Electronics Co., Ltd. jiddikjara li din trasmettitur enerġija baxxa hija konformi mar-rekwiżiti essenzjali u dispożizzjonijiet rilevanti oħra tad-Direttiva 2014/53/KE
Polish	Niniejszym Guangdong Transtek Medical Electronics Co., Ltd. oświadcza, że ten nadajnik o małej mocy jest zgodny z zasadniczymi wymaganiami i innymi istotnymi przepisami dyrektywy 2014/53/WE
Portuguese	Por este motivo, a Guangdong Transtek Medical Electronics Co., Ltd. declara que este transmissor de baixa potência está em conformidade com os requisitos essenciais e outras disposições relevantes da Diretiva 2014/53/CE
Slovak	Guangdong Transtek Medical Electronics Co., Ltd. týmto vyhlasuje, že tento vysielač s nízkym výkonom je v súlade so základnými požiadavkami a ďalšími príslušnými ustanoveniami smernice 2014/53/ES
Slovene	S tem, Guangdong Transtek Medical Electronics Co., Ltd. izjavlja, da je ta nizka moč oddajnik v skladu z bistvenimi zahtevami in drugimi ustreznimi določbami Direktive 2014/53/ES

Spanish	Por este medio, Guangdong Transtek Medical Electronics Co., Ltd. declara que este transmisor de baja potencia cumple con los requisitos esenciales y otras disposiciones pertinentes de la Directiva 2014/53/EC
Swedish	Guangdong Transtek Medical Electronics Co., Ltd. förklarar härigenom att denna låg effekt sändare överensstämmer med de väsentliga kraven och andra relevanta bestämmelser i direktiv 2014/53/EG

This product can be used with the following restriction(s):

France — Outdoor use is limited to 10mW EIRP within the band 2454 to 2483.5MHz.

Norway — Does not apply for the geographical area within a radius of 20km from the center of Ny-Ålesund.

Effective Isotropic Radiated Power (EIRP)

International radio compliance

South Korea	Korea Communications Commission (대한민국 방송통 신위원회) - KCC	Class A Equipment (Industrial Broadcasting & Communication Equipment) A급 기기 (업무용 방송통신기자재)	This equipment is Industrial (Class A) electromagnetic wave suitability equipment and seller or user should take notice of it, and this equipment is to be used in the places except for home. 이 기기는 업무용(A급) 전자파적합기기로서 판 매자 또는 사용자는 이 점을 주의하시기 바라 며, 가정외의 지역에서 사용하는 것을 목적으로 합니다.
Taiwan	National Communications Commission (國家通訊傳播委員會) NCC		低功率電波輻射性電機管理辦法 第十二條 經型式認證合格之低功率射頻電機，非經許可，公司、 商號或使用者均不得擅自變更頻率、加大功率或變更原設計 之特性及功能。 第十四條 低功率射頻電機之使用不得影響飛航安全及干擾合法 通信；經發現有干擾現象時，應立即停用，並改善至無干擾 時方得繼續使用。
Singapore			This device complies IMDA Regulations
Philippines			Type Approved No. ESD-1920202C
Hong Kong			Certified for Use in Hong Kong Certificate No. HK0012002117
South Africa	Independent Communications Authority of South Africa	ICASA	TA2019-1251
Oman			RA/TA-R/7759/19
Jordan			TRC/28/5519/2020

United Arab Emirates	TRA ER72256/19 Dealer No: DA44647/15
Qatar	ictQATAR CRA/SM/2019/R-7925

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 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 www.welchallyn.com/support.

Approved accessories

Item	Description
REUSE-11L	Adult long cuff (25–34cm)
107041	RPM BP AC Adapter. This adapter is an alternate power source for the blood pressure device.

For a list of additional cuff sizes visit www.welchallyn.com/probp2000.

EMC guidance and manufacturer's declarations

EMC guidance

1. This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2. * Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3. **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.
4. Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
5. * Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Emissions and immunity information

Electromagnetic emissions		
The ProBP™ 2000 Digital Blood Pressure Device is intended for use in the electromagnetic environment specified below. The customer or user of the ProBP™ 2000 Digital Blood Pressure Device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ProBP™ 2000 Digital Blood Pressure Device 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.
RF emissions CISPR 11	Class B	The ProBP™ 2000 Digital Blood Pressure Device is suitable for use in all establishments, other than domestic 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	

Guidance and manufacturer's declaration – electromagnetic immunity			
The ProBP™ 2000 Digital Blood Pressure Device is intended for use in the electromagnetic environment specified below. The customer or the user of the ProBP™ 2000 Digital Blood Pressure Device 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 ± 15 kV air	± 8 kV contact ± 15 kV 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	power supply lines: ±2 kV input/output lines : ±1 kV	power supply lines: ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV line(s) to earth: ± 2 kV 100kHz repetition frequency	line(s) to line(s): ±1 kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	0% 0.5 cycle At 0°, 45°, 90°,135°, 180°, 225°, 270° and 315°	0% 0.5 cycle At 0°, 45°, 90°,135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
IEC 61000-4-11	0% 1 cycle and 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 1 cycle and 70% 25/30 cycles Single phase: at 0 0% 300 cycle	
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration –electromagnetic immunity				
The ProBP™ 2000 Digital Blood Pressure Device is intended for use in the electromagnetic environment specified below. The customer or the user of the ProBP™ 2000 Digital Blood Pressure Device should assure that it is used in such an environment.				
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**	
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	**Recommended separation distance** Portable and mobile RF communications equipment should be used no closer to any part of the ProBP™ 2000 Digital Blood Pressure Device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: d=0.35; d=1.2	
Radiated RF IEC 61000-4-3	10V/m, 80% Am at 1kHz	10V/m, 80% Am at 1kHz	80 MHz to 800 MHz: d=1.2 800 MHz to 2.7 GHz: d=2.3	where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, 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: 
Note1: 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.				

Guidance and manufacturer's declaration –electromagnetic immunity

If the measured field strength in the location in which the ProBP™ 2000 Digital Blood Pressure Device is used exceeds the applicable RF compliance level above, the ProBP™ 2000 Digital Blood Pressure Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ProBP™ 2000 Digital Blood Pressure Device.

[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 ProBP™ 2000 Digital Blood Pressure Device

The ProBP™ 2000 Digital Blood Pressure Device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ProBP™ 2000 Digital Blood Pressure Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated max. output power of transmitter (W)	**150 kHz to 80 MHz** $d = 3.5$	**80 MHz to 800 MHz** $d = 1.2$	**800 MHz to 2.7 GHz** $d = 2.3$
0.01	0.12	0.12	0.23
0.1	0.37	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

Guidance and manufacturer's declaration –electromagnetic immunity

The ProBP™ 2000 Digital Blood Pressure Device is intended for use in the electromagnetic environment specified below. The customer or the user of the ProBP™ 2000 Digital Blood Pressure Device should assure that it is used in such an environment.

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency (MHz)**	**Band a (Mhz)**	**Service a)**	**Modulation b)**	**Modulation b) (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27

Guidance and manufacturer's declaration –electromagnetic immunity							
	450	380-390	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/ 900, TETRA 800 iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Blue-tooth, WLAN, 802. 11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217Hz	2	0.3	28
	5240	5100-5800	WLAN802. 11 a/n	Pulse modulation b) 217Hz	0.2	0.3	9
	5785						

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) 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.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = 6/d \sqrt{P}$

Where *P* is the maximum power in *W*, *d* is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.