WHO Protocol Embedded | ESH Protocol Embedded | AHA Protocol Embedded

Welch Allyn®

Advancing Frontline Care™

ProBP 2400
Digital Blood Pressure Device

Directions for use

EN → 1

CAUTION Federal law restricts this device to sale by or on the order of a physician or licensed healthcare provider

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Introduction

This directions for use manual is a comprehensive guide designed to help you understand the capabilities and operation of the ProBP 2400 digital blood pressure device. Read this manual thoroughly before attempting to setup, configure, use, troubleshoot, or maintain the device.

Intended use

The ProBP 2400 is a non-invasive digital blood pressure device using oscillometric technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures, pulse rate and mean arterial pressure (MAP).

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected preeclampsia.

The ProBP 2400 combines the advantages of an automatic blood pressure device and auscultatory sphygmomanometer. It is designed to provide convenient, accurate and reliable office blood pressure measurements according to guidelines of the European Society of Hypertension (ESH)[1], American Heart Association (AHA)[2], and World Health Organization (WHO)[3] with the only modification that the ProBP2400 performs 3 repeated measurements always, regardless of the result of the first two measurements.

Pregnancy

Approximately 20% of women develop hypertension during pregnancy (Pre-eclampsia or Toxemia) which may affect pregnancy. Pre-eclampsia, can usually be recognized by a clear increase in blood pressure and high urine protein levels after 20 weeks of gestation. Since many oscillometric devices appeared to be unsuitable for use in pregnancy and Pre-eclampsia health care authorities require that blood pressure monitors used for this vulnerable patient group are specifically tested. The Welch Allyn ProBP 2400 digital blood pressure monitor has successfully passed this validation and therefore may be recommended for use during pregnancy and Pre-eclampsia.

[1] Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the subcommittee of professional and public education of the american heart association council on high blood pressure research. Circulation 2005;111:697-716.

[2] Whitworth JA. 2003 World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension. J Hypertens 2003;21:1983-92.

[3] O'Brien E, Asmar R, Beilin L, et al. Practice guidelines of the European Society of Hypertension for clinic, ambulatory and self blood pressure measurement. J Hypertens 2005;23:697-701. E, Asmar R, Beilin L, Imai Y, et al. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. European Society of Hypertension Working Group on Blood Pressure Monitoring. J Hypertens 2005;23:697-701.2003,21:1983-1992.

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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.

Consult operating instructions/directions for use (DFU). A copy of the DFU is available on this web site. A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 calendar days.

Helpful notes.

Shipping, storing, and environment symbols

Fragile; handle with care

Recovery/Recyclable

Recycle the product separate from other disposables

Keep dry

Control symbols

Power on/Power off

Start/Stop

Memory

Adjust measurement interval times

Adjust maximum inflation pressure

Single Reading Mode

Manual Mode

Three Reading Average Mode

General warnings and cautions

Miscellaneous symbols

Meets essential requirements of European Medical Device Directive 93/42/EEC

EC REP Regulatory Affairs Representative

Type BF applied parts

Manufacturer

WARNING The information in this directions for use is a comprehensive guide to the operation of ProBP 2400. For best results, read this directions for use thoroughly before using the device.

WARNING The device is intended for use only in environments with clinician supervision.

WARNING The device is designed for medical clinician use. Although this directions for use may illustrate medical spot-check techniques, only a trained clinician should use this device.

WARNING The device is not intended for use during patient transport.

WARNING Fire and explosion hazard. Do not operate the device in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide; in oxygen enriched environments.

WARNING Every three months, inspect the blood pressure cuff and other accessories for fraying or other damage. Replace as necessary.

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

WARNING Electric shock hazard. Do not open the device or attempt repairs. There are no user-serviceable parts inside ProBP 2400 other than battery replacement. Only perform routine cleaning and maintenance procedures specifically described in this directions for use. Inspection and servicing of internal parts shall only be performed by qualified service personnel.

WARNING The device complies with applicable domestic and international standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using the device in close proximity to other equipment.

WARNING Welch Allyn is not responsible for the integrity of any mounting installation. Welch Allyn recommends that customers contact their Biomedical Engineering Department or maintenance service to ensure professional installation for safety and reliability of any mounting accessory.

WARNING The device may not function properly if dropped or damaged. Do not use the device if you notice any signs of damage. Qualified service personnel must check any device that is dropped or damaged for proper operation before putting the device back into use.

WARNING Defective batteries can damage the device. If the battery shows any signs of damage, leakage, or cracking, it must be replaced immediately, and only with a battery recommended for or supplied with the device.

WARNING Improper disposal of batteries may create an explosion or contamination hazard. Never dispose of batteries in refuse containers. Do not dispose of the battery in fire. Always recycle batteries according to local regulations.

WARNING Improper handling of the battery can lead to heat generation, smoke, bursting, or fire.

WARNING Do not disassemble, modify, or solder the battery.

WARNING For proper patient electrical isolation and battery charging, use only the provided external power supply to charge the device.

WARNING Electric shock hazard. Before cleaning the device, disconnect the power cord from the power source and the device.

WARNING Take care to prevent water or other fluid from entering any connectors on the device. Should this occur, dry the connectors with warm air. Check the accuracy of all operating functions.

Avoid simultaneously connecting patients to the device and high frequency surgical equipment.

CAUTION The device is not heat-resistant. Do not autoclave.

CAUTION Use the device within stated operating temperature ranges. The device will not meet performance specifications if used outside these temperatures ranges.

CAUTION Always unplug the external power source from the outlet before moving the device to a new location.

CAUTION Use only Welch Allyn approved accessories. Use of unapproved accessories with the device can affect patient and operator safety, and can reduce product performance and accuracy.

CAUTION Federal law restricts this device to sale by or on the order of a physician or licensed health care provider

NIBP (non-invasive blood pressure) warnings and cautions

WARNING ProBP 2400 is not intended to measure blood pressure on children younger than 12 years of age.

WARNING Do not compress the blood pressure hose or cuff. This may cause system errors or patient safety risks to occur.

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

WARNING Use only blood pressure cuffs and hoses listed as approved accessories to ensure safe and accurate of blood pressure measurements.

WARNING Patient injury risk. When several blood pressure measurements are taken on the same patient, regularly check the cuff site and extremity for possible ischemia, purpura, and/or neuropathy.

WARNING Do not allow a blood pressure cuff to remain on the patient more than 5 minutes when inflated above 15 mmHg. Excessive cuff tightness may cause venous congestion, peripheral nerve injury, discoloration of the limb, and patient distress.

WARNING Patient injury risk. Never install Luer Lock connectors on Welch Allyn blood pressure tubing. Using these connectors on blood pressure cuff tubing creates the risk of mistakenly connecting this tubing to a patient's intravenous line and introducing air into the patient's circulatory system.

WARNING NIBP measurements may be inaccurate in the presence of excessive motion artefact. Minimize extremity and cuff motion during blood pressure readings.

WARNING The position and physiologic condition of the subject can affect a blood pressure reading.

CAUTION If the blood pressure cuff is not at heart level, note the difference in reading due to the hydrostatic effect.

CAUTION Proper blood pressure cuff size and placement is essential to the accuracy of the blood pressure determination. See Blood pressure cuff selection for sizing information.

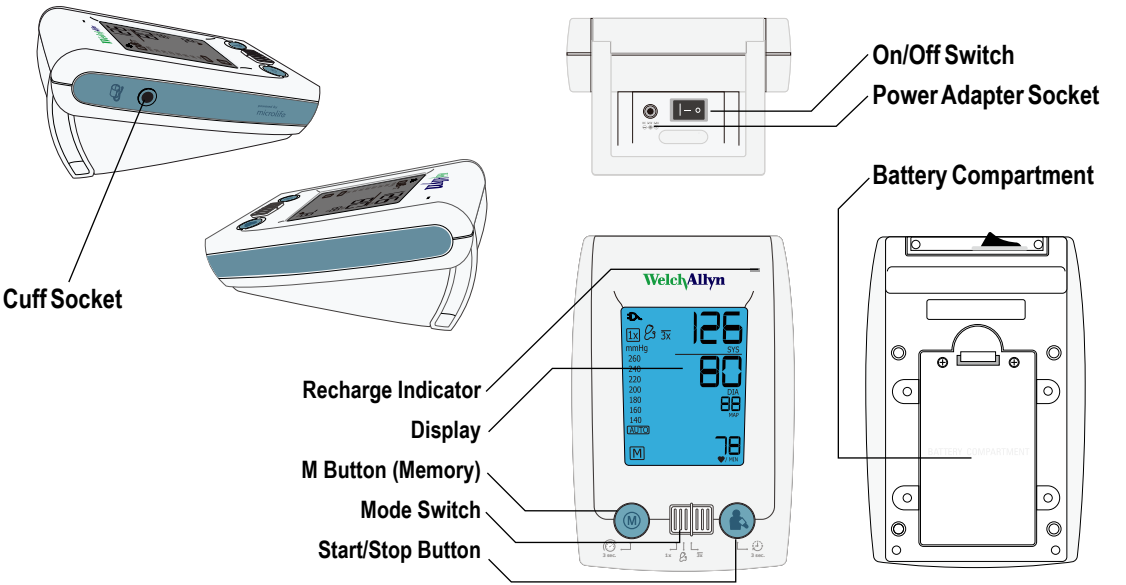
CAUTION The blood pressure cuff must be properly positioned to ensure blood pressure accuracy and patient safety. Wrapping the cuff too loosely (preventing proper inflation) may result in inaccurate blood pressure readings.

CAUTION The patients should be comfortably seated, legs uncrossed, feet flat on the floor, back and arm supported. The middle of the cuff should be at the level of the heart.

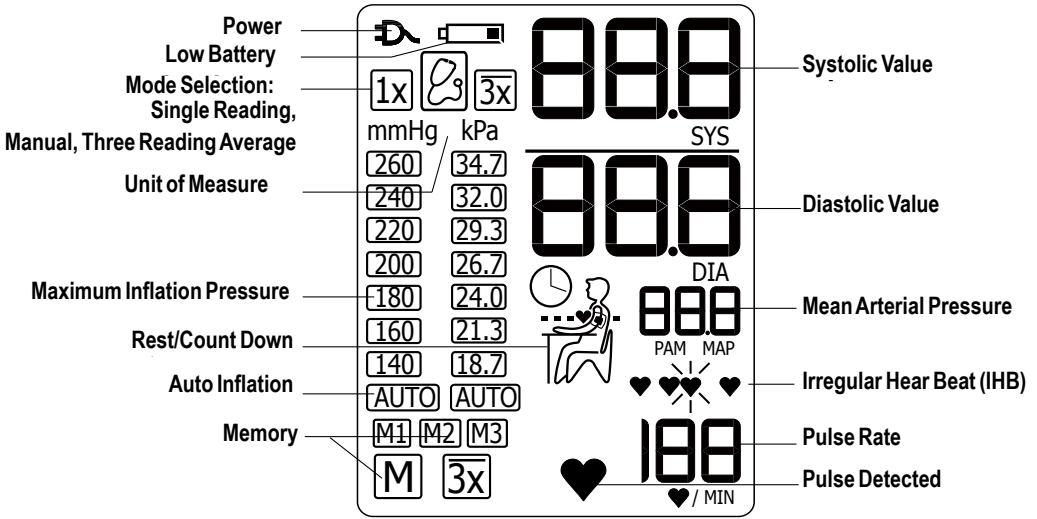
CAUTION Recommend the patients to sit down and relax for at least 5 minutes prior to the measurement and not talk during the measurement procedure.

Product description

Name of parts

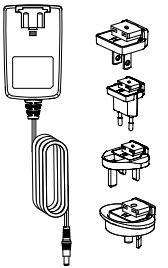


Display


Power
Low Battery
Mode Selection:
Single Reading,
Manual, Three Reading Average
Unit of Measure
Maximum Inflation Pressure
Rest/Count Down
Auto Inflation
Memory
Systolic Value
Diastolic Value
Mean Arterial Pressure
Irregular Hear Beat (IHB)
Pulse Rate
Pulse Detected
1x
3x
mmHg
kPa
260
240
220
200
180
160
140
34.7
32.0
29.3
26.7
24.0
21.3
18.7
AUTO
AUTO
M1
M2
M3
M
3x
SYS
DIA
PAM
MAP
/ MIN

ProBP 2400 components and accessories

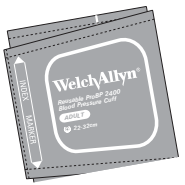
1 X ProBP 2400



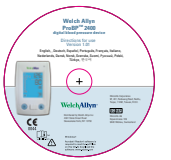
1 X Power Adapter

4 X Power Plugs (US, Europe, UK, Australia)

(Input: 100-240V~50/60Hz 0.48A
Output: +7.5V 1.5A)



1 X Adult (22cm~32cm)
1 X Large adult (32cm~42cm)

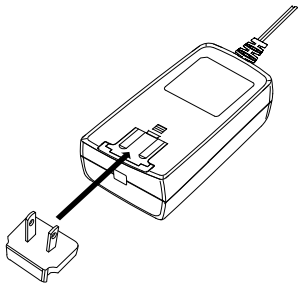


1 X CD Directions For Use

Initial set up

Attaching the power plug to the power adapter

Select a proper power plug and attach to the power adapter as shown below.



Charge the battery completely

When using for the first time, charge the battery until the recharge indicator on the device turns to green.

☞ Refer to page 27 for the section of “Using a power adapter“.

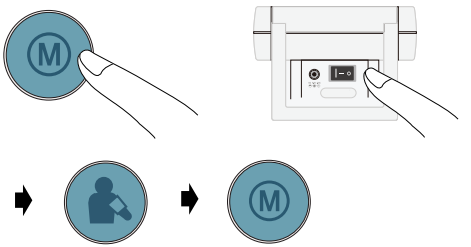
☞ Refer to page 27 for the section “Rechargeable Battery“

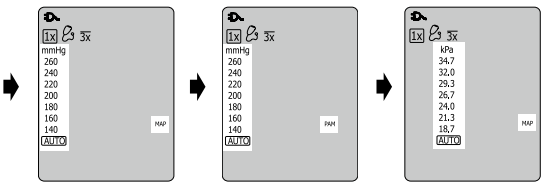
Selecting units of measure

1) Make sure the device is switched off.
2) Press and hold the M Button and then turn on the power with the On/Off Switch.
3) Release the M Button when backlight illuminates.
4) Press the Start/Stop Button to select the preferred pressure unit (mmHg or kPa).
5) Press M Button to confirm the selection.

		Units	MAP or PAM
1	➧	mmHg	MAP
2	➧	mmHg	PAM
3	➧	kPa	MAP

☞ Factory default setting





☞ MAP is the abbreviation of Mean Arterial Pressure.

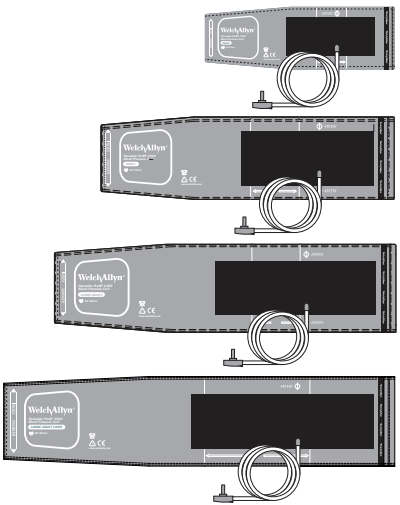
☞ PAM or MAP is chosen depending on language preference.

Before using the device

Selecting the correct cuff

A variety of different cuff sizes are available. Adult and Large Adult cuffs are provided with the device. Use the cuff marker to select the cuff size that best matches the circumference of the patient's upper arm.

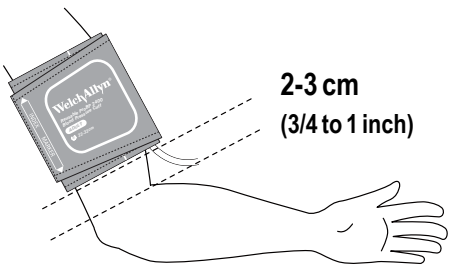
Cuff Size	Circumference (cm)	Circumference (inch)
Child	14 - 22	5.5 - 8.7
Adult	22 - 32	8.7 - 12.6
Large Adult	32 - 42	12.6 - 16.5
Large Adult Long	32 - 52	12.6 - 20.5

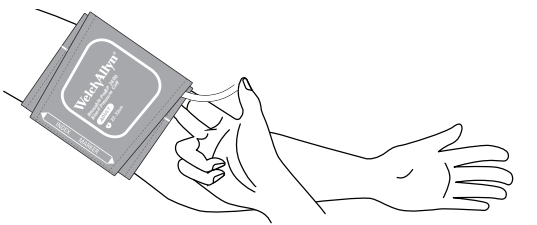


- ☞ Each cuff is provided with 130 cm air tube.
- ☞ Use only cuffs provided by Welch Allyn!
- ☞ Contact Welch Allyn or its authorized distributor to purchase cuffs.
- ☞ Adult and Large Adult cuffs are included as standard accessories.
- ☞ Child and large adult long cuffs are not available in the USA. Check your local representative for availability.

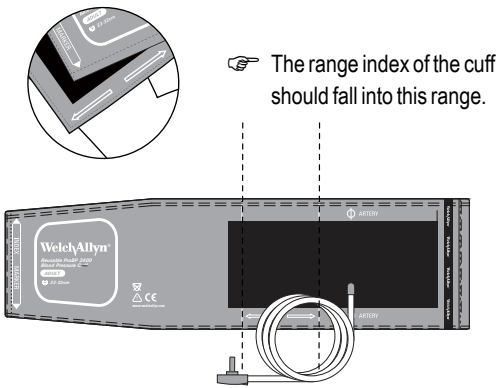
Fitting the cuff properly

1) Place the cuff over the upper arm so that the air tube and artery mark arrow point towards the lower arm. The artery mark on the cuff must be placed over the brachial artery.
2) Lay the cuff on the arm. Make sure that the lower edge of the cuff lies approximately 2 to 3 cm (¾ to 1 inch) above the elbow.
3) Wrap and tighten the cuff around the arm.
4) Leave free space with the size of 2 fingers between the arm of the patient and the cuff. Excessive tightness may cause venous congestion and discoloration of the limb. If the cuff is wrapped too loosely, it cannot be inflated properly and the measured values may be inaccurate. Remove all clothing covering or constricting the measurement arm. Clothing may interfere with measurement accuracy.





5) Cuffs that do not fit properly may lead to inaccurate readings. Use a different size cuff if the range index at the end of the cuff does not fall into the range specified by the range stripes.



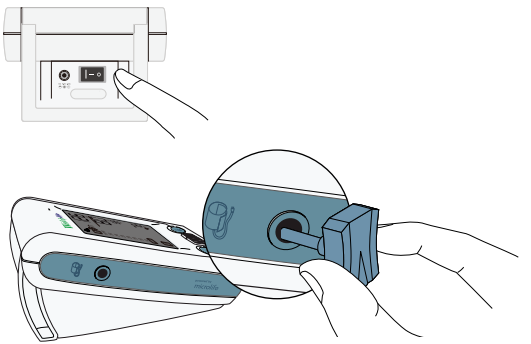
Taking measurements in 1x, Manual and $\overline{3x}$ Mode

Turn on the power

Turn on the device by pressing the On/Off Switch at the back of the device to the ON position.

Connect the cuff to the device

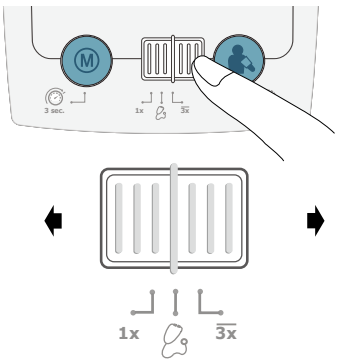
Connect the cuff to the device by inserting the cuff connector into the cuff connector socket.



Set maximum inflation pressure

Select desired maximum inflation pressure or "AUTO".

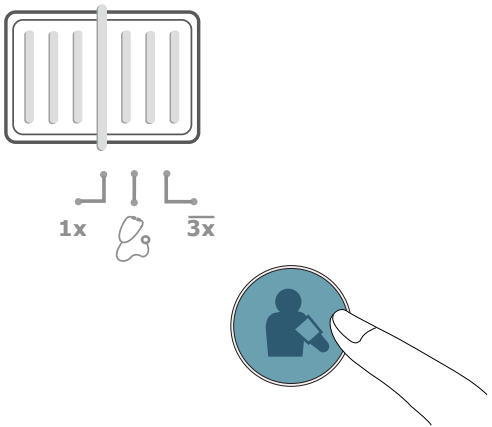
☞ Refer to page 22 for the section of “Set maximum inflation pressure“



Select an operation mode

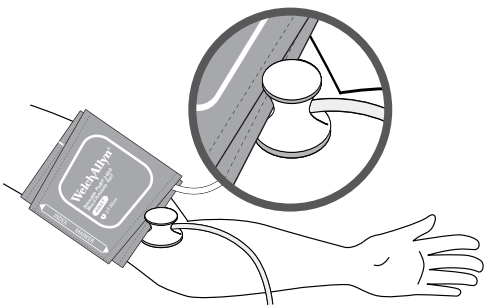
There are three measurement modes that can be used.
Slide the switch to select **1x** (standard single measurement), **Manual or $\overline{3x}$ Mode** (automatic three reading average).

«1x» Mode (standard single measurement)
Select «**1x**» Mode then press the «**Start/Stop**» Button to perform a single blood pressure measurement. The measurement reading is displayed and saved after the measurement.



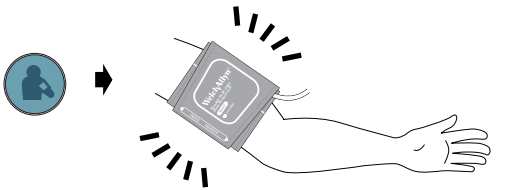
«Manual» Mode

Select «**Manual**» Mode if auscultatory blood pressure measurement is preferred above using the oscillometric method. In «Manual» Mode, the device serves only as a pressure gauge. No oscillometric measurements will be taken. The user can hear the systolic and diastolic Korotkoff sounds by means of a stethoscope placed over the Brachial artery.



Start inflation – Press the **Start/Stop** Button to start inflation of the cuff.

When maximum inflation pressure is reached, the ProBP 2400 will automatically begin linear deflation at a rate of 3mmHg/sec.



Re-inflate – Push and Hold the M Button during deflation when the cuff pressure is below 200mmHg to re-inflate for as long as the button is held (up to a max of 200mmHg) Release the button to continue deflation. An additional push and hold of the M Button will allow reinflation past 200mmHg to a max of 299mmHg.

When the cuff pressure reaches 20mmHg during the deflation cycle, the remaining pressure is vented and the ProBP 2400 goes into the Stand by mode.

Push the «**Start/Stop**» at any time to start fast deflation and set the ProBP 2400 to Stand by.

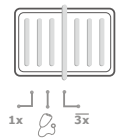
Take note – Take note of the systolic and diastolic values in the same manner as performed with sphygmomanometer measurements.

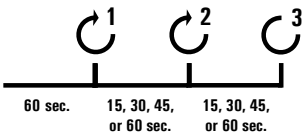
Set to 'Stand by' – The device can be set to "Stand by" by pressing the «**Start/Stop**» Button without turning off the power. The device will automatically switch to 'Stand by' if there is no operation for one minute.

«$\overline{3x}$» Mode (automatic three reading average)
Select «$\overline{3x}$» Mode then press the «**Start/Stop**» Button to perform automatic triple blood pressure measurements to determine a three reading average.

The countdown time before the first measurement is set at 60 seconds.

The interval times between measurements is user adjustable to 15, 30, 45 or 60 seconds. The average measurement reading is displayed and saved after the measurements are complete.





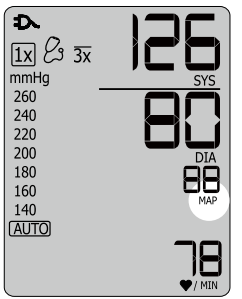
☞ The user can manually select up measurement interval times of 15, 30, 45 or 60 seconds in $\overline{3x}$ Mode. (Please refer to special functions section page 21 "Setting measurement interval times").

☞ The 60 second wait period before the first measurement is not adjustable but may be bypassed by pressing the Start/Stop Button a second time. This will start the first reading immediately.

Special Functions

MAP (Mean Arterial Pressure)

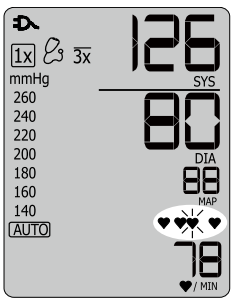
The device measures the true mean arterial pressure (MAP) of the patient. Each measurement includes a single MAP value. The MAP value will always be displayed together with the systolic and diastolic blood pressure value.



☞ The Mean Arterial Pressure, MAP is determined from the maximum peak of the oscillometric envelope curve.

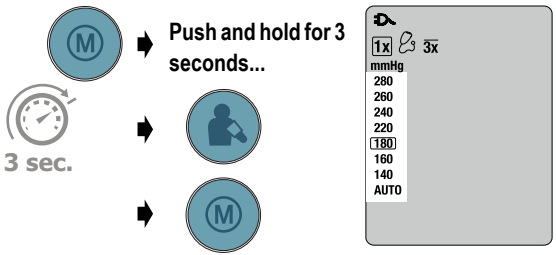
Irregular heartbeat detector in «1x» Mode

The device detects irregular heartbeat in «**1x**» Mode. The irregular heartbeat symbol shows up if during a blood pressure measurement the heart rate has varied by more than 25%. In case of an irregular heartbeat the blood pressure measurement might be affected. It is recommended to repeat the measurement or to choose the «**Manual**» Mode for verification.



Set maximum inflation pressure

1) Press and hold the M Button for 3 seconds until the column with pressure values flashes.
2) Press the Start/Stop Button to select the preferred pressure value (after value '260' has been reached the next selection option will be "AUTO" at the bottom of the list)
3) Press the M Button to confirm the selected value.



☞ The inflation pressure selection (mmHg/kPa) can be done in 1x, $\overline{3x}$, or Manual Mode. The default setting is "AUTO"

☞ When set to AUTO, the ProBP 2400 will automatically determine the maximum inflation pressure as it inflates the cuff.

If the maximum inflation pressure selected (or the maximum inflation pressure as determined while in AUTO mode) is not adequate to determine systolic pressure, the device will reinflate to a pressure 30 mmHg higher than the previous inflation pressure and attempt another cycle. This can be repeated increasing the maximum inflation by 30 mmHg each time. If a maximum inflation pressure of 280 mmHg is reached, and the ProBP 2400 is unable to determine a blood pressure, an error code will be displayed.

It is recommended at this point to switch to the manual mode and determine blood pressure with a stethoscope using traditional Korotkoff method. (See «**Manual**» Mode)

Taking fewer than three measurements in «$\overline{3x}$» Mode

The measurement sequence can be stopped at any time during the measurement sequence by pressing the Start/ Stop Button. The device enters 'Stand by' and remaining measurements are cancelled. Data from the measured blood pressure can be viewed by pushing the M Button.

➧ **Cancel remaining measurements at any time during the measurement sequence.**

Skipping countdown time in «$\overline{3x}$» Mode

The countdown before and between measurements in «$\overline{3x}$» Mode can be skipped by pressing the Start/Stop Button. When the Start/Stop Button is pressed during countdown, the device will immediately begin the next measurement.

➧ **Skip the countdown time and begin the measurement.**

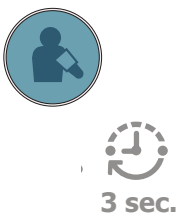
☞ The device can be set in 'Stand by' Mode by pressing the Start/ Stop Button after completion of measurements. The device will automatically switch to 'Stand by' Mode if left unattended for 1 minute.

➧ **Stand by**

Setting measurement interval times in «3x» Mode

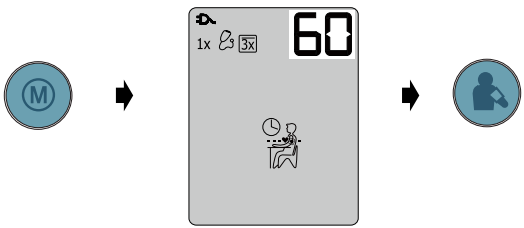
The default measurement interval time is 60 seconds. The interval times can be set as 15, 30, 45 or 60 seconds.

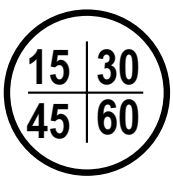
1) Press and hold the Start/Stop Button for 3 seconds.



Press and hold for 3 seconds...

2) Press the M Button to adjust the measurement interval time, then press the Start/Stop Button to confirm. The device will go back to 'Stand by'.



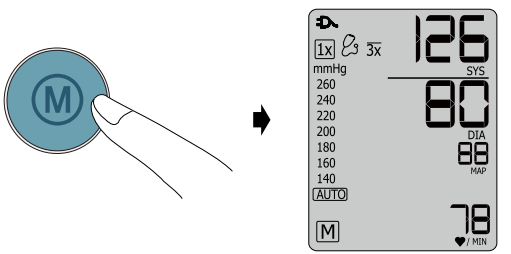


Viewing stored values

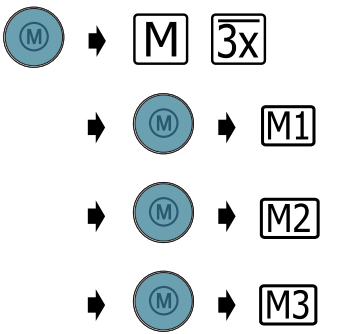
Viewing stored values

The device only stores blood pressure values of the last measurement procedure in **«1x»** and **«$\overline{3x}$»** Mode. Press the M Button to review the stored readings when the device is in 'Stand by' mode.

1) In **«1x» Mode** –



2) In **«$\overline{3x}$» Mode** –
Press the M Button to reveal the average of the triple measurements. Continue pressing the M Button to review individual measurements.

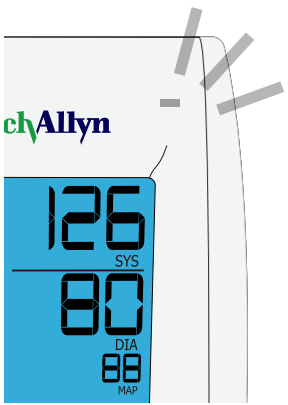


☞ The device stores only the last measurement completed in «1x » Mode and the last three measurements completed in «$\overline{3x}$» Mode.

Rechargeable battery and power adapter

Rechargeable Battery

The ProBP 2400 features a built-in, rechargeable Ni-MH battery pack that provides up to 600~700 measurement cycles on a full charge. The battery can be recharged with the power adapter provided. The empty battery indicator is displayed when the battery is low.

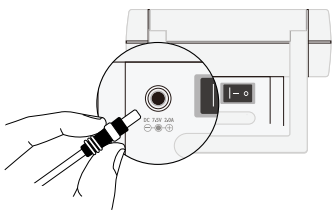


- ☞ When using for the first time, charge the battery until the recharge indicator turns to green.
- ☞ The orange recharge indicator means that the recharge is in progress.
- ☞ A green recharge indicator means that the recharge is completed.

Using a power adapter

Only use the adapter supplied with ProBP 2400 to recharge the device.

1) Plug the adapter cable into the power socket of the device.
2) Plug the adapter plug into the wall socket. The battery will be recharged as long as the device is attached to an AC power source. After the battery is fully recharged, the charging will stop. No battery power will be used as long as the adapter is plugged in. The battery has to remain in the ProBP 2400 also when using the AC power.
3) If the battery starts losing capacity, contact your local dealer for replacement battery. The battery is user replaceable.

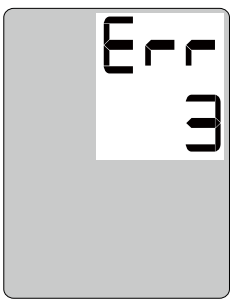


Troubleshooting

Problem	Possible cause	Solutions
No power (No LCD display)	Power supply is not properly plugged in	Plug the power supply into the wall socket.
	Battery is fully discharged	Recharge the rechargeable battery by plugging in the power supply.
Cuff does not inflate properly	Loose connection of the tube	Make sure the tube of the cuff is securely connected to the device.
	Leakage of the tube / bladder	Check for cracks on the tube or the bladder. Replace the blood pressure cuff if necessary.
No result displayed after measurements	Device is in Manual Mode	Switch to **«1x»** or **«$\overline{3x}$»** Mode and repeat the measurements.

Error messages

If an error occurs during a measurement, the measurement is interrupted and an error message «Err» is displayed.



Error	Description	Potential cause and remedy
«**Err 1**»	**Signal too weak**	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.
«**Err 2**»	**Error signal**	During the measurement, error signals were detected by the cuff caused, for instance, by movement or muscle tension. Repeat the measurement keeping patient's arm still.

«Err 3»	**No pressure in the cuff**	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Replace the blood pressure cuff if necessary. Repeat the measurement.
«Err 5»	**No valid results**	The measuring signals are inaccurate therefore no result can be displayed. Switch to Manual Mode and determine blood pressure with a stethoscope using traditional Korotkoff method.

«HI»	**Pulse rate or cuff pressure too high**	The pressure in the cuff is too high (over 300 mmHg) OR the pulse is too high (over 200 beats per minute). Have the patient relax for 5 minutes and repeat the measurement.
«LO»	**Pulse too low**	The pulse is too low (less than 40 beats per minute). Repeat the measurement.

Safety, care, accuracy test and disposal

Safety and protection

This device may be used only for the purpose described in this directions for use manual. The device comprises of sensitive components and must be treated with care. The manufacturer cannot be held liable for damage caused by incorrect application.

- Only activate the pump when the cuff is connected to the device.
- Do not use the device if you think it is damaged or if anything appears unusual.
- Read further safety instructions in the individual sections of the instruction manual.

Observe the storage and operating conditions described in the “Technical specifications” section of this directions for use manual.

Protect the device from water and moisture

Protect the device from direct sunlight

Protect the device from extreme heat and cold

Avoid proximity to electromagnetic fields, such as those produced by mobile phones

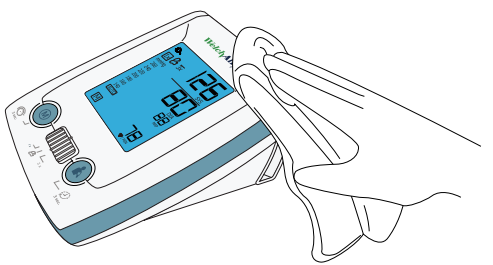
Never open device

Protect device from impact and drops

Device care

Use a soft cloth with one of the following recommended cleaning solutions to wipe the exterior of the device:

1) Mild soap and water
2) Hydrogen peroxide solution (3% diluted with water)
3) Sodium hypochlorite solution (1:10 dilution of household chloride bleach in water)

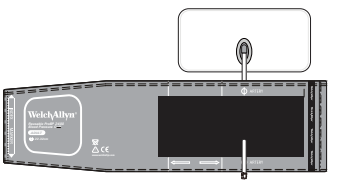


Cleaning the cuff

Remove the bladder. Fold and place the cuff cover inside a washing bag. Wash the cuff cover with warm water (43°C; 110°F) and a mild detergent in the washing machine.

Pasteurization: wash the cuff cover in 75°C (167°F) hot water for 30 minutes.

Air dry the cuff. DO NOT iron the cuff cover

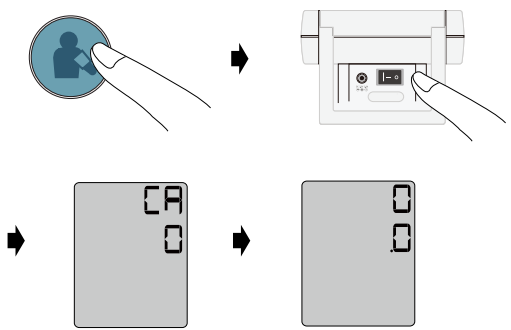


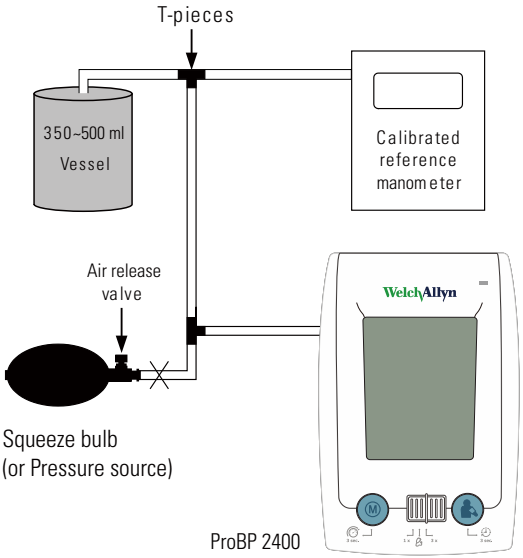
Do not iron the cuff!

Transducer accuracy test (Calibration Verification)

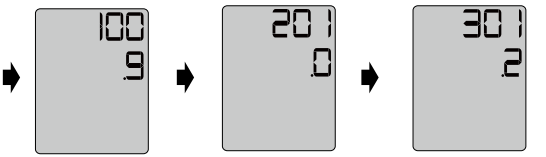
We recommend the device to be tested for accuracy every 2 years or after mechanical impact (e.g. been dropped).

1) Setup for accuracy test
2) Push and hold “Start/Stop” Button and turn the power on then release the “Start/Stop” Button. Wait until ““CA 0”, then “0 0“ is displayed.





3) Pump the pressure to nearly 100mmHg. Compare the pressure displayed on the screens of the device and the reference manometer. For example, the “100 .9” displayed on the device stands for “100.9 mmHg”.
4) Pump the pressure to nearly 200mmHg. Compare the pressure displayed on the screens of the device and the reference manometer. For example, the “201.0” displayed on the device stands for “201.0 mmHg”.
5) Pump the pressure to nearly 300mmHg. Compare the pressure displayed on the screens of the device and the reference manometer. For example, the “301.2” displayed on the device stands for “301.2 mmHg”.
6) If the difference between the device and the reference manometer at any calibration point exceeds ±3mmHg plus the stated accuracy of the reference manometer, you may contact Welch Allyn to obtain calibration service.



Disposal

Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, and not as domestic waste.

Technical specifications

Operation temperature/ humidity:	10 to 40 °C (50 to 104 °F)
Storage temperature/ humidity:	-20 to 55 °C (-4 to 131 °F) 15 - 90 % relative maximum humidity
Weight:	800 g (including rechargeable battery pack)
Dimensions:	200 x 125 x 90 mm
Measuring method:	Oscillometric, Systolic blood pressure = K1 Diastolic blood pressure = K5
Measurement range:	30 - 280 mmHg – blood pressure 40 - 200 beats per minute – pulse
Cuff pressure display:	Range: 0 - 299 mmHg Resolution: 1 mmHg Static accuracy: pressure within ± 3 mmHg Pulse accuracy: ±5 % of the readout value
Power source:	Rechargeable battery pack; 4.8V 2400 mAh (optional 4.8V 3500mAh) Mains power supply DC 7.5V, 1.5 A

Welch Allyn reserves the right to alter technical specifications without prior written notice.

Reference to Standards: Device corresponds to the requirements of the standard for non-invasive blood pressure monitor.
IEC 60601-1: 2005+A1:2012
IEC 60601-1-2: 2007/AC:2010
ANSI/AAMI/ISO 81060-2
ANSI/AAMI/ISO/IEC 80601-2-30

Electromagnetic Compatibility: Device fulfills the stipulations of the standard IEC 60601-1-2.

CE 0044 The stipulations of the EU Directive 93/42/EEC for Medical Devices Class IIa have been fulfilled.

Type BF applied part

ETL CLASSIFIED

Intertek 5000497

CONFORMS TO AAMI STD ES 60601-1, IEC STD. 60601-1-6, IEC STD. 80601-2-30

CERTIFIED TO CSA STD C22.2 NO. 60601-1, NO. 60601-1-6, NO. 80601-2-30

EC REP Microlife AG
Espenstrasse 139
9443 Widnau, Switzerland

Microlife Corporation
9F, 431, RuiGuang Road, NeiHu,
Taipei, 11492, Taiwan, R.O.C.

Annex of Report

Manufacturer's Declaration of the EUT

(altogether 5 pages)

Report No.: TRE14120020 A2 Issued: 2014-12-15

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer's declaration – electromagnetic emission		
2	The ProBP 2400 Digital Blood Pressure Device is intended for use in the electromagnetic environment specified below. The customer or the user of ProBP 2400 Digital Blood Pressure Device should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	The ProBP 2400 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.
5	RF emissions CISPR 11	Class B	The ProBP 2400 Digital Blood Pressure Device 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.
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The ProBP 2400 Digital Blood Pressure Device is intended for use in the electromagnetic environment specified below. The customer or the user of the ProBP 2400 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	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 IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ProBP 2400 Digital Blood Pressure Device requires continued operation during power mains interruptions, it is recommended that the ProBP 2400 Digital Blood Pressure Device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity

The ProBP 2400 Digital Blood Pressure Device is intended for use in the electromagnetic environment specified below. The customer or the user of the ProBP 2400 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
			Portable and mobile RF communications equipment should be used no closer to any part of the ProBP 2400 Digital Blood Pressure Device, 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 150 kHz to 80 MHz	3V	$d = [\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz 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 metres (m).[b] 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:

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

NOTE 2 These guidelines may not apply in all situations. Electromagnetic 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 ProBP 2400 Digital Blood Pressure Device is used exceeds the applicable RF compliance level above, the ProBP 2400 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 2400 Digital Blood Pressure Device .

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the ProBP 2400 Digital Blood Pressure Device

The ProBP 2400 Digital Blood Pressure Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ProBP 2400 Digital Blood Pressure Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ProBP 2400 Digital Blood Pressure Device as recommended below, according to the maximum output power of the communications equipment

	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Rated maximum output of transmitter W	$d = [\frac{3.5}{V_1}]\sqrt{P}$	$d = [\frac{3.5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$
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

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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.

WARRANTY

Welch Allyn will warranty the ProBP 2400 device to be free of defects in material and workmanship and to perform in accordance with manufacturer specifications for a period of two years from the date of purchase from Welch Allyn or its authorized distributors or agents. Accessories are covered for a period of one year from 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:

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.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WELCH ALLYN'S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. WELCH ALLYN IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY.

For the addresses and phone numbers of all Welch Allyn regional locations, visit: welchallyn.com/locations.

IB ProBP 2400 EN_FDA 1615