Blood Pressure Unit
User Guide

Blood Pressure Unit Quick Start

Before You Start

- Make sure you read and understand the Blood Pressure Unit User Guide.

Taking Your Blood Pressure

To begin, sit down, put on the blood pressure cuff, and press the **START/STOP** button. Your blood pressure (BP) is measured and displayed automatically.

1. Sit comfortably with your left forearm resting on a flat surface so that the center of your upper arm is at about the same height as your heart.
2. Loosen the blood pressure cuff so that you can slide the cuff over your arm. Place your hand into the cuff.
3. Slide the cuff up your forearm.
4. As you slide the cuff on, position the cuff so that the bottom of the cuff is on your upper arm and about one inch above the elbow crease; make sure that the air hose dangles on the inside of your arm.
5. Pull on the cuff end to tighten it. The cuff does not have to be pulled very tight. For comfort, you can leave room for one finger to fit under the cuff.
6. Fold the cuff end back over the metal D-ring, and fasten the cuff end to the Velcro® closure.
7. Press the **START/STOP** button. Sit still and do not move your arm during the measurement. If you want to stop the measurement at any time, press the START/STOP button. Wait 15 minutes before taking your blood pressure again.

8. A series of numbers and symbols appear in the display window. The cuff inflates and may feel tight. A long beep signals the end of the BP measurement and the cuff deflates. The display window shows your final BP measurement and pulse rate.

WARNING: As you watch the display, if you notice the pressure increase above 330 mmHg OR if the pressure decreases and remains at 15 mmHg for more than 3 minutes, press the **START/STOP** button to stop the measurement. The BP Unit is defective. Contact your Health Care Provider.

9. You can remove the cuff. The BP Unit has taken your blood pressure and pulse rate. The BP Unit turns off automatically.

Note: Do not store the BP Unit with the air hose twisted or wrapped tightly around the display.

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Note: All Agilent devices must be initially installed by an Agilent installer or responsible party. The installation information provided in this guide is for reference only.

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Introduction

Welcome to Agilent Technologies' Interactive Healthcare Services. Your Health Care Provider has enrolled you in a progressive program to measure, transmit, and review your vital signs on a daily basis. This program's approach will help you and your provider make better informed decisions about your care.

Your patient measurement set—which may include a Scale, Blood Pressure Unit, Rhythm Strip Recorder, and Home Hub—is designed to let you quickly and easily take your vital signs. The data you collect in a few minutes each day are automatically transferred via the Agilent Home Hub, using your existing phone line, to your Health Care Provider's computer system. The Home Hub is smart enough to know when you're not on the phone, and that's when it will make the data transfer. You do not need to do anything. Feel free to use the phone at any time. The Home Hub also recognizes if the connection was interrupted and will automatically re-transmit stored information later.

If any of the devices in your patient measurement set is not functioning properly, please advise your Health Care Provider and Agilent will repair or replace the device.

As a user of Interactive Healthcare Services, you are taking an active role in providing your Health Care Provider with accurate, relevant, and timely information—information we expect will go a long way toward improving your quality of life.

The Blood Pressure Unit User Guide explains how you can measure your blood pressure and pulse rate from the convenience and comfort of your own home. This guide provides you easy-to-understand information about operation and maintenance. Agilent and your Health Care Provider appreciate your efforts to actively participate in your home health care plan.

Precautions

- It is important that you use this Blood Pressure Unit (BP Unit) as directed by your Health Care Provider. This BP Unit is provided for **your personal use only**. Please do not allow others to use this BP Unit.

- Your Health Care Provider will tell you when and how often to take your blood pressure. Please follow your Health Care Provider's directions carefully. Report any change in the way you take your blood pressure (BP) to your Health Care Provider.

- Follow your physician's instructions regarding symptoms that require direct contact with your Health Care Provider. Keep in mind that use of this BP Unit is not a substitute for medical care. Only your Health Care Provider is qualified to interpret the results. If you have any questions regarding how to use your BP Unit, please contact your Health Care Provider.

- **Caution:** Avoid storing your BP Unit inside a metal container or drawer, such as a file cabinet.

- **Caution:** Do not attempt to service or repair the BP Unit yourself. If a mechanical problem occurs, contact your Health Care Provider for further instructions.

- **WARNING:** It is important for you to watch the display when taking your blood pressure measurement. If the numbers go up to 330 mmHg, press the **START/STOP** button to stop the measurement. The BP Unit is defective. Contact your Health Care Provider for further instructions.

Precautions

- **WARNING:** As you watch the display when taking your blood pressure measurement, if the BP numbers drop down to 15 mmHg and stay that way for more than 3 minutes, press the **START/STOP** button to stop the measurement. The BP Unit is defective. Contact your Health Care Provider for further instructions.

- If you received an error message, aborted the BP measurement while in progress, or feel that the reading might be in error, wait 15 minutes before taking your blood pressure again.

- **Caution:** Avoid storing the BP Unit where children or pets have access to it. There may be a risk of injury if children or pets get tangled in the air hose or if the cuff inflates.

- **WARNING:** Do not allow children to use this BP unit. This BP unit is intended for the patient only.

Blood Pressure Unit Symbols

Symbol Definitions


Type B Patient Applied Parts as defined in IEC 60601-1. Not suitable for direct cardiac application.


Attention: Consult accompanying documents.

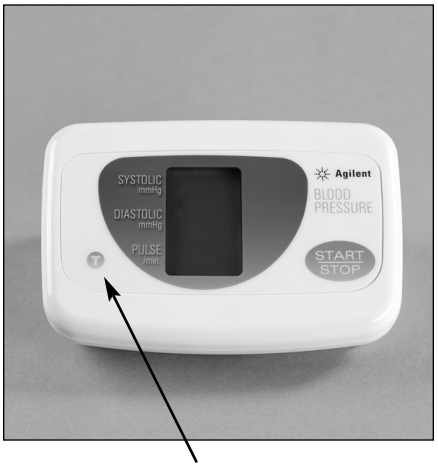

Complies with Canadian Standards Association.


Complies with Class B standard.

Blood Pressure Unit Components

The BP Unit is made up of the BP Unit and a cuff assembly. An air socket is on one side of the BP Unit. The cuff assembly has a cuff (with metal D-ring) and an air hose (with air connector).

The BP Unit face has a **START/STOP** button, a display window (for the BP and pulse measurement), and a Radio Test button.



Radio Test button

Blood Pressure Unit Components

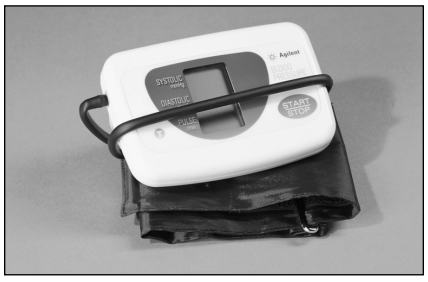
The BP Unit back has a battery compartment.

Battery compartment

Storage Between Uses

Store the BP Unit so that the hose is not bent. Do not wrap the hose around the BP display unit.

Right Way



Wrong Way

Installation

- Locate and store your BP Unit within 20 feet of the Home Hub. In addition to transmitting data when you take your blood pressure, your BP Unit sends periodic updates to the Home Hub.
- Hazards for children are packing materials that can be swallowed or plastic bags that can be pulled over the head. Discard and safely dispose of these materials immediately.
- **Caution:** Avoid storing the BP Unit where children or pets have access to it. There may be a risk of injury if children or pets get tangled in the air hose or if the cuff inflates.
- **Caution:** Avoid storing your BP Unit inside a metal container or drawer, such as a file cabinet.

Installation Setup

The measurements you take cannot be transmitted to your Health Care Provider until you install the Home Hub.

You must install the Home Hub before you set up the BP Unit. Refer to the Home Hub User Guide.

After you have performed the installation for the Home Hub, insert alkaline batteries into the BP Unit, perform the Radio Test, and prepare the cuff assembly. Then, you must return to the Home Hub User Guide and complete the connection steps.

WARNING: Do not allow children to use this BP unit. This BP unit is intended for the patient only.

It is important to take your blood pressure as instructed by your Health Care Provider. Your Health Care Provider may contact you if they do not receive blood pressure measurements as scheduled.

Installation

Inserting Four Type AA (1.5 Volt) Alkaline Batteries

Caution: Use alkaline batteries only. Replace all four batteries at the same time. Do not use rechargeable batteries. Always replace old batteries with four new batteries.

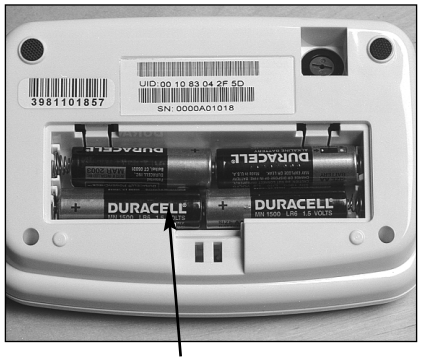
WARNING: Do not use this equipment with the battery door removed.

1. Remove the battery compartment cover on the back of the BP Unit by gently lifting up the tab marked with the arrow symbol and popping the cover off.

Arrow symbol

Installation

2. Place the batteries in the compartment with the positive (+) and negative (-) terminals matching those shown in the compartment. To prevent the batteries from popping out, insert the batteries in the bottom row first. Make sure that the battery terminals make contact with the compartment terminals.



Bottom row

3. Replace the cover by inserting its tabs into the slots of the compartment and gently pressing the cover into place.

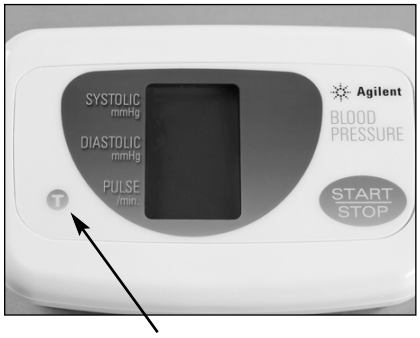
4. Perform a Radio Test as described in the next section.

Installation

Performing a Radio Test

Perform a Radio Test when you set up the BP Unit, change batteries, or change the testing location.

1. The Radio Test button appears as a circle with a "**T**" inside it on the lower left of the display (for SYSTOLIC, DIASTOLIC, PULSE) on the front of the BP Unit. Press and hold the Radio Test button for at least 3 to 5 seconds until the Home Hub starts beeping (at a rate of one beep per second).



Radio Test button

Note: If the Home Hub's **using phone** light turns on while performing the Radio Test, stop and wait until the **using phone** light turns off before resuming the Radio Test.

2. If the Home Hub does not beep, determine if there are any obstacles (such as large metal objects) between the BP Unit and the Home Hub.

Installation

3. If obstacles are present, move the BP Unit so that no obstacles are between the BP Unit and the Home Hub. If no obstacles are present, move the BP Unit closer to the Home Hub.

4. Press and hold the Radio Test button until the Home Hub beeps. If the Home Hub does not beep within 5 seconds, contact your Health Care Provider.

   Note: If you accidentally press the Radio Test button, it is OK.

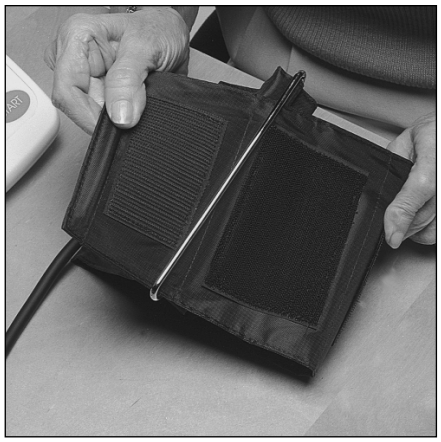
If you are performing the Radio Test for the first time, stop now and return to the Home Hub User Guide, and then complete the steps to connect the Home Hub. Otherwise, you can begin using your BP Unit as usual.

Preparing the Cuff Assembly

1. Insert the air connector at the end of the air hose into the socket on the side of the BP Unit. Gently rotate the air connector as you insert it into the socket. You should feel the air connector snap into place.

Installation

2. If the cuff has not been threaded through the metal D-ring, thread the cuff end through now. Then, fold the cuff end back over the D-ring so that the end fastens to the Velcro® closures.



The BP Unit is now ready for use.

How to Take Your Blood Pressure

To begin, sit down, put on the BP cuff, and press the **START/STOP** button. Your blood pressure is measured and displayed automatically.

Caution: Do not talk or move during the measurement.

Before you take your BP measurement, do the following:

- Sit within 20 feet of the Home Hub.
- Relax for about 15 minutes.
- Remove restrictive clothing or roll up a loose garment sleeve. You will be placing the cuff on your bare upper arm.
- Use the left arm for the BP measurement unless instructed otherwise by your Health Care Provider.

How to Take Your Blood Pressure

Taking Your Blood Pressure

1. Sit comfortably with your left forearm resting on a flat surface so that the center of your upper arm is at about the same height as your heart.

Note: If you desire, you may lie down while someone else takes your blood pressure.

It is important to be consistent in the way you take your blood pressure (either sitting or lying down). Report any changes in how you take your blood pressure to your Health Care Provider immediately.

How to Take Your Blood Pressure

2. Place your hand into the cuff.

3. Slide the cuff up your forearm.

How to Take Your Blood Pressure

4. As you slide the cuff on, position the cuff so that it is on your upper arm and the bottom of the cuff is about 1 inch above the elbow crease; make sure that the air hose dangles on the inside of your arm.

WARNING: Do not allow the air hose to kink or twist while you are taking your blood pressure.

5. Pull on the cuff end to tighten it, and fold the cuff end back over the metal D-ring.

How to Take Your Blood Pressure

Note: The cuff should be snug but not tight. For comfort, you can leave room for one finger to fit under the cuff.

6. Fasten the cuff end to the Velcro® closure.

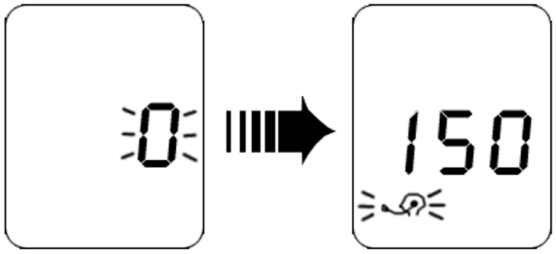
7. Make sure that your hand is open, relaxed, and palm up.

How to Take Your Blood Pressure

8. Press the **START/STOP** button. Sit still and do not move your arm during the measurement.

Note: If you want to stop the measurement at any time, press the **START/STOP** button. Wait 15 minutes before taking your blood pressure again.

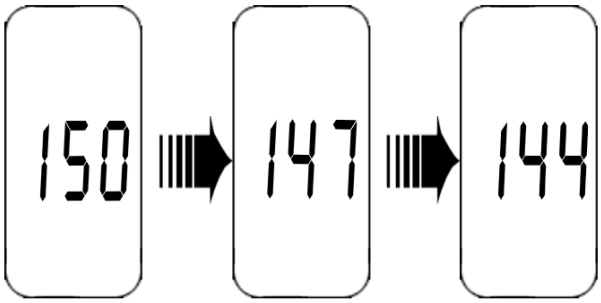
9. Watch the display window. A series of numbers and symbols will appear in the display window. The cuff inflates and may feel tight. The BP Unit displays pressure numbers that change and increase to just beyond 150 mmHg.



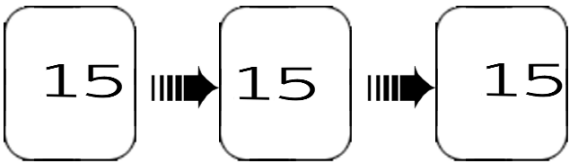
How to Take Your Blood Pressure

WARNING: It is important for you to watch the display. If the numbers go up to 330 mmHG, press the **START/STOP** button to stop the measurement. The BP Unit is defective. Contact your Health Care Provider for further instructions.

10. As the cuff pressure automatically decreases, watch the display screen. The BP Unit emits a series of beeps while the pressure decreases.



WARNING: As you watch the display, if the BP numbers drop down to 15 mmHg and stay that way for more than 3 minutes, press the **START/STOP** button to stop the measurement. The BP Unit is defective. Contact your Health Care Provider for further instructions.



How to Take Your Blood Pressure

11. A long beep signals the end of the BP measurement and the cuff deflates. The display window shows your final BP measurement and pulse rate.

Note: If you received an error message, stopped the BP measurement while in progress, or feel that the reading might be in error, wait 15 minutes before taking your blood pressure again.

12. You can remove the cuff. The BP Unit has taken your blood pressure and pulse rate. The BP Unit turns off automatically.

Note: Do not store the BP Unit with the air hose twisted or wrapped tightly around the display.

What Display Symbols Mean

DISPLAY SYMBOLS	EXPLANATION
	Appears during the blood pressure measurement; blinks and beeps with each detected pulse beat
	Appears when the batteries need to be replaced; also appears briefly at the start of your blood pressure measurement
 or  or 	When an error message appears, check your equipment, wait 15 minutes and retake your blood pressure before contacting your Health Care Provider. You may be able to troubleshoot these error messages as described later in the Troubleshooting section.

Maintenance

Replace the batteries when instructed to by your Health Care Provider or when you see the Low Battery symbol on the BP Unit display.

Caution: Avoid exposing the BP Unit to extremes in temperature, humidity, direct sunlight, shock, dust, spills, or standing water.

Clean the BP Unit only as required. Clean the BP Unit with a dry, soft cloth or a soft cloth dampened with tap water and mild detergent, if desired. Never use alcohol, acetone, benzene, thinner, or other harsh chemicals to clean the BP Unit, cuff, or air hose.

Caution: Avoid storing the BP Unit so that the cuff assembly is twisted or folded tightly.

Caution: Avoid tugging at the air hose or carrying the BP Unit by the air hose.

Caution: Avoid storing the BP Unit where children or pets have access to it. There may be a risk of injury if children or pets get tangled in the air hose or if the cuff inflates.

Troubleshooting

The only user-serviceable parts are the batteries.

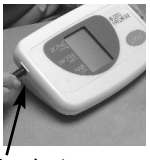
Caution: Do not attempt to service or repair the BP Unit yourself. If a mechanical problem occurs, contact your Health Care Provider for further instructions.

When an error message appears, check your equipment and retake your blood pressure before contacting your Health Care Provider. Remember to relax for 15 minutes before taking your BP again.

You may be able to perform minor troubleshooting when error messages appear on the display.

DISPLAY SYMBOL	CONDITION/CAUSE	CORRECTIVE ACTION
	Appears when the systolic and diastolic measurements are within 10 mmHg of each other	Check for air leakage; check that the air hose is properly connected by unplugging it and firmly replugging it in.
	Appears if the pressure value is unstable due to movement during reading	Wait 15 minutes, and then take your blood pressure again **BUT** remain very still.

Troubleshooting

DISPLAY SYMBOL	CONDITION/CAUSE	CORRECTIVE ACTION
Err 3	Appears if the pressure value did not increase during cuff inflation or if the cuff is not fastened	Check that the air hose is properly connected by unplugging it and firmly replugging it in. Make sure the cuff is securely fastened.
Err 3  Socket	Appears if the air connector of the air hose is not inserted properly into the BP Unit socket	Refer to step 1 of Preparing the Cuff Assembly. Check that the air hose is properly connected by unplugging it and firmly replugging it in.
 LOW BATTERY	Appears when the battery voltage is too low for the BP Unit to work properly	Replace all four batteries immediately and perform a Radio Test.

If you are unable to troubleshoot these error messages by following these corrective actions, contact your Health Care Provider for further instructions.

If your BP Unit is defective or no longer necessary, please contact your Health Care Provider.

Specifications

Model	M3815A
Type	• Oscillometric •  Type B Patient Applied Part • IPXO Ordinary Equipment • Continuous operation
Display	• Digital, 16 mm character height • Pressure/pulse displayed simultaneously
Measurement range	• Pressure: 20 to 280 mmHg • Pulse: 40 to 200 pulses per minute
Accuracy	• Pressure; ±4 mmHg or 2%, whichever is greater • Pulse ±6%
Pressurization	Automatic, using micropump
Depressurization	Constant-air release-valve system
Deflation	Automatic exhaust
Power source	Four type AA (1.5 volt) alkaline batteries connected in series (6.0 volts), included
Battery Life	Approximately 6 months with 1 daily measurement

Specifications

Operating environment	• 50º to 104º F (10º - 40º C) • Less than 85% relative humidity • Atmospheric altitude pressure 5.72 - 1013 hPa (0 - 15,000 feet or 0 - 4,600 meters of altitude) • **WARNING:** This equipment is not suitable for use in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
Storage environment	• 15º to 130º F (-9º - 54º C) • Less than 85% relative humidity • Atmospheric pressure 572 - 1013 hPa (0 - 15,000 feet or 0 - 4,600 meters of altitude)
Dimensions (approx.)	• Length: 6.5” (165 mm) • Width: 4.4” (112 mm) • Height: 2.7” (69 mm)
Weight (approx.)	1 lb., 4 oz. (570 gms) with batteries

Electromagnetic Compatibility

The electromagnetic compatibility (EMC) validation of the M3815A Blood Pressure Unit included testing performed according to the international standard for EMC with medical devices. See the Manufacturer's Declaration for details.

Electromagnetic Compatibility Testing

During the test program, the BP Unit was subjected to many EMC tests, including both international standard and Agilent proprietary tests. During most of the testing, no anomalies were observed.

For one of the tests, EN 61000-4-3 Radiated Immunity reduced performance was observed. EN 61000-4-3 specifies that the product be subjected to a field of 3 Volts/meter over a frequency range of 26 to 1000 MHz with no degradation of performance or loss of function below the performance level specified when equipment is operated as intended. At many of the test frequencies over the specified range, no anomalies were observed. However, at a number of test frequencies, radio communications from the BP Unit to the M3812A Home Hub was disrupted. These reduced levels are as low as 0.48 V/m in the range from 902.278 MHz to 948.302 MHz.

The phenomena discussed above are not unique to this BP Unit, but are characteristic of radio instrumentation in use today. The Home Hub is a radio receiver, and its reception of M3815A BP Unit signals can be degraded by electromagnetic interference.

Electromagnetic Compatibility

Avoiding Electromagnetic Interference Problems

Eliminating or moving the source of interference can prevent electromagnetic interference. Possible sources of interfering radio frequency radiation are cellular telephones, cordless telephones, or other products that contain radio transmitters. The BP Unit has a Radio Test button that sends a reduced strength test radio signal to the Home Hub, which sounds an audio tone if the test signal is successfully received. This test can be used to determine whether sources of interference are present. These sources can be turned off or moved away to reduce their strength and reduce interference. In addition, the BP Unit and the Home Hub can be placed closer to each other so that the radio transmission from the BP Unit to the Home Hub has less distance to travel and interfering radio signals have less effect. The radio transmission from the BP Unit is repeated periodically so that an intermittent source of interference should only delay, not prevent, reception.

FCC Regulations

This equipment 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. If it is not installed and used in accordance with the instructions, it might 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 or more of the following measures:

- Re-orient or relocate the Home Hub.
- Increase separation between the measurement devices or the Home Hub and the device being interfered with; e.g., the television.
- Consult your Health Care Provider.

Note: Any changes or modifications to the equipment that are not expressly approved by Agilent could void the user's authority to operate this equipment.

Conclusion

Agilent and your Health Care Provider appreciate your efforts to participate in your home health care plan. By learning about and using the Blood Pressure Unit as directed, you actively participate in your Health Care Provider's plan to keep track of your important measurements.

If you have any problems or questions, please contact your Health Care Provider.

If desired, place Health Care Provider information label here.