

7.0 *Instruction Manual*

Attached is a draft instruction manual for the device. Note the required FCC warning information on the second to last page.

♥
**USER
GUIDE**
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HP© Home Blood Pressure Unit

Model M3815

Professional-quality instruments for home health care

♥NOTICE

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WARNING!: Failure on the part of the responsible Health Care Provider prescribing the use of this equipment to implement satisfactory training for installation, use, and maintenance may cause undue equipment failure and possible health hazards.

♥INTRODUCTION

Welcome to Hewlett-Packard's© line of professional-quality instruments for home health care. HP© and your Health Care Provider have joined together to provide medical monitoring instruments that allow you to take your vital statistics from the convenience and comfort of your own home.

In less than a minute, the HP Home Blood Pressure Unit measures and displays your blood pressure and pulse rate. Then the BP Unit transmits the blood pressure (BP) measurement to your Health Care Provider, who records and interprets your vital statistics.

Your Health Care Provider will assist you in learning how to install, operate, and maintain your BP Unit. Afterwards, please refer to this guide when using the BP Unit.

Take your blood pressure daily or as instructed by the Health Care Provider.

©PRECAUTIONS

- Use this BP Unit only as directed by your Health Care Provider. Use of this medical instrument is not a substitute for medical care. Only your Health Care Provider is qualified to interpret the results.
- If you feel unwell, contact your Health Care Provider or call 911.
- Because this BP Unit is intended for your personal medical history, please do not allow others to use this unit.
- Do not attempt to service or repair the BP Unit yourself. If a mechanical problem occurs, contact your Health Care Provider and replace the BP unit, as required.
- Avoid exposing the BP unit to extremes in temperature, humidity, direct sunlight, shock, and dust
- Clean the BP Unit with a dry, soft cloth or a cloth dampened with tap water and mild detergent, if desired. **Never use alcohol, benzene, thinner, or other harsh chemicals** to clean the BP Unit.
- Avoid storing the cuff or hose tightly folded or twisted.

©BP UNIT COMPONENTS

The BP Unit is made up of a monitor and a cuff assembly. The monitor face has a START button, a display window, and a Radio Test button. The monitor back has a battery compartment and an adjustment screw. An air socket is on one side of the monitor. The cuff assembly has a cuff and an air hose with air connector.

©BEFORE YOU START

The only setup required is to insert alkaline batteries, perform the Radio Test, and prepare the cuff assembly. Upon each installation of batteries, you must perform the Radio Test (as described on page 4).

Insert four type AA (1.5 volt) alkaline batteries

CAUTION: Use alkaline batteries only. Replace all four batteries at the same time. Do not replace them individually. Always follow instructions on the battery package when handling batteries.

1. Remove the battery compartment cover on the back of the monitor by gently pushing down on the arrow symbol (Δ) and popping the cover off.
2. Place the batteries in the compartment with the positive (+) and negative (-) terminals matching those shown in the compartment. Be sure that the battery terminals make contact with the compartment terminals.
3. Replace the cover by sliding it into the compartment and gently pressing it into place.

Perform a Radio Test

Perform a Radio Test when you change batteries or change the testing location.

1. The Radio Test button appears as a shadowy dot to the left of the STANDSTILL and STEP OFF lights on the front of the BP Unit's monitor. Press and hold the Radio Test button for at least two seconds until the Hub starts beeping (at a rate of one beep per second). The display shows **rF**.
 - a. If the Hub does not beep, determine if there are any obstacles (such as large metal objects) between the BP Unit and the Hub.
 - b. If no obstacles are present, move the BP Unit closer to the Hub.
 - c. Press the Radio Test button again. If the Hub beeps, the BP Unit is operating properly. If the Hub does not beep, replace the BP Unit as instructed by your Health Care Provider.

NOTE: If you accidentally press the Radio Test button, there are no negative results.

Prepare the cuff assembly

1. Insert the air connector at the end of the cuff hose into the air socket on the side of the monitor. Gently rotate the connector as you insert it into the socket; the connector snaps into place.
2. If the cuff has not been threaded through the metal ring, thread the cuff end through now. Then fold the cuff end back over the ring so that the end fastens to the VELCRO® closures.



NOTE: If you require a Small or Large cuff, you must perform an adjustment to the exhaust rate, as described on page 21 in TROUBLESHOOTING.

The Home Blood Pressure Unit is now ready for use!

©WHAT DISPLAY SYMBOLS MEAN

While using the BP Unit, you will see symbols and numbers appear in the display window.

Display Symbol	Explanation
	Appears during the BP measurement; blinks and beeps with each detected pulse beat
	Appears when the batteries need to be replaced
	NOTE: When an ERROR message appears, check your equipment and retake your BP before contacting your Health Care Provider. You may

	<p>be able to troubleshoot these ERROR messages as described in TROUBLESHOOTING.</p>
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♥HOW TO TAKE BLOOD PRESSURE

Before you take your BP measurement, do the following:

- Sit within 20 feet of the Hub.
- Relax for about 15 minutes.
- Remove restrictive clothing or roll up a loose garment sleeve.
- Use the left arm for the measurement unless instructed otherwise by your Health Care Provider.
- Do not eat, drink, smoke, or talk during the measurement.



Take 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. If desired, you may lie down while someone else takes your BP measurement.



2. Loosen the cuff so that you can slide the cuff over your arm.



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



4. Pull on the cuff end to tighten it, fold the cuff end back over the metal ring, and fasten the cuff end to the Velcro® closure.



NOTE: The cuff does not have to be pulled very tight. For comfort, you can leave room for two fingers to fit under the cuff.

5. Press the START button.



6. The monitor emits a long beep and displays the Measurement In Progress symbol, as well as large ZERO numbers.

7. The monitor displays a blank ZERO and emits three short beeps. The cuff begins inflating. The Measurement In Progress symbol disappears. The monitor displays diastolic numbers that change and increase up to 150 mmHg.

NOTE: If you wish to stop inflation at any time, press the START button again.

(*I noticed that the measurement went over 150 – do we need to mention this number?)

8. The Measurement In Progress symbol appears in the display window, and the monitor beeps at every detected pulse beat. As cuff pressure automatically decreases, the monitor displays diastolic numbers that decline as your BP measurement is being taken.

9. As the cuff pressure automatically decreases, watch the display screen. Notice that the diastolic numbers decline in increments of two to five mmHg. The increment is called the exhaust rate. The monitor emits a series of beeps while the diastolic pressure decreases.

NOTE: You may need to use the exhaust rate to troubleshoot Error messages or when you change cuff size.

10. A long beep signals the end of the BP measurement and the cuff deflates. The Measurement In Progress symbol disappears. The display window shows your final BP measurement and pulse rate.

NOTE: If you detected 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.

HINT: After you take the first BP measurement, just slide the cuff off of your arm. Next time, you will not need to adjust the cuff – just slide it back on your arm and begin the BP measurement!

♥ MAINTENANCE

Store the BP Unit so that the cuff assembly is not twisted or folded tightly.

Replace the batteries when instructed by your Health Care Provider.

NOTE: 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 measurements as scheduled.

TROUBLESHOOTING

You may be able to perform minor troubleshooting when ERROR messages appear on the display. Here are some causes and corrective actions:

Display Symbol	Condition/Cause	Corrective Action
	Appears when the systolic and diastolic measurements are within 10 mmHg of each other	Check for air leakage; make sure the cuff hose is properly connected to the monitor and that the exhaust rate is between two and five mmHg.
<p style="text-align: center;">WARNING!: If you check for air leakage and retake the BP measurement, and the measurement is still so low that it registers this ERROR 1 message – you may have a medical emergency.</p> <p>You may want to verify the reading with a conventional BP monitor. Handle as instructed by your Health Care Provider.</p>		
	Appears if the pressure value is unstable due to movement during reading	Take your blood pressure again and remain very still.

	<p>Appears if the pressure value did not increase during cuff inflation, the cuff is not fastened, incorrect air connector is used, or the air connector is not inserted into the correct ends of the hose and monitor</p>	<p>Make sure the cuff hose is properly connected to the monitor, the cuff is securely fastened, and the exhaust rate is between two and five mmHg. Check for the correct air connector. Make sure that the air connector is inserted into the hose and monitor.</p>
	<p>Appears when the battery voltage is too low for the monitor to work properly</p>	<p>Normally, your Health Care Provider notifies you that batteries need to be replaced. However, if you see a Low Battery symbol, replace batteries immediately and perform a Radio Test.</p>

If you are unable to troubleshoot the ERROR messages by following these corrective actions, replace the BP Unit as instructed by your Health Care Provider.

NOTE: If you do not take a daily BP measurement, your Health Care Provider may contact you to determine why.

Replace Cuff and Adjust Cuff Velocity

If you replace a standard cuff with a Small or Large cuff, you must check and adjust the cuff velocity.

Replace the cuff and adjust the cuff velocity as follows:

1. Install the new cuff and take a blood pressure reading. If the exhaust rate is not between two and five mmHg, turn off the BP unit and continue with the following steps. If the exhaust rate is within the range, do nothing.

NOTE: Refer to step 9 of How To Take Blood Pressure for information on the exhaust rate.

2. Locate the adjustment screw cover on the back, upper right-hand corner of the monitor. Use the end of a large, straightened paperclip to pry off the black-circle cover of the adjustment screw.

NOTE: This cover is very thin. Do not push the paperclip end in very far. Push the end in just enough to pry off the cover.

3. With a small Flathead screwdriver, rotate the adjustment screw about 1/8 turn clockwise to raise the exhaust rate; or turn the screw counterclockwise to lower the rate.

4. Take another BP measurement, and continue adjusting the screw until the exhaust rate is between two and five mmHg.

5. Replace the adjustment screw cover.

Further adjustments are not required unless you change the cuff again.

♥SPECIFICATIONS

Model	M3815A
Type	Oscillometric
Display	Digital, 16 mm character height Pressure/pulse displayed simultaneously
Measurement range	Pressure: 10 to 280 mmHg Pulse: 40 to 200 pulses per minute
Accuracy	Pressure : ±3 mmHg or 2%, whichever is greater Pulse: ±5%
Pressurization	Automatic, using micropump
Depressurization	Constant-air release-valve system
Deflation	Automatic exhaust
Power source	Four type AA (1.5 volt) alkaline batteries (not included)
Battery life	Approximately 4 months with only 1 daily measurement
Operating environment	50° to 104°F (-10° to 60°C) Less than 85% relative humidity
Storage environment	14° to 140° F (-10° to 60°C) Less than 95% relative humidity
Dimension (approx.)	Length: 6.5" (163.7 mm) Width: 4.4" (111 mm) Height: 2.7" (66.7 mm)
Weight (approx.)	15.65 oz. (<500 g) without batteries

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:

- Reorient or relocate the receiving antenna.
- Increase separation between equipment and receiver.
- Connect equipment to an outlet on a circuit different from that to which the receiver is located.
- Consult your reseller or an experienced radio/TV technician.

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

♥CONCLUSION

HP and your Health Care Provider appreciate your efforts to participate in your home health care plan. By learning about and using the HP Home Blood Pressure Unit as directed, you actively participate in your Health Care Provider's plan to monitor your vital statistics.

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

Place Health Care Provider label here



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