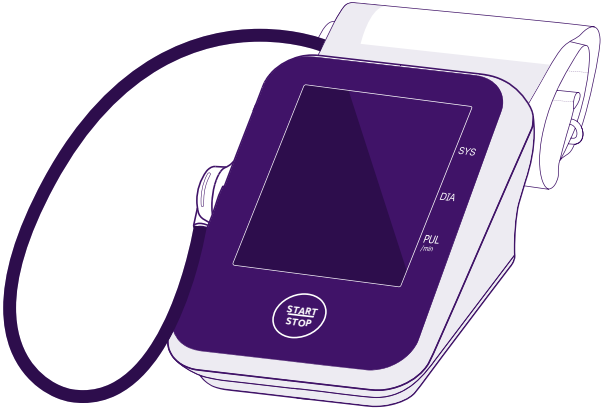
HT945 Connected Blood Pressure Monitor User Guide

Teladoc® HEALTH



Contents

Welcome!

This new approach to managing high blood pressure makes it easy to improve your lifestyle choices. It comes with a connected blood pressure monitor and arm cuff, as well as anytime access to expert coaches, personalized insights, reports and much more.

If you have any questions, please call Member Support at **(800) 945-4355** or email us at **membersupport@teladochealth.com**.

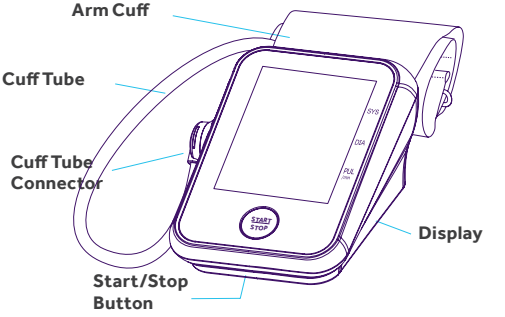
We're available 24 hours a day, 7 days a week.

Getting Started

Open the Teladoc Health app and log in. If you don't have the app yet, download it from the iOS App Store or Google Play Store.

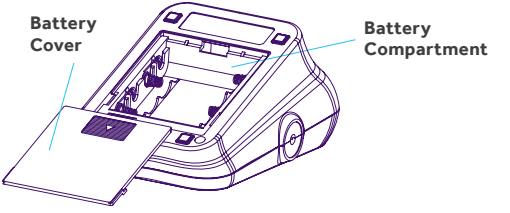
Open the app to get started with your connected blood pressure monitor. Follow the steps for setup and review the instructions on the following pages.

Components of the Device

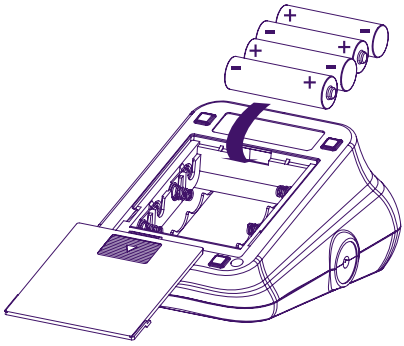


Component list of pressure measuring system:

- Cuff
- Air pipe
- PCBA
- Pump
- Valve



Installing the Batteries



If this is your first time using the device:

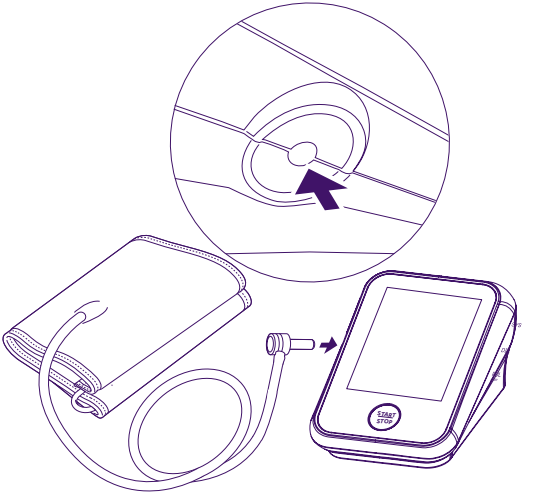
1. Slide open the battery door on the back of the device.
2. Install the batteries provided with the device.
3. Follow the diagram inside the battery compartment for correct polarity — the springs should align with the negative sign (-) on the batteries.
4. Slide the battery door closed.

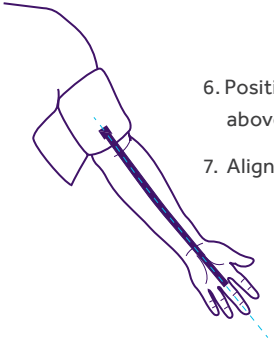
Caution:

- Do not insert the battery with the polarities (+/-) in the wrong direction.
- Use only 4 AA alkaline batteries with this device.
- Do not use other types of batteries. Do not use new and used batteries together.
- Remove the batteries if the device will not be used for three months or more.
- Do not dispose of batteries in fire. Batteries may explode or leak.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.
- Dispose of the old batteries from the device following your local recycling guidelines.
- If battery fluid should get on your skin or clothing, immediately rinse with plenty of clean water.

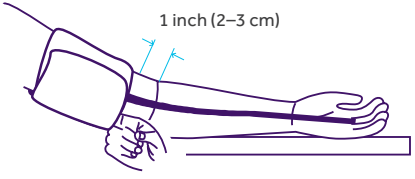
Securing the Cuff

1. Plug the connector on cuff tube into the device.
2. Expose your left upper arm by removing or adjusting clothing and jewelry. Make sure blood flow is not constricted by a rolled-up sleeve.
3. Open the cuff and loosen fully.
4. Orient the cuff so that the tube exits toward your hand.
5. Place your arm through the cuff loop, with your palm facing up.





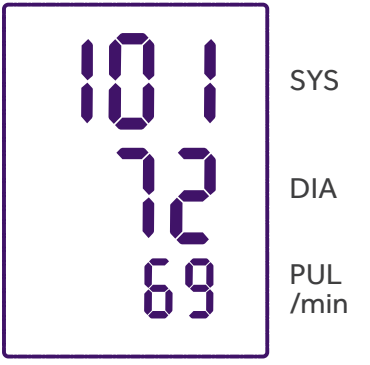
6. Position the cuff's edge about an inch (2–3 cm) above the elbow.
7. Align the tube with the center of your arm.



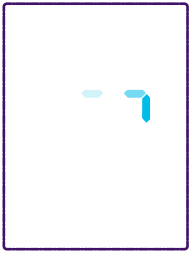
8. Tighten the cuff evenly around your arm by pulling on the end — make sure the tube stays aligned with the center of your arm.
9. Wrap the end of the cuff over your arm to secure it in place. Don't make it too tight — allow a finger to fit between the cuff and your arm.

Taking a Measurement

1. Rest for at least 5 minutes and avoid exercise and caffeine for at least 30 minutes before you take a reading. Lay your arm on a table with your palm facing up. The cuff should be at the same height as your heart. Sit up straight and rest your feet flat on the ground. Make sure the tube is not kinked or pinched.
2. Press the START/STOP button on the device to turn it on.
3. Wait for the device to power on, and perform the measurement while the cuff inflates. Try not to speak or move during this time.
4. When the measurement concludes, results are shown on the display, and the cuff automatically deflates.
5. Remove the cuff after it deflates.



6. The device automatically transmits measurement results. During this process an indicator is shown in the middle of the display.



Transmission in progress

Transmission successful

7. When the measurement is successfully transmitted, the device shows the above right indication before powering off.

Notes:

- If you wish to abort the measurement while the cuff is inflating, press and hold the START/STOP button for 5 seconds.
- If the device detects an irregular heartbeat, the display will show this indicator along with the measurement results. While this may not be a reason for immediate concern, contact your primary care provider if you see this symbol frequently.
- The first-time setup in a new location could take 1 to 5 minutes to locate cellular tower connectivity.
- This device measures blood pressure using the oscillometric method. Before each measurement, the device establishes a zero point based on the atmospheric pressure. The cuff is then inflated, and the device measures the oscillations in pressure created by the user's heartbeat.

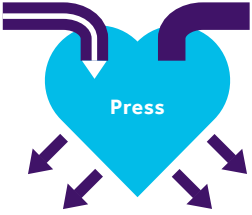
Contraindications

- Consult a medical professional before using this device if you have an implanted cardiac device, such as a pacemaker or defibrillator.
- Consult a medical professional before using this device during pregnancy.
- Do not use this device on infants.

Systolic and Diastolic Blood Pressure

When ventricles (the part of the heart that pumps blood) contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.

Systolic



Blood is pumped out through arteries

Diastolic

Blood enters via veins

Standard Blood Pressure Classification

The chart below is the standard blood pressure classification published by the American Heart Association (AHA). If you have been diagnosed with high blood pressure (hypertension), the AHA recommends keeping your blood pressure below 130/80 mmHg.

Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal	Less than 120	and	Less than 80
Elevated	120–129	and	Less than 80
High Blood Pressure (Hypertension) Stage 1	130–139	or	80–89
High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher
Hypertensive Crisis (Consult your doctor immediately)	Higher than 180	and/or	Higher than 120

Caution: Please consult a physician if your blood pressure measurement falls outside the suggested range of below 130/80 mmHg.

Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, the monitor records all the pulse intervals and calculates the average:

- If there are two or more pulse intervals, and the difference between each interval and the average is more than the average value of ±25%; OR
- If there are four or more pulse intervals, and the difference between each interval and the average is more than the average value of ±15%;

In such cases, the irregular heartbeat symbol appears on the display when the measurement results appear.

Caution: The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination but serves to detect pulse irregularities at an early stage.

Precautions

- Only use alkaline AA batteries with this device, as these offer the longest battery life. Other types may not be able to provide sufficient power for cellular data transmission.
- Only use a cuff that has been approved by the manufacturer for this device model.
- This device is for adults. Do not use it on children unless otherwise instructed by a medical professional.
- Keep the device, cuff and batteries away from children, as their components may pose a risk of choking or strangulation if used improperly.
- Do not apply the cuff on an arm that has: an unhealed wound, another medical device attached, or an intravenous drip or a blood transfusion attached.
- The accuracy of this device has not been specifically validated for use:
    - during pregnancy.
    - on users with an implanted cardiac device, such as a pacemaker or defibrillator.
    - on users with premature ventricular beats, atrial fibrillation or peripheral arterial disease.
    - on users undergoing intravascular therapy or with arteriovenous (AV) shunt.

  Consult a medical professional before use.
- Do not use this device if you have pre-eclampsia or if you have undergone a mastectomy.
- Do not use this device with high-frequency (HF) surgical equipment.
- Do not use this device if you are allergic to polyester, nylon or plastic.

- This device is intended for indoor, home use. This device is not intended for public use.
- If in doubt, contact your medical professional before use.
- The device may require up to 30 minutes to warm up/cool down from the minimum/maximum storage temperature before it is ready for use.
- Do not use the device where flammable gases are present or in environments with high oxygen concentration.
- Measurements may not be accurate if the device is used in close proximity to devices generating strong electromagnetic fields, such as microwave ovens, wireless charging stations, X-ray machines, etc.
- Wireless communication devices, such as Wi-Fi access points, mobile phones and cordless phones may cause interference that may affect the accuracy of measurements. A minimum distance of 1 ft (30 cm) should be kept from such devices during measurement.
- The device is not intended for use on extremities other than the arm or for any purpose other than measuring blood pressure and pulse rate.
- Do not confuse self-monitoring with self-diagnosis.
- This device allows you to monitor blood pressure.
- Do not begin or alter medical treatment without consulting a medical professional.
- Do not take frequent, consecutive measurements, as these may constrict blood flow and lead to injury.
- This unit is not suitable for continuous monitoring during medical emergencies or operations.

- This device is not anesthesia proofed (AP/APG), and it is not suitable for use in the presence of flammable anesthetics.
- Do not touch the batteries during measurement.
- This device is portable but should not be operated in transit.
- You can use this device to take your own measurement; no third-party operator is required.
- In rare occasions, the device may remain inflated after a measurement. If this occurs, make sure to disconnect the tube from the device to release pressure. Prolonged pressurization of the cuff may lead to ecchymosis or other injury.
- Do not kink, fold, stretch, compress or otherwise deform the tube during measurement as it may lead to an inaccurate result or excessive inflation of the cuff, which may cause injury.
- Accuracy of pressure measurement (at 50 and 200 mmHg) and the rate of air leakage from the system should be checked after repair, maintenance and every two years of use.
- The device must only be serviced and repaired by authorized service personnel.
- At the request of authorized service personnel, circuit diagrams, component part lists, descriptions and calibration procedures will be made available by the manufacturer or distributor.
- Do not use the device while under maintenance or being serviced.
- Dispose of the device, its accessories and batteries according to your local waste disposal regulations and guidelines.

Troubleshooting

Problem	Possible Reason	Resolution
Device doesn't power on when START/STOP button is pressed. or Cuff does not inflate. (display remains off)	Batteries completely drained.	Replace all batteries with new ones.
	Batteries inserted incorrectly.	Remove batteries and reinstall them, making sure the + and - polarity symbols on the batteries match those inside the battery compartment.
Cuff does not inflate. (display turns on)	Cuff not plugged in correctly.	Make sure the connector on cuff tube is plugged all the way into the device.
Cuff doesn't form a loop around arm.	Cuff not assembled.	To form a loop: Pass the end of the cuff farthest away from the tubing through the long metal D-ring. The smooth side (without the hook and loop fasteners) should be on the inside of the cuff loop.

Problem	Possible Reason	Resolution
Readings too high or low. or Readings vary significantly between measurements.	Cuff not positioned correctly.	Review instructions on Securing the Cuff, and then retry measurement.
	Movement during measurement.	Place your arm on a table with your palm facing up. The cuff should be at the same level as your heart. Make sure you stay still and don't talk during measurement.
Measurement results differ from those measured at doctor's office.	Measurements taken in a medical/ professional environment (white coat effect) may affect your blood pressure.	Measurements taken in a more relaxed, home environment may avoid effects experienced in clinical settings. Continue taking readings as usual. If in doubt, contact a medical professional.
Error code shown after measurement.	Measurement accuracy may be affected or transmission may have been unsuccessful.	Consult the Error Codes table on pages 20–21 for more information and further instructions.

Error Codes

Code	Description	Resolution
Er 1	Battery low	Replace all batteries with new ones.
Er 2	Movement detected	Avoid moving or talking while taking a measurement. After securing the cuff and assuming the correct posture, consider waiting for 5 minutes to settle down before starting a measurement.
Er 3	Measurement out of range	If systolic blood pressure <60 mmHg or >230 mmHg or diastolic blood pressure <30 mmHg or >130 mmHg is detected, the device will indicate a measurement error showing Er 3 on the display. Configuration of this alarm condition does not change after replacing the batteries. Alarm Priority: Low, Display delay: 10ms, Operator's position: 11.81 in (30 cm) to 39.37 in (1 m) from the display.
Er 4	No cellular coverage	Move to another area, closer to a window. Use the device at a location where you get a strong cellular signal with your mobile phone.
Er 5	Cellular connection error	
Er 6	Data transmission error	
Er 7	Internal error	Replace all batteries with new ones. If the issue persists, contact Member Support.
Er 9	Provisioning error	Retake measurement. If this issue persists, contact Member Support.

Code	Description	Resolution
Er 10	Cellular connectivity suspended	Contact Member Support.
Er 11	Device is permanently deactivated	Contact Member Support.
Er 15–19	System error	Contact Member Support.
Er 20	Cuff did not inflate	Confirm the cuff is secured correctly around your arm and the cuff tube is plugged into the monitor. Retake measurement. If this issue persists, contact Member Support.
Er 21	Pulse not detected	Confirm the cuff is secured correctly around your arm and the cuff tube is plugged into the monitor. Retake measurement. If this issue persists, contact Member Support.
Er 22	Measurement error	Check cuff placement and make sure the cuff tube is plugged into the monitor. Retake measurement. If this issue persists, contact Member Support.
Er 23–24	System error	Contact Member Support.

Storage and Maintenance

Do not open the system or attempt any repairs. There are no serviceable parts in this system. There are no parts of the system that are designated as repairable by service personnel. The system uses delicate electrical components and an intricate air unit that could be damaged. If you cannot fix the problem using the Troubleshooting instructions on pages 18–19, contact Member Support.

Store your device and cuff in a clean and dry place.

Avoid exposure to direct sunlight, moisture, extreme heat, cold or humidity.

Avoid exposure to vibration, shaking or other mechanical stresses.

Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during use and storage.

Avoid washing or splashing the device or cuff with water.

Clean both device and cuff with a soft, dry cloth. If necessary, use a dampened cloth and natural detergent.

Do not use alcohol, benzene or other harsh chemicals.

Symbols

Symbol	Description	Symbol	Description
	Type BF applied part		Temperature range
	Cuff circumference		The device should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling
	Manufacturer	REF	Reference number
	Complies with FCC regulations	SN	Serial number / IMEI
	Humidity limitation	IP21	The device could be protected against solid foreign objects of 12,5mm Φ and greater and against vertically falling water drops
	Caution is necessary when operating the device or control close to where the symbol is placed		Refer to the instruction manual/booklet
	Atmospheric pressure limitation		Direct current
	Keep dry		Keep away from sunlight
	Date of manufacture	LOT	Batch code
	Consult instructions for use or consult electronic instructions for use		

Technical Specifications

Model	HT945	
Measurement Method	Oscillometric measurement	
Measurement Range	Systolic pressure: Diastolic pressure: Pulse rate:	60–230 mmHg (8.0–30.7 kPa) 40–130 mmHg (5.3–17.3 kPa) 40–199 beats/min
Rated Cuff Pressure	0–299 mmHg (0–399 hPa)	
Accuracy	Pressure: Pulse:	±3 mmHg (0.4 kPa) ±5%
Working Conditions	Temperature: Relative humidity: Pressure:	41°F–104°F (5°C–40°C) 15–90% non-condensing 70–106 kPa

Transport/Storage Conditions	Temperature: -4°F–140°F (-20°C–60°C) Relative humidity: 0–93% non-condensing
Power Supply	4 x 1.5V alkaline AA batteries
Cuff Size	8.6–17.7 inches (22–45 cm) arm size
Device Weight	274 g (excluding batteries and cuff)
Dimensions	102 x 143 x 73 mm
International Protection	IP21
Applied Part	Type BF
Software Version	A01
Extended Lifetime	5 years or 10,000 measurements (may vary based on usage conditions)
Battery Life	50–60 measurements (may vary based on usage conditions)

Intended Use

This digital blood pressure monitor was designed to measure the blood pressure and heartbeat rate of adults with an arm circumference of 8.6–17.7 inches (22–45 cm). The device can be used to detect an irregular heartbeat. This device is intended for adult indoor use only.

Compliance Statement

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

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 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 or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult your program's member support or an experienced radio/TV technician for help.

California Proposition 65 Warning
WARNING: This product can expose you to BPA, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.

Warning: Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

TECHNICAL DESCRIPTION:

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

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

Emissions Test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable
Surge IEC61000-4-5	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	Not applicable	Not applicable
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz

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

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710 745 780	704-787	LTE Band 13,17	Pulse modulation b) 217Hz	0.2	0.3	9
	810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Manufacturing Information

Manufactured by: Guangdong Transtek
Medical Electronics Co., Ltd.
Zone A, No. 105, Dongli Road, Torch
Development District, 528437
Zhongshan, Guangdong, China

Manufactured for Teladoc Health, Inc.
560 S Winchester Blvd., Suite 400
San Jose, CA 95128

Contact Information

Member Support
(800) 945-4355
membersupport@teladochealth.com

Your Welcome Kit includes:

- 1 Blood Pressure Monitor
- 1 Blood Pressure Arm Cuff (Accessories, applied part)
- 1 User Guide
- 1 Quick-Start Guide
- 1 Travel Case
- 4 AA Batteries (Detachable parts)

PL015943 Rev. C December 2023