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)

HT900 Connected Blood Pressure Monitor User Guide

Teladoc.

Livongo° by Teladoc Health



Contents

| Welcome | 5 |
|--|----|
| Getting Started | 6 |
| Components of the Device | 7 |
| nstalling the Batteries | 8 |
| Securing the Cuff | 9 |
| Taking a Measurement | 11 |
| Contraindications | 13 |
| Systolic and Diastolic Blood Pressure | 14 |
| Standard Blood Pressure Classification | 15 |
| rregular Heartbeat Detector | 16 |
| Precautions | 17 |

| Troubleshooting | 20 |
|---------------------------|-----|
| Error Codes | 22 |
| Storage and Maintenance. | 24 |
| Symbols | 25 |
| Technical Specifications | 26 |
| Intended Use | 28 |
| Compliance Statement | 28 |
| EMC Guidance | 30 |
| Manufacturing Information | 34 |
| Contact Information | 3/1 |

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@livongo.com.

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

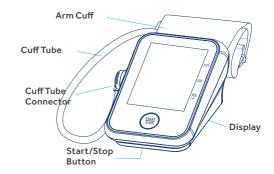
Getting Started

Depending on your service, open the Teladoc Health or Livongo app and log in. If you don't have the app yet, download it from the iOS App Store or Google Play Store. The app will be your home base for the Livongo program.

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

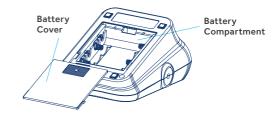
Components of the Device





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.
- 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.

+ + 0

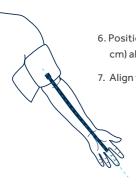
Caution:

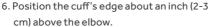
- \cdot Do not insert the battery with the polarities (+/-) in the wrong direction.
- · Use only 4 Duracell AA alkaline batteries with this device.
- \cdot Do not use other types of batteries. Do not use new and used batteries together.
- · Remove the batteries if the device will not be used for three months or more.
- · Do not dispose of batteries in fire.
- \cdot If battery fluid should get on your skin or clothing, immediately rinse with plenty of clean water.

Securing the Cuff

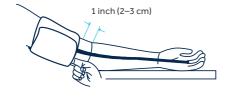
- 1. Plug the connector on cuff tube into the device.
- Expose your left upper arm by removing or adjusting clothing and jewelry. Make sure blood flow is not constricted by a rolled-up sleeve.
- 3. Open the cuff and loosen fully.
- 4. Orient the cuff so that the tube exits toward your hand.
- 5. Place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







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.
- 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

- 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 inflating the cuff. Try not to speak or move during this time.
- When the measurement concludes, results are shown on the display, and the cuff automatically deflates.
- 5. Remove the cuff after it deflates.



SYS

DIA

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



Transmission in progress



Transmission successful

 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 middeator 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.



Blood discharging artery



Blood entering vein

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 130/80 mmHq.

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, the difference between each interval and the average is more than the average value of $\pm 25\%$, or there are four or more pulse intervals, the difference between each interval and the average is more than the average value of $\pm 15\%$, 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 Duracell alkaline AA batteries with this device as these offer the longest battery life.
 Other brands 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 they 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, 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.
- $\cdot \ \ \text{Do not confuse self-monitoring with self-diagnosis}.$
- · This device allows you to monitor blood pressure.
- $\cdot \ \ \text{Do not begin or alter medical treatment without consulting a medical professional}.$
- $\cdot \ \, \text{Do not take frequent, consecutive measurements as these may constrict blood flow and lead to injury.}$
- · This unit is not suitable for continuous monitoring during medical emergencies or operations.

- · This device is not an esthesia proofed (AP/APG), and it is not suitable for use in the presence of flammable an esthetics.
- · 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 were to occur, 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.
- $\cdot \ \, \text{The device must only be serviced and repaired by authorized service personnel}.$
- 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. | Batteries completely drained. | Replace all batteries with new ones. |
| or | Batteries inserted incorrectly. | Remove batteries and reinstall them, making sure the + and - polarity symbols |
| Cuff does not inflate. (display remains off) | | 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. | Cuff not positioned correctly. | Review instructions on Securing the Cuff, and retry measurement. |
| Readings vary significantly between measurements. | 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 22–23 for more information and further instructions. |

Error Codes

| Code | Description | Resolution |
|------|---------------------------|--|
| Er 1 | Batterylow | 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 |
| Er 5 | Cellular connection error | where you get a strong cellular signal with your mobile phone. |
| 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 20–21, 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.

 $A void\ exposure\ to\ vibration,\ shaking,\ or\ other\ mechanical\ stresses.$

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 | 1 | Temperature range |
| Ů | Cuff circumference | Ø | Do not dispose of this product as unsorted municipal waste; take it for electronic recycling. |
| ••• | Manufacturer | REF | Reference number |
| FC | Complies with FCC regulations | SN | Serial number / IMEI |
| <u></u> | Upper and lower limits of relative humidity | IP21 | Ingress protection: against solid objects of 12.5 mm or greater and vertically falling water drops |
| Δ | Cautionsymbol | (3) | Follow instructions for use |
| \$ | Upper and lower limits of pressure | | Direct current |
| T | Keep dry | 淤 | Keep away from sunlight |

Technical Specifications

| Model | HT900 | |
|---------------------|---------------------------|-------------------------------|
| Measurement Method | Oscillometric measurement | |
| Measurement Range | Systolic pressure: | 60–230 mmHg (8.0–30.7 kPa) |
| | Diastolic pressure: | 40–130 mmHg (5.3–17.3 kPa) |
| | Pulse rate: | 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: | 41°F–104°F (5°C–40°C) |
| | Relative humidity: | 15-90% non-condensing |
| | Pressure: | 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 | 9–17 inches (22–42 cm) |
| 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 9–17 inches (22–42 cm).

This device is intended for indoor, home use.

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
- 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.
- $\bullet \quad \text{Consult your program's member support or an experienced radio}/TV\, technician for help.$

California Proposition 65 Warning

THIS PRODUCT CONTAINS CHEMICALS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER AND BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM.

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 excepted 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 | Notapplicable |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Notapplicable |

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 | ±8 kV contact |
| | ±2 kV, ±4 kV, ±8 kV, ±15 kV air | ± 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 | 10 V/m |
| | 80 MHz – 2,7 GHz | 80 MHz – 2,7 GHz |
| | 80 % AM at 1 kHz | 80 % AM at 1 kHz |

${\bf Guidance\, and\, Manufacturer's\, Declaration-Electromagnetic\, Immunity}$

| Radiated RF IEC61000- 4-3 (Test specifications for ENCLOSURE PORTIMMUNITY to RF wireless communications equipment) | Test Frequency (MHz) | Band (MHz) | Service | Modulation | Maximum Power (W) | Distance (m) | Immunity Test Level (V/m) |
|--|----------------------------|---------------|--|-------------------------------------|----------------------|-----------------|---------------------------------|
| | 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

 ${\bf Manufactured}\, {\bf by:}\, {\bf Guangdong}\, {\bf Transtek}$

Medical Electronics Co., Ltd.

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Zhongshan, Guangdong, China

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