



LIVEMETRIC



LiveOne

Model: LM1P Clinical

Non-invasive Blood Pressure Monitor

USER MANUAL
FOR HEALTH CARE PROVIDERS

VERSION 3.10

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YOUR LIVEONE PACKAGE INCLUDES:

LIVEONE BOX

- LiveOne Wristband
- Charging Cable
- User Manual
- Pocket Instructions Card

COMPANION DEVICE BOX

- Surface Tablet
- Charger
- User Manual
- Quick setup instructions



Please read this user manual thoroughly before using the wristband and keep it for future reference.

ABOUT LIVEONE

Thank you for choosing LiveOne, LiveMetric's innovative wrist-worn blood pressure monitor, for use in a clinical setting. This device can be used in a home or clinical setting; the following manual is intended for health care providers. Please refer to the general User Manual for patient-specific instructions.

The LiveOne is a non-invasive blood pressure monitor that utilizes a single patient use non-invasive pressure sensor placed on the wrist over the radial artery, and an electronic interface module. The device uses proprietary algorithms to analyze the radial artery pressure and display diastolic, systolic, and mean blood pressure, pulse rate and a pressure waveform. The device allows 3 modes of operation:

Single Measurement Mode – This mode of operation is intended for prescribed patients only, it provides only systolic, diastolic and heartrate values on the screen

ABPM Measurement Mode Clinical – This mode of operation enables healthcare providers to configure parameters such as time, frequency and timeout of monitoring blood pressure in a clinical setting.

Single Measurement Mode Clinical – This mode of operation enables the healthcare provider to monitor blood pressure (based on visual waveform) in a clinical setting without predefined parameters.

LiveOne utilizes highly responsive sensors in conjunction with advanced Artificial Intelligence technology to provide accurate measurements of systolic and diastolic blood pressure, as well as pulse rate. It is simple and convenient to use, without any uncomfortable inflation, or complicated calibrations. LiveOne is an efficient device in the maintenance of optimal health.

LiveOne wristband is suitable for placement on the wrist within the circumference range of ≥ 6.19 in (155 mm) and ≤ 8.26 in (210 mm).

INTENDED USE

LiveOne is a non-invasive blood pressure monitor. The blood pressure waveform is measured on the patient's wrist.

The LiveOne provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow, as well as various hemodynamic parameters derived from these pressure signals.

The Interpretation of the numerical values will be made by medical professionals only.

The device does not report any diagnosis but provides numerical values. It is the physician's responsibility to make proper judgments based on these numbers.

LiveOne is also intended for use by a physician or other qualified healthcare provider for the calculation of heart rate and heart rate variability based on waveform analysis.

INDICATION FOR USE

The LiveOne is intended to be used in patients who have a need for a noninvasive blood pressure and hemodynamic monitor.

The LiveOne is intended to be used on subjects ≥ 18 years old and who have a palpable radial pulse. Software is used to provide data to qualified medical professionals for the purpose of assessing the patient's cardiac health via blood pressure readings taken during daily activity for up to a 24-hour period. LiveOne is intended only for measurement and display; it makes no diagnosis.

CONTRAINDICATIONS

The device is not indicated for use on patients who are:

under 18 years old; pregnant; do not have at least one wrist with skin intact; have a wrist circumference less than 6.19 in (155mm); have a wrist circumference greater than 8.26 in (210mm); have implanted VADs or other mechanical circulatory support device, whether intracorporeal or extracorporeal; have impaired cognition; or have physical disability that inhibits use of device.



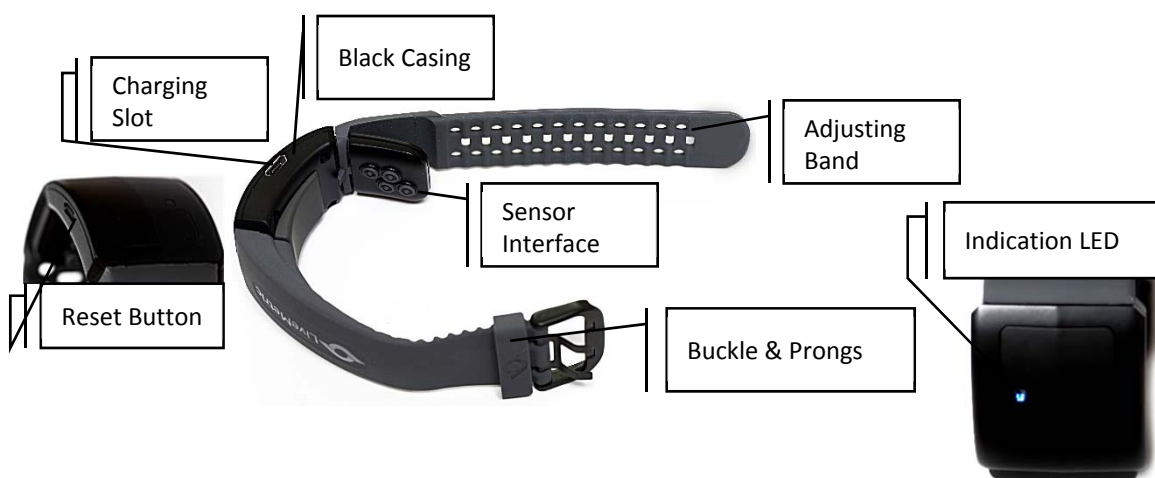
IMPORTANT SAFETY INFORMATION:

- ⚡ Please carefully read all instructions before using the LiveOne device
- ⚡ Do not prescribe LiveOne to patients without providing full instructions and safety information; ensure that the patients demonstrate full understanding before prescribing home use
- ⚡ MAKE PATIENT AWARE THAT SELF-DIAGNOSIS OF MEASUREMENT RESULTS AND SELF-TREATMENT ARE DANGEROUS!
- ⚡ Patients should NOT self-adjust medication based on the measurement results
- ⚡ Be cautious when considering the use of LiveOne for patients with severe blood flow problems or blood disorders, as tightening the wristband may cause internal bleeding and/or damage blood flow in internal blood vessels.
- ⚡ Do not apply the device on a wrist with an unhealed wound or under medical treatment
- ⚡ If itching, skin rash and/or local edema appear, please remove and avoid using the wristband
- ⚡ The presence of any of the following medical conditions increases the risk of obtaining an inaccurate reading using the device: shock; cardiac arrhythmias; atrial or ventricular premature beats; atrial fibrillation; arterial sclerosis; poor perfusion; vessel anomalies; very low blood pressure; pregnancy; diabetes; pre-eclampsia; renal diseases; having undergone breast or axillary lymph node removal operation; with an arteriovenous shunt; with an intravenous drip or blood transfusion; with implanted electrical device such as cardiac pacemaker; with other medical electrical equipment attached; with a condition that may compromise circulation; severe blood flow problems or blood disorders (increased risk of bruising); trembling or shivering.
- ⚡ NEVER CHARGE THE WRISTBAND WHILE PLACED ON WRIST
- ⚡ If black casing becomes heated, please remove the wristband immediately and consult customer service
- ⚡ DO NOT use this device on newborns, infants, children, toddlers or persons who cannot express their intentions
- ⚡ Do not use the wristband for any purpose other than measuring blood pressure

- ❖ Do not use a mobile phone or other devices that emit electromagnetic fields, near the device; it may result in incorrect operation of the device
- ❖ Do not use the device with other medical electrical equipment simultaneously
- ❖ Do not use the device where high frequency surgical equipment, magnetic resonance imaging (MRI), computerized tomography (CT) scanner or X-ray machine is operating
- ❖ Do not use the device near electromagnetic fields emission equipment such as cellular phones, microwave ovens or televisions
- ❖ Do not use the device where flammable gases (e.g. anesthetics gas, oxygen and hydrogen) or flammable liquids (e.g. alcohol) are present
- ❖ Do not use the device in a moving vehicle such as car or airplane
- ❖ Do not use the device outside the specified environment, it may cause an inaccurate reading
- ❖ The product contains small parts that may cause a choking hazard to infants and children; keep the device and its parts out of reach of infants and children
- ❖ Do not attempt to open, disassemble, repair, modify or adjust the device by yourself, it may cause accidents, damage the device, cause inaccurate measurement, and void the user warranty
- ❖ Do not subject the device to strong knocks (e.g. dropping the unit on the floor), extreme in temperature, high humidity, direct sunlight, dust or chemicals; this may damage the device.
- ❖ Do not replace battery on your own
- ❖ Do not take measurements after bathing, drinking alcohol or caffeine, smoking, exercising or eating
- ❖ Read and follow the “Important information regarding Electro Magnetic Compatibility (EMC)” in the Technical Data Section
- ❖ Read and follow the “Correct Disposal of This Product” in the Technical Data Section when disposing of the device and any used accessories or optional parts
- ❖ The device is not water resistant. Avoid water, rain or sweat from infiltrating the device.

OVERVIEW

MAIN UNIT



APPLICATION

- ❖ Log-in Screen (Windows)

- Home Screen (LiveMetric's logo)
- Terms of Use Screen
- Profile Setting Screen
- Pairing Screen
- Placement screen
- Monitoring Configuration Screen (in ABPM mode)
- Signals Screen
- ABPM Measurements Screen
- Single Measurement Mode Screen

SETUP LIVEMETRIC

- Take your new LiveOne out of the box and carefully read the user manual.
- We recommend that you keep the pocket card available while using LiveOne
- Take the tablet out of the box and read the user manual in the tablet box
- Charge the tablet
- Charge the LiveOne wristband using the charging cable and connecting it to the USB port located in the tablet's charger
- To operate LiveMetric's wristband, use the LiveMetric app for Windows 10 installed on the tablet provided.

APPLICATION SETUP

- Open the tablet and log-in to windows
- Use the password GL1234 for initial setting
- You can change your password following the Windows 10 instructions
- The LiveMetric Home Screen will open
- Click the start button at the bottom of the screen
- The Terms of Use Screen will open please read using the scroll bar on the right
- Check "I agree and accept terms of use " box to continue
- Should you decline terms, the application will remain on the Home Screen
- You can always access the terms of use from a button on the home screen
- Profile Setting Screen will open
- Please fill in patient's demographic data in mandatory fields to continue
- You need to fill in the patient date of birth, weight, height, and gender correctly (we do not share and/or sell data)
- Leaving the "Save" box checked will store current information as default for the next session; leave the box checked to perform multiple sessions with the same patient, uncheck the box to clear the fields for a new patient session.

GETTING STARTED

- If it is the first use, please continue from the profile setting screen after following the "Application setup" instruction above
- Click next and follow the instruction detailed below (which are applicable for the second session and onward)
- Starting from the second session
- Log in using your password

- Click next on Home Screen
- Pairing Screen will open
- Double tap the black casing on the wristband, a blue LED light should appear
- If you don't see the blue light, double tap more firmly
- Click "pair" on the screen
- A message will confirm successful pairing and the LED light on the black casing should be blinking blue
- If pairing has not been successful – click the troubleshooting button for possible corrective actions
- Follow the suggested option, or consult LiveMetric customer service
- Placement Screen will open
- Follow the instructions on the screen for best placement and accurate results
- Select which form of monitoring you would like to conduct;
 - **ABPM** – Holter like automatic measurements mode which allows you to configure parameters for monitoring
 - **Single Mode** – Enables you to follow the patient's waveform line, while manually updating periodically the BP and HR values
- Signals screen will open and present 4 waveform lines, representing the 4 sensors
- When a good signal has been established at a sensor, the corresponding waveform line will turn green
- If you fail to get a green waveform line please refer to the section "How to identify a good waveform line"
- You can click measure if you see at least one green or good waveform line
- If you fail to get a green or a good waveform line, reposition the wristband – outward, inward, towards the palm, away from the palm
- Please allow a few seconds after repositioning for the sensor signals to adjust
- When you have one or more steady green lines, click measure
- If you selected ABPM, the Monitoring Configuration Screen will open
- Select the total time for monitoring the patient from a drop-down menu
- Select the frequency of measuring the patient
- Select the timeout of each measuring attempt
- Click next to open the ABPM measurement screen
- The most updated values will be presented on the top of the page, in the corresponding boxes (Systolic, Diastolic, Heart Rate)
- A list of previous measurements taken in the current session will be presented in a list below
- Each measurement value has a timestamp and a date
- During the ABPM monitoring session, the patient can move around the room, but within a close radius from the companion device
- If patient needs to leave the room, wristband can be left or companion device should be taken as well
- If pairing is lost and device disconnected, a message will appear on the screen
- The session needs to be restarted
- Clicking Stop will halt the session, while measurements are still presented on screen
- Clicking Done, will halt the session, and open the Home Screen
- To save the measurement you can handwrite them or photograph the screen using a mobile phone camera
- If you selected Single Mode, Single Measurement Screen will open

- The screen contains value boxes (systolic, diastolic, heart rate) and a plot area presenting the active sensor's waveform line
- To get the most updated values, click Refresh periodically
- Please instruct the patient to breath calmly and avoid any movements after clicking refresh, as the message "Measurement in Progress" is presented under the plot area
- When measurement process is finalized, the message "Measurement Done"
- In case no values are presented and an error message appears, consider repositioning the wristband

Identify a Good Waveform Line

With the device properly placed on your wrist, observe the waveform lines that appear on the application screen. There will be 4 waveforms corresponding to signals from the 4 sensors on the wristband. It is necessary for at least one of these waveforms to be accurate in order to get a successful blood pressure measurement.

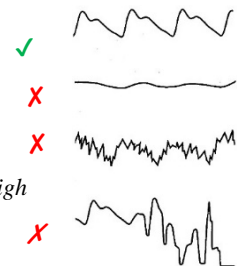
To identify a good waveform line, look for a continuous pattern approximately resembling the upper shape in image.

The exact pattern will vary from person to person, however the overall shape must contain one high peak (systolic) and one low peak (diastolic) per beat.

If you do not see this basic shape in the waveform, it is likely that the sensors are not positioned over the radial artery; and the device needs to be vertically or horizontally adjusted. Feel again for the point at the base of the thumb where your pulse is strongest; replace the device with the sensors directly over this point.

Once you establish the basic pattern in your waveform, a good signal will be smooth, without excessive noise (jagged line of waveform). Excessive noise may indicate that the wrist band needs to be tightened.

Once you achieve a waveform that meets the preceding criteria for at least 1 of the 4 sensors, you may continue with the instructions to obtain an accurate measurement.



OPERATING THE WRISTBAND

For best and accurate measurements, the patient needs to be relaxed and comfortably seated, in a clement room. For optimal accuracy, we recommend that the patient avoids bathing, drinking alcohol or caffeine, smoking, exercising or eating at least 30 minutes prior to taking measurements.

IDEAL PATIENT POSITIONING

- Patient should be seated on a chair with feet flat on the floor; upright with a straight back
- The wrist and hand should be relaxed; patient should avoid bending the wrist back or forward; and avoid clenching into a fist
- Place forearm and elbow on a flat surface with palm and thumb facing upward

CORRECT DEVICE PLACEMENT (PLEASE INSERT PLACEMENT IMAGES)

- Place the sensors' pads in line with the base of the thumb as high as possible on the wrist (on the radial artery, where the pulse is felt)
- Insert the tip of the band into the buckle and allow the prongs to latch the holes and tighten snugly – make sure the wristband is not moving freely, yet, not painful

Please note:

- The black casing should be positioned on the side of the wrist (top);
- The buckle on the side of the wrist (bottom);
- The strap part with the logo on the upper side of the wrist (as if it was a watch);

- ☞ The strap part with the holes on the bottom side of the wrist

To readjust please consider moving the wristband: Inward or outwards

- ☞ Toward the palm or away from palm

Please consider the following safety measures:

- ☞ Do not place wristband on injured skin
- ☞ Do not place wristband on clothing
- ☞ Place the wristband directly on intact skin

IMPORTANT NOTICE FOR PATIENT INSTRUCTION:

- ☞ Research suggests that the following values can be used as a guide to high blood pressure for measurements taken at home:
- ☞ Systolic Blood Pressure ≥ 135 mmHg
- ☞ Diastolic Blood Pressure ≥ 85 mmHg
- ☞ Wait 2 - 3 minutes between additional blood pressure measurements. This allows the arteries to return to normal condition.
- ☞ Blood pressure can differ between the right arm and the left arm, in which case the measured blood pressure values will also be different.

TROUBLESHOOTING

Please find the following solutions the possible problems you may encounter:

#	problem	Source	Corrective actions
1.	Cannot click next	Terms of Use Screen	Please check the box "I agree and accept the terms of use"
2.	Cannot click next	Profile setting Screen	Please follow the error messages on the screen
3.	Pairing unsuccessful	Pairing Screen	Please check if the blue LED light is on. If not please follow the corrective actions of problems 6-8
4.	Pairing unsuccessful	Pairing Screen	Please check if the blue LED light is on. If so, please remove the dongle located on the upper right side of the screen, and re-insert it
5.	Pairing unsuccessful	Pairing screen	After following corrective actions 3-4 and 6-8, call customer service
6.	No Blue LED	Black Casing in the wristband	Please double-tap firmly on black casing
7.	No Blue LED	Black Casing in the wristband	Please charge the wristband
8.	No Blue LED	Black Casing in the wristband	Please hold the reset button for 30 seconds
9.	Cannot place the wristband	UI	Please follow the illustrations and instruction on the screen
10.	The wristband is inflicting pain on my wrist	Wristband	Please loosen the wristband using the buckle
11.	The wristband keeps moving on the wrist	Wristband	Please tighten the wristband using the buckle
12.	None of the waveform lines turn green	Wristband	Try to reposition wristband; inward, outward, toward palm, away from palm
13.	The waveform lines are flattened every time the wristband is moved	Wristband	Allow few seconds for the sensors' signals to adjust, and then see if you get a green waveform line
14.	After multiple repositioning attempts, no green waveform line	Wristband	Check if the LED light is blinking blue-green;

15.	Blue-Green LED light is not blinking (following 14) only blue LED light is on	Wristband	Click cancel and pair device
16.	Blue Green LED is not blinking and Blue LED light is not on (following 14)	Wristband	Click cancel and double-tap casing to pair device after blue LED is on
17.	Blue Green LED is not blinking and Blue LED light is not on (following 16); even after double tapping	Wristband	Charge the wristband
18.	Cannot place the wristband	UI	Please follow the illustrations and instruction on the screen
19.	The wristband is inflicting pain on my wrist	Wristband	Please loosen the wristband using the buckle
20.	The wristband keeps moving on my wrist	Wristband	Please tighten the wristband using the buckle
21.	Not sure the placement is good	Wristband	Click next to view the waveform lines and follow instructions on screen
22.	The LED is stopped blinking	Wristband	Click Cancel and start again
23.	What is ABPM	Placement Screen	ABPM is a mode that allows you to monitor a patient automatically in a clinical setting for a predefine period of time. In this mode you can configure the monitoring parameters; please refer to troubleshooting in ABPM Setting.
24.	What is Single Mode	Placement Screen	Single Mode allows you to monitor patient waveform line derived from the active sensor. Periodically you can update the BP and HR values
25.	I don't have enough measurements	ABPM Setting Screen	Please note that if choose the total time 1 hour, it is best to select frequency of 10 /15/20 minutes in order to get significant number of measurements
26.	What is timeout?	ABPM Setting Screen	For how long should the wristband attempt to get successful measurement, in each session of measuring during the monitoring process
27.	Did not get any value; I get "- -"	ABPM Measurement Screen	Please consider repositioning the wristband
28.	Did not get any value; I get "- -"	ABPM Measurement Screen	Please check that the patient is not moving while LED is blinking blue & green
29.	Did not get any value; I get "- -"	ABPM Measurement Screen	Make sure the patient has rested before measurement has taken place
30.	Did not get any value; I get "- -"	Wristband is not blinking	Please click Done to restart the session. The connection could not be restored
31.	I got a pop up message that the connection cannot be restored	ABPM Measurement Screen	Please click Done to restart the session. The connection could not be restored
32.	Did not get any values; Waveform looks flat	Single Measurement Screen	Please consider repositioning the wristband
33.	Did not get any values; Waveform is irregular	Single Measurement Screen	Please check that the patient is not moving

34.	Did not get any value;	Wristband is not blinking	Please click Done to restart the session. The connection could not be restored
35.	The waveform line looks noisy	Single Measurement Screen	Consider removing electromagnetic interference while monitoring
36.	I got a pop up message that the connection cannot be restored	ABPM Measurement Screen	Please click Done to restart the session. The connection could not be restored
37.	Did not get any values	Measurement Screen	Please click re-measure and follow actions 12-13 and onward
38.	Did not get any values	Measurement Screen	Please click done, and start the process of measuring from the beginning

Error Messages

The following error messages will be presented on the application when applicable:

Error	Description	Correction actions
Please fill in day data	Cannot click next on profile setting screen	Please complete day of birth
Please fill in missing month data	Cannot click next on profile setting screen	Please complete month of birth
Please fill in missing year data	Cannot click next on profile setting screen	Please complete year of birth
Please fill in missing gender data	Cannot click next on profile setting screen	Please select gender
Please fill in missing weight data	Cannot click next on profile setting screen	Please complete weight
Please fill in missing height data	Cannot Click next on profile setting screen	Please complete height
Battery level is critical – please charge the wristband	Cannot operate device	Please charge wristband
Battery level is low – please charge the wristband after current measurement	Error message appears	Please Complete measurement and charge wristband
Battery Low	Error message from tablet	Please charge the tablet

TECHNICAL DATA

PERFORMANCE

Accuracy of pressure: ± 3 mmHg or $\pm 2\%$ of reading

Accuracy of Heart Rate: $\pm 4\%$ of reading

Measurement Unit: Systolic: 50-250 mmHg / Diastolic: 30-180 mmHg

Measurement Range: Pulse Rate: 40-199 / minute

SENSORS

LiveOne LiveMetric contains the following sensors:

Accelerometer, which tracks your motion patterns

4 pressure sensors (add details)

MATERIALS

The LiveOne LiveMetric wristband is made of a flexible, durable elastomer material similar to that used in many sports watches, Silicon 60 shore A (Shin-Etsu Silicon CHN) and includes a stainless steel black anodized buckle. The black casing is made of black anodized aluminum. The upper antenna cover is made of PC. The bottom support is made of ABS.

WIRELESS TECHNOLOGY

LiveMetric contains a Bluetooth 4.0 radio receiver and LiveOne.

BATTERY

LiveMetric contains a rechargeable 1 cell lithium-polymer battery.

MEMORY

LiveMetric does not store any private / personal / identifiable data

WRISTBAND SIZE

Wristband sizes are shown below. Please note that we recommend measuring wrist prior to purchase as shown on the packaging.

Large – Fits a wrist between 7.1 - 8.26 inches (180 - 210 mm) in circumference

Small – Fits a wrist between 6.10 – 7.1 inches (155 - 180 mm) in circumference

ENVIRONMENTAL CONDITIONS

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment

Operating Temperature	14° to 113° F (-10° to 45° C)
Non-operating Temperature	-4° to 14° F (-20 to -10° C) 113° to 140° F (45° to 60° C)
Water Resistance	IP22
Maximum Operating Altitude	28,000 feet (8,534 m)