

CONTENTS

I.CH-S691L Installation	01
A.Product Components	01
B.Operating Environment	02
C.Installation Instructions	02
D.Setup	07
E.Precautions for Maintenance	09
F.Instructions for Use and Maintenance of Rechargeable Lithium Battery	10
II.Blood Pressure Measurement	12
A.Precautionary Steps	12
B.Measurement Instructions	13
C.Application of The Arm Cuff	14
D.Measurement Procedure	14
E.Measurement Posture	16
F.Functionality	17
III.Transportation and Storage	18
A.Cautions During Transportation	18
B.Repacking Instructions	19
C.Transportation and Storage Environment	20
IV.FAQ	20
A.Error Code	20
B.Regarding the Equipment	22
C.Regarding the Measurement	23
V.Others	26
A.Exterior and Functions	26
B.Safety Information	27
C.Product Classification	29
D.Blood Pressure Classification	29
E.Product Specifications	30
F.EMC Information (Declaration)	31

I.CH-S691L Installation

Intended purpose: The automatic blood pressure monitor is designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference ranging from 7.1 inches (18.0 cm) to 16.5 inches (42 cm).

Intended patient population: adults

Contraindications:

1. Those with arm trauma and skin ulcers don't use this device.
2. Patients with severe heart (including significantly irregular heart rhythm, tachycardia, isolated ventricular premature beat (VPB), atrial fibrillation), liver or kidney disease or blood circulation disorders;
3. Patients are Pregnant.
4. Patients have been diagnosed with preeclampsia.
5. Patients with diabetes.
6. Patients who are undergoing vasoactive treatment.
7. Patients with arrhythmias.
8. Patients with peripheral artery disease or other conditions that affect arterial compliance.

Side Effect: The side effects of automatic blood pressure monitor is the pressure of the arm cuff make the subject feel uncomfortable.

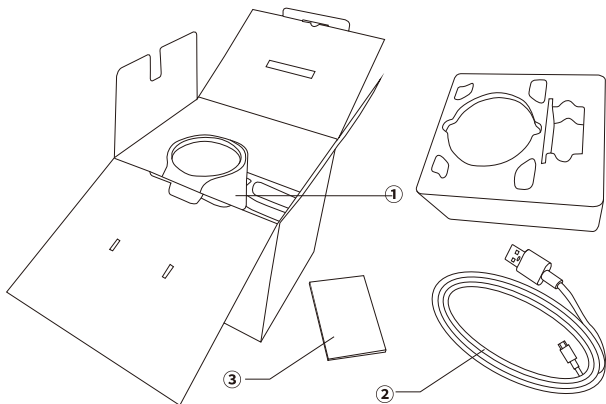
A.Product Components

The CH-S691L consists of the following components, make sure all of the following components are present.

Please check each component of the system for damage prior to installation.

Basic Components

- ① The CH-S691L
- ② USB-C charging cord (5V/2A)
- ③ User manual



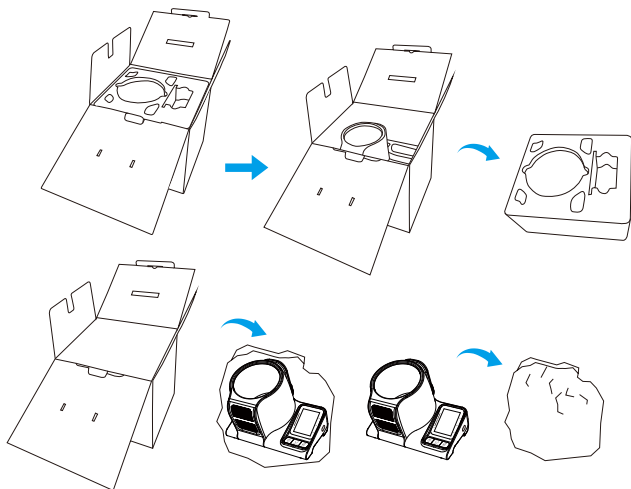
B. Operating Environment

Please make sure the environment is adequate for the CH-S691L installation. This equipment is designed for indoor use. If installing the equipment outdoors, the following requirements must be fulfilled.

Temperatures range	5°C to 40°C (41°F to 104°F)
Relative humidity	15% to 90%
Atmospheric pressure range	70kPa to 106 kPa

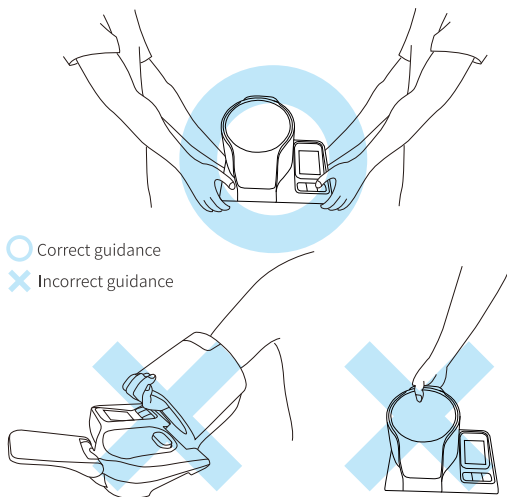
C. Installation Instructions

1. Open the CH-S691L box, and remove the packing pads. Take off the protective vinyl out of the CH-S691L, and take out the CH-S691L from the box. Remove the packing material.



⚠ Caution

- Please do not move the device by inserting your wrist into it.
- Please keep the original packaging of the CH-S691L equipment for future repackaging. Dispose of waste according to local regulations.
- Please refer to the illustration below to transport the CH-S691L equipment.



2. Place the equipment on a stable table that can withstand the weight of the CH-S691L.

⚠ Caution

- Install the CH-S691L on the flat, vibration free surface.

If the equipment is installed where the floor is not flat, it may topple during a measurement or the measurement results may be inaccurate.

3. Connect the USB-C charging cord provided with the CH-S691L. (The charging symbol  will flash internally when charging)

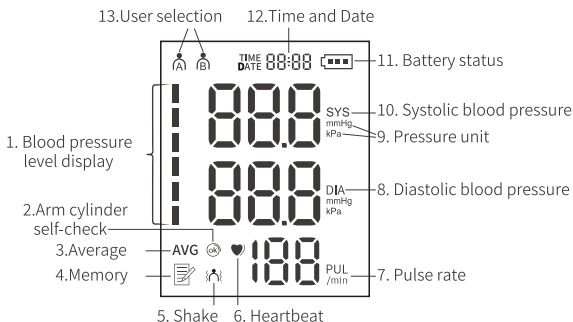
Warning

- Do not plug or disconnect the power cable with wet hands. There is a risk of electric shock.
- Do not disassemble the equipment arbitrary. This may cause electric shock or injury, product malfunction, and inaccurate results. Unauthorized disassembly will void the manufacturer's warranty.
- Do not let the CH-S691L touch with other electronic devices when on. This may cause in electric shock.
- The device provides a DC input port connected to external AC adapter. the adapter should meet the following conditions: class II equipment, output voltage: DC 5V, current: $\geq 2.0\text{A}$, and compliance with IEC60950-1, IEC 60601-1 or IEC 62368-1, provide at least two MOOP insulation between AC input and DC output.
- External adapter connected to medical electrical equipment through the DC input port must comply with the respective IEC or ISO standards (e.g. IEC 60950 or IEC 62368-1 for data processing equipment). Further more all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, 60601-1-2, respectively).
- Anybody connecting external adapter to medical electrical equipment configurations a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

Caution

- Plugging the device into an ungrounded outlet may cause malfunction or electric shock and inaccurate results.
- Please use the device with caution. Strong external impact may cause equipment failure.

4. When the CH-S691L is turned on, the following screen is displayed and a calibration is automatically performed.



⚠ Caution

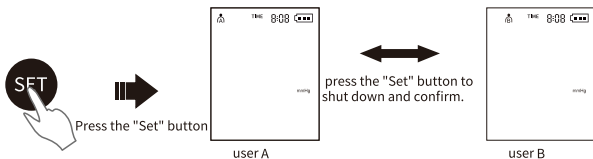
• Do not operate or touch the device while it is calibrating. It may cause errors to future measurements.

D.Setup

Setup consists of User Selection, time settings, and pressure unit setting .

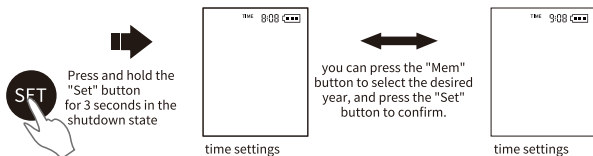
User Selection

Press the "Set" button once to automatically enter the user setting state when the user A or user B icon is On , press the "Set" button to select user A or user B, and press the "START/STOP" button to shut down and confirm.



Time Settings

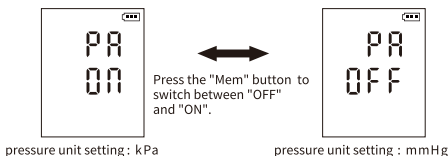
Press and hold the "Set" button for 3 seconds in the shutdown state to automatically enter the time setting state. The numerical character representing "year" in the time icon will flash. At this time, you can press the "Memory" button to select the desired year, and press the "Set" button to confirm. Set the month, date, hour, and minute in sequence using this method. (If the time is not set, it defaults to the factory time of the machine).



Pressure Unit Setting

After the time setting is completed, the blood pressure value unit setting mode is automatically entered, and the screen will display "PA" and "OFF" below

Press the "Memory" button to switch between "OFF" and "ON". Select "OFF" to select mmHg as the unit, select "ON" to select kPa as the unit, press the "Memory" button to select the blood pressure unit, and press the "Set" button to confirm.



E. Precautions for Maintenance

⚠ Caution

- Never move the equipment while the power is on.
- External substances, like dust and liquid to enter the device. External substances can damage electric components.
- Clean the exterior of the equipment gently with a lint-free cloth once a week. Do not scratch the LCD screen while cleaning the equipment.
- The cuff of this product cannot be replaced, please do not disassemble it privately.
- Packing material and other wastes should be disposed of according to the relevant laws and regulations.

Check the Following before Turning the Equipment on.

- Ensure the equipment was not damaged from impact.
- Ensure the equipment is not contaminated.
- Ensure the equipment is not wet.
- Ensure the power cord is completely plugged in.
- Ensure the power cord is not damaged.
- Ensure the power cord is not a tripping hazard.

The CH-S691L calibrates automatically when it is turned on. but it may be necessary for a specialist to inspect the device once every two years to maintain its performance and safety. If an error message appears during the calibration, please contact product support.

Disposal

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

- The device is not suitable for use in the presence of flammable

anesthetic mixtures with air or with oxygen or nitrous oxide.

Cleaning

Method of cleaning: to thoroughly clean the device, immediately after each use, rubbing device (including markings) such as the housing, button and LCD screen by hands without undue pressure with 70% isopropyl alcohol wipes for 3 minutes after each measurement.

⚠Caution: Ensure that no liquid enters the interior of the monitor, never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the instrument in water or other cleaning liquids. Wait 10minutes after cleaning, allowing the monitor to air-dry before taking a blood pressure measurement.

Visual Inspection: after cleaning, there should be no visible blotches and soil stains on the device under nature light, if there are still blotches and soil stains existed, repeat the cleaning steps mentioned above until there is no visible blotches and soil stains.

F.Instructions for Use and Maintenance of Rechargeable Lithium Battery

Proper Use of Lithium Batteries:

- Charge according to standard times and procedures, even for the first three times.
- Charge as soon as possible when the device's low battery indicator appears.
- The activation of lithium batteries does not require special methods. They will naturally activate during normal use of the device.
- Note: When using lithium batteries, it is important to note that the battery will enter a dormant state if left unused for a period of time, and its capacity will be lower than normal, reducing the usage time. Lithium batteries are easily activated, and by going through 3-5 normal charging and discharging cycles, the battery can be activated and return to its normal capacity.

- To better ensure the stability of the product performance, it is recommended not to use the product above 40 ° C or below 5 ° C environment.
- Complete one charging cycle per month for the lithium battery.
- Note: Used lithium batteries and devices that have reached the end of their service life may cause environmental pollution. Please follow local laws and regulations to dispose of them properly.
- Under normal circumstances, lithium batteries are recommended to be used more than 10,000 times or replaced every 2 years.
- Do not replace the lithium battery by yourself. If you need to replace the lithium battery, please contact the manufacturer.

Lithium Battery Recycling Precautions

- When the battery no longer holds a charge, it should be replaced. The batteries are recyclable. Remove the old battery from the CH-S691L and follow your local recycling guidelines.
- Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

II. Blood Pressure Measurement

A. Precautionary Steps

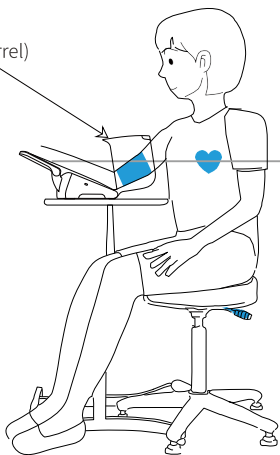
Caution

- User should rest at least 10 minutes before measurement.
- Do not roll up the user's sleeve, but take off thick clothes.
- User should sit up straight in the chair.
- Insert the user's arm until the elbow contact switch position.
- Adjust the height of the chair so that the inserted upper arm and the heart are horizontal.
- Measurement in a relaxed state.
- User should not talk or move during the measurement.
- Do not use this product to measure blood pressure if there is a wound on the measurement site, or it may cause further aggravation of the wound and secondary injury.
- Keep the equipment away from children and pets.
- Please do not use it in an environment with flammable, explosive and anesthetic gases.
- Please make sure that the device must be checked for safe operation and in normal working condition before use.
- Do not apply the device on the patient's side arm during mastectomy surgery, it may cause impaired reflux and lead to danger.
- Application of the cuff and its compression on any extremity where endovascular access or treatment, or an arterio-venous (A-V) shunt, exists due to temporary interference with blood flow, may result in patient injury.

B.Measurement Instructions

1.Adjust the height of the chair so that the inserted upper arm and the heart are horizontal.

Blood Pressure Cuff (Arm Barrel)



2. Rest for at least 10 minutes before the measurement.

*If examined in a bit unstable condition, the measurement result may be incorrect, and generally it will turn up higher than your usual blood pressure.

3.During measuring, the middle of the arm cuff is consistent with the heart height.

4.During the measurement, don't use force with your hands, do not speak, and keep your body sitting still and straight until the measurement is finished.

5.If an emergency occurs during the measurement, you can press the "Emergency button"stop measurement.

6.During measuring, please maintain a good sitting posture and keep your feet flat on the floor.

7.Do not sit with your legs crossed during measurement.

8.When measuring, relax your body as much as possible, keep your back straight, and keep the forearm of the measuring arm close to the support plate and in a stable condition.

C. Application of the Arm Cuff

1. The arm cuff features an ergonomic design, allowing it to adjust vertically to fit arms of different lengths (see Figure 1)
2. Blood pressure measurements should be taken in the position described below.
3. When inserting your left arm into the cuff, align your elbow with the elbow contact switch position (see Figure 2).
4. Assume the correct measurement posture and prepare to initiate the blood pressure reading.

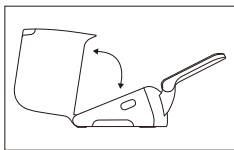


Figure 1

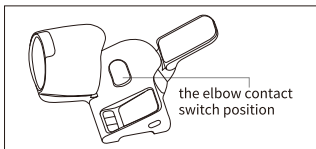


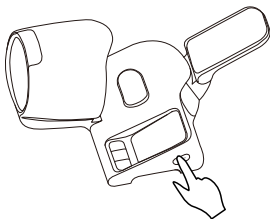
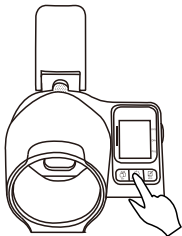
Figure 2

Caution

Repeated measurements will cause congestion in the arm and affect the outcome of the measurements. Improvement method: you can hold your left hand high and hold it put your fist several times and then measure.

D. Measurement Procedure

1. After sitting in the correct position, put the left arm into the arm cuff and adjust the elbow position. (Refer to use method).
2. Press the "START/STOP" button to start the measurement.



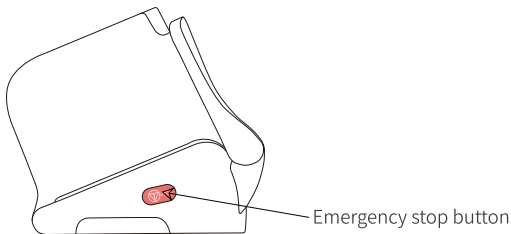
3. Pressure is automatically applied to the cuff, and the blood pressure is measured.

Do not talk or move during the measurement.

Relax while sitting up straight.

Caution

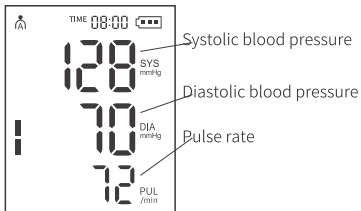
1. If an emergency occurs during the measurement, press  button or  button on the front bottom of the CH-S691L. The cuff will release quickly.



2. Consult a professional to explain the measured blood pressure value.

3. The cuff is automatically released after completing the measurement. wait for the cuff to fully loosen and pull out your arm.

4. Check the results on the screen. After the measurement is completed, the results will be displayed on the display screen.



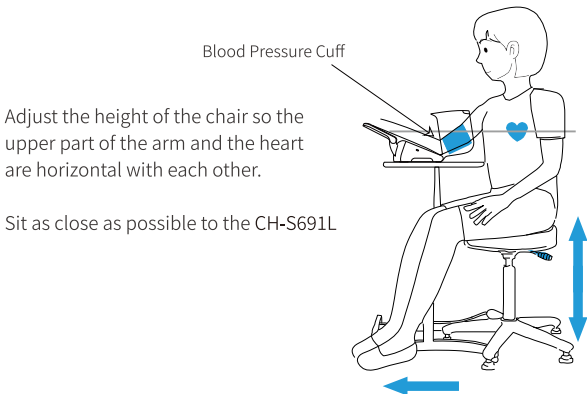
Warning

- If the user wants to measure the blood pressure again, please take a rest sufficiently more than 10 minutes.
- Blood pressure can vary depending on the situation. Please consult your physician for accurate diagnosis.
- Please perform regular checks on the emergency stop button to avoid danger due to its failure.
- Do not take measurements too frequently as this may cause injury to the user due to blood flow disturbances, take a sufficient break of 10 minutes or more.
- Do not place the ME device in a position where it is difficult to disconnect the power supply unit.
- When the housing is tilted up to 15 degrees, it prevents contact with hazardous parts with fingers and prevents water droplets from falling vertically!

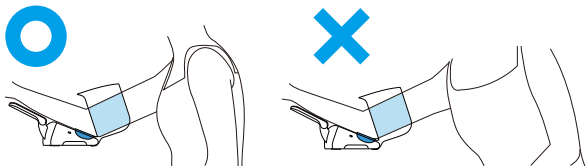
E.Measurement Posture

For a correct measurement result, sit with proper posture while taking the measurement.

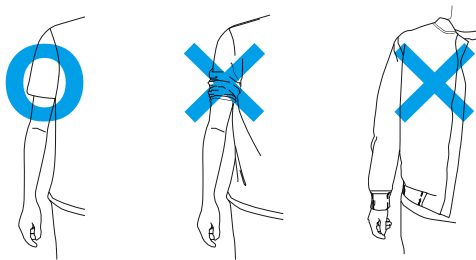
*CH-S691L allows users to measure with either arm.



*Be sure to place the elbow in elbow contact switch position starting the measurement.



*Remove thick clothes. Do not roll up sleeves.



F.Functionality

1.Memory function

•Viewing memories

In the power off state, short press the memory button once, the unit displays the average value of the first three blood pressure measurements, short press the memory button again to display the value of the first measurement, then short press it again to display the value of the second blood pressure measurement, and so on.

•Deleting memories

Short press the Memory button once in the power off state, after the memory value appears, then long press the memory button until all the data disappears, that is, to delete all the memory values under the current user in the machine.

⚠ **Caution:** The sphygmomanometer is unable to delete some of the measurements, to delete the measurements stored in the sphygmomanometer will delete them all. (It is recommended that you keep a blood pressure record before deleting measurements for future reference).

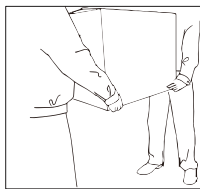
2.Static Stress Test Function

Under the state of power off, press the “Set” button once, then press the “Set” button and “Memory” button at the same time to display the software version of the machine. After this information, release the two keys successively to enter the static pressure test mode.

III.Transportation And Storage

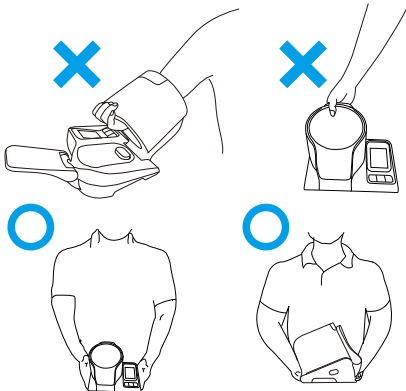
A.Cautions During Transportation

To transport the CH-S691L safely, two people should keep the equipment parallel to the ground.



⚠ **Caution**

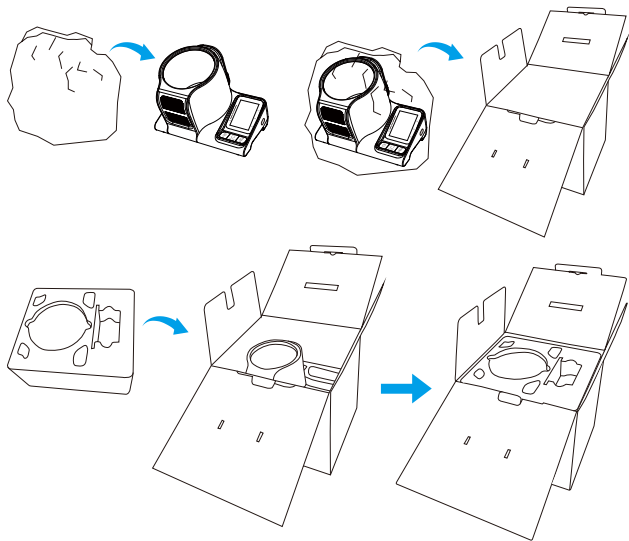
When transporting the equipment alone, keep the equipment horizontal while transporting.



B.Repacking Instructions

1.Turn off the CH-S691L.

2.Remove all connected cables and put the packing material into the CH-S691L. Wrap package in protective vinyl and insert the packing pads into the box.



Caution

When repacking the equipment, protective packing materials provided by this company must be used.

C.Transportation and Storage Environment

The CH-S691L should be transported or stored under the following conditions.

Temperatures range -25°C ~ 55°C (-13°F to 158°F)

Relative humidity 15% to 93% (No Condensation)

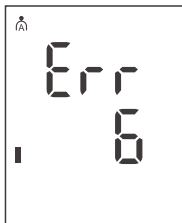
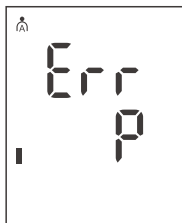
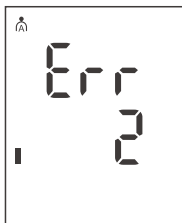
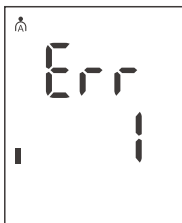
Atmospheric pressure range 70kPa to 106 kPa

IV.FAQ

If the problem persists, please contact product support.

A.Error Code

The error messages can be displayed on the screen if they occur during the measurement.



Error symbols	Cause	Measures
	Sensor error	Squeeze the cuff before measuring to empty the air in the cuff
	No pulse signal or abnormal pulse signal was detected	1. Insert the arm cylinder correctly according to the position indicated in the instruction manual, and place the elbow correctly 2. Keep quiet and do not move during the measurement 3. Don't take measurements in thick clothes
	Inflation error	1. Check whether the arm cuff is fitted too tight or too loose, to make sure there is no air leakage. 2. Check whether the air tube is blocked
	Pressure over limit	Your systolic or diastolic blood pressure measurement exceeds the measuring and display ranges of the blood pressure monitor, please go to the hospital for further examination.
	Interference or misaction during measurement	Keep quiet and do not move during the measurement

B.Regarding The Equipment

If problems cannot be resolved with the information below, please contact product support.

Question	Answer
ERR 1 The sensor is abnormal	Squeeze the cuff before measuring to expel the air inside it.
ERR 2 No pulse signal or pulse signal abnormalities were detected	1. Wear into the arm cuff correctly according to the instruction manual, and put the elbow position correctly 2. Keep quiet and do not move during the measurement 3. Do not measure in thick clothes
ERR 6 Interference or misoperation in the measurement	Keep quiet during the measurement
ERR P Inflation is abnormal	1. Check whether the air circuit is open 2. Check whether the arm cuff is too tight or too loose 3. Check whether the air tube is blocked
ERR HI Pressure over limit	Please stay relaxed or consult your healthcare professional

Caution

- The company is not liable for the problems occurred when others repair and inspect the equipment except employees of the company

Caution

- Since error messages and things of detail such as incorrect result sheets can be used as a basis for A/S, please record or keep all of them.

C.Regarding The Measurement

If problems cannot be resolved with the information below, please contact product support.

Question:

The measurement results are incorrect.

Answer:

The arm and heart are not aligned during the measurement. Adjust the height of the chair to align the arm and heart.



Correct measuring posture. The height of the arm and the heart is aligned.



Incorrect measuring posture. The arm is higher than the heart. Blood pressure value will be measured lower.

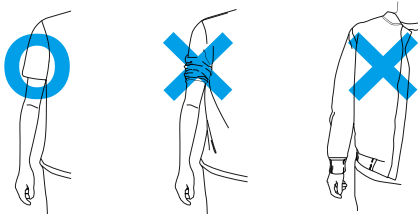


Incorrect measuring posture. The arm is lower than the heart. Blood pressure value will be measured higher.

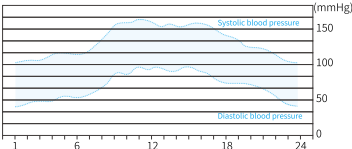
• Inserting the arm too far or not far enough may produce incorrect results. Please place your elbow on the elbow contact switch position for accurate results.



- Thick clothes or rolled up sleeves may lead to incorrect results .
- The blood pressure value will be measured higher. Remove thick clothes. Do not roll up sleeves.



- The user may have measured without sufficient rest. Take the measurement after resting at least 10 minutes.
- The first reading may be high even after taking a sufficient rest.
- Do not talk or move during the measurement.
- Blood pressure may vary through the day. Manufacturer recommends measuring at different times of the day.

Question	Answer
When should blood pressure be measured?	Blood pressure may vary throughout the day, as shown below.  Therefore, the best time to measure is when users can measure regularly on a daily basis. It is recommended to measure at the same time each day under the same conditions.

Question	Answer
How frequently can measurements be done?	The automatic blood pressure monitor applies pressure to the arm to measure blood pressure. Consecutive measuring may put a strain on blood vessel. Rest for about 5 minutes between measurements.
Is there any case that I should not measure?	Automatic blood pressure monitor applies pressure to the arm to measure blood pressure. If you had blood drawn or had an injection given in the either arm, it is recommended to wait at least 1 hour before measuring, or measure with another arm.
Can results vary depending on the measuring environment and temperature?	• The CH-S691L can operate at 5°C-40°C (41°F-104°F). However, if the user feels that the temperature is low or high, this feeling makes the blood vessels expand or contract, so it will ultimately affect the blood pressure results. It is recommended to measure in a stable condition in an environment where no cold or heat is felt. • The user will not be able to perform a natural and stable measure if the user is measuring in a loud or distracted environment. It is recommended to measure in an environment free from noise and disturbances.
The blood pressure values are different at home and at the hospital.	• The blood pressure may change: -Within 1 hour after meals -After drinking alcohol or consuming caffeine -After smoking -After taking a bath -After exercise -After urination or defecation -When measuring in an unfamiliar location

Question	Answer
The blood pressure values are different at home and at the hospital.	• Blood pressure readings can be influenced by the environment. Therefore, to ensure consistency, it is important to perform measurements under similar conditions. • Psychologically, people tend to feel more stable at home than at hospital. Hospital-measured blood pressure tends to be higher than home-measured blood pressure.

V.Others

*The CH-S691L was manufactured by the quality control procedure of Cemho Medical Technology (Guangdong) Co., Ltd. Cemho Medical Technology (Guangdong) Co., Ltd. complies with ISO13485 which are international quality management systems.

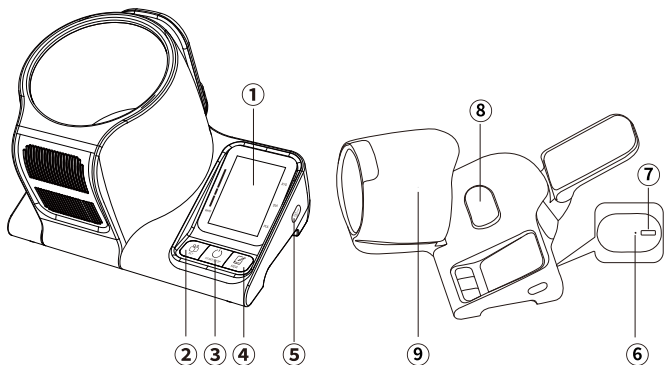
*This equipment satisfies the common standard for electrical and mechanical safety of medical devices and the common standard for the safety of medical devices.

A.Exterior and Functions

The names and functions of each part of the CH-S691L are as followings.

* Please check each component of the system for damage prior to installation.

- | | |
|-------------------------|----------------------------|
| ① Display screen | ② Setup button |
| ③ Start/Stop button | ④ Memory button |
| ⑤ Emergency stop button | ⑥ Indicator light |
| ⑦ USB-C charging port | ⑧ Elbow positioning button |
| ⑨ Arm barrel | |



B. Safety Information

Warning

- If this equipment has been altered, it must be inspected to ensure that it can be used safely.

Results can only be interpreted by experienced healthcare professionals. It cannot be used for diagnosis, medication, or other treatments performed at the consumer's discretion without a doctor prescription.

Warning

- Excessively high or low temperatures, humidity and pressure may affect the operation of the equipment and may cause malfunction. Use blood pressure monitor within the range specified in the product specifications.
- Packing material and other wastes should be disposed of according to the relevant laws and regulations.

Safety Symbols/Meaning			
	Danger high voltage		Date of manufacture
	Caution		Batch code
	Medical device		BF-type
	Warning		Unique device identifier

Etc. Symbol	
	Serial number
	Manufacturer
	Direct current
	Alternating current
	See instruction for use
IP22	Ingress protection(protected against access to hazardous parts with a fingerand against vertically falling water drops when enclosure tilted up to 15
	MR unsafe
	Importer

C.Product Classification

This device is an oscillometric electronic blood pressure monitor with the following classifications:

- Electric shock protection type: Class II (Internally powered equipment)
- Electric shock protection level: Type BF
- Electromagnetic radiation emission class: Class A
- Water ingress protection: General Equipment (no special protection against external water infiltration)

D.AHA Blood Pressure Classification

• Standards to assess high blood pressure have been established by the American Heart Association (AHA). as shown below:

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (top/upper number)	and/or	DIASTOLIC mm Hg (bottom/lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120-129	and	LESS THAN 80
STAGE 1 HYPERTENSION (High Blood Pressure)	130-139	or	80-89
STAGE 2 HYPERTENSION (High Blood Pressure)	140 OR HIGHER	or	90 OR HIGHER
SEVERE HYPERTENSION (If you don't have symptoms*, call your health care professional.)	HIGHER THAN 180	and/or	HIGHER THAN 120
HYPERTENSIVE EMERGENCY (If you have any of these symptoms*, call 911.)	HIGHER THAN 180	and/or	HIGHER THAN 120

*symptoms: chest pain, shortness of breath, back pain, numbness, weakness, change in vision or difficulty speaking

⚠ Caution: There is no definition about hypopiesia, and generally SYS(systolic pressure) less than 90mmHg or DIA (diastolic pressure) less than 60mmHg is called hypotension.

E. Product Specifications

Measurement instructions	Oscillography
Cuff measurement range	Pressure: 0mmHg to 295 mmHg
Systolic and diastolic blood pressure ranges	Systolic: 55mmHg~255mmHg (7.33kPa~33.99kPa) Diastolic : 25mmHg~200mmHg (3.33kPa~26.66kPa)
Applicable arm circumference	7.1in-16.5in
Pulse rate range	(40~199) beats/min
Allowable error	Pressure: ± 3 mmHg pulse rate: $\pm 5\%$
Measurement result	Systolic blood pressure, diastolic blood pressure, pulse rate
Measurement time	Approx. 30 seconds on average (20-50 seconds depending on the pulse and blood pressure value)
Pressurization time	Approx. 10 seconds
Resolution	1mmHg/0.1kPa
Screen type	LCD(3.5 in)
Memory storage	2*99 sets
Energy saving	Automatically enters the energy saving mode after 1 minute and ± 10 s of the idle time.
Dual safety mechanism	1. Air releases when START/STOP is pressed 2. Automatic release if pressure >300mmHg 3. Manual release via Emergency Stop button (The multiple security mechanisms enables the cuff to release the air regardless of the central controller when the Emergency Stop button is pressed.)
Dimensions	About 283mm (W) $\times$ 244mm (D) $\times$ 244mm (H) About 11.1in (W) $\times$ 9.6in (D) $\times$ 9.6in (H)
Weight	About 2 kg (4.4lbs)
Operating environment	Temperature: 5°C~40°C (41°F~104°F) , Humidity: 15%~90%, Atmospheric pressure: 70kPa~ 106 kPa
Rechargeable battery	Type: Lithium battery Nominal voltage: 3.7V Nominal capacity: 2000mAh Model: CEL18650
Service life	5 years

- * For purposes of improvement, specifications are subject to change without notice.
- * This product is a ‘Medical Equipment’ . Please read the guide and cautions before using this blood pressure monitor.
- * This product was investigated according to ISO 81060-2: 2018+ A1: 2020.
- * Software version: V1.0

Package lists: Main unit x 1, USB-C charging cord x 1, user manual x 1.

F.EMC Information (Declaration)

1.Instructions for use

The ME equipment or ME system is suitable for home healthcare environments

Warning

Do not place this equipment near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances are 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 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



Caution

The [name and model or type reference of the ME equipment or ME system] was measured according to the recommendations of Technical Report IEC 60601-4-2: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity; performance of medical electrical equipment and medical electrical systems.

~~Product accessories: USB-C charging cord~~

Number	Name	Maximum length (m)	Whether shielded cable is present or not	Notes
1	USB-C charging cord	1	Not	/

Caution: cables include external connection cables (power cables, adapter cables, port connection wires, and wiring terminal wires) and connection cables between product components.

ESSENTIAL PERFORMANCE: the maximum change in the reading for the measurement of the cuff pressure at any point of the nominal measurement range shall be less than or equal to 3 mmHg (0.4 kPa).

2. Technical description

Guidance and manufacturer's declaration -electromagnetic

Table 1

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	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
	30 kHz	CW	8	8
	134.2 kHz	Pulse modulation 2.1 kHz	65	65
	13.56 MHz	Pulse modulation 50 kHz	7.5	7.5

Table 3

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	± 2 kV power supply lines ± 1 kV signal input/output 100 kHz repetition frequency	± 2 kV power supply lines 100 kHz repetition frequency
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	± 0.5 kV, ± 1 kV differential mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 Power frequency magnetic field IEC 61000-4-8	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle 30 A/m 50Hz/60Hz	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle 30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 2Hz	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 2Hz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 2Hz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 2Hz
NOTE UT is the a.c. mains voltage prior to application of the test level.		

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 –470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13,17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					