Instruction Manual

Automatic Wrist Blood Pressure Monitor



Model No. HL158AU-D

This manual and product are not meant as a substitute for advice provided by your

You are not to use the information contained herein, or this product for diagnosing or treating a health problem or prescribing any medication. If you have or suspect that you have a medical problem, promptly consult your healthcare provider.

Intended Use

This device automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method during deflation. All values can be read out in one LCD panel. Measurement position is at human being's wrist. The intended use of this over-the-counter device is for adults aged 18 years and older with wrist circumference ranging from 5.3 inches to 7.7 inches (approx. 135 mm to 195 mm) and for home use.

HL158AU-D detects the appearance of irregular heartbeats during measurement; an indicated symbol will appear with measuring reading. And the Risk Category Indicator will show the information with the readings on the screen for the user tracking their blood pressure level.

Additionally, the Wrist Position Guide is used as an aid in determining if the device is at correct position in relationship to the heart.

About Blood Pressure

1. What is blood pressure?

Blood pressure is the measurement of the force of blood pushing against the walls of the arteries. Arterial blood pressure is constantly fluctuating during the course of the cardiac cycle. The highest pressure in the cycle is called the systolic blood pressure, and represents the pressure in the artery when the heart is beating. The lowest pressure is the diastolic blood pressure, and represents the pressure in the artery when the heart is at rest. Both the systolic and the diastolic pressure are necessary for a physician to evaluate the status of a patient's blood pressure.

Many factors such as physical activity, anxiety or the time of day, can influence your blood pressure. Blood pressure is typically low in the mornings and increases from the afternoon to the evening. It is on average lower in the summer and higher in the winter.

2. Why is it useful to measure blood pressure at home?

Having one's blood pressure measured by a doctor in a hospital or a clinic, is often associated with a phenomenon called "White Coat Hypertension" where the patient becomes nervous or anxious, thus raising his blood pressure. There are also numerous other factors that might cause your blood pressure to be raised at a specific time of day. This is why medical practitioners recommend home monitoring as it is important to get readings of blood pressure during different times of the day to really get an idea of your real blood pressure.

Medical practitioners generally recommend the "Rule of 3", where you are encouraged to take your blood pressure three times in a row (at $3 \sim 5$ minute interval), three times a day for three days. After three days you can average all the results and this will give you an accurate idea of what your blood pressure really is.

A. WHO blood pressure classifications:

Standards for assessment of high or low blood pressure without regard to age, have been established by the World Health Organization (WHO), as shown in the chart. However this

is not exact for classification of blood pressure

and it's intended to be used as a guide in understanding non-invasive blood pressure measurements. Please consult with your physician for proper diagnosis.

B. Variations in blood pressure:

Individual blood pressures vary greatly both on a daily and a seasonal basis. These variations areeven more pronounced in hyper tense patients. Normally the blood pressure rises while at work and is at its lowest during sleeping

(hyper tense: means a person who has high blood pressure symptom.)

The graph below illustrated the variations in blood pressure over a whole day with measurement taken every five minutes.

The thick line represents sleep. The rise in blood pressure at 4 PM (A in the graph) and 12 AM (B in the graph) correspond to an attack of pain.

Precautions

- * Read the Instruction Manual thoroughly before measuring and keep it at hand for your reference at any time
- * The device is designed for home use and not suitable for clinical use.
- * The patient is an intended operator, who can operate the device by himself or herself. not necessarily by a physician or operator.
- * This monitor is not intended for use in the MR environment.

- The device should not be used to either self-diagnose Hypertension or exclude the diagnosis of Hypertension. If your blood pressure reading is out of normal range, please consult your physician. Even your blood pressure reading is within the "normal" range, the device cannot exclude the diagnosis of
- Do not take a measurement in a low (less than 41 °F/5 °C) and high (more than 104 °F/40 °C) temperature. nor in a place outside humidity ranges (15 % \sim 93 % R.H.), and atmospheric pressure ranges (700 \sim 1060 hPa), or you may get inaccurate readings.
- Wait 30 ~ 45 minutes before measurement if you've just consumed caffeinated beverages or smoked
- Rest at least 5 ~ 10 minutes before taking a measurement
- To allow your blood vessels to return to the condition prior to taking the measurement, please wait at least 3 ~ 5 minutes in between measurements. You may need to adjust the wait time according to your personal physiological situation
- We recommend you using the same wrist (preferably the left wrist) and measuring around the same time each day.
- Perform measurements in a quiet and relaxed environment at room temperature.
- Do not move or shake the device during a measurement. Please keep guiet and do not talk during
- The device has no any interface (e.g. USB) to transfer data or provide updates/upgrades and therefore device is no security vulnerabilities
- This product is not suitable for:
- Pregnant women
- People with arrhythmias
- Undergoing intravenous injection on any limb
- Currently in a dialysis treatment
- In pre-eclampsia condition
- For those who have had a mastectomy or lymph node clearance, it is recommended to take a measurement on the unaffected side
- When used among medical electronic equipments on the same limb, pressurization of the cuff may cause temporarily malfunction to other devices
- If you have one of the circulatory problems as arteriosclerosis, diabetes, liver disease, kidney disease, severe hypertension, peripheral circulation...... please consult your healthcare professional before using
- Blood pressure measurements taken with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultation method and are within the accuracy limits prescribed by the Standard of EN 1060-4.
- The applied part is cuff.

*Attention!

1. Do not use the device on infants, children, or those who cannot express their own intentic

- 2. The medical device should not used adjacent to or stacked with other equipment. When the blood pressure monitor are used in a high level radio frequency electromagnetic fields (e.g. close to the wireless communication equipment), it may lose or degrade essential performance, such as device giving the error code, deviated readings, or malfunction. B. Consider the electromagnetic compatibility of the device (ex. power disturbance, radio frec
- Please use it indoor only. Over high frequency measurements may result in blood flow interference, which is likely to cause uncomfortable sensations, such as partial subcutaneous hemorrhage, or temporary numbness to your wrist. In general, these symptoms should not last long. However, if you do not recover in time, please seek your medical practitioners for help.

Device Overview **Product components**

AAA (LR03) (1.5 V)

Unit display

ALKALINE BATTERY X 2







lour : Minute ents YEAR in Setting Mode

Symbol Definitions

MONTH/DATE

Average of Last 3 Measurements

BP Category Indicator

SYMBOLS	Definitions
Low Battery Symbol	This symbol appears when the battery power is excessively low or the polarity reverses. — We suggest you replace all batteries with new ones, and make sure the +/- polarities are properly positioned.
Pulse Symbol	Once pulse is detected, the symbol flashes with each pulse beat. → Our suggestion: Please do not talk or move during measurements.
Irregular Heartbeat Detector	This symbol appears when an irregular heart beat was detected. → Our suggestion: Repeat the measurement after resting for at least 5 minutes, and restart your measurement while sitting down comfortably and quietly. If symbols appear frequentity, please contact your physician.
Excessive Body Motion Detector	Displayed if body movement is detected during measurement, especially, the movement on the wrist the blood pressure monitor is worn on. Besides, if cuff is worn improperly, or the shape of the wrist is unusual, excessive gap might exist between the wrist cuff and the wrist. Notice: The measured blood pressure reading may not be accurate if the icon is displayed.
Cuff Fitness detection Symbol	Displayed if the cuff was wrapped incorrectly, which is too tight or too loose. This is the function aid in detecting if the cuff is wrapped properly.
BP Category Indicator	The arrowhead points out the specific BP Category that your measurement reading fits in.
Wrist Position Guide	The Wrist Position Guide is used as an aid in determining if the device is at the appropriate angle and height.
AVG. 3 Average of Last 3 Measurements	This symbol appears when LCD displays average value of last 3 readings.

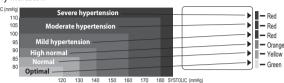
Features

BP Category Indicator

This device is equipped with BP Category Indicator which classifies your blood pressure measurements into six stages (Optimal to Severe hypertension) as shown in below chart:

Sta Pre	ges of Blood essure Levels	Systolic (mmHg)	Diastolic (mmHg)	Color	Recommendations by SIGN 49: Hypertension in older people
Grade 3	Severe Hypertension	≥180	≥110	Red	Confirm immediately and repeat BP in one day and again within one week depending on clinical situation.
Grade 2	Moderate Hypertension	160~179	100~109	Red	Serial blood pressures repeated within one month.
Grade 1	Mild Hypertension	140~159	90~99	Red	Provide advice about lifestyle modification and confirm within two months.
High-Normal		130~139	85~89	Orange	Provide advice about lifestyle modification and recheck in one year.
Normal		120~129	80~84	Yellow	Recheck in 2 - 5 years.
Optimal		<120	<80	Green	(patients aged > 75 years offered annual health check)
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After each measurement is completed, LCD display will show your position automatically on the six segments of the bar indicator which corresponds to BP Category Indicator.



*Note!

When a person's systolic and diastolic pressures fall into different categories, the higher category should apply.

e.g. systolic pressure 181 & diastolic pressure 99 → Red category (Severe Hypertension) e.g. systolic pressure 110 & diastolic pressure 95 → Red category (Mild Hypertension)

The above table is not exact for classification of blood pressure and it's intended to be used as a guide in understanding non-invasive blood pressure measurements.

Usually this is not a cause for concern; however we recommend you consult with your physician for proper diagnosis or seek medical advice according to our recommendation mentioned above. Please note that the device does not appropriate to diagnose hypertension, and it is only for user reference on blood pressure monitoring

Irregular Heartbeat Detector

The symbol will appear on screen indicating a certain heartbeat irregularity was detected during measurement.

The heartbeat rhythm that is more than or less than 25% from the average rhythm is usually defined as an irregular heartbeat rhythm. Talking, moving, shaking or an irregular pulse during the measurement can result in the

appearance of this symbol Usually this is not a cause for concern, however if the symbol appears often, we recommend you seek medical advice.

And please note that the device does not replace a cardiac examination, but serves to detect pulse

irregularities at an early stage.

- The pulse display is not suitable for checking the frequency of heart pacemakers. If a certain pulse irregularity is detected during measurement often, we recommend you seek medical advice
- As a safeguard, we recommend that if you have arrhythmias such as atrial or ventricular premature beats and atrial fibrillation or any other special conditions you should check with your physician before using your device.
- The IHB function is not designed for use by people with arrhythmias nor for diagnosing or treating an arrhythmic problem.
 In order to filter the unstable status of user and avoid affecting the detection of heart rate from any movement, shaking or talking in the beginning of measurement, the method of averaging heart beat intervals of subject device is calculated with the three proper heart beat pulses detected in the beginning of measurement and that is different from a strict mathematical averaging of all recorded intervals.

 • At least 3 beats with at least 25 % difference from the average heart beat interval will generate the IHB icon on the screen.

HL158AU-D has a built-in the Wrist Position Guide will be used as an aid to help user determining if the device is at appropriate angle and height

Turning wrist position guide ON/OFF

This function default setting is on. User can switch the function ON and OFF.

Under standby mode, user can by pressing " (b)" button in a few seconds, the device will enter to setting year, date, month, hour, minute. When these setting are done, press the "+" button again, use "+" button to switch the Wrist Position Guide function ON and OFF





Wrist Position Guide OFF

Wrist Position Guide ON

How to use the wrist position guide

After you press (1) button, the display will illuminate with different icons that are designed to guide you move your wrist. Once the appropriate angle and height is found, the Pulse () Symbol will flash with beep sound for 3 times and measurement will begin

SYMBOL	ACTION		
19	Move your wrist up.		
19	Move your wrist down.		

This Wrist Position Guide is only for reference on blood pressure measurement. Due to difference in individual size, physique, and being dependent on the height of the table and desk, in addition to the position of the hand in comparison to the horizontal plane of reference and the heart, this feature may not heighful in all cases. If you feel the position of the wrist according to Wrist Position Guide does NOT match your heart level, you can select to turn this feature off and consolit workshifters aroundly.

Installing Batteries

When LOW BATTERY SYMBOL appears on the display, or no reaction toward operation, please change

Replace all worn-out batteries with new ones and do not mix new and used batteries. Do not mix alkaline. standard (carbon-zinc) or rechargeable (cadmium) batteries either. Such action may shorten the battery life or cause the device to malfunction

All batteries used must be the same type

Slide the battery cover, prepare 2 AAA (1.5V, LR03) alkaline batteries. Insert one battery on the outside first, and then insert another inside as shown on the figure below. Please make sure the polarities "+" and "-" ends are coinciding with similar markings engraved on the battery housing.









*Attention

- Batteries are hazardous waste. Do not dispose of them together with the household garbage. Please discard worn-out batteries to the recycling sit
- o prolong the battery life and prevent damage caused by leakage, remove the batteries from the device if the device is not to be used for a long period
- Replacing batteries clear all stored memory.
 After replacing the batteries, reset date and time.

Applying the Cuff

- Do not place the pressure cuff over a jacket or sweater sleeve. Wrap the pressure cuff around the bare wrist with the monitor
- Wrap the cuff snugly. Do not make it too tight.
- Fold the remaining part of the cuff back out of the way.
- Leave approximately 0.4 inch (10 mm) between the cuff and the bottom of your hand palm.

*Note!

- Do not use this device if your wrist has any wound or injury. • Do not wrap the cuff around any body part other than your wrist.
- In case the cuff kept pumping up non-stop, unwrap the cuff at once.
- Positioning Guide

It is extremely important that the cuff be at the same height as the heart. Having the cuff higher or lower may cause inaccurate results.

- 1. Sit on a chair comfortably, put your feet flat on the floor and lay your forearm of the table, make sure your back and arm supported, legs uncrossed.
- 2. Position the blood pressure monitor on your wrist. 3. Place your elbow on the table and rest the back of your hand on the device
- storage case or other object. 4. Rest your wrist on the armrest until it's at the sameheight as your heart.
- 5. Relax your hand and turn your palm upwards.

Measurement Procedure

Switch on the Monitor

A. Press 🖒 button to switch on the monitor. The monitor will automatically turn to standby mode

Setting Year, Date and Time

- A. Under standby mode, press (button, then YEAR digit flashes. Use + button to select current year.
- B. When above settings are done, press 🕒 button to adjust current MONTH. Press + button to select current MONTH. C. Continue to set current DATE (varies from 1 to 31),HOUR(1,2.....12PM,
- 1PM.....,12) and MINUTE (00,01.....,59) by following Step B. D. Users can adjust YEAR-MONTH-DATE-HOUR-MINUTE in an orderly manner.

Taking a Measurement

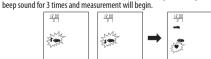
A. Press + button to select User 1, User 2.



B-1. Start a Measurement: (with Wrist Position Guide off) With the cuff wrapped around your wrist, press 🖒 button to start measurement. All display units appear on the screen for 1.5 seconds

B-2. Start a Measurement: (with Wrist Position Guide on) 1. With the cuff wrapped around your wrist, press (1) button to start measurement. All display units appear on the screen for 1.5 seconds 2. Adjust the position of your wrist according to the Wrist Position Guide symbol appears on the display. When

the device senses that your wrist is in the appropriate angle and height, the Pulse Symbol (🖤) will flash with



3. Even if the monitor is not in the ideal position after 10 seconds, the measurement will still begin. If this occurs, the wrist symbol will appear and be stored in the memory with



C. After the initial inflation of the cuff, the pressure will slowly decrease. When pulse is detected, Pulse symbo will start flashing. Remain still and do not move until the entire measurement process is completed. The device will detect your pulse and determine the blood pressure.







D. After the monitor has determined your blood pressure and heart rate, the cuff automatically deflates. Your systolic rate, diastolic rate, heart rate, corresponding Risk Category Indicator Irregular Heartbeat Detector, excessive body motion detector and wrist position guide (if any) are displayed with date and time for 1 minute and save results to memory automatically.



III

E. Without any operation for 1 minute, device automatically shuts off.

- This monitor will re-inflate automatically if the system detects that your body requires more pressure
- If the cuff does not stop inflating, remove the cuff at once.

 To stop measurement, press 🕁 button, the cuff will deflate immediately after the button is pressed.

Memory Function

Storing data

 $After\ eac\bar{h}\ measurement,\ your\ systolic,\ diastolic,\ heart\ rate\ and\ corresponding\ BP\ Category\ Indicator,\ Irregular$ Heartbeat Detector, Excessive body motion detector and wrist position guide (if any) with the time and date will be automatically stored

The monitor can store up to 120 memory sets for 2 users, and automatically replace the oldest data with new

Recalling data

A. Press + button to select User 1 or User 2.

B. Press M button to enter Memory Mode.

If there is no data stored before, nothing (except month, date, and time) will appear on the display. If yes, the first reading will be the average of last 3 measurements. C. Every new press of the **M** button will recall a previous reading. The latest reading will be

Use + button to scroll through all stored measuring results from the earliest to the latest one.

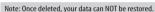
D. To stop reading the memories, press (1) button to switch to Standby Mode.

Erasing data

A. Press + button to select User 1, User 2.

B. Press M button to enter Memory Mode.

C. Press and hold () and + buttons at the same time, all the data for the selected user



Storage and Maintenance

General Use

Do not in any way twist the cuff.

■ Do not press START/STOP button if the cuff is not wrapped around your wrist.

■ Do not drop the product and avoid any strong impacts.

Maintenance

To ensure that your device is in optimal use and to avoid damage, please refer to the following instructions:

Clean the device and cuff with a soft dry cloth, or

■ Use a dry cloth with water to clean the device (not directly flush, do not soak in water, and hold the device

■ Do not use detergent or any strong chemicals to clean the device.

■ Make sure the cuff is completely dry before using.

According to the use environment of the sphygmomanometer, the recommended disinfection method and frequency are as follows:

- Only use it yourself (home use), it can be cleaned at ordinary times, and wipe it once a month with a commercially available 75% alcohol cotton sheet (for the cuff) for more than 30 seconds each time.
- If it is used for more than one person (home use), it can be cleaned at ordinary times. It is disinfected once a week (for the cuff belt) with a commercially available 75% alcohol cotton sheet, for more than 30
- After cleaning / disinfection/ before use, please make sure that there are no blood stains or soil on the LCD, the device and cuff. If there is any blood stains or soil, please dispose the device without reuse.
- If it is used in a complex environment (such as a hospital) or after multiple people (non-family), please discard the old cuff and replace it with a new one.

- If the device is not to be used for a long time, please remove the batteries from the device (leaking of battery acid can cause the device to malfunction).
- Always store the unit in the storage case after use. It is intended to be transported or stored in a carrying
- Do not place the device directly under sunlight, in high temperature, or in humid or dusty places

Troubleshooting

	_			
SYMBOLS/ SYMPTOMS	CONDITIONS/CAUSES	INDICATION/CORRECTION		
Unit does not turn on when (1) button	Worn-out batteries.	Replace them with 2 new AAA (LR03) alkaline batteries.		
is pushed.	Battery polarities have been positioned incorrectly.	Re-insert the batteries in the correct positions.		
Measuring Error Symbol appears when blood pressure value displayed is excessively low or high.	Cuff has been placed incorrectly.	Wrap the cuff properly so that it is positioned correctly.		
Measuring Error Symbol	Air circuit abnormality. Cuff tube may not be plugged into monitor correctly.			
Measuring Error Symbol	Inflation pressure exceeding 300 mmHg.	Switch the unit off, then measure again.		
	Can't determine blood pressure measurement data.	Wrap the cuff properly and keep steady. Measure again.		
Measuring Error Symbol	Cuff is worn improperly	Wrap the cuff snugly so that it is positioned correctly. If you have any question about the cuff wearing and/or measurement result, please consult your healthcare professional.		
Excessive Body Motion Detector	Body movement during measurement, especially, the movement on the wrist the blood pressure monitor is worn on. e.g. Talking, moving or shaking of the arm with the cuff on while measurement.	Measure again. Keep arm steady during measurement.		
Notice: The measured blood pressure reading may not be accurate if the icon is displayed.	Cuff is worn improperly, or the shape of the wrist is unusual, excessive gap might be exist between the cuff and the wrist.	Wrap the cuff properly and keep steady. Measure again. If you have any question about the cuff wearing and/or measurement result, please consult your healthcare professional.		
Cuff Fitness detection Symbol	The cuff was wrapped incorrectly (for example too loosely or too tightly).	Please reference "applying the Cuff " section to wrap the cuff correctly		
Note: If "EP" appears on the display, just return the device to your local distributor or importer.				

Limited Warranty

Warranty For Two Years from the manufacturing date

Please note that this warranty does not cover damage caused by misuse or abuse; accident; the attachment of any unauthorized accessory; alteration to the product; improper installation; unauthorized repairs or modifications; improper use of electrical/power supply; loss of power; dropped product; malfunction or damage of an operating part from failure to provide manufacturer's recommended maintenance; transportation damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of importers or distributors

In case it is needed to have the device checked for calibration, please consult the distributor. This is recommended to be considered every two years.

HL158AU-D

Specifications

Model Number

Measurement Method	oscillometric (deflation)		
Rated Range of Cuff Pressure	0~300 mmHg		
Rated Range of Determination	40~280 mmHg		
Measurement Range of Heart Rate	Pulse : 40 ~ 199 Beats / Minute		
Accuracy	Pressure: ± 3 mmHg Pulse: ± 5 % Max.		
Inflation	Automatic Inflation (Air Pump)		
Deflation	Automatic Air Release Control Valve		
Display	Liquid Crystal Display		
Memory	240 Memory Total for 2 Users		
Unit Dimensions	60.2 mmx 71.5 mmx 23.5 mm (L x W x H)		
	2.37 x 2.81 x 0.93 inch (L x W x H)		
Unit Weight	78 g ± 5 g (2.75 oz ± 0.18 oz)		
(Without Cuff & Batteries)			
Cuff Size	5.3 ~ 7.7 inch (approx.135 ~ 195 mm)		
Storage/Transportation	Temperature: -25 °C ~ 70 °C (-13 °F ~ 158 °F)		
Environment	Humidity: ≤ 93 % R.H.		
Operation	Temperature: 5 °C \sim 40 °C (41 °F \sim 104 °F)		
Environment	Humidity: 15 % ~ 93 % R.H.		
	Atmospheric pressure: 700 hPa ~ 1060 hPa		
Power Supply	DC 3 V, AAA "LR03" (1.5 V) Alkaline Battery x 2		
Battery Life	Approx. 250 Measurements		
Shelf life (battery)	3 years (Temperature: 20 ± 2 °C;		
	Relative humidity: $65 \pm 20\%$ RH)		
Product Life	5 Years (4 times per day)		
Sleeping Mode Without any operation for 1 minute, device auto			
	shuts off.		
Accessories	Instruction Manual, 2 AAA (LR03) Alkaline Batteries,		
	Storage Case		

The contents and the specifications of the device covered above are subject to change for improvement without notice

Note

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EN 60601-1 Medical electrical equipment part 1: General requirements for safety

EM Sandard: EN 60601-1-2 Medical electrical equipment part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility- Requirements and tests Performance standards:

Performance standards:
El 11663-8 Non-invasive sphygmomanometers - Supplementary requirements for electromechanical blood pressure measuring systems.
El 11664-4 Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers roward in the contractive phygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (partially applied) ENISO 81060-1 Non-invasive sphygmomanomenters - Part 1: Requirements and test methods for non-automated measurement type (partially applied) EIG 8001-3-20 Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanoments.

Evalanation of symbols

Explanation of symbols :					
Symbol	Explanation	Health & Life Information			
ϵ	CE conformity marking	-			
0197	Notified Body (NB) number	-			
②	Refer to instruction manual/booklet	-			
†	TYPE BF Applied Part	-			
	To avoid inaccurate results caused by electromagnetic interference	Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the device, Otherwise, degradation of the performance of this equipment could result.			
X	Waste of electrical and electronic equipment (WEEE)	Discard the used product to the recycling collection point according to local regulations.			
3	Manufacturer	HEALTH & LIFE Co., Ltd. 9F, No.186, Jian Yi Road, Zhonghe District 23553, New Taipei City, Taiwan www.healthandlife.com.tw			
M	Date of manufacture	M YYYY-MM			
EC REP	Authorized representative in the European Community	ECTREP EMERGO EUROPE Prinsessegracht 20, 2514 AP The Hague, The Netherlands			
SN	Serial number	SN YYMMXXXXXX			
IP22	Ingress Protection Rating	First characteristic numeral- Degree of protection against access to hazardous parts and against solid foreign objects N1=2 (Protected against solid foreign objects of 12.5 mm Ø and greater) Second characteristic numeral- Degree of protection against ingress of water N2=2 (Protected against vertically falling water drops when ENLCOSURE titled up to 15")			
Ø 93 %	Humidity limitation (Storage/Transportation condition)	R.H.: ≦93 %			
-25 °C (-13 °F)	Temperature limit (Storage/Transportation condition)	Temperature: -25 °C ~ 70 °C (-13 °F ~ 158 °F)			
700 hPa	Atmospheric pressure limitation (Operating condition)	Atmospheric pressure: 700 hPa~1060 hPa			
93 % 15 %	Humidity limitation (Operating condition)	R.H.: 15 % ~93 %			
+5 °C (41 °F)	Temperature limit (Operating condition)	Temperature: 5 °C \sim 40 °C (41 °F \sim 104 °F)			
((<u>(</u>)))	Non-ionizing electromagnetic radiation	-			
Device infor	mation:				

Device information:

- Internally powered equipment

- Not suitable for use in presence of flammable anesthetic mixture with air or with

Oxygen or nitrous oxide
- Continuous operation with short-time loading

Manufacturer: HEALTH & LIFE CO., LTD. 9F, No. 186, Jian Yi Road, Zhonghe District 23553, New Taipei City, Taiwan www.healthandlife.com.tw

Appendix

Guidance and manuf	acturer's declaratio	n — electromagnetic emissions
		ctromagnetic environments listed below,
and should only be us	ed in such environ	ments:
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments, and those directly
Harmonic emissions IEC 61000-3-2	Not Applicable	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	ригрозсэ.

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments: mmunity test IEC 60601 Compliance Electromagnetic environment test level level guidance Electrostatic \pm 8 kV contact \pm 8 kV contact In the case of air discharge testing, the discharge (ESD) discharge discharge climatic conditions shall be within the IEC 61000-4-2 following ranges: Ambient Temperature: 15 °C ~35 °C ± 15 kV air ± 15 kV air

Guidance and manufacturer's declaration - electromagnetic immunity

discharge discharge Relative Humidity: 30 %~60 %. Power frequency magnetic fields should Power frequency 30 A/m 30 A/m (50/60 Hz) 50 or 60 Hz 50 or 60 Hz be at levels characteristic of a typical magnetic field location in a typical commercial or IEC 61000-4-8 hospital environment.

Guidance and manufacturer's declaration — electromagnetic immunity The device is intended for use in the electromagnetic environments listed below, and

hould only be used in such environments:				
mmunity test	IEC 60601	Compliance	Electromagnetic environment -	
	test level	level	guidance	
Conducted RF EC 61000-4-6	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.	
Radiated RF EEC 61000-4-3 Proximity fields from RF wireless communica- tions equipment EC 61000-4-3	10 J/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	Recommended separation distance Considering to reduce the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distances for higher IMMUNITY TEST LEVELS distance in m, and E is the IMMUNITY TEST LEVELS in VITM. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b laterference may accur in the vidnity of equipment marked with the following symbol:	

OTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. OTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption of reflection from structures, objects and people.

and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radii smateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic survey should be considered. If the neasured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the levice should be observed to verify normal operation. If abnormal performance is observed, additional measures may be excessary, such as reolenting or relocating the device.

Over the frequency range 15 Okt Rtt to 80 MHz, relds strengths should be less than 3 V/m

Test specifications for enclosure port immunity to RF wireless communications equipment.

Test frequency (MHz)	Modulation	IMMUNITY TEST LEVEL (V/m)	
385	Pulse modulation 18 Hz a)	27	
450	FM \pm 5 kHz deviation 1kHz sine $^{\rm b}$)	28	
710		9	
745	Pulse modulation 217 Hz ^a)		
780			
810			
870	Pulse modulation 18 Hz ^a)	28	
930			
1720			
1845	Pulse modulation 217 Hz ^a)	28	
1970			
2450	Pulse modulation 217 Hz a)	28	
5240			
5500	Pulse modulation 217 Hz ^a)	9	
5785			
NOTE:	•		

NOTE:

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m, The 1 m test distance is permitted by IEC 61000-4-3.

a). The carrier shall be modulated using a 50% duty cycle square wave signal.
b). AS an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Blood Pressure Diarv

Date Time Systolic/ Diastolic Pulse ☐Before Meal ☐Before Meal After Before

Meal After ☐ Before Meal After Before Mea After ☐ Before Meal After Before Meal After ☐ Before Meal □After Before Meal □After ☐ Before Meal After ☐ Before Meal ☐ Before Meal □After Before Meal After Before After Before Mea □After ☐ Before Meal □After

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