Wrist Type Blood Pressure Monitor

BPM27

EN




IP 22 RoHS REACH

EC REP

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Importer

Distributor

INSTRUCTION MANUAL
Please read this instruction manual carefully before operating this unit

Contents

Intended Use

The product automatically measures human begins Systolic, Diastolic blood pressure and pulse rate by oscillometric method. The measurement results are displayed on the LCD. Measurement position is at human being's arm. The intended use of this over-the-counter device is for adults with arm circumference ranging from 125 mm to 210 mm (Approx. 4.9 ~ 8.3 inches) and for home use. When the device detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring readings.
This device is designed only for adults.

Contra-indications

Do not use in this case. (e.g. common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, patient motion, trembling, shivering, handicapped)

⚠ CAUTION:

- Beware of blood flow interference and resulting harmful injury to the patient caused by continuous cuff pressure.
- Pressurization of the cuff can temporarily cause loss of function of monitoring ME equipment simultaneously being used on the same limb.
- Reading can be affected by the measurement site, the position of the patient, exercise, or patient's physiologic condition.
- Automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.
- Frequent measurements can cause injury to the patient due to blood flow interference.

- Check that operation of the automated sphygmomanometer does not result in prolonged impairment of patient blood circulation.
- Retake the measurement if unexpected readings are obtained

- Ensure that the cuff is not placed on an arm in which the arteries or veins are undergoing medical treatment, e.g., intravascular access or therapy, or an arteriovenous (AV) shunt.

- This product is suitable for use in the home healthcare environment.
- Keep this device out of the reach of children. Strangulation may result from baby or child entanglement in cables.
- Please keep this device away from pets, pests, and children.
- Preventing potential allergic reaction, please avoid the device in direct contact to patient's wound.

- Do not use with pregnant or pre-eclamptic patients
- Do not use the cuff on people who have undergone a mastectomy.
- Do not apply the cuff over a wound, as this can cause further injury.
- Do not use this device other than the intended purposes.
- Do not use in these cases (e.g. Device for use in an ambulance, helicopter or professional environment)

- Cuff pressure 0 – 300 mmHg
- Reduction rate: ≦30S Refer to IEC 80601-2-30
- No modification of this equipment is allowed.

Important Information Before Use

1. Blood pressure measurements should only be interpreted by a physician or a trained health care professional who is familiar with your medical history. Through regular use of this device and recording of your measurements, you can keep your physician informed of the changes in your blood pressure.
2. Perform your measurement in a quiet place. You should be seated in a relaxed position.
3. Avoid smoking, eating, taking medication, alcohol consumption or physical activity 30 minutes prior to taking a reading. If you are exhibiting signs of stress, avoid taking your measurement until the feeling subsides.
4. Rest 15 minutes prior to taking a reading.
5. Remove any constrictive clothing or jewelry that may interfere with the cuff placement.
6. Keep the monitor stable during measurement to achieve an

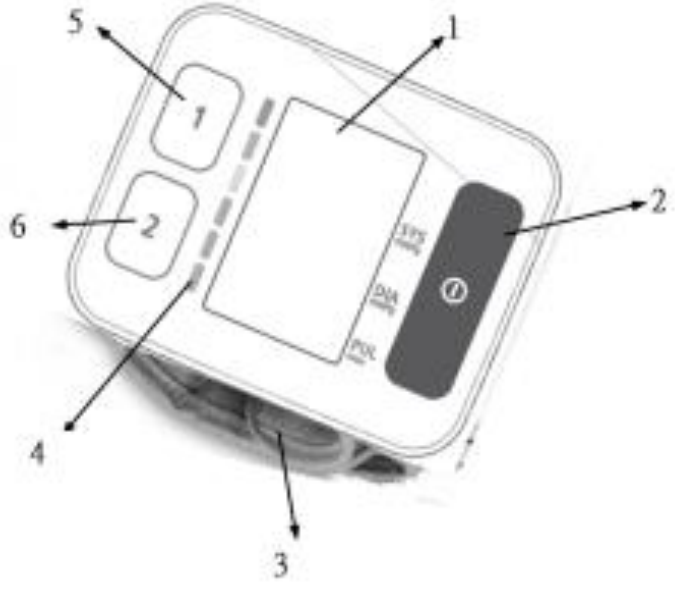
accurate reading. Remain still; do not talk during the measurement.

7. Record your daily blood pressure and pulse readings on a chart.
8. Take your readings at the same time, each day or as recommended by your physician to get an accurate indication of change in your true blood pressure.
9. Wait a minimum of 15 minutes between readings to allow for the blood vessels to return to normal. The wait time may vary depending on your individual physiological characteristics.
10. Although such cases are rare, for those with an extremely weak pulse or irregular pulse, errors may result which prevent proper measurement. If abnormal variations are noticed, consult with your physician or trained healthcare professional.
11. This device is intended for adult use. While taking a measurement, you can stop the inflation or deflation process of the cuff at any time by pressing the POWER button.
12. If any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent

authority of the Member State in which the user is established.

For Customer Service, It is recommended that the accuracy should be checked by manufacture every 2 years. To obtain the service please contact AViTA Corp. for the address of the repair location. Enclose the Proof of Purchase. Include $10.00 USD for the return shipping and handling. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested. If in need of assistance of setting up, using, maintaining or to report unexpected operation/events please contact manufacturer or local representative for further information and assistance. Avoid the sensor degrading; it is needed calibrate the device every 2 year.

Product Identification

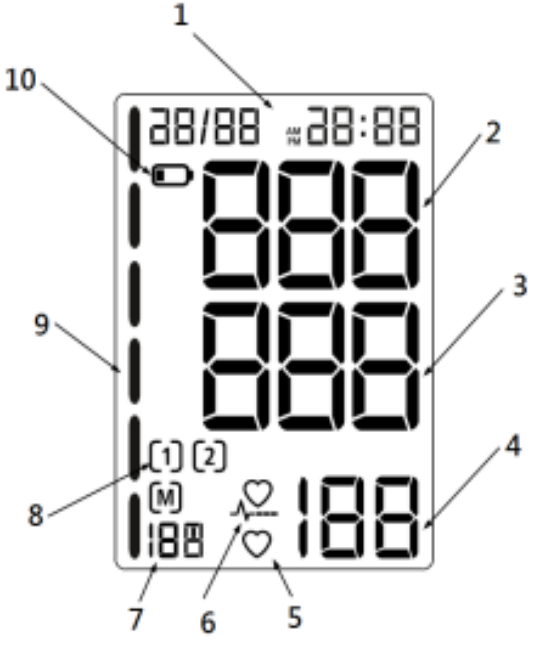


3

1. Display
2. ON/OFF button
3. Wrist Cuff
4. WHO Indicator
5. Memory 1 button, USER1
6. Memory 2 button, USER2

Description of LCD Display

1. Date and Time
2. Systolic Pressure
3. Diastolic Pressure
4. Pulse Value
5. Pulse Symbol
6. Irregular Heart Beat Symbol
7. Memory space number / memory display average value(A), morning(AM), evening(PM)
8. User memory [1] [2]
9. Classification of measurements
10. Low Battery Symbol



Battery Installation

Positioning / changing the batteries

■ Open the battery cover on the bottom of the device. Insert the batteries (see Chapter 11 - Technical Information). Ensure correct polarity (+ and –) when inserting batteries. Close the battery lid. or flashes on the display. Set date and time as described below.
■ If the ‘Change battery’ symbol is permanently illuminated, blood pressure can no longer be measured and you need to replace all of the batteries.

Setting the Date and Time

Be sure to set the date and time correctly. This is the only way to save your measured values correctly with date and time for subsequent retrieval.

To switch to Settings, reinsert the batteries or press the START/STOP button for 5 seconds. Proceed as follows:

Hours

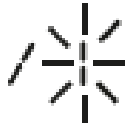
The hour format flashes on the display.

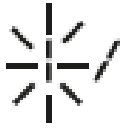
- Select the desired hour format using the Save buttons (1) / (2) and confirm using the START / STOP button ⏻.

Date

The display shows the year (a), the month (b) and the day (c).

- Depending on the display, use the Save buttons [1] / [2] to select the year, the month or the day and confirm using the START / STOP button ⏻.

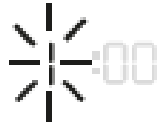




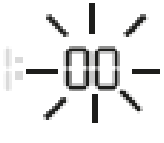
If the 12-hour format is selected, the month is displayed before the day.

Time

The hour (d) and the minutes (e) flash in sequence on the display.



- Depending on the display, use the Save buttons [1] / [2] to select the current hour or minutes and confirm using the START / STOP button ⏻.



The device switches off automatically once all data have been set.

Applying Your Cuff

Applying the blood pressure monitor

- Blood pressure must be measured on a bare wrist. The cuff should not be positioned over protruding wrist bones as it will not fit evenly around the wrist.
- The monitor has a fixed connection to the cuff and the cuff must not be detached from the monitor.
- Now pull the cuff over the wrist. The blood pressure monitor is positioned centrally on the inside of the wrist approx. 1-1.5 cm from the crease (carpus) of the wrist.

The cuff should fit firmly, but not tightly. Please note that incorrect positioning of the cuff may produce an incorrect measurement. Use the Veroval® BPW 22 only with the specially approved cuff supplied. It has a cuff circumference of 12.5 -21 cm. Using a Veroval® upper arm blood pressure monitor is recommended for wrist circumferences larger than

that, because the accuracy of the blood pressure readings cannot be guaranteed otherwise.

This innovative Veroval® device with Comfort Air Technology ensures comfortable measurement. Inflation to 190 mmHg is required for the first measurement. For subsequent measurements, inflation pressure is adjusted individually based on the blood pressure values recorded previously. This allows for more comfortable measurements.

Measurement of Pulse Rate and Blood Pressure

Taking the measurement

- Rest for approx. 5 minutes before taking the measurement.
- You should take your blood pressure in a quiet place, in a relaxed and comfortable seated position.
- Measurement can be taken on the right or left wrist. We recommend performing the measurement on the left wrist. Over the long term, the wrist giving higher readings should be used for blood pressure monitoring. However, if there is a very clear difference between readings on either wrist, you need to check with your doctor which wrist you should use for the measurement.
- Always take measurements on the same wrist.
- Take measurements on a bare wrist and while sitting upright.
- We recommend that you measure your blood pressure while sitting with your back against the back of the chair. Place both feet fl at on the floor next to each other. Do not cross your legs. Be sure to support your

arm and bend it. Always ensure that the cuff is positioned at the level of the heart. If not, measurements may vary considerably. Relax your arm and the palm of your hand.

- Do not measure your blood pressure after taking a bath or playing sport.
- Do not eat, drink or exercise for at least 30 minutes before the measurement.
- Please wait for at least one minute between two measurements.
- Always take measurements at the same time of day. Only regular measurements taken at the same time each day over an extended period give a meaningful assessment of blood pressure values.
- Do not measure when you have a strong urge to urinate. A full bladder can increase blood pressure by about 10 mmHg.
- Do not start a measurement until you have put the device on. Press the START/STOP button . The appearance of all display segments, followed by time and date, indicates that the device is carrying out an automated check and is ready for use.

■ Check the display segments for completeness (see Chapter 1).
■ The cuff automatically inflates after about 0.5 seconds. If this inflation pressure is insufficient or if the measurement is interrupted, the device continues to pump in increments of 40 mmHg until a high enough pressure is reached. During inflation, the result display on the left also increases at the same time.

Important: Do not speak or move for the duration of the measurement.

■ As the cuff pressure is released, the heart symbol flashes and the drop in cuff pressure is shown on the display.
■ After the measurement is complete, the systolic and diastolic blood pressure as well as the pulse rate are shown simultaneously.
■ In addition to the measured values, the time, date, associated user memory or and associated memory numbers (e.g. M) are shown. The measured value is automatically stored in the displayed user memory. While the result of the measurement is displayed, you can assign the

values to the corresponding user memory by pressing the or button. If you do not assign them, the measured values are automatically stored in the user memory shown on the display. You can use the result indicator on the left in the display to classify your measurement result.

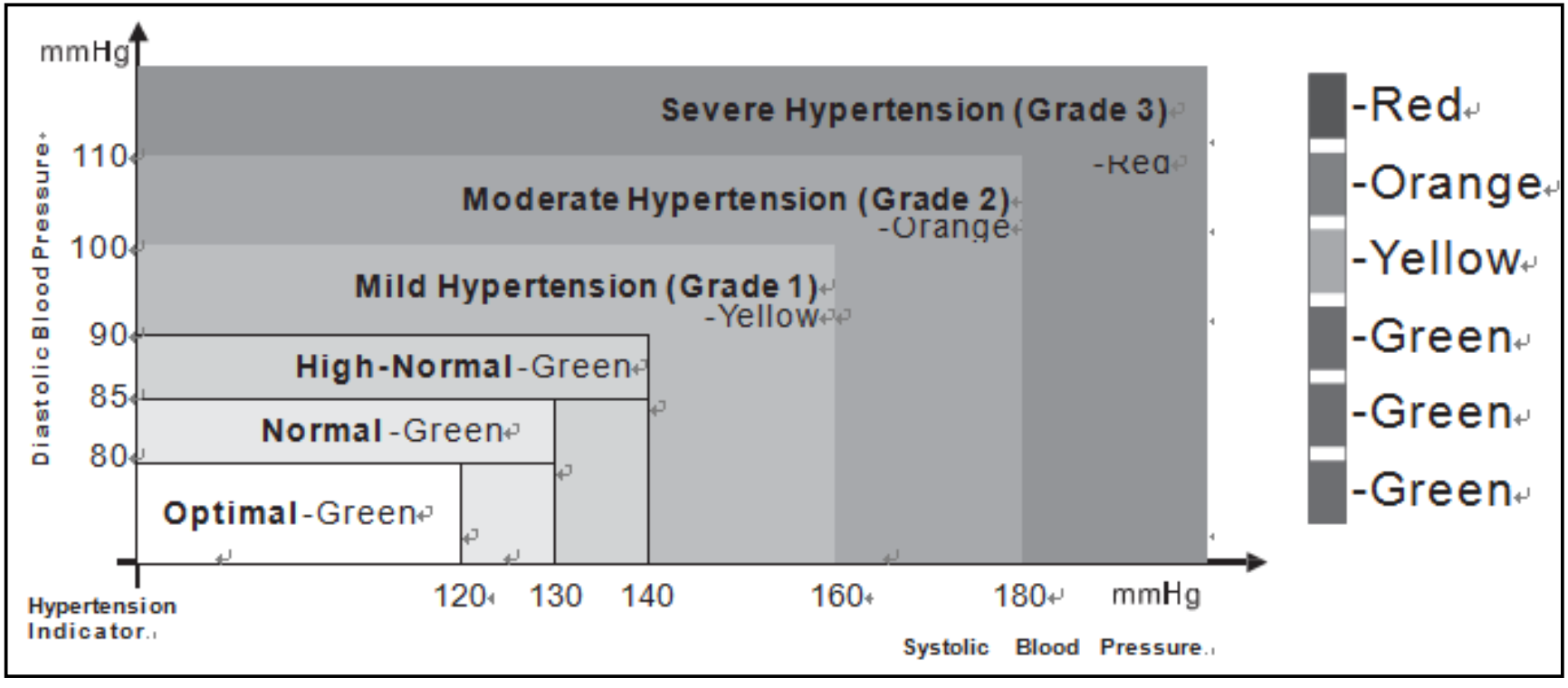
■ To switch off the device, press the START/STOP button , otherwise the device switches off automatically after 60 seconds.

If you wish to stop the measurement for any reason, simply press the START/STOP button . The inflation or measurement process is interrupted and cuff pressure is automatically released.

■ If this symbol is shown in the display, the device has detected an irregular heartbeat during the measurement. However, the measurement may also have been interrupted by body movement or speaking. It is best to repeat the measurement. If you see this symbol regularly when measuring your blood pressure, we recommend that your doctor checks your heart rhythm.

Hypertension Indicator

This monitor comes equipped with a Hypertension Indicator that automatically compares each reading to defined levels established by the World Health Organization and provides a helpful cue if your reading falls into one of the stages that could potentially indicate increased risk. Please note that cues provided by this monitor are only intended to assist you in using this table. The table and cues are only provided for convenience to help you understand to the level information. They are not a substitute for a medical examination by your physician. It is important for you to consult with your physician regularly. Your range as well as the point at which you may actually be considered to be at risk.


mmHg
Diastolic Blood Pressure
110
100
90
85
80
Severe Hypertension (Grade 3)
-Red
Moderate Hypertension (Grade 2)
-Orange
Mild Hypertension (Grade 1)
-Yellow
High-Normal -Green
Normal -Green
Optimal -Green
120
130
140
160
180
mmHg
Hypertension Indicator
Systolic Blood Pressure
-Red
-Orange
-Yellow
-Green
-Green
-Green

Irregular Heartbeat Detector

Your digital blood pressure monitor features an Irregular Heartbeat Detector. Irregular Heartbeats may influence the results of the measurement. If the monitor detects the Irregular Heartbeats during measurement, the symbol will appear on the display with the measurement values. You can take another measurement to make sure the values are not influenced by moving during measurement or Irregular Heartbeat.

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

IMPORTANT INFORMATION:

This blood pressure monitor is not designed for use by people with arrhythmias nor for diagnosing or treating an arrhythmia problem. 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 blood pressure monitor.

Memory Function

User memory

■ The Veroval® BPW 22 stores up to 100 measurements in each user memory. Once the memory is full, the oldest value is deleted.

■ Memory recall is activated by pressing the or button when the device is switched off. For values saved in the first user memory, press the button, for the second user memory press the button.

Average values

■ After selecting the respective user memory, the corresponding symbol or and an A appear on the display. The average value of all the data stored for that particular user memory is displayed.

■ By pressing the button again (or the button if you are in user memory 2), the average values for all morning measurements ‘AM’ (5 am to 9 am) taken over the last 7 days are shown.

■ By pressing the button again (or the button if you are in user memory 2) the average values for all evening measurements ‘PM’ (6.00 pm to

8.00 pm) taken over the last 7 days are shown. Individual measured values

■ By pressing the button again (or the button, if you are in user memory 2), all memory values can be retrieved one after the other, starting with the most recently measured value.

■ If an irregular heartbeat was detected during measurement, that information is also stored and displayed when the measured value is retrieved from the device’ s memory, along with the systolic and diastolic blood pressure readings, pulse rate, time, date and year.

■ You can cancel memory recall at any time by pressing the START/ STOP button . The device switches off automatically otherwise after a few seconds.

■ The stored values will still be available even if the power supply is interrupted, e.g. when changing the batteries.

Deleting stored readings

All data saved for each user can be deleted separately for user memory and user memory . To do this, press the key of the corresponding user memory (or). The average value is then shown on the display. Press and hold the user memory button for 5 seconds. ‘CL 00’ appears on the display. All data in the selected user memory have now been deleted. If you release the button early, no data will be deleted.

Error Codes

Error that occurred	Possible causes	Remedy
Monitor cannot be switched on	Batteries are missing, positioned incorrectly or flat.	Check batteries. If necessary, replace with two new identical batteries.
E1	The measuring signals could not be detected at all or read correctly. This can be caused by applying the cuff incorrectly, by moving or talking, or by a very weak pulse.	Check that the cuff has been positioned correctly. Do not talk or move during measurement.
E2	Incorrect measurement due to movement.	Do not talk or move during measurement.
E3	The cuff was not applied correctly.	Check that the cuff has been positioned correctly.
E4	Error during measurement.	Contact customer service if this error message appears.
E5	Inflation pressure is higher than 300 mmHg.	Please rest for at least 1 minute, then take the measurement again.
E6	A system error has occurred.	Contact customer service if this error message appears.
	The batteries are almost flat.	Replace the batteries.
Implausible measurements	Implausible measurements often occur if the device is handled incorrectly or if mistakes were made during the measurement process.	Please refer to Chapter 5 - Measuring Blood Pressure, as well as the Notes on Safety. Then repeat the measurement.

Switch the device off if an error message appears. Check for possible causes as well as the notes on performing the measurement yourself in Chapter 2 - Important Notes. Relax for at least 1 minute and then take the measurement again.

Troubleshooting

Problem	Cause	Remedy
The reading is extremely low (or high).	The wrist cuff is not at heart level.	Measure while in the correct posture.
	The cuff is not wrapped snugly around the wrist.	Wrap the cuff correctly.
	The arms and shoulders are tense.	Relax and try taking the measurement again.
	Movement or talking during measurement.	Remain still and do not talk during measurement.

Problem	Cause	Remedy
The blood pressure is different each time. The reading is extremely low (or high).		Blood pressure readings constantly vary with time of day and how relaxed you are. Take several deep breaths and try to remain relaxed before taking a measurement.
Nothing happens when you press the buttons.	The batteries have been inserted incorrectly	Insert the batteries with the correct (+/-) polarity.
Overpressure protection		The machine must be adjusted according to the instruction manual and with professional. equipment

Problem	Cause	Remedy
Errors with wrist positional		The machine must be adjusted according to the instruction manual and with professional

Cleaning and Disinfecting

- Clean your blood pressure monitor carefully using a slightly damp cloth only.
- Do not use any detergents or solvents.
- Never hold the instrument under water as otherwise liquid can penetrate and damage the instrument
- Never place any heavy objects on the instrument. Please note: For home use device disinfection, 75% Ethanol or Isopropyl alcohol(available in the phWristacy) can be used receipt requested.

Technical Specification

- Measuring range :
  Blood Pressure : 30~280 mmHg
  Pulse Rate : 40~199 beats/min
- Calibration Accuracy :
  Pressure : ± 3 mmHg
  Pulse rate : ± 4% of reading
- Operating environment :
  10℃~40℃ (50℉~104℉)
  with relative humidity up to 85% (non condensing)
  Atmospheric Pressure: 700~1060 hPa
- Storage/ Transportation environment :
  -20℃~+50℃ (-4℉~+122℉)
  with relative humidity up to 85% (non condensing)
  Atmospheric Pressure: 700~1060 hPa
- Power Source : 2 x 1.5 V AAA batteries

- Weight : approx. 115g (exclude batteries)
- Dimensions : approx. L 70 mm x W 85 mm x H 24 mm
- Cuff circumference : approx. 125~210 cm
- Life time: 3 years;
- Battery life: above 300 times

EMC Tables

BPM27 is intended for use in the electromagnetic environment specified below. The customer or the user of **BPM27** must make sure that it is used in such an environment.		
Guidance and manufacturer’ s declaration - Electromagnetic emissions		
Phenomenon	CISPR 11 Group 1 Class A (Not BLE Function) Group 2 Class A (With BLE Function)	CISPR 11 Group 1 Class B (Not BLE Function) Group 2 Class B (With BLE Function)
Conducted and radiated RF MISSIONS	Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested	
Harmonic distortion	Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested	
Voltage fluctuations and flickering	CISPR 11 Group 1 Class A (Not BLE Function)	

<table>
<tr><td colspan="2"></td><td colspan="2">Group 2 Class A (With BLE Function)</td></tr>
<tr><td colspan="4">a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive acceptance limits of Group 1 Class B (CISPR 11) have been considered and applied. The equipment is suitable for use in the mentioned environments when directly connected to the Public Mains Network.
b) The test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEM used will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.</td></tr>
<tr><td colspan="4">Guidance and manufacturer’ s declaration - Electromagnetic immunity - Enclosure port</td></tr>
<tr><td rowspan="2">Phenomenon</td><td rowspan="2">Basic EMC standard or test method</td><td colspan="2">Immunity test levels</td></tr>
<tr><td>Professional healthcare facility environment</td><td>HOME HEALTHCARE ENVIRONMENT</td></tr>
<tr><td>ELECTROSTATIC</td><td>IEC 61000-4-2</td><td colspan="2">± 8kV contact</td></tr>
</table>

DISCHARGE		± 2 kV, ±4kV ±, ±8 kV, ±15 kV air	
Radiated RF EM fields	IEC 61000-4-3	a)	10 V/m b) 80MHz - 2.7 GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	COMPLIANT NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the **BPM27** can be requested from supplier using the contact information provided in this manual. However, it is advisable to keep the electromechanical aerosol equipment at an adequate distance of, at least, 0.5 m from mobile phones or other RF communications transmitters to minimise possible interference.	
RATED power	IEC 61000-4-8	30 A/m c)	

frequency magnetic fields.		50 Hz or 60 Hz
a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive IMMUNITY acceptance limits have been considered and applied. b) Before modulation is applied. c) This test level assumes a minimum distance of at least 15 cm between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic fields.		

Explanation of Symbols

CE 2797	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of Regulation (EU) 2017/745
MD	Medical Device
	Manufacturer

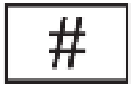
EC REP	Authorized representative in the European Community
	Date of manufacture (YYYY-MM-DD or YYYY-MM)
LOT	Batch code (YYMMWWWW)
SN	Serial number (YYMWWWXXXXX)

	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

	Caution
	Consult the instruction for use
	Disposal information: Should you wish to dispose of the article, do so in accordance with current regulations. Details are available from your local authority. WEEE 2012/19/EU Directives
RoHS	This product fulfilling the requirements of the RoHS Directive 2011/65/EU.

REACH	This product fulfilling the requirements of the REACH Directive EC 1907/2006 and its amendments, do not contain Substances of Very High Concern in concentration above the limit of 0.1 %. No substance(s) is/are present in the parts of the product above the concentration of 0.1 % weight by weight.
	“ON/OFF” (push-push)
	Device classification type BF

IP 22	This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (protection against solid foreign objects of 12.5mm ∅ and greater and against vertically falling water drops when enclosure tiled up to 15°)
	The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.
	Importer

	Distributor
	Model Number
	Country of Manufacturer
	Unique Device Identifier

BPM27P-22004AV
2022-12-14