Arm Type Blood Pressure Monitor

Model: # BPM65

INSTRUCTION MANUAL

PLEASE READ THIS INSTRUCTION MANUAL COMPLETELY
BEFORE OPERATING THIS UNIT

EN

EC REP
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Importer

Distributor

Contents

Intended Use

The product automatically measures human being' s 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 upper arm. The intended use of this over-the-counter device is for adults with upper arm circumference ranging from 220 mm to 420 mm (Approx.8.7 ~ 16.5 inches) and for home use. When the device detects the appearance of irregular heartbeats such as atrial or ventricular premature beats during measurement, an indicated symbol will appear with measuring readings.

This device is designed only for adults.

Type of Use/ Reuse

Multiple patient multiple use

Intended User

The Arm type blood pressure monitor is intended or both professional and consumer, and the patient is the intended operator.
Patient selection criteria: Handicapped persons and children are the exception, as of handicapped persons and children need assistance by another person to use the device.

Contra-indications
Do not use in these cases: common arrhythmias such as atrial or ventricular premature beats, atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, renal diseases, patient motion, trembling, shivering.

⚠ CAUTION:

- Beware of blood flow interference and resulting harmful injury to the patient caused by continuous cuff pressure.
- While using monitoring ME equipment and blood pressure monitor simultaneously being used on the same limb, pressurization of the cuff may cause monitoring ME equipment temporarily dysfunction.
- 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.

- Improper operation of automated sphygmomanometer may result in prolonged impairment of patient blood circulation, please read manual for proper use, if still not clear, contact professional health care personnel or local distributor for assistant.
- 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 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 apply the cuff other then the original manufacturer provided.
- 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.
- High BMI health condition users may result varied.
- Users shall notify serious adverse event to the central competent authority or its commissioned agency, legal entity, or manufacture.

Important Information before Use

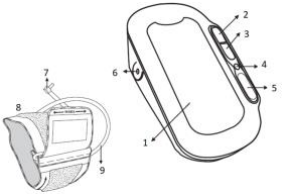
1. Blood pressure measurements should only be interpreted by a physician or a trained health care professional who is familiar with your medical history. Through regular use of this device and recording of your measurements, you can keep your physician informed of the changes in your blood pressure.
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.
13. Do not expose the device to extreme temperatures, humidity dust or direct sunlight as this may cause it to malfunction.
14. Please comply with the storage and operating conditions defined in 'Technical Specification'. Storing or using the device outside of the specified temperature and humidity range can affect measurement accuracy or the function of the device.
15. If the device was not stored within the minimum/maximum permissible storage conditions, a waiting period of at least 2 hours must be observed before using it under the specified operating conditions ('Technical Specification') or an ambient temperature of approx. 20 °C.

For Customer Service, the blood pressure monitor is calibrated when manufactured; it is recommended that the accuracy should be maintained and calibrated by manufacture triennially (every 3 years). To obtain the service please contact AViTA Corp. for the address of the

repair location. Enclose with the Proof of Purchase. Include $10.00 USD for the return shipping and handling. Accompany with a letter, with your name, address, phone number, and description of the specific problem or routine check-up. Pack the device carefully with bubble wraps (if there is) to prevent damages cause during transit. Due to possible losses in transit, it is recommended insuring the device with return receipt requested. If in any way of assistance of setting up, using, maintaining or to report unexpected operation/adverse events please contact manufacturer or local representative for further assistance.

Product Identification



1	Display
2	MEMORY Recall 1 button (M 1)
3	MEMORY Recall 2 button (M 2)
4	MODE Button
5	Start/Stop button (Power key)
6	Air socket
7	Cuff connector
8	Cuff
9	Cuff tube

Description of LCD Display

	Low battery indicator
	WHO indicator
	Date & Time
	Alarm Clock
	Irregular Heartbeat Symbol
AVG	Average measurement Symbol
	Memory Symbol
	Memory Set
	Heartbeat Symbol
	Pulse rate
	Release air
	Systolic Pressure
	Diastolic Pressure
SYS mmHg	Unit of Measurement Symbol for Systolic Pressure
DIA mmHg	Unit of Measurement Symbol for Diastolic Pressure

Battery Installation

Low battery warning:
It is necessary to replace the batteries when the Low Battery symbol "  " appears on the display, or when the display does not turn on after the POWER key is pressed.

Replacing the Battery::
1. Press down on latch and lift the cover on the bottom of the monitor.
2. Insert or replace 4x 1.5 V AA batteries into the battery compartment, ensuring to match the indicated polarity symbols. Always use new batteries.
3. Replace the battery cover.

⚠ CAUTION:

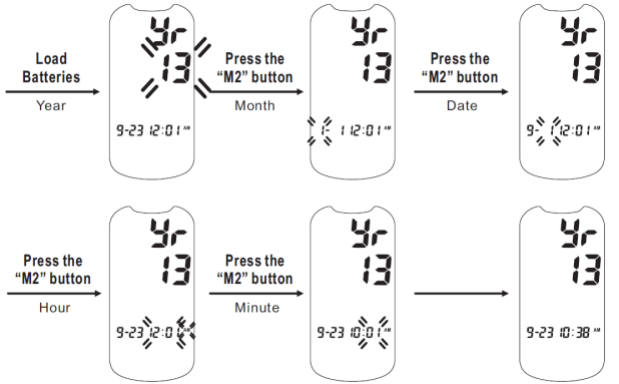
Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.

NOTE: Battery-operated
1. Please properly dispose of the batteries away from small children and heat. Avoid the children accidentally swallow the battery.
2. It is recommended to remove the batteries if the unit will not be used for more than 1 month.
3. Batteries must be disposed of in accordance with local environmental and institutional policies.
4. It is recommended not to use rechargeable, unqualified or different spec battery may damage the device or cause circuit shortcut.

Setting the Date and Time

It is necessary to set the date and time for the unit every time batteries are initially installed or replaced.

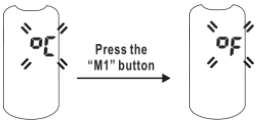
To set the date and time, proceed as follows:
1. Loading 4 AA alkaline batteries; the Year value will begin to flash on the display.
2. Press the MEMORY Recall "M1" button to advance the display to the desired year, press MEMORY Recall "M2" button to confirm the year.
3. Next, the month will blink. Repeat steps 2 to set the month and date, then hours, then minutes.
4. After setting the minutes, the unit will automatically exit out of the date/time setting mode and briefly show the word OFF before shutting down.



Setting the Monitor for Ambient Temperature

Note:
After the date and time are set, the monitor will prompt you to set the temperature for either Fahrenheit or Celsius readings.

1. Select the "M1" button to toggle between ℃ or ℉.
2. Select the "M2" button to confirm the entry.
3. After initial set up, select the POWER button to turn the unit off. Press the POWER button again to turn on the unit to take a blood pressure reading.
4. You can check the Ambient Temperature and Date/Time when press the "MODE" button during Power-off mode. Keep press the "MODE" button to enter Alarm Clock setting procedure.
5. The unit will automatically shut-off after approximately 2 minutes idling.

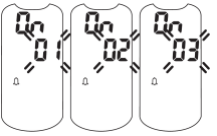


Note:
The ambient temperature showing on the LCD is for reference only.

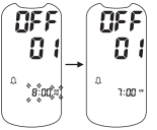
Setting the Alarm Clock

This monitor features an alarm clock setting, allowing the user to set reminders for up to three daily alarms. The alarm clock function serves as a reminder for those users who may need to track measurements at consistent, specific times of the day.

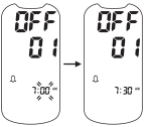
1. Press the "Mode" button to enter Alarm Clock Setting procedure.



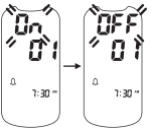
2. Continue to press the "Alarm set" button until you have selected which alarm to set (alarm 1, 2 or 3).
3. With the chosen alarm screen displayed, the hour will begin to flash.
4. Press the MEMORY Recall "M1" button to advance to the desired "hour". Press the MEMORY Recall "M2" button to confirm.



5. Press the MEMORY Recall "M1" button to advance to the desired "minutes". Press the MEMORY Recall "M2" button to confirm.



6. Press the MEMORY Recall "M1" button to toggle between ON and OFF. Press the MEMORY Recall "M2" button to confirm your selection.



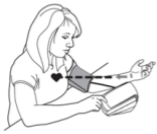
7. If setting more than one alarm reminder, repeat all steps for the 2nd and 3rd alarm clock.
8. Press the POWER button to turn off the unit. The alarm will sound at the appropriate set time even though the unit is powered OFF.

Placement of the Pressure Sleeve

It is important to avoid smoking, eating, taking medication, alcohol consumption or physical activity 30 minutes prior to taking a reading. If for any reason you are unable to or should not use your left arm, please modify the instructions for cuff application to your right arm. Your physician can help you identify which arm is best for you to take measurements from.

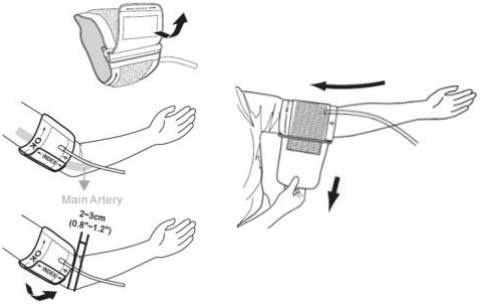
1. Remove any constrictive clothing or jewelry that may interfere with cuff placement.
2. Be seated at a table or desk with your feet flat on the floor.
3. The cuff should not be plugged into the monitor until after the cuff is applied to your arm.

Note:
Blood pressure naturally varies from one arm to the other; therefore, measure your blood pressure on the same arm to ensure comparability of the two readings.



4. Position the cuff on a solid surface with the tubing facing up and away from you. The metal ring/bar on the cuff should be to the left of the tubing.
5. Open the cuff by pulling or rolling the bottom of the cuff to the right. This should open the cuff without fully unrolling it, creating a cylinder. Do not fully unwrap or unroll the cuff.

6. Insert your left arm into the created cuff cylinder.



7. The bottom edge of the cuff should be positioned approximately one inch above the elbow joint.
8. Reaching underneath your left arm with your right hand, pull the end of the cuff towards your body to tighten the cuff. Wrap and secure the cuff, making sure in place as shown.
9. The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger easily between your arm and the cuff.

Note:
If you are not comfortable with applying your cuff, please seek the assistance of another member of your household or work with your physician to practice the cuff application. Incorrectly applied cuffs may result in inaccurate readings.

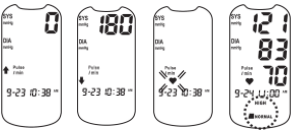
Measurement of Pulse Rate and Blood Pressure

Please read the preceding portions of this manual prior to taking your first reading.

1. Position the monitor on a flat, stable surface with the digital display in view.
2. Insert the cuff tubing connector into the port on the left side of your monitor.
3. Rest your elbow on a solid surface with your palm facing upward. Elevate your arm so that the cuff is at the same level as your heart. Relax your left hand.

1. Press the Power key to turn the power on. After full display is shown, the values for the last reading will appear on the display. If there is no measurement, the unit displays the value "0".

2. After the self-test, the blood pressure monitor starts to measure. The cuff will automatically begin to inflate, with the display showing the increasing pressure in the cuff.
3. As the pressure increases, the indicator will increase upwards according to the pressure value on the display.
4. As the cuff inflates, the monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation.



5. To detect the heartbeat, the heartbeat symbol will appear and continuous flashes on the LCD display.
6. Your blood pressure measurement and pulse will display simultaneously on the screen.
7. The Hypertension Indicator will indicate your reading range on the display separately.
8. Press the Power key to turn the unit off and conserve energy and battery life.

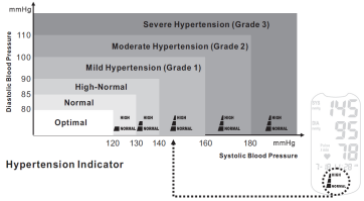
The unit will automatically shut-off approximately 2 minutes.

Note:

1. Users are recommended to use BPM65 daily at a fixed time, frequency of usage from 1 to 3 times can be suggested from physician or doctor’ s advice.
2. Base on individual body condition the typical operation time takes approximately 30 seconds to 1 minute.

Hypertension Indicator

This unit features our unique Hypertension Indicator. The World Health Organization has established globally accepted standards for the assessment of high or low blood pressure readings. The below chart should be considered only as a guideline, always consult with your physician or health care professional to interpret your individual results.



Irregular Heartbeat Detector

Your digital blood pressure monitor features an Irregular Heartbeat Detector. This feature allows users to accurately monitor blood pressure even if an irregular heartbeat should occur. When an irregular heartbeat "♡" is detected, the icon will appear on the display.

Note:
Please consult with your physician or trained healthcare professional for further information regarding an irregular heartbeat and if this symbol appears frequently.

INPORTANT 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.

Atrial Fibrillation (AFIB)

This device is a blood pressure monitor that also analyses heart rate variability during measurement.
While in power off mode, press Power key into select AF mode, and use "M" key to select "ON" or "OFF" the AF mode. Confirm your selection with the Power key to turn the power on and start to measure your blood pressure.

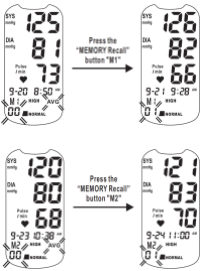
This feature allows users to accurately monitor blood pressure even if atrial fibrillation should occur. When atrial fibrillation is detected, the "AF" icon will appear on the display.

Note:
1. Please consult with your physician or trained healthcare professional for further information regarding an atrial fibrillation if this symbol appears frequently.
2. Even if the AF symbol does not appear, there is still a possibility of Afib.

Memory Function

Recalling Measurements in Memory:
You can recall up to 60 measurements per memory bank, 120 total, plus an average of last 3 currently stored measurements in memory to share with your physician or trained healthcare professional.

1. Press and release the M1 or M2 button. The unit will first display the average of last 3 currently stored measurements.
2. Continue to press the M1 or M2 button to successively view the next previously stored measurements. Measurements will appear on the display from most current to oldest; the memory number will appear on the lower left corner. appear on the lower left corner.
3. All results for a given measurement will display, including measurement results, pulse rate, Hypertension Indicator, Irregular Heartbeat alert, and date/time stamp.
4. Each memory bank stores up to 60 readings; when the number of readings exceeds 60, the oldest data will be replaced with the new record.
5. Press the Power button to turn the monitor OFF at any time during review of the stored measurements.



Clearing Measurements from Memory:

From power display off, press and hold down the "MEMORY Recall" Button until the display shows CLr. This indicates that all measurements have been erased.

Error Codes

Err Code	Meaning	Corrective Action
Err 00	No pulse or detect pulses not enough.	Take off heavy clothes and retry again.
Err 01	The cuff is not fastened correctly, cuff pressure leakage or inflation too low or Overpressure protection	The Arm cuff is not fastened properly. Re- apply the cuff, and take a measurement again.
Err 02	Inaccurate reading	Rest a while, relax and retry again.
Err 03	Inflation or deflation fail during the measurement	The Arm cuff is not fastened properly. Re- apply the cuff, and take a measurement again.
Err	Memory error.	Take off batteries to reboot the device, then take another measurement.
	Low batteries	Replace all batteries with new ones.

Troubleshooting

Problem	Probable Cause	Recommended Action
Nothing appears in the display even when the power is turned on.	Batteries are drained.	Replace all batteries with new ones.
	Battery are not correctly aligned with terminals.	Reinsert batteries in the correct position.
Low Battery Symbol appears.	Batteries are drained.	Replace all batteries with new ones.
	In colder temperatures batteries have weaker electrical charges.	Warm up the batteries, or use the device in a warmer setting.
Device operation time is inconsistent.	Different battery brands have different life spans.	Use Alkaline batteries and replace all batteries at the same time with same brand batteries.
No reading after measurement.	Batteries are drained.	Replace all batteries with new ones.
Suspicious blood pressure results.	Perhaps the cuff was improperly positioned.	Adjust patient and Arm cuff to measure.
	Blood pressure naturally varies throughout the day.	Rest a while, relax and measure again.
Suspicious pulse rate results.	Bodily movement during device use.	Refrain from moving during measurement.
	Measurement shortly after exercise or exposure to the outdoors.	Do not take measurements after exercise or coming back from the outdoors.
Power switches off automatically.	System design.	Push the power button again, and then begin measure again.
During measuring, air re- inflates.	It could be a normal action if the user's blood pressure is higher than the initial pressure value, the device automatically pumps to a higher pressure by 40mmHg each time.	Relax, and try to take a measure again.
	The Arm cuff is not fastened properly.	Check that the Arm cuff is fastened properly and retake the measurement.

Cleaning and Disinfecting

- Only use a soft, damp cloth to clean the monitor. Please do not use thinner, alcohol, detergents or solvents.
- The cuff can be cleaned carefully using a slightly damp cloth and mild soap solution. Do not completely immerse the cuff in water.
- It is recommended to clean and disinfect the cuff regularly or after each use, especially when used by several users, to prevent infection. The cuff should be disinfected, particularly on the inside, by wiping with a disinfectant. Use a disinfectant that is compatible with the cuff materials, e.g. 75 % ethanol or isopropyl alcohol.
- Keep the monitor in the appropriate carriage to protect it from external influences. And store it at appropriate condition.

Technical Specification

- Measuring range :
  Blood Pressure : 30~280 mmHg
  Pulse Rate : 40~199 beats/min
- Calibration Accuracy:
  Blood Pressure : ± 3 mmHg
  Pulse rate : ± 4% of reading
- Operating environment :
  10°C~40°C 

  15% to 85% relative humidity (non-condensing)
  700-1060 hPa ambient pressure
- Storage/ Transportation environment :
  -20 to 50 °C 

  15% to 85% relative air humidity (non-condensing)
  700-1060 hPa ambient pressure
- Power Source : 4 x 1.5V LR6 (AA) alkaline
- Weight : approx. 300g (exclude batteries) +/- 5%
- Dimensions :
  92.5mm x 144mm x 49mm (L x W x H)
- Cuff circumference (M and L Size) :
  M Size approx. 22.9 ~ 33 cm (9" ~ 13")
  L Size approx. 33 ~ 43.2 cm (13" ~ 17")
- Lifetime : 3 years
- Expected service life : 10,000 measurements

Note: After 3 years life time or 10,000 measurements, device material may experience degradation, measurement accuracy may vary.

EMC Tables

<table>
<tr><td colspan="4">BPM65 is intended for use in the electromagnetic environment specified below. The customer or the user of BPM65 must make sure that it is used in such an environment.</td></tr>
<tr><td colspan="4">Guidance and manufacturer’ s declaration - Electromagnetic emissions</td></tr>
<tr><td>Phenomenon</td><td colspan="2">CISPR 11
Group 1 Class A (Not BLE Function)
Group 2 Class A (With BLE Function)</td><td>CISPR 11
Group 1 Class B (Not BLE Function)
Group 2 Class B (With BLE Function)</td></tr>
<tr><td>Conducted and radiated RF MISSIONS</td><td colspan="2">Not applicable
(Note: Power by Battery or DC Input)
Only the AC input needs to be tested</td><td></td></tr>
<tr><td>Harmonic distortion</td><td colspan="3">Not applicable
(Note: Power by Battery or DC Input)
Only the AC input needs to be tested</td></tr>
<tr><td>Voltage fluctuations and flickering</td><td colspan="3">CISPR 11
Group 1 Class A (Not BLE Function)
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 **BPM65** can be requested from supplier using the contact information provided in this manual. However, it is advisable to keep the 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 frequency magnetic fields.	IEC 61000-4-8	30 A/m c) 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

Symbol	Definition
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.
	Stand-by
	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 ø 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
	Keep away from sunlight

Electronic IFU available at http://www.avita.com.tw

BPM65-22572AV
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