



SMARTMETER
Engaging Health Data

CELLULAR BLOOD PRESSURE MONITOR UPPER ARM UA-651CEL-SM

Instruction Manual



Greetings

The iBloodPressure® 2.0 from A&D and Smart Meter is one of the most advanced blood pressure monitors available and is designed for ease of use and accuracy. This device will facilitate your daily blood pressure regimen. We recommend that you read through this manual carefully before using the device for the first time.

Intended Use

- The monitor is designed for use on adults only. Do not use on newborns or infants.
- Environment for use: This monitor is intended for home healthcare environment.
- This monitor is designed to measure blood pressure and pulse rate of people for diagnosis

Precautions

- Precision components are used in the construction of this device. Extremes in temperature, humidity, direct sunlight, shock or dust should be avoided.
- Clean the device and cuff with a dry, soft cloth or a cloth dampened with water and a neutral detergent. Never use alcohol, benzene, thinner or other harsh chemicals to clean the device or cuff.
- Avoid tightly folding the cuff or storing the hose tightly twisted for long periods, as such treatment may shorten the life of the components.
- The device and cuff are not water resistant. Prevent rain, sweat and water from soiling the device and cuff.
- Measurements may be distorted if the device is used close to televisions, microwave ovens, cellular telephones, X-ray or other devices with strong electrical fields.
- When using the device, confirm that the device is clean.
- Used equipment, parts and batteries are not treated as ordinary household waste, and must be disposed of according to the applicable local regulations.

Precautions

- When the AC adapter is used, make sure that the AC adapter can be readily removed from the electrical outlet when necessary.
- Do not modify the device. It may cause accidents or damage to the device.
- To measure blood pressure, the arm must be squeezed by the cuff hard enough to temporarily stop blood flow through the artery. This may cause pain, numbness or a temporary red mark to the arm. This condition will appear especially when measurement is repeated successively. Any pain, numbness, or red marks will disappear with time.
- Take care to avoid accidental strangulation of babies or infants with the hose and cable.
- Do not twist the air hose during measurement. This may cause injury due to continuous cuff pressure.
- Wireless communication devices, such as home networking devices, mobile phones, cordless phones and their base stations, walkie-talkies can affect this blood pressure monitor. Therefore, a minimum distance of 30 cm (12") should be kept from such devices.
- Measuring blood pressure too frequently may cause harm due to blood flow interference. Check that the operation of the device does not result in prolonged impairment of blood circulation, when using the device repeatedly.
- If you have had a mastectomy, please consult a doctor before using the device.
- Do not let children use the device by themselves and do not use the device in a place within the reach of infants.
- There are small parts that may cause a choking hazard if swallowed by mistake by infants.
- Do not apply the cuff on an arm in which another medical device is attached. The equipment may not function properly.
- People who have a severe circulatory deficit in the arm must consult a doctor before using the device, to avoid medical problems.

Precautions

- Do not self-diagnose the measurement results and start treatment by yourself. Always consult your doctor for evaluation of the results and treatment.
- Do not apply the cuff on an arm with an unhealed wound.
- Do not apply the cuff on an arm receiving an intravenous drip or blood transfusion. It may cause injury.
- Do not use the device where flammable gases such as anesthetic gases are present. It may cause an explosion.
- Do not use the device in highly concentrated oxygen environments, such as a high-pressure oxygen chamber or an oxygen tent. It may cause a fire or explosion.
- This device complies with Part 15 of FCC rules and contains the FCC ID XMR201912BG77. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operations.
- This device complies with Industry Canada licence-exempt RSS standard(s) and contains IC 8595A-UBX19KM01. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.
- Unplug the AC adapter when not in use during the measurement.
- Use of accessories not detailed in this manual may compromise safety.
- Should the battery short-circuit, it may become hot and potentially cause burns.
- Allow the device to adapt to the surrounding environment before use (about one hour).
- Clinical testing has not been conducted on newborn infants and pregnant woman.

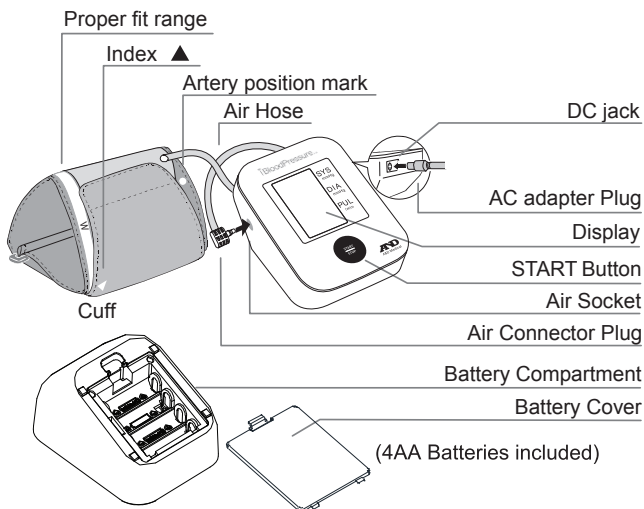
Precautions

- Do not touch the batteries, the DC jack, and the patient at the same time. That may result in electrical shock.
- Do not inflate without wrapping the cuff around the upper arm.
- A&D Medical and Smart Meter cannot accept liability for any damages incurred due to impaired operation or data loss, etc. that occur through the use of this product.

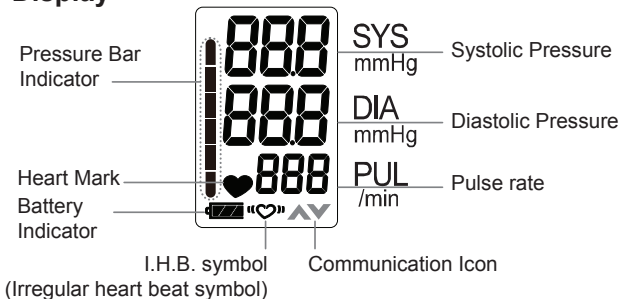
Contents

Parts Identification	E-6
Symbols	E-7
Network Connectivity	E-8
Using the Monitor	E-9
Taking your Blood Pressure	E-14
What is an Irregular Heartbeat	E-17
Pressure Bar Indicator	E-17
AHA Classification	E-18
About Blood Pressure	E-19
Troubleshooting	E-21
Maintenance	E-22
Technical Data	E-23
Warranty	E-28

Parts Identification



Display

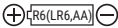


Symbols

Symbols	Function/Meaning	Recommended Action
	Appears while measurement is in progress. It blinks when the pulse is detected.	Measurement is in progress. Remain as still as possible.
	Irregular Heartbeat symbol (I.H.B.) appears when an irregular heartbeat is detected. It may light when a very slight vibration like shivering or shaking is detected.	_____
	FULL BATTERY – The battery power indicator during measurement.	_____
	LOW BATTERY The battery is low when it blinks.	Replace all batteries with new ones when the indicator blinks.
	Unstable blood pressure due to movement during the measurement.	Take another measurement. Remain still during the measurement.
	The systolic and diastolic values are within 10 mmHg of each other.	Apply the cuff correctly, and try the measurement again.
	The pressure value did not increase during inflation.	
	The cuff is not applied correctly.	
	Pulse display error. The pulse is not detected correctly.	
	Device internal error	Remove the batteries and press the  button, and then install the batteries again. If the error still appears, contact the dealer.
		
	The product is connecting to the cellular network.	_____

Symbols

Symbols printed on the device case

Symbols	Function/Meaning
	Standby and turn the device on.
SYS	Systolic blood pressure in mmHg
DIA	Diastolic blood pressure in mmHg
PUL/min	Pulse per minute
	Battery installation guide
	Direct current
IP	International protection symbol
SN	Serial number
	Refer to instruction manual/booklet
	Keep dry
	Polarity of DC jack

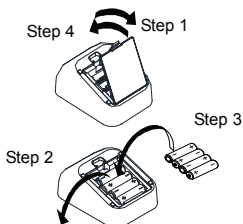
Network Connectivity

The SIM in this monitor is equipped with the capability to connect to multiple cellular carrier networks and will allow the device to operate on the strongest available network in the device's geographic area. In the event there is a service interruption, the SIM will switch to another available network, maintaining an uninterrupted connection. Note, the initial reading may take longer than subsequent readings, as the device needs to establish carrier availability.

Using the Monitor

Installing/Changing the batteries

1. Remove the battery cover.
2. Remove the used batteries from the battery compartment when changing them.
3. Insert new batteries or replace used batteries as shown, taking care that the polarities (+) and (-) are correct.
4. Replace the battery cover. Use only AA batteries.



CAUTION

- Insert the batteries as shown in the battery compartment. If installed incorrectly, the device will not work.
- When  blinks on the display and the device indicates that the battery needs to be replaced, replace all batteries with new ones. Do not mix old and new batteries. It may shorten the battery life, or cause the device to malfunction. Replace the batteries two seconds or more after the device turns off.
- If  does not appear, then the batteries are completely drained.
- The battery life varies with the ambient temperature and may be shorter at low temperatures. Generally, four new AA batteries will last approximately for one year when used twice for measurement each day.
- Use the specified batteries only.
- Remove the batteries if the device is not to be used for a long time. The batteries may leak and cause a malfunction.

Using the Monitor

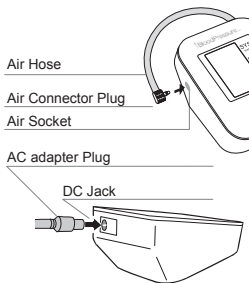
Connecting the Air Hose

Insert the air connector plug into the air socket firmly.

Connecting the AC Adapter

Insert the AC adapter plug into the DC jack. Then, insert the AC adapter into an electrical outlet. The AC adapter part # TB-233, is sold separately.

- Use the specified AC adapter.
(See Technical Data)
- When disconnecting the AC adapter from the electrical outlet, grasp the body of the AC adapter plug and gently pull the AC adapter out of the outlet.
- When disconnecting the AC adapter plug from the blood pressure monitor, grasp the monitor and gently pull the AC adapter plug out of the monitor.



Using the Monitor

Transmitting Temporarily Stored Data

In cases when the network cannot receive measurement data, the measurement data is temporarily stored in the monitor memory. The data stored in the memory is transmitted the next time a connection is successfully made to the network. A total of 5 sets of measurement data can be stored. When the amount of data exceeds 5 sets, the oldest data is deleted and the new data is stored.

Time

This monitor has a built-in clock. The date and time a measurement was taken is included in the measurement data. The built-in clock is designed to be automatically adjusted by syncing with the cellular network. This monitor has no clock adjustment function.

Selecting the correct cuff

Using the correct cuff size is important for an accurate reading. If the cuff is not the proper size, the reading may yield an incorrect blood pressure value.

The arm size is printed on each cuff.

The index ▲ and proper fit range, on the cuff, tell you if you are applying the correct cuff. For further information, refer to "Applying The Arm Cuff".

If the index ▲ points outside of the range, contact your care provider about getting a replacement cuff.

The arm cuff is a consumable. If it becomes worn, contact your care provider.

Part Number	Description	Specification
UA-420	Wide Range cuff	8.6-16.5" (22 to 42cm)
UA-291	Large cuff	12.2-17.7" (31 to 45cm)

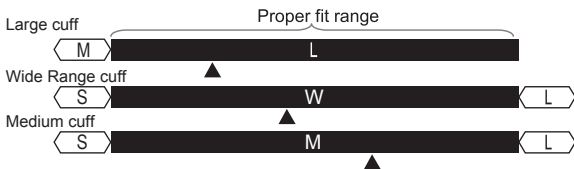
Arm size: The circumference at the biceps.

Note: Model UA-651CEL-SM is not designed to use a small cuff.

Using the Monitor

Symbols that are printed on the cuff

Symbols	Function/Meaning	Recommended Action
●	Artery position mark	Set the ● mark on the artery of the upper arm or in line with the ring finger on the inside of the arm.
▲	Index	_____
REF	Catalog number	_____
LOT	Lot number	_____
	Type BF: Cuff is designed to provide special protection against electrical shocks.	_____
W	Proper fit range for the Wide Range cuff.	_____
L	Proper fit range for the Large cuff.	_____
M	Proper fit range for the Medium cuff.	_____
S	Under range printed on the medium cuff and Wide Range cuff.	_____
M	Under range printed on the large cuff.	Use the Medium cuff
L	Over range printed on the medium cuff and Wide Range cuff.	Use the large cuff instead of the medium cuff or the Wide Range cuff.

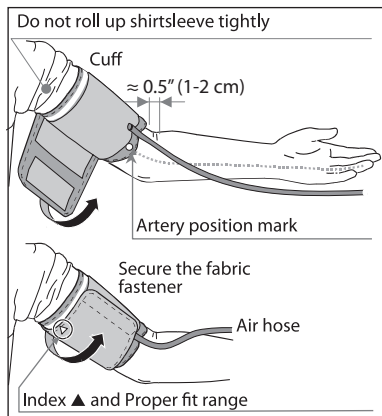


Using the Monitor

Applying the arm cuff

1. Wrap the cuff around the upper arm, about 0.5" (1-2 cm) above the inside of the elbow as shown.
2. Place the cuff directly against the skin, as clothing may cause a faint pulse and result in a measurement error.
3. Constriction of the upper arm, caused by rolling up a shirtsleeve, may prevent accurate readings.
4. Confirm that the index ▲ points within the proper fit range.

Note: During measurement, it is normal for the cuff to feel very tight.



Taking your Blood Pressure

This blood pressure monitor is designed to detect the pulse and to inflate the cuff to a systolic pressure level automatically.

Tips for Taking Blood Pressure

Before Your Measurement:

- For 30 minutes prior to taking your blood pressure
 - » Do not exercise
 - » Do not drink coffee, caffeinated soda or alcohol
 - » Do not smoke
- Sit quietly for 5-10 minutes
- Ensure you are using the right cuff size

During Your Measurement:

- Do not talk
- Sit with your back straight and supported
- Uncross your legs and place feet flat on floor
- Rest your arm on a table and keep the cuff at heart level
- Measure two times a day, in the morning and evening

Notes for Accurate Measurement

- This monitor bases its measurements on the heartbeat. If you have a very weak or irregular heartbeat, the monitor may have difficulty determining your blood pressure.
- Should the monitor detect a condition that is abnormal, it will stop the measurement and display an error symbol. Refer to the section "Symbols" for the description of the symbols.
- If you have emotional stress, the measurement will reflect this stress as a higher (or lower) than normal blood pressure reading and the pulse reading will usually be faster than normal.
- An individual's blood pressure varies constantly, depending on what you are doing and what you have eaten. What you drink can have a very strong and rapid effect on your blood pressure.

Taking your Blood Pressure

Normal Measurement

1. Place the cuff on the arm (preferably the left arm). Sit quietly during measurement.
2. Press the START button. All of the display segments are displayed. Zero is displayed blinking briefly. Then the display changes, as indicated in the figure to the right, as the measurement begins. As the cuff inflates, it is normal to feel the cuff tighten around your arm. During inflation, a pressurization bar is displayed, as shown in the figure to the right.

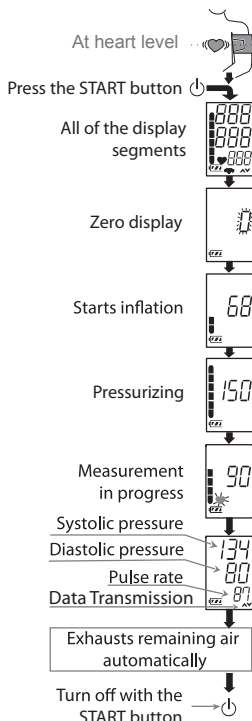
Note: If you wish to stop inflation at any time, press the START button again.

3. When inflation is complete, deflation starts automatically and the ♥ (heart mark) blinks, indicating that the measurement is in progress. Once the pulse is detected, the ♥ blinks with each pulse beat.

Note: If an appropriate pressure is not obtained, the device starts to inflate again automatically.

4. When the measurement is complete, the systolic and diastolic pressure readings and pulse rate are displayed. The device starts data transmission. The cuff exhausts the remaining air and deflates completely.
5. Press the START button again to turn off the power.

Note: This product is provided with an automatic power shut-off function, which turns the power off approximately one minute after measurement.

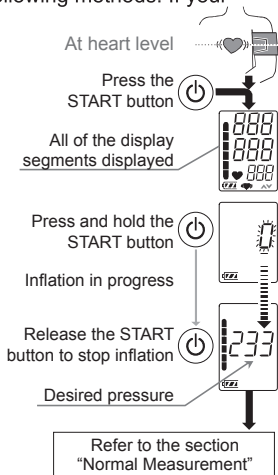


Taking your Blood Pressure

Measurement with the Desired Systolic Pressure

If re-inflation occurs repeatedly, use the following methods. If your systolic pressure is expected to exceed 230 mmHg, use this procedure.

1. Place the cuff on the arm at heart level (preferably the left arm).
2. Press the START button.
3. During the zero blinks, press and hold the START button until a number about 30 to 40 mmHg higher than your expected systolic pressure appears.
4. When the desired number is reached, release the START button to start measurement. Then continue to measure your blood pressure as described on the section "Normal Measurement".



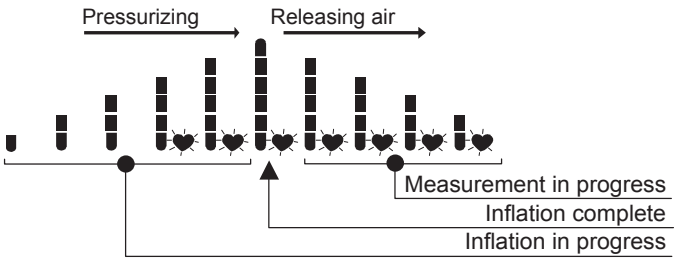
What is an Irregular Heartbeat

An irregular heartbeat is defined as a heartbeat that varies from the average of all heartbeats. When the monitor detects an irregular rhythm during the measurements, the IHB indicator will appear on the display with the measurement values.

Note: We recommend contacting your physician if you see this «» IHB indicator frequently.

Pressure Bar Indicator

The indicator monitors the progress of pressure during measurement



AHA Classification

Blood Pressure Classification	Systolic (mmHg)		Diastolic (mmHg)
Normal	< 120	and	< 80
Elevated	120-129	and	< 80
Hypertension Stage 1 (High Blood Pressure)	130-139	or	80-89
Hypertension Stage 2 (High Blood Pressure)	≥ 140	or	≥ 90
HYPERTENSIVE CRISIS (consult your doctor immediately)	> 180	and / or	> 120

About Blood Pressure

What is Blood Pressure?

Blood pressure is the force exerted by blood against the walls of the arteries. Systolic pressure occurs when the heart contracts. Diastolic pressure occurs when the heart expands. Blood pressure is measured in millimeters of mercury (mmHg). One's natural blood pressure is represented by the fundamental pressure, which is measured first thing in the morning while one is still at rest and before eating.

What is Hypertension and How is it Controlled?

Hypertension, an abnormally high arterial blood pressure, if left unattended can cause many health problems including stroke and heart attack. Hypertension can be controlled by altering lifestyle, avoiding stress, and with medication under a doctor's supervision. To prevent hypertension or keep it under control:

- Do not smoke
- Exercise regularly
- Reduce salt and fat intake
- Have regular physical checkups
- Maintain proper weight

Why Measure Blood Pressure at Home?

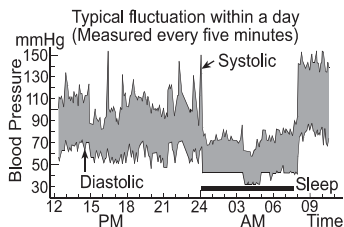
Blood pressure measured at a clinic or doctor's office may cause apprehension and can produce an elevated reading, 25 to 30 mmHg higher than that measured at home. Home measurement reduces the effects of outside influences on blood pressure readings, supplements the doctor's readings and provides a more accurate, complete blood pressure history.

About Blood Pressure

Blood Pressure Variations

An individual's blood pressure varies greatly on a daily and seasonal basis. It may vary by 30 to 50 mmHg due to various conditions during the day. In hypertensive individuals variations are even more pronounced. Normally, the blood pressure rises while at work or play and falls to its lowest levels during sleep. So, do not be overly concerned by the results of one measurement.

Take measurements at the same time every day using the procedure described in this manual to get to know your normal blood pressure. Regular readings give a more comprehensive blood pressure history. Be sure to note the date and time when recording your blood pressure. Consult your doctor to interpret your blood pressure data.



Troubleshooting

Problem	Possible Reason	Recommended Action
Nothing appears in the display, even when the power is turned on.	Batteries are drained.	Replace all batteries with new ones.
	Battery terminals are not in the correct position.	Reinstall the batteries with negative and positive terminals matching those indicated on the battery compartment.
The cuff does not inflate.	Battery voltage is too low.  (LOW BATTERY mark) blinks. If the batteries are drained completely, the  does not appear.	Replace all batteries with new ones.
The device does not measure. Readings are too high or too low.	The cuff is not applied properly.	Apply the cuff correctly.
	You moved your arm or body during measurement.	Make sure you remain very still and quiet during measurement.
	The cuff position is not correct.	Sit comfortably and still. Place your arm on a table with your palm facing upward and the cuff at the same level as your heart.
	_____	If you have a very weak or irregular heartbeat, the device may have difficulty in determining your blood pressure.
Other	The value is different from that measured at a clinic or doctor's office.	At a clinic or doctor's office apprehension may cause an elevated reading. Home measurement reduces the effects of outside influences on blood pressure readings, supplementing the doctor's readings.
	_____	Remove the batteries. Place them back properly and try the measurement again.

Note: If the actions described above do not solve the problem, contact the dealer. Do not attempt to open or repair this product, as any attempt to do so will make your warranty invalid.

Maintenance

Do not open the device. It uses delicate electrical components and an intricate air unit that could be damaged. If you cannot fix the problem using the troubleshooting instructions, contact your care provider.

Technical Data

Type	UA-651CEL-SM
Measurement method	Oscillometric measurement
Measurement range	Pressure: 0-299 mmHg Systolic pressure: 60-279 mmHg Diastolic pressure: 40-200 mmHg Pulse: 40-180 beats /min
Measurement accuracy	Pressure: ± 3 mmHg Pulse: ± 5 %
Power supply	4 x 1.5V batteries (AA) or AC adapter (TB-233) (<i>Not included</i>)
Rating	DC6V 3W
Classification	Internally powered ME equipment (<i>Supplied by batteries</i>)/Class II (<i>Supplied by adapter</i>) Continuous operation mode
Clinical test	According to ISO81060-2:2013 In the clinical validation study, K5 was used on 85 subjects for determination of diastolic blood pressure.
Wireless communication	4G LTE CAT-M1

Technical Data

Frequency band	Band 2: 1900 MHz Band 4: 1700 MHz Band 12: 700 MHz
Maximum RF output power	25 dBm (316 mW)
Modulation	QPSK
EMD	IEC60601-1-2:2014
Operating conditions	+10 to +40 °C / 15 to 85 %RH / 800 to 1060 hPa
Transport/Storage conditions	-20 to +60 °C / 10 to 95 %RH / 700 to 1060 hPa
Dimensions	Approx. 96 [W] x 68 [H] x 130 [D] mm
Weight	Approx. 250 g, excluding the batteries
Ingress protection	Device: IP20
Applied part	Cuff Type BF 
Useful life	Device: 5 years (<i>when used six times a day</i>) Cuff: 2 years (<i>when used six times a day</i>)

NOTE: Specifications are subject to change without prior notice. The AC adapter is required to be inspected or replaced periodically. IP classification is the degrees of protection provided by enclosures in accordance with IEC 60529. This device is protected against solid foreign objects of 12 mm diameter and greater such as a finger. This device is not protected against water.

Technical Data

FCC CAUTION

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment. 15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference and
- 2) this device must accept any interference received, including interference that may cause undesired operation of the device.

Technical Data

EMD Technical Data

Battery-operated or AC Adapter-operated Blood Pressure Monitor

Medical Electrical Equipment needs special precautions regarding EMD and needs to be installed and put into service according to the EMD information provided in the following.

Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment.

The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit.

Table 1 - EMISSION Limits -

Phenomenon	Compliance
Conducted and radiated RF EMISSION CISPR 11	Group 1, Class B
Harmonic distortion IEC 61000-3-2	Class A
Voltage fluctuations and flicker IEC 61000-3-3	Compliance

Table 2 - IMMUNITY TEST LEVELS : Enclosure Port -

Phenomenon	IMMUNITY TEST LEVELS
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table 4
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3 - IMMUNITY TEST LEVELS : Input a.c. power Port -

Phenomenon	IMMUNITY TEST LEVELS
Electrical fast transients / bursts IEC 61000-4-4	±2 kV 100 kHz repetition frequency

Technical Data

Phenomenon	IMMUNITY TEST LEVELS
Surges Line-to-line IEC 61000-4-5	± 0.5 kV, ± 1 kV
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips IEC 61000-4-11	0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
	0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0°
Voltage interruption IEC 61000-4-11	0% U_T ; 250/300 cycle
NOTE U_T is the AC mains voltage prior to application of the test level.	

Table 4 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment -

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						

Technical Data

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
1720	1700 - 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Accessories are sold separately

Part Number	Description	Specification
UA-420	Wide Range Cuff	8.6-16.5" (22-42 cm)
UA-291	Large Cuff	12.2-17.7" (31-45 cm)
<i>Arm size: The circumference at the biceps.</i>		
TB-233	AC Adapter	Input: 120V Output: 6V  500mA   

Warranty

Limited Warranty:

Smart Meter LLC warrants that this product will be free from defects in materials and workmanship for two years from the date of purchase.

This warranty does not apply to the performance of an iBloodPressure®2.0 meter that has been altered, misused, tampered with or abused in any way. This warranty applies only to the original purchaser of the iBloodPressure®2.0.

[illegible]

Weight/Peso:

[illegible]



Manufactured by:

A&D Company, Limited

1-243 Asahi, Kitamoto-shi,
Saitama-ken, 364-8585 Japan

Manufactured for:

Smart Meter LLC

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