Model UA-651SLPlus Instruction Manual

1. Dear Customers

Thank you for purchasing a state-of-the-art A&D blood pressure monitor. 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.

2. Preliminary Remarks

- This device conforms to the Medical Device Regulations (EU 2017/745) and UKCA Medical Device Regulations 2002 for Medical Products.
 This is made evident by the CE2797 and UKCA0086 mark of conformity. (2797 and 0086: The reference numbers to the involved notified body.)
 The device is designed for use by people 13 years and older, not newborns or infants.
 This device fulfils the following provisions.
- - C € 2797 Medical Device Regulation (EU 2017/745)

UK CA 0086 UKCA Medical Devices Regulations 2002

3. Intended Purpose

The UA-651SLPlus Digital Blood Pressure Monitor is intended to be used by patients to measure systolic and diastolic blood pressure and pulse rate in the home environment. The UA-651SLPlus provides the patient with an indication of an irregular heartbeat allowing further medical attention to be sort.

4. Clinical Benefit

Successful assessment of blood pressure reading in accordance with the device's intended purpose.

- 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, benzine, 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.
- Take care to avoid accidental strangulation of babies or infants

- Take care to avoid accidental strangulation of babies or infants with the hose and cable.

 Do not twist the air hose during the measurement. This may cause injury due to continuous culf pressure.

 The device and culf are not water resistant. Prevent rain, sweat and water from damaging the device and culf.

 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.

 Wireless communication devices, such as home networking devices, mobile phones, cordless phones and their base stations, and walkie-talkies can affect this blood pressure monitor.

 Therefore, a minimum distance of 30 cm should be kept from such devices. such devices. When reusing 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.

 Do not modify the device. It may cause accidents or damage to the device.
- Do not modify the device. It may cause accurence or carriago 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.

 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.

 Clinical testing has not been conducted on newborn infants and pregnant woman. Do not use on newborn infants or pregnant woman.
- Clinical testing has not been conducted on newborn infants and pregnant woman. Do not use on newborn infants or pregnant woman. If you have had a mastectomy or lymph node clearance, 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. This may cause accidents or damage.

 There are small parts that may cause a choking hazard if swallowed by mistake by infants.

 Do not touch the batteries, the DC jack, and the patient at the same time. That may result in electrical shock.

 Unplug the AC adapter when not in use during the measurement.

 Use of accessories not detailed in this manual may compromise safety.

- 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

- Allow the device to adapt to the surrounding environment before use (about one hour).

 Do not inflate without wrapping the cuff around the upper arm. This is a medical device for use by a lapperson. Please consult your healthcare provider with any questions or concerns you may have regarding your condition.

 When any serious incident occurs in relation to this device, report to its manufacturer and the competent authority in your country.

 Confirm for proper operation before use, if the packaging is damaged, unintentionally opened and exposed to environmental conditions outside of those specified.

 This device is not intended to diagnose heart arrhythmias. If the
- This device is not intended to diagnose heart arrhythmias. If the Irregular Heart Beat indicator illuminates frequently and is unrelated to patient movement during blood pressure measurement, further medical attention must be sort.

- measurement, further medical attention must be sort.

 Contraindications

 The following are precautions for proper use of the device.

 Do not apply the cuff on an arm with another medical electrical equipment attached. The equipment may not function properly.

 People who have a severe circulatory defict in the arm must consult a doctor before using the device, to avoid medical problems.

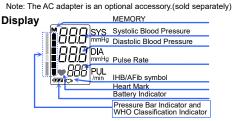
 Do not self-diagnose the measurement results and start treatment by yourself. Always consult your doctor for evaluation of the results and treatment. Do not apply the cuff on an arm with an unhealed wound.

- Do not apply the cuff on an arm with an unhealed wound.
 Do not apply the cuff on an arm receiving an intravenous drip or blood transfusion. It may cause injury or accidents.
 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.
 Do not provide any servicing and perform maintenance while the medical device is in use.

6. Parts Identification per fit range DC jack Artery position mark Air Hose AC adapter plug START Button Arm Cuff

Battery Compartment

Battery Cover



7.	Sy	m	ıbo	IS		
_						

7. Symbols							
Symbo	Symbols that appear on the display						
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.					
((\(\right)\))	IHB/AFib symbol appears when an irregular heartbeat is detected. It may light when a very slight vibration like shivering or shaking is detected.	Apply the cuff correctly, ther take another measurement. If the © symbol continues to appear, we recommend you to consult with your physician.					
М	Displayed when the data in memory is displayed.						
c //	FULL BATTERY The battery power indicator during the measurement.						
[LOW BATTERY The battery power is low when it blinks.	Replace all batteries with new ones when the mark blinks.					

ErE		Remove the batteries and press the START button,	
Errg	Device internal error	and then install the batteries again. If the error still appears, contact the dealer.	
Err	Unstable blood pressure due to movement during the measurement.	Take another measurement. Remain still during the measurement.	
	The systolic and diastolic blood pressure values are within 10 mmHg from each other.		
	The pressure value did not increase during the inflation.	Apply the cuff correctly, and	
Err CUF	The cuff is not applied correctly.	take another measurement.	
F	PUL DISPLAY ERROR	1	
С	The pulse is not detected correctly.		

	The pulse is not detected correctly.					
	The symbols that are printed on the device and the packaging.					
ı	Symbols Function / Meaning					
	(l)	Press \circlearrowleft to turn on the device.				
ı		Press 🖰 during measurement to enter standby.				
	SYS	Systolic blood pressure in mmHg				
	DIA	Diastolic blood pressure in mmHg				
	PUL/min	Pulse per minute				
	R6(LR6,AA)	Battery installation guide				
	===	Direct current				
	À	Type BF applied part				
;	C € 2797	CE marking				
	EC REP	European Authorized Representative				
	UK CA 0086	UK Conformity Assessed marking				
	UK REP	UK Responsible Person				
	MD	Medical Device				
		Manufacturer				
	2023	Date of manufacture				
	<u>X</u>	WEEE label				
	SN	Serial Number				
	UDI	Unique Device Identifier				
	©	Refer to instruction manual/booklet *1				
	⊖⊕⊕	Polarity of DC jack				
	IP	International protection symbol				
	<u> </u>	Keep dry				
	_\r	Temperature limit				
		Humidity limitation				
		Atmospheric pressure limitation				
	***	EU Importer				
	UK Importer	UK Importer				

*1 The symbol color: Blue 8. Using the Monitor

8.1. Inserting / Changing the Batteries

Remove the battery cover. Remove the used batteries from

- the battery compartment in case of changing them.
 Insert new batteries into the
- battery compartment as shown. making sure that the polarities (+) and (-) are correct.
- Putting on the battery cover. Use only R6P, LR6 or AA batteries.

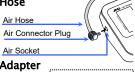
CAUTION

- Insert the batteries as shown in the battery compartment. If inserted
- when the batteries as shown in the battery companies. If meeted the incorrectly, the device will not work. When 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. After the device turns off, wait a few seconds before replacing the batteries. before replacing the batteries.

 date does not appear when the batteries are drained.
 The battery life varies with the ambient temperature and may become

- Senerally, four new R6P batteries will last approximately for three months when used twice for measurement each day. Use the specified batteries only. The batteries provided with the device are for testing and may have a limited life. Remove the batteries if the device is not to be used for a long time. The batteries may cause leakage and operational issues.

8.2. Connecting the Air Hose Insert the air connector plug into the air socket firmly.



Step 1

Step 3

8.3. 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, the

model TB-233C is sold separately. When disconnecting the AC adapter from the electrical outlet, hold and pull the AC adapter body out of the outlet.



Recommended Action mark on the

When disconnecting the AC adapter plug from the blood pressure monitor, hold and pull the AC adapter plug out of the monitor.

8.4. Selecting the Correct Cuff Size

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

- uispiayeu.

 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. Refer to "8.5 Applying the Arm Cuff".

 If the index △ points outside of the range, contact your local dea

- purchase a replacement curr.
 The arm cuff is a consumable. If it becomes worn, purchase a new

Arm Size	Recommended Cuff Size	Catalog Number	
31 cm to 45 cm	Large Adult cuff	CUF-D-LA-ISO	
22 cm to 42 cm	Wide range cuff	CUF-I-ISO	
23 cm to 37 cm	Semi Large cuff	CUF-D-MA-ISO	
22 cm to 32 cm	Adult cuff	CUF-F-A-ISO	
16 cm to 24 cm	Small Adult cuff	CUF-D-SA-ISO	
Arm size: The sizeumforence of an upper arm			

-	Is printed on the	cuff.
Symbols	Function / Meaning	

Small Adult cuff

		Artery Position Mark	Set the O mark on the artery of the upper arm or in line with the ring finger on the inside of the arm.	number in the order of the nev "∩□ I". The M symbol in th you are viewing previous data
	A	Index		10.1. Recalling Data
	REF	Catalog number		 When nothing is displayed
	L	Proper fit range for the large adult cuff. It's printed on the large adult cuff.		and hold the START butto recall the stored data.
	W	Proper fit range for the wide range cuff. It's printed on the wide range cuff.		Release the button when displaying the average dat
	М	Proper fit range for the semi large cuff. It's printed on the semi large cuff.		The data number and store are automatically displayed order from the last measure
	Α	Proper fit range for the adult cuff. It's printed on the adult cuff.		The display will be turned of the state
	S	Proper fit range for the small cuff. It's printed on the small cuff.		automatically after all data displayed.
•		Over range printed on the adult cuff/semi large cuff/wide range cuff.	Use the large adult cuff instead of the adult cuff /semi large cuff /wide range cuff.	Note: If you press the START while recalling data, the
l	S	Under range printed on the adult cuff/semi large cuff/wide range cuff.	Use the small cuff instead of the adult cuff / semi large cuff / wide range cuff.	turns off.
	M/A	Over range printed on the small cuff.	Use the adult cuff/ semi large cuff instead of the small cuff.	10.2. Clearing Data 1. When turning off the device
	M	Under range printed on the large adult cuff.	Use the semi large cuff instead of the large adult cuff.	press and hold the START
	D	Lot number	<u> </u>	button until the "[[r no " is displayed.
	Large Adu	ılt cuff Proper fit ran	ge	2. Select "[[[- YE5" to clear
		M L		data.
	Wide rang			Data is cleared when the mark blinks.
	Semi Laro	W W		The device turns off
		S M		automatically.
	Adult cuff			
		S A		

- 8.5. Applying the Arm Cuff What the cuff around the upper arm, about 1 to 2 cm above the inside of the elbow, as shown.

 Apply the cuff directly against the skin, as clothing may cause a faint pulse and result in a measurement error.

 Constriction of the upper arm, caused by rolling up a shirtsleeve, may cause inaccurate readings.
- cause fraccurate readings.

 3. Confirm that the index △ points within the proper fit range.

 Note: During the measurement, it is normal for users to feel tight. (Do not

Do not roll up shirtsleeve tightly Cuff Artery position mark Secure the fabric fastene Index riangle and Proper fit range

At heart level

Zero display

Starts inflation

Pressurizing

Measurement in progress

Systolic blood pressure

Diastolic blood pressure

WHO classification

Exhausts remaining air

automatically

Turn off with the

START button

Press the START button 🖒=

Pulse rate

68

150

90

8<u>0</u>

♣

Press the START button ()

Measurements

9.1. Normal Measurement

level (preferably the left arm). Sit quietly during the measurement.

2. Press the START button. All of the display segments are All of the display segments displayed. Zero is displayed blinking briefly. Then the display changes, as indicated in the figure at the right, as the measurement begins. The cuff starts to inflate. It is normal for the users to feel tight. A pressure bar indicator is displayed, as in the figure on the right, during the

press the START button again. 3. When inflation is completed

Note: If you want to stop inflation at any time.

deflation starts automatically and the (heart mark) blinks, indicating that the measurement is in progress. Once the pulse is detected, the mark 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

completed, the systolic and diastolic blood pressure readings and pulse rate are displayed. The cuff exhausts the remaining air and deflates completely.

5. Press the START button again to turn off the power. Note: The device is provided with an automatic power shut-off function. Allow at least 3 minutes between measurements on the same 9.2. Measurement with the Desired Systolic Blood

Pressure If re-inflation occurs repeatedly, use the following methods. If your At heart level

systolic blood pressure is expected to exceed 230 mmHg, use this procedure. 1. Apply the cuff on the arm at heart

- level (preferably the left arm). Press the START button.
- During the zero blinks, press and hold the START button until a number about 30 to 40 mmHg highe than your expected systolic blood pressure appears.
- reached, release the START button to start measurement. Then continue to measure your blood pressure as on the section Normal Measurement"

Press and hold the START button Inflation in progress Release the START button to stop inflation When the desired number is Refer to the section

- 9.3. Notes for Accurate Measurement

 Sit comfortably on a chair. Rest your arm on the table. Do not cross your legs. Keep your feet on the floor and straighten your back.

 Sit down in a comfortable position. Place your arm on a table with your palm facing upward and the cuff at the same level as your heart.

 Relax for about five to ten minutes before taking the measurement. If you are excited or depressed by emotional stress, the blood pressure reading may be higher (or lower) than a normal blood pressure reading may be higher (or lower) than a normal blood pressure reading and the pulse rate will usually be faster than normal.

 Remain still and keep quiet during the measurement.

 Do not measure immediately after physical exercise or a bath. Rest for twenty or thirty minutes before taking the measurement.

 An individual's blood pressure varies constantly, depending on what you are doing and what you have eaten. What you drink may have a strong and rapid effect on your blood pressure.

 This device bases its measurements on the heartbeat. If you have a weak or irregular heartbeat, the device may have difficulties determining your blood pressure.

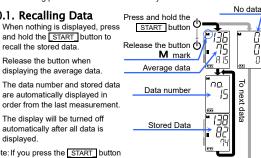
 If the device detects a condition that is abnormal, it will stop the measurement and the error symbol will be displayed. Refer to the section "7 Symbols" for the description of the symbols.

 This blood pressure monitor is intended for use by people 13 years and older.

- Try to measure your blood pressure at the same time every day.
 The automatic blood pressure monitor's performance may be affected by excessive temperature or humidity, or altitude.

10.Recalling the Memory Data

The device automatically stores up to sixty blood pressure and pulse measurements in memory. Data stored in memory are assigned a data number in the order of the newest to the oldest. The oldest data displays as "no 'i'. The M symbol in the upper left corner of the display indicates that you are viewing previous data stored in memory. ou are viewing previous data stored in memory.



te: If you press the START button while recalling data, the device turns off.

When turning off the device press and hold the START_ button until the "[[r no displayed.

- Select "[[] yes" to clear data.
- Data is cleared when the M mark blinks. The device turns off
- automatically.

M/A

Press and hold the START button 🔱 Release the $\overset{\downarrow}{\mathbb{O}}$ button uo j Select "[[r 965" to clear data The M mark blinks Data is cleared. Turns off automatically

Turns off automatically

11.What is the IHB/AFib

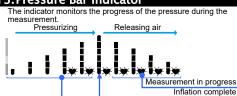
When the monitor detects an irregular rhythm during the measurements, the IHB/AFib indicator will appear on the display with the measurement values.

We recommend contacting your physician if you see this IHB/AFib symbol frequently.

12.What is AFib

The heart contracts due to electrical signals occurring in heart and sends blood through the body. Atrial fibrillation (AFib) occurs when the electrical signal in the atrium becomes confused and leads to disturbances in the pulse interval. AFib can cause blood to stagnate in the heart, which can easily create clots of blood, a cause of stroke and heart attack.

13. Pressure Bar Indicator



14. About Blood Pressure

What is Blood Pressure?

Blood pressure is the force exerted by blood against the walls of the arteries. Systolic blood pressure occurs when the heart contracts. Diastolic blood pressure occurs when the heart expands. Blood pressure is measured in millimeters of mercury expands. Slood pressure is measured in millimeters of merc (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.

Inflation in progress

15.WHO Classification Indicator

Each segment of the bar indicator corresponds to the WHO blood pressure classification. WHO Classification Indicator

Severe hypertension : The indicator displays a Moderate hypertension segment, based on the Mild hypertension current data, High normal corresponding to the Normal WHO classification

		Optimal
16.Trou	bleshooting	
Problem	Possible Cause	Suggestion
Nothing appears on	Batteries are drained.	Replace all batteries with new ones.
the display, even when the power is turned on.	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 power is too low. blinks. If the batteries are drained completely, the mark does not appear.	Replace all batteries with new ones.
	The cuff is not applied properly.	Apply the cuff correctly.
The device	Movement is detected	Make sure to remain still and quiet during the measurement.
does not measure. Readings are too high	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.
or too low.		If you have a very weak or irregular heartbeat, the device may have difficulties in determining your blood pressure.
		At a clinic or doctor's office, an

Note: If the suggestions described above do not solve the problem, contact the authorized dealer. Do not attempt to open or repair this product, otherwise your warranty may be invalid.

At a clinic or doctor's office, an

of outside influences on blood

apprehension may cause an elevated reading. Home measurement reduces the effect

pressure readings, supplements the doctor's readings.

Remove the batteries. Put them back properly and take another

17.Maintenance

The value is

ffice.

different from that

measured at a

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 the authorized dealer in your area or our customer service department. The A&D customer service will provide technical information, spare parts and units to authorized dealers.

The device is designed and manufactured for a long service life. However, it is generally recommended to have the device inspected every 2 years, to ensure proper functioning and accuracy. Please contact the authorized dealer in your area or A&D for maintenance.

18.Technical Data

Number of measur

Applied part Useful life

Contents *2

Acc

Сι

UA-651SLPlus Type Measurement method Joscillometric measurement
Pressure: 0 - 299 mmHg
Systolic blood pressure: 60 - 279 mmHg
Julse: 40 - 180 beats / minute
Pressure: ±3 mmHg
Julse: +5 % Diastolic blood p Pressure: 4 x 1.5V batteries (R6P, LR6 or AA) Power supply Optional AC adapter (TB-233C) (Not included)

Classification

lents Approx. 700 times LR6 (alkaline batteries)
Approx. 200 times R6P (manganese batteries)
With pressure value 180 mmHg, room temperature 23 °C.
Internally powered ME equipment (Supplied by batteries) / Class II (Supplied by adapter)
Continuous operation mode
According to ISO 81060-2:2018+A1:2020
In the clinical validation study, K5 was used on 85 subjects for determination of diastolic blood pressure. Clinical test

blood pressure. IEC 60601-1-2:2014+A1:2020 IEC 60601-1-2:2014+A1:2020
Last 60 measurements
+10 to +40 °C / 15 to 85 %RH / 800 to 1060 hPa
-20 to +60 °C / 10 to 95 %RH / 700 to 1060 hPa
Approx. 96 [W] x 68 [H] x 130 [D] mm
Approx. 240 g, excluding the batteries
Device: IP20
Cuff Tens PST EMD Memory
Operating conditions
Transport/Storage condition
Dimensions Weight Ingress p s protection

Device: IP20
Cuff Type BF ★
Device: 5 years (when used six times a day)
Cuff: 2 years (when used six times a day)
AC adapter:5 years (when used six times a day)
AB adapter:5 years (when used six times a day)
AB load Pressure Monitor, 1 Cuff, 4 Batteries
Instruction Manuals, 1 Carrying case,
2 EMD Technical Documentations

//TB233C

IB233C
The adapter is to connect the device to a power source at home. Input: AC 100-240V 50/60Hz 0.15A
Output: DC 6V 500mA
Please contact your local A&D dealer for purchasing. The AC adapter is required to be inspected or replaced periodically. do the AC adapter.

Symbols that are printed on the AC adapter. Function / Meaning For indoor use only

Class II device EAC certification device label Polarity of AC adapter plug Alternating current

	Refer to section 7 for the meanings of the other symbols.					
essories sold separately						
uff Catalog Number		Cuff Size	Arm Size			
	CUF-D-LA-ISO	Large Adult cuff	31 cm to 45 cm			
	CUF-I-ISO	Wide range cuff	22 cm to 42 cm			
	CUF-D-MA-ISO	Semi Large cuff	23 cm to 37 cm			
	CUF-F-A-ISO	Adult cuff	22 cm to 32 cm			

CUF-D-SA-ISO Small Adult cuff 16 cm to 24 cm Arm size: The circumference of an upper arm. Catalog Number Plug (Outlet type) TB-233C Type C *2: Confirm that all of the parts are included to ensure that the medical device is ready to perform safely and as intended.

Note: Specifications are subject to change without prior notice. IP classification is the degrees of protection provided by enclosures in accordance with IEC 60529. This device is protected against solid foreign objects with a diameter of 12 mm or greater, such as a finger. This device is not protected against water.