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)

CA0086 UKCA Medical Devices Regulations 2002

3. Intended Purpose

The UA-611Plus and UA-651Plus Digital Blood Pressure Monitor are intended to be used by patients to measure systolic and diastolic blood pressure and pulse rate in the home environment. The UA-611Plus and UA-651Plus provide 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 rith the device's intended purpose.

5. 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 culf 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.

- Avoid agrilly rolang the curr 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 with the hose and cable.

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

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

 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.

 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 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.

 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.

- crimical testing has not desert conducted on Teachon 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. 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).

 Do not inflate without wrapping the cuff around the upper arm. This is a medical device for use by a layperson. 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

- 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 Irregular Heart Beat indicator illuminates frequently and is unrelated to patient movement during blood pressure measurement, further medical attention must be sort.

Contraindications

- Contraingleations
 The following are precautions for proper use of the device.

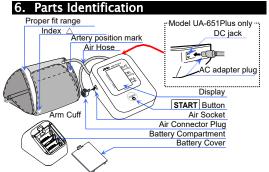
 Do not apply the cuff on an arm with another medical electrical equipment attached. The equipment may not function properly.

 People who have a severe circulatory deficit 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.



Note: Model UA-611Plus doesn't have the DC jack for AC adapter. The DC jack is located on the rear of the model, UA-651Plus only. The AC adapter is an optional accessory. (sold separately)

Display MEMORY SYS Systolic Blood Pressure mmHg Diastolic Blood Pressure DIA DIA mmHg Pulse Rate BOB PUL IHB/AFib symbol Heart Mark Battery Indicator Pressure Bar Indicator and WHO Classification Indicator

7. Symbols Symbols that appear on the display

-,		
Symbols	Function / Meaning	Recommended Action
М	Displayed when the data in memory is displayed.	
•	Appears while measurement is in progress. It blinks when the pulse is detected.	Measurement is in progres Remain as still as possible

	((\(\sigma\))	IHB/AFib symbol appears when an irregular heartbeat is detected. It may light when a very slight wibration like shivering or shaking is detected.	Apply the cuff correctly, then take another measurement. If the ">> symbol continues to appear, we recommend you to consult with your physician.	
	[//	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.	
е	Err Err 9	Device internal error	Remove the batteries and press the START button, and then install the batteries again. If the error still appears, contact the dealer.	
		Unstable blood pressure due to movement during the measurement.	Take another measurement. Remain still during the measurement.	
	Err	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 EUF	The cuff is not applied correctly.	take another measurement.	
	Ε	PUL DISPLAY ERROR The pulse is not detected correctly		

Symbols	Function / Meaning
Ф	Press $$ to turn on the device. Press $$ 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
★	Type BF applied part
C € ₂₇₉₇	CE marking
EC REP	European Authorized Representative
UK C A 0086	UK Conformity Assessed marking
UK REP	UK Responsible Person
MD	Medical Device
<u>l</u>	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
	Keep dry
	Temperature limit
<u>_</u> <u>@</u> _	Humidity limitation
_6	Atmospheric pressure limitation
₩	EU Importer

8. Using the Monitor

*1 The symbol color: Blue

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 cor incorrectly, the device will not work

Step 2

·Model UA-651Plus only AC adapter Plug

DC jack

Recommended Action

- When device will not work.

 When device will not work.

 When device announces 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. After the device turns off, wait a few seconds before replacing the batteries.
- does not appear when the batteries are drained.

 The battery life varies with the ambient temperature and may become

- The battery life varies with the ambient temperature and may become shorter at low temperatures.

 Generally, 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. Air Connector Plug

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 into 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.
- 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
- The arm size is printed on each cuff.
- The index \triangle 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 \triangle points outside of the range, contact your local dealer to
- purchase a replacement cuff.
 The arm cuff is a consumable. If it becomes worn, purchase a new

one.			
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 circumference of an upper arm.			

Symbols printed on the cuff.

Function / Meaning

Symbols

LOT Lot numbe

	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.]
A	Index		2
REF	Catalog number		1
L	Proper fit range for the large adult cuff. It's printed on the large adult cuff.		;
W	Proper fit range for the wide range cuff. It's printed on the wide range cuff.		4
М	Proper fit range for the semi large cuff. It's printed on the semi large cuff.		1
Α	Proper fit range for the adult cuff. It's printed on the adult cuff.		
S	Proper fit range for the small cuff. It's printed on the small cuff.],
	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.	
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.	2
M/A	Over range printed on the small cuff.	Use the adult cuff/ semi large cuff instead of the small cuff.	:
M	Under range printed on the large adult cuff.	Use the semi large cuff instead of the large adult	'

Proper fit range Large Adult cuff M Wide range cuff М M/A

8.5. Applying the Arm Cuff

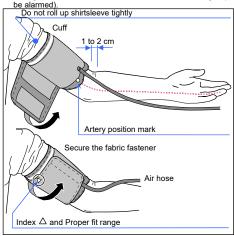
Wrap the cuff around the upper arm, about 1 to 2 cm above the inside of the elbow, as shown. Apply the cuff directly against the skin, as clothing may cause a faint pulse and result in a measurement error.

pulse and result in a measurement end.

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



9. Measurements

9.1. Normal Measurement Apply the cuff on the arm at heart level (preferably the left arm). Sit quietly during the measurement. Press the START button.

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 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 inflation.

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

3. When inflation is completed, deflation

press the Start Journal again.

When inflation is completed, 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.

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.

 Press the START button again to turn off the power.

Note: Model UA-611Plus and UA-651Plus are provided with an automatic power shut-off function. Allow at least 3 minutes between measurements on the same persor

9.2. Measurement with the Desired Systolic Blood Pressure

fre-inflation occurs repeatedly, use the following methods. If your systolic blood pressure is expected to exceed Press the START button O 230 mmHg, use this procedure.

- 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 higher than your expected systolic blood pressure
- 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 "9.1 Normal

Press and hold the START button Inflation in progress Release the START button to stop inflation Refer to the section "9.1 Normal Measurement"

9.3. Notes for Accurate Measurement

- .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. Place the center of 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 pormal blood pressure reading.
- reading may be higher (or lower) than a normal blood pressure reading and the pulse rate will usually be faster than normal.
- and the pulse rate will usually be laster intall infilmation. 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.

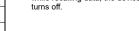
 If the device detects a condition that is abnormal, it will stop the
- measurement and the error symbol will be displayed. Refer to the section "7 Symbols" for the description of the symbols. This blood pressure monitor is intended for use by people 13 years
- our blood pressure at the same time ever
- 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 easurements in memory. Data stored in memory are assigned a data imber in the order of the newest to the oldest. The oldest data displays as a limit of the newest to the oldest. The oldest data displays as a limit of the oldest data displays as a limit of the oldest. you are viewing previous data stored in memory. Press and hold the No data

10.1. Recalling Data

- When nothing is displayed, press and hold the START button to recall the stored data. 2. Release the button when displaying
- the average data. The data number and stored data are automatically displayed in order from the last measurement
- 4. The display will be turned off automatically after all data is displayed. Note: If you press the START button while recalling data, the device



- 10.2. Clearing Data When turning off the device, press and hold the START button until the "[[r
- 2. Select "[Lr YE5" to clear data 3. Data is cleared when the ${f M}$
- mark blinks.
 The device turns off automatically.

Release the button $\mathring{\mathbf{b}}$ M mark Average data Data number Stored Data Turns off automatically Press and hold the START button 🛈= Release the & no J button *9*85

5 seconds

START button 🕩

Select "[[r 4E5]

to clear data.

The M mark blinks

Turns off automatically

Data is cleared.

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

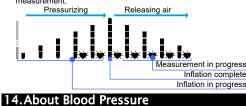
We recommend contacting your physician if you see this (()) IHB/AFib symbol frequently.

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

The indicator monitors the progress of the pressure during the measurement.



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. Blood pressure is measured in millimiters of ment (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.

15.WHO Classification Indicator

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

: The indicator displays a segment, based on the current data, corresponding to the

WHO classification

At heart level ---

Pressurizing

Measurement in progress

Systolic blood pressure

Diastolic blood pressure

WHO classification

Exhausts remaining air

automatically

Turn off with the

At heart level ---

START buttor

Pulse rate

Ū

68

150

90

Press the START button (1)

display segments

WHO Classification Indicator Severe hypertension Moderate hypertension
Mild hypertension High normal Normal Optimal

16. Troubleshooting Problem Possible Cause Suggestion Ratteries are eplace all batteries with new einstall the batteries with Battery terminals egative and positive terminals are not in the atching those indicated on the correct position attery compartment. The cuff Replace all batteries with new loes not appear. The cuff is not Apply the cuff correctly. applied properly Movement is detected Make sure to remain still and quiet during the measurement. Sit comfortably and still. Place your arm on a table with your The cuff position i Readings are too higl ot correct. palm facing upward and the cuff at the same level as your heart. f you have a very weak or rregular heartbeat, the device nay have difficulties in letermining your blood pressure At a clinic or doctor's office, an The value is apprehension may cause an elevated reading. Home measurement reduces the effect of outside influences on blood different from that neasured at a clinic or doctor's pressure readings, supplements the doctor's readings. Remove the batteries. Put them back properly and take another measurement ffice

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.

17. 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 the authorized dealer in your area or our customer service department.

autriorized dealer in your area of 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

UA-611Plus, UA-651Plus
Oscillometric measurement
Pressure: 0 - 299 mmHg
Systolic blood pressure: 60 - 279 mmHg
Diastolic blood pressure: 40 - 200 mmHg
Pulse: 40 - 180 beats / minute
Pressure: ±3 mmHg
Pulse: ±5 %
4 x 1.5V batteries (R6P, LR6 or AA)
Optional AC adapter (TB-233C) (Not included)
ents Type Measurement method Measurement range

Classification

Clinical test EMD

EMD
Memory
Operating conditions
Transport/ Storage conditions
Dimensions
Weight
Ingress protection
Applied part
Liseful life 5 years (when used six times a day) 2 years (when used six times a day) Device: Useful life

AC adapter:5 years (when used six times a day)
1 Blood Pressure Monitor, 1 Cuff, Contents *2 truction Manuals, 4 Batteries 1 EMD Technical Documentation, 1 Carrying case (Model UA-651Plus only) Accessory AC adapter/TB233C

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

Output: DC 6V 500mA
Please contact your local A&D dealer for purchasing. The AC adapter is required to be inspected or replaced periodically. Symbols that are printed on the AC adapter.

Symbols	Function / Meaning
갑	For indoor use only
	Class II device
EAC	EAC certification device label
⊖.€ ⊕	Polarity of AC adapter plug
~	Alternating current

Refer to section 7 for the meanings of the other symbols

Cuff	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 unner arm			unner arm

AC Adapter 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.

11.What is the IHB/AFib