UM-102 Digital Sphygmomanometer

Instruction Manual Manuel d'instructions Manual de instrucciones Manuale di Istruzioni 使用手冊

Original Traduction Traducción Traduzione 翻譯



1WMPD4002909B

UM-102

Digital Sphygmomanometer Instruction Manual

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1. Dear Customers

Congratulations on purchasing a state-of-the-art A&D sphygmomanometer, one of the most advanced monitors available on the market today. Designed for ease of use and accuracy. We recommend that you read through this manual carefully before using this device for the first time.

Intended User:	This device is designed to be used by people who can measure blood pressure by auscultation.
Applicable Patient:	The device is designed for use on adults and children aged 3 and older.
Environment for Use:	The device is designed for use in a medical facility.
Intended purpose:	This device is designed to measure human blood pressure and heart rates.

Features Measurement

This sphygmomanometer is designed to monitor and display cuff pressure during cuff inflation (by rubber bulb) and deflation (by exhaust bulb) while the user determines the patient's blood pressure level by listening for Korotkoff sounds with a stethoscope.

Safety

- □ This sphygmomanometer is designed to measure a patient's blood pressure without the use of mercury, therefore protecting your local environment.
- □ An automatic quick exhaust valve is installed in the device to prevent over pressurization of 300mmHg or higher, therefore protecting the patient.

2. Preliminary Remarks

Compliance

□ This device conforms to the European Directive 93/42 EEC for Medical Products. This is made evident by the **C €**₀₁₂₃ mark of conformity. (0123: The reference number to the involved notified body)

Definitions

SYS	Systolic Blood Pressure
DIA	Diastolic Blood Pressure
PUL	Pulse
Exhaust	This means "releasing the cuff air as soon as possible".
Constant exhaust	This means, "releasing the cuff air at a constant depressurization rate".

Batteries

- □ Use alkaline batteries (LR6 type, AA type) or equivalent batteries.
- Do not mix new and used batteries.
- Remove the batteries from the device and store them separately if the device will not be used for a month or more. Otherwise, the batteries may degrade.
- The battery life varies with the ambient temperature and may be shorter at low temperatures. Generally, two new LR6 batteries will last approximately for two months when used forty times for measurement each day.

A Defective Sphygmomanometer

Stop using the device immediately if the device does not work properly.
 Please attach a note with the following "Do not use this sphygmomanometer" to prevent any further use. This defective device should be stored in a safe place to avoid any misuse until it has been sent for repair.

Repair

- Do not attempt to open the device. Contact your nearest A&D authorized dealer and they will repair or replace the device.
- Do not modify the device. It may cause accidents or damage to the device.

Blood Pressure Measurement

- Do not use on patients with blood flow disorders.
- The user should stop using the device if there is an abnormality, such as the patient feeling excessive arm pain, and remove the cuff to protect the patient.

Contraindications

- Do not use the device in an ambulance or air ambulance. Doing so will prevent the device from providing accurate measurements.
- Do not apply the cuff to an arm with another medical electrical equipment attached. The equipment may not function properly.
- 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.
- When the cuff is infected by blood or body fluid, it should be safely disposed of according to local instructions or protocol to avoid any potential spread of infectious disease.

3. Notes for Proper Use

Storage

- Do not store the device where it could be splashed with water or other liquids. The device and cuff are not water resistant. If the device is immersed by accident, it may require servicing. (Do not use the device before it has endured a full service.)
- Do not store the device in a high temperature or high humidity environment, or in direct sunlight.
- Do not store the device where it could be influenced by vibration or shock.
- Do not store the device in a dusty, salty or sulfuric environment.
- Do not store the device where medicines are stored, or where medicines are evaporating.
- □ Store the cuff, air hose, and rubber bulb so that they are not bent or blocked. Doing so may cause an accident or damage to the device.

Before Use

- Make sure that the device works correctly and that measurement values are accurate.
- □ Make sure that the cuff and air hoses are properly connected.
- □ Check and maintain the cleanliness of the parts in direct contact with the patient.
- □ Avoid placing the device near a strong magnetic field or static electricity.
- □ Avoid placing the device near high frequency surgical equipment.
- □ When reusing the device, confirm that the device is clean.

During Use

- □ This device was not designed for patients' own use so care must be taken to ensure accurate results and to avoid possible accidents.
- Regularly confirm patient status when measurement is performed frequently or for a long time. Otherwise, damage may be caused due to peripheral arterial disease.
- □ Stop using the device immediately, if the patient feels pain during a measurement or if the device does not work properly.
- □ Stop using the device if you notice any abnormalities (for example; liquid inside the device) and request a full service.
- 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, numbress or a temporary red mark to the arm. This condition will appear especially when measurement is repeated successively. Any pain, numbress, or red marks will disappear with time.
- □ This is a device which needs to handle with care. Strong impact may result in malfunction of the device.
- □ Be careful not to get hurt when handling the damaged device.
- Do not replace the batteries while the device is in use.
- Do not touch the batteries and the patient at the same time.
- □ Should the batteries short-circuit, they may become hot and potentially cause malfunctions and scalding.
- Use the device so that the air hose is not bent or blocked. Using the cuff with the air hose kinked or bent may result in peripheral circulatory failure due to hemostasis in the arm (caused by air remaining in the cuff).

After Use

- Clean the device, cuff and accessories with a dry, soft cloth or a wet cloth with water or a neutral detergent. Do not pull or kink the hoses. Do not use any organic solvent, (antiseptic solution or other harsh chemicals) to clean the device, cuff or accessories.
- □ Press ⁽)</sup>START/STOP button to turn off the power after measurement.
- □ Keep the original box for further transportation after purchasing the device.
- □ Be careful not to get your fingers caught when folding the device.

Periodic Maintenance

- This device is a precision instrument and contains electronic circuitry. Please check all functions periodically. Contact your nearest A&D authorized dealer for official calibration/check-up, according to your local regulations.
- □ Used equipment, parts and batteries are not treated as ordinary household waste, and must be disposed of according to the applicable local regulations.
- The user authority (the hospital, clinic, etc.) is responsible for the safe use and maintenance of this electronic medical device. Care should be taken to follow the specified daily maintenance and inspection procedures for safe use.

How to Take Proper Measurements

For the most accurate blood pressure measurement:

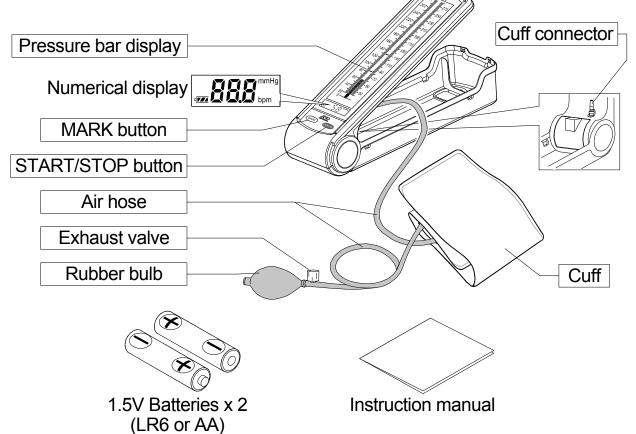
- Confirm that a patient does not cross the legs, patient's legs touch on the floor and patient's back and arms are supported.
- Let a patient relax for about five to ten minutes before measurement.
- □ Place the center of the cuff at the same height as a patient's heart.
- □ A patient must remain still and keep quiet during measurement.
- Do not measure right after exercising or taking a bath. A patient must rest for twenty to thirty minutes before the measurement.

Notes for Proper Measurement

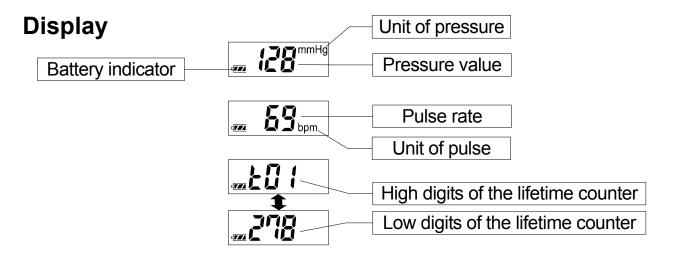
- □ Let a patient sit down in a comfortable position. Confirm that the patient does not cross their legs, that their feet touch the floor (if possible), and that their back and the arm being measured are supported.
- Let a patient relax for about five to ten minutes before taking a measurement. If a patient is excited or depressed by 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 a patient is doing and what a patient has eaten. What a patient drinks can have a very strong and rapid effect on patient's blood pressure.
- Should the device detect a condition that is abnormal, it will stop the measurement and display an error symbol. Refer to page 8 for the description of symbols.
- This sphygmomanometer is intended for adults and children aged 3 and older. Do not use this device on newborns or infants.
- Measurement may be affected by the position of the cuff, as well as the patient's posture (standing, sitting, supine), movement, or physiological condition.

4. Parts Identification

Main Body and Accessories



	Function	
START/STOP Button	Turns on or off the device.	
MARK button	During measurement Puts a marker at a pressure value After turned off Indicates a lifetime counter	
Numerical display	During measurement Indicates pressure value After exhausted air Indicates pulse rate	



5. Symbols

Symbols	Function / Meaning	Recommended Action
Ċ	Standby and Turn the device on	
MARK	Pressure value holding and lifetime counter	
⊕ (<u>R6(AA)</u>)	Battery installation guide	
SN	Serial number	
2015 ~~	Date of manufacture	
Ŕ	Type BF: Device, cuff and tubing are designed to provide special protection against electrical shocks.	
	Full Battery The battery power indicator during measurement.	
۲	Low Battery The battery is low when it blinks.	Replace all batteries with new ones, when the indicator blinks.
Er l	Pressure remains in the cuff.	Exhaust it with the
Erd	Measurement overtime	exhaust valve.
Er3	Device is out of order.	Send for service.
Err	The pulse is not detected correctly.	Take another measurement.
mmHg	Unit of pressure	
bpm	Unit of pulse	
CE 0123	EC directive medical device label	
	WEEE label	
	Manufacturer	
EC REP	EU-representative	
6	Refer to instruction manual/booklet	

6. Using the Monitor

Installing / Changing the Batteries

- 1. Remove the battery cover.
- Insert a new set of batteries into the battery compartment as shown. Make sure the polarities (+) and (-) are correct. Use only LR6, AA or equivalent batteries.
- 3. Close the battery cover.

CAUTION

- Insert the batteries in the battery compartment.
 If not, the device will not work.
- Battery life varies with the ambient temperature and may be shorter at low temperatures.
- Only the specified batteries should be used with this device. The batteries provided with the device are for testing the device performance and may have a limited life.
- Remove the batteries from the device and store them separately if the device will not be used for a month or more. Otherwise, the batteries may degrade.

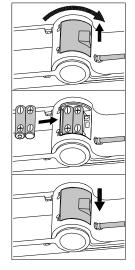
Connecting the Air Hose

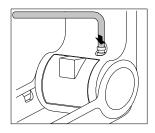
Insert the air hose into the cuff connector firmly.

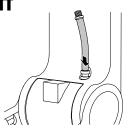
Connecting the Connector and Plug for the Cuff

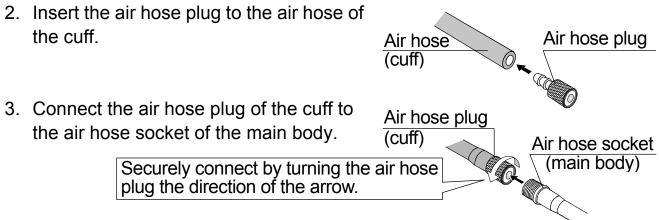
(Sold separately)

1. Insert the air hose socket into the cuff connector.









□ Use the specified connector. (Refer to page 16)

Selecting the Proper Cuff

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

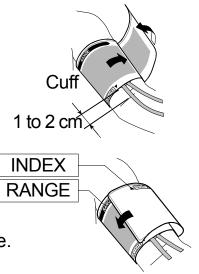
□ The INDEX and RANGE markings on the cuff will indicate that you are using the proper cuff or not. (Refer to "Attaching the Arm Cuff" in the next section)

Arm Size	Cuff Size	Catalog Number
41 cm to 50 cm	LL cuff	CUF-KW-LL
31 cm to 45 cm	Large Adult cuff	CUF-KW-LA
22 cm to 32 cm	Adult cuff	CUF-KW-A
16 cm to 24 cm	Small Adult cuff	CUF-KW-SA
12 cm to 17 cm	SS cuff	CUF-KW-SS

Arm size: The circumference of the biceps

Attaching the Arm Cuff

- Wrap the cuff around the upper arm, about 1 to 2 cm above the elbow as shown on the right. Place the cuff directly against the skin, as clothing may cause a faint pulse and could result in a measurement error.
- 2. Constriction of the upper arm, caused by rolling up a shirtsleeve, may interfere with accurate readings.
- 3. Make sure that the index points are within the range.



Symbols that are printed on the cuff

Symbols	Function / Meaning	
	Dropor fit ropoo	
RANGE	Proper fit range	
ARTERY	Artery position mark	
THIS SIDE TO PATIENT	Instructions to the patient	
REF	Catalog number	
LOT	Lot number	
ADULT	Cuff size 22 cm to 32 cm	
LL	Cuff size 41 cm to 50 cm	
LARGE ADULT	Cuff size 31 cm to 45 cm	
SMALL ADULT	Cuff size 16 cm to 24 cm	
SS	Cuff size 12 cm to 17 cm	
	Operation suggestions	

English 12

7. Measurements

- 1. Place the cuff on the arm (preferably the left arm). Keep the patient still during measurement.
- 2. Press the O START/STOP button.
 - When the OSTART/STOP button is pressed, all of the display symbols will appear for about one second.
 - □ When □ starts flashing, the device is ready for measurement. If air is remaining in the cuff when the

 \bigcirc START/STOP button is pressed, the display will indicate an error code $\boxed{\epsilon_r}$.

Turn the device off (press the ③ START/STOP button again) and turn the exhaust valve counterclockwise once to release all the air in the cuff. Then press the ④ START/STOP button again to reactivate the device.

- 3. Place the stethoscope on the brachial artery and pressurize the cuff by squeezing the rubber bulb. (Make sure the exhaust valve is completely closed.)
 - While the cuff is inflating, the pressure bar will move and in turn the LCD will display a number indicating the pressure.
 - □ Inflate the cuff to 30 to 40 mmHg higher than the patient's expected systolic value.
- Note: If you wish to stop inflation at any time, press either the OSTART/STOP button or turn the screw of the exhaust valve to release the air.
- 4. When inflation is complete.
 - □ Turn the exhaust valve screw to release air slowly.
 - □ Measure the systolic pressure and the diastolic pressure by stethoscopy.
- 5. The heart rate is shown on the numerical display when the measurement is complete or meets the following conditions.
 - □ When you pressurize 80mmHg or higher for the measurement.
 - □ When the pressure drops to 20mmHg or lower.



At heart level

- 6. Turn the exhaust valve screw counterclockwise to release all the air from the cuff.
 - If a measurement is taken with insufficient pressure, the --- mark will be displayed. Re-pressurize the cuff to a pressure that is about 30 to 40 mmHg higher than the previous attempt.
- 7. Press the OSTART/STOP button again to turn off the power.
- Note: Model UM-102 has an automatic power-off function. Allow at least three minutes between measurements on the same person.

8. Useful Features

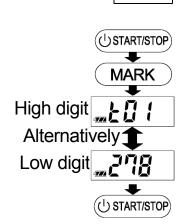
Measurement with MARK Button

You can put a marker at a certain pressure value when the MARK button is pressed during the measurement process. Up to 5 markings can be shown over the range of 40mmHg.

Lifetime Counter

When the MARK button is pressed while the device is off, the lifetime counter is displayed.

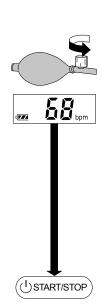
This counter function indicates the hours the device was in use and helps to determine when maintenance is necessary. High digits and Low digits are alternatively displayed. The example indicates that the device has been in use for 1,278 hours.



50

Marker

Marker



9. Troubleshooting

Problem	Possible Reason	Recommended Action
Nothing appears	Batteries are empty.	Replace all batteries with new ones.
in the display, even when the power is turned on. Battery polarities are not in the correct position.		Reinstall the batteries with the negative and positive ends matching those indicated in the battery compartment.
The cuff is not inflated.	The cuff is not connected properly. There is leakage of air from the cuff or rubber bulb.	Check the twist of the air hose, and connection of the cuff and air hose. Replace the cuff or rubber bulb with a new one.
Remain a display of 2888 (pm).	Error symbol is displayed one minute later.	Refer to "5. Symbols".

Note: If the recommendations above do not solve the problem, contact your nearest authorized A&D dealer. Do not attempt to open or repair this product by yourself, as any attempt to do so will render your warranty invalid.

10. Maintenance

Do not attempt to open the device as the delicate electrical components and intricate air unit inside could be damaged. If you cannot solve the problem using our troubleshooting guide, request assistance from your authorized dealer or from any A&D service group.

The device was 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 either your authorized dealer or A&D for maintenance.

CAUTION

- The sphygmomanometer is not waterproof device. Do not splash water on it and avoid exposure to moisture.
- Do not use a organic solvent such as thinner or benzine.
- □ The sphygmomanometer cannot be sterilized by autoclave, EOG or formaldehyde etc.

Cleaning

- □ When cleaning the device and cuff, turn off the power by pressing ⁽⁾START/STOP button and remove the batteries.
- When the main body or cuff is dirty, wipe them fully by using a gauze or cloth dampened with water or warm water avoiding excess water.
- To prevent a risk due to infection, disinfect the main body and cuff regularly.
 When disinfecting them, wipe them gently by using the gauze or dampened cloth with local antiseptic solution then wipe the moisture off the surface by using a dry soft cloth.
- □ <u>Use the following disinfectants to clean the main body and cuff.</u>

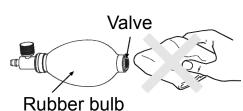
Ethanol (70%) Isopropanol (70%)

Chlorhexidine Gluconate Solution (0.5%)

Benzalkonium Chloride Solution (0.05%)

Sodium Hypochlorite (0.05%)

Do not wipe off the valve and its vicinity with gauze soaked in disinfectant solution. It will cause stuffing of the rubber bulb.



□ Clean the device about once every month, based on the policy or instruction specified by the user authority.

Disposal

This unit and its batteries are not treated as ordinary household waste and must be disposed of according to the applicable local regulations.

Item	Parts	Material
Package	Box	Cardboard
	Cushion	Cardboard
	Bag	PE
Main unit and	Enclosure	ABS
accessories	Internal parts	General electronic components
	Batteries	Alkaline battery

11.Technical Data

Model Measurement method UM-102

od By applying pressure, enabling the determination of blood pressure by the auscultatory method.

Measurement range Numerical display

Pressure: 0 - 300 mmHg

English 15

	Pulse:	40 - 180 beats / minute
Pressure bar display	Pressure:	20 - 280 mmHg
Measurement accuracy		
Numerical display	Pressure:	±3 mmHg
	Pulse:	±5 %
Power supply	2 x 1.5 V alk	aline batteries (LR6 or AA)
Upper arm circumference	22 - 32 cm u	ising the adult cuff
Number of measurements	Approx. 2000	D measurements, when AA
	alkaline batte	eries are used, with pressure value
	of 180 mmH	g at room temperature of 23°C
Classification	Internally po	wered ME equipment
	Continuous	operation mode
EMD	IEC 60601-1	I-2: 2014
Operating conditions	+10°C to +4	0°C / 15%RH to 85 %RH
	800 hPa to 1	
Transport / Storage conditions	-20°C to +60	0°C / 10%RH to 95 %RH
	700 hPa to 1	060 hPa
Dimensions	Approx. 98 [W] x 324 [H] x 67[D] mm
Weight	Approx. 520	g, excluding batteries
Applied part	Cuff Type B	
Useful life	Device: 5 ye	ears
	Cuff: 2 years	6
	Rubber bulb	unit: 2 years
A according and concretely		

Accessories sold separately

Cuff

Catalog Number	Cuff Size	Arm Size
CUF-KW-LL	LL cuff	41 cm to 50 cm
CUF-KW-LA	Large adult cuff	31 cm to 45 cm
CUF-KW-A	Adult cuff	22 cm to 32 cm
CUF-KW-SA	Small adult cuff	16 cm to 24 cm
CUF-KW-SS	SS cuff	12 cm to 17 cm

Rubber bulb unit

	Catalog Number
	UM-102-10

Connector and Plugs for cuff replacement

	Catalog Number		
W IID W IID W IID	UM-102-11		

Note: Specifications are subject to change without prior notice.

EMD Technical Data Battery-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.

Phenomenon		Compliance
Conducted and radiated RF EMISSION	CISPR 11	Group 1、Class B

Table 2 - IMMUNITY TEST LEVELS : Enclosure Port-

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

Table 3 -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	$380 \sim 390$	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	$430 \sim 470$	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 \sim 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
810		GSM 800/900 TETRA 800				
870	$800 \sim 960$	iDEN 820 CDMA 850	Pulse modulation 18 Hz	2	0.3	28
930		LTE Band 5				
1720		GSM 1800 CDMA 1900				
1845	1700~1990	GSM 1900 DECT	Pulse modulation 217 Hz	2	0.3	28
1970		LTE Band 1,3,4,25 UMTS				
2450	2400~2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240			Dules medulatic:			
5500	5100~5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5785						

MEMO



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