



Instruction Manual

Upper Arm Blood Pressure Monitor with Voice Broadcast Technology



Model: AES-U121
Item: 16984
Manual Version: V1.0
Issue date: 2021-07-14

INTENDED USE

This device measures adult systolic blood pressure, diastolic blood pressure and pulse rate. When used properly, readings taken by this device are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

SAVE THESE INSTRUCTIONS

This instruction manual contains important safety and care information and provides step-by-step instructions. Read this manual thoroughly before using this device.

SAFETY INFORMATION

The following signs might appear in this instruction manual, labeling or other component(s). They are a standard requirement for safety and use.

	PROHIBITED Forbidden with detailed items expressed in words or figures within or beside the mark. This symbol means Generally Forbidden
	MUST OBSERVE Obligatory with detailed items expressed in words or figures within or beside the mark. Left one means General Compulsory
	Symbol for "Read and follow the instruction manual"
	Symbol for "TYPE BF APPLIED PARTS"
	CAUTION Symbol for "Consult accompanying documents"
	Symbol for "Do not dispose with household garbage. Remove the old batteries from the device and follow local recycling guidelines"
	Transport package shall be kept away from rain
	Do not roll

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	Transport package shall not be exposed to sunlight
	Contents of the transport package are fragile therefore it shall be handled with care
	Indicates temperature limits within which the transport package shall be stored and handled
SET/	Set User, Date, Time, Voice, Alarm, and Unit of Measurement
	Start measurement, stop measurement, turn off
MEM/	When the MEM icon is flashing, the user can save or recall memories
IP21	IP21: Protected against solid foreign objects of 0.5" (12.5 mm) and greater. Protection against vertically falling water drops
	Symbol for "RF transmitters"

CAUTION

This device is intended for adult use only. This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement. Do not confuse self-monitoring with self-diagnosis. This device allows you to monitor your blood pressure. Do not begin or end medical treatment based solely on this measurement. Consult your physician for treatment advice. If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.

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SPECIFICATIONS

Internal Power Supply	DC 6V (4 x 1.5V AAA batteries)
Measurement Method	Oscillographic mode
Measurement Range	Pressure 0 - 39kPa (0 - 290mmHg)
Pulse Value	40 - 199 beats/minute
Accuracy	Pressure ± 0.4 kPa (± 3 mmHg), Pulse value $\pm 5\%$
Memory	2 x 90 (90 readings per user)
Operating Conditions	Temperature 41°F - 104°F (5°C - 40°C), Relative humidity 15% - 80%, Pressure 70 - 106kPa
Storage & Transportation Conditions	Temperature -4°F - 131°F (-20°C - 55°C), Relative humidity 15% - 93%, Pressure 70 - 106kPa
Weight	Approx. 9.7oz (275g) (Excluding the batteries and cuff)
Product Dimensions	5.4" x 4.5" x 2.6" (13.7cm x 11.4cm x 6.5cm)
Shelf Life	This product is designed to provide approximately five years of use or 10,000 inflations.
Arm Circumference	8.7" - 12.6" (22cm - 32cm)

This device is not suitable for continuous monitoring during medical emergencies or operations. If the cuff pressure exceeds 40 kPa (300 mmHg), this device will automatically deflate. Should the cuff not deflate when pressures exceeds 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.

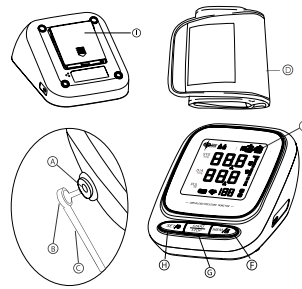
To avoid measurement errors, carefully read this instruction manual before using this device. The equipment is not an AP/AGP equipment. This device is not suitable for use in the presence of a flammable anesthetic mixture of air with oxygen or nitrous oxide.

To avoid measurement errors, avoid strong electromagnetic field radiation.

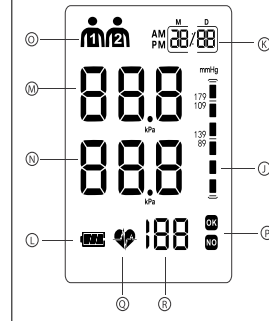
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KNOW YOUR UNIT

- (A) Air Jack
- (B) Air Plug
- (C) Air Tube
- (D) Arm Cuff
- (E) Display Screen
- (F) Memory Button
- (G) START/STOP Button
- (H) Settings Button
- (I) Battery Cover



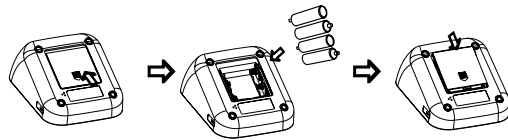
- (J) Blood Pressure Level Indication
- (K) Time Icon
- (L) Low Battery Symbol
- (M) High Pressure Value (Systolic Pressure)
- (N) Low Pressure Value (Diastolic Pressure)
- (O) Number of User Groups
- (P) Cuff Detection
- (Q) Heartbeat Icon
- (R) Pulse Rate Display



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INSTALLING AND REPLACING THE BATTERIES

- Open the battery cover.
- Install the batteries by matching the correct polarity, as shown.
- Replace the battery cover.



REPLACE THE BATTERIES WHENEVER THE BELOW HAPPENS:

- is flashing.
- The display is dim.
- The display does not light up.

CAUTION

- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose of the batteries in a fire. Batteries may explode or leak.
- Remove batteries if this device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose with household garbage.
- Remove the old batteries from this device and follow local recycling guidelines.

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SETTINGS

It is important to set the clock before using this device, so that a time stamp can be assigned to each record that is stored in memory. Turn off the unit.

WHILE THE DEVICE IS OFF:

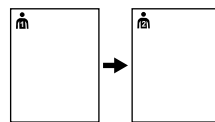
Step 1: Press the SET/ button for 3 seconds.

- The figure symbol will flash to confirm you are in **USER SETTING** mode.

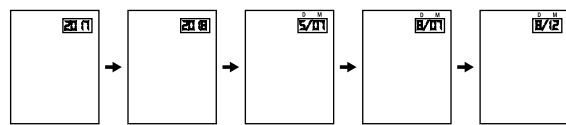
Step 2: Press the MEM/ button to select or toggle through values.

Step 3: Press SET/ to enter the next parameter setting mode.

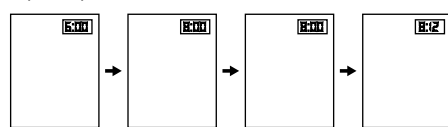
Repeat steps 1 - 3 to set the **USER**



Repeat steps 2 and 3 to set the **DATE**:

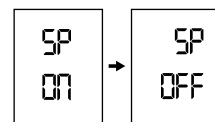


Repeat steps 2 and 3 to set the **TIME**:



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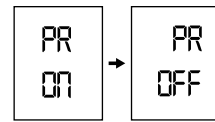
Repeat steps 2 and 3 to set the **VOICE BROADCAST**:



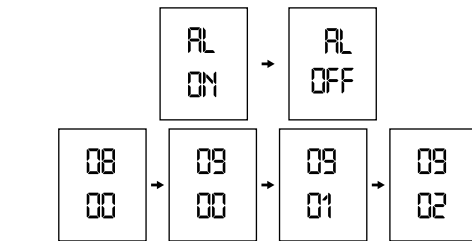
Select SP ON to turn voice ON.
Select SP OFF to turn voice OFF.

Repeat Steps 2 and 3 to set the **UNIT OF MEASUREMENT**:

For kPa, set to ON. For mmHg, set to OFF.



Repeat steps 2 and 3 to set the **ALARM ON/OFF** and **ALARM TIME**:

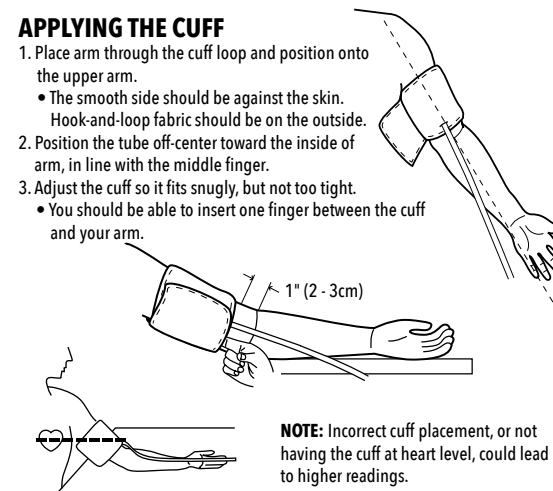


NOTE: When settings are complete, the monitor will turn off automatically.

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APPLYING THE CUFF

- Place arm through the cuff loop and position onto the upper arm.
 - The smooth side should be against the skin.
 - Hook-and-loop fabric should be on the outside.
- Position the tube off-center toward the inside of arm, in line with the middle finger.
- Adjust the cuff so it fits snugly, but not too tight.
 - You should be able to insert one finger between the cuff and your arm.



NOTE: Incorrect cuff placement, or not having the cuff at heart level, could lead to higher readings.

TIPS FOR SUCCESSFUL BLOOD PRESSURE MONITORING

To help ensure accurate readings:

- Wait at least one hour after eating or drinking
- Avoid smoking or caffeine (coffee, tea)
- Measure when your bladder is empty
- Remain still and do not speak during measuring
- Avoid taking blood pressure in a cold environment



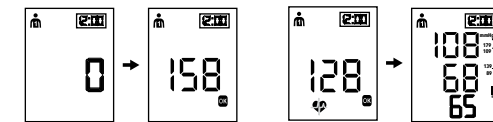
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TIPS FOR MEASUREMENT

- Sit comfortably with your left arm resting on a flat surface.
- Rest for 5 minutes before measuring.
- Wait at least 3 minutes between measurements for blood circulation to recover.
- For meaningful comparison, try to measure under similar conditions.
 - Take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

TO BEGIN MEASURING:

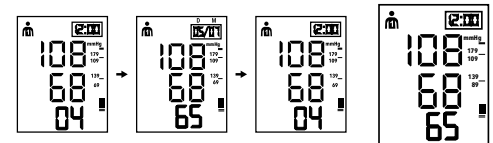
- Press START/STOP.
- The cuff will inflate and measure blood pressure automatically.
- The cuff will deflate and turn off automatically when measuring is complete.
- Press START/STOP to turn off the device manually at any time.



RECALL THE RECORDS

When the device is finished measuring:

- Select the user
- Press "MEM/ " to view an average of the last 3 records.
- Press "MEM/ " to toggle through the previous records.



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DELETING RECORDS

TO DELETE ALL RECORDS

While the device is OFF:

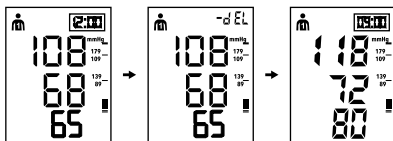
1. Press and hold the MEM/☑ button for 3 seconds.
2. Press the SET/⊗ button.
 - The display shows "ALL EE" to confirm all records have been deleted.



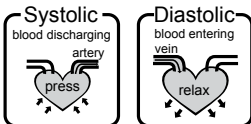
TO DELETE A SINGLE RECORD

While the device is OFF:

1. Press the "MEM/☑" button to select the record to be deleted. Press and hold the "SET/⊗" button for 5 seconds. The record will delete and show the next record in memory.



WHAT IS SYSTOLIC PRESSURE AND DIASTOLIC PRESSURE?



When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.

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Electromagnetic Compatibility

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

Warning: DO NOT use near active HF surgical equipment and/or the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.

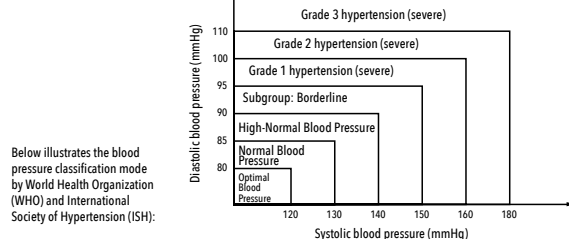
If any: A list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: The performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.
2. Guidance and manufacturer's declaration -electromagnetic emissions and immunity.

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WHAT IS THE STANDARD BLOOD PRESSURE CLASSIFICATION?



Below illustrates the blood pressure classification made by World Health Organization (WHO) and International Society of Hypertension (ISH):

Level	Optimal	Normal	High-Normal	Mild	Moderate	Severe
SYS	<120	<130	130 - 139	140 - 159	160 - 179	≥180
DIA	<80	<85	85 - 89	90 - 99	100 - 109	≥110

CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

WHY DOES MY BLOOD PRESSURE FLUCTUATE THROUGHOUT THE DAY?

1. Individual blood pressure varies naturally throughout the day.
2. Cuff placement and body position can also affect readings, so try to take the measurement under the same conditions.
3. Certain medications may cause blood pressure to vary.
4. For comparison, wait at least 3 minutes between measurements.

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Table 1

Guidance and manufacturer's declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR11	Class B
Harmonic emissions IEC 61000-3-2	N/A
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A

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WHY ARE MY BLOOD PRESSURE READINGS AT HOME DIFFERENT FROM AT THE HOSPITAL?

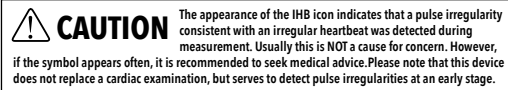
1. A variety of factors may cause blood pressure to fluctuate throughout the day, such as emotions, exercise, or the weather.
2. The "white coat effect" may also affect blood pressure if you feel nervous or anxious in a clinical setting.
3. When taking blood pressure at home, make sure:
 - The cuff is placed on the upper arm and positioned correctly
 - The cuff is not too tight or too loose
 - You relax for five minutes before measuring and take 5-6 deep, calming breaths

WILL THE RESULTS BE THE SAME IF MEASURING ON THE RIGHT ARM?

It is ok to measure on either arm, but results may vary. We suggest you measure the same arm every time.

IRREGULAR HEARTBEAT INDICATOR

An irregular heartbeat is detected when a heartbeat rhythm varies while this device is measuring the systolic and diastolic blood pressure. During each measurement, the monitor records all of the pulse intervals and calculates the average; if there are two or more pulse intervals, the difference between each interval and the average is more than the average value of ±25%, or if there are four or more pulse intervals, the difference between each interval and the average is more than the average value of ±15%, the irregular heartbeat symbol appears on the display when the measurement results are displayed.



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Table 2

Guidance and manufacturer's declaration - electromagnetic immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV input/output lines: ±1 kV	N/A
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV. line(s) to earth: ±2 kV. 100 kHz repetition frequency	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	N/A
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	N/A
Radiated RF IEC61000-4-3	10 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

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CARE AND MAINTENANCE:

1. Replace the batteries whenever the low battery symbol is flashing or the display is dim/not visible.
 - DO NOT mix old and new batteries.
 - DO NOT mix alkaline, standard (carbon-zinc), or rechargeable (Ni-Cd, Ni-MH, etc.) batteries.
2. Gently clean with a soft, damp cloth to remove dirt if necessary.
 - Avoid hard rubbing, as this may cause air leakages.
 - DO NOT immerse this device in water or any other liquids.
 - DO NOT allow water or other liquid to enter the air hose.
 - NEVER clean the blood pressure monitor with thinners or benzene.
3. Periodically inspect this device for any visible damage.
4. DO NOT drop the blood pressure monitor or subject it to other shocks or vibration.
5. Remove the batteries if this device will not be used for a long period.
6. DO NOT attempt to disassemble this device. (User may open the battery cover for new battery installation only).
7. Store in a clean, dry, well-ventilated location.
 - DO NOT store this device in locations exposed to direct sunlight, high temperatures (over 131°F / 55°C), low temperatures (below -4°F / -20°C), high relative humidity (over 93%) or excessive amounts of dust.
 - Keep this device out of reach of children, pets, and insects.
8. At the end of its useful product life, dispose of this device and batteries in accordance with local recycling regulations.
 - DO NOT dispose of electrical appliances as unsorted municipal waste. Follow local regulations for disposal of this device.
 - If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and enter the food chain. Contact your local government for information regarding the collection system.

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Table 3 Guidance and manufacturer's declaration - electromagnetic immunity

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (M)	Immunity Test Level (V/M)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	380 - 390	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	1.2	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						
1720	1700 - 1990	GSM 1900, CDMA 1900, GSM 1900, DCS, 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	1.2	0.3	9
5500						
5785						

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TROUBLESHOOTING

ISSUE	CAUSE	SOLUTION
LCD shows Low Battery icon	Batteries are low	Install new batteries
Shows abnormal result	Cuff is not tightened properly or is positioned incorrectly	Tighten cuff correctly and refer to "Applying the Cuff"
	Arm movement during measuring	Stay calm. Make sure arm remains steady. Do not move during measuring
	Interference in inflation or wrong operation during measuring	Refer to the Measuring instructions on pages 8-9 of this instruction manual
After power ON, no display on LCD	Battery problem or wrong battery polarity	Install batteries correctly or replace with new batteries. If the device is still not activated, stop using it
Cuff inflation rate is too low or does not inflate	Cuff or bladder inside the cuff is leaking air	Purchase a new cuff
Cuff deflates too quickly	Cuff has been applied too loosely	Make sure cuff is wrapped correctly
Measurement result is different from the hospital or value is inconsistent	This is normal	Blood pressure value varies throughout the day and will also be affected by emotional and physical conditions and other factors
LCD shows "Err 1"	Weak or undetectable pulse/insufficient inflation	Reposition the cuff, re-inflate and measure again
LCD shows "Err 2"	Noise interference	
LCD shows "Err 3"	Measurement is incorrect	
LCD shows "Err P"	Inflation failed	
LCD shows "Err H"	Over-inflated pressure	
Shows abnormal result	Speaking, feeling nervous or excited during measurement	Do not speak. Take 2-3 deep breaths to help relax
	Wrong position	Adjust position; refer to "Applying the Cuff"

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LIMITED WARRANTY

This product has a limited warranty of 3 year(s) on the blood pressure monitor, 2 year warranty on the cuff and accessories (except batteries) from the original date of purchase against workmanship and defects in material. If under normal use, your product fails to operate, please contact our customer service department at info@stareliteinc.com. A refund or replacement will be provided to you with proof of purchase. Star Elite Inc. may deny claims of damage caused by misuse or modifications of this product.

If you have any problems, please do not contact the store.
 Contact our customer service at 1-877-383-6399
 (8:30 am - 5:00 pm EST) Monday - Friday
 or contact us at
 info@stareliteinc.com
 Our customer service will be happy to assist you.

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