

alaira

Mattress Replacement System Owners and Operators Manual



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DANGER

Explosion hazard – Do not use in the presence of flammable gases.

WARNINGS

The cover of this product is not air permeable and may present a suffocation risk. It is the responsibility of the caregiver to ensure that the patient can use this product safely.

Do not use the Alaira control unit in the presence of flammable gases (e.g. anesthetic agents). Possible explosion hazard if used in the presence of flammable anesthetics.

Ensure that the Alaira mattress is securely attached to the bed frame prior to use. Care should be taken to ensure that the straps do not interfere with the normal operation of the bed.

To reduce the risk of entrapment of the patient between the mattress and the bed frame, make sure that the mattress is securely attached to the bed frame and any space between the headboard, footboard and the mattress is less than two inches at any point.

If side rails are used with the Alaira mattress, care must be taken to reduce the risk of entrapment of the patient. Make sure that any space between the side rails and the mattress is less than two inches.

Never drop or insert any object into the opening on the Alaira control unit.

CAUTIONS

Do not use in the presence of smoking material or open flame. Air flowing

Risk of electric shock, do not remove the back cover of the control unit. Refer all service to qualified service personnel.

IMPORTANT

The AC power cord acts as the main disconnect for this device.



Emergency Deflate is accomplished by disconnecting the hose connector from the control unit.



Introduction

Thank you for purchasing the Therapeutic Mattress Systems, Alaira Mattress Replacement System manufactured by Accuro Medical Products, LLC.

The Alaira mattress replacement system is quiet, comfortable, easy to use, and is suitable for the care and prevention of all stages of pressure ulcers as well as patients that have been assessed to be at high risk from the complications of immobility. This high quality medical product, if properly used and cared for, will provide many years of trouble free service and outstanding clinical performance for all of your patients weighing between 70 and 350lbs.

Alaira replaces the standard mattress on most hospital, long-term care and home-care bed frames. Its low friction low shear top cover, interface pressures below capillary closure, and many therapy options ensure that Alaira will meet your clinical needs.

Please take the time to read the contents of this manual before using the system, and retain it for future reference.



System Features



CONTROL UNIT FEATURES

- Compact lightweight power unit is quiet with robust features
- Patient weight capacity: 70-350 lbs.
- Individual Patient Weight Settings
- Seven Comfort settings
- · Four alternating pressure modes
- · Four Air Loss therapy modes
- Rapid system inflation
- Max Inflate (auto-firm) function with automatic return to therapy mode
- Auto-deflate
- Patient position sensor optimizes support when the head of the bed is elevated
- Reusable air filter
- · Integrated carrying handle for portability
- Crisp, easy to read graphics for intuitive setup and therapy control
- Automatic panel lockout to prevent tampering (Note: This is an optional feature and must be requested at time of ordering)
- Audible and visual power fail alarm
- Audible alarm mute
- Integrated hanging brackets that automatically adjust to footboards up to 2" thick
- "Quick disconnect" mattress connection allows for rapid setup and CPR deflate at the control unit

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Mattress Features



- Alaira provides pressure relief therapy to patients from 70 to 350 pounds.
- Its easy to clean and ultra low maintenance design makes the system ideal for ownership.
- The eight inch deep air cells allow the system to operate at very low pressures, which enhances the ability of the system to provide very low interface pressures.
- The durable non-slip vinyl bottom-cover of the mattress protects internal components while being very easy to clean. Nylon attachment straps ensure the stability of the mattress on the bed frame.
- The low friction, low shear waterproof top-cover of the mattress prevents contamination of internal components while providing a shear and friction reducing laying surface.
- Alaira's Air Loss Top-sheet delivers four levels of both direct and indirect low air loss providing outstanding moisture management.
- Four Alternating Pressure settings allow you to select the therapy that works best for each patient.
- CPR deflation in less than 60 seconds.
- Integrated side bolsters that provide a firm side to the mattress that helps to reduce the risk of patient falls.
- Integrated patient safety rails reduce your patient's risk of a fall by adding an additional 3 inches of side bolster above the mattress surface. Patient Safety Rails can be inflated or deflated with the push of a button.
- Automatic pressure equalization system supports the patient in the event of a power failure for approximately 24 hours.
- Emergency Evacuation handles allow patients to be evacuated on the support surface.



System Specifications

Weight:

Control Unit 14.5 lbs.	(6.6 Kg)
Mattress	(10.6 Kg)
Max patient weight 350 lbs.	(160 Kg)

Dimensions:

Control Unit	16(W) x 12(H) x 7(D) in.	(40 x 30 x 18 cm)
Mattress	36(W) x 80(H) x 10(D) in.	(91 x 203 x 25 cm)

Electrical Specifications:

USA	.Europe/Australia
115V AC, 60 Hz,	.220V/240V AC, 60/50 Hz,
2A	.2A

Equipment Symbols:



Refer to user manual

SN:

Serial Number

CE Mark:



Environmental Conditions

Operating Conditions:

Storage and Shipping Conditions:

Ambient Temperature:	-10°C to +40°C
Relative Humidity:	10% to 100%

Agency Approvals

UL Classified Medical Equipment UL 60601-1 Can/CSA C22.2 No. 601.1 Risk Class 2G Note: UL Classification refers to Power Unit only, not complete mattress replacement system.

Safety Instructions

- 1. To avoid damaging the Alaira control unit, be sure the power available at your location matches the power call-out on the rear of the Control Unit (i.e. 110VAC, USA; 220VAC Europe/Australia)
- 2. To avoid electric shock, always plug the Alaira Control Unit into a properly grounded receptacle. If you are uncertain if the outlet you wish to use is grounded have the outlet inspected by a licensed electrician.
- 3. Do not spill food or liquids onto the Alaira Control Unit. If a spillage does occur, disconnect it from its power supply and allow at least 24 hours for drying. During the drying time other arrangements must be made to meet the patient's clinical needs.
- 4. Do not insert items into any openings of the Alaira Control Unit. Doing so may cause fire or electrical shock by shorting internal components.
- 5. Keep unit away from radiators or other heat sources.
- 6. Be sure nothing is placed on the power cable and ensure it is not located where it can be stepped on or tripped over.
- 7. Do not attempt to service the Control Unit except as explained in this guide. Always follow installation and servicing instructions closely.





Service and repair must only be performed by an authorized Accuro Medical Products, LLC Technician.



Quick Start Instructions

- 1. Remove the existing mattress from the bed and store it.
- 2. Unroll the Mattress with the hose connection at the foot of the bed with the nylon side up.
- 3. Secure the ten (10) straps securely to the bed frame. Being careful not to impede the moving parts of the bed frame.
- 4. Hang the Alaira Control Unit on the foot of the bed facing away from the bed. Attach the hose connector to the Control Unit.
- 5. Plug in the Control Unit power cord. The yellow "Standby" light will illuminate.
- 6. If you are going to use the Adjustable Air Loss Therapy Sheet, apply it at this time.
- 7. If the patient is being transferred from a wheelchair or standing position he/she should be placed on the bed at this time. If the patient is being transferred onto the surface in a laying position he/she can be placed on the bed at this time or after the system is fully inflated.
- 8. Press the Power Key. The Unit starts and the Green "On" light illuminates (mattress can be inflated with patient on the mattress).
- 9. Select the appropriate weight range.
- 10. The rapid inflate cycle will start automatically. The mattress will quickly inflate to the appropriate pressure. This is based on the weight range selection and the comfort setting.
- 11. If you want to reposition the patient or transfer the patient onto the surface in a laying position press the "Max Inflate" key. The surface will quickly become very firm. The max inflate cycle will last for 12 minutes or until the "Max Inflate" key is pressed again.
- 12. If the patient is being transferred onto the bed in a laying position, he/she should be transferred at this time.
- 13. Inflate the Patient Safety Rails.
- 14. Select an Air Loss Therapy Mode.
- 15. Select an Alternating Pressure Therapy Mode.
- 16. Allow the unit to operate for several minutes prior to changing the Comfort Adjustment.



INFORMATION

It is recommended that you only change the Comfort Adjustment one level every few minutes. This allows the system to equalize.

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Detailed Explanation of Functions



- 1. Power
- 2. Patient Weight
- 3. Alternating Pressure Adjustment
- 4. Comfort Adjustment
- 5. Low Air Loss Adjustment
- 6. Alarm Mute

- 7. Patient Safety Rails
- 8. Max Inflate
- 9. Deflate
- 10. Scroll Down
- 11. Scroll Up

Keypad Functions

1. Power Button



Turns the Alaira on and off. The 'Standby' indicator light glows yellow when the unit is plugged into the main electrical supply but is not turned on.

- To activate the unit press the power button. The yellow 'Standby' light will turn off, and the green 'On' light will illuminate.
- To turn the unit off press the power button. The green "On" light will go off and the yellow 'Standby" light will turn on.

2. Patient Weight Button



Used to select patient's weight.

- Press the 'Patient Weight' button. The Weight setting is displayed on the screen.
- Use the Up and Down arrows to adjust the weight setting to match the patient's weight.

3. Alternating Pressure Adjustment



This changes the pressure profile of the alternating pressure cycle. When "Off" is selected the mattress is in static pressure relief mode. In this mode the mattress provides continuous pressure relief. "Low" indicates a low level alternating pressure. This mode provides gentle pressure changes on an eight (8) minute cycle. "Medium" indicates a moderate level of alternating pressure. This mode provides moderate pressure changes on an eight (8) minute cycle. "High" indicates aggressive alternating pressure therapy, loading and unloading the tissue on an eight (8) minute cycle.

- Press the 'Alternating Pressure' button. The current setting is displayed on the screen.
- Use the Up and Down arrows to select the desired alternating pressure profile.



4. Comfort Adjustment Button



This is a micro adjustment that fine tunes the softness and firmness of the mattress. There are seven choices, three that are firmer, three that are softer and one that is no adjustment. The unit powers up at no adjustment.

- Press the 'Comfort Adjustment' button. The current setting is displayed on the screen.
- To increase firmness, press the up arrow. To decrease firmness, press the down arrow.

5. Low Air Loss Adjustment



This function is used to adjust the Air Loss Therapy. It requires the use of the optional Air Loss Top-sheet. When the unit powers up the Air Loss feature is set to Off. There are four levels of Air Loss Therapy. Off, Low, Medium, and High. Each level adjusts the amount of air that is released into the Top-sheet.

- Press the 'Low Air Loss' button. The current setting is displayed on the screen.
- Continue pressing the button to select the desired level of Low Air Loss therapy.

6. Alarm Mute



Alarm Mute is used to either temporarily or permanently mute the Alaira Alarms. This is normally done to allow the provider to correct alarm conditions.

 Press the 'Alarm' button to mute for 30 minutes. Press and hold for 3 seconds to permanently mute all alarms until the unit is put in "Stand By" mode or the "Alarm Mute" button is depressed and held for 3 seconds.



CAUTION: In most circumstances it is not recommended to permanently mute the Alarms and should only be done when absolutely necessary.

7. Patient Safety Rails



Patient Safety Rails are used as an additional safety feature that will help prevent patients from falling out of bed. They add a full 3 inches to the height of the side bolsters above the mattress surface. The Patient Safety Rails will help to reduce the need for side-rails.

- · Press the Patient Safety Rail key to inflate the Patient Safety Rails
- To deflate the Patient Safety Rails press the Patient Safety Rail key

8. Max Inflate



This function is used to rapidly inflate the mattress or to make the mattress very firm for in-bed procedures. The system will return to the previous mode settings after 12 minutes.

- Press the 'Max' button to activate this feature.
- To turn Max Inflate off press the 'Max' button again.

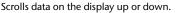
9. Deflate



This function is used to deflate the entire mattress without unplugging the unit or using the CPR deflate.

- Press the 'Deflate' button. The unit will immediately start deflating.
- To re-inflate to the previous settings press the 'Deflate' button again.

10. & 11. Scroll Buttons



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Lock Out

The lock out function is turned on or off at the time of manufacturing. If not requested the unit is built with this function disabled. This function is used to lock the keyboard so that settings are not accidentally changed. The lock out function automatically activates after 10 minutes of inactivity. When the Lock Out function is engaged the Power 'On' light begins to flash indicating 'Lockout' is enabled.

for 3

To "Unlock" and make adjustments to the settings press and hold the Power Key seconds.

Other Features

CPR

The hose connection at the Control Unit is marked "CPR", Disconnect the hose from the Control Unit. Initiate organization's CPR procedures. To re-inflate the mattress, re-attach the hose to the Control Unit.

Power Failure System

The Power Failure System that is incorporated into the Alaira Mattress Replacement System helps to ensure that pressure relief therapy is maintained if power is lost to the unit. In the event of a power failure the pressure is equalized in the mattress.

During a power failure it is recommended that the patient's head of the bed be lowered to the flat position to help keep interface pressures as low as possible. If the patient has medical conditions that make this unsafe or impractical hand checks should be done every two hours to ensure the patient is not bottoming out.

To perform a hand check, unzip the top cover from the mattress, slide one hand between the cushions directly under the patients buttock. You should have at least two fingers width of space between the buttock and the bottom of the mattress. If your hand check revels that you do not have adequate space a turning schedule should be implemented immediately and the patient should be transferred to another surface as soon as possible.



CAUTION: If the hose connector is disconnected from the control unit during a power failure the system will deflate and cannot be re-inflated until the power is restored.

Once power is restored the unit will start up in "On" mode and begin operation with the previously saved settings.

To ensure the patient is protected you should perform a hand check every four to six hours to ensure that the system is providing adequate pressure relief. If at any time you determine there is less than two fingers worth of air under the patients buttock, he/she should be transferred to another surface as soon as possible and a turning schedule initiated immediately.



Transport

To transport the patient on the mattress with the mattress attached to the bed frame: Press the power button placing the Unit in Standby. Unplug the Unit (the mattress will hold air during the transport). Secure the power cord. When the transport is complete, plug the Unit in and press the power button to enter the Run mode.

To transfer the patient on the mattress to another bed frame: Max inflate the mattress. Inflate the patient safety rails. Remove the mattress straps from the bed frame. Place the new bed frame next to the old bed frame (making sure the top of the two bed frames are even. Place the mattress blower in standby. Unplug the mattress blower and place gently between the patients legs. Make sure all power cables are not tangled up. Pull the mattress across to the new bed frame. Secure all straps. Hang the blower on the foot of the bed, plug in and turn on.

Emergency Evacuation

To use the Alaira as an evacuation device: Inflate the Patient Safety Rails, Max Inflate the mattress, remove the straps from the bed frame, power unit off, unplug the unit from wall power, place the control unit on the mattress, use the handles on the sides of the mattress to remove the mattress from the bed and evacuate the patient.

If necessary you can use gate belts to secure patient to mattress. Care must be taken when positioning the gate belts to prevent injury to the patient. Power should be restored to the Alaira as soon as possible so that therapy can be resumed.



CAUTION: During evacuation Alaira is not providing pressure relief therapy. The unit should be plugged in and power restored as soon as possible.

Ground Pin

The Alaira control unit has a conveniently located ground pin. This pin is used to conduct ground testing. To use the ground pin plug the control unit into the test device, place the ground test lead in contact with the ground pin and read the results on the test device.

Alarms

The Alaira mattress replacement system monitors several functions and will alarm if the system detects a condition that is effecting the normal operation of the system. There are both visual and audible alarms. Please refer to the following explanation of alarm conditions and follow the instructions provided to correct the condition. If the problem persists contact Accuro Medical's customer service department at 1-800-669-4757.

Check Hose Connector:

The Check Hose Connector alarm will sound if the system detects a leak. This is determined by the microprocessor if the system is unable to maintain the expected pressures during operation. The most common reasons for this alarm condition are:

• The hose connector is not properly attached to the control unit

To correct this alarm condition, disconnect the hose connector for the control unit, re-align the slot in the connector with the key on the control unit, turn ¼ turn.

• One of the tubing connector "O" rings is damaged or missing in the hose connector. Disconnect the hose connector from the control unit.

Make sure that there is an "O" ring on each of the four white tubing connectors. Do this by looking inside the hose connector

If any of the "O" rings are damaged or missing then replace.



• If the alarm condition cannot be corrected as outlined above contact Accuro Medical Products LLC for further advice.

Power Failure

The Power Failure alarm will sound whenever the unit is running and loses power. The alarm will sound and the power failure light will illuminate.



Cleaning and Maintenance

The Alaira is designed to keep bodily fluids out of the inside of the mattress. Follow facility protocol with respect to: cleaning between patients, cleaning if the surface becomes soiled, cleaning while in use. Use the same cleaning schedule protocol for the Alaira mattress system that you use for your standard hospital mattresses.

If at any time you are concerned that bodily fluids have penetrated the exterior of the mattress contact Accuro Medical Products LLC for further instructions.



WARNING: Disconnect the power cord from the wall outlet before attempting to replace the filter or clean the control unit.

General Cleaning Guidelines

- 1. Patient care equipment that does not come in contact with mucous membranes or non-contact skin requires low-level disinfection. Wiping surfaces with a properly prepared detergent/ disinfectant carries out low level disinfecting.
- 2. Processing of dirty patient care equipment should take place in an area away from clean or sterile supplies and food preparation areas.
- 3. Detergent/disinfectants should not be mixed with other germicides or detergents. Using the proper dilution ensures the most effective killing power of the disinfectant. Always follow the disinfectant manufacturer's instructions.
- 4. Wash hands often and well, including after removal of gloves, paying particular attention to around and under fingernails and between fingers.

Control Unit Cleaning

Wipe off dust. If necessary, clean the housing exterior with a disinfectant solution or a mild detergent and a damp cloth. Then wipe dry.

DO NOT HEAT OR STEAM AUTOCLAVE THE CONTROL UNIT.

Filter Cleaning & Maintenance

Check the air filter on the rear of the unit on a monthly basis for the buildup of dust/dirt. If buildup is visible turn off the blower then remove the filter by grasping the filter and pulling. Replace with a clean filter. Ensure the replaced filter covers the whole filter region. Hand-wash the removed filter in warm soapy water and allow to air dry. When dry, store the filter in a safe place for the next filter maintenance.



CAUTION: Do not put a moist filter back in the unit. Do not operate the unit without a filter. Doing so could result in permanent damage to the system.

Mattress Cleaning

The Alaira mattress top cover and bottom covers are both designed to prevent any moisture for entering the inside of the mattress. Both the top cover and the bottom cover of the mattress can be wiped down with a disinfectant solution or a mild detergent using a damp cloth. Mattress should be dry before the patient is placed back on the mattress.

If support surface becomes soiled (such as with food, medication, or other non-human waste materials) and can be easily cleaned:

- Don protective gloves,
- Wipe soiled area using detergent/disinfectant,
- Dry with a clean cloth or towel.

If support surface becomes grossly soiled, or becomes soiled with body substances:

- · Don protective gloves, protective apparel, and eye protection device ,
- Remove patient from surface,
- Remove any visible bodily substance from surface and dispose of per facility protocol,
- Using an approved disinfectant cleaner, wipe down the entire mattress. Follow manufactures guidelines on proper use of disinfectant cleaner,
- Remove and dispose of gloves and protective apparel per facility protocol,
- Return patient to surface.



Top-Sheet Cleaning

The Adjustable Air Loss Top-sheet is designed to allow a variety of air loss therapies to the patient and therefore will allow liquids to penetrate the surface. The materials that the Top-sheet is made out of are antibacterial in nature. The Top-sheet should be replaced or cleaned if it becomes soiled. If used on an extended period of time the Top-sheet should be replaced or deep cleaned on a monthly basis.

Light Cleaning of Top-sheet

Light cleaning should be done at least once a week or if the top-sheet becomes soiled (such as with food, medication, or other non-human waste materials) and can be easily cleaned:

- Don protective gloves,
- · Wipe soiled area using detergent/disinfectant,
- Turn Air Loss therapy on high and allow Top-sheet to dry completely before returning the patient to the mattress.

Deep Cleaning of Top-sheet

If support surface becomes grossly soiled, or becomes soiled with body substances:

- Don protective gloves, protective apparel, and eye protection device,
- Remove patient from surface,
- · Remove any visible bodily substance from surface and dispose of per facility protocol,
- Remove the top-sheet from the mattress,
- Remove the hose from the top-sheet,
- · Place the top-sheet in a standard household clothes washer,
- · Wash with warm water, standard laundry soap, and one cup of bleach,
- Either air dry or dry in standard household clothes dryer on NO HEAT.

Between Patients Cleaning Procedure

Don protective gloves, protective apparel, and eye protection device Prepare detergent/disinfectant (reg. by EPA as hospital disinfectant) solution according to manufacturer's instructions for correct use-dilution.

Mattress

- remove any visible bodily substance from surface and dispose of per facility protocol,
- remove Top-sheet from mattress,
- with the system inflated, thoroughly wipe down the entire mattress surface following detergent/disinfectant manufacturer's instructions. Normally there is no need to clean internal components as the outer cover is water proof,
- · allow all components to air dry,
- wrap mattress in plastic and return to storage area.

Control Unit

- Thoroughly wipe down outside of control unit and allow to air dry,
- remove the filter by grasping the filter and pulling,
- replace with a clean filter. Ensure the replaced filter covers the whole filter region
- · cover control unit with plastic and return to storage area

Top-sheet

- remove the hose from the Top-sheet,
- place the Top-sheet in a standard household clothes washer,
- wash with warm water, standard laundry soap, and 1 cup of bleach,
- either air dry or dry in standard household clothes dryer on NO HEAT

Storage and Care

Control Unit

After disinfecting the unit as outlined above, Accuro Medical recommends that it be placed in a plastic bag for dust resistance and then stored in the Mattress Cart (or other clean area used to store electromechanical medical devices).

Support Surface

After disinfecting the mattress gently roll it up, use the attached straps to secure it. Accuro Medical recommends that it be placed in a plastic bag for dust resistance and then stored in the Mattress Cart (or other clean area used to store electromechanical medical devices).



Warranty

This warranty is extended only to the original purchaser and does not affect statutory rights.

Accuro Medical Products LLC, (the warrantor) warrants the Mattress Components (see below) to be free from defects in materials and workmanship for a period of three (3) years covering all materials and labor costs. If within such warranty period the product shall be proven to the warrantor's reasonable satisfaction to be defective, it shall be repaired or replaced, at warrantor's option; warrantor's sole obligation, and your exclusive remedy under this warranty being limited to such repair or replacement.

Mattress Components – Mattress base, air sacks, hosing and mattress covers are warranted for three years from the original date of purchase. In the event of a defect in materials or workmanship the items will be replaced with new soft goods in exchange for the defective product.

Top-sheet – Top-sheets are warranted for a period of ninety (90) days from the original date of purchase. In the event of a defect in materials or workmanship the items will be replaced with new Top-sheet in exchange for the defective product.

If the product is deemed by the warrantor not to be covered under warranty a quote will be sent to you for your approval before work will begin. If you do not want the work performed a minimum charge of \$45 will be charged and your product will be sent back C.O.D. using the shipper of your choice.

Warranty service in the United States can be obtained during the warranty period from Accuro Medical Products LLC. Please call 800-669-4757 to obtain a return authorization number (RA number).

No product will be accepted for return without an RA number.

Shipping – The purchaser is responsible for shipping costs incurred returning defective product to Accuro Medical Products LLC. Accuro Medical Products LLC will pay all shipping costs incurred in returning repaired or replacement parts to the purchaser.

Limits and Exclusions

There are no express warranties except as listed above.

The warrantor does not warranty the merchantability or fitness of this product for a particular purpose.

THIS WARRANTY DOES NOT COVER NORMAL WEAR AND TEAR OR DAMAGE WHICH OCCURS IN SHIPMENT OR FAILURES WHICH ARE CAUSED BY PRODUCTS NOT SUPPLIED BY THE WARRANTOR OR FAILURES WHICH RESULT FROM ACCIDENT, MISUSE, ABUSE, NEGLECT, MISHANDLING, MISAPPLICATION, ALTERATION, FAULTY INSTALLATION, MODI-FICATION, OR SERVICE BY ANYONE OTHER THAN THE WARRANTOR OR DAMAGE THAT IS ATTRIBUTABLE TO ACTS OF GOD.THE WARRANTOR SHALL NOT BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OF THIS PRODUCT, OR ARISING OUT OF ANY BREACH OF THIS WARRANTY. ALL EXPRESS AND IMPLIED WARRANTIES ARE LIMITED TO THE APPLICABLE WARRANTY PERIOD SET FORTH ABOVE.





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