

Evaluating the Efficacy of Two Air-Assisted Patient Repositioning Systems for Proper Patient Positioning & Caregiver Safety

Premarket Validation Trial Conducted at Ranchos Los Amigos, Downey California & EHOB's Simulated Acute Care Setting, Indianapolis, IN

Premarket Product Validation Trial Project

Introduction

Due to staffing shortages, time, and lack of equipment, clinicians are often faced with turning, positioning, and boosting patients without assistance or safe patient handling equipment.

Repetitive lifting and pulling required to reposition patients can lead to debilitating musculoskeletal injuries for staff. Market research and clinician feedback have identified a need for patient repositioning devices that can be left under the patient and include features such as air-assist and multi-use. EHOB has developed the BAM Air™/BAM Air +™ Repositioning Sheet to address these needs.

Objective

The goal was to validate that the product is clinically effective and safe when used as intended for assisting in lateral transfers and maintaining proper patient positioning while managing moisture and reducing the risk of musculoskeletal injuries in health care providers.

Methods

Validation Trial Locations

Rancho Los Amigos, Downey, California

• Acute Medical Spinal Cord Injury Rehabilitation Unit /Acute Med/Surg Unit EHOB SIM Rom, Indianapolis, Indiana

Patient Inclusion Criteria

- Patients under 600 lbs., and under 1200 lbs.
- Patients requiring assistance with lateral transfers or repositioning
- Patients at risk of pressure injury
- Patients in need assistance in maintaining proper positioning
- Patients at risk for moisture associated skin damage

Additional Information

- Facility used Comfort Glide Drypad instead of CTES
- Facility chose to use pillows instead of wedges
- At the time of the evaluation, facility did not use air-assisted devices

Results

Product Efficacy

Repositioning Sheet: There were no reports of staff injury while using BAM Air or BAM Air+. Clinician feedback confirmed the BAM Air and BAM Air+ were used successfully in repositioning, lateral transfers and boosts.

CHALLENGE:

• Some difficulties were reported while completing patient turns. Feedback indicated that clinicians could not maintain proper body mechanics due to handle options. The reinforced handles were not long enough to hand off to a clinician on the opposite side of the bed.

SOLUTION:

• Extender straps were added to each product to assist with turning.

Additional holes were added to the bottom of each product to allow more air to escape and allow the patient to better immerse into the product.

Air Pump: Reports indicate the EHOB Air Pump and EHOB Cart worked well. The cart reportedly rolls very smoothly and takes up minimal space.

CHALLENGE:

Feedback indicated the pump was easy to use, however, it was missing a
way to indicate which setting was in use. It wasn't clear which button
would turn off the pump.

SOLUTION

• In response to the feedback, EHOB Product

Development added a backlight indicator to

the high and low buttons to easily identify which button was in use

Clinical Validation Summary

EHOB's Clinical Team validated that the changes corrected the issues.

- New extender straps allowed one caregiver to easily hand off the straps to another caregiver on the opposite side of the bed without jeopardizing safe body mechanics.
- Additional holes allowed the patient to slightly immerse into the product during the turn rather than laying high on top of a very firm product.
- Backlights on the Air Pump make it simple to identify the mode in which the pump was running.

NOTE: It was determined that using the product with no inflation for lighter weight patients (approximately less than 200 pounds) was a good option. There were 2 staff "injuries" reported, but upon further inquiry it was discovered that both were from clinicians who bumped into the cart.

Evaluation Summary







indicated for:

- ✓ Assisting in lateral transfers
- ✓ Maintaining proper patient positioning
- ✓ Managing moisture

Conclusion

✓ Reducing the risk of musculoskeletal injuries in healthcare providers

Based on the premarket validation evaluation results,

EHOB Clinical Affairs has determined the BAM Air and

BAM Air+ Repositioning Sheets along with the EHOB

Air Pump and EHOB Cart are clinically safe and

effective for clinicians and patients when used as

No patient handling incidents or injuries were reported during the trial.





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