



Evaluating the Efficacy of a Wipeable Turning & Repositioning System with Handles & Moisture Management Capabilities

Premarket Validation Trial Conducted in an Acute Care Facility in the Southwest US

Premarket Product Validation Trial Project

Introduction

Due to staffing shortages, time, and lack of equipment or storage of equipment, clinicians are 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 turning and repositioning devices that can be left under the patient, so they are always immediately available. Product wipeability is also desired to extend the life of the repositioning sheet. EHOB has developed the BAM Pro™(A0162) to address these needs.

Objective

Prior to releasing the BAM Pro System, EHOB sought clinician feedback to confirm the product's efficacy and durability. The goal was to validate that when properly used for repositioning, lateral transfers and fluid management, no staff injuries or patient moisture associated skin damage would occur.

Methods

Through the assistance of EHOB Sales, a regional medical center was secured for conducting a premarket validation trial. Unit champions were identified to serve as contacts and staff resources during the evaluation. EHOB Clinical, Sales, and unit champions provided education to participating clinicians on how to use the BAM Pro System prototype and the *EHOB Premarket Product Validation Trial Packet*.

- The unit was provided with 16 BAM Pro Systems
- Patients included in the evaluation were those who required assistance with turning, repositioning, and/or transfers and/or patients who are at risk of moisture associated skin damage from urine, blood, stool, or other fluids
- Product was suggested for patients with LOS greater than 3 days and/or units on which turning and repositioning devices are less likely to be available *including but not limited to: Med-Surg; Post-Surgical*
- EHOB Clinical and Sales were available for consultation as needed throughout the trial
- Length of Validation: 14 days
- Unit champions provided EHOB Clinical and/or Sales with the completed *Premarket Validation Data Collection* forms and any additional feedback or comments related to the BAM Pro System prototype
- All data was compiled and analyzed by EHOB Clinical

Results

Caregiver Safety			Patient Protection		
During patient repositioning			Discomfort during repositioning		
YES – 15	NO – 0	N/A – 0	YES – 2	NO – 12	N/A – 1
During lateral transfers			Discomfort during lateral transfers		
YES – 13	NO – 0	N/A – 2	YES – 0	NO – 13	N/A – 2
During patient handling			Moisture-related skin damage		
YES – 14	NO – 0	N/A – 1	YES – 0	NO – 12	N/A – 3
Product Efficacy					
	YES		NO		N/A
Infographics helpful	13		1		1
Labeling helpful*	13		0		1
Easy wipeability	8		1		6
Damage to product after wiping clean	1		7		7
Wedges remained in place during turns*	8		1		5
Product preferred over current option	15		0		0
Quality concerns	0		15		0
Met expectations	14		1		0
Suggestions for improvement	0		12		3

* One evaluation was left blank for this question

Clinician Feedback – Quality and Design

- Feedback confirmed the BAM Pro was successful in repositioning, lateral transfers, boosts, and moisture management while maintaining proper patient positioning.
- No new pressure injuries were reported during the trial
- No reports of staff injury while using the BAM Pro System
- No reports of moisture-related skin damage while product was in use.
- Two patients reported some discomfort while the product was in use, however it was noted that it was not product related, as the patients felt the same pain with movements prior to the BAM Pro use
- Zero product failures throughout the trials
- Staff reported that the product managed safe patient handling and moisture BETTER than the current product options and have recommended that the BAM Pro System be stocked at the facility
- Provided a dry environment for a patient with diaphoresis, who was previously requiring frequent linen changes

Evaluation Summary

EVALUATIONS 16 	COMPLETED 15 	WEIGHT 98 lbs – 445 lbs
CLINICIANS Med/Surg Post-Anesthesia 	SURFACES Standard Hospital Beds 	UNIT Med/Surg

Products were used between 3 and 8 days

Conclusion

- ✓ The BAM Pro System proved to be a safe and effective wipeable patient movement system
- ✓ No staff injuries reported
- ✓ No new pressure injuries reported
- ✓ No reports of moisture-related skin damage

The product effectively stayed under patients and provided immediate access and reduced effort for staff needing to turn, transfer, or reposition patients in various settings.



Product Tried: EHOB BAM Pro System, Standard

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