

Therapeutic Support Surfaces Survey
Compliance Documentation

PressureGuard® Air Therapy Surfaces



Span-America Medical Systems, Inc.
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Greenville, SC 29615
800-888-6752

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Keys to a Positive Survey Experience:

This package is supplied by Span-America to support a positive survey experience. “Surveyors are not in the facility to intimidate or dig up dirt. The surveyor’s job is to ensure the residents are being treated with the care they deserve and the regulations governing care are met.” “Managers, please be sure that all MDS assessments are coded correctly and submitted in a timely fashion.” “States Here!”: Demystifying the Long-Term Care Survey, allnurses.com 1/9/15

Surveyors are concerned that prevention and treatment of pressure injuries is based on risk assessment, pressure injury assessment (if present on admission), MDS documentation and compliance with the F Tag 686 (formerly F-Tag 314) requirements.

Assessment of pressure injury risk level, development of a prevention care plan and documentation of intervention and outcomes of the care plan are required. If the resident has a pressure injury; assessment, detailed documentation, care plan development and implementation are necessary. If a pressure injury develops in the facility, there are specific documentation criteria that must be met for the injury to be considered “Unavoidable” or the Facility will be cited for non-compliance of F Tag 686 (formerly F-Tag 314)¹.

Surveyors expect nursing personnel to know the basic nursing fundamentals but also want to have staff demonstrate knowledge of wound care. The dressing choice and change frequency are expected to be based on and match the needs of the wound (assessment). The staff is expected to challenge MD orders if they feel that the prescribed dressing is not appropriate for the wound based on the current standard of care and the wound assessment. This can be problematic if the staff has not had expert education on wound care. Support surfaces for prevention and treatment of pressure injuries need to be used according to manufacturer instructions and guidelines; surveyors will ask to see these instructions. Documentation of MD involvement, assessment and interventions for hydration and nutrition will also be reviewed.

Documentation of ongoing monitoring, reassessment and revising interventions is important. The resident’s refusal of interventions (which is their right) and the recommendations for and the discussion of alternative interventions must also be reflected in the documentation.

Surveyors may question the use of specific support surfaces based on the patient’s assessment or appearance. The bullet points below list some of the items with which staff should be familiar in case of a surveyor visit.

- The answers to questions concerning the support surface choice or where to find them
- Support Surface policies/procedures of the facility (make sure they are up to date)
- The support surface manufacturer’s guidelines/indications for product use and literature if necessary

Overview of Span-America PressureGuard® Series Products and NPUAP/ S3i Testing

Span-America Medical Systems has designed and manufactured the industry's most comprehensive line of specialty solutions for pressure management and patient positioning for more than four decades. While its PressureGuard® series of air therapy products are recognized in medical facilities throughout North America, the company's other clinically proven product lines include **Geo-Mattress®** therapeutic mattresses, **Geo-Matt®** overlays and seat cushions, **Span+Aids®** patient positioners, **Isch-Dish®** wound care seating products, and **Selan®** skin care products.

Span-America's principal manufacturing facility is located in Greenville, South Carolina. This facility, which encompasses nearly 200,000 square feet, is located on a 13-acre site. All PressureGuard products are designed, produced, tested and shipped at this location in strict accordance with International Organization for Standardization (ISO) standards 9001 and 1345 to which it is certified. The company also operates a distribution center in Salt Lake City, UT.

Span is a corporate member of the National Pressure Ulcer advisory Panel (NPUAP). The company is heavily involved in the work of the Support Surface Selection Initiative ("S3i"), through which the NPUAP is coordinating the development of a uniform terminology, test methods and reporting standards for support surfaces. The guidelines will provide an objective means for evaluating and comparing support surface characteristics. Test methods and reporting standards will improve the process of selection and procurement. Clinicians, patients and other users would benefit from having product information and test data presented in a consistent manner. S3i is designated by the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) as the committee responsible for producing standard test methodologies for support surfaces in the United States.

NPUAP, S3i and interface testing:

Four standards are currently in draft form and are in the approval process. Each evaluates a specific performance characteristic and does not individually determine a support surface's efficacy in maintaining tissue integrity. These standards will include tests for "envelopment" and "immersion", which will provide objective, repeatable measurements of pressure redistribution characteristics of a given support surface. As such, these standards will finally allow accurate side-by-side comparisons that are currently not possible using the older computerized pressure mapping results that has been traditionally been published by manufacturers in support of their products [note: Span-America archived pressure mapping or number data on file.] Because these new standards will not be available to the public until after they are approved and published, manufacturers are currently unable to test products and publish results.

PressureGuard® Series MSDS and F Tag 686 Statement (formerly Tag F314)



Survey Requirements of the Minimum Data Set (MDS) 3.0

The Minimum Data Set (MDS) Version 3.0, Section M Skin Condition, Item 5b indicates the use of a “Pressure reducing device(s) for the bed.”

The October 2010 Update for CMS’s RAI Manual Version 3.0 gives the following clarification for this item:

b. Pressure Reducing Device(s) for Bed – Includes air fluidized, low air loss therapy beds, flotation, water or bubble mattress or pad placed on the bed. Include pressure relieving, pressure reducing, or pressure redistributing devices. Do not include egg crate mattresses in this category.

Survey Requirements of the F Tag 686 (formerly Tag F314) for Pressure Injuries

In the Guide to Long Term Care Survey¹, the F Tag 686 (formerly Tag F314c)² addresses Pressure Sores:

“F Tag 686 (formerly Tag F314) is intended to ensure a resident does not develop a pressure ulcer. If a pressure ulcer develops, the facility must show consistent documentation of “unavoidable” and the facility must provide services to promote healing and prevention of further pressure ulcers”.¹

Regulation: A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

On November 12, 2004 CMS issued guidance³ regarding the F Tag 686 (formerly Tag F314). This guidance substantially expands on previous guidance. Regarding support surfaces, the guidance states:

Support Surfaces and Pressure Redistribution. Redistribution refers to the function or ability to distribute a load over a surface or contact area. Redistribution results in shifting pressure from one area to another and requires attention to all affected areas. Pressure redistribution has incorporated the concepts of both pressure reduction (reduction of interface pressure, not necessarily below capillary closure pressure) and pressure relief (reduction of interface pressure below capillary closure pressure).

In addition:

- Static pressure redistribution devices (e.g., solid foam, convoluted foam, gel mattresses) may be indicated when a resident is at risk for pressure injury development or delayed healing. A specialized pressure redistribution cushion or surface, for example, might be used to extend the time a resident is sitting in a chair; however, the cushion does not eliminate the necessity for periodic repositioning.
- Dynamic pressure reduction surfaces may be helpful when: 1) The resident cannot assume a variety of positions without bearing weight on a pressure injury, 2) The resident completely compresses a static device that has retained its original integrity, or 3) The pressure injury is not healing as expected, and it is determined that pressure may be contributing to the delay in healing.

¹ <http://www.npuap.org/resources/educational-and-clinical-resources/minimum-data-set-3-0-mds-3-0/>

Mcknights.com July 2

² Reference: Thomas, D., The New F-tag 314: Prevention and Management of Pressure Ulcers. Clinical Practice in Long-term Care 10/2006

No. 3. Rockville, MD: US Department of Health and Human Services. Public Health Services, Agency for Health, Research and Quality (formerly AHCPR). publication No. 92-0047, May 1992. <http://www.npuap.org/resources/educational-and-clinical-resources/npuap-selected-quality-of-care-regulations-made-easy/>

³ CMS Manual System, Pub. 100-07 State Operations, March 8, 2017

Note: pressure sore, ulcer and injury are all terms for the same condition.

PressureGuard® Series Description

Product Description:

The PressureGuard Series of mattresses incorporate several features into powered surfaces providing pressure redistribution used mainly for the treatment of pressure injuries, or the prevention of pressure injuries for those at high-risk for breakdown.

The features include:

- 1) Surface layer of all of these models is cut with our clinically proven Geo-Matt® design^{1, 2}. Over 800 individually responsive cells distribute load and reduce shear, while the ring-of-air at the base of each cell ventilates heat and moisture,
- 2) Longitudinally oriented air support cylinders
- 3) Shaped, slotted inner bolsters surround air cylinders, providing a stable surface for patient function and safety
- 4) Firmer perimeter bolsters gently prompt the patient toward the center of the bed, facilitating safer transfers and stable edge-of-bed sitting
- 5) Exclusive Heel Slope that re-distributes load from the heels and onto the more pressure-tolerant calves
- 6) Cover is vapor barrier, bacteriostatically treated, and flame resistant.

Warranty: 2 years on Turn Select and Easy Air, 5 years on CFT and Renew, 18 months on APM2, 5 years on Custom Care series mattresses, 2 years for Custom Care series control units.

Fire Code: All models are certified for conformance to NFPA101 (Life Safety Code) – ASTM E1590; Cal Tech Bulletin #117; and 16 CFR Parts 1632 and 1633 by an independent testing organization.

Manufacturer:

Span-America Medical Systems, Inc.
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Below is a chart that outlines the Medicare Group II criteria and the Span-America products and codes that fit in the Group II criteria.
DMERC/SADMERC letters on file.

Medicare Group II Support Surface CMS Coding Eligibility



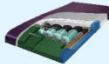
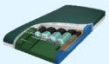
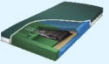
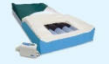



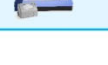
DOES THE PATIENT HAVE:

- Multiple Stage 2 pressure injuries (ulcers) located on the trunk or pelvis
AND
- Patient has been on a comprehensive injury (ulcer) treatment program for at least the past month which has included the use of an appropriate Group I surface
AND
- The injury (ulcer) has worsened or remained the same over the past month **OR**
- Large or multiple stage 3 or 4 pressure injuries (ulcers) on the trunk or pelvis **OR**
- Recent myocutaneous flap or skin graft for a pressure injury (ulcer) on the trunk or pelvis (surgery within the last 60 days)
AND
- The patient has been on a group II or III support surface immediately prior to a recent discharge from a hospital or

YES

NO

Patient does not
qualify for Group II.

Code	Span-America Options	Description
EO373 Non-powered Advanced Pressure Redistribution Surface	 PressureGuard® Custom Care® Convertible LAL	Effective non-powered pressure management through proprietary design features, including Star Chamber™ air system and Geo-Matt® surface geometry. Converts to powered modalities (alternating pressure, lateral rotation and low air loss).
	 PressureGuard® Custom Care® Convertible	Effective non-powered pressure management through proprietary design features, including Star Chamber™ air system and Geo-Matt® surface geometry. Converts to powered modalities (alternating pressure and lateral rotation).
	 PressureGuard Custom Care®	Non-powered reactive pressure redistribution through proprietary design features including Shear Transfer Zones® cover, Geo-Matt® surface geometry, ultra-high performance foam and interconnected support chambers.
EO277 Powered Pressure Redistribution Surface (alternating pressure, low air loss, lateral rotation)	 *PressureGuard® APM Series (APM, APM2, Safety Supreme)	Effective powered pressure management. Multi-mode air therapy with alternating pressure and lateral rotation at the flip of a switch.
	 *PressureGuard Easy Air® Series	High performance microclimate management (low air loss) with alternating pressure. LR Model includes lateral rotation.
	 PressureGuard® Custom Care® Convertible (with control unit)	Effective powered pressure management through proprietary design features, including Star Chamber™ air system and Geo-Matt® surface geometry. Includes powered modalities, alternating pressure and lateral rotation.
	 PressureGuard® Custom Care® Convertible LAL (with control unit)	Effective powered microclimate management (low air loss) through proprietary design features, including Star Chamber™ air system and Geo-Matt® surface geometry. Includes powered modalities, alternating pressure, lateral rotation and microclimate management (low air loss).
	 PressureGuard® Protocol™	Microclimate management (low air loss) with alternating pressure therapy

* Available in Bariatric

This is a summary. Consult your DME MAC, or
your supplier manual for complete guidelines.

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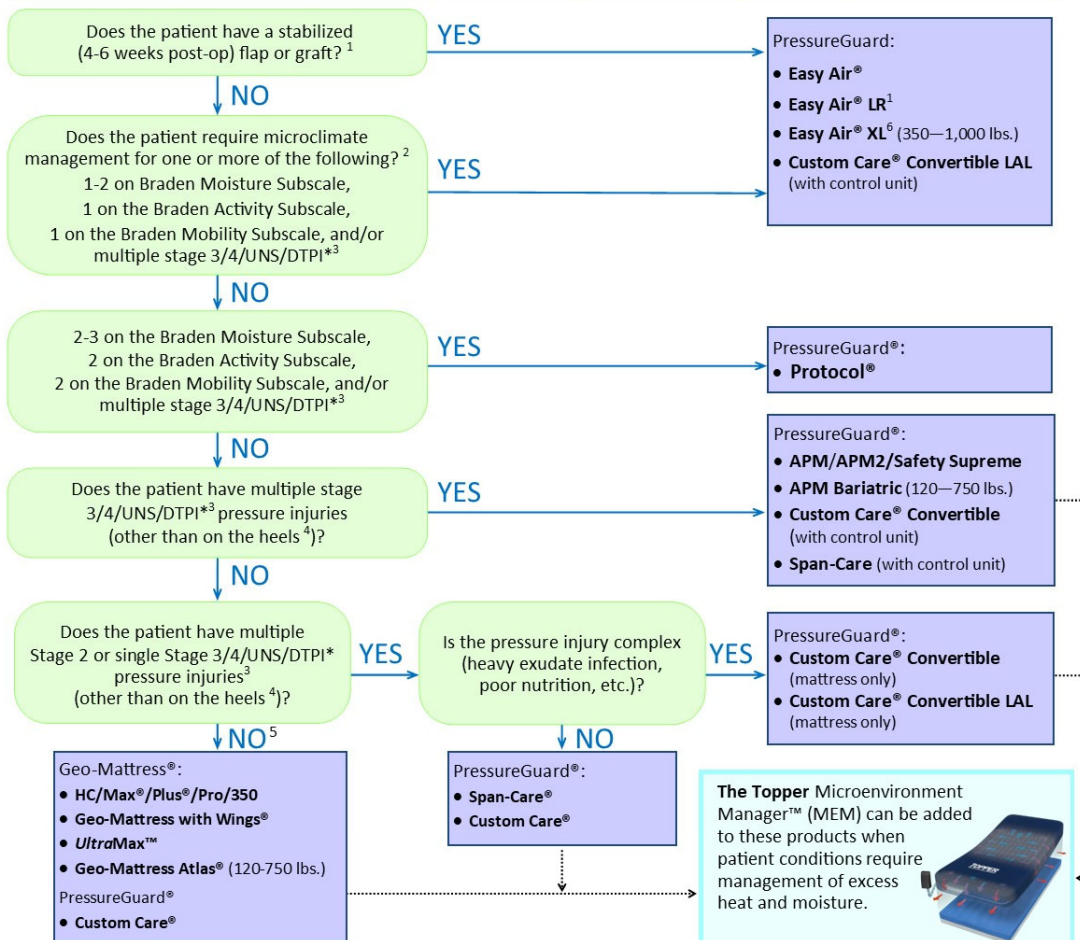
SSM-2 PG 10/15

The standard Span-America Support Surface Management algorithm shows the recommended Span-America support surfaces based on the number, location and severity of pressure injuries.



Support Surface ALGORITHM

This algorithm is meant as a guide, not a substitute for clinical judgment. It should be used only as an adjunct to a full patient assessment, and **should not preclude use of any product positioned higher on the algorithm.**



Notes/Clinical References:

1. If patient has a flap or graft that is less than 4 weeks post-op, total off-loading (proning) or air fluidized therapy is required. Avoid sliding patient on surface during repositioning, ADLs & transfers. Only float or alternating pressure modes (not lateral rotation) should be used when the patient is placed directly on the flap or graft. Source: *Wound Care Practice*, Sheffield, P. 1st edition, 2004, Chapter 17, P. 345. Other Span surfaces may be appropriate if used according to the guidelines.
2. Patients with excessive moisture due to sweating, decreased mobility, lack the ability to reposition, be repositioned, refuses to be or stay repositioned. Patients with macerated skin due to any of the previous. Patients with increased skin or body temperature due to infection, sepsis or other conditions.
3. Patients with multiple, complex (heavy exudate, infection, poor nutrition, etc.) pressure injuries may be placed on the Easy Air, Easy Air LR, Custom Care Convertible LAL (with control unit)
4. Heel injuries are difficult to heal and should be elevated off of the bed. Consider using Heel Manager™ or other Span positioners.
5. UltraMax may also be appropriate for multiple Stage 2 or single Stage 3 pressure injuries, and Max, Plus, Pro, Wings, Atlas or 350 may be appropriate for single Stage 2 pressure injuries, based on full assessment of skin status and repositioning required, according to best clinical practice and judgment.
6. The Easy Air XL is not designed to ensure sufficient pressure redistribution and comfort for users weighing less than 350 lbs.. For these users, standard Easy Air or Easy Air LR should be selected.

*UNS— Unstageable Pressure Injury: observed full-thickness skin and tissue loss. DTPI— Deep Tissue Pressure Injury: persistent deep red, maroon or purple discoloration. NPIAP Definitions, 2019

Span, PressureGuard, Geo-Mattress, Max, Span-Care, and The Topper Microenvironment manager are registered trademarks of Span-America Medical Systems, Inc. Greenville SC USA.

PL Standard Surface Algorithm R7 CO# 2556
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Span America Product Statement Documents Available

You may request Product Statement Documents to address the following subjects:

1. Attachment of PressureGuard Surface to Healthcare Bed Frames
2. Comfort Level Settings
3. CPR
4. Flammability
5. Flaps and Grafts
6. Heel Protection
7. HOB Elevation Cause and Effect
8. Impact of the Topper on Entrapment Risk
9. Lateral Rotation for Pressure Management
10. Latex-free Statement
11. Microclimate Management and Low Air Loss
12. Overlays
13. Pivot Assist Devices
14. Raise Perimeter Mattress
15. Resident Room Evacuation with Encore Bed
16. Support Surface Selection for Unstable Spinal Cord Injuries
17. Understanding the Evaluation and Documentation of Side Rail Use
18. Use of Linens

PressureGuard® Abstracted Studies / White Papers



Achieving Clinically Efficacious Pressure Redistribution Without the Use of Low Air Loss

Julie Ho RN, MS, CWCN

Poster Presentation, NPUAP Bi-Annual Conference 2015

Nine facilities, 125 patients, No LAL rentals, 3 HPAUs resolved, All IADs resolved, \$92,500.00 saved over 5 years

Unity (Formerly White County Medical Center)

Searcy, AR

In February of 2014, approximately 200 mattresses were delivered to Unity. Each unit's main mattress is the Custom Care (non-powered) with a few Custom Care Convertibles and a pump available for the high risk and/or patients with pressure ulcers. The prevalence rate was 7.3% of 6168 patients in 2014 and 13.7% of 8707 patients in 2015. The Incidence/Hospital Acquired pressure ulcer rate was 3.3% of 6168 patients in 2014 prior to new support surfaces and 2.9% of 8707 patients in 2015 post implementation of Span-America's Custom Care and Custom Care Convertible mattresses. The Incidence/Hospital Acquired rate decrease shows a positive effect on prevention of pressure ulcers using the new support surfaces even with a higher census (8707 vs 6168).

United Health Care Prevalence and Incidence Pre and Post Easy Air LR Recessed Deck

Lateral Rotation Mattresses for Wound Healing

Carol Anderson, RN, PHN, and Laurie M. Rappl, PT, CWS; *Ostomy/Wound Management* April 2004;50(4):50-62.

Report on use of Lateral Rotation mode on APM2 for Stage 2, 3, 4 pressure ulcers on 30 patients in home health and long term care. Results: Stage 2 ulcers averaged 9 weeks to closure, Stage 3 and 4 ulcers averaged 11 weeks to closure. Closure rate of 16% per week for Stage 2 ulcers and 12% per week for Stage 3 and 4 ulcers compare favorably with 5% per week on low-air-loss recently reported in literature.

Botsford General Hospital

Farmington Hills, MI

Documents the use of the PressureGuard APM² on eight patients with respiratory involvement who are transferring out of ICU or CCU and who have existing pressure ulcers on the sacrum, or who require a ventilator. Results: All showed improvement during their hospitalization.

Promina Gwinnett Health System

Lawrenceville, GA

Case study using APM2 on 77-year-old resident in hospice, with end-stage lymphoma and four Stage II-IV pressure ulcers on trunk/pelvis. Patient's medical condition made wound healing an unrealistic goal. Result: Stage II ulcers healed, Stage IV ulcer stabilized, patient noted much more comfort in sleep, uninterrupted by staff coming in to turn her through the night.

Valley Falls Terrace, Inc.

Spartanburg, SC 29303

Use of the PressureGuard APM2 in treatment of a long-term-care resident with multiple Stage I/II's on trunk and lower extremities. Patient's medical condition. Result: Resolution of Stage I's, Stage II on sacrum decreased in depth by 50% in 3 weeks.

Rotational Therapy: A Case Study in Healing and Prevention

Allison Patterson, OT(C) and Laurie Rappl, PT, CWS

Documents the cost-effectiveness of rotational therapy for healing a long-standing wound in a bed ridden patient after low-air-loss, air-filled, and air/foam surfaces had failed.

Rotational Therapy in the Treatment of Multiple, Weight-Bearing Pressure Ulcer Sites

Kay James, PT and Melissa Dunn, RPTA

Report on the use of rotational therapy for the treatment of a medically complex patient with 21 pressure ulcers on his lower body. Patient had severe limitations in mobility due to contractures and poor nutrition. Results: After installation of rotational therapy, notable improvement – 100% in some cases – was seen in the patient's ulcers, most significantly, in those on the weight-bearing surfaces.

A Proposed Method for Quantifying Low-Air-Loss Mattress Performance by Moisture Transport

Richard S. Figliola, PhD, PE, Clemson University, Clemson, SC.

Ostomy/Wound Management. 2003;49(1):32-41.

Describes a proposed test to objectively measure the effectiveness of a low-air-loss mattress in removing moisture from an imposed load. Demonstrates the test on six popularly used low-air-loss mattresses in the United States.

Low-Air-Loss Therapy: New Product Design Overcomes Modality's Long-Recognized Limitations

Laurie Rappl, PT, CWS

A primer on the modality of low-air-loss: purpose, design, construction, method of function, effectiveness, quantification of moisture removal, and solutions to common shortcomings of low-air-loss models.

Low-Air-Loss Reduces Excessive Patient Sweating

Mary Ellen Arsulowicz, RN

Clinical Reports July, 2002

Case study of an older, long-term-care resident with advanced multiple sclerosis and body sweat necessitating 2 changes of clothing and bed linens daily, and 6 soaker pads per day. After instituting PressureGuard Easy Air, sweat was decreased such that only 1 change of clothing per day and use of 2 soaker pads was necessary.

“Constant Force Technology’ vs. Low-Air-Loss in the Treatment of Wounds”

Raquel Branom, RN, BSN, CETN, Vencor, San Diego and Laurie Rappl, PT, CWS; *Ostomy/Wound Management* September 2001:47(9):38-46.

This study compares the effects of the PressureGuard CFT (Constant Force Technology) with low-air-loss surfaces on wound healing rates and patient outcomes. Patients with Stage III or IV ulcers were randomized to either the CFT or low-air-loss, and followed over 8 weeks. The CFT resulted in a 60% faster rate of wound closure. In addition, 100% of the patients placed on the CFT met, were meeting, or exceeded their goal of wound maintenance or closure, compared with 63% of the patients on low-air-loss.

"Effectiveness of the PressureGuard CFT Bariatric Model for the Obese Patient"

Valerie Barnes, RN, CETN, Grady Health System, Atlanta, GA

Clinical Reports: Series on Skin and Wound Care Management, Oct. 1997.

This article documents the results of using the PressureGuard CFT Bariatric Model for six patients between 350 and 700 lbs. All achieved their goals for skin management - prevention of ulcers - or wound management.

"PressureGuard CFT in Acute Care, ICU, and Post-Graft: Performance and Cost-Savings"

Karen Ross, RN, MA, CETN, Highland Hospital, Oakland, CA; in *Clinical Reports: Series on Skin and Wound Care Management, Dec 1998.*

The CFT gave us similar patient outcomes to low-air-loss for those patients requiring a treatment surface – those who are at high risk for breakdown, who have existing pressure ulcers, or who are immediately post-flap or post-graft. As a result of replacing our 35 ICU beds with the CFT in January 1997, our incidence rate in ICU's on our yearly audit went from 14.25% to 0%, and hospital-wide incidence rate went from 9.4% to 6.2%. The CFT replaced so many rental low-air-loss surfaces that we saved \$54,200 the first year.

"A Dynamic Non-Powered Surface vs. Air-Fluidized Therapy"

Laurie M. Rappl, PT, CWS, in *Clinical Reports: Series on Skin and Wound Care Management, March 1998.*

Documents pressure mappings on a thin, bony man with recent complete high cervical spinal cord lesion, and halo bracing. Pressure mappings were done both in supine and in 13° head-of-bed elevated on the PressureGuard CFT and on the Clinitron by Hill-Rom. With head flat, maximum pressures on the CFT were only 8 mm. Hg. higher than on Clinitron. With HOB elevated 13°, maximum pressures on CFT were 6 mm Hg. higher than on Clinitron. CFT pressure readings were considered well within safe limits, and improved with head-of-bed elevated.

HealthSpan Home Medical Equipment Services

Minneapolis, MN

Use of the CFT as a Group 2 mattress in the treatment of more than 100 patients between 1996 and 1998.

Result: 95% success in treating patients with Stage III and IV wounds or as step-down product after wound closure.

ICP (Institutional Care Pharmacy)

Tiffin, OH

Use of the CFT in 30 long-term-care facilities for patients with multiple stage II's or II's or stage IV on ischials.

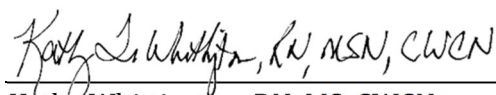
Result: CFT has replaced alternating air overlays and powered pressure reducing mattresses (Prime Aire, Zone Aire). Average usage 4 times in each of 30 homes over two years.

Select Specialty Hospital

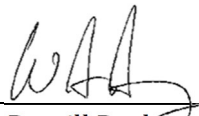
Sioux Falls, SD

Report on the successful use of the CFT for treatment of approximately 35 patients with wounds ranging from Stage II-IV. Results: Performance of the mattress has been equivalent to rented powered mattresses previously used.

Copies of any of the above articles and testimonials can be obtained on request. Please contact Customer Service at



Kathy Whittington, RN, MS, CWCN
Manager, Clinical Support



Derrill Darky
Vice President, Quality