



TECHNICAL DOCUMENTATION SUMMARY

HOVERMATT® AIR ASSIST SYSTEM

Considering An Air-Assisted System?

No other product is “just like a HoverMatt®.” Understand the differences in quality and safety.

ALL HOVERMATTS	
Indications	Single care giver boosting, turning, and repositioning; lateral transfer minimum 2 caregivers.
✓ Radiolucency	Radiolucency studies were conducted in a clinical radiology environment testing 24 different anatomical views. No artifacts were found in any of the images.
✓ Attenuation	Attenuation studies were conducted in a clinical oncology environment using Clinac® Model 2100EC. Testing was conducted on both reusable and Single-Patient Use HoverMatts using 6Mv and 18Mv with a 10cm x 10cm sample area. Tests at 6Mv measured .9974 and 18Mv measured .9977. A test score of 1.0 indicates full amplitude and intensity of radiation therapy. Test scores indicate that the HoverMatt does not cause attenuation of radiation waves from the table through the HoverMatt to the patient, and there is no risk of skin burns.
✓ Megadyne	The MEGA Soft® Patient Return Electrode System was tested by Megadyne with both the reusable and Single-Patient Use HoverMatt devices on adult patients over 150lbs. The MEGA Soft system (MEGA 2000, MEGA Soft or MEGA Soft Dual Cord) can be safely used in procedures with the HoverMatt and Single-Patient Use HoverMatt. It is important to limit additional linens and layers between the pad and the patient. Excessive materials between the patient and pad may diminish the surgical effect at the active electrode at equivalent power settings when compared to a typical sticky return electrode.
✓ Heat Transfer	Cincinnati Sub-Zero performed tests to evaluate the heat transfer from the 876 MaxiTherm® Lite pad and the 195P Gelli-Roll® through the HoverMatt using a 200lb. simulated load. Thermocouplers were located in the head, back, and buttock of the simulated patient. When the HoverMatt was used on top of either a Maxitherm Lite or a Gelli-Roll, the temperature drop across the HoverMatt was approximately 1°C, which was deemed to be clinically insignificant.
✓ Flammability	An independent laboratory conducted flammability testing to STD 16 CFR 1610-97 and 16-CFR Part 1632.4 on the HoverMatt and Single-Patient Use HoverMatt. Both products passed flammability testing.



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REUSABLE HOVERMATTS	
✓ Heat Sealed	Heat-sealed technology eliminates needle holes as a conduit for microorganisms to enter the inside of the HoverMatt, as well as thread that wicks and encourages this migration in sewn products. An independent laboratory conducted tests on the inside and outside of a pre-soiled HoverMatt after being laundered according to protocol.
	The inside and outside of the HoverMatt were tested post-laundering after being handled by a person with and without gloves. When the handler was wearing gloves, the HoverMatt tested less than the detection limit of the test (<1CFU/cm ²) on the inside and outside surfaces. When the handler was not wearing gloves, the outside of the HoverMatt tested “very slightly positive” (1CFU/cm ²), while the inside tested at less than the detection limit of the test (<1CFU/cm ²).
✓ MRI Compatibility*	MR imaging was conducted at a leading independent testing laboratory using a 3-Tesla MR system (General Electric Healthcare), a send-receive RF body coil, and the following pulse sequences: (1) T1-weighted, spin echo pulse sequence, and (2) Gradient echo (GRE) pulse sequence.
	Reusable HoverMatt products did not produce loss of signal, image distortion, or apparent artifacts associated with MRI performed at 3-Tesla.

SINGLE-PATIENT USE HOVERMATTS	
✓ Pressure Injury Prevention	Third party lab testing based on the latest industry-recognized surface testing recommended by NPIAP (formerly NPUAP) was performed on the HoverMatt SPU, HoverSling Repositioning Sheet and HoverSling Split-Leg. The compatibility testing was performed with both the Hill-Rom Sport 2 and the Stryker ISO Gel low air loss mattresses.
	Results of this testing, including Body Analog, Immersion, Microclimate (MVTR), Envelopment and Sliding Resistance, illustrate that the products have high evaporative properties and do not raise temperature levels. The combination of these important qualities help create the ideal microclimate between the patient and the product. They are fully compatible with low air loss surfaces and do not interfere with the efficacy of these types of mattresses.
✓ Particle Study	Gelbo Flex Tests were conducted by an independent laboratory in accordance with USFDA (21 CFR Part 58) regulations on three Single-Patient Use air-assisted lateral transfer devices to determine and compare the level of material particle shed (linting).
	The Single-Patient Use HoverMatt® Air Transfer System produced 96 particles ≥ 10 microns in size during testing. This is 81.9% fewer than Competitor 1’s comparative product, which produced 530 particles, and 94.6% fewer than Competitor 2’s product, which produced 1773 particles under the same testing conditions.

**The HoverMatt is MR conditional by rationale. The device is made from all non-ferrous materials. As a result, MR safety testing was not performed. Based on rationale, the HoverMatt is electronically non-conductive and non-magnetic. When using a HoverMatt in an MRI environment a 25 ft. specialty MRI hose is required, thus making these products MRI conditional. The HoverTech air supply and regular hose are conductive and magnetic and are MR Unsafe.*