HOVERTECH International

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TECHNICAL DOCUMENTATION SUMMARY

HOVERMATT® AIR TRANSFER SYSTEM

Considering An Air-Assisted Transfer System?

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

ALL HOVERMATTS	
√ Skin Integrity	An independent board certified ergonomist conducted pressure mapping studies of both reusable and Single-Patient Use (SPU) HoverMatts on patients of various sizes over extended durations.
	There was no significant difference between trials with and without the HoverMatt technology. Utilization of either the standard reusable HoverMatt or the SPU HoverMatt did not cause increased pressure at the patient/mat interface. It was also noted that pressure distributions over time for the Single-Patient Use HoverMatt were favorable to the standard HoverMatt, though not statistically significant.
√ 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.
	The HoverMatt products did not produce loss of signal, image distortion, or apparent artifacts associated with MRI performed at 3-Tesla.
√ 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 6 Mv and 18 Mv with a 10 cm x 10 cm sample area.
	Tests at 6 Mv measured .9974 and 18 Mv 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 150 lbs.
	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 200 lb. 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 mat, 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).
√ Micropel	Micropel® is an anti-microbial additive that is included in the construction of all reusable HoverMatts and is part of HoverTech's commitment to infection control.
	An ounce of polyurethane coating infused with Micropel is added to the inside of the nylon HoverMatt. A laminate layer of polyurethane is attached to this coating. If a patient is sweating or bleeding, the Micropel is drawn through the nylon to attack bacteria. If body fluids should somehow enter the inside of the HoverMatt, the Micropel will be drawn through the polyurethane laminate to attack the bacteria there. A list of all microorganisms controlled by Micropel is available from HoverTech.

SINGLE-PATIENT USE HOVERMATTS

√ 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.
√ Pressure Ulcer Prevention and Healing	A study randomized 26 long term care patients into 2 groups: those treated with a HoverMatt SPU 24/7 (intervention group), or those receiving usual care (control group). The patients were studied for 5 1/2 months.
	At the start of the study, there were 4 pre-existing pressure ulcers in the control group and one in the intervention group. Three of the four healed in the control group, and the only pre-existing ulcer healed in the intervention group. Of the five new pressure ulcers during the study, three were in the control group and two in the intervention group. None of the pressure ulcers healed in the control group, while both healed in the intervention group. These data suggest that leaving an uninflated SPU under patients full time does not increase the risk of pressure ulcers.[1]

Source

1 Deter L, Kiely D, White-Chu EF. A Descriptive View of the Impact of an Air-Assisted Device on Pressure Ulcer Prevention and Healing. *AM J SPHM*. December 2013; Vol. 3, No. 4, 138–143.