Technical documentation summary

HoverMatt Air Transfer System is multifunctional and makes patient transfers, boosting and repositioning easier, while taking care of the carers working environment.

All HoverMatts

Radiolucency

- Radiolucency studies were conducted in a clinical radiology environment testing 24 dierent anatomical views.
- No artifacts were found in any of the images.

Skin test

- Tests of irritation and delayed-type hypersensitivity according to the EN ISO 10993-10:2013. Biological evalution of medical devices.

Skin integrity

- 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 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 insignicant.

Flammability

- An independent laboratory conducted ammability 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.

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.

**The HoverMatt SPU is MRI safe by logic. The device is made from all non-metal materials. Product will not produce loss of signal, image disortion, or artifacts. image distortion, or artifacts.*

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/cm2) on the inside and outside surfaces. When the handler was not wearing gloves, the outside of the HoverMatt tested “very slightly positive” (1CFU/cm2), while the inside tested at less than the detection limit of the test (<1CFU/cm2).

Antimicrobial

- An antimicrobial additive 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 antimicrobial 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 antimicrobial is drawn through the nylon to attack bacteria. If body uids should somehow enter the inside of the HoverMatt, the antimicrobial will be drawn through the polyurethane laminate to attack the bacteria. A list of all microorganisms controlled by antimicrobial 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

Technical Studies Supporting 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.

Passed ignition test

- Testing of ignitability according to ISO 12952-1:2010 Textiles - Assessment of igniability of bedding items.
  Part 1: Ignition source: smouldering cigarette.
- Testing of ignitability according to EN 1021-1:2014,
  Furniture - Assessment of ignitability of upholstered furniture - Part 1: Ignition source smouldering cigarette.

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