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.

HoverMatt Single–Patient Use (SPU)

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 the HoverMatt SPU device 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 SPU. 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 SPU using a 200 lb. simulated load. Thermocouplers were located in the head, back, and buttock of the simulated patient.
- When the HoverMatt SPU was used on top of either a Maxitherm Lite or a Gelli-Roll, the temperature drop across the HoverMatt SPU 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 SPU.
- The product passed flammability testing.

MRI Compatibility

- 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.

HoverMatt Single–Patient Use

Particle Study

- Gelbo Flex Tests were conducted by an independent laboratory in accordance with USFDA (21 CFR Part 58) regulations on the Single-Patient Use air-assisted lateral transfer device 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. 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 product 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. It is 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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