A pneumatic compression device for daily home treatment of chronic venous ulcers and lymphedema

The ACTitouch system, a segmented pneumatic compression device with gradient compression, provides effective, daily at-home treatment of chronic venous ulcers and lymphedema. Designed to mimic the action of the calf muscle pump through application of optimal gradient pressures, the ACTitouch system has been shown to heal chronic venous leg ulcers and reduce lower extremity edema.

ACTITOUCH COMPONENTS

Control Unit (E0651)
The control unit is a compact, portable sequential pneumatic device which is inserted directly into the compression sleeve, allowing it to be worn under the pant leg for ease of use in any environment.
• Microprocessors continuously measure and precisely adjust the delivery of pneumatic compression so that preset gradient pressures are continuously applied, regardless of fluctuation in edema, alleviating concerns of over- or under-compression.
• Pressure profiles are based on clinical research findings, balancing pressure application with patient tolerance. For optimal patient outcomes, the ACTitouch system applies intermittent pneumatic compression of 50 mmHg at the foot and ankle, 45 mmHg mid calf, and 40 mmHg upper calf.
• Small, lightweight and quiet, the device can be worn comfortably and discreetly under the pant leg and with the patient’s own shoes, allowing for ease of use at home or work and enhancing compliance.
• In addition to intermittent pneumatic compression, the control unit can also apply precise sustained gradient compression for a complete daily compression solution.

Included with the Control Unit:
• AC/DC power adaptor/charger used to power the device directly during intermittent pneumatic compression (IPC) mode or to recharge the battery for ambulatory use.
• Undersocks (3-pack) – The under sock is designed to draw perspiration and moisture away from the skin and has padding in key areas to provide additional comfort during compression.

Calf-Foot Garment (E0669)
The garment consists of a four-chamber compression sleeve that inflates to apply preset gradient pressure to foot, ankle and lower leg. Simple wrap-around design with hook and loop fasteners:
• can be fitted to a variety of leg shapes
• allows for easy application and removal for bathing, sleeping and wound dressing changes

PRODUCT SPECIFICATIONS

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<tr>
<th>FDA Status</th>
<th>Cleared to market (Class II in March 2008)</th>
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<tbody>
<tr>
<td>Controller Unit</td>
<td>Weight: 0.49 lbs, Dimensions: 7.4” x 2.7” x 1.3”</td>
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<tr>
<td>Garment Fabric</td>
<td>Outer fabric nylon, mattress material is polyurethane (No Latex)</td>
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<tr>
<td>Sock Fabric</td>
<td>35% Polyester, 35% Cotton, 28% Nylon, 2% Elastane</td>
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