



Intelli-Flo® Technology

A brief overview

Background

Motorized cold therapy devices deliver a continuous flow of ice water from an insulated fluid reservoir through pads that are applied to a patient's postoperative site. Pad temperature in most portable motorized cold therapy devices is controlled by the rate of water flow through the pad. With the exception of the BREG Kodiak, most motorized cold therapy devices either allow the user to adjust the flow to accommodate the physician's recommended temperature range, or the device flows at a predetermined flow rate. For devices that allow the user to control the temperature, there is a risk that the patient will not receive instructions from their medical professional regarding the proper temperature range, and even if the patient receives the proper instruction, he or she may not follow the prescribed treatment protocol. A patient who uses the unit for extended periods of time at temperatures below their practitioner's recommendation (typically in the range of 45°F - 55°F for a patient without risk factors) may be at risk of a cold induced skin injury. Skin injury can range from minor to severe damage. For devices set at a pre-determined flow rate, the device does not take into account variables such as the varying amounts of heat transfer given out by different body parts. (Example: A shoulder has more heat transfer than an ankle.)

Design

Pad surface temperature characteristics are the result of pad design, heat transfer, type of flow restriction, and pad surface area. Each Intelli-Flo Pad is designed with a unique flow restrictor built inside the pad, and is designed according to each individual body part's unique characteristics. The flow restriction is designed in such a manner as to keep the temperature range generally within 45°F - 55°F (50°F - 60°F for extremities). Acceptable extended cold therapy application temperature has been determined through review of medical literature and medical consult to be safe and effective when the patient contact temperature is generally not colder than 45°F (50°F for extremities). One critical factor in using most, if not all, cold therapy units is the application of an insulation barrier between the pad and skin. Intelli-Flo Pad surface temperatures when applied to a patient and used with an insulation barrier meet such criteria. (See the Intelli-Flo Pad Instructions for Use for more detail on appropriate barriers.)

The temperature range for each Intelli-Flo pad is generally as follows:

Intelli-Flo Pad	Temp. Range (°F)
Ankle	50° - 60°
Ankle Small	50° - 60°
Back	45° - 55°
Hand/Wrist	50° - 60°
Knee	45° - 55°
Multi-Use	45° - 55°
Shoulder	45° - 55°
Shoulder XL	45° - 55°

Testing

In determining proper Intelli-Flo Pad surface temperatures, average heat transfer from patients was analyzed by collecting human patient data for each pad design. Human patient data was recorded on 10 human volunteers per pad design to characterize heat transfer between each pad and human skin. This heat transfer was then simulated in an environmental chamber by adjusting the temperature and humidity of the chamber accordingly. Intelli-Flo Pad surface temperatures (with an insulation barrier) were directly measured by a thermal imaging system mounted inside an environmental chamber, and appropriate flow rates for each type of pad were established to meet the acceptance criteria. Because this study did not test applications mixing joint specific pads on other joints (for example, using a knee pad on a foot) the product labeling warns against such unintended use. Also described in the product labeling, the Multi-Use Pad is intended to be used on knees, backs, hips, and shoulders only.

Conclusion

Intelli-Flo Pads incorporate a unique form of flow control specific to the body part, which is an exclusive BREG technology. Intelli-Flo Pads customize the temperature to each body part, and as a result, increase patient comfort and compliance during use. All pads must still be used with an appropriate barrier between the pad and skin, and all risk factors, contra-indications, and precautions, such as checking the skin, must be followed to ensure safe usage of Intelli-Flo Pads and all other Polar Care products.