

Brain Cooling FAQ

Q - Why would we want to cool the brain?

A - Cooling the brain will help to achieve therapeutic hypothermia, which is one of the most potent interventions for hypoxic-ischemic brain injury.

Q - Why start cooling in the pre-hospital setting?

A - Pre-hospital treatment has unique benefits over exclusively in-hospital cooling. Induction of therapeutic hypothermia immediately after return of spontaneous circulation (ROSC) can be crucial to patient survival. According to the American Heart Association Guidelines 2010, "Hypothermia should be initiated as soon as possible after return of spontaneous circulation with a target temperature of 32°C-34°C."

Q - What is hypoxic-ischemic brain injury?

A - This term covers a broad constellation of conditions that deprive tissue of oxygen (hypoxia) and/or blood (ischemia) -- this term includes TBI, cardiac arrest and stroke.

Q - What is mild therapeutic hypothermia?

A - Mild therapeutic hypothermia is a medical treatment that lowers a patient's body temperature to 32°C - 34°C in order to help reduce the risk of the ischemic injury following a period of insufficient blood flow. Major medical societies recommend temperature management as the standard of care therapy for many critically ill or surgical patients, including those suffering acute hypoxic-ischemic injuries.

Q - How does therapeutic hypothermia help to remedy hypoxic-ischemic brain injury?

A - Therapeutic hypothermia appears to limit tissue damage by reducing oxygen metabolism and inflammation, while maintaining cell membrane integrity.

Q - We have used whole body cooling to achieve therapeutic hypothermia in the past. What differentiates this solution?

A - Most current applications use whole body cooling, which has numerous drawbacks, including coagulation abnormalities and impaired immune function. Existing solutions also may easily miss the

treatment window because they are not practical in the pre-hospital setting. Our system remedies these shortcomings, enabling ultra-early delivery of moderate cranial hypothermia while maintaining a higher core temperature to avoid the physiological side effects of systemic hypothermia.

Q – Can brain cooling be used for other demyelinating afflictions, such as MS, chronic brain injury, or sub-concussive brain injury?

A - Traumatic brain injury, multiple sclerosis and many neurological disorders damage or destroy myelin, the insulating layer that protects nerve fibers, called axons. This results in disruption of nerve impulses throughout the nervous system and can manifest in a diverse constellation of symptoms ranging from paralysis and insensitivity to seizures and hypersensitivity. Studies have shown that demyelinated axons are sensitive to changes in temperatures, and that cooling can both improve signal conduction (by increasing nerve signal amplitude and safety factor) and induce remyelination (by redistributing sodium channels and activating oligodendrocytes, which repair myelin). Thus, cooling can improve symptoms in the near-term and, as part of a long-term treatment regimen, can help reverse the underlying damage.

Q – Why not just use ice or gel packs?

A - Ice is difficult to apply consistently to the head, and because of the cervical collar ice cannot be effectively applied to this important area. As ice begins to melt the interface to the head is water, which provides poor heat transfer because of the temperature gradient between stagnant water at the contact area and the ice.

Gel Packs create an insulating front between the non-frozen and frozen elements of the pack, resulting in the same poor heat transfer that you get from ice. Also, initially gels are too cold at the contact area causing vasoconstriction (the body insulating itself from dangerously cold contact) and even skin damage.

Our system is applied to the patient concurrently with the cervical collar (it is integrated with it) and provides much broader and consistent cooling throughout the cranium and neck, including the carotid arteries. The Head-Neck cooling device uses air counter-pressure to significantly increase intimate contact with the head and neck and therefore it

rapidly cools the brain.

Additionally, both ice and gel packs have a relatively short time of usage while our technology provides four hours or more of consistent cooling and less than one minute to change-out the cooling cartridge.

Q – How easy is this device to apply? Can a non-medical professional apply it on a patient?

A – This technology is very easy to apply, and with minimal instruction, any non-medical professional should be able to use it. The EMT System was designed to be easy to operate. Deploying a headliner is fast and only one button is pressed to turn on the system and start cooling.

Q – Has the FDA cleared the EMT/ICU Systems?

A – Yes, with the following indications for use:

The WElkins EMT Temperature Management System is a thermal regulating system, indicated for temperature reduction in patients where clinically indicated.

The WElkins ICU Temperature Management System is a thermal regulating system, indicated for temperature reduction in patients where clinically indicated and monitoring of patient temperature.

Q – Are there any contraindications for this technology?

A – There are no known contraindications for the use of a temperature reduction system. That said, caution should be exercised when using the System with any patient who has a history of skin allergies or sensitivities, or on skin that has signs of ulceration, burns, hives or rash. Users should periodically examine the patient's skin under the cooling pads, especially for those at higher risk of skin injury.

Q – Is this technology MRI/CT Compatible?

A – Yes