



Temperature Management White Paper

An All-In-One Platform for Core and Surface-based Temperature Management

Abstract

The use of the Thermogard Temperature Management System has been well-established in providing core cooling via catheter-based temperature management in various applications. More recently, the FDA has cleared the Thermogard Temperature Management System to provide surface-based temperature reduction in adult patients where clinically indicated, e.g., in hyperthermic patients. This whitepaper describes the all-in-one treatment capabilities of the upgraded Thermogard System.

System description

The Thermogard System includes a console that has full temperature management capabilities (cooling and warming) and is compatible for both core (intravascular) and surface usage using the respective Start-Up Kits and components. This versatility allows for the device to be used interchangeably, which means that temperature management can be initiated with one method and then exchanged with the other. The heat transfer medium used for both intravascular and surface components is a solution of propylene glycol (PG), which has been well-established as an antibacterial and antifungal agent in both hospital and household environments. This property allows for an effective heat transfer medium as well as ease of maintenance, since the PG only needs to be drained and replaced during an annual preventative maintenance cycle, and no additional disinfectants are required. The PG is contained within the console and does not contact the patient through any direct or airborne pathways.

The core cooling function of the Thermogard System has been described in many previous publications, and the Thermogard Surface components include the same console as described above as well as a Surface Start-Up Kit and the STx™ Vest. The Surface Start-Up Kit includes a reservoir bag which can be filled with tap or sterile water. Water is then circulated throughout the circuit (Start-Up Kit + STx Vest) while being cooled by the console. The STx Vest is secured around the patient's midsection and maintains direct contact with the patient's skin effectively without the use of adhesives or gel. Upon completion, the Start-Up Kit and STx Vest can be discarded without the need for draining or purging, which other water-circulating blankets or surface pads may require.

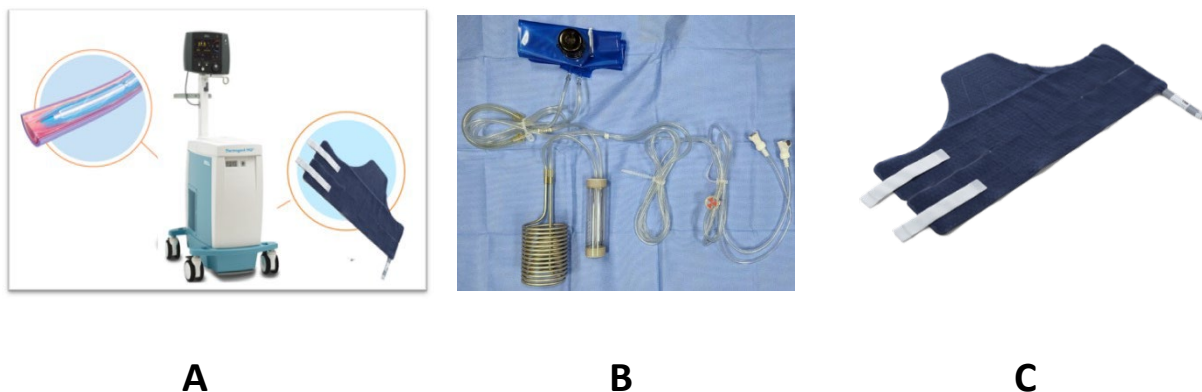


Figure 1. Components for Thermogard Surface temperature management. A: Thermogard console (model HQ pictured) with both intravascular and surface temperature management capabilities. B: Thermogard Surface Start-Up Kit. C: STx Vest.

Summary of initial clinical experience with Thermogard Surface cooling

An initial cohort of five patient cases was conducted in Latin America and Asia using Thermogard Surface temperature management for subarachnoid hemorrhage (SAH), sepsis, and other neuro applications. Of note, the percentage of time within $\pm 0.5^{\circ}\text{C}$ of the target temperature was 90%, and all five cases exhibited good performance as noted by the clinical staff. In addition, shivering was not observed in any of the five initial patient cases, and the duration of vest usage was up to 251 hours (11 days). No skin injuries were observed over the treatment duration.

Two examples from the initial patient cohort are provided below, along with pertinent patient history and device performance details.

Case #1:

Location: Chile

Patient history overview: 100 kg patient, treated for SAH, patient refractory to antipyretics; patient temperature prior to treatment was spiking to 39°C . Thermogard Surface temperature management was used for 3.3 days.

Device performance: Achieved target temperature of 36.5°C and patient temperature was maintained within $\pm 0.5^{\circ}\text{C}$ 95% of the time.

Clinician feedback: No shivering or skin injuries were reported. Clinicians commented regarding ease of equipment set up and maintenance, and that therapy was well-tolerated by the patient.

Temperature graph: Solid black line represents patient temperature; solid blue line represents target temperature. Regions shaded in light grey indicate the system was in standby.

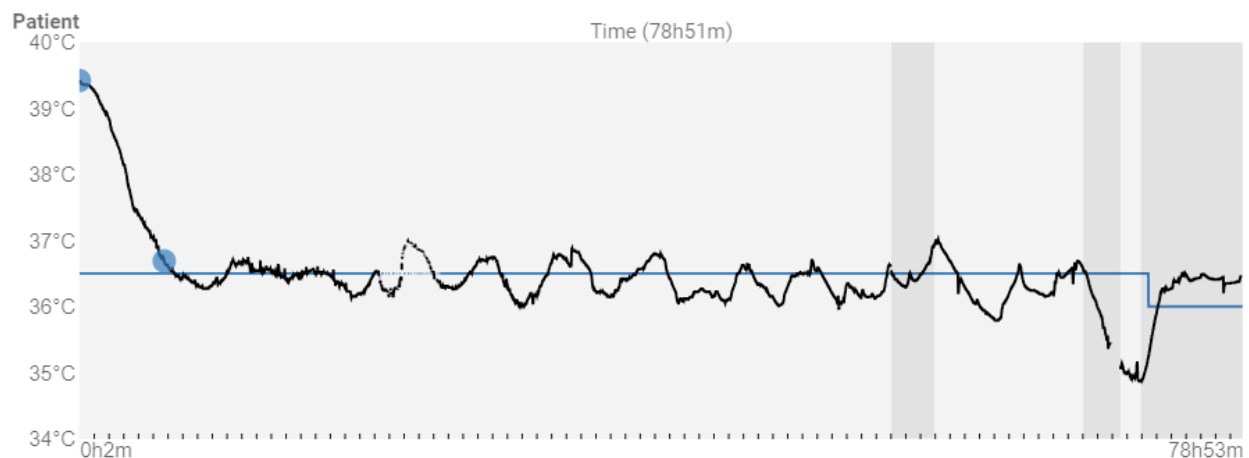


Figure 2. Temperature graph for Case #1, Chile.

Case #2:

Location: Chile

Patient history overview: 55 kg patient, atypical meningioma resected; presented with intracranial hypertension that required double decompressive craniectomy. Thermogard intravascular temperature management (IVTM) was used for 3.5 days, and then fever presented after the catheter was removed. Thermogard Surface temperature management was then initiated and maintained for an additional 6 days (patient's initial temperature prior to vest placement was 37.7°C).

Device performance: Device maintained target temperature within $\pm 0.5^{\circ}\text{C}$ 95% of the time (IVTM 99%, Surface 91%).

Clinician feedback: No shivering or skin injuries were reported. Also, no complications were noted pertaining to transition from IVTM to surface temperature management.

Temperature graph: Solid black line represents patient temperature; solid blue line represents target temperature. Regions shaded in dark grey indicate the system was off. Regions shaded in light grey indicate the system was in standby.

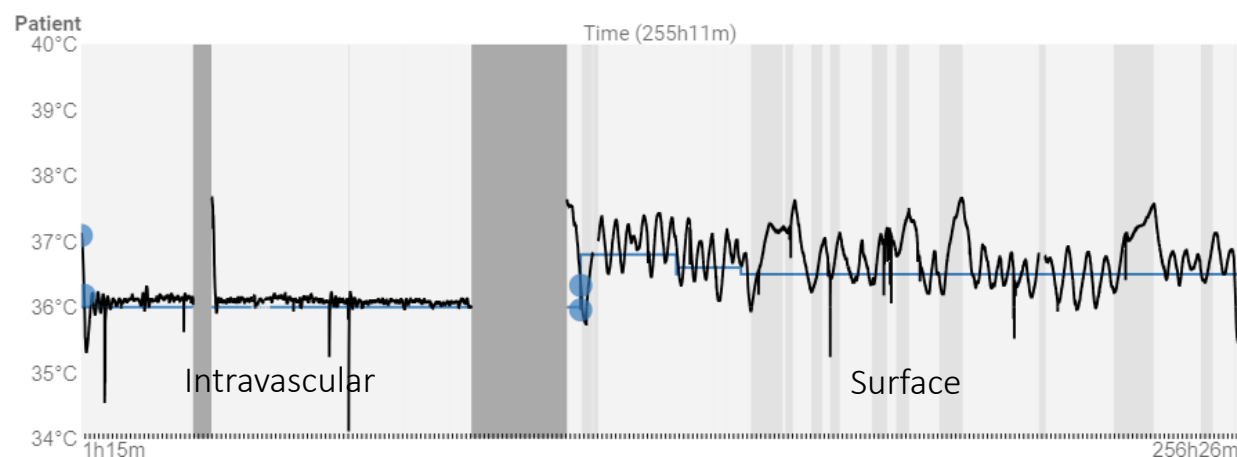


Figure 3. Temperature graph for Case #2, Chile.

Protocol examples

From the standpoint of temperature management, many hospitals have documented and used well-established protocols for patient treatment. With the ability to integrate both intravascular and surface temperature management using the same system, existing protocols can now be enhanced and treatments more easily managed. The Thermogard System now allows for more protocol therapy options, all while using the same console. Figure 4 provides an example of a potential fever protocol, while Figure 5 shows an example of a targeted temperature management (TTM) protocol that can be used to effectively manage treatment using a single system.

Sample Fever Protocol

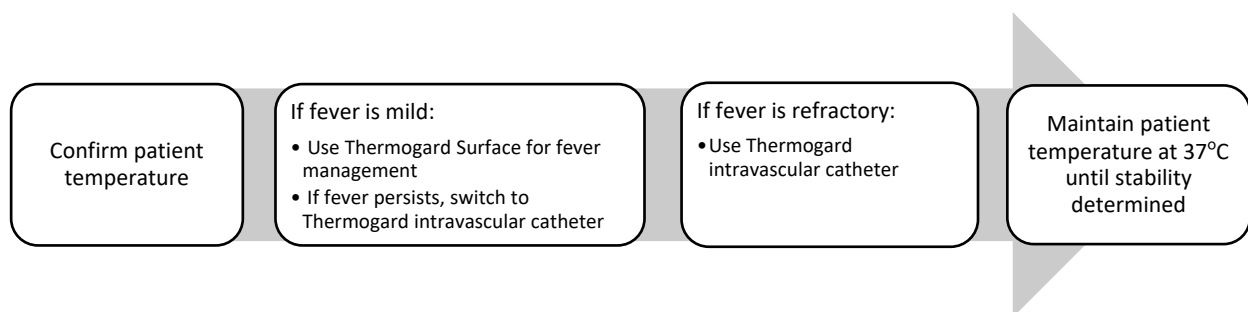


Figure 4. Sample fever protocol utilizing both intravascular and surface temperature management capabilities of the Thermogard system.

Sample TTM Protocol

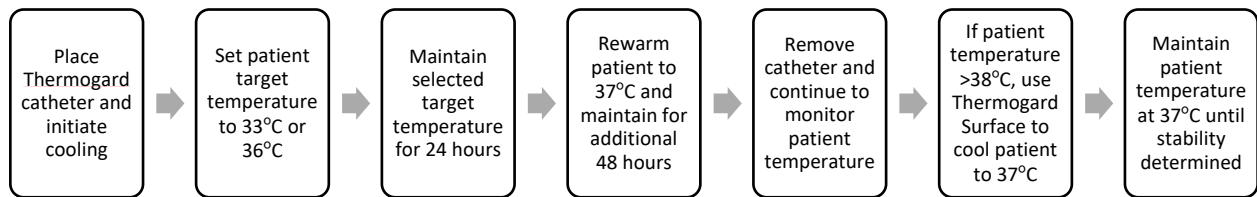


Figure 5. Sample TTM protocol utilizing both intravascular and surface temperature management capabilities of the Thermogard system.

Conclusion

The Thermogard System now has the unique capability of offering both intravascular and surface temperature management within a single machine. An initial patient cohort showed that the Thermogard Surface temperature management can be conducted for fever management effectively, with both intravascular and surface cooling methods showing the ability to maintain target temperature within $\pm 0.5^{\circ}\text{C}$ throughout the duration of treatment. This new treatment approach allows for a wide variety of applications where cooling and maintaining a patient's temperature at normothermia is desired, all while using a single, multifunctional platform offering high-quality patient care.