

RAPID Response to questions from readers

Convective Warming Systems— Maintaining Normothermia in the Operating Room

by Jesús A. Cabrera, MD, PhD

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IN RESPONSE:

Thank you for engaging with Smiths Medical regarding our Level 1® Equator® Convective Warming Device and Level 1 Snuggle Warm® Convective Warming Blanket. We received the report of two patients who experienced burn injuries during robotic prostatectomy surgery. Fortunately, the injuries resolved with conservative treatment and did not result in permanent injury. At Smiths Medical, our top priorities are always quality and patient safety, and this report provides an opportunity to partner with our customers and the patient safety community to investigate the potential causes.

Smiths Medical follows standard procedures to investigate product complaints and patient safety concerns. In accordance with these procedures, we requested the products in question to be returned for evaluation. The two returned devices were thoroughly tested and found to perform within specifications. The alarm systems were also assessed and found to be functioning within specifications.

As part of our procedure, we also reviewed our Periodic Safety Update Report (PSUR), which includes available post-market data for the previous five years regarding the safety and performance of the marketed products. The products in question have been in use globally for more than 10 years, and in the past five years, Smiths Medical sold more than 40 million blankets. The PSUR review did not identify any recurrent patient safety issues that would suggest a need to modify the risk/benefit concerns and the product was determined to be acceptable for manufacture, sale, and distribution. The PSUR is an ongoing regularly scheduled safety assessment.

Following the assessment that the two devices were performing within specifications by Smiths Medical Service and Repair personnel, we were asked to opine upon these cases and offer suggestions to anesthesia professionals regarding safe use of convection warming devices. In reviewing Janik et al.'s manuscript, it is reassuring that his department has posi-

tive and successful experiences with these devices for greater than a decade. Furthermore, our sales representative had the privilege of interacting with the clinical team at NorthShore. Based on the report and our discussion with the clinical team we would offer the following commentary.

First, I am in complete agreement with Janik's statement that thermal injuries are rare when manufacturer's instructions are followed. In the Equator's Operating Manual, the section named "Important Safety Information" includes a warning stating that "The hose nozzle **MUST** be connected to a Snuggle Warm convective warming blanket. Do not treat patients with the hose alone. Thermal injury may occur." In the section named "Operating Instructions," Step 4 illustrates the attachment of the hose nozzle to the convective warming blanket.¹ (Figure 1)

Smiths Medical also published a document entitled "Equator Convective Warming System Step-by-Step Guide."² This guide also illus-

trates the proper connection of the hose nozzle into the collar ring of the blanket.

Janik et al. notes the hose nozzle (air manifold) was missing on one device and that the hose was directly connected to the blanket. As noted, this manifold is designed to ensure a proper connection of the hose to the blanket and distribute the air evenly. For clarification, it is not designed to cool the warmed air, as suggested by Janik and Lewandowski.

Another consideration is the potential patient safety implications associated with robotic prostatectomy. A number of concerns for robotic-assisted prostatectomy have been reviewed in the anesthetic literature. Danic et al.³ and Gainsburg⁴ both described the complications that can arise associated with the extreme lithotomy and steep Trendelenberg positioning common in this procedure. For example, they both note the potential for nerve injuries. Maintaining normothermia is an important goal of anesthetic care facilitated with the
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Step 4: Attach the Hose to Convective Warming Blanket

WARNING

The hose nozzle **MUST** be connected to a Snuggle Warm® convective warming blanket. Do not treat patients with the hose alone. Thermal injury may occur.

- 1 Insert the hose nozzle (a) into the collar ring (b).
- 2 Ensure the hose barb (c) snaps into the collar ring (b).
- 3 If the hose has locking tabs (d), secure the hose to the convective warming blanket using the hose retainer wings (e). The hose tabs will protrude through the retainer wings (e).

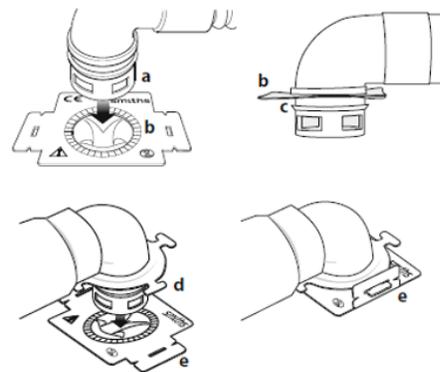


Figure 1: Instructions for Hose Nozzle Connection into the Collar Ring of the Blanket from the Operators Manual—Equator Convective Warmer (page 14).

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use of a convection warmer. This report raises the question that thermal injury may be another potential complication associated with robotic prostatectomy. Secure placement of the hose nozzle is important to the safe use of this product and may be difficult in this procedure. Furthermore, tucking the warming blanket to the patient’s sides has the potential to restrict airflow. If the nozzle is not well secured to the blanket as designed, and the flow into the blanket restricted, one could imagine a jet of hot air continuously projected upon the skin surface for a length of time sufficient to cause a burn injury, as described in the Warnings of the Operator’s Manual.

The clinical team at NorthShore University HealthSystem graciously invited our sales representatives into their facility. In the conversations between the clinical team and Smiths Medical, it was found that there were hose nozzles that were missing on a number of devices and replacements have been delivered to that institution.

We are proud that the Level 1 Equator Convective Warming Systems have a long history of safe and effective use for more than 10 years in operating theaters around the globe. I believe the complaints presented here illustrate important learning points. The hose nozzle is a critical part designed to assure a good connection between hose and blanket to safely deliver warming therapy to patients. This report is a reminder to inspect and evaluate the Equators within operating theaters to assure hose nozzles are present and used as described in the Operating Manual. Also, patient positioning can make it difficult to use devices as intended and in accord with recommended operating procedures. As described in the user’s manual, the highest setting of output temperature should only be used when rapid correction of hypothermia is essential and then only for as long as necessary.

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2. Smiths Medical Level 1 Equator Convective Warming System: Step-by-Step Guide.
3. Danic MJ, Chow M, Alexander F, et al. Anesthesia considerations for robotic-assisted laparoscopic prostatectomy: a review of 1,500 cases. *J Robotic Surg.* 2007;1:119–123.
4. Gainsburg DM. Anesthetic concerns for robotic-assisted laparoscopic radical prostatectomy. *Minerva Anesthesiol.* 2012;78:596–604.