Performance and Filtration:
Two Key Considerations in Convective Patient Warming System Selection

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Introduction

MAINTAINING NORMOTHERMIA IS CRITICAL FOR OPTIMIZING SURGICAL OUTCOMES

In a surgical setting, inadvertent perioperative hypothermia (core temperature <36°C) can dramatically increase the risk for surgical complications. Patients who become hypothermic are at increased risk for:[1-4]

- Adverse myocardial outcomes
- Surgical site infections
- Increased blood loss
- Impaired wound healing
- Prolonged recovery and hospitalization time
- Increased transfusion requirements

Active warming is needed to counteract the negative effects of anesthesia on resting core body temperature[5] and convective warming technology continues to be the standard of care.

CONSIDERATIONS WHEN SELECTING THE RIGHT CONVECTIVE AIR WARMING SYSTEM FOR YOUR PRACTICE

When selecting a convective air warming system, clinicians are faced with two important considerations:

1. Warming Performance: Does the device provide the required warming environment to maintain normothermia of a patient under general anesthesia?
2. Air Filtration: Does the device filter the air it recirculates in the operating room?

A ROBUST SOLUTION: THE KOZEE CONVECTIVE WARMING SYSTEM

The KoZee Convective Warming System provides clinicians with a robust solution with both superior warming performance and air filtration.

1. Warming Performance: The KoZee System creates a warmer microclimate when compared to a leading competitor.[6] This is achieved through:
    a. A high-performance air heater supplying warm air into the blanket.
    b. The blanket's diffused airflow design more efficiently retains warm air under the blanket, keeping the patient warmer. This contrasts with the forced air design of the leading competitor's blankets, which exhaust more waste heat into the operating room where it warms the surgical staff as well as the patient.
2. Air Filtration: The KoZee System provides redundant air filtration when it recirculates air in the operating room. This is achieved through:
    a. A High Efficiency Particulate Air (HEPA) filter at the device air inlet provides strong filtration of microbiological contamination, following ASHRAE standards and guidance for operating room ventilation systems as a best practice.[7]
    b. The KoZee blanket's proprietary diffused airflow design which provides an additional layer of filtration of airborne contaminants such as bacteria and viruses, far exceeding that of the leading competitor's blanket's forced air system.[8]

The following sections will explore each consideration in greater detail.

> **The microclimate is the physical space between the patient and the blanket that is critical to transferring heat energy to the patient.**

Warming Performance: Creating a Warmer Microclimate with the KoZee System

WHAT IS A MICROCLIMATE AND WHY IS THE BLANKET IMPORTANT?

When an air blanket is properly positioned on the patient, the space between the blanket and the patient's body forms a microclimate (Figure 1). When the patient warming system is activated, warm air is forced through the blanket filling the microclimate, transfering heat to the patient.

Given an operating room (OR) is typically cool, creating a warm microclimate around a patient will shield them from the effects of exposure to a cold OR environment, helping to keep the patient normothermic. Thus, the blanket design has two critical functions:

- Create a microclimate around the patient by isolating them from the surrounding OR environment (Figure 1).
- Distribute warm air from the patient warming system into the microclimate.

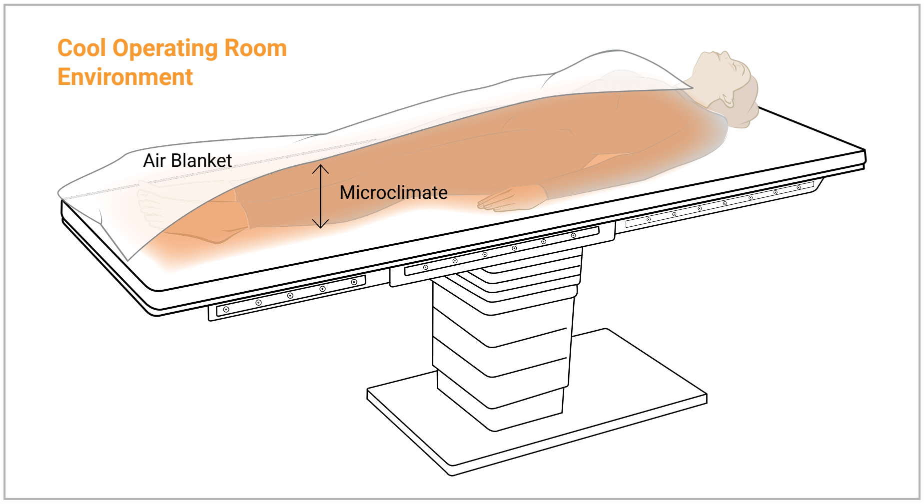

Figure 1: The microclimate created between a patient and a KoZee air blanket

BEWARE OF DECEPTIVE HEAT MAPS

In a convective air warming system, patients are warmed by convective heat transfer from the warm air in the microclimate. This is an important detail to distinguish because air blanket contact surface temperature heat maps are often misrepresented to demonstrate convective air heat transfer to the patient. However, these contact surface temperature heat maps only measure conductive heat transfer from the blanket surface. The intended purpose of these maps is to demonstrate blanket safety as required by medical device standards, not heat transfer to the patient.[9]

Heat Transfer Consideration	Convective Air Warming Systems Warm a Patient Through:	Contact Surface Temperature Heat Maps Measure:
Mechanism	Convection	Conduction
Medium	Warm air in the microclimate	Contact with blanket surface

THE EFFECT OF A WARM MICROCLIMATE ON PERIPHERAL TISSUE HEAT LOSS AND HEAT REDISTRIBUTION

According to Dr. Daniel Sessler, a leading anesthesiologist and key opinion leader in patient warming, heat redistribution from the patient's core to peripheral tissue is the primary cause of hypothermia for anesthetized patients, accounting for 81% of heat loss during the first hour after administration.[10] Sessler further explains that this redistribution is a result of heat loss across the temperature gradient from the warmer core to the cooler vasodilated peripheral tissue (Figure 2, Top).[10, 11] To counteract this, the proprietary design of the KoZee System increases the temperature within the microclimate, thereby increasing total heat content of the patient and warming the peripheral tissue. By keeping the peripheral tissue warmer, the temperature gradient between the core and the peripheral tissue is reduced. This minimizes heat redistribution from the core to the peripheral tissue and supports maintaining the patient's normothermic core temperature[12] (Figure 2, Bottom).

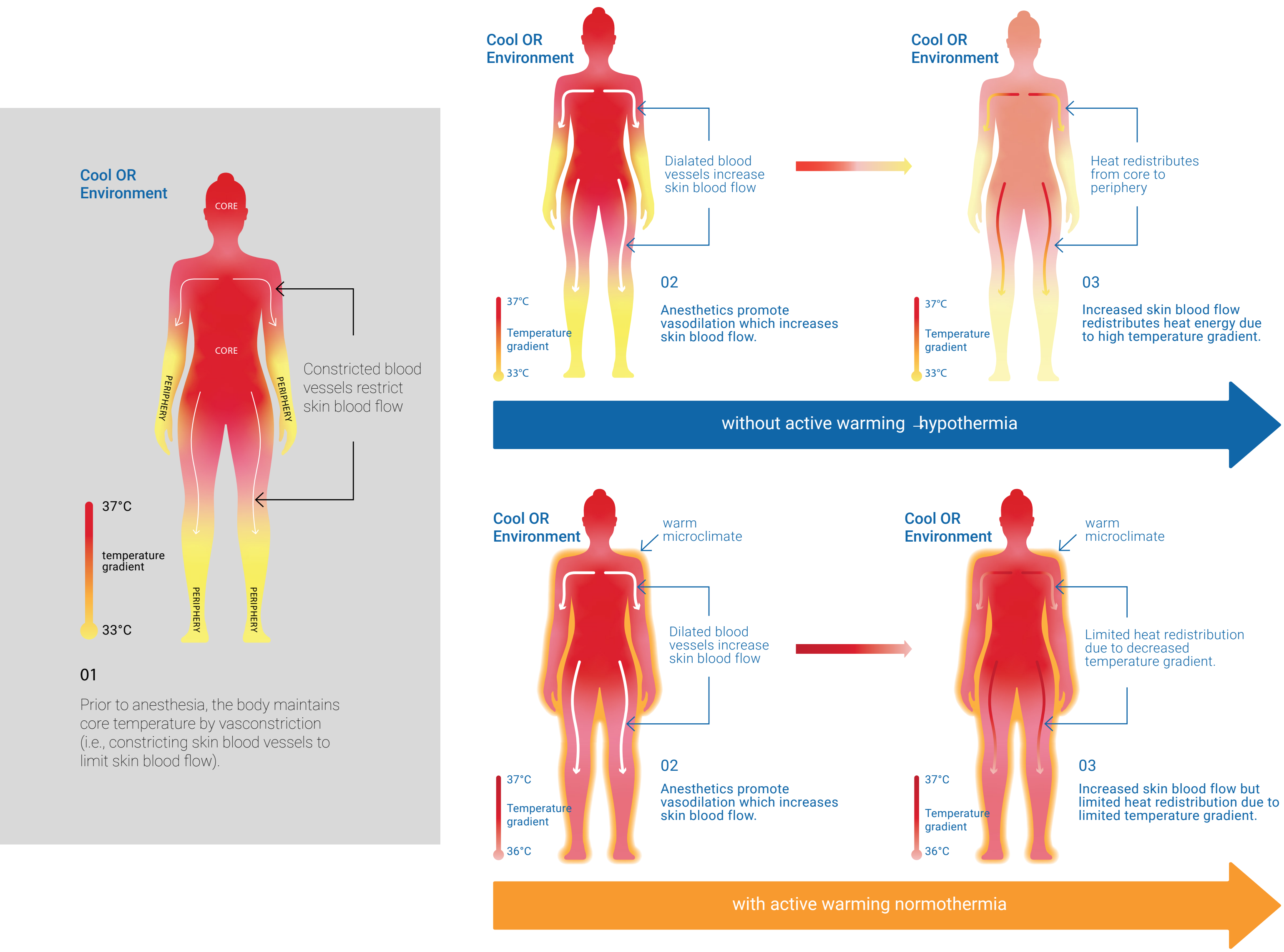

Figure 2: Left (prior to anesthesia): Under normal physiological conditions, the body maintains a normothermic core temperature in cool environmental conditions. This is achieved by controlling blood flow through vasodilation of skin blood vessels in the peripheral tissue; Top Right (under anesthesia without active warming): Cooler peripheral tissue causes a large temperature gradient with the warmer core. This increases heat frow from the core to the periphery (i.e., increases redistribution), thereby causing hypothermia; Bottom Right (under anesthesia with active warming of the microclimate): A warm microclimate warms the peripheral tissue, reducing the temperature gradient between the core and peripheral tissue. This reduces heat frow from the core (i.e., reduces redistribution), thereby supporting normothermia.

MICROCLIMATE TEMPERATURE COMPARISON STUDY

The data in Figure 3 compares the microclimate temperature produced by the KoZee System to a leading competitor in a simulated OR environment and workflow.6 The air blankets were set up over a patient model and the temperature of the microclimate was measured. In this workflow, three distinct phases of interest were observed in the microclimate.

1. Patient Prep: The patient is sedated and the air blanket and a cotton linen are placed on the patient while the unit is still off. During this time, the microclimate equilibrates between the patient's heat energy production and the OR's ambient environmental conditions.
2. Initial Warming: When the procedure begins, the air warming unit is turned on causing a rapid rise in the microclimate temperature.
3. Warmed Microclimate: Finally, the microclimate equilibrates with the added heat energy from the patient warming system.

Full Body Blankets

Blanket Model: M21004

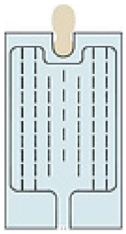

Figure 3: Patient microclimate temperature data during simulated operating room use case. Both systems were tested with adult full body blankets covered with a cotton linen. Data presented are mean ± standard deviation (error bars) across multiple trials (n=6).

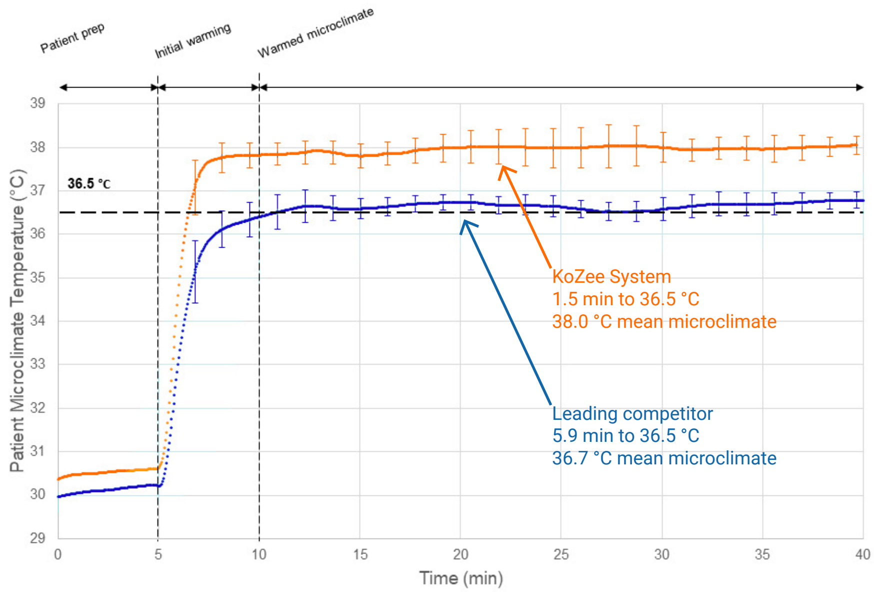

Figure 3 shows that the KoZee System used with adult full body blankets generated a significantly warmer microclimate than the leading competitor (99% CI, 1.30-1.32 °C; $p < 0.001$) and also heated the microclimate to the optimal temperature faster. Achieving a warmer microclimate in a shorter time frame is clinically important to quickly resist the momentum of redistribution which acts to continuously decrease the core temperature.[13]

Full Body Blankets

M21004 without a cotton linen

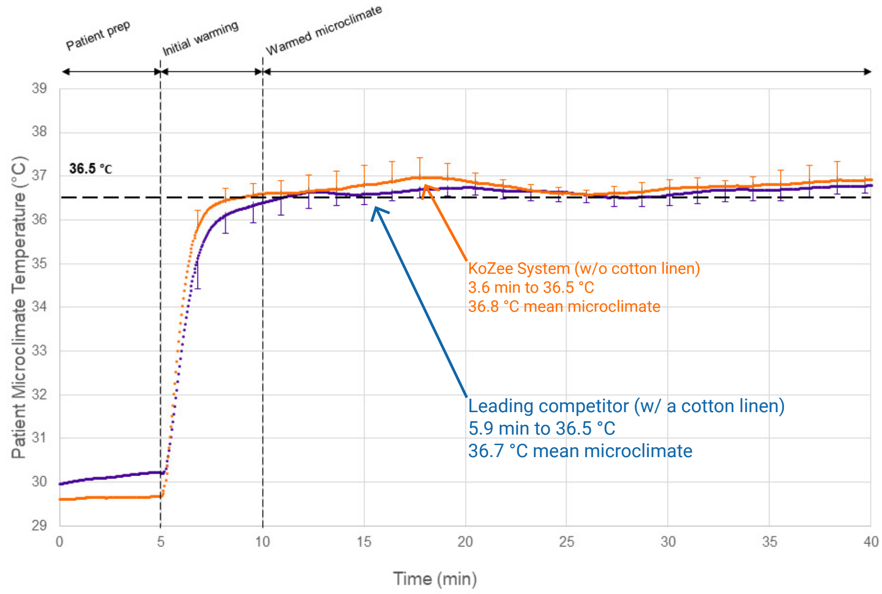

Figure 4: Patient microclimate temperature data during simulated operating room use case. Both systems were tested with adult full body blankets. The leading competitor's blankets were covered with a cotton linen but the KoZee blankets were tested without the cotton linen. Data presented are mean ± standard deviation (error bars) across multiple trials (n=6). For clarity, only upper and lower error bars are only shown for KoZee System (without cotton linen) and leading competitor system, respectively.

The KoZee System with adult full body blankets was further challenged by repeating the previous test but without using a cotton linen. The test results are provided in Figure 4, showing that the KoZee System, when used without a cotton linen, also generates a significantly warmer microclimate in less time than the leading competitor blankets with a cotton linen (99% CI, 0.11-0.13 °C; $p < 0.001$). Given the leading competitor blankets often require a cotton linen to prevent them from floating off the patient, these results show that the KoZee blankets can decrease cost and waste, simplify workflows, and provide superior performance.

Table 1: Summarized patient microclimate test results comparing the KoZee System to the leading competitor with full, upper, and lower body blankets. The KoZee System was superior with all blanket types in mean patient microclimate temperature as well as speed to reach the optimal patient microclimate temperature. Additionally, the KoZee System, when used without a cotton linen, provided superior performance to the leading competitor (which often requires use of a cotton blanket to prevent floating off the patient).

Blanket Type	KoZee Advantage (with cotton linen)	KoZee Advantage (without cotton linen)
Adult Fully Body Model: M21004	1.3 °C warmer patient microclimate 3.9 times faster to optimal temperature	0.1 °C warmer patient microclimate 1.6 times faster to optimal temperature
Lower Body Model: M21002	1.3 °C warmer patient microclimate 2.9 times faster to optimal temperature	0.2 °C warmer patient microclimate 1.3 times faster to optimal temperature
Upper Body Model: M21003	1.7 °C warmer patient microclimate 2.6 times faster to optimal temperature	0.3 °C warmer patient microclimate 1.2 times faster to optimal temperature

Testing was repeated for upper and lower body blankets with similar results. All test results are summarized in Table 1 (additional plots are provided in the appendix). These results suggest that the superior performance extends across the entire KoZee blanket portfolio.[6] Creating a warmer microclimate temperature is important for overcoming the combination of factors drawing heat energy from the patient, such as prolonged exposure during patient prep, patient positioning, procedure length and cold OR temperatures. Getting to the optimal microclimate temperature faster helps counteract the patient's thermal inertia to continue to redistribute heat to the peripheral tissue which, according to published clinical data, causes the fastest decrease in their core temperature within the first hour after administering the anesthetic.[11]

THE DIFFUSED AIRFLOW DIFFERENCE

The KoZee System's superior warming performance compared to the leading competitor is the result of the system's proprietary diffused airflow design. The diffused airflow design flows warm air through a nanoporous fabric, which reduces the positive pressure of the warm air as it enters the microclimate. Low positive pressure in the microclimate results in less warm air forced out of the microclimate and into the OR environment as waste energy.

The leading competitor's forced air design creates a high positive pressure under the blanket as air is pushed through open punched holes in the blanket fabric. This in turn forces warm air to flow out from underneath the blanket into the OR environment as waste heat energy, where it can warm the surgical staff – an unwanted outcome. Additionally, this high pressure causes the leading competitor's blankets to float off the patient, disrupting the patient warming process and often requiring an additional cotton linen to weigh down their air blankets to prevent lofting, adding cost, waste, and unnecessary complexity to the workflow.

Not only does the KoZee System's diffused airflow design keep warm air where it belongs, in the microclimate, it also keeps the blanket where it should be, on the patient.

Air Filtration: Superior Air Filtration with the KoZee System

OPERATING ROOM FILTRATION STANDARDS

Air filtration in the OR remains a concern for hospitals. In response to the SARS-CoV-2 pandemic, ASHRAE (the globally recognized organization that publishes standards and guidance for hospital ventilation systems) increased the ratings of its OR filtration requirements in 2021. Given there is no standard for air filtration of convective air warming systems and that ASHRAE states that "HEPA filters provide the greatest air-cleaning efficiency currently available,"[14] the KoZee System design follows ASHRAE standards as a best practice by providing a HEPA filter at the air intake of the system.

2021 ASHRAE RATINGS REQUIRE A MINIMUM OF: [7]

- MERV-16 filtration for general OR space.
- HEPA filtration where orthopedic procedures, transplants, neurosurgery, or dedicated burn unit procedures are conducted.

"The greatest amount of bacteria found in the operating room comes from the surgical team and is a result of their activities during surgery. During an operation, most members of the surgical team are near the operating table, creating the undesirable situation of concentrating contamination in this highly sensitive area." – 2019 ASHRAE Handbook[14]

"The staff emits the vast majority of microbiological contamination that may initiate SSIs." - Sadizedeh et al.[15]

"HEPA filters provide the greatest air-cleaning efficiency currently available." – 2019 ASHRAE Handbook[14]

"The role of [HEPA] filters becomes crucial if the OR air is partially recirculated back into the OR environment." - Sadizedeh et al.[15]

BACTERIAL AND VIRAL FILTRATION EFFICIENCY STUDY

The proprietary KoZee blanket design works as a filter against aerosolized bacteria and viruses when compared to the leading competitors forced air design with open punched holes in their blanket's material. This was quantified by an external laboratory by performing standardized bacterial and viral filtration efficiency testing (VFE and BFE, respectively)[8] and summarized in Figure 5. KoZee blankets are 99.4% efficient at filtering aerosolized bacteria, significantly more efficient compared to 58% by the leading competitor (99% CI, 35%-47% more efficient; $p < 0.001$). Additionally, viral filtration efficiency tests showed similar results.

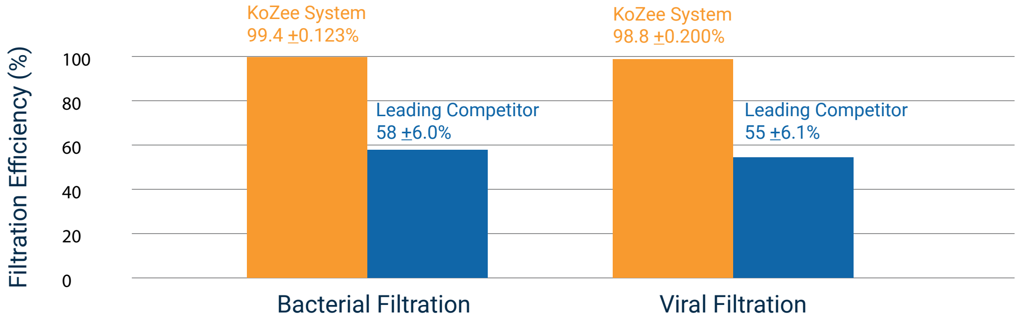

Figure 5: Bacterial and viral filtration efficiency testing results for blankets. Testing performed by an external lab per ASTM F2101-23 and EN 14683 medical face mask evaluation standards.

MULTI-FACTOR FILTRATION

The combination of the KoZee blanket's filtration efficiency in addition to the HEPA filter is designed to give peace of mind and ease concerns when it comes to recirculating air in the OR.

The KoZee System surpasses the leading competitor by creating a warmer microclimate between the patient and the blanket and providing superior air filtration. The proprietary diffused airflow design produces a warmer microclimate in less time, reduces flow of waste warm air to the OR, and prevents the blanket from floating. The blankets are also proven by third-party testing to provide higher efficiency in filtering bacteria and viruses which, with the added HEPA filter, provides superior filtration of air that passes through the system.

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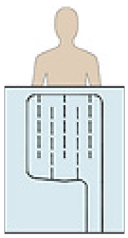
Appendix[6]

Lower Body Blankets

Blanket Model: M21002



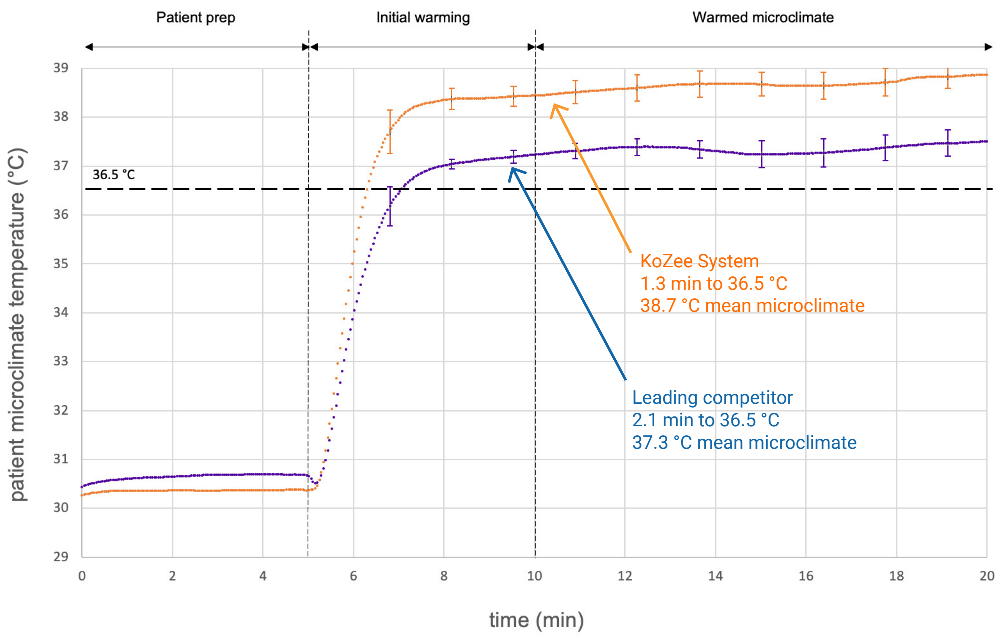


Figure A1: Patient microclimate temperature data during simulated operating room use case. Both systems were tested with adult lower body blankets covered with a cotton linen. Data presented are mean ± standard deviation (error bars) across multiple trials (n=6).

Lower Body Blankets

M21002 without a cotton linen

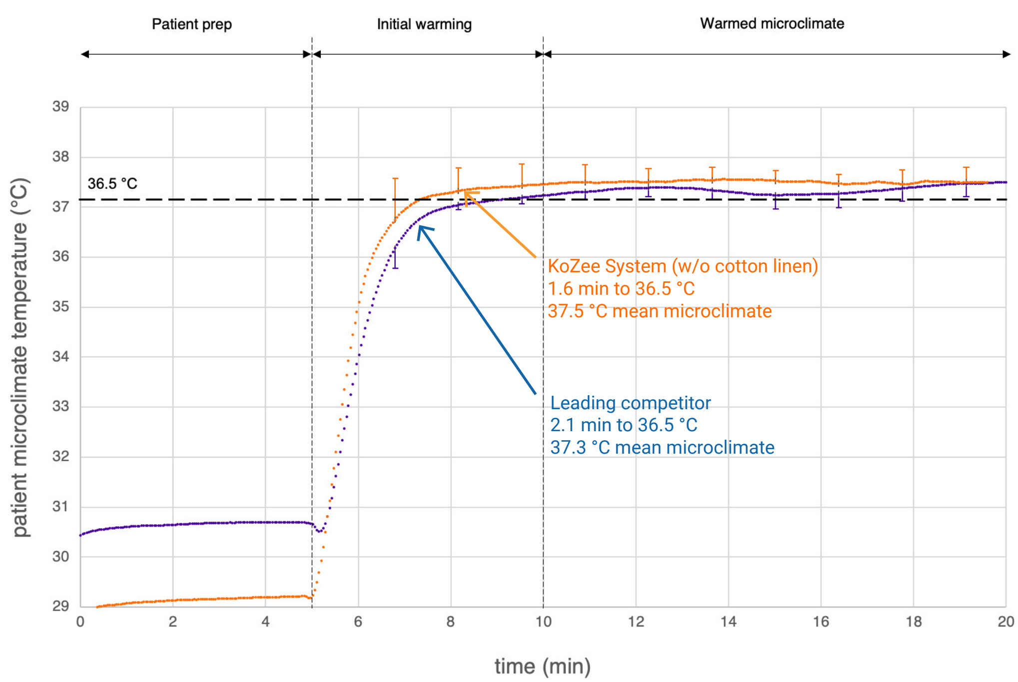


Figure A2: Patient microclimate temperature data during simulated operating room use case. Both systems were tested with adult lower body blankets. The leading competitor's blankets were covered with a cotton linen but the KoZee blankets were tested without the cotton linen. Data presented are mean ± standard deviation (error bars) across multiple trials (n=6). For clarity, only upper and lower error bars are only shown for KoZee System (without cotton linen) and leading competitor system, respectively.

Upper Body Blankets

Blanket Model: M21003

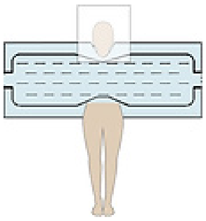
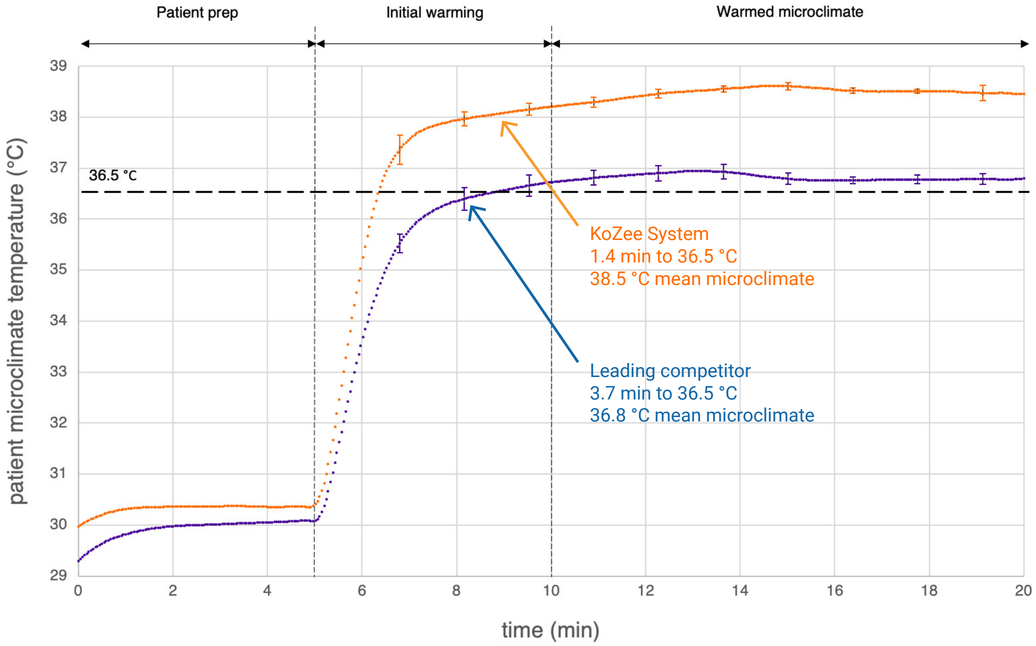


Figure A3: Patient microclimate temperature data during simulated operating room use case. Both systems were tested with adult upper body blankets covered with a cotton linen. Data presented are mean ± standard deviation (error bars) across multiple trials (n=6).



Upper Body Blankets

M21003 without a cotton linen

Figure A4: Patient microclimate temperature data during simulated operating room use case. Both systems were tested with adult upper body blankets. The leading competitor's blankets were covered with a cotton linen but the KoZee blankets were tested without the cotton linen. Data presented are mean ± standard deviation (error bars) across multiple trials (n=6). For clarity, only upper and lower error bars are only shown for KoZee System (without cotton linen) and leading competitor system, respectively.