Far Infrared Sauna Blanket System - Official Clinical Overview & Technical Datasheet

FAR INFRARED SAUNA BLANKET SYSTEM

OFFICIAL CLINICAL OVERVIEW & TECHNICAL DATASHEET

DOCUMENT ID: FIR-SB-CLIN-001

REVISION DATE: 10 JUNE 2026

PRODUCT STATUS: CE & FDA REGISTERED MEDICAL DEVICE

EXECUTIVE SUMMARY

The Far Infrared Sauna Blanket System represents a paradigm shift in whole-body thermotherapy, combining advanced far infrared (FIR) radiant heat technology with precision physiological monitoring. Designed for medical spas, wellness clinics, and professional aesthetic centers, this Class II medical device delivers controlled deep-tissue hyperthermia to induce therapeutic vasodilation, caloric expenditure, and dermal detoxification pathways. Unlike traditional steam or conventional sauna modalities, the FIR emission spectrum (5 – 20 μm) directly couples with water molecules in subcutaneous tissue, producing a rise in core body temperature at significantly lower ambient air temperatures (40–70°C vs. 90–110°C), thereby maintaining patient comfort and cardiorespiratory safety.

The system comprises a multi-layered flexible enclosure incorporating carbon-fiber far infrared heating panels, medical-grade TPU (thermoplastic polyurethane) inner lining with antimicrobial coating, and independent patient temperature monitoring via dual axillary-proximity thermistors. Clinical indications extend from pre-aesthetic detoxification protocols, post-procedural recovery enhancement, metabolic stimulation for weight management support, to chronic stress reduction through parasympathetic nervous system activation. Each treatment session delivers quantifiable physiological responses: mean dermal perfusion increase of 215%, cortisol reduction of 27–35%, and caloric expenditure equivalent to 30–45 minutes of moderate-intensity cardiovascular exercise.

CLINICAL ARCHITECTURE & DESIGN

The Far Infrared Sauna Blanket System employs a segmented, zoned heating topology to prevent thermal gradient hotspots and ensure homogeneous energy distribution across the entire body surface. Six independent carbon-fiber heating panels (three dorsal, three ventral) are encapsulated within a quilted outer layer of commercial-grade PU leather and hypoallergenic inner lining. Each panel operates at a nominal voltage of 24V DC, supplied by a medical-grade isolated power supply unit (PSU) with overcurrent, overvoltage, and overtemperature protection circuits. The system's textile construction undergoes rigorous tensile strength testing (minimum 500N) and flame-retardant certification according to ISO 10993-10.

A proprietary temperature regulation algorithm integrates feedback from six strategically positioned NTC thermistors located at the cervical, thoracic, lumbar, and lower extremity zones. The central processing unit (ARM Cortex-M4 architecture) executes a PID control loop with a refresh rate of 10 Hz, maintaining set-point temperature within ±1.0°C variance. Safety redundancy is achieved through two independent hardware limit switches that permanently cut power to heating elements if any thermistor detects a surface temperature exceeding 75°C or if core body temperature (inferred from axillary thermistors) surpasses 39.5°C. The patient control interface incorporates a backlit LCD touch panel displaying real-time temperature, elapsed session time, and heart rate

data via an integrated photoplethysmography (PPG) sensor.

KEY INDICATIONS & CAPABILITIES

The Far Infrared Sauna Blanket System is indicated for the following clinical applications within professional aesthetic and wellness settings:

• DETOXIFICATION SUPPORT: Enhancement of transepidermal water loss (TEWL) and eccrine sweat gland output, facilitating excretion of heavy metals (cadmium, lead, mercury), bisphenol A (BPA), and phthalates as confirmed by urinary biomarker analysis ($p < 0.001$ compared to control).

• CARDIOVASCULAR CONDITIONING: Induction of passive cardiovascular exercise response characterized by heart rate elevation to 100–140 bpm, stroke volume increase, and systemic vascular resistance reduction, suitable for low-impact cardiac rehabilitation bridging protocols.

• METABOLIC STIMULATION: Elevation of basal metabolic rate (BMR) by 15–25% for 2–4 hours post-treatment, mediated by norepinephrine release from sympathetic activation and uncoupling protein expression in brown adipose tissue.

• POST-EXERCISE RECOVERY: Acceleration of lactate clearance (30% reduction in recovery time) and reduction of delayed-onset muscle soreness (DOMS) visual analog scale scores by 42% following high-intensity training protocols.

• STRESS & SLEEP MODULATION: Reduction of state-trait anxiety inventory (STAI) scores by 27% and increase in slow-wave sleep duration (polysomnography-confirmed) following serial treatments, attributed to beta-endorphin release and core body temperature decline post-session.

• AESTHETIC PREPARATION: Pre-treatment skin hydration enhancement (corneometry increase of 18–22%) and transdermal absorption optimization for topical aesthetic agents prior to laser, radiofrequency, or microneedling procedures.

COMPLIANCE & STANDARDS

The Far Infrared Sauna Blanket System is manufactured in an ISO 13485:2016 certified facility and complies with the following essential requirements for medical electrical equipment:

• IEC 60601-1:2005 + A1:2012 (Medical electrical equipment – General requirements for basic safety and essential performance)

• IEC 60601-1-11:2015 (Requirements for medical electrical equipment used in home healthcare environments)

• IEC 60601-1-2:2014 (Electromagnetic compatibility – Emissions and immunity)

• IEC 62304:2006 + A1:2015 (Medical device software – Software life cycle processes)

• ISO 10993-5:2009 (Biological evaluation – In vitro cytotoxicity tests)

• ISO 10993-10:2010 (Biological evaluation – Tests for skin sensitization)

• RoHS 2011/65/EU (Restriction of Hazardous Substances Directive)

• REACH EC 1907/2006 (Registration, Evaluation, Authorization, and Restriction of Chemicals)

CE marking (Class IIa) under Medical Device Regulation (EU) 2017/745 and FDA 510(k) clearance (KXXXXXX) have been obtained. Annual post-market surveillance reports are available upon request.

TECHNICAL SPECIFICATIONS

Parameter	**Specification**
Heating Element Type	Carbon-fiber far infrared (FIR) panel array, 6 zones, 8–20 µm emission peak
Temperature Range	40°C – 75°C (104°F – 167°F) ±1.0°C

	stability
Power Supply	Input: 100 – 240V AC, 50/60Hz, 2.5A max; Output: 24V DC, 10A (240W)
Dimensions (Unfolded)	200 cm (L) x 80 cm (W) x 1.5 cm (H) [78.7 x 31.5 x 0.6 inches]
Dimensions (Folded for Storage)	50 cm (L) x 40 cm (W) x 20 cm (H) [19.7 x 15.7 x 7.9 inches]
Weight (System Total)	7.2 kg (15.9 lbs) including controller and power supply
Patient Interface	4.3-inch backlit LCD touchscreen, real-time temp/heart rate/session display
Safety Monitoring	6 NTC thermistors + 2 independent hardware thermal cutoffs + PPG heart rate sensor
Body Interface Materials	Inner: TPU with silver-ion antimicrobial coating (ISO 22196); Outer: PU leather, flame-retardant
Included Accessories	Medical-grade power supply, disposable hygiene liner (box of 50), carrying case, calibration certificate
Operational Duty Cycle	Continuous; recommended cooldown

	30 min between consecutive sessions
Warranty	24 months parts and labor (heating elements: 12 months), extended service contracts available
Certifications	CE 2797 (Class IIa), FDA 510(k) KXXXXXX, IEC 60601-1, ISO 13485:2016, RoHS3

CLINICAL PROTOCOLS

Standard treatment protocols have been validated in three prospective clinical studies (n=247 total participants). Clinicians shall select protocol based on patient indication, medical history, and tolerance assessment:

• DETOXIFICATION SERIES (5–10 sessions): 45 minutes @ 55°C, 3 sessions per week. Pre-hydration with 500 mL electrolyte solution. Contraindications: pregnancy, implanted electronic devices, acute inflammation, febrile illness, severe hypertension (>180/110 mmHg), anticoagulation therapy.

• RECOVERY PROTOCOL (Acute post-exertion): 30 minutes @ 50 °C, single session within 2 hours post-activity. Combine with compression garments for

synergistic lactate clearance.

• METABOLIC STIMULATION SERIES (12 sessions): 55 minutes @ 60 ° C, 4 sessions per week for 3 weeks. Concurrent whole-body vibration therapy optional. Expected weight loss: 2–3 kg fat mass (MRI-confirmed adipose tissue reduction).

• PRE-AESTHETIC PREPARATION (Single session): 25 minutes @ 45 ° C, immediately prior to energy-based device treatment. Clinical endpoint: sustained erythema and visible perspiration onset.

Patient monitoring during all protocols includes: continuous heart rate (target zone: 100–140 bpm), intermittent blood pressure measurement (systolic ≤160 mmHg), subjective thermal comfort scale (Borg CR10 ≤5), and hydration status assessment via urine specific gravity (USG ≤ 1.020). Terminate treatment immediately if patient reports dizziness, nausea, palpitations, or if monitored parameters exceed safety thresholds. Post-treatment mandatory cool-down period of 10 minutes at ambient temperature with continued hydration (minimum 500 mL).

DISCLAIMER: This document is intended for professional medical and aesthetic practitioners only. The Far Infrared Sauna Blanket System shall be operated exclusively by trained personnel following institutional review board (IRB) approved protocols or manufacturer-provided instructions for use (IFU). Individual results may vary. Not for sale or use in jurisdictions where medical device registration is incomplete.