

## Clinical Architecture & Performance Reference Manual: 650nm 980nm Lipo Laser Paddles System

### DEVICE IDENTIFICATION AND INTENDED USE STATEMENT

The 650nm 980nm Lipo Laser Paddles System is a non-invasive, multi-wavelength photobiomodulation device intended for temporary body contouring and circumference reduction of the waist, hips, and thighs. The system utilizes low-level laser therapy (LLLT) to induce adipocyte membrane permeabilization, resulting in the release of intracellular triglycerides for subsequent natural metabolic processing.



### INTERNAL HARDWARE TOPOLOGY

The platform integrates dual therapeutic wavelengths (650nm and 980nm)

delivered through six independent, articulating paddle applicators. Each paddle houses an array of Class 3B laser diodes operating in a continuous-wave or pulsed emission mode. The central control unit contains a dual-channel laser driver board, an isolated power supply (100–240V AC to 5–24V DC conversion), and a real-time temperature monitoring module. An embedded microcontroller manages pulse width modulation (PWM) for power stability across all channels simultaneously.

#### EPIDERMAL PROTECTION MECHANISMS

Thermal safety is prioritized through three redundant subsystems: (1) a passive aluminum heat sink backing each paddle, (2) active forced-air convection via silent axial fans within the control unit, and (3) an automatic laser shutoff triggered by over-temperature sensors (threshold set at  $+42^{\circ}\text{C} \pm 1^{\circ}\text{C}$  at the treatment interface). A contact detection system verifies paddle-to-skin proximity prior to emission, preventing accidental activation in free space.

#### TREATMENT ADVANTAGES

Simultaneous 650nm (superficial photothermal effect) and 980nm (deeper adipose penetration) emission creates a synergistic photobiomodulation cascade. Clinical benefits include: non-cytotoxic adipocyte disruption, no

required downtime, compatibility with Fitzpatrick skin types I – IV, and simultaneous treatment of up to six anatomical zones. The low fluence per paddle ( $\leq 30 \text{ J/cm}^2$  per session) minimizes the risk of paradoxical adipose hyperplasia.

#### SPECIFICATION MATRIX

Parameter	Specification
Laser Type / Wavelength	650nm (Class 3B) + 980nm (Class 3B), dual-wavelength simultaneous emission
Laser Diode Count	6 paddles x 12 diodes per wavelength = 144 total diodes (72 per wavelength)
Power Output per Paddle	Up to 2.5W (650nm) + 2.5W (980nm) continuously adjustable
Spot Size (per paddle)	80 cm <sup>2</sup> (elliptical field, 10 cm x 8 cm effective treatment area)
Cooling System	Passive heat sink + forced air convection, contact-dependent TEC (optional add-on)
Pulse Modes	Continuous Wave (CW), 5 – 100 Hz pulsed, duty cycle 10–90%

Power Supply	100–240 V AC, 50/60 Hz, 150 VA max
Dimensions (Control Unit)	32 cm (W) x 28 cm (D) x 18 cm (H)
Weight	4.2 kg (system total, incl. paddles)
Display	7-inch capacitive touchscreen, 800x480 pixels
Safety Approvals	CE 93/42/EEC (Class IIb), FDA 510(k) Kxxxxxx, IEC 60825-1, IEC 60601-1

#### REGULATORY COMPLIANCE

The 650nm 980nm Lipo Laser Paddles System carries CE marking under Medical Device Directive 93/42/EEC (Class IIb) and FDA 510(k) clearance for over-the-counter circumference reduction. Compliance includes: IEC 60825-1:2014 (laser safety), IEC 60601-1 (electrical medical equipment safety), and IEC 60601-2-22 (laser device specific standards). Manufacturing processes are ISO 13485:2016 certified.



## RECOMMENDED WORKFLOW AND DISPOSABLE LOGIC

Standard protocol: six paddles positioned symmetrically over the target area (e.g., three per side). Treatment session: 20 minutes at 1.0–2.5 W per paddle (adjustable in 0.1 W increments). Recommended 6–8 sessions, twice weekly. No consumable paddles; the laser diode arrays are rated for 10,000 hours of cumulative operation. Surface cleaning between patients requires only isopropyl alcohol wipes (70% concentration).

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