

Medical CE & FDA Technical Compliance Register: Professional Coolsculpting  
Alternative Machine

DEVICE IDENTIFICATION

Product Designation: Professional Non-Invasive Cryolipolysis &  
Multi-Wavelength Aesthetic System (Coolsculpting Alternative Platform)

Model Series: CS-ALT / PRO-SCULPT Series

Intended Use: Non-invasive subcutaneous adipose tissue reduction via  
controlled cooling (cryolipolysis) and adjunctive radiofrequency/diode laser  
energy for skin tightening in medical and aesthetic practices.



INTERNAL HARDWARE TOPOLOGY

The platform integrates a dual-module cryo-electric generation unit

(TEC2-12715) with a reverse Carnot cycle heat exchanger. A 7.0-inch capacitive touch host communicates via isolated CAN bus to three independent handpiece drivers. The hydraulic circuit includes a 2.5L reservoir, variable speed DC pump (max flow 4.2L/min), and dual 120mm axial fans (CFM rating: 89.2). Redundant thermal fuses (two per channel) interrupt power at 44°C +/- 1.5°C.

#### EPIDERMAL PROTECTION MECHANISMS

Active surface thermistors (NTC type, tolerance +/-0.2°C) sample at 10Hz with closed-loop PID control. Cooling ramp: -0.8°C/sec to target temperature range (-9°C to +5°C). A secondary passive copper cold spreader eliminates hot spots. Vacuum pressure is dynamically modulated between 55-75kPa to prevent soft tissue traction injury. Emergency mechanical release valve engages at >80kPa.

#### TREATMENT ADVANTAGES

- Adipocyte crystallization confirmed at -5°C maintained for 60 min (in vitro data).
- Average patient-reported pain score (VAS 0-10): 2.1 (n=204, 6-week follow-up).
- Clinical fat thickness reduction: 22% - 28% per single cycle (ultrasound validation).

- Ability to treat up to 4 zones simultaneously, reducing per-session time by 58% vs. single-nozzle legacy systems.

#### SPECIFICATION MATRIX

Parameter	Specification
Laser Type / Wavelength	Diode 808nm (optional 755/1064nm module) / Cryolipolysis via TEC + Vacuum
Spot Size	Cryo cup: 45x90mm, 55x110mm / Laser handpiece: 12x12mm, 15x20mm
Cooling System	TEC + Sapphire contact plate + Closed-loop water chiller (2.5L) + Dual fan

#### REGULATORY COMPLIANCE

- CE Mark (MDR 2017/745) – Class IIa
- FDA 510(k) Cleared – Cryolipolysis for flank, abdomen, and submental fat
- IEC 60601-1 (3.1) – Electrical Medical Equipment Safety
- IEC 60601-1-2 (4.0) – Electromagnetic Compatibility

- RoHS 3 & REACH SVHC compliant component sourcing
- ISO 13485:2016 certified manufacturing facility

