

Portable Fat Freezing Unit - Medical CE & FDA Technical Compliance Register

MEDICAL CE & FDA TECHNICAL COMPLIANCE REGISTER

DEVICE IDENTIFICATION

Device Name: Portable Fat Freezing Unit

Model Number: PF-2000 (Clinical), PF-2000Pro (Research)

Intended Use: Non-invasive subcutaneous adipose tissue reduction via controlled cryolipolysis for patients with BMI <30 and visible fat bulges in the flanks, abdomen, thighs, and submental areas.

Risk Class: IIa (EU MDR 2017/745) / Class II (FDA 21 CFR 878.5890)



INTERNAL HARDWARE TOPOLOGY

The Portable Fat Freezing Unit integrates a closed-loop thermoelectric cooling assembly with dual TEC1-12706 Peltier modules, a peristaltic anti-freeze

circulation pump, and a 9.6 cm (3.8 inch) full-color touch controller. The compact chassis (29.5 x 24.5 x 13.5 cm) houses an industrial-grade STM32 microprocessor that continuously monitors skin-surface temperature via three NTC thermistors embedded in the 4×6 cm (1.6 x 2.4 inch) flat applicator. The system achieves a cooling capacity of -11°C to +5°C at the treatment interface, with an adjustable vacuum suction mechanism for vascular isolation and tissue stabilization.

EPIDERMAL PROTECTION MECHANISMS

- Active Real-Time Thermal Feedback: Sampling frequency 10 Hz. Automatic power cut when temperature deviates $\pm 0.8^{\circ}\text{C}$ from setpoint.
- Contactless Gel Membrane Interface: Single-use, 0.3 mm thickness, prevents cold burns and cross-contamination.
- Manual Safety Interlock: Treatment halts immediately if vacuum pressure falls below 35 kPa or exceeds 65 kPa.
- Overcool Protection: Timer-limited session durations (max 60 minutes per zone) plus mandatory 5-minute cooldown between zones.

TREATMENT ADVANTAGES

- Zero Downtime: Non-surgical, no anesthesia, no recovery period.
- Verified Adipocyte Apoptosis: 20-27% average subcutaneous fat layer reduction at 12 weeks post 2 sessions (clinical study, n=64).

- Ultra-Portable: 3.2 kg total weight with carry case; operates on standard 110-240V AC 50/60Hz.
- Audible & Visual Alerts: Real-time status of cooling, suction, and timer.

SPECIFICATION MATRIX

Parameter	Specification
Cooling Technology	Dual TEC Peltier with closed-loop glycol circulation
Applicator Area	24 cm ² (60 mm x 40 mm) flat + vacuum cup optional
Set Temperature Range	-11°C to +5°C (accuracy ±0.5°C)
Treatment Timer	Adjustable 10–60 minutes (preset: 45 min)
Vacuum Suction	-45 kPa to -60 kPa continuous, user-adjustable
Power Consumption	Max 180W (idle 12W)
Dimensions (W x D x H)	295 x 245 x 135 mm
Weight	2.9 kg (unit only) / 3.2 kg (with applicator and cable)

REGULATORY COMPLIANCE

- Medical CE: EN 60601-1 (safety), EN 60601-1-11 (home healthcare environment), EN 60601-2-35 (heating/cooling devices). Notified Body: TÜV SÜD (CE 0123).
- FDA: 510(k) Clearance K223456 – Indication: Flank and abdomen fat reduction.
- ISO 13485:2016 Certified Manufacturing.
- RoHS 3 & REACH Compliant.



WARRANTY & SERVICE

- 24 months on main unit, 12 months on applicator and tubing set.
- Global technical support via authorized OEM distributors. Spare parts availability guaranteed for 7 years post-discontinuation.