

Air Pressure Detoxification Machine - Official Clinical Overview & Technical Datasheet

PRODUCT IDENTIFICATION

Device Name: Air Pressure Detoxification Machine (Sequential Pneumatic Compression System)

Model Series: APD-9000 Series (Pro, Elite, Mobile)

OEM Manufacturer: [Placeholder for OEM Name] – Class II Medical Device Manufacturer

Role: Non-invasive, closed-loop pneumatic pressure therapy system for interstitial fluid mobilization and lymphatic drainage.



CLINICAL ARCHITECTURE & DESIGN

The Air Pressure Detoxification Machine operates on the physiological principle of Sequential Gradient Pneumatic Compression. The system generates a controlled, multi-chamber air pressure waveform that propagates directionally (distal-to-proximal) across eight independent overlapping cells within the medical-grade extremity garment.

Key engineering subsystems:

- Electro-pneumatic pressure regulation module (accuracy ± 2 mmHg)
- Eight-zone sequential air cell array
- Rapid exhaust valve system (≤ 200 ms decompression)
- DSP-controlled pressure ramp profiles
- Emergency pneumatic bleed-off safety circuit

INDICATIONS FOR USE (Cleared Applications)

- Adjunctive treatment for venous and lymphatic return
- Reduction of temporary lower extremity edema
- Pre- and post-surgical decongestion protocols
- Management of mild-to-moderate lipedema symptoms
- Post-exercise metabolic waste clearance acceleration
- Contraindications: DVT, severe arteriopathy, acute infection, pregnancy, malignancy

TREATMENT PROTOCOL STANDARDS

Session duration: 25-45 minutes

Pressure range: 30-120 mmHg (adjustable in 1 mmHg increments)

Hold time: 0-10 seconds per chamber

Cycle delay: 0-6 seconds

Treatment modes: Sequential, Wave, Massage, Gradient Boost

Garment types: Full leg, hip & abdomen, arm, multi-limb

Parameter	Specification
Maximum Air Pressure	120 mmHg \pm 2 mmHg
Number of Pressure Chambers	8 overlapping cells per garment
Cycle Time per Chamber	0–99 seconds (programmable)
Pressure Rise Time (0 to 120 mmHg)	\leq 4.5 seconds
Exhaust Time (120 to 5 mmHg)	\leq 1.2 seconds
Operating Pressure Accuracy	\pm 2 mmHg from setpoint
Dimensions (Control Unit)	280 mm W x 220 mm D x 140 mm H
Weight (Base Unit)	3.8 kg
Electrical Input	100–240V AC, 50/60Hz, 1.8A
Patient Garment Material	Medical-grade TPU laminated nylon, latex-free

COMPLIANCE & SAFETY CERTIFICATIONS

- IEC 60601-1 (Medical electrical equipment – General requirements)
- IEC 60601-1-2 (Electromagnetic compatibility)
- ISO 13485:2016 (Quality management systems – Medical devices)
- FDA 510(k) clearance (Class II – Product Code: BYO)
- CE MDR (Regulation EU 2017/745)
- RoHS 3 (Directive 2015/863/EU)
- Reach compliant

Built-in redundancies: Dual overpressure sensors, automatic shutoff at 130 mmHg, 24-hour self-diagnostics, power-loss rapid deflation valve.

CLINICAL WORKFLOW INTEGRATION

Pre-treatment assessment: Contraindication screening + baseline limb circumference measurement

User interface: 7-inch capacitive touch display, patient protocol presets, real-time pressure curve visualization

Data export: USB port for session logs (CSV format) | HL7 ready for EMR

integration (optional module)

Cleaning protocol: Intermittent duty cycle, surface disinfectant compatibility (quaternary ammonium compounds)



OPERATIONAL & WARRANTY SPECIFICATIONS

Duty cycle: 24/7 continuous operation (active cooling fan)

Acoustic noise: ≤ 55 dB(A) at 1m

Power consumption: 180W maximum

Warranty: 24 months hardware | 12 months pneumatic hose assembly | Lifetime software updates

Included accessories: 1 pair standard leg garments (S/M/L/XL), 4m pneumatic hose, field-replaceable inline bacterial filter (0.2 μ m), hanging hooks

Service interval: Annual pneumatic calibration check (audible + digital log)