

# Nano Microneedling Infusion System - Official Clinical Overview & Technical Datasheet

## EXECUTIVE SUMMARY

The Nano Microneedling Infusion System represents a paradigm shift in transdermal drug delivery and dermal remodeling. By combining ultra-fine, medical-grade stainless steel nano-needles (0.15mm diameter) with a precision-controlled oscillation motor and optional electroporation or sonophoresis assist modules, this platform achieves consistent micro-channel creation at depths adjustable from 0.25mm to 2.5mm. The system minimizes epidermal trauma while maximizing absorption of topical serums, growth factors, or active pharmaceutical ingredients. Designed for medical spas, dermatology clinics, and plastic surgery centers, the device delivers repeatable clinical outcomes for skin rejuvenation, scar revision, and melasma management.



## CLINICAL ARCHITECTURE & DESIGN

The handpiece integrates a disposable, single-use nano-cartridge containing 11x11 arrays of conical nano-needles. The proprietary SmartDepth motor delivers vertical oscillation at 110-150 Hz, ensuring perpendicular entry and exit to reduce drag and patient discomfort. A vacuum stabilization ring flattens the treatment area (10mm x 10mm aperture) prior to needle deployment, enhancing channel uniformity. The console features a 7-inch capacitive touchscreen with pre-programmed protocols for face, neck, décolleté, and body indications. Real-time impedance monitoring adjusts motor speed to maintain consistent puncture depth across varying tissue densities.

## KEY INDICATIONS & CAPABILITIES

- Primary: Fine lines & rhytides, atrophic acne scars, surgical scars
- Secondary: Melasma (adjunct with depigmenting serums), stretch marks, alopecia (scalp micro-channeling)
- Compatibility: Hyaluronic acid, vitamin complexes, exosomes, PRP, and small-molecule peptides
- Contraindications: Active acne, open wounds, keloid predisposition, anticoagulant therapy

#### COMPLIANCE & STANDARDS

The system carries CE MDR (Class IIa) and FDA 510(k) clearance for microneedling with drug-free use. ISO 13485:2016 certified manufacturing. Electrical safety to IEC 60601-1, electromagnetic compatibility to IEC 60601-1-2. Needle cartridges are sterile, endotoxin-free, and validated for single-use per ISO 10993 biocompatibility series.

#### TECHNICAL SPECIFICATIONS

Parameter	Specification
Needle Material	Medical grade 316 stainless steel
Needle Diameter	0.15 mm (cone-shaped tip 0.08mm)
Needle Array	11 x 11 per cartridge (121 needles)

Penetration Depth	0.25 mm to 2.5 mm (0.25 mm increments)
Oscillation Frequency	110 - 150 Hz (adjustable)
Motor Type	Brushless DC servo with position feedback
Vacuum Pressure	-15 to -25 kPa adjustable
Treatment Aperture	10 mm x 10 mm square
Infusion Compatibility	Viscosity up to 15 cP (e.g., HA, PRP, exosomes)
Power Supply	100-240V AC, 50/60 Hz, 2.0A
Console Dimensions	280 mm (W) x 350 mm (D) x 180 mm (H)
Weight	4.8 kg (console only)
Display	7 inch capacitive touchscreen, 1024x600
Operating Environment	10 ° C to 30 ° C, 30% to 75% RH non-condensing

## CLINICAL PROTOCOLS

Standard facial rejuvenation: Needle depth 0.5-1.0mm, speed Medium (120 Hz),

2-3 passes, no overlapping. Post-procedure: sterile saline rinse followed by serum infusion under occlusion for 15 minutes. Scar revision: Depth 1.5-2.0mm, speed Low (110 Hz), 3-4 passes with cross-hatching. Stretch marks: 2.0-2.5mm, speed High (145 Hz), 2 passes with vacuum active. Always perform patch test 48 hours prior. Recommended treatment interval: 4-6 weeks. Maximum 6 sessions per anatomical site annually.

