

# Vaginal Tightening HIFU Console - Official Clinical Overview & Technical Datasheet

## EXECUTIVE SUMMARY

The Vaginal Tightening HIFU Console represents a paradigm shift in non-invasive feminine wellness, employing precision High-Intensity Focused Ultrasound (HIFU) technology to deliver targeted thermal coagulation at predetermined depths within the vaginal mucosa and submucosa. This proprietary system is engineered to stimulate neocollagenesis and neoelastogenesis, effectively addressing vaginal laxity, stress urinary incontinence (SUI), and overall sexual health without surgical intervention. Designed with an unwavering commitment to patient safety, clinical efficacy, and operational efficiency, this console establishes a new gold standard for aesthetic and gynecological practices.



## CLINICAL ARCHITECTURE & DESIGN

The console's core architecture integrates a state-of-the-art HIFU transducer engine with a proprietary real-time impedance monitoring system. This closed-loop feedback mechanism ensures the consistent delivery of therapeutic energy (typically ranging from 0.1 to 1.5 Joules per focal point) to the precise anatomical target, the deep lamina propria and superficial muscularis layers, at depths of 2.0mm, 3.0mm, and 4.5mm. The system's advanced 7-inch high-definition touchscreen interface provides the clinician with intuitive control over treatment parameters. Furthermore, a proprietary Smart Depth Selection technology automatically adjusts energy delivery based on real-time tissue response data, ensuring optimal clinical outcomes while minimizing patient discomfort. The system includes three specialized handpieces, each color-coded for specific anatomical applications, ensuring

absolute procedural clarity.

## KEY INDICATIONS & CAPABILITIES

This versatile platform is clinically indicated for a broad spectrum of feminine health concerns. Primary indications include the improvement of vaginal laxity, the reduction of mild to moderate stress urinary incontinence symptoms, and the enhancement of overall sexual function and satisfaction. Additionally, the system is indicated for the treatment of vulvovaginal atrophy and to support post-partum recovery. The unique micro-focused energy delivery pattern creates a 3D thermal coagulation matrix, which triggers the body's natural healing cascade, leading to tissue remodeling, increased vascularity, and a significant improvement in tissue tone and elasticity. The entire procedure is typically completed in under 30 minutes, making it an efficient and highly scalable aesthetic offering.

## COMPLIANCE & STANDARDS

The Vaginal Tightening HIFU Console is manufactured in an ISO 13485:2016 certified facility and complies with all applicable medical device directives. It holds CE marking (Class IIa) and has received 510(k) clearance from the U.S. Food and Drug Administration (FDA). The system is rigorously tested against

IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-62 for electromagnetic compatibility and basic safety. Comprehensive risk management has been implemented per ISO 14971:2019. A robust post-market surveillance (PMS) program is in place to ensure continuous monitoring of device performance and clinical safety.

## TECHNICAL SPECIFICATIONS

The system is engineered for performance and reliability, characterized by the following detailed parameters. Energy delivery is governed by a sophisticated algorithm that compensates for tissue density variations, ensuring uniform therapeutic effect. The handpiece incorporates advanced motion-sensing technology, which pauses energy delivery if the handpiece is moved too quickly, preventing unintended tissue overtreatment and ensuring operator safety. The cooling circuit utilizes a high-efficiency thermoelectric (TEC) module and a precision fluid pump to maintain tip temperature at a consistent 5-10 °C, ensuring patient comfort and protecting the epidermal surface. The device's software includes a comprehensive patient database, allowing for the storage and retrieval of patient records and treatment parameters for seamless clinical workflow integration.

Parameter	Specification
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HIFU Focal Depth	2.0mm / 3.0mm / 4.5mm ( $\pm 0.5$ mm)
Energy per Shot	0.1J – 1.5J (Adjustable in 0.1J increments)
Shot Count per Session	Up to 400 lines (Configurable per protocol)
Focal Point Dimensions	1.5mm (L) x 0.3mm (W) x 3.0mm (D)
Pulse Repetition Rate	1Hz – 10Hz (Variable)
Cooling System	Active TEC + Sapphire Tip + Closed-Loop Water Cooling
Display	7-inch HD Capacitive Touchscreen (1280 x 720)
Input Power	100-240V AC, 50/60Hz, 350VA max
Dimensions (W x D x H)	430 x 420 x 1200 mm (Console)
Weight	35 kg (Console with integrated cart)
Handpiece Weight	280g (Without cable)
Operational Modes	Standard, Pulse, Burst (Selectable)

## CLINICAL PROTOCOLS

A comprehensive suite of clinical protocols is pre-programmed into the system, allowing for rapid, evidence-based treatment customization. Each protocol is

structured to deliver a specific number of lines and shots per anatomical zone. For optimal results, a standard treatment regimen comprises two sessions, spaced approximately four weeks apart, with a follow-up assessment at three and six months post-treatment. The system's integrated 'Duty Cycle Monitor' ensures the handpiece is operated within its thermal tolerance, preventing overheating and extending the device's operational lifespan. A complete treatment log is automatically generated for each patient, providing a comprehensive record for medico-legal purposes and facilitating long-term patient follow-up. The system software is upgradeable via a secure USB port, ensuring the device remains at the forefront of clinical innovation.

