

Selective Photothermolysis Architecture Reference Document: Redacted
Technical Construction File (TCF) Sample

SELECTIVE PHOTOTHERMOLYSIS ARCHITECTURE REFERENCE DOCUMENT:
REDACTED TECHNICAL CONSTRUCTION FILE (TCF) SAMPLE

EXECUTIVE SUMMARY

This document serves as the definitive technical reference for the Redacted Technical Construction File (TCF) Sample, a Class IV medical aesthetic laser platform engineered for precise selective photothermolysis. Designed for integration into high-volume dermatology clinics and premium med spa environments, this system represents a paradigm shift in hair reduction and skin rejuvenation therapy. The platform integrates advanced diode laser technology with a proprietary active cooling system, ensuring optimal epidermal protection while delivering therapeutic fluence to target chromophores. This whitepaper delineates the system's clinical architecture, hardware topology, treatment parameters, and global regulatory compliance status, providing clinical engineers and procurement specialists with a comprehensive overview of its operational capabilities and strategic asset value.



CLINICAL ARCHITECTURE & DESIGN

The Redacted TCF Sample is built upon a modular, high-efficiency optical engine that houses a bank of high-power laser diodes. The system's architecture is predicated on a multi-wavelength emission profile, offering selectable wavelengths of 755nm, 808nm, and 1064nm, thereby enabling clinicians to tailor treatments to a broad spectrum of skin phototypes (Fitzpatrick I to VI). The internal topology is characterized by a sealed optical path that minimizes energy loss and ensures consistent output. A sophisticated thermal management system, comprising a copper heatsink and forced-air convection, maintains the laser bars at optimal operating temperatures, guaranteeing pulse-to-pulse stability and prolonging the operational lifespan of the optical source.

KEY INDICATIONS & CAPABILITIES

This platform is primarily indicated for permanent hair reduction and the treatment of benign pigmented lesions. The system's versatility is underscored by its configurable spot sizes, which range from 10x10mm for high-fluence, deep-penetrating treatments to 15x15mm for rapid, large-area coverage. The integrated contact-cooling sapphire tip operates at a nominal temperature range of -5°C to 5°C, providing continuous epidermal cooling both pre-, during, and post-laser pulse. This mechanism not only enhances patient comfort but also allows for the delivery of higher fluences without compromising safety, thereby accelerating clinical outcomes and reducing the total number of required sessions.

COMPLIANCE & STANDARDS

The Redacted TCF Sample has been meticulously engineered to comply with the essential requirements of the Medical Device Regulation (MDR) 2017/745 and has secured FDA 510(k) clearance. The device carries the CE mark, confirming its conformity with applicable European health, safety, and environmental protection standards. Full compliance is maintained with IEC 60825-1 for laser safety, classifying the device as a Class 4 laser product requiring appropriate safety controls. The accompanying Technical

Construction File provides exhaustive documentation on risk management (ISO 14971) and performance evaluation, ensuring complete traceability for Notified Body review.

TECHNICAL SPECIFICATIONS

Optical Source: High-Power Diode Laser Bars

Available Wavelengths: 755 nm, 808 nm, 1064 nm (Selectable)

Maximum Output Power: 2000W (Platform Dependent)

Fluence Range: 5 J/cm² to 120 J/cm²

Pulse Width: 5ms to 400ms (Adjustable)

Repetition Rate: Up to 10 Hz

Spot Size Array: 10x10 mm, 12x12 mm, 15x15 mm, 10x20 mm

Cooling System: Active TEC + Sapphire Contact Cooling (-5 °C to 5 °C) & Water/Air Circulation

Display Interface: High-Resolution 10.4-inch Color Touchscreen

Dimensions (WxDxH): 450mm x 400mm x 1100mm

Weight: Approximately 35 kg

Electrical Requirements: 110-240 VAC, 50/60 Hz, 15A

Parameter	Specification
Laser Type / Wavelength	Diode Laser / 755nm, 808nm, 1064nm

	(Selectable)
Spot Size	10x10 mm, 12x12 mm, 15x15 mm, 10x20 mm (Configurable)
Cooling System	Active TEC + Sapphire Contact Cooling + Water/Air Circulation
Maximum Fluence	120 J/cm ²
Pulse Width Range	5ms - 400ms
Repetition Rate	Up to 10 Hz
Display	10.4-inch Color Touchscreen
Weight	Approx. 35 kg
Electrical	110-240 VAC, 50/60 Hz, 15A
Regulatory Status	CE Mark (MDR 2017/745) & FDA 510(k) Cleared

CLINICAL PROTOCOLS

To achieve optimal clinical efficacy, it is imperative to adhere to established treatment protocols based on skin type and hair color. For lighter skin phototypes (I-III), a combination of 755nm and 808nm wavelengths at higher fluences (40-80 J/cm²) is recommended to target melanin-rich follicles effectively. For darker skin types (IV-VI), the 1064nm wavelength should be

utilized at moderate fluences (30-50 J/cm²) to mitigate the risk of thermal injury to the epidermis, leveraging the longer wavelength's deeper penetration and reduced melanin absorption. The proprietary cooling mechanism permits the safe application of aggressive fluences, but clinicians must maintain proper skin contact and utilize the device's built-in skin temperature monitoring feature to ensure a constant epidermal temperature of approximately 15°C. A standard full-face treatment typically requires 15-20 minutes, with subsequent maintenance sessions scheduled at 4-6 week intervals.

