

Out-of-Box Audit (OBA) Checkpoints Standard Form - Official Clinical Overview & Technical Datasheet

DEVICE IDENTIFICATION: OUT-OF-BOX AUDIT (OBA) CHECKPOINTS STANDARD FORM

This document serves as the definitive clinical and technical reference for the Out-of-Box Audit (OBA) Checkpoints Standard Form, a critical quality assurance instrument for the verification and validation of medical aesthetic devices upon receipt and prior to clinical deployment. The OBA protocol ensures that every system meets stringent OEM performance, safety, and cosmetic integrity benchmarks, safeguarding both clinical outcomes and patient safety.



INTERNAL HARDWARE TOPOLOGY & INSPECTION PROTOCOL

The OBA Checkpoints Standard Form is systematically structured to guide biomedical engineers and clinical technicians through a non-invasive and, where applicable, invasive hardware audit. The inspection cascade is designed to validate the foundational subsystems without compromising the factory-sealed optical path. Key checkpoints include:

- CHASSIS AND EXTERNAL INTEGRITY: A meticulous visual inspection for cosmetic blemishes, structural deformation, and integrity of all external panels and fasteners. This includes verification of serial number alignment and tamper-evident seals.
- CONTROL INTERFACE FUNCTIONALITY: A complete validation of the high-resolution touchscreen and membrane switches. This check ensures pixel integrity, touch sensitivity, and responsiveness of all haptic and auditory feedback mechanisms. A systematic test of the emergency stop (E-Stop) and keylock functions is mandatory.
- ELECTRICAL AND POWER SUBSYSTEM: Verification of mains input stability, power supply unit (PSU) voltage rails, and internal cabling security. This includes an assessment of all internal fans for acoustic anomalies and confirming that the thermal management system (heat sinks, TEC assemblies) is free from debris and physical obstructions.
- OPTICAL DELIVERY PATH: A critical visual and borescopic inspection of the optical train, including the laser bars, mirrors, and fiber optic couplings (if

applicable). The audit confirms the absence of dust, condensation, or micro-cracks on optical surfaces. A preliminary energy meter test is conducted to verify calibration before full clinical use.

EPIDERMAL PROTECTION MECHANISMS & SAFETY CHECKPOINTS

A dedicated section of the OBA form focuses on the patient safety subsystems. The audit rigorously tests the dynamic cooling interfaces, including the Sapphire contact cooling plate and the cryogen spray system (if equipped). The form guides the auditor through a series of timed temperature and pressure tests to verify rapid epidermal cooling, ensuring that the device can maintain a safe and comfortable skin surface temperature during high-fluence treatments. The verification of the skin contact sensor and the continuous impedance monitoring circuits are also embedded in this phase to guarantee fail-safe operation.

TREATMENT ADVANTAGES & OPERATIONAL VALIDATION

Completion of the OBA checkpoints confers significant operational advantages. A certified OBA guarantees that the device is ready for immediate, high-precision clinical use, eliminating costly downtime and reducing the risk of non-billable service calls. The validation ensures:

- IMMEDIATE CLINICAL READINESS: The device is certified to perform at peak specifications from the first treatment.
- WARRANTY PRESERVATION: The audit documentation serves as the official record required to activate and maintain the comprehensive OEM warranty.
- OPTIMAL PATIENT OUTCOMES: Confirms that the energy delivery, pulse duration, and spot size profiles are within factory tolerances, ensuring predictable and consistent clinical results for a wide range of Fitzpatrick skin types.

SPECIFICATION MATRIX & CHECKPOINT REGISTER

The OBA Standard Form features a detailed specification matrix that correlates the hardware checks with specific performance metrics. This register allows technicians to compare measured values against factory baseline data, ensuring zero drift in critical parameters.

OBA Checkpoint Category	Parameter / Test	Acceptance Criterion	Technician Sign-off
External / Chassis	Panel Gap & Finish	≤ 0.5mm variance, no scratches	Initials and Date

Optical Delivery	Beam Profiling & Energy Output	$\pm 5\%$ of factory-set energy	Initials and Date
Cooling System	TEC/Sapphire Plate Temperature	$5^{\circ}\text{C} \pm 1^{\circ}\text{C}$ in steady state	Initials and Date
Electrical Safety	Ground Continuity & Leakage	$< 100 \mu\text{A}$ (Earth Leakage)	Initials and Date

REGULATORY COMPLIANCE & STANDARDS ALIGNMENT

The OBA Checkpoints Standard Form is drafted in strict alignment with international medical device regulatory standards, including the Medical Device Regulation (MDR) (EU) 2017/745 and the FDA 21 CFR Part 820 Quality System Regulations. The audit protocol incorporates checkpoints to verify compliance with:

- IEC 60601-1: General requirements for basic safety and essential performance.
- IEC 60601-2-22: Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment.
- ISO 13485: Medical devices – Quality management systems – Requirements

for regulatory purposes.

This structured framework ensures that every device delivered is not only clinically effective but also meets the highest standards of global regulatory and safety governance.

