

Clinical Architecture & Performance Reference Manual: 7-Year Archiving Policy for Quality and Calibration Data

EXECUTIVE SUMMARY

The 7-Year Archiving Policy for Quality and Calibration Data represents the foundational data governance framework within our premium medical aesthetic device ecosystem. This policy is engineered to ensure longitudinal traceability, regulatory defensibility, and operational continuity across the entire clinical lifecycle of our aesthetic systems. By mandating a comprehensive, immutable record of all quality assurance (QA) and calibration events, this archiving standard transcends mere compliance—it establishes a clinical-grade data backbone that empowers practitioners to demonstrate due diligence, optimize treatment outcomes, and facilitate seamless device maintenance over the long-term asset lifecycle. The policy is meticulously aligned with international medical device regulations, including FDA 21 CFR Part 11, ISO 13485, and the Medical Device Regulation (MDR) 2017/745, ensuring that every treatment parameter, calibration curve, and diagnostic output is preserved in a secure, auditable, and easily retrievable format.

The strategic implementation of a 7-year data retention lifecycle is rooted in the typical operational lifespan of our devices and the statutory requirements for medical records across major jurisdictions. This policy not only protects the

clinic's investment by providing an unassailable history of device performance but also enhances patient safety by enabling precise retrospective analysis of treatment delivery. This document serves as the official technical datasheet and overview for this policy, detailing its clinical architecture, operational components, and the specific data types captured to ensure the highest standards of quality and safety.



CLINICAL ARCHITECTURE & DESIGN

The 7-Year Archiving Policy is not an adjunct feature but is intrinsically woven into the core data management architecture of our aesthetic systems. The framework is built on a resilient, three-tiered structure: Data Acquisition, Data Encryption & Storage, and Data Retrieval. This architecture is designed to function seamlessly in the background, capturing critical data points with zero

operational interruption to clinical workflow, ensuring that the clinical team remains focused on patient care while the system maintains an immutable record of every action.

Data Acquisition Tier: This layer is responsible for the real-time capture of all clinically relevant data generated by the device. Sensors, logic controllers, and treatment software continuously monitor and record a comprehensive dataset that includes, but is not limited to, system start-up self-tests, pre-treatment calibration verification, selected treatment parameters (fluence, pulse duration, spot size, repetition rate), real-time energy delivery metrics, cooling system performance (temperature curves, flow rates), and post-treatment system diagnostics. This data is timestamped with high-precision, synchronized clocks to ensure a verifiable chronology of events.

Data Encryption & Storage Tier: Once acquired, the data is immediately encrypted using Advanced Encryption Standard (AES-256) to ensure confidentiality and integrity, both in transit and at rest. The encrypted data is then stored in a dual-redundancy, solid-state memory module within the device, designed to withstand power loss and hardware failures. Simultaneously, this data is formatted and securely transmitted via an encrypted channel (using TLS 1.3 protocol) to a secure, cloud-based archival repository, providing an off-site backup. The cloud infrastructure is hosted in ISO 27001-certified data centers,

with geographically redundant storage to guarantee data durability and availability over the full 7-year period. This dual storage mechanism provides a failsafe against local hardware failure, fire, or theft, ensuring that the historical record is never lost.

Data Retrieval & Audit Tier: The policy mandates that all data is stored in a structured, non-proprietary format (such as JSON or XML) with a robust indexing system. This allows for efficient, query-based retrieval through the device's own secure interface or via a dedicated clinician portal. The retrieval system is equipped with granular access controls, ensuring that only authorized personnel can access specific data sets, with a complete audit log of all retrieval activities. This tier is essential for meeting regulatory audits, conducting internal quality reviews, performing root-cause analysis on any system anomalies, or providing evidence in the event of a malpractice claim.

KEY INDICATIONS & CAPABILITIES

The 7-Year Archiving Policy is a critical capability for a wide range of clinical and operational applications, providing a powerful tool for quality assurance, risk management, and clinical research. It serves as a definitive, time-stamped record of device performance and treatment delivery, offering functionalities that extend beyond mere compliance.

Capability 1: Comprehensive Calibration Traceability: The policy captures the entire life history of the device's calibration, documenting when calibrations were performed, the standards used, the pre- and post-calibration readings, and the identity of the technician. This provides irrefutable proof that the device has been maintained according to the manufacturer's specifications, a key factor in defending against claims of device malfunction or improper operation. The data enables proactive identification of calibration drift, allowing clinics to schedule maintenance before it impacts clinical performance.

Capability 2: Robust Compliance and Audit Trail: In the event of a regulatory inspection or an internal audit, the archive provides a complete and unalterable record of the device's operational history. This is vital for demonstrating compliance with ISO 13485, MDSAP, and other quality management system standards. The audit trail ensures that every treatment delivered is linked to a verified state of the device, providing absolute legal defensibility and patient safety assurance.

Capability 3: Evidence-Based Quality and Performance Analysis: The archive transforms historical data into a strategic asset. Clinics can analyze aggregated, anonymized data to identify optimal treatment parameters for specific skin types, track device performance trends over time, and benchmark their

outcomes. This data can be instrumental for clinical research, publication, and refining treatment protocols to achieve superior patient results while minimizing adverse events.

COMPLIANCE & STANDARDS

Our 7-Year Archiving Policy is engineered to exceed the stringent requirements set by the world's leading regulatory and standards bodies. It is a core component of our commitment to providing medical devices that meet the highest standards of safety, efficacy, and data governance.

ISO 13485:2016 (Medical Devices - Quality Management Systems): The archiving policy is an integral part of our certified Quality Management System, ensuring that we meet all requirements for document and record control, as well as traceability throughout the product lifecycle.

FDA 21 CFR Part 11 (Electronic Records; Electronic Signatures): The policy incorporates strict controls to ensure the trustworthiness, reliability, and equivalent legal status of our electronic records to paper records. This includes the use of secure, validated systems, audit trails, and digital signature capabilities.

Medical Device Regulation (MDR) (EU) 2017/745: Our policy is fully aligned with the MDR's requirements for technical documentation and post-market surveillance, ensuring that all necessary data is maintained for the full lifecycle of the device, which is typically a minimum of 10 years from the date of placing the device on the market.

ISO 27001 (Information Security Management): The cloud-based storage infrastructure used for the off-site archival complies with ISO 27001 standards, ensuring that the highest level of information security is applied to the protected health information (PHI) and device data that is stored.

TECHNICAL SPECIFICATIONS

The technical specifications for the 7-Year Archiving Policy are defined to ensure its robustness, security, and ease of integration into existing clinical workflows.

Data Acquisition: Continuous, real-time capture of treatment parameters, system diagnostics, and calibration events, with a timestamp resolution of 1 millisecond.

Data Security: End-to-end AES-256 encryption for data in transit and at rest.

Secure data transmission using TLS 1.3. Role-based access control with full audit logging for all data retrieval events.

Storage Capacity: On-device storage capacity is 256GB (solid-state drive), sufficient to store the full operational history of the device, which typically exceeds 10,000 treatment sessions. Cloud storage is virtually unlimited and prorated based on clinic usage.

Data Format: All records are stored in a structured, non-proprietary, and machine-readable format (JSON/XML) to ensure long-term accessibility and avoid data obsolescence. Data export is available in industry-standard formats (e.g., CSV, HL7).

Parameter	Specification
Data Security Standard	AES-256 Encryption (in transit & at rest)
Compliance Framework	ISO 13485, FDA 21 CFR Part 11, EU MDR 2017/745, ISO 27001
Retention Period	7 Years (statutory minimum)
On-Device Storage	256GB Solid-State Drive
Data Format	Structured, Non-proprietary (JSON/XML)

Clock Synchronization	NTP (Network Time Protocol) for verifiable timestamps
Data Retrieval Access	Role-Based Access Control (RBAC) with audit trails

CLINICAL PROTOCOLS

Successful implementation of the 7-Year Archiving Policy requires the adherence to standardized clinical protocols. These protocols are designed to be seamlessly integrated into daily operations, ensuring that the archival process is robust and complete.

Protocol 1: Standard Pre-Treatment Verification: Prior to every treatment session, the device initiates an automated self-test and calibration verification. This data, including pass/fail status and the specific verification values, is automatically captured and recorded. Clinicians are expected to visually confirm the 'Ready' status on the user interface, which indicates that the device has successfully completed its checks and is within its specified calibration parameters. Any out-of-tolerance condition will generate a system alert, preventing treatment until the issue is resolved by a qualified technician.

Protocol 2: Treatment Session Logging: During each treatment session, the system automatically logs all user-selected parameters and the actual energy delivered for every pulse. This creates a granular and verifiable record of the treatment. No manual data entry is required, minimizing the risk of human error. The session log is automatically assigned a unique session ID and timestamped. Clinicians are required to enter the patient's unique identifier (e.g., patient ID or medical record number) into the system prior to treatment initiation to ensure accurate linkage between the device data and the patient's clinical record. After the session, the clinician verifies the session details on the screen and confirms the log, which finalizes the encrypted record.

Protocol 3: Regular Data Backups and Annual Review: While the system provides automated dual storage (on-device and cloud), clinical staff should, on a monthly basis, perform a manual verification of the cloud synchronization status via the administrative portal. This is a quick check to ensure that all treatment logs and calibration data are successfully uploaded. On an annual basis, a comprehensive review of the archived data is recommended as part of the clinic's quality management review. This involves analyzing aggregated data for trends in device performance, treatment parameters, and energy delivery, which can inform decisions on preventative maintenance, staff training, and optimizing treatment protocols for the patient population.

