**Calibration Procedure – LifePulse™ Surgical Laser System**

**Document ID:** QP-12  
**Revision:** 3.1  
**Effective Date:** August 15, 2025  
**Author:** Maria Lopez, Senior Process Engineer  
**Approved By:** Dr. John Stevens, Director of Quality Assurance

**1. Scope**

This procedure applies to the **LifePulse™ Surgical Laser System**, used in the precision welding and micro-cutting of implant-grade titanium components. Calibration ensures the laser’s power output, beam alignment, and pulse timing remain within validated ranges critical for patient safety and product integrity.

**2. Purpose**

To guarantee that every pulse of the LifePulse™ laser delivers **life-saving precision**, consistent with design intent and ISO 13485 requirements.  
Calibration is more than compliance—it’s a promise: every spark of light must meet the same exacting standard that defines our mission to build devices that heal.

**3. References**

* ISO 13485:2016 – *Clause 7.6: Control of Monitoring and Measuring Equipment*
* ISO/IEC 17025:2017 – *Calibration Competency Requirements*
* Internal Form FM-21 – *Laser Calibration Record*
* Internal Form FM-22 – *Deviation and CAPA Report*
* Manufacturer Specification Sheet – *LifePulse™ Laser Model L-900X*

**4. Responsibilities**

| **Role** | **Responsibility** |
| --- | --- |
| **Laser Operator** | Verify calibration sticker and log serial number before each shift. |
| **Calibration Technician** | Perform full power, beam alignment, and timing verification tests. |
| **QA Specialist** | Review calibration data, issue approval, and archive documentation. |
| **Engineering Manager** | Investigate any out-of-tolerance results and coordinate CAPA. |

**5. Equipment Identification**

Each LifePulse™ unit is identified by a unique **Laser ID** and barcode label.  
Calibration status must be indicated with a **blue “CALIBRATED” tag** displaying:

* Calibration Date
* Next Due Date
* Technician Initials
* Calibration Certificate Number

Equipment found outside calibration validity shall be tagged **“DO NOT USE – OUT OF TOLERANCE.”**

**6. Calibration Standards**

Calibration shall be performed using **traceable power meters and beam analyzers** certified by the **National Institute of Standards and Technology (NIST)**.  
Reference devices must demonstrate calibration uncertainty less than ±0.5% of full scale.

**7. Procedure**

1. **Visual Inspection**
   * Confirm optical path cleanliness and lens integrity.
   * Inspect fiber couplings for dust, debris, or misalignment.
2. **Power Output Verification**
   * Set the laser to 100%, 70%, and 40% output levels.
   * Measure energy output using a NIST-traceable power meter.
   * Verify that readings are within ±2% of target output.
3. **Beam Alignment Check**
   * Use the internal beam profiler to confirm center deviation ≤ 0.05 mm.
   * Document profile snapshot and attach to *Form FM-21*.
4. **Pulse Timing Accuracy**
   * Trigger test sequence of 100 pulses.
   * Measure pulse duration and frequency with oscilloscope.
   * Ensure variance ≤ 0.5% from specification.
5. **Calibration Data Entry**
   * Record all results, instruments used, and technician signature on *FM-21*.
   * Submit records to QA within 24 hours.
6. **Approval and Labeling**
   * QA reviews results. If all criteria met, apply blue calibration tag.
   * Store certificate digitally in the *Calibration Master Database*.

**8. Acceptance Criteria**

| **Parameter** | **Specification** | **Tolerance** |
| --- | --- | --- |
| Laser Power Output | 100 W | ±2% |
| Beam Alignment | Center offset ≤ 0.05 mm | — |
| Pulse Frequency | 20 Hz | ±0.5% |
| Pulse Duration | 50 µs | ±0.5% |

Failure to meet any tolerance shall trigger a *Deviation Report (FM-22)* and CAPA investigation.

**9. Handling Non-Conformities**

If calibration fails:

1. Tag the unit as **OUT OF TOLERANCE – HOLD FOR INVESTIGATION.**
2. Notify QA and Engineering immediately.
3. Assess all lots processed since the last valid calibration date.
4. Initiate impact analysis and CAPA in accordance with *QP-08 Corrective Actions Procedure*.
5. Document root cause and corrective measures within 5 business days.

**10. Training**

Only certified **Laser Calibration Technicians** trained in optical safety and metrology may perform this procedure.  
All training records are maintained under *HR-04: Technical Competency File*.

**11. Records and Retention**

All calibration records, beam profiles, and deviation reports must be retained for **10 years** to support post-market surveillance and regulatory inspections.

**12. Revision History**

| **Rev** | **Date** | **Description** | **Author** | **Approved By** |
| --- | --- | --- | --- | --- |
| 3.1 | 2025-08-15 | Added LifePulse™ specifications, CAPA linkage, and visual inspection criteria | M. Lopez | Dr. J. Stevens |
| 2.0 | 2024-08-01 | Updated procedure for traceability to NIST | M. Lopez | J. Stevens |
| 1.2 | 2022-03-15 | Formatting updates only | M. Lopez | — |

**✨ *A Note from Engineering***

Every photon that leaves the LifePulse™ chamber carries purpose. Calibration is not just about numbers—it’s how we translate precision into healing. Each test ensures that when our laser fires, it fires true.