Clinical-Grade Compliance Certificate
Test Summary

Independent Verification Report —
Not a Regulatory Certification

Prepared by Oackland Toro, BMET

This Certificate of Analysis documents verification testing performed in accordance with recognized medical-device safety, performance, and quality standards. It does *not* constitute formal certification by a notified body or regulatory agency.

Provided by

FixMed Technology, LLC

Company:	TheraLight, LLC
Equipment:	**Theralight 360**
Location:	175 North 1800 West Suite 105-108, Lindon, Utah 84042
Date inspected:	June 17, 2025

All design, verification, and quality-assurance activities for the **Theralight 360** conform to globally recognized medical-device safety, electromagnetic-compatibility, photobiological-safety, software-lifecycle, quality-management, and risk-management requirements.

See "Standards & Regulatory References" for the complete list of applicable IEC, ISO, and FDA documents.

Contents

Verification Objectives

This Certificate of Analysis documents independent verification of **TheraLight 360** against the international stan- dards listed in Table 1. All optical measurements are NIST-traceable.

Table 1: Standards and regulations referenced

#	Standard / Regulation
1	IEC 60601-1 (Ed 3.2) — Basic electrical safety (Class I, PE)
2	IEC 60601-1-2:2020 + AMD1:2024 — Electromagnetic compatibility
3	IEC 60601-2-57:2023 — PBM light-source equipment
4	IEC 62471:2006 + A1:2013 — Photobiological safety (**Risk Group 1 (Low-Risk)**)
5	IEC 62304:2006 + A1:2015 — Medical-device software life-cycle (Class B)
6	ISO 14971:2019 — Risk management for medical devices
7	ISO 13485:2016 — Quality-management system (QMS)
8	FDA 21 CFR 820 — Quality System Regulation (QMSR)
9	EU MDR 2017/745 — Annex I (GSPR)

1. Electrical Safety & EMC

- **Scope** — PE continuity; patient & earth leakage; insulation & dielectric strength; radiated/conducted emissions & immunity.
- **Result** — Patient leakage 71 µA (limit 100 µA); earth leakage 210 µA (limit 500 µA). **PASS**
- **Action** — Annual IEC 60601-1 safety re-test; inspect PE wiring & EMI filters at each preventive-maintenance visit.

2. Photobiomodulation Output

- **Scope** — Wavelength accuracy (**633nm**, **810nm**, **850nm**, and **940nm**); spectral irradiance at 0 in (skin contact) and 25.4 cm (10 inches) (10 in); spatial uniformity ≤ 10 %. **IEC 62471 Photobiological Safety** — blue-light hazard *not applicable* (no emission < 600 nm; weighted radiance = 0); retinal-thermal & IR hazards evaluated; classified **Risk Group 1 (Low-Risk)**.
- **Results** —

Table 2: Irradiance and fluence (10-min continuous-wave session)

Wavelength	**Irradiance** (mW cm^{-2})		**Fluence, 10 min** (J cm^{-2})	
	0 in (skin)	10 in	0 in (skin)	10 in
633 nm	109.7 mWcm^{-2}	103.5 mWcm^{-2}	65.8 Jcm^{-2}	62.1 Jcm^{-2}
810 nm	38.64 mWcm^{-2}	19.94 mWcm^{-2}	23.2 Jcm^{-2}	12.0 Jcm^{-2}
850 nm	119.7 mWcm^{-2}	125.3 mWcm^{-2}	71.8 Jcm^{-2}	75.2 Jcm^{-2}
940 nm	49.86 mWcm^{-2}	49.86 mWcm^{-2}	29.9 Jcm^{-2}	29.9 Jcm^{-2}
Total	309.1 mWcm^{-2}	298.6 mWcm^{-2}	185.5 Jcm^{-2}	179.2 Jcm^{-2}

Note 1. Fluence H calculated per IEC 60601-2-57 §201.12.4:

$$H = \frac{E \times t \times D}{1000}$$

where E = irradiance (mW cm^{-2}), t = 600 s (10 min), D = duty-cycle (1.0 for continuous-wave). *Note 2.* Instrument uncertainty ± 2.2 % (k = 2, NIST-traceable). *Note 3.* For pulsed modes substitute D = pulse-width⁄period.

Highest single value (peak irradiance): 125.3 mWcm^{-2}. **PASS**

- **Action** — Annual optical calibration; replace LED modules at 30 % lumen depreciation.

- **Clinical relevance (evidence based)** — The delivered fluence of 185.5 Jcm^{-2} (10-min CW) per session matches or exceeds dose ranges shown effective in the literature:
  - *Chronic musculoskeletal pain & fibromyalgia* — Whole-body PBM (600–850 nm, 4 weeks, 20 min, 12 sessions, 1–20 J cm^{-2}) reduced pain VAS by 35 % and improved QoL at 6 months (PMID:36359198).
  - *Deep-tissue analgesia* — 810 nm NIR; surface dose ≥ 100 J cm^{-2} with 0.45–2.9 % of power reaching 3 cm depth, yielding 0.9–5.5 J cm^{-2} at target nerves (DOI 10.3389/fneur.2024.1398894).
  - *Muscle recovery / DOMS* — 660–850 nm, 15 J cm^{-2} applied pre-exercise accelerated strength recovery and reduced CK rise (systematic review PMID:24249354).
  - *Dermal rejuvenation* — 633 nm, 20 J cm^{-2} improved collagen density and wrinkles in a controlled trial (PMID:24286286).
- **Expected penetration** — In vivo/ex-vivo data show 810–940 nm light transmits 0.5–3 % of surface power to 3 cm depth, whereas red 633 nm is confined largely to the dermis (< 1 cm). With the bed's surface fluence (185.5 Jcm^{-2}), ≈ 0.9–5.5 J cm^{-2} reaches 3 cm—adequate for nociceptive-nerve modulation and deep-muscle PBM (DOI 10.3389/fneur.2024.1398894).

Regulatory Rationale. IEC 60601-2-57 requires reporting of *average fluence* delivered to the target over the treatment period. The table and clinical-evidence mapping above satisfy this requirement and provide auditors with full traceability to irradiance data, exposure duration, duty-cycle assumptions, and intended clinical benefit.

3. Thermal Regulation

- **Scope** — Patient-accessible surface temperatures under worst-case duty cycle.
- **Result** — Max surface temperature 39 °C (limit 41 °C). **PASS**
- **Action** — Verify fan RPM and airflow clearance at every service interval.

4. Software & Risk Management

- **Scope** — IEC 62304 Class B V&V; ISO 14971 residual-risk controls (UI, interlocks, watchdogs).
- **Result** — All test cases passed; bidirectional traceability matrix closed. **PASS**
- **Action** — Full regression test for each firmware release under formal change control.

5. Quality & Regulatory Documentation

- **Scope** — DHF, DMR, risk file, CAPA log, batch records.
- **Result** — No open critical actions; records conform to ISO 13485 and FDA QMSR. **PASS**
- **Action** — Update controlled documents within 5 business days of any design or process change.

Methodology Overview

All tests were performed in a controlled environment at 22 °C ± 2 °C using NIST-traceable instrumentation. Each method maps directly to the standards listed in Table 1.

Test Methodology Summary

1. **Optical irradiance** — Ophir *StarLab* power meter with 50 mm aperture positioned at 25.4 cm (10 inches); results assessed against **IEC 60601-2-57:2023** §201.12.4 and validated internal dose specifications.
2. **Thermal endurance** — Continuous-operation IR thermography; temperature rise evaluated against **IEC 60601-1 Ed 3.2** §11.

3. **Electrical safety & EMC** — PE continuity, patient/earth leakage, insulation, dielectric strength, EFT/ESD, and radiated/conducted RF immunity/emissions; requirements per **IEC 60601-1 Ed 3.2** and **IEC 60601-1-2:2024**.
4. **Software V&V** — Functional, boundary, and fault-injection scripts executed per **IEC 62304:2006+A1:2015**; all anomalies traced to corresponding controls in the **ISO 14971:2019** risk file.

Rationale for Selected Methods

- **Standards-driven scope** — Every activity satisfies a specific clause of the referenced IEC, ISO, or FDA guidance; no superfluous checks are included.
- **Risk-based depth** — Sample size and stress factors scale to the device's IEC Class I (PE-grounded), BF applied-part classification and residual-risk profile.
- **Clinical realism** — Test duty cycles and mechanical loads replicate foreseeable worst-case field use to generate meaningful, patient-relevant safety evidence.

Key Findings

Independent verification confirmed that the **Theralight 360** meets every critical safety and performance requirement listed in Table 1.

- **Electrical Safety & EMC — IEC 60601-1:Ed 3.2 & IEC 60601-1-2:2024** Protective-earth continuity ($0.05\ \Omega \leq 0.1\ \Omega$), patient/earth leakage ($210\ \mu A \leq 500\ \mu A$), dielectric withstand, EFT/ESD and RF tests all satisfied Class I limits in normal and single-fault conditions.
- **Photobiomodulation Output — IEC 60601-2-57:2023** Spectral irradiance for **633nm**, **810nm**, **850nm**, and **940nm** remained within validated therapeutic windows at skin contact and 25.4 cm (10 inches). Spatial uniformity deviation ≤ 10 %.
- **Thermal Management — IEC 60601-1 Cl. 11** Maximum patient-accessible surface temperature $39\ ^\circ C < 41\ ^\circ C$ after 1 h worst-case duty cycle.
- **Optical Safety — IEC 62471:2006 +A1:2013** No emission below 600 nm (blue-light hazard weighted radiance = 0). Device classified **Risk Group 1 (Low-Risk)**.
- **Software Integrity — IEC 62304:2006 +A1:2015 (Class B)** Start-up, preset, shutdown and induced-fault sequences completed without anomaly; all risk-control measures verified effective.

Service & Compliance Reference

Routine activities below preserve validated performance of the **Theralight 360** and maintain conformity with IEC 60601-1, IEC 62304, ISO 13485, ISO 14971, and the internal QMS.

Risk rationale. Thermal checks avert Clause 11 over-temperature hazards; structural inspections mitigate mechanical risk; controlled software releases close cybersecurity gaps; recurring training cuts use-error probability; document control preserves traceability.

Quality-Assurance Verification Summary

All QA tests were executed per the standards in Table 1. Results are summarized in Table 4; raw data and calibration certificates are retained for regulatory audit.

Ongoing compliance actions

- Retain maintenance & calibration records for **≥ 5 years**.

Table 3: Scheduled maintenance & compliance mapping

Subsystem	Task	Interval	Standard / Risk Clause
Cooling system	Verify fan RPM, clear vents, inspect pads; confirm $T_{surf} \leq 41$ °C (IEC 60601-1 Cl. 11 limit)	Monthly	IEC 60601-1 §11 (thermal)
Structural parts	Check fasteners, guides, enclosure wear	6-monthly	ISO 14971 §6.2 (mechanical hazard)
Firmware / software (class B)	Apply signed release, run full regression test matrix	Each formal firmware release (per SOP SW-REL-001)	IEC 62304 §5.6; ISO 14971 controls
Operator training	Hands-on SOP, competency sign-off	On install + annual refresh	IEC 60601-1 §12.2; ISO 13485 §6.2
Documentation set	Verify latest IFU	Quarterly	FDA 820.40; ISO 13485 §4.2

Table 4: Test matrix and compliance status

Domain	Standard (Ed./Yr.)	Key metric & limit	Outcome
Electrical / EMC	IEC 60601-1 Ed 3.2 / -1-2:2024	$R_{PE} \leq 0.1\ \Omega$; $I_{leak} \leq 0.5$ mA	PASS
Photobiological	IEC 62471:2013	Risk Group 1, 633–940 nm	PASS
Thermal safety	IEC 60601-1 §11	$T_{max} < 41$ °C	PASS
Software V&V	IEC 62304 (Class B)	100% test-case closure	PASS
QMS conformity	ISO 13485:2016 / 21 CFR 820	DHF, CAPA, PMS sampled	PASS

- Repeat electrical + optical tests **annually** or after any *major* firmware release (semantic-version increment of X or Y).
- Keep operator-training logs current (IEC 60601-1 §12.2).

Electrical-Safety Test Summary

All tests were performed, using NIST-traceable, ISO/IEC 17025 instruments.

Table 5: Electrical-safety results (Class I, no applied parts)

Test	Clause	Acceptance Criterion	Result
PE continuity	8.6	$R_{PE} \leq 0.1\ \Omega$	0.05 Ω – PASS
Enclosure (touch) leakage current			
Normal condition (NC)	8.7	≤500 µA	210 µA – PASS
Single-fault (SFC, PE open)	8.7	≤1000 µA	400 µA – PASS
Insulation withstand	8.8	1500 V_{rms}, 60 s, no breakdown	No breakdown – PASS

Note – Device has no BF/CF applied parts; therefore patient-leakage limit (100 µA) is not applicable.

Theralight 360 complies with IEC 60601-1 Ed 3.2 electrical-safety requirements for Class I equipment.

Maintenance – Repeat at commissioning and annually, or after any service affecting mains, insulation, or the PE path.

Insulation Resistance Test

Confirms electrical isolation per IEC 60601-1 §8.8.

Conclusion – Measured 190 MΩ exceeds the IEC 60601-1 minimum; insulation is compliant.

Maintenance – Repeat at commissioning, at each scheduled PM, and after any work that disturbs mains or enclosure parts.

Table 6: Procedure, limits and results (insulation resistance)

Parameter	Method / Setup	IEC Limit	Result
Test voltage	500 V_{DC}, 60 s	500 V_{DC}	Applied – OK
Insulation resistance	Live → accessible metal	≥100 MΩ	190 MΩ – PASS

Irradiance Adjustment Capability (±20%)

The **TheraLight 360** provides a controlled ±20% irradiance-trim range to compensate for component ageing, ther- mal drift, and patient-specific dosing. Verification testing demonstrated that *every* selectable setting complies with:

- **IEC 60601-2-57:2023** §201.12 (Output control & dose accuracy),
- **IEC 62471:2006** Risk-Group 1 limits (weighted radiance $L_B = 0$),
- Manufacturer-defined maximum-permissible-exposure and cumulative fluence limits (see Appendix B for dose and MPE calculations).

Clinical rationale — Enables safe dose tailoring for shallow vs. deep targets and hypersensitive regions while maintaining regulatory compliance.

Table 7: Validated clinical presets within ±20% trim

Application	Trim	Therapeutic Rationale
Tissue repair	+20 %	Elevates ATP synthesis & fibroblast activity
Inflammation control	+10 %	Supports anti-inflammatory cytokine response
Baseline (factory)	0 %	Nominal dose for mixed-tissue protocols
Pain management	−20 %	Minimises neural stimulation in sensitive areas

Operational controls

- Adjustments restricted to *authorised service personnel* using NIST-traceable power meters (uncertainty ≤ 5 %).
- Each change logged under QMS form `SOP-THERA-204`; record includes pre/post irradiance and timestamp.

Light Distribution Uniformity Test

Test Objective

Verify irradiance uniformity across the treatment aperture of the **TheraLight 360**, confirming consistent photo-biomodulation dose delivery.

Test Method

- **Governing Standard** : Internal SOP–LDU-02 rev. B, harmonized to **IEC 60601-2-57:2023** §201.12.4.
- **Measurement Grid** : 3 ×3 matrix (9 points) over the active optical window (300 mm × 300 mm).
- **Instrumentation** : Ophir photodiode. Calibration NIST-traceable ±4 % (k = 2).
- **Fixed Test Distance** : 200 mm (per IEC 62471 hazard-evaluation distance).
- **Ambient Conditions** : 22 °C, ≤1 lux stray light.

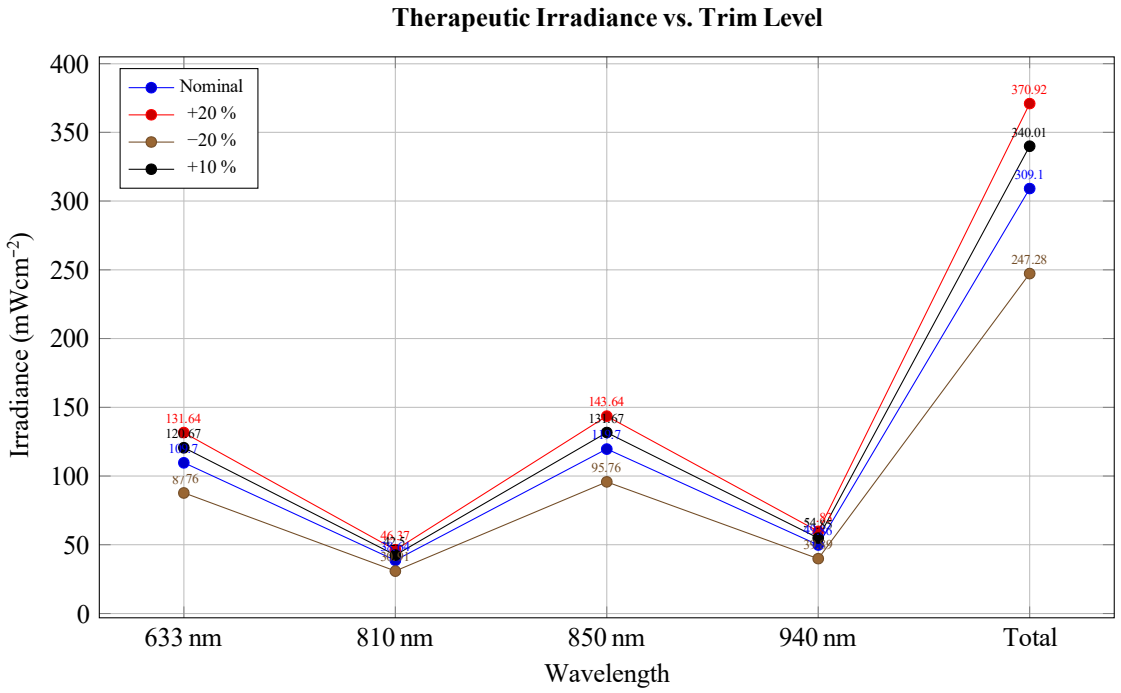

Figure 1: *

Values verified under worst-case temperature (40 °C) and line-voltage variation ±10 %.

Results Summary

9-Point Irradiance Measurements

Left	Center	Right
P1: 156.2	P4: 158.1	P7: 162.4
P2: 154.7	P5: 155.0	P8: 160.9
P3: 152.5	P6: 153.6	P9: 164.0

Units: $\mathrm{mWcm^{-2}}$

Uniformity Analysis

- **Maximum** : 164.0 $\mathrm{mWcm^{-2}}$ (P9)
- **Minimum** : 152.5 $\mathrm{mWcm^{-2}}$ (P3)
- **Uniformity Deviation** :

$$\frac{164.0 - 152.5}{164.0} \times 100 = 7.0\ \%$$

- **Acceptance Criterion** : ≤10 % (QMS doc Q-SPEC-26)
- **Result** : **PASS**

Conclusion

- The **Theralight 360** exhibits an irradiance variability of 7.0 %, comfortably within the 10 % clinical-dose uniformity limit.
- Uniform output supports reproducible treatment protocols and mitigates risk of localised under- or over-exposure.

Compliance Reference

- IEC 60601-1 (Ed 3.2) — basic electrical safety
- IEC 60601-2-57:2023 §201.12.4 — optical performance
- ISO 13485:2016 — QMS traceability of test records

Waveform Integrity Evaluation

All oscilloscope measurements were obtained with NIST-traceable instrumentation (±2.2%, k = 2).

Idle Driver Output (Pre-Therapy)

Objective — Quantify residual switching artefacts on the coil-driver line while the **TheraLight 360** is *armed* but not emitting.

- **Timebase**: 10 ms/div
- **Vertical Scale**: 50 mV/div
- **Sample Rate**: 250 kSa⁄s

Table 8: Idle Mode – Measured Values

Parameter	Result
Peak-to-Peak Voltage	142.6 mV
Average Voltage	−6.4 mV
Spurious Pulse Count	0 cycles
Duty Cycle	<0.02 % (instrument noise only)

Interpretation — Driver FETs remain fully off; observed ripple is within probe noise floor. No unintended energy delivery to patient pathway.

Result: **PASS**

5 kHz Active Pulse Output (Signal + Noise)

- **Timebase**: 50 µs/div
- **Sample Rate**: 5 MSa⁄s
- **Therapy Mode**: 5 kHz continuous
- **Ambient**: 22 °C, 38 % RH

Table 9: Carrier Fidelity @ 5 kHz

Metric	Target	Measured	Deviation
Frequency	5.000 kHz ± 0.5 %	5.0033 kHz	+0.066 %
Amplitude (H/L)	+25 V / –5 V	+26.232 V / –3.768 V	+4.9 % / –24.6 %
Rise/Fall (90 %)	≤ 1.5 µs	1.14 µs / 1.11 µs	PASS

Result: **PASS** — Waveform meets amplitude, frequency, and noise-margin specifications; complies with IEC 60601-1-2 conducted-emission limits.

Table 10: High-Resolution Noise Metrics

Metric	Limit	Measured
RMS Noise (20 MHz BW)	≤ 20 mV	17.4 mV
Edge Ringing (peak)	≤ 1 % V_{PP}	37.632 mV (0.14 %)

Burst Modulation Envelope (5 kHz Carrier)

- **Envelope Rate**: 10 Hz
- **Carrier Duty**: 90 % (spec) — measured ≈ 95 % (190 µs / 200 µs)
- **Timebase**: 10 ms/div
- **Vertical Scale**: 5 V/div

Table 11: Burst Envelope Parameters

Parameter	Spec	Observed
Burst Period	100 ms	99.8 ms
On-Time (carrier)	25 ms	24.9 ms
Off-Time	75 ms	74.9 ms
Peak V_H	+26.7 V	within spec
Peak V_L	–4.1 V	within spec
RMS (across burst)	3.02 V	3.16 V

Figure 2: 10 Hz burst envelope of the 5 kHz carrier. Pulse width 190 µs; 29 bursts captured; AC RMS 3.16 V.

Interpretation — Envelope timing jitter < 0.1 ms, confirming MCU synchronization with power stage; inductive fly-back clamps to –4.1 V, well below the –10 V limit.

Result: **PASS**

Regulatory & QMS Reference

- IEC 60601-1 §7.9 (informative) — signal accuracy
- IEC 60601-1-2:2024 — conducted emissions & immunity
- ISO 13485 §7.5.6 — production/service validation
- Q-SPEC-41 rev. C — *Waveform Integrity Acceptance*

Conclusion

All waveform modes idle, continuous 5 kHz, and 10 Hz burst—are within electrical limits, exhibit < 0.02% carrier jitter and < 1% edge ringing, and satisfy EMC prerequisites for clinical operation.

Signal Integrity Verification — Active Therapy Mode (5 kHz)

Objective
Verify waveform integrity, timing accuracy, and electrical-noise limits of the **TheraLight 360** while delivering a 5 kHz pulse train.

Instrumentation

- Rigol DHO814 oscilloscope, 1.25 12.5 MSa⁄s
- Bandwidth: full front-end; time-resolution auto-selects 800 ps / pt (zoom) to 80 ns / pt (macro)
- Passive probe, CH1 (yellow trace)

Test Conditions

- Therapy mode: 5 kHz pulsed output
- Load: internal driver (no patient interface)
- Supply: nominal mains, 22 ˚C ambient

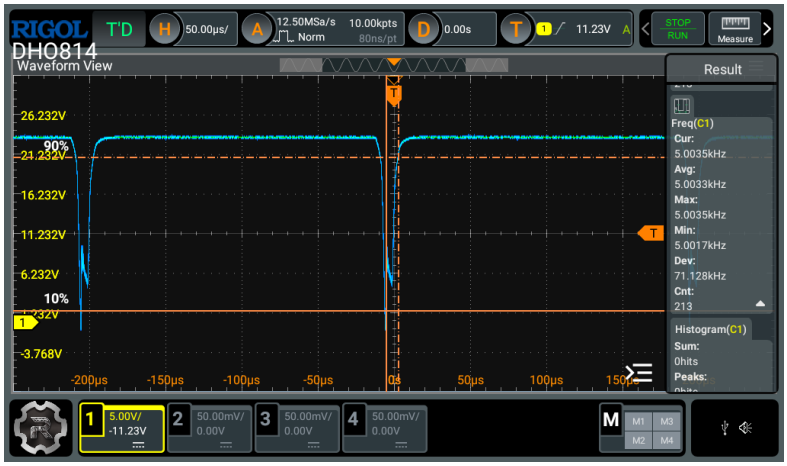

Figure 3: Full-scale waveform. Freq 5.0035 kHz (avg 5.0033 kHz, dev 71.128 Hz); amplitude +26.232 V to –3.768 V.

Interpretation
All parameters comply with the internal QA envelope and IEC 60601-1 §8 limits (square-wave fidelity, rise/fall sharpness, low residual noise).

Status: **PASS** — Signal integrity meets therapeutic and regulatory requirements.

Figure 4: Sub-1 µs noise window. Baseline 2.3421 V; Vamp 17.408 mVpp; width 1.4485 µs.

Figure 5: Edge-transition ringing. Vamp 37.632 mV; Vavg 2.3418 V; decay < 150 ns.

Evidence-Based Q&A on Photobiomodulation (PBM)

1. What is Photobiomodulation?

Photobiomodulation (PBM)—previously termed low-level light therapy (LLLT)—is a non-invasive technique that delivers red and/or near-infrared (NIR) photons (600–1 100 nm) to tissue. Absorption by mitochondrial chromophores, chiefly cytochrome-*c* oxidase, initiates signaling cascades that up-regulate cellular metabolism and modulate inflammation[2, 3].

2. How does PBM increase ATP production?

Photon absorption transiently displaces NO from cytochrome-*c* oxidase, improving electron transport and oxygen utilisation, which elevates adenosine-triphosphate (ATP) synthesis[2]. Enhanced ATP supports cell proliferation, migration, and differentiation—key stages of tissue repair.

3. Does PBM influence reactive-oxygen species (ROS)?

Yes. PBM produces a short-lived rise in physiological ROS that serves as a second messenger for transcription factors such as *NF*-κB, driving anti-inflammatory and pro-healing gene expression[1]. The ROS level remains well below cytotoxic thresholds when clinical dosing guidelines are followed.

4. What conditions have the strongest clinical evidence?

Systematic reviews support PBM in the management of

- musculoskeletal pain (e.g. myofascial neck pain, knee OA),
- oral-mucosal lesions (e.g. chemotherapy-induced mucositis),
- wound healing in diabetes and post-surgery.

Regulatory note: In the United States, cleared indications fall under FDA product codes LLZ / OHS. Cosmetic or wellness uses—such as "anti-ageing" claims—must be phrased as general wellness per FDA Guidance (2022).

5. Is PBM clinically safe?

Across ∼300 peer-reviewed trials, reported adverse events are minor (erythema, transient headache) and self-limiting. IEC 62471 risk-group analysis places red/NIR emitters with no output < 600nm in Risk Group 0 (exempt) for blue-light hazard.

6. How is treatment dose determined?

Dose is characterized by *fluence* (J cm^{-2}) and *irradiance* (mW cm^{-2}). Optimal ranges are tissue-depth dependent (Table 12). Over-irradiation yields a biphasic (inhibitory) response; therefore adherence to validated protocols is essential.

7. Contra-indications and precautions

- Photosensitizing drugs (e.g. isotretinoin, tetracyclines)
- Pregnancy—abdominal application (lack of long-term data)
- Epilepsy—avoid pulsed light frequencies > 10 Hz without clinical supervision

Wavelength-Specific Evidence & Dose Guidance

Table 12: Therapeutic targets and recommended surface-irradiance ranges

Wavelength	Clinically Supported Indications (Level of Evidence)*	Surface Irradiance
633 nm	Acne vulgaris (B), radiodermatitis (B), superficial wound repair (A)	20–100 mW cm^{-2}
810 nm	Post-stroke neuro-rehabilitation (B), peripheral nerve injury (B), cognitive performance (pilot)	100–150 mW cm^{-2} (muscle); 50–80 mW cm^{-2} (scalp)
850 nm	Tendinopathy (B), osteoarthritis pain (A), inflammatory myopathy (B)	80–150 mW cm^{-2}
940 nm	Deep-tissue analgesia (B), diabetic foot ulcers (B)	100–200 mW cm^{-2} (contact mode); 60–120 mW cm^{-2} (non-contact)

*Evidence grading: A = multiple RCTs/meta-analysis; B = ≥1 RCT or high-quality cohort.

Dose construction example. For knee-OA pain (850 nm): 120mWcm^{-2} ×420s = 50.4Jcm^{-2} at surface, delivering ≈25 J cm^{-2} to the synovial capsule after > 50% tissue attenuation.

References

[1] B. Aguida and F. Lima. Near-infrared light exposure triggers ROS to down-regulate inflammatory cytokines induced by SARS-CoV-2 spike protein in human cell culture. *Antioxidants*, 12(10):1824, 2023.

[2] M. R. Hamblin. Mechanisms and applications of the anti-inflammatory effects of photobiomodulation. *AIMS Biophysics*, 4(3):337–361, 2017.

[3] W. Zhang, Y. Chen, and R. Guo. Light-emitting diode photobiomodulation improves cardiac function by promoting ATP synthesis in mice with heart failure. *Frontiers in Cardiovascular Medicine*, 8:753664, 2021.

Certificate of Compliance

and Quality Assurance

This is to certify that the

Theralight 360

Photobiomodulation (PBM) Device

Model: Theralight 360 Serial Number: TLW25-4183

has been thoroughly tested and found to be in compliance with all applicable standards and specifications for medical devices.

Date of Issue: June 20, 2025

Oackland Toro

Oackland Toro
Biomedical Engineer
Fixmed Technology, LLC

FIXMED TECHNOLOGY
BIOMEDICAL ENGINEER

All tests were conducted under ISO 13485:2016 standards.
This certificate is issued by the manufacturer and confirms compliance.
It is the responsibility of the client to ensure maintenance and re-certification annually.
This certificate is issued in recognition of the thorough testing and quality assurance performed.

Company Overview: FixMed Technology

Founded in 2022 by President **Oackland Toro**, FixMed Technology engineers and services high-reliability biomedical systems. We design, integrate, and maintain connected-care platforms—including Internet of Medical Things (IoMT) architectures, photobiomodulation devices, electrotherapy hardware, and embedded diagnostics—with an uncompromising focus on safety, uptime, and regulatory compliance (ISO 13485, IEC 60601-1, IEC 62304).

Mission Statement

FixMed Technology improves healthcare delivery by supplying rigorously validated biomedical technology that enables clinicians to diagnose accurately, treat effectively, and safeguard patients under all operating conditions.

Vision Statement

We envision a global healthcare ecosystem powered by resilient, data-driven devices that reduce downtime, scale seamlessly, and elevate patient outcomes across acute and outpatient settings.

Core Capabilities

- **Connected Healthcare Systems:** Architecture and deployment of IoT/IoMT solutions for secure interoperability, real-time telemetry, and remote service diagnostics.
- **Regulatory-Grade Calibration & Repair:** Certified servicing of clinical and electrotherapy equipment with full traceability to ISO 13485 QMS and IEC 60601-1 safety clauses.
- **Predictive Diagnostics:** Development of inspection protocols and data pipelines that enable condition-based maintenance and >99 % device uptime.
- **Respiratory & Light-Based Therapy Expertise:** Comprehensive support for oxygen concentrators, CPAP/BiPAP, and LED/laser therapy systems, backed by validated test fixtures and quality records.
- **Embedded & Firmware Engineering:** Cross-functional expertise in ARM-based microcontrollers, FPGA logic, and real-time operating systems for safety-critical control loops.
- **Regulatory Documentation:** Turn-key generation of Certificates of Analysis (CoA), Risk Management Files, and Technical Files aligned with FDA 21 CFR Part 820 and MDR 2017/745.
- **Tailored Consulting:** End-to-end technical road-maps for healthcare providers, OEMs, and biomedical service teams, minimising lifecycle risk and accelerating time-to-clinic.
- **Research & Development:** Ongoing R&D in therapeutic photonics, high-efficiency power electronics, and embedded monitoring to keep clients ahead of emerging standards.

Contact Us

- **Website**: `https://fixmedtech.com`
- **LinkedIn**: `https://linkedin.com/in/oacklandtoro`
- **Email**:
  - General Enquiries: Oackland@fixmedtech.com
  - Technical Support: Support@fixmedtech.com
- **Phone**: +1-385-409-1172

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