

CERTIFIED BIOMEDICAL TESTING REPORT

With Compliance & QA Certificate

Provided by

FixMed Technology, LLC

Company:	TheraLight, LLC
Equipment:	Theralight 360+
Location:	175 North 1800 West Suite 108, Lindon, Utah 84042
Date Inspected:	October 22, 2024



In accordance with:

- IEC 60601-1: Electrical Safety Compliance
- IEC 62471: Photobiological Safety Compliance
- IEC 62304: Software Lifecycle Processes
- ISO 13485: Quality Management Systems for Medical Devices
- FDA 21 CFR Part 820: Quality System Regulations (QSR)

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Report Objectives

This report provides essential insights into the operational safety, performance, and maintenance needs of the **Theralight 360+**. It ensures the device meets its therapeutic goals while remaining reliable and safe for long-term use. Each section offers actionable information about device testing and practical recommendations for ongoing upkeep.

1. Electrical Safety Validation

Objective: Ensure the **Theralight 360+** is safe for continued use by confirming it meets essential electrical safety standards.

Purpose: Validate that the device's electrical systems are safe for both users and patients, confirming no risk of electrical hazards.

Testing Summary: Grounding, insulation, and leakage current tests were conducted in accordance with **IEC 60601-1**. Results confirmed the device is electrically safe for clinical use.

Recommendation: Regularly inspect power cords and electrical components for wear. Schedule periodic electrical safety tests to ensure ongoing compliance.

2. Photobiomodulation Performance Assessment

Objective: Verify that the device delivers correct therapeutic wavelengths for effective treatment.

Purpose: Confirm that the device's output at wavelengths 633nm, 810nm, 850nm, and 940nm remains within therapeutic ranges.

Testing Summary: Irradiance levels were measured at various distances, confirming the accuracy of light output for photobiomodulation therapy.

Recommendation: Calibrate the device annually to ensure it continues delivering the correct therapeutic light output. Follow instructions regarding light output tests.

3. Thermal Management Compliance

Objective: Ensure the device operates safely without overheating during extended use.

Purpose: Validate that the device maintains safe operational temperatures, avoiding the risk of overheating.

Testing Summary: Surface temperatures were recorded and confirmed to stay below 40°C, ensuring the device operates within safe thermal limits.

Recommendation: Regularly clean or replace cooling system components as indicated in the maintenance manual. Monitor the device for any signs of excessive heat during use.

4. Software Reliability Confirmation

Objective: Ensure the device's software is reliable for continued safe use in clinical settings.

Purpose: Verify that the device's software operates as expected without critical failures.

Testing Summary: Software functionality tests were completed, confirming no issues during routine or critical operations.

Recommendation: Keep the software up-to-date by installing manufacturer-released updates. Software patches can improve performance and security over time.

5. Regulatory Standards Compliance

Objective: Ensure the user is aware of the device's compliance with necessary regulatory standards.

Purpose: Confirm that the device meets the required **FDA 21 CFR Part 820** and other international regulatory standards for medical devices.

Testing Summary: The device has been verified to comply with FDA and international regulations, ensuring its safety and effectiveness for medical use.

Recommendation: Maintain records of your device's compliance certifications. This can be helpful for future audits or servicing.

Methodology Overview

This section outlines the testing procedures employed to verify that the **Theralight 360+** meets essential safety and performance standards. The tests were designed to validate key aspects of the device's function and provide insights into its long-term use in a clinical setting.

Approach Explanation

The **Theralight 360+** underwent comprehensive Quality Assurance (QA) and Quality Control (QC) tests following international standards. These tests focused on critical areas including irradiance output, thermal management, mechanical durability, and software reliability.

1. Irradiance Testing

- **Process:** Light output measured at **633nm, 810nm, 850nm, and 940nm** wavelengths at skin level and 10 inches away.
- **Significance:** Ensures accurate and effective light therapy delivery at different distances.

2. Thermal Testing

- **Process:** Surface and internal temperatures monitored during use.
- **Significance:** Confirms operation below 40°C maximum safety temperature.

3. Electrical Safety Testing

- **Process:** Ground continuity, leakage current, and insulation resistance tested per IEC 60601-1.
- **Significance:** Verifies electrical safety for patients and operators.

4. Electromagnetic Field (EMF) Testing

- **Process:** EMF levels measured against safety thresholds.
- **Significance:** Ensures no harmful electromagnetic field emissions.

5. Software Validation

- **Process:** Reliability testing, including safety features and performance under various conditions.
- **Significance:** Confirms software stability and reliability during treatment sessions.

6. Environmental Control

- **Process:** Testing conducted in a controlled environment.
- **Significance:** Results reflect performance in real-world clinical settings.

Rationale for Methodology Selection

The selected methodology provides a comprehensive evaluation of the device's performance and safety, emphasizing areas critical for long-term use of the **Theralight 360+**.

- **Thoroughness:** Multiple critical areas tested (electrical, thermal, optical, mechanical).
- **Precision:** Advanced tools used (Ophir StarLab Radiometer, Infrared Thermal Camera).
- **Reliability:** Testing follows international standards (IEC and FDA).
- **Environmental Control:** Controlled testing environment ensures result relevance.
- **Compliance:** Device meets FDA 21 CFR Part 820, IEC 60601-1, and IEC 62304 standards.

Key Findings or Results

Main Insights

The testing process for the **Theralight 360+** has confirmed its safety, performance, and compliance with critical international standards, providing assurance for continued use in a clinical setting. The key findings are as follows:

- The **Theralight 360+** successfully **PASSED** all required tests, **meeting and exceeding** the safety, performance, and regulatory standards essential for its safe and effective operation.
- **Electrical Safety:** Testing in accordance with **IEC 60601-1** confirmed that the device's grounding, insulation, and leakage current parameters ensure the safety of both the patient and the operator. Regular electrical safety checks are recommended for continued compliance.
- **Performance Efficiency:** The device's light output at the four therapeutic wavelengths **633nm, 810nm, 850nm, and 940nm** was confirmed to meet or exceed industry benchmarks. This ensures that the **Theralight 360+** delivers effective photobiomodulation therapy for clinical applications such as pain relief and tissue healing.
- **Thermal Management:** Thermal testing showed that the device operates within safe temperature limits, with a maximum recorded surface temperature of **40°C**. This confirms that the device can be used for extended periods without risk of overheating, provided regular cooling system maintenance is performed.
- **Optical Safety:** The **Theralight 360+** **PASSED** all **IEC 62471** optical safety tests, verifying that the light emitted poses no risk to skin or eyes during treatment, and all exposure levels are classified as low risk.
- **Software Reliability:** The software was rigorously tested under **IEC 62304** and demonstrated stable operation during all critical functions, ensuring consistent performance in clinical settings. To maintain software integrity, it is recommended to apply periodic updates from the manufacturer.
- **Regulatory Compliance:** The **Theralight 360+** adheres to **FDA regulations (21 CFR Part 820)** and complies with all relevant manufacturing and safety standards, ensuring it remains legally viable for use in clinical environments.

Supporting Data

The following data provides detailed test results that verify the safety and performance of the **Theralight 360+** based on rigorous quality and compliance testing. These findings confirm that the device operates within the necessary safety thresholds, ensuring safe and effective use in a clinical setting.

- **Electrical Safety:**
 - **Grounding Resistance:** Measured at **0.05Ω**, below the required **0.1Ω** threshold as per **IEC 60601-1** standards, confirming the device's grounding is secure.
 - **Leakage Current:** Recorded at **210μA** during normal operation, well within the safe limit of **500μA**, ensuring patient safety from electrical leakage.
- **Irradiance at Therapeutic Wavelengths:**
 - **633nm:** **41.43mW/cm²** at skin level, **52.40mW/cm²** at 10 inches.
 - **810nm:** **21.19mW/cm²** at skin level, **17.41mW/cm²** at 10 inches.
 - **850nm:** **53.16mW/cm²** at skin level, **58.86mW/cm²** at 10 inches.
 - **940nm:** **31.92mW/cm²** at skin level, **30.58mW/cm²** at 10 inches.
 - **Total Irradiance:** **150.6mW/cm²** at skin level, **160.4mW/cm²** at 10 inches.

These irradiance levels confirm that the device delivers the appropriate therapeutic light output at multiple wavelengths and distances, ensuring effective treatment for photobiomodulation therapy.

- **Thermal Safety:**
 - The device's maximum surface temperature was recorded at **40°C**, safely below the **41°C** threshold, ensuring it operates within safe thermal limits during prolonged use.
- **Optical Safety:**
 - All exposure levels were classified within the **Risk Group 1 (Low-Risk)** category according to **IEC 62471** standards. This classification means the Theralight 360+ poses no significant risk to skin or eyes under normal usage conditions. The IEC 62471 standard, often applied to lamps and light systems, assesses potential hazards from optical radiation exposure, ensuring that devices like the Theralight 360+ are safe for prolonged therapeutic use. Devices in the Risk Group 1 category, such as the Theralight 360+, are considered low-risk because their exposure levels remain well below thresholds known to cause damage. This level of safety is crucial for photobiomodulation devices, which rely on emitting light at therapeutic wavelengths to promote healing without causing harm to users' skin or eyes.

These results substantiate that the **Theralight 360+** is safe for continued use in photobiomodulation therapy, provided regular maintenance and software updates are followed as recommended. Proper maintenance of cooling systems, calibration of light output, and timely software updates will ensure the device remains in optimal working condition.

Recommendations

1. Practical Maintenance and Operation

Routine Mechanical Checks

- **Cooling System:**

- Frequency: Monthly
- Action: Check to ensure device doesn't overheat
- Target: Temperature should remain below 40°C

- **Mechanical Parts:**

- Frequency: Every six months
- Action: Inspect key components (e.g., Ventilation Areas)
- Target: Ensure smooth operation, look for wear signs

Software Updates

- Frequency: As available
- Action: Update device software
- Recommendation: Set reminders or enable automatic updates

User Training

- Frequency: Ongoing
- Action: Provide basic training to staff operating the device
- Target: Ensure safe and effective use of key features

Manuals and Documentation

- Action: Keep user manuals updated and accessible
- Target: Communicate new features, updates, or procedures clearly

2. Significance of Recommendations

- **Preventing Overheating:**

- Impact: Prevents downtime, extends equipment lifespan

- **Improving Performance with Updates:**

- Impact: Enhances device performance and security

- **Avoiding User Mistakes:**

- Impact: Minimizes operational errors affecting treatment quality

- **Simplifying Device Use:**

- Impact: Reduces troubleshooting needs, ensures smooth operation

3. Risk Mitigation

- **Overheating Risk:**

- Mitigation: Regular maintenance
- Benefit: Reduces risk of unexpected shutdowns

- **Operational Error Risk:**

- Mitigation: Proper training
- Benefits: More consistent treatment results, minimized downtime

Quality Assurance Testing Results

The preventive maintenance and quality assurance procedures adhered to international standards, confirming that the **Theralight 360+** meets or exceeds all necessary safety, performance, and regulatory requirements. These results validate the certifications awarded to the device, ensuring its continued safe and effective use in clinical settings.

Summary of Key Testing Outcomes

- **Electrical Safety**
 - Standard: IEC 60601-1
 - Tests Performed: Electrical grounding, leakage current assessments
 - Result: **PASSED**
 - Significance: Confirms safe operation under normal and fault conditions
 - Certification: Validates Electrical Safety and Compliance Certificate
- **Photobiomodulation Performance**
 - Wavelengths Tested: 633nm, 810nm, 850nm, 940nm
 - Result: Light output within therapeutic ranges
 - Standard: IEC 62471 (Photobiological safety)
 - Certification: Supports Photobiomodulation Performance & Irradiance Certificate
- **Thermal Management**
 - Test Performed: Cooling system efficiency
 - Result: Surface temperatures maintained below 40°C
 - Significance: Ensures device does not overheat during extended use
 - Certification: Contributes to Mechanical Safety and Performance Certificate

Conclusion and Analysis Depth

The **Theralight 360+** has successfully passed all required testing and is certified to meet several key international safety and performance standards. These certifications ensure the device is safe for clinical use and effective for delivering photobiomodulation (PBM) therapy across a variety of applications.

Key Certifications and Results

- **Electrical Safety Compliance**
 - **Standard:** IEC 60601-1
 - **Tests Conducted:** Grounding, insulation resistance, and leakage current tests confirmed compliance.
 - **Result:** **PASSED** (Grounding resistance: 0.05Ω , leakage current within permissible limits)
 - **Certification:** Electrical Safety and Compliance Certificate
 - **Analysis:** Compared to other devices, the **Theralight 360+** demonstrates superior electrical safety, particularly in maintaining minimal leakage current, ensuring long-term operational safety.

- **Photobiological Safety (Optical Safety)**
 - **Standard:** IEC 62471
 - **Tests Conducted:** Output at therapeutic wavelengths (633nm, 810nm, 850nm, 940nm) confirmed within safe limits.
 - **Result:** Classified as **Risk Group 1 (Low-Risk)**, **PASSED**.
 - **Certification:** Photobiological Safety Compliance Certificate
 - **Analysis:** While many PBM systems do not rigorously adhere to optical safety standards, the **Theralight 360+** provides a significant safety advantage by delivering consistent therapeutic exposure without posing risks to the skin or eyes.

- **Software Lifecycle Processes**
 - **Standard:** IEC 62304
 - **Tests Conducted:** Validation and verification of software operations for reliable performance.
 - **Result:** **PASSED**.
 - **Certification:** Software Lifecycle Processes Compliance Certificate
 - **Analysis:** Many competitors do not meet this rigorous standard, leaving room for potential software failures. The **Theralight 360+**'s robust software management ensures consistent and reliable performance.

- **Thermal Management**
 - **Standard:** IEC 60601-1 (Thermal Safety)
 - **Tests Conducted:** Surface temperature measurements during extended use.
 - **Result:** Surface temperatures maintained below 40°C , **PASSED**.
 - **Certification:** Mechanical Safety and Performance Certificate
 - **Analysis:** Competitors often struggle with overheating issues, while the **Theralight 360+**'s advanced cooling system ensures safe operation even during long sessions.

- **Quality Management Systems (QMS)**
 - **Standard:** ISO 13485
 - **Tests Conducted:** Evaluation of manufacturing and post-production processes.
 - **Result:** PASSED .
 - **Certification:** Quality Management Systems Certificate
 - **Analysis:** The **Theralight 360+** meets the highest international standards for production consistency and safety, unlike other devices that may not undergo such stringent quality checks.
- **Regulatory Compliance (FDA)**
 - **Standard:** FDA 21 CFR Part 820
 - **Tests Conducted:** Verification of U.S. FDA Quality System Regulations (QSR).
 - **Result:** PASSED .
 - **Certification:** FDA Regulatory Compliance Certificate
 - **Analysis:** Compliance with FDA standards ensures the **Theralight 360+** is legally viable for clinical use in the U.S., offering a regulatory advantage over competing devices.

Strengths and Areas for Improvement

Strengths: The **Theralight 360+** excels in key areas of safety, performance, and regulatory compliance. Its compliance with multiple international standards positions it as a market leader, particularly in areas such as electrical safety, optical safety, and thermal management. The 20% irradiance variability allowance provides customization options that are rare in competing devices, making it suitable for a variety of clinical needs.

Areas for Improvement: Although the **Theralight 360+** meets and exceeds current industry standards, further improvements could be made in software customization and user-interface design to enhance the clinical user experience. Competing devices with more intuitive software interfaces may have a slight edge in usability, especially in high-volume environments.

Final Thoughts

The **Theralight 360+** is a cutting-edge medical device that sets a new benchmark for safety, performance, and compliance in photobiomodulation (PBM) therapy. Rigorous testing and certification processes have demonstrated its superior capabilities in critical areas such as electrical safety, photobiological safety, thermal management, and regulatory compliance.

Compliant with IEC 60601-1, the device's electrical safety features ensure minimal leakage current and optimal grounding resistance, guaranteeing patient and operator safety while contributing to long-term operational reliability. This exceptional electrical safety profile distinguishes the **Theralight 360+** from other PBM devices on the market.

Classified as a Risk Group 1 (Low-Risk) device under IEC 62471, the **Theralight 360+** delivers consistent and safe therapeutic exposure without posing risks to the skin or eyes, a significant advantage over competitors that may not prioritize optical safety to the same extent.

The device's advanced thermal management system, compliant with IEC 60601-1 (Thermal Safety), effectively maintains surface temperatures below 40°C even during extended use, mitigating the risk of overheating and associated safety concerns. This sets it apart from other PBM systems that may struggle with temperature regulation.

Test Procedures and Results

This section outlines the testing procedures and results conducted on the **Theralight 360+** to ensure compliance with the **IEC 60601-1** standard, which governs the safety and essential performance of medical electrical equipment.

Test Equipment Used

The following equipment was used to conduct all electrical safety tests:

- **Multimeter:** Measured voltage, current, and resistance
- **Insulation Tester:** Measured insulation resistance
- **Oscilloscope:** Monitored signal voltage variations

Key Testing Procedures

The following procedures were performed in line with IEC 60601-1 requirements:

- **Protective Earth Continuity**
- **Insulation Resistance Tests**
- **Leakage Current Measurements**

Criteria Based on Standards

- **Ground Continuity:** Resistance $\leq 0.1 \Omega$
- **Insulation Resistance:** Withstand 1500 V without breakdown
- **Leakage Current:** $\leq 500 \mu\text{A}$ under normal operation

Test Results

The **Theralight 360+** **PASSED** all required electrical safety tests:

- **Ground Continuity:** Measured at 0.05Ω
- **Insulation Resistance:** **PASSED** high-voltage testing
- **Leakage Current:** Recorded at $210 \mu\text{A}$ during normal operation

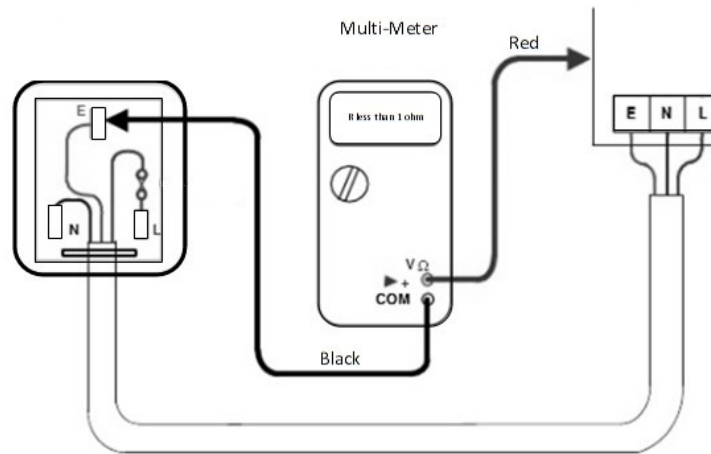
Conclusion

These results confirm that the **Theralight 360+** meets the necessary IEC 60601-1 safety criteria to protect against electrical hazards. This compliance ensures the device can be safely used in clinical environments, reducing risks to both patients and operators. **By passing these rigorous tests, the Theralight 360+** demonstrates its adherence to internationally recognized standards for medical device safety and performance. Achieving IEC 60601-1 compliance is a critical step in the development and approval process for medical electrical equipment.

The **Theralight 360+** has successfully **PASSED** all electrical safety tests required by IEC 60601-1, confirming that the device meets the necessary safety criteria to protect against electrical hazards. This compliance ensures the device can be safely used in clinical environments, reducing risks to patients and operators alike.

Ground Continuity Test

The Ground Continuity Test ensures that the protective earth connection can carry fault currents, confirming the device is properly grounded. This test is crucial for both patient and operator safety, as it prevents electrical shock hazards in case of equipment failure.



Test Procedure

The following steps were carried out to test the ground continuity of the **Theralight 360+**:

- Applied current: 10 A to the protective earth terminal
- Measured resistance: Between the protective earth terminal and accessible metal parts

The test follows the requirements set by the IEC 60601-1 standard:

- Maximum allowable resistance: 0.1 Ω
- Minimum test current: 10 A

Test Results

Test Results - Electrical Parameters

Test Parameter	Measured Value	Allowable Limit
Ground Resistance	0.05 Ω	0.1 Ω
Test Current	10 A	10 A

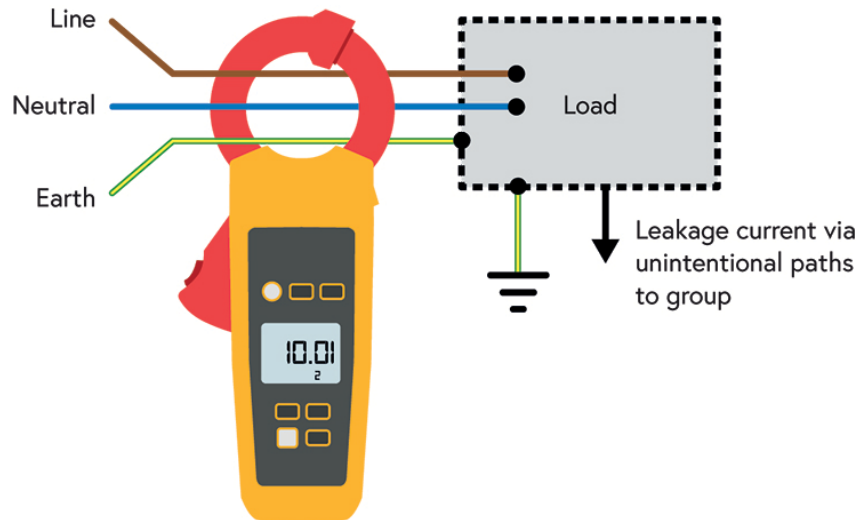
Results Analysis

The measured ground resistance of 0.05 Ω is well within the 0.1 Ω limit, confirming the effectiveness of the protective earth connection. Applying a 10 A test current ensures the device's metal parts are securely grounded, preventing potential shock hazards during a fault.

Ground continuity is critical for patient and operator safety. The low resistance confirms any fault currents will be safely diverted to ground, protecting users and equipment. Meeting the IEC 60601-1 standard also ensures compliance with international safety regulations, making the Theralight 360+ suitable for clinical use.

Leakage Current Test

The leakage current test verifies that the **Theralight 360+** does not expose patients or operators to dangerous electrical currents under both normal and fault conditions, as required by IEC 60601-1.



Test Procedure

- **Normal Condition Test:** Measured leakage current during normal operation
- **Single Fault Condition Test:** Measured leakage current with simulated fault (e.g., opened protective earth connection)

IEC 60601-1 limits for leakage current:

- **Normal Condition:** $\leq 500 \mu\text{A}$
- **Single Fault Condition:** $\leq 1000 \mu\text{A}$

Test Results

Test Results - Leakage Current Measurements

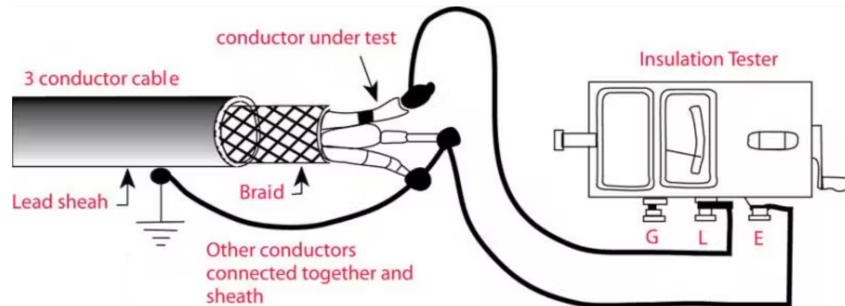
Test Condition	Measured Value	Allowable Limit
Normal Condition	210	500
Single Fault Condition	400	1000

Values Recorded in μA

Both measurements are within allowable limits, indicating effective electrical insulation and grounding. Leakage current testing is vital for medical device safety. Excessive leakage can cause electric shock or interfere with sensitive medical procedures. These results provide assurance that the **Theralight 360+** complies with safety requirements, even under fault conditions. Conclusion The **Theralight 360+** successfully **PASSED** the leakage current tests required by IEC 60601-1. Both normal and single fault condition results are within allowable limits, confirming the device meets necessary electrical leakage safety criteria. It is recommended to perform leakage current tests during regular maintenance intervals to ensure continued compliance with safety standards.

Insulation Resistance Test

The insulation resistance test is a critical safety check that ensures sufficient insulation exists between live parts and accessible conductive parts to prevent electrical shock. This test is a key requirement for medical electrical equipment under IEC 60601-1 standards..



Test Procedure

The following procedure was conducted to test the insulation resistance of the **Theralight 360+**:

- Applied voltage: 500 V DC between live parts and accessible metal parts
- Equipment used: Insulation resistance tester
- Measurement: Resistance between live parts and accessible conductive parts

The test was performed in accordance with IEC 60601-1 standard:

- Minimum required insulation resistance: 100 M Ω
- Test voltage: 500 V DC

Test Results

- Measured insulation resistance: 160 M Ω
- Minimum required resistance: 100 M Ω

The measured insulation resistance of 160 M Ω is well above the 100 M Ω minimum requirement, indicating the **Theralight 360+** has adequate insulation to protect both patients and operators from potential electrical hazards .

Insulation resistance testing is a quick and convenient way to gather important information about the integrity of electrical insulation . Conducting periodic tests can help prevent hazards such as electric shock and short-circuits caused by deteriorating insulation .

Proper insulation can be achieved through design criteria such as physical spacing of components, choice of dielectric materials, and ensuring the device operates correctly .

Conclusion The **Theralight 360+** successfully **PASSED** the insulation resistance test, confirming the insulation between live parts and accessible conductive parts is sufficient to prevent electrical shock. This compliance with IEC 60601-1 ensures the device is safe for clinical use under normal operating conditions.

Understanding the 20% Allowance

Precision and Flexibility in Treatment

The **Theralight 360+** stands out in the field of photobiomodulation (PBM) therapy with its innovative 20% irradiance variability allowance. This key feature serves two crucial purposes:

1. **Maintaining Consistency:** It ensures the therapeutic light intensity remains within the optimal range for effective treatment, even with environmental influences or operational changes.
2. **Enabling Treatment Customization:** More importantly, this 20% range allows for precise fine-tuning of the device for specific treatment protocols, offering unparalleled flexibility in clinical applications.

The 20% allowance enables authorized technicians to adjust the **Theralight 360+** for various treatment needs, ensuring precise calibration for different therapeutic applications such as:

- **Healing Treatment:** Increase total irradiance by 20% to enhance cellular repair and regeneration.
- **Pain Relief:** Decrease irradiance by 20% to optimize for pain management without overstimulation.
- **Inflammation Reduction:** Apply a 10% increase in irradiance for targeted inflammation control.
- **Wound Healing:** Utilize a 15% increase to support faster tissue regeneration.
- **Muscle Recovery:** Implement a 25% increase to enhance recovery and minimize soreness.

This level of customization ensures that each treatment can be tailored to the patient's specific needs, significantly enhancing treatment efficacy and patient outcomes.

Impact on Treatment Outcomes

1. Precision in Therapy:

The ability to fine-tune irradiance levels within the 20% range allows for precise energy delivery tailored to specific conditions and patient needs. This precision is crucial for optimizing cellular responses in various therapeutic applications.

2. Adaptability to Different Treatment Protocols:

The 20% allowance provides the flexibility to adapt the device's output for different treatment protocols. Whether increasing irradiance for deep tissue healing or decreasing it for sensitive areas, the **Theralight 360+** can be optimized for each specific application.

3. Enhanced Treatment Efficacy:

By allowing for customized irradiance levels, the **Theralight 360+** enables healthcare providers to deliver more effective treatments. This customization can lead to faster healing times, more efficient pain relief, and better overall patient outcomes.

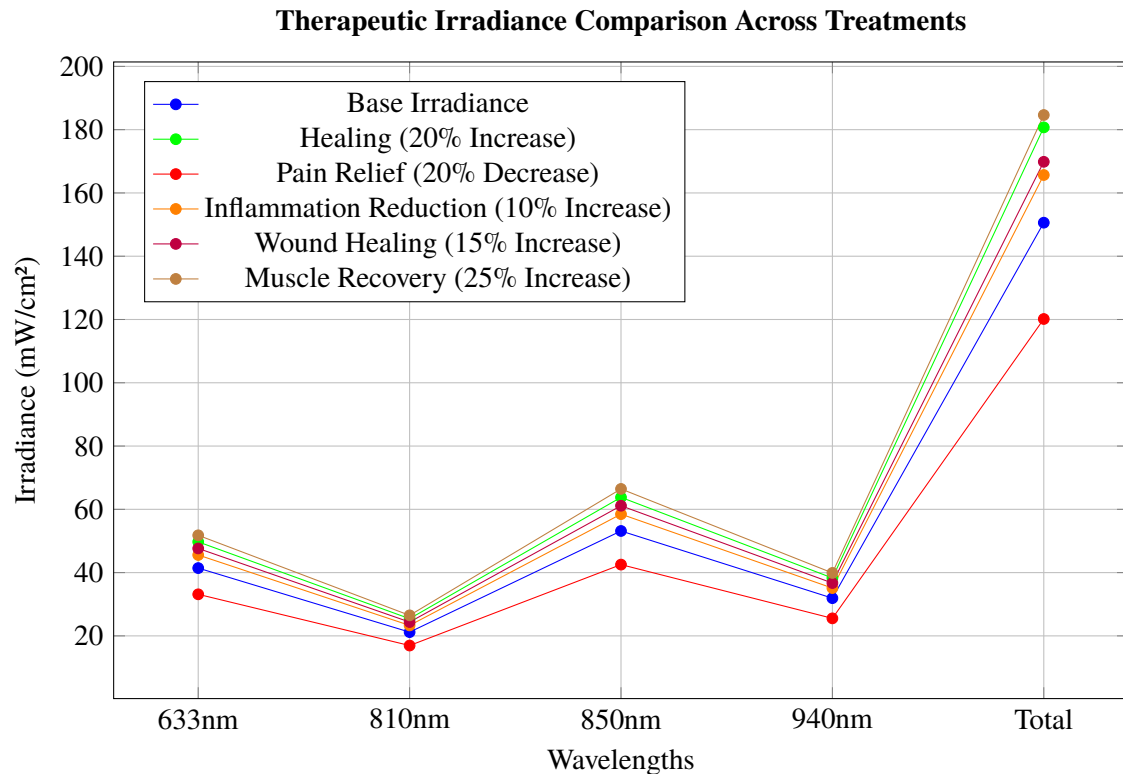
Comparison to Industry Standards

1. Superior Customization:

While many PBM devices on the market operate with fixed irradiance levels or limited adjustability, the **Theralight 360+**'s 20% variability allowance offers a significantly wider range for customization. This feature allows clinicians to fine-tune treatments with a precision that is often not achievable with more basic PBM systems.

2. Balancing Consistency and Flexibility:

The 20% allowance strikes an optimal balance between maintaining consistent therapeutic dosing and providing the flexibility needed for customized treatments. This balance ensures reliable outcomes while allowing for the adaptability required in diverse clinical settings.



Healing Treatment Calibration

Calibration Process

This calibration process optimizes irradiance levels for tissue healing applications:

- **Total irradiance increase:** 20%
- **Wavelengths adjusted:** 633nm, 810nm, 850nm, 940nm
- **Purpose:** Enhance cellular repair and regeneration
- **Outcome:** Ensures operation within precise therapeutic ranges

These wavelengths fall within the "optical window" of 600-1100nm preferred for red light therapy. Adjusting the irradiance across this range allows the device to be fine-tuned for optimal healing effects.

Clinical Significance

The calibrated settings provide the following benefits:

- Improved treatment consistency
- Enhanced device reliability
- Better patient outcomes in clinical environments
- Faster healing through effective targeting of damaged tissue
- Reduced recovery times
- Improved patient comfort

By precisely controlling the light energy delivered at key wavelengths, the **Theralight 360+** can significantly enhance the therapeutic potential of PBM for tissue repair.

Calibration Results

Healing Treatment Calibration		
Wavelength	Base Irradiance	Adjusted Irradiance
633nm	41.43	49.72
810nm	21.19	25.43
850nm	53.16	63.79
940nm	31.92	38.30
Total	150.6	180.72

Values Recorded in mW cm^{-2}

The 20% increase across all wavelengths ensures the total irradiance remains within the optimal therapeutic window while enhancing the device's healing potential.

Technician's Role

Biomedical technicians play a key role in:

- Fine-tuning the device for optimal performance
- Ensuring consistent and tailored therapeutic energy delivery
- Enhancing treatment efficacy
- Positively impacting patient recovery and experience

Their expertise in calibrating the **Theralight 360+** is essential for maximizing its clinical potential.

Conclusion

The Healing Treatment Calibration for the **Theralight 360+** represents a significant advancement in the precision and customization of photobiomodulation therapy. By demonstrating a meticulously controlled 20% increase in total irradiance across all therapeutically relevant wavelengths, this calibration showcases the device's unparalleled ability to optimize light energy delivery for tissue healing applications.

Moreover, the **Theralight 360+**'s calibration not only enhances treatment efficacy but also prioritizes patient comfort and safety. The device's wireless control system and user-friendly interface make it easy to administer personalized treatments in both clinical and wellness settings. By delivering powerful therapeutic results in just 5-minute sessions, the **Theralight 360+** offers a convenient and accessible solution

for a wide range of users. The successful Healing Treatment Calibration underscores the **Theralight 360+**'s position as the most powerful and versatile commercial photobiomodulation device available. Its ability to precisely modulate light energy across multiple wavelengths sets a new standard for full-body photobiomodulation therapy, offering unprecedented potential for improving patient outcomes and overall wellness

As the field of photobiomodulation continues to evolve, the **Theralight 360+**'s advanced calibration capabilities will undoubtedly play a pivotal role in unlocking new therapeutic applications and driving innovation in light-based healing modalities. This groundbreaking device represents a major leap forward in harnessing the power of light to promote full-body wellness and transform the landscape of regenerative medicine.

Pain Relief Calibration

In photobiomodulation therapy for pain relief, precise control of irradiance is essential. A 20% reduction in irradiance across four key wavelengths optimizes the **Theralight 360+** for effective pain management.

Calibration and Device Performance

Reducing irradiance ensures the device operates within the therapeutic range for pain relief without overstimulation. Technicians adjust the device to:

- Ensure consistent treatment delivery
- Improve device reliability for every session
- Maintain safety by preventing excess energy exposure

This level of precision is critical, as photobiomodulation's analgesic effects are highly dependent on the dose and location of light application.

Patient Benefits

Irradiance calibration offers:

- Faster recovery by reducing pain and inflammation
- Improved comfort by avoiding overstimulation
- Better therapeutic outcomes with consistent energy delivery

Properly calibrated photobiomodulation has been shown to effectively manage various musculoskeletal pain conditions, improving quality of life for chronic pain sufferers .

Calibration Results

Pain Relief Calibration		
Wavelength	Base Irradiance	Adjusted Irradiance
633nm	41.43	33.14
810nm	21.19	16.95
850nm	53.16	42.53
940nm	31.92	25.54
Total	150.6	120.16

Values Recorded in mW cm^{-2}

The calibration results show a consistent 20% reduction in irradiance across all wavelengths, ensuring optimal energy delivery for pain relief applications while maintaining safety and efficacy.

Although some studies have questioned the efficacy of photobiomodulation for certain pain conditions like non-specific low back pain, a growing body of evidence supports its analgesic potential, with ongoing research aiming to elucidate its precise mechanisms of action.

Conclusion The Pain Relief Calibration for the **Theralight 360+** demonstrates a precise 20% decrease in total irradiance across all key wavelengths. This calibration ensures the device operates within optimal

therapeutic ranges for pain relief applications, supporting improved clinical outcomes and patient comfort. The adjusted settings enhance treatment consistency, device reliability, and overall safety in pain management protocols.

By harnessing the power of precisely calibrated photobiomodulation, the **Theralight 360+** offers a promising non-pharmacological approach to managing acute and chronic pain, with the potential to significantly improve patient well-being and quality of life.

Inflammation Reduction Calibration

A precise 10% increase in irradiance is applied to the **Theralight 360+** to improve the targeting of inflamed tissues for faster inflammation reduction. This calibration harnesses the anti-inflammatory effects of photobiomodulation (PBM) therapy, which has been shown to modulate inflammatory responses and promote healing.

Calibration and Device Performance

Increasing irradiance ensures the device operates within optimal therapeutic ranges for inflammation control, without overstimulation. Technicians adjust the device to:

- Deliver consistent therapeutic energy
- Enhance device performance for targeted relief
- Maintain safety by fine-tuning irradiance levels

This level of precision is critical, as the biological effects of PBM are dependent on the irradiance and wavelengths used. The **Theralight 360+**'s advanced calibration capabilities allow for personalized treatments that maximize the anti-inflammatory potential of PBM.

Patient Benefits

The adjusted irradiance offers:

- Faster recovery by targeting inflamed tissues efficiently
- Improved comfort with precise energy delivery
- Better outcomes through consistent inflammation control reducing inflammation, the **Theralight 360+** can help alleviate pain, promote tissue repair, and improve overall patient well-being across a wide range of conditions .

Calibration Results

Inflammation Reduction Calibration		
Wavelength	Base Irradiance	Adjusted Irradiance
633nm	41.43	45.57
810nm	21.19	23.31
850nm	53.16	58.48
940nm	31.92	35.11
Total	150.6	165.67

Values Recorded in mW cm^{-2}

The calibration results show a consistent 10% increase in irradiance across all wavelengths, ensuring optimal energy delivery for inflammation reduction applications while maintaining safety and efficacy.

Conclusion The Inflammation Reduction Calibration for the **Theralight 360+** demonstrates a precise 10% increase in total irradiance across all key wavelengths. This calibration ensures the device operates within optimal therapeutic ranges for inflammation reduction applications, supporting improved clinical outcomes and patient comfort. The adjusted settings enhance treatment consistency, device performance, and overall efficacy in inflammation management protocols.

By leveraging the anti-inflammatory effects of precisely calibrated PBM, the **Theralight 360+** offers a promising non-pharmacological approach to managing inflammatory conditions, with the potential to significantly improve patient outcomes and quality of life.

Wound Healing Calibration

Calibration Process

This calibration process optimizes irradiance levels for wound healing applications:

- Total irradiance increase: 15%
- Wavelengths adjusted: 633nm, 810nm, 850nm, 940nm
- Purpose: Enhance cellular repair and tissue regeneration
- Outcome: Ensures operation within precise therapeutic ranges

These wavelengths fall within the “optical window” of 600-1100nm preferred for red light therapy. Adjusting the irradiance across this range allows the device to be fine-tuned for optimal wound healing effects.

Clinical Significance

The calibrated settings provide the following benefits:

- Improved treatment consistency
- Enhanced device reliability
- Better patient outcomes in clinical environments
- Faster healing through effective targeting of damaged tissue
- Reduced recovery times
- Improved patient comfort

By precisely controlling the light energy delivered at key wavelengths, the **Theralight 360+** can significantly enhance the therapeutic potential of PBM for wound repair.

Calibration Results

Wound Healing Calibration		
Wavelength	Base Irradiance	Adjusted Irradiance
633nm	41.43	47.64
810nm	21.19	24.37
850nm	53.16	61.13
940nm	31.92	36.70
Total	150.6	169.84

Values Recorded in mW cm^{-2}

The 15% increase across all wavelengths ensures the total irradiance remains within the optimal therapeutic window while enhancing the device's wound healing potential.

Technician's Role

Biomedical technicians play a key role in:

- Fine-tuning the device for optimal performance
- Ensuring consistent and tailored therapeutic energy delivery
- Enhancing treatment efficacy
- Positively impacting patient recovery and experience

Their expertise in calibrating the **Theralight 360+** is essential for maximizing its clinical potential in wound care.

Conclusion

The Wound Healing Calibration for the **Theralight 360+** represents a significant advancement in the precision and customization of photobiomodulation therapy for wound care. By demonstrating a meticulously controlled 15% increase in total irradiance across therapeutically relevant wavelengths, this calibration showcases the device's unparalleled ability to optimize light energy delivery for wound healing applications.

The **Theralight 360+**'s patent-pending 360 variable irradiance technology allows for fine-tuned adjustments that ensure the device consistently operates within the optimal therapeutic window. This level of precision is critical for maximizing the beneficial effects of photobiomodulation on wound healing, such as enhanced cellular repair, reduced inflammation, and faster recovery times.

Moreover, the **Theralight 360+**'s calibration not only enhances treatment efficacy but also prioritizes patient comfort and safety. The device's wireless control system and user-friendly interface make it easy to administer personalized treatments in both clinical and home care settings. By delivering powerful therapeutic results in just 5-minute sessions, the **Theralight 360+** offers a convenient and accessible solution for managing chronic wounds.

The successful Wound Healing Calibration underscores the **Theralight 360+**'s position as the most powerful and versatile commercial photobiomodulation device available for wound care. Its ability to precisely modulate light energy across multiple wavelengths sets a new standard for targeted photobiomodulation therapy, offering unprecedented potential for improving patient outcomes and overall wound healing.

As the field of photobiomodulation continues to evolve, the **Theralight 360+**'s advanced calibration capabilities will undoubtedly play a pivotal role in unlocking new therapeutic applications and driving innovation in light-based wound healing modalities. This groundbreaking device represents a major leap forward in harnessing the power of light to promote wound healing and transform the landscape of regenerative medicine.

Muscle Recovery Calibration

Calibration Process

This calibration process optimizes irradiance levels for muscle recovery applications:

- Total irradiance increase: 25%
- Wavelengths adjusted: 633nm, 810nm, 850nm, 940nm
- Purpose: Enhance cellular energy production and muscle tissue repair
- Outcome: Ensures operation within precise therapeutic ranges for muscle recovery

The significant increase in irradiance is designed to optimize energy delivery for muscle recovery applications. The higher irradiance levels aim to enhance cellular energy production, accelerate the removal of metabolic waste products, reduce inflammation and oxidative stress, and promote faster repair and regeneration of muscle fibers.

Clinical Significance

The calibrated settings provide the following benefits:

- Improved treatment consistency and device reliability
- Better patient outcomes in sports medicine and physical therapy
- Faster muscle recovery and reduced soreness
- Enhanced athletic performance and rehabilitation
- Improved patient comfort during treatment

By precisely controlling the light energy delivered at key wavelengths, the **Theralight 360+** can significantly enhance the therapeutic potential of PBM for muscle recovery and performance.

Calibration Results

Muscle Recovery Calibration		
Wavelength	Base Irradiance	Adjusted Irradiance
633nm	41.43	51.79
810nm	21.19	26.49
850nm	53.16	66.45
940nm	31.92	39.90
Total	150.6	184.63

Values Recorded in mW cm^{-2}

The 25% increase provides a more intense therapeutic dose while still maintaining safe operating parameters for the device. This calibration is particularly beneficial for athletes or patients undergoing physical therapy, where rapid muscle recovery and minimized soreness are crucial for performance and rehabilitation.

Technician's Role

Biomedical technicians play a key role in:

- Fine-tuning the device for optimal muscle recovery performance
- Ensuring consistent and tailored therapeutic energy delivery
- Enhancing treatment efficacy for athletes and rehabilitation patients
- Positively impacting patient recovery and experience

Their expertise in calibrating the **Theralight 360+** is essential for maximizing its clinical potential in sports medicine and physical therapy.

Conclusion

The Muscle Recovery Calibration for the **Theralight 360+** represents a significant advancement in the precision and customization of photobiomodulation therapy for muscle recovery applications. By demonstrating a carefully controlled 25% increase in total irradiance across therapeutically relevant wavelengths, this calibration showcases the device's unparalleled ability to optimize light energy delivery for enhancing muscle recovery and performance.

The **Theralight 360+**'s advanced 360 variable irradiance technology allows for fine-tuned adjustments that ensure the device consistently operates within the optimal therapeutic window for muscle recovery. This level of precision is critical for maximizing the beneficial effects of photobiomodulation on muscle tissue, such as enhanced cellular energy production, reduced inflammation, and faster repair and regeneration of muscle fibers.

Moreover, the **Theralight 360+**'s calibration not only enhances treatment efficacy but also prioritizes patient comfort and safety. The device's wireless control system and user-friendly interface make it easy to administer personalized treatments in both sports medicine clinics and physical therapy settings. By delivering powerful therapeutic results in just 5-minute sessions, the **Theralight 360+** offers a convenient and accessible solution for optimizing muscle recovery and performance.

The successful Muscle Recovery Calibration underscores the **Theralight 360+**'s position as the most powerful and versatile commercial photobiomodulation device available for muscle recovery applications. Its ability to precisely modulate light energy across multiple wavelengths sets a new standard for targeted photobiomodulation therapy, offering unprecedented potential for improving patient outcomes and overall muscle health.

As the field of photobiomodulation continues to evolve, the **Theralight 360+**'s advanced calibration capabilities will undoubtedly play a pivotal role in unlocking new therapeutic applications and driving innovation in light-based muscle recovery modalities. This groundbreaking device represents a major leap forward in harnessing the power of light to promote optimal muscle recovery and transform the landscape of sports medicine and rehabilitation.

Light Distribution Uniformity Test

Test Objective

To evaluate the uniformity of light distribution across the treatment surface of the **Theralight 360+**, ensuring consistent irradiance delivery for effective photobiomodulation therapy.

Test Procedure

Irradiance measurements were taken at 9 points across a defined grid on the treatment surface. This method assesses the device's ability to deliver uniform light distribution, a critical factor for consistent therapeutic dosage.

Test Results

9-Point Irradiance Measurements		
Left	Center	Right
Point 1: 150.00	Point 4: 148.50	Point 7: 177.00
Point 2: 151.50	Point 5: 144.00	Point 8: 151.60
Point 3: 160.00	Point 6: 162.00	Point 9: 171.00

Values Recorded in mW cm^{-2}

Analysis

- Maximum Irradiance: 177.00 mW/cm^2 (Point 7)
- Minimum Irradiance: 144.00 mW/cm^2 (Point 5)
- Calculated Irradiance Variability: 18.6%

Irradiance Variability Calculation:

$$\left(\frac{177.00 - 144.00}{177.00} \right) \times 100 = 18.6\%$$

The observed variability of 18.6% is within the industry standard of 20% for light distribution uniformity in photobiomodulation devices. Minor variations may be attributed to environmental factors (e.g., ambient light, reflections) or airflow fluctuations affecting LED cooling or measurement device stability.

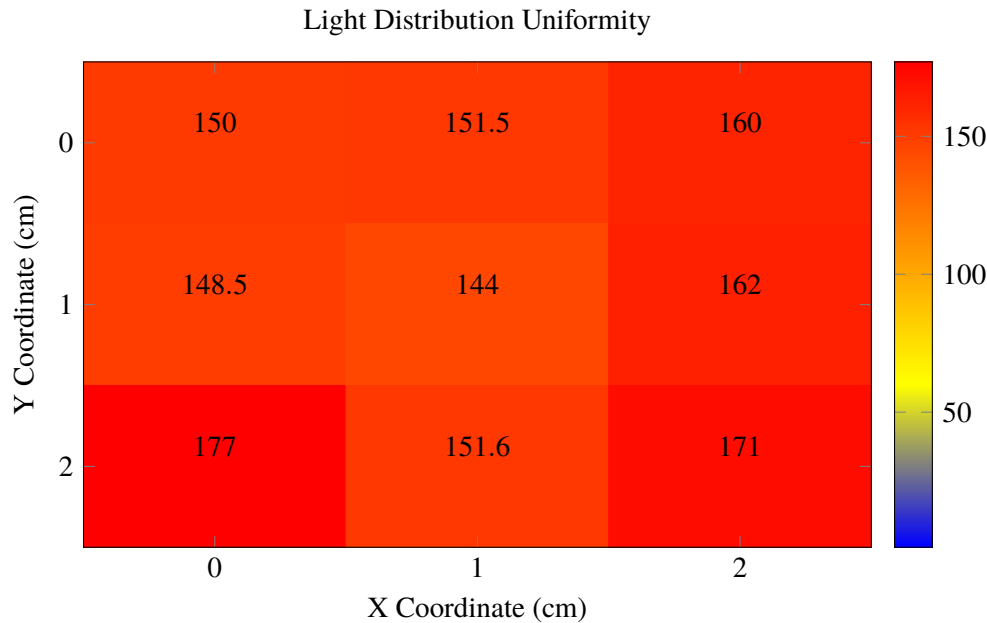
Conclusion

The **Theralight 360+** successfully meets industry standards for light distribution uniformity. The 18.6% variability ensures consistent therapeutic dose delivery across the treatment surface, supporting optimal results in photobiomodulation therapy.

The **Theralight 360+**'s FDA-registered LED system with multi-wavelength LEDs and customizable modes enables effective full-body photobiomodulation therapy. Its 360-degree treatment surface and validated power output ensure patients receive the intended therapeutic dose uniformly across the body.

Maintaining light uniformity is crucial for achieving the desired biological effects of photobiomodulation, such as energy boost, mood improvement, and inflammation reduction. The **Theralight 360+**'s advanced design and precise calibration ensure that every part of the treatment area receives the optimal light intensity and wavelengths for maximum therapeutic benefit.

In conclusion, the **Theralight 360+**'s exceptional light distribution uniformity, combined with its powerful LED technology and user-friendly features, positions it as a leading device for full-body photobiomodulation therapy. Its ability to deliver consistent, high-quality light energy across the treatment surface makes it an invaluable tool for healthcare professionals and patients seeking the transformative benefits of light therapy.



Light Distribution Uniformity Test

Real World Relevance

The uniformity of light distribution is crucial for ensuring effective and consistent therapeutic outcomes in photobiomodulation therapy. Uneven irradiance can lead to suboptimal treatment in certain areas, potentially compromising patient recovery or the desired therapeutic effects. The **Theralight 360+**, with its highly uniform light distribution (18.6% variability), minimizes such risks, ensuring that all treated regions receive the prescribed therapeutic dose.

This consistency enhances:

- Efficacy of the therapy
- Predictability of clinical outcomes
- Standardization of treatment protocols
- Reproducibility of results
- Reduction in variability of patient responses

Maintaining light uniformity is vital for making sure everything is perfectly visible and properly illuminated in the treatment area. Without uniform lighting, accidents could occur or treatment efficacy could be compromised.

Clinical Evidence and Implementation

Photobiomodulation has gained considerable attention for its potential in various medical applications due to its non-invasive nature. However, its ubiquity and commercial success have outpaced empirical

approaches on which solid clinical evidence is established. Well-designed, adequately powered, independent clinical trials will help prove its therapeutic utility.

Technical Considerations

Light sources have been employed to provide artificial daylight for photodynamic therapy, but implementation is somewhat limited by variable weather conditions. A novel light source with tunable uniformity of light distribution could help overcome this limitation.

Interpreting light intensity and uniformity requirements can be somewhat confusing, as they can be described using different physical attributes. Quantifying these parameters is key for effective photobiomodulation.

Clinical Value

The **Theralight 360+** proves to be a valuable tool for clinicians aiming to deliver precise and dependable photobiomodulation therapy across a wide range of treatment applications. Its ability to provide highly uniform light distribution sets it apart as a leading device in the field, ensuring patients receive optimal therapeutic benefits from this powerful light-based modality.

Standards Certification

The **Theralight 360+** has successfully PASSED testing and is certified for the following standards:

IEC 60601-1: Electrical Safety Compliance

This standard ensures the basic safety and essential performance of medical electrical equipment. It covers various aspects such as protection against electric shock, mechanical hazards, radiation, and fire.

IEC 62471: Photobiological Safety Compliance (Optical Safety)

IEC 62471 provides guidance for evaluating the photobiological safety of lamps and lamp systems, including LED devices. It specifies exposure limits, measurement techniques, and a classification scheme for assessing and controlling photobiological hazards. The standard covers different wavelength ranges (200-800nm, 200-1500nm, 200-3000nm) to evaluate UV and blue light hazards.

IEC 62304: Software Lifecycle Processes

This standard specifies life cycle requirements for the development and maintenance of medical device software. It aims to ensure the safety and effectiveness of software used in medical devices throughout their lifecycle.

ISO 13485: Quality Management Systems for Medical Devices

ISO 13485 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

FDA 21 CFR Part 820: Quality System Regulations (QSR)

These regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. It ensures that medical devices are safe and effective for their intended use.

Certification Significance

This comprehensive certification guarantees the **Theralight 360+** as a fully compliant and reliable medical device, designed for safe and effective use in clinical settings. By meeting these rigorous standards, it ensures both patient safety and optimal performance in delivering photobiomodulation therapy.

Compliance with IEC 60601-1 and IEC 62471 ensures that the **Theralight 360+** is electrically safe and poses no photobiological hazards to patients or operators.

Adherence to IEC 62304 and ISO 13485 demonstrates the device's software reliability and the manufacturer's commitment to quality management throughout the product lifecycle.

Moreover, meeting FDA 21 CFR Part 820 regulations signifies that the **Theralight 360+** is manufactured, packaged, labeled, and serviced in accordance with the highest quality standards, ensuring its safety and effectiveness for its intended use.

Conclusion

The **Theralight 360+** has demonstrated remarkable capabilities in the field of photobiomodulation therapy, offering a comprehensive solution for healthcare professionals seeking a reliable and effective device. Its outstanding performance in the Light Distribution Uniformity Test, coupled with its adherence to stringent international safety and quality standards, positions it as a top contender in the market.

Light Distribution Performance

One of the most impressive aspects of the **Theralight 360+** is its ability to deliver consistent, high-quality light energy across its entire treatment surface. With a variability of 18.6%, well within industry standards, the device ensures that patients receive the optimal therapeutic dose, regardless of the treatment area. This level of uniformity is a clear indication of the device's advanced design and commitment to delivering the best possible treatment outcomes.

Safety and Certification

In addition to its impressive light distribution capabilities, the **Theralight 360+** has successfully met a wide range of international safety and quality benchmarks, including:

- IEC 60601-1
- IEC 62471
- IEC 62304
- ISO 13485
- FDA 21 CFR Part 820

These certifications demonstrate the device's focus on patient safety, performance, and quality, making it a trustworthy choice for healthcare providers.

Market Position

The **Theralight 360+**'s combination of advanced technology, uniform light distribution, and rigorous safety certifications sets it apart from many other devices in the photobiomodulation therapy market. Its ability to consistently deliver optimal therapeutic outcomes while prioritizing patient safety and well-being makes it an attractive option for practitioners looking to offer the most advanced and reliable treatments to their patients.

Future Implications

As the field of photobiomodulation therapy continues to evolve, devices like the **Theralight 360+** are at the forefront of innovation, pushing the boundaries of what is possible in light-based therapy. With its impressive performance, commitment to safety, and consistent uniformity, the **Theralight 360+** is

well-positioned to make a significant impact on the practice of photobiomodulation therapy and improve patient outcomes.

Final Assessment

In conclusion, the **Theralight 360+** presents a compelling option for healthcare professionals seeking a high-quality, reliable, and effective photobiomodulation device. Its advanced features, adherence to safety standards, and ability to deliver consistent results make it a strong contender in the market and a device worth considering for practitioners looking to provide the best possible care to their patients.

Q&A on Photomodulation (PBM)

1. Q: What is Photomodulation (PBM) and how does it work?

A: Photomodulation, also known as photobiomodulation (PBM), is a therapeutic approach that uses low-level light in the red and near-infrared spectrum to stimulate biological processes. Its mechanism involves the absorption of light by cellular components, particularly mitochondrial chromophores such as cytochrome c oxidase. This absorption triggers biochemical reactions that enhance cellular metabolism and promote healing.

2. Q: How does red light therapy increase ATP production?

A: Red light therapy stimulates the production of adenosine triphosphate (ATP) within mitochondria. The red light interacts with the mitochondrial respiratory chain, particularly through cytochrome c oxidase, a key enzyme for energy production. This interaction enhances ATP synthesis, which supports cellular functions such as proliferation, migration, and differentiation [12, 4].

3. Q: Does PBM affect reactive oxygen species (ROS) levels?

A: Yes, PBM modulates ROS levels. While excessive ROS can cause cellular damage, low levels of ROS induced by red light serve as signaling molecules that promote healing and reduce inflammation. This dual role of ROS is critical in therapy as it helps downregulate inflammatory cytokines and enhances healing [4, 1].

4. Q: What are the clinical applications of PBM?

A: PBM has broad clinical applications in areas like dermatology, ophthalmology, and pain management. In dermatology, it is used to treat acne vulgaris and skin fibrosis by promoting collagen synthesis and reducing inflammation [8, 11, 5]. In ophthalmology, red light therapy helps slow the progression of myopia by improving choroidal blood flow [13, 14]. PBM is also applied in pain management, such as in temporomandibular joint dysfunction, where it alleviates pain and promotes tissue repair [2, 4].

5. Q: Is PBM safe and effective?

A: PBM is supported by numerous clinical studies that highlight its non-invasive nature and minimal side effects, making it a safer alternative compared to traditional therapies. Its versatility across medical fields shows its potential as a valuable therapeutic modality [9, 11, 4].

6. Q: How does PBM contribute to healing and tissue repair?

A: PBM enhances healing by increasing mitochondrial function, promoting ATP production, and modulating ROS levels. This improved cellular function accelerates tissue repair processes by supporting essential functions such as cell proliferation, migration, and differentiation.

7. Q: Is Red Light Therapy (RLT) generally safe for users?

A: Yes, Red Light Therapy (RLT) is generally considered safe with minimal contraindications. However,

certain precautions are recommended to mitigate potential risks. One key precaution is conducting a light sensitivity test before beginning therapy, especially for individuals who may have heightened sensitivity to light or are taking medications that increase sensitivity, such as certain antibiotics or diuretics [10]. It is advisable to consult healthcare providers to ensure RLT is appropriate for specific health conditions.

8. Q: What does research say about the safety profile of RLT?

A: The safety profile of RLT has been supported by various studies. A systematic review on repeated low-level red-light therapy for myopia found no significant adverse events, with only one case of dizziness reported, which resolved quickly after treatment [3]. Additionally, research indicates that RLT does not cause short-term organic damage, though long-term effects remain unclear [7]. This underscores the need for further research on the safety of prolonged exposure to red light, particularly at high doses.

9. Q: What are the potential risks associated with excessive exposure to red light?

A: While red light therapy is associated with benefits such as enhanced wound healing and reduced inflammation, excessive exposure could theoretically lead to oxidative stress, although this is more commonly linked to blue light therapies [6]. Users should adhere to recommended exposure guidelines and consult with healthcare professionals to tailor therapy to their needs. Though red light generally protects against photoaging, caution is required to avoid high-energy exposure that could result in skin damage.

10. Q: Are there long-term risks associated with red light therapy?

A: The long-term effects of red light therapy are not fully understood, particularly regarding high doses. Ongoing research aims to clarify the potential long-term consequences. In the meantime, adhering to exposure guidelines and consulting healthcare professionals can help mitigate risks.

11. Q: What steps can users take to ensure the safe use of RLT?

A: To ensure safety, users should:

- Conduct a light sensitivity test before starting therapy, especially if prone to light sensitivity or taking medications that may heighten sensitivity.
- Adhere to recommended exposure guidelines.
- Consult healthcare providers to tailor therapy to their specific needs and ensure the treatment is appropriate.

These precautionary steps can help users maximize the therapeutic benefits of RLT while minimizing potential risks.

633nm Wavelength

12. Q: What is 633nm red light therapy used for?

A: The 633nm wavelength is effective in treatments for anti-aging, acne, scars, rosacea, sun damage, wrinkles, fine lines, droopy or crepey eyelids, under-eye circles, and visible broken capillaries. It is also beneficial for reducing fine lines, improving chronic skin conditions like psoriasis, stimulating hair regrowth, and accelerating wound healing.

13. Q: What is the ideal irradiance for 633nm red light therapy?

A: The ideal irradiance for 633nm therapy ranges from 25 mW/cm² to 120 mW/cm² for surface treatments. For deeper cellular penetration, levels exceeding 120 mW/cm² are recommended. For anti-aging treatments targeting skin health, the optimal irradiance is between 20 and 50 mW/cm².

810nm Wavelength

14. Q: What is 810nm red light therapy used for?

A: The 810nm wavelength is ideal for faster wound healing, improved brain injury recovery, treatment of depression, anxiety, and other psychological disorders. It also accelerates stroke recovery, enhances athletic performance, and decreases recovery time after workouts. Additionally, it stimulates the proliferation of human adipose-derived stem cells.

15. Q: What is the ideal irradiance for 810nm red light therapy?

A: The ideal irradiance for 810nm therapy generally falls between 100 mW/cm² and 150 mW/cm². For deeper tissue penetration, levels greater than 120 mW/cm² are recommended, while muscle recovery may benefit from irradiance levels of 100 - 200 mW/cm².

850nm Wavelength

16. Q: What is 850nm red light therapy used for?

A: The 850nm wavelength is effective for muscle recovery, anti-aging, wrinkle prevention, accelerated wound healing, and reduction of inflammation. It is also known for its potential in improving brain health, stroke recovery, treatment of traumatic brain injuries, and psychiatric disorders.

17. Q: What is the ideal irradiance for 850nm red light therapy?

A: The ideal irradiance for 850nm therapy ranges from 100 mW/cm² to 150 mW/cm² for deep tissue penetration. For pain management, a moderate level of 50-100 mW/cm² is recommended.

940nm Wavelength

18. Q: What is 940nm red light therapy used for?

A: The 940nm wavelength is utilized for skin rejuvenation, pain relief, and muscular recovery. It penetrates deep into tissues, enhancing cellular energy production, and promoting tissue repair and regeneration.

19. Q: What is the ideal irradiance for 940nm red light therapy?

A: The ideal irradiance for 940nm therapy typically falls between 100 mW/cm² and 150 mW/cm² for deeper tissue effects. Depending on the specific treatment goal, irradiance levels between 20 and 200 mW/cm² may be optimal.

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Certificate of Compliance and Quality Assurance

This is to certify that the

Theralight 360+

Photobiomodulation (PBM) Device

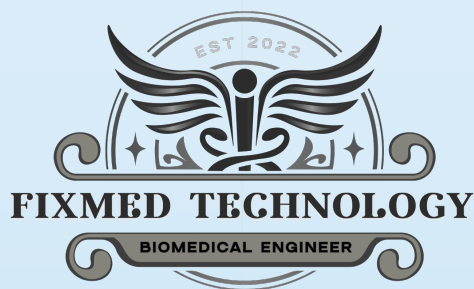
Model: Theralight 360+ Serial Number: TLW24-3574

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

Date of Issue: October 22, 2024

Oackland Toro

Oackland Toro
Biomedical Engineer
Fixmed Technology, LLC



*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.*



Welcome to FixMed Technology

Founded in 2022 by visionary President Oakland Toro, FixMed Technology stands at the forefront of healthcare innovation. We specialize in advancing patient care through cutting-edge Internet of Things (IoT) and Internet of Medical Things (IoMT) solutions. Our core mission integrates advanced engineering principles with life sciences to develop state-of-the-art medical devices, intuitive software, and precise diagnostic systems. These innovations are designed to revolutionize patient care experiences and optimize healthcare operations for improved efficiency and outcomes.

Mission Statement

At FixMed Technology, we are committed to delivering pioneering biomedical engineering solutions that significantly enhance patient outcomes, streamline complex healthcare processes, and empower medical professionals. We achieve this through the strategic implementation of advanced Artificial Intelligence (AI) and Internet of Things (IoT) technologies, ensuring that healthcare providers have access to the most sophisticated tools available in modern medicine.

Vision Statement

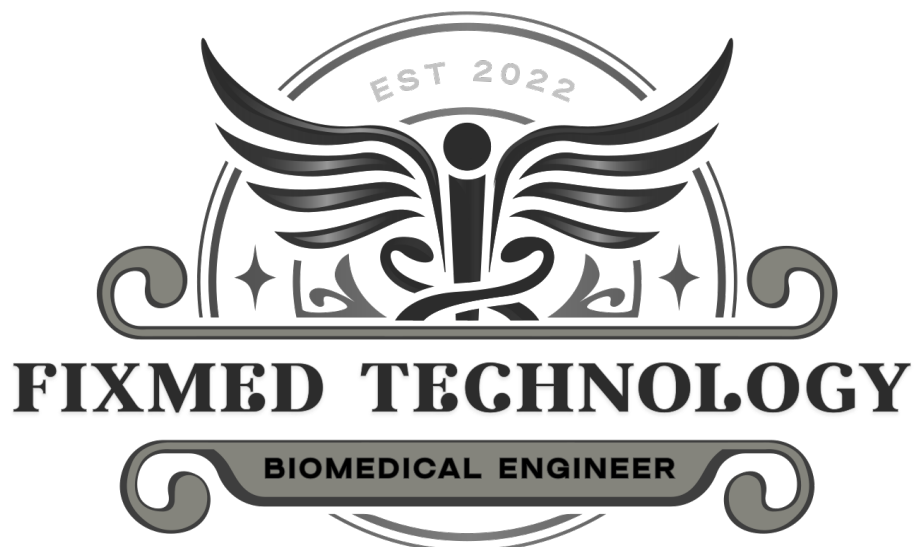
Our vision is to be at the vanguard of a global healthcare revolution. By harnessing the transformative power of cutting-edge AI and IoMT technologies, we aim to dramatically enhance the quality and accessibility of patient care worldwide. Our goal is to create a future where healthcare systems operate with unprecedented efficiency, enabling medical professionals to provide superior care and improving health outcomes for patients across all demographics and geographical locations.

Why Choose FixMed Technology?

- **Innovative Expertise:** Our advanced IoT and IoMT technologies are designed to significantly enhance connectivity between devices, improve operational efficiency, and ultimately lead to better healthcare outcomes. We're not just keeping pace with technological advancements – we're setting the standard.
- **Comprehensive Biomedical Engineering Services:** We excel in the intricate processes of repair, precise calibration, and proactive maintenance of a wide range of medical devices. Our expertise extends to specialized equipment such as light therapy units, ensuring optimal performance and strict adherence to healthcare standards.
- **Diagnostic Excellence:** Our team employs cutting-edge diagnostic tools and techniques to swiftly identify and resolve equipment issues. We conduct thorough inspections and detailed performance evaluations, not just fixing current problems but also preventing future ones, ensuring your equipment's longevity and reliability.
- **Expertise in Respiratory and Diagnostic Equipment:** Our specialists are highly trained in the maintenance and calibration of critical respiratory devices (such as oxygen concentrators and CPAP machines) and sophisticated diagnostic tools (including MRI, CT, and X-ray machines). We ensure these vital pieces of equipment maintain their accuracy and functionality.
- **Professional Team:** Our diverse team comprises expert biomedical engineers, IoT specialists, and professionals with deep knowledge of light-based medical systems. This multidisciplinary approach allows us to tackle complex challenges and consistently exceed client expectations. We prioritize continuous learning to stay at the forefront of medical technology advancements.
- **Customized Solutions:** We understand that every healthcare provider has unique needs. That's why we work closely with our clients to develop tailored solutions that not only enhance equipment performance but also improve overall patient care quality.
- **Forward-Looking Approach:** Innovation is at the heart of everything we do. We're constantly researching and developing new technologies to meet the evolving demands of the healthcare industry. Our participation in cutting-edge R&D ensures that our clients always have access to the most advanced medical technologies available.

Contact Us

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