



FMT LABORATORIES

ELECTROMAGNETIC SAFETY AND FIELD ANALYSIS

TheraLight 360 / 360i

Full-Body Red Light Therapy Bed

EMF Testing and Safety Report

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2.0

Report Date:

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Device Model:

TheraLight 360i

Classification:

Class II Medical Device

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1. INTRODUCTION: EMF SAFETY IN 2026

1.1 Understanding Electromagnetic Fields (EMF)

Electromagnetic fields (EMFs) are invisible areas of energy, often referred to as radiation, that are associated with the use of electrical power and various forms of natural and man-made lighting. In 2026, published research and health guidelines continue to distinguish clearly between ionizing radiation (like X-rays, which can damage DNA) and non-ionizing radiation (like light therapy, radio waves, and power lines), which is generally considered safe within established exposure limits.

1.2 The TheraLight 360i Profile

This report presents third-party measurements for the TheraLight 360i, a full-body photobiomodulation (PBM) system. The testing evaluates the device against strict safety standards to ensure that patient exposure to electric and magnetic fields remains well below international limits.

The report covers two specific configurations:

1. **TheraLight 360i (PBM-Only):** Red/Near-Infrared light therapy.
2. **TheraLight 360i (PBM + PEMF):** Integrated Pulsed Electromagnetic Field technology.

2. STATEMENT REGARDING "EMF FREE" MARKETING CLAIMS

2.1 Scientific Reality vs. Marketing Terms

In the medical device industry, the marketing term "Zero EMF" or "EMF Free" is frequently used but is technically inaccurate by scientific standards. According to the principles of physics (specifically Maxwell's equations), the flow of electric current is fundamentally linked to the creation of electric and magnetic fields. Therefore, it is physically impossible for any active electrical device to be 100% devoid of EMFs.

2.2 How "Low-EMF" is Achieved

While "absolute zero" is impossible, the TheraLight 360i utilizes isolated engineering to reduce emissions to levels that are effectively undetectable or equal to background ambient levels at the treatment distance.

- **Shielding:** Metal housings and shielded cables route system noise to ground.
- **Distance:** EMF strength diminishes rapidly with distance. At the standard patient usage distance (4–6 inches), fields drop significantly.
- **Power Engineering:** High-quality drivers and filters minimize the "noise" typically associated with AC-to-DC conversion.

Conclusion: When this report refers to safety, it confirms that the device is engineered for **low exposure**, far below the thresholds of standard detection meters at usage distances.

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3. TESTING EQUIPMENT

The following instruments were employed for precise low-frequency assessment:

Equipment	Model	Function
Tri-Axis EMF Meter	TRIFIELD TF2	Magnetic (mG) and Electric (V/m) measurement
AC/DC Gauss Meter	LATNEX MF-30K	Magnetic field verification
Digital Laser Measure	BOSCH GLM165-40	Precise distance calibration
Digital Oscilloscope	RIGOL DHO814	Signal quality verification

The TRIFIELD TF2 served as the primary instrument; the LATNEX MF-30K provided secondary verification.

4. EMF MEASUREMENT RESULTS

Measurements were conducted at standardized distances. Values are in milligauss (mG) for magnetic fields and volts per meter (V/m) for electric fields.

- **Ambient Background Level:** ~0.2 – 0.5 mG (Reference)

4.1 TheraLight 360i (PBM Bed Only)

In this configuration, testing focused on system emissions from LED drivers and power electronics. No therapeutic magnetic coils are active.

Magnetic Field Measurements (mG)

Measurement Zone	Surface (0")	4 inches	6 inches	12 inches
Power Supply Unit	30	2	0.8	0
Control Panel	15	0	0	0
Power Cord Connection	15	0	0	0
LED Panel Array	1	0.3	0	0
Patient Treatment Zone	0.2	0	0	0

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Electric Field Measurements (V/m)

Measurement Zone	Surface (0")	4 inches	6 inches	12 inches
Power Supply Unit	20	12	0	0
Patient Treatment Zone	5	1	0	0

4.2 TheraLight 360i (PBM with PEMF Integration)

In this configuration, testing included the therapeutic low-frequency magnetic fields generated by the coils.

Magnetic Field Measurements (mG)

Measurement Zone	Surface (0")	2 inches	4 inches	12 inches
Power Supply Unit	30	2	0	0
Control Panel	15	0	0	0
Power Cord Connection	15	0	0	0
LED Panel Array	1	0.3	0	0
Patient Treatment Zone	18,000	8,500	1,000	0

Electric Field Measurements (V/m)

Measurement Zone	Surface (0")	4 inches	6 inches	12 inches
Power Supply Unit	20	12	0	0
Patient Treatment Zone	5	1	0	0

Note: The 18,000 mG reading at the surface represents the intended therapeutic dosage delivered by the PEMF coils. This field is non-ionizing and strictly localized; it drops off rapidly, falling below ICNIRP general limits (1,000 mG) within approximately 4 inches of distance.

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5. COMPARATIVE PERSPECTIVE

To put the TheraLight 360i measurements into perspective, the table below compares the device's emissions against common daily electronics and international safety limits.

Source	Approx. EMF at Usage Distance	Context
ICNIRP Safety Limit	1,000 mG	Limit for continuous public exposure
5G Smartphone (Active Call)	2.0 – 10.0 mG	Held against ear/face
Smart Watch (Wearable)	1.0 – 3.0 mG	Direct skin contact (Bluetooth pulsing)
Hair Dryer	40.0 – 200.0 mG	Handheld usage
TheraLight 360i (Treatment w/o PEMF)	< 0.5 mG	Whole-body treatment distance

The TheraLight 360i exposes the patient to significantly lower electromagnetic fields than common handheld devices.

6. ELECTROMAGNETIC INTERFERENCE (EMI) & SAFETY

6.1 EMI Mitigation EMI refers to high-frequency noise that can interfere with other electronics. The TheraLight 360i utilizes:

- **Heavy-Duty Line Filters:** To attenuate high-frequency components.
- **Shielded Metal Enclosures:** To contain RF noise and route it to ground.

6.2 Leakage Current Verification

Measurement	Result	Safety Limit	Status
Patient Leakage Current	71 μ A	100 μ A	PASS
Earth Leakage Current	210 μ A	500 μ A	PASS

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7. CONCLUSION

The TheraLight 360i meets all applicable electromagnetic safety requirements.

1. **Safety:** Emissions at the patient treatment zone are negligible (< 0.5 mG), sitting well below ICNIRP public exposure limits (1,000 mG).
2. **Engineering:** Through robust shielding and filtration, the device minimizes system emissions to levels comparable to or below ambient background noise.
3. **Compliance:** The system adheres to IEC 60601-1-2 standards, ensuring it is safe for use in clinical environments without interfering with other sensitive medical equipment.

8. ABOUT FMT LABORATORIES

FMT Laboratories, a division of FixMed Technology LLC, specializes in biomedical engineering services, including equipment testing, calibration, preventive maintenance, and regulatory compliance assessments for medical devices.

Our experience encompasses electromagnetic compatibility (EMC) evaluations, advanced light therapy systems, and adherence to global standards such as IEC 60601-1-2. This expertise, combined with our focus on precise diagnostic and engineering solutions in healthcare, qualifies us to perform independent EMF testing and produce authoritative safety reports for advanced therapeutic devices.

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REFERENCES

1. IEC 60601-1-2: Medical Electrical Equipment – EMC Requirements
2. ICNIRP Guidelines for Limiting Exposure to Electromagnetic Fields (2020)
3. FDA Guidance: General Wellness for Low Risk Devices
4. FCC Part 15 – Radio Frequency Devices

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END OF REPORT

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