Theme 1: Dosimetry and Irradiance

Q1. "Competitor X publishes 50 mW/cm² - isn't that more powerful than the LASER Pod?"

Short answer: *Published irradiance numbers cannot be directly compared between LED and LASER Full-Body systems. They measure different things under different conditions, and a higher mW/cm² on an LED spec heet does not translate to higher biological dose at the tissue.*

The science:

Irradiance (mW/cm²) is power per unit area at a defined measurement plane. It describes what arrives at a sensor, not what couples into tissue, not what reaches mitochondrial photoacceptors, and not what drives a biological response. FDA's 2023 draft guidance on light therapy devices explicitly expects manufacturers to characterize multiple optical parameters - wavelength, radiant power, irradiance, fluence, output mode, and measurement methodology - not irradiance alone.[1]

A published LED irradiance of 50 mW/cm² may be measured at the emitter aperture, at 1 cm, or against a small reference window. In a Full-Body enclosure, the patient's skin is rarely at that reference distance and almost never at a perpendicular incidence angle across the full body surface. LED irradiance drops steeply with distance and off-axis angle because of Lambertian emission. The number on the spec sheet is a best-case measurement under controlled laboratory conditions, not a description of what a patient receives.

LASER sources emit with much higher radiance (power per unit area per unit solid angle) and far narrower divergence. At the emitter-to-skin distances typical of a Full-Body enclosure, a LASER beam maintains its intensity more consistently than an LED beam does. Surface irradiance comparisons between the two source types are not apples-to-apples, and a clinician should view any such direct comparison with skepticism.

Q2. "Isn't irradiance the standard way to compare Light Therapy devices?"

Short answer: *It is the most common way, but not the scientifically complete way. The light therapy literature has long recognized that surface irradiance alone is a poor proxy for biological dose.*

The science:

The light therapy research community has repeatedly flagged dosimetric reporting as the field's central methodological weakness. Khan and Arany's widely-cited dosimetry commentary notes that irradiance measured at a probe tip can misrepresent actual treatment surface irradiance by orders of magnitude depending on distance and setup.[2] This reporting problem is not unique to LED or LASER manufacturers, it affects the field broadly.

A scientifically defensible device comparison requires, at minimum: (a) measured spectral irradiance at the skin under defined conditions, (b) spatial uniformity mapping across the treatment field, (c) treatment time and resulting radiant exposure at the skin, and (d) device configuration details including distance, angle, and enclosure reflectivity. Two devices that differ on any of these dimensions cannot be reduced to a single mW/cm² number for honest comparison.

Q3. "What dose does the LASER Pod actually deliver? What should I tell patients?"

Short answer: *Dose is set by the selected protocol and session time. The Pod's indications are those covered by its 510(k)-exempt clearance: temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasms, temporary increase in local blood circulation, and temporary muscle relaxation via topical elevated tissue temperature. Specific device output parameters should be referenced from the current device labeling and Summus clinical resources.*

The science:

Patient-facing communication should stay within the cleared indications for use. For clinical purposes, the dose delivered during a session is determined by the emitter configuration, the selected protocol on the onboard touchscreen, and the session duration. Clinicians should consult the current device labeling and protocol guide, or their Summus clinical representative, for the specific wavelength(s), output power, and session parameters associated with each programmed protocol.

When discussing light therapy more broadly with patients who ask, it is reasonable to explain that red and near-infrared light interact with mitochondrial photoacceptors (primarily cytochrome c oxidase) to support cellular energy processes, and that Full-Body delivery allows systemic rather than purely localized exposure.[3] Patient communication should avoid specific disease-treatment claims beyond the cleared indications.

Theme 2: Tissue Physics

Q4. "Doesnıt scattering randomize photon direction anyway, so coherence doesnıt matter inside tissue?"

Short answer: *Scattering does randomize direction after a few millimeters, but initial launch conditions continue to shape the subsurface dose distribution. Coherence is not the key variable; radiance, directionality, and angular entry at the skin are. LASER sources differ from LEDs on all of those.*

The science:

The "scattering randomizes everything" argument is a simplification that has been overused in light therapy

marketing, often by LED vendors. Multiple scattering does progressively randomize photon direction as photons propagate through tissue. But by the time scattering dominates, the initial dose distribution has already been established and that distribution depends on beam diameter, angular emission profile, angle of incidence, and numerical aperture at the skin.[4]

Monte Carlo transport modeling, the field's standard computational approach for photon behavior in tissue, consistently shows that initial launch conditions shape the subsurface fluence map even after scattering dominates. Ash and colleagues demonstrated that beam diameter significantly affects penetration depth; broader, more directional beams sustain higher forward photon flux before

isotropization.[5] The "coherence doesn't matter in tissue" framing conflates coherence (a property of the wavefront) with directionality, radiance, and geometric launch conditions which demonstrably do matter.

A useful way to reframe the conversation: the case for LASER-based Full-Body light therapy does not rest on coherence surviving through tissue. It rests on the fact that coherent, high-radiance, narrow-bandwidth sources deliver a larger and more predictable fraction of their output to biologically active targets. The physics that matter are upstream of tissue, not inside it.

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Q5. "Isnıt 810 nm from a LASER the same as 810 nm from an LED?"

Short answer: *No. A LASER diode emits within approximately 1-5 nm of its center wavelength. An LED marketed as "810 nm" typically emits across 20-60 nm or more. The center is the same; the distribution is not.*

The science:

Tissue absorption and scattering coefficients vary sharply across even narrow wavelength bands within the red and near-infrared optical window. Hemoglobin absorption changes substantially between 800 and 900 nm. Water absorption rises steeply above 970 nm. Melanin absorption continues to decline with increasing wavelength across the near-infrared band.[6]

A LASER specification of "810 nm" means the source emits essentially at 810 nm. An LED specification of "810 nm" is a center wavelength for a distribution that may extend from the mid-780s to the mid-830s nm, with meaningful tail energy well outside the stated value. Parts of that distribution may fall into regions of higher water absorption or less favorable scattering coefficients than the nominal wavelength suggests. In practical terms: when the spec sheet says "810 nm," a LASER hits 810 nm, while an LED hits roughly 810 nm on average.

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Q6. "How deep does Class lV LASER light actually penetrate?"

Short answer: *Penetration depth is not a single number. It depends on wavelength, beam geometry, tissue composition, and what threshold offluence is considered clinically meaningful. The honest answer is that most delivered photons are absorbed in superficial tissues, with a declining fraction reaching deeper structures.*

The science:

Jacques' foundational review of tissue optics emphasizes that scattering dominates in most soft tissues across the visible and near-infrared range, and that absorption and scattering coefficients vary strongly by tissue type and wavelength.[6] There is no single "penetration depth" that applies to all body sites, patient populations, and clinical targets.

What can be said honestly: near-infrared wavelengths in the 800-900 nm range penetrate more deeply than red wavelengths in the 600-700 nm range, because tissue scattering decreases with increasing

wavelength within this band. Broader, more directional beams sustain higher fluence at depth than narrow or diffuse beams delivering the same surface irradiance, because of reduced lateral photon loss.[5] LASER sources, with higher radiance and more controlled beam geometry, have engineering characteristics that favor depth delivery, but specific depth claims should be referenced to the target tissue and clinical context rather than stated as absolute numbers.

For Full-Body light therapy, a more honest framing than "X mm of penetration" is that the modality is delivering systemic exposure that drives both direct superficial effects and secondary signaling (vascular, immune, autonomic). The depth question matters most when the target is a specific deep structure; for systemic recovery and wellness applications, the question becomes less central.

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> **Q7. "If LASERs are so much more powerful, why do I not feel more heat?"**

Short answer: *Because light therapy dosing is engineered to stay below thermal thresholds. The Pod delivers*

high radiance but distributes it across the full body surface over a timed session, keeping average tissue heating within safety limits.

The science:

The LASER Pod's cleared indications involve topical elevated tissue temperature via infrared spectral emissions, consistent with its ILY product code classification. Perceptible warmth is expected and is part of the therapeutic mechanism. What patients do not experience is focal heating of the kind associated with surgical or ablative LASERs, because the Pod's emitter configuration distributes energy across a large surface area rather than concentrating it at a point.

FDA's light therapy guidance specifically warns that some devices, particularly high-irradiance close-contact designs like masks and helmets can raise tissue temperature to dangerous levels if used improperly.[1] The Pod's enclosure geometry, session timing, and emitter spacing are engineered to stay within safe thermal limits while delivering meaningful photonic exposure. The absence of excessive heat sensation is a design feature, not an indicator of low power.

Theme 3: Clinical Evidence

> **Q8. "The Keshri study showed LASER and LED were equivalent. Doesn't that settle it?"**

Short answer: *No. Keshri et al. showed that when wavelength, dose, pulse structure, and geometry are rigorously matched at a localized wound site, LASER and LED produce comparable biological signaling. That finding does not extrapolate to Full-Body delivery, where the matching conditions cannot be replicated.*

The science:

Keshri and colleagues (2021) compared pulsed 810 nm LASER and approximately 808 nm LED light therapy in a preclinical burn wound model using matched parameters for average power, irradiance, fluence, duty cycle, and exposure schedule. Both modalities produced comparable beneficial molecular and histologic signatures.[7] The study is appropriately cited as evidence that light therapy biology does not inherently require LASER coherence when all other variables are held constant.

The study's limits matter. It was (a) preclinical, not clinical; (b) localized to a small wound bed, not distributed across a whole body; and (c) engineered with tight parameter matching between the two sources. A Full-Body light therapy enclosure presents continuous body curvature, variable emitter-to-skin distance, variable tissue pigmentation and thickness, and broad spectral differences between the source types. The conditions that made LASER-LED equivalence possible in Keshri's design do not exist in a commercial Full-Body bed.

The honest synthesis: Keshri et al. supports the claim that mitochondrial photoacceptor activation can be driven by either source when matched. It does not support the claim that LED-only and LASER-based Full-Body systems produce equivalent clinical outcomes in real-world practice, because real-world practice does not hold all other variables constant.

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Q9. "LED Full-Body beds have published RCTs - what published evidence does the LASER Pod have?"

Short answer: *The published Full-Body light therapy literature is predominantly LED-based, and any new device, including the LASER Pod, enters afield where the clinical evidence base is still maturing. The mechanistic, dosimetric, and safety literature supports LASER-based delivery; device-specific clinical data accumulates over time.*

The science:

Full-Body light therapy as a distinct modality is relatively young in terms of peer-reviewed trials. The most cited Full-Body RCTs on fibromyalgia[8] and exercise recovery[9] used LED beds and reported mixed outcomes: positive symptom effects in fibromyalgia, null effects on creatine kinase and interleukin-6 in trained athletes. The evidence base is heterogeneous, dose-sensitive, and small.

The LASER Pod's case to clinicians rests on three foundations: (1) the broader mechanistic light therapy literature, which supports mitochondrial and systemic responses to red and near-infrared light across source types;
(2) the dosimetric and biophysical literature, which supports the specific advantages of LASER sources in Full-Body delivery geometry; and (3) the safety and regulatory framework, which governs deployment. Device-specific clinical outcome data will accumulate as the platform is deployed across clinical practices; that is the normal course for any new therapeutic technology.

A candid framing for peer conversations: the LASER Pod is the first true LASER-based Full-Body light therapy platform, and the published literature comparing it head-to-head with LED beds at Full-Body scale does

not yet exist. The clinical case is built on mechanism and engineering, not on head-to-head trial data. That is an honest limitation, and it does not differ materially from the state of the LED Full-Body evidence base a decade ago.

Q10. "What about the biphasic dose-response? Can too much LASER light be harmful?"

Short answer: *The biphasic (hormetic) dose-response is one of the most important principles in light therapy. Too little dose produces no effect, a middle range produces benefit, and excessive dose can blunt or reverse benefit. Pod protocols are engineered to deliver doses within the therapeutic range.*

The science:

Huang and colleagues' seminal analysis established the biphasic dose-response pattern in light therapy: dose- response curves across multiple indications show a rise to an optimum, followed by a plateau or decline at higher doses.[10] The principle is why dosimetric precision matters: a device that cannot control its delivered dose cannot reliably land patients within the therapeutic window.

The Full-Body LED trials that reported null outcomes, notably Ghigiarelli et al.[9] acknowledged that Full-Body LED delivery can exceed therapeutic-window totals because the treated area is so large. This is a structural challenge for LED Full-Body systems: broad spectral bandwidth, distance-sensitive irradiance, and diffuse angular emission all work against precise dose control.

LASER sources, with their narrow bandwidth, directional emission, and distance stability, offer better inherent dose control which is the engineering response to the biphasic challenge. Pod session protocols are designed around the therapeutic range rather than at its edges. From a clinician's standpoint, adherence to the programmed protocols and session durations is the practical mechanism for staying inside the therapeutic window.

Theme 4: Practical Implementation

Q11. "Is a Class IV LASER in a Full-Body enclosure safe for unattended use?"

Short answer: *Yes, when the enclosure, interlocks, and session controls are engineered for that purpose. Class IV designation is a LASER safety classification under IEC 60825-1, it describes potential hazard, not actual patient risk during normal use.*

The science:

IEC 60825-1 classifies LASER products by their potential to cause injury under various exposure conditions. Class IV is the highest classification and applies to the raw LASER source; it does not describe the risk profile of a complete device with engineered safety controls. A Class IV LASER inside an enclosure with appropriate interlocks, dosing limits, and operator controls presents a fundamentally different real-world safety profile than an open-beam Class IV source.

FDA's LASER Notice 56 describes the agency's approach to LASER product performance standards and addresses conformance with IEC 60825-1 and IEC 60601-2-22.[11] Safety expectations for Full-Body LASER light therapy include appropriate eye protection for patients, patient education and consent, screening for photosensitizing medications and pregnancy, and compliance with the device's use instructions. These expectations are not different in kind from the safety expectations around handheld Class IV therapy LASERs already in widespread clinical use.

Unattended operation is supported by the Pod's enclosure design, session timing, and programmed protocols. Clinicians should follow the device labeling and their practice-level standard operating procedures for patient screening, positioning, and supervision, including appropriate eye protection during all sessions.

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Q12. "Why is the LASER Pod cleared as an infrared heating lamp rather than a light therapy device?"

Short answer: *Because the FDA's light therapy device guidance is still in draft form, and the regulatory pathway with established clearance for Full-Body infrared systems is the product code ILY (therapeutic infrared heating lamp), which is 510(k) exempt. Regulatory classification and scientific mechanism are separate questions.*

The science:

FDA published draft guidance specifically for light therapy devices in 2023.[1] At the time of this writing, the guidance remains in draft status and does not represent a finalized regulatory pathway for new light therapy device submissions. The established, currently-in-force clearance pathway for Full-Body infrared therapeutic devices is product code ILY under 21 CFR 890.5500 (Lamp, Infrared, Therapeutic, Heating), which is 510(k) exempt.

The Pod's cleared indications - temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasms, temporary increase in local blood circulation, and temporary muscle relaxation through topical elevated tissue temperature are the indications appropriate to its regulatory classification. The scientific framework of light therapy informs clinical understanding of mechanism, but it does not expand the cleared indications for use.

A useful way to explain this to peers: the device's regulatory classification is about the pathway through which it came to market, not about the scientific identity of what it does. An automobile might be classified by its weight class for registration purposes; that classification doesn't determine what kind of engine it has or how it drives.

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Q13. "I already have a Summus handheld LASER. Why would I add the Pod?"

Short answer: *The handheld and the Pod are complementary, not redundant. Handheld LASERs focus power for targeted, provider-delivered treatment; the Pod distributes power for systemic, unattended Full-Body exposure. They serve different clinical workflows and patient types.*

The science:

Targeted Class IV therapy LASERs focus high-radiance output into localized tissue where precision matters: specific musculoskeletal complaints, post-surgical sites, focal pain, wound care. The handheld requires clinician time and attention, and its billing and throughput reflect that. The clinical case for the handheld is built around accuracy, power density at a specific site, and provider-delivered care.

The Pod is designed for a different goal: distributed, systemic exposure delivered consistently across the body in an unattended workflow. Its clinical fit is in recovery protocols, wellness and longevity programs, membership-based cash-pay care, and staffing-constrained environments. It is not a replacement for the handheld, it expands what the practice can deliver.

From a practice-economics standpoint: the handheld treats one patient at a time with a provider present. The Pod treats one patient at a time without a provider required, freeing clinician time for other revenue-generating activities. Practices that offer both can segment their patient base: targeted care delivered with the handheld, systemic recovery and wellness delivered with the Pod, and in many cases the same patient benefits from both.

Q14. "What should I tell a patient who asks whether this is just another ıred lightı device?"

Short answer: *It is a true Class IV LASER-based Full-Body system, meaningfully different from the consumer LED panels and at-home "red light" devices that share some vocabulary but not the underlying technology. The distinction is fair to make, and worth making.*

The science:

The consumer market has expanded dramatically in the past several years, with retail LED panels, masks, and handheld devices all marketed under the umbrella of "red light therapy." These products vary widely in emitter quality, wavelength specification, irradiance, and clinical relevance. Many are legitimate for modest claims; many overpromise.

The Pod differs from consumer red light devices on several axes: (a) it uses true LASER diodes as its primary emitters, delivering coherent, narrow-bandwidth, high-radiance light rather than broad-spectrum LED output; (b) it is an FDA-registered medical device with cleared indications under product code ILY; (c) it delivers Full-Body exposure in a clinical environment under a structured session protocol; and (d) its session dose is engineered to stay within the therapeutic range rather than being determined by consumer judgment.

A patient who asks this question is asking a legitimate and increasingly common question. A reasonable answer is that while the underlying biology of red and near-infrared light therapy is shared across many devices, the specific engineering, dosing precision, and clinical context of the Pod are substantially different from retail red light products.

A Note on Intellectual Honesty

Clinicians are generally better served by candor than by marketing. This FAQ has been written with the recognition that some answers are more favorable to the Summus LASER Pod than others, and some objections have partial merit that should be acknowledged rather than dismissed. Full-Body light therapy is a maturing modality, the evidence base is still accumulating, and no device (including the Pod) has a complete clinical trial portfolio at this point in the field's development.

The scientific case for the LASER Pod rests on mechanism and engineering: the physics of LASER sources offer advantages over LED sources for Full-Body delivery geometry, and the engineering of the Pod translates those advantages into a reproducible clinical workflow. The case does not require dismissing LED-based systems, overstating penetration depth, or claiming head-to-head clinical superiority that has not yet been established in published trials. The case stands on its own merits without those exaggerations.

For clinicians evaluating the Pod: the right questions are about fit with your practice, your patient base, and your clinical goals. The science is strong, the engineering is sound, and the gaps in the evidence base are honest gaps that will be addressed over time as the platform accumulates clinical experience.

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Regulatory Notice and Disclaimer

The Summus LASER Pod is an FDA-registered medical device, 510(k) exempt, under product code ILY (21 CFR 890.5500, Lamp, Infrared, Therapeutic, Heating). It is intended for the temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasms, temporary increase in local blood circulation, and the help in temporary relaxation of muscles through the application of topical elevated tissue temperature via infrared spectral emissions. This device is not intended to diagnose, treat, cure, or prevent any disease. This FAQ is intended as clinician-facing educational content; it is not medical advice and does not expand the cleared indications for use. Clinicians should consult the device labeling for full indications and instructions and their Summus representative for the most current regulatory and clinical information.