

Martin®

MAC ONE BEAM



**READY TO LIGHT
U.S. STAGES**

MAC ONE BEAM FDA FAQs

The Martin **MAC One Beam** is considered a LILI (Laser Illuminated Lighting Instrument) which is a type of demonstration laser product in US. Its light source consists of a small blue laser shooting at a phosphor, converting the coherent blue laser light into incoherent white light. The concept is the same as in a common white light LED, where incoherent blue light is used for conversion.

Because a laser source is used inside this lighting fixture, it falls under the jurisdiction of the FDA and CDRH in the United States. This raises some questions which we intend to answer in this document.

WHY DID WE DECIDE TO USE A LASER-BASED SOURCE?

LED sources do not provide a high enough flux-density, which makes it impossible to create a narrow near-parallel beam based on an LED source.

Discharge lamps are being phased out due to various legal regulations and have a short lifetime.

So, the MAC One Beam uses a laser-based light source, just like most competitors in the beam market.

IS THERE LASER LIGHT COMING OUT OF THE MAC ONE BEAM?

A part (60%) of the laser light, generated by the laser inside the engine, is converted into visible white light in the phosphor inside the engine. Another part (40%) of laser light scatters through the phosphor, hence becoming incoherent (non-laser), intense and visible blue light (it then mixes with the yellowish light from the phosphor to create a mixed white).

WHAT IF THE PHOSPHOR BREAKS? DOES LASER LIGHT THEN EMIT FROM THE FIXTURE?

The laser-based light engine used in the MAC One Beam is being used in the automotive industry (car headlights) and features extreme safety measures inside. The safety features in the light engine and driver circuitry will shut off the light source if the phosphor gets damaged in any way.



WHAT IS AN FDA OWNER'S VARIANCE?

In the context of LILI (Laser Illuminated Lighting Instruments) used in entertainment and stage lighting, an FDA Owner's Variance is an authorization issued by the U.S. FDA's Center for Devices and Radiological Health (CDRH) that permits the use of laser-based entertainment devices that would otherwise exceed the standard regulatory limits for demonstration laser products.

Historically, the FDA distinguished between:

- **Manufacturer Variance:** Held by the manufacturer of the laser device, allowing the product to be imported, marketed and used under specified conditions. Harman obtained such variance in August 2026.
- **Show/Operator/Owner Variance:** Held by the company or individual distributing, dealing, purchasing or operating the laser equipment in shows or installations.

In practical entertainment lighting discussions, an "Owner's Variance" usually means that the entity that owns and operates the laser equipment has FDA authorization to use it in a laser show or installation.

CAN A MARTIN LILI (MAC ONE BEAM) BE ADDED TO AN EXISTING FDA OWNER'S VARIANCE?

Existing FDA variance holders may submit a supplemental variance request to include our MAC One Beam product. However, FDA generally prefers a clean, separate variance where products may be subject to different variance conditions.

A supplemental variance may be considered where the existing variance already covers a comparable LILI. However, variance conditions can differ between products, including between different LILIs, and therefore combining multiple products under the same variance may not always be appropriate.

In particular, an existing variance for a conventional laser projector should generally not be supplemented to include a LILI, as these products are significantly different and are subject to different variance conditions. In such cases, FDA recommends submitting a new variance application.

HOW TO OBTAIN AN FDA VARIANCE TO DEPLOY THE MAC ONE BEAM?

1. Obtain the manufacturer's FDA laser product documentation and accession numbers and/or docket number from Harman.
2. Prepare a Cover Sheet, Laser Light Show Report (FDA Form 3640) including application for variance (FDA Form 3147). Harman can provide templates for this.
3. Submit the entire package to the FDA requesting a variance. Harman can provide guidance for this.
4. Wait for FDA approval before conducting operations requiring the variance.

CAN THE MAC ONE BEAM BE USED OUTDOORS?

The MAC One Beam is an IP20-rated fixture, so it can only be used in dry locations (protected from rain).

If any laser beam or laser-based light can enter navigable airspace, additional coordination with the FAA is required. Outdoor laser operations that could affect pilots, aircraft, airports, or flight paths require notification and review before operation.

Notifying the FAA is required for such outdoor shows and Harman can provide additional calculations and documents to get a letter of non-objection.

For Canada, you will have to notify Transport Canada. Here is a link to the information on the Transport Canada website: [CLICK HERE](#)

Complete the [Notice of proposal to conduct outdoor laser operation\(s\)](#) and send it to the [Transport Canada regional office closest to you.](#)



THE MAC ONE BEAM IS CLASSIFIED AS LASER CLASS 1, RISK GROUP 3. WHAT DOES THIS MEAN?

Usually moving head lighting fixtures in entertainment and stage lighting are only classified in Risk Groups and Application Groups (BLH). However, with a laser being used in the product, it also needs to be assessed according to the IEC 60825 standard for the safety of laser products that are also recognized in US through FDA Laser Notice 56.

Laser Class 1 is the safest laser classification worldwide. A Class 1 laser product is designed so that, during normal operation, human exposure to accessible laser radiation does not exceed the maximum permissible exposure (MPE) limits for this class and no coherent laser light external to the fixture is considered hazardous to eyes or skin.

Due to the high intensity and collimated beam, the fixture is classified as Photobiological Risk Group 3 (RG3) per retinal thermal, which is the highest hazard classification in the IEC 62471 standard series for the photobiological safety of lamps and lamp systems. A fixture classified as RG3 (High Risk) is considered hazardous even for momentary exposure and can potentially cause injury to the eyes or skin without relying on natural aversion responses such as blinking or looking away (< 0.25 s for eye).

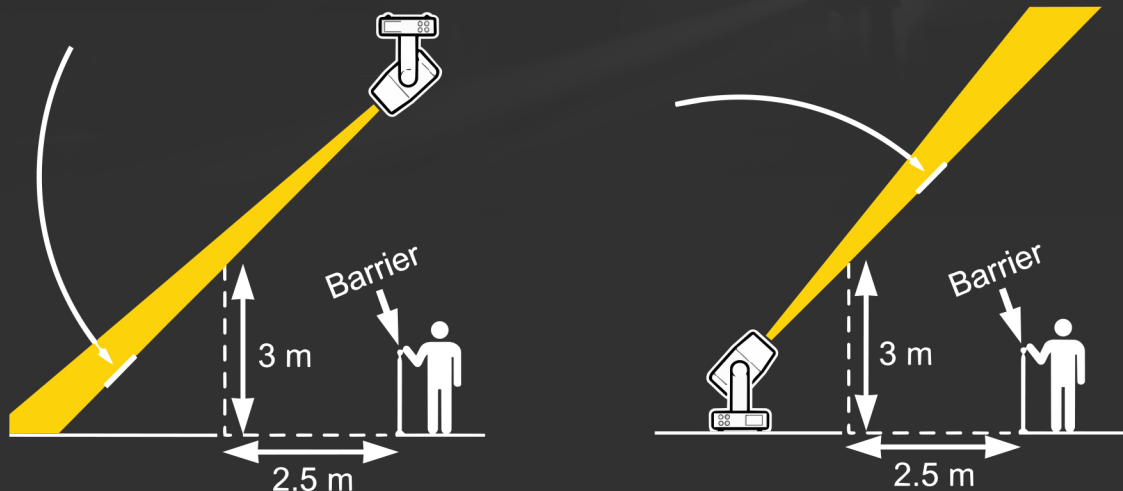
The MAC One Beam is, however, only classified as Risk Group 3 within the first 16.5 feet (5 m) from the lens. Further away from the fixture, the MAC One Beam is classified as Risk Group 2.

Due to current FDA regulations in US, a Laser Class 1 / RG3 fixture will be considered a demonstration laser product equivalent to ordinary Laser Class IIIb or IV (IEC 60835-1 Class 3B or 4) equipment per CFR 1040, hence a variance approval is still needed.

Photobiological Risk Group 2 (RG2) is contrary considered moderate risk, as such the fixture may only present a photobiological hazard if a person deliberately stares into it for an extended time period, or lacks natural aversion response (> 0.25 s), e.g. due to disability, drugs or disease and the like.

The MAC One Beam user manual therefore states that dimming zones must be set up for areas where people can get closer than 16.5 feet (5 m) to the fixture, to prevent intensive light exposure of people's eyes. Beyond 16.5 feet (5 m), it reduces to Risk Group 2, like most other (regular) lighting fixtures, provided magnifiers, telescopes, binoculars or similar optical instruments may not concentrate the light output significantly.

The Dimming Zones must also include an area in front of and around the fixture beam that is 10 ft. (3 m) vertically from the floor and 8 ft. 3 in. (2.5 m) horizontally from the beam. Access to all areas that are not protected by Dimming Zones must be prevented using barriers or the like.



Take reflections from mirrored surfaces, mirror balls and any other reflective stage artifacts or surfaces into account when defining Dimming Zones.

WHAT IS REQUIRED BEFORE A SALE CAN GO THROUGH ON THE MAC ONE BEAM?

Harman is legally obliged to check if the buyer possesses an FDA Owner's variance. Once confirmed, Harman is legally obliged to document the buyer's variance number and effective date and archive this for a future FDA audit.

WHAT IS REQUIRED FOR DROP SHIPMENTS?

For drop shipments, where Harman ships products directly to a distributor's or dealer's customer, the distributor or dealer is responsible for verifying and documenting the customer's FDA variance. Harman is only required to verify and document the FDA variance of the distributor or dealer placing the order.

