# URGENT: MEDICAL DEVICE CORRECTION

## Quest Spectrum® 3

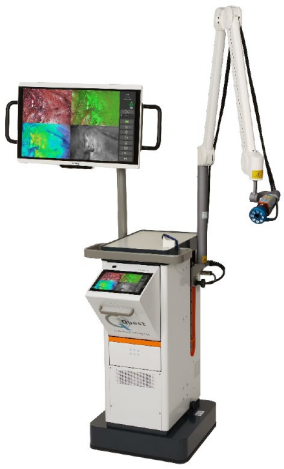
| Model | Name | UDI | Serial Numbers |
|---|---|---|---|
| **ART-SYS-0029** | Quest Spectrum® 3 Fluorescent Imaging System | 08719324487047 | All |
| **ART-SYS-0030** | Quest Spectrum® 3 Fluorescent Imaging System | 08719324487047 | All |

Date: September 24, 2024

Attention: Operating Room Director, Risk Management

Dear Healthcare Provider:

Quest Photonic Devices, an Olympus subsidiary, is writing to inform you of a Field Corrective Action pertaining to the Quest Spectrum® 3, ART-SYS-0029 and ART-SYS-0030 ("Spectrum 3") The Quest Spectrum®3 is a fluorescent imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used during plastic and reconstructive surgeries. See image below.



**Reason for Action:**

Quest has become aware that the Spectrum® 3 products currently on the market do not meet the requirements for electromagnetic compatibility (EMC) of the standard IEC 60601-1-2. The purpose of EMC is to keep interferences of electrical devices interconnected or close to each other under control in the way that electrical and electronic equipment does not generate, or is not affected by, electromagnetic disturbance.

Quest has received two complaints that are potentially applicable to this issue.

Olympus requires you to take the following actions:

- Discontinue use of the Spectrum 3 until you receive additional instructions from Quest for corrections.
- Devices should be quarantined and marked appropriately by your site to prevent usage.

**Risk to Health:**
Failure to meet electromagnetic compatibility (EMC) of the standard IEC 60601-1-2 can lead to potential patient harms. Electromagnetic interference occurring during a procedure may cause the device to malfunction requiring the replacement of the device. This could potentially result in a prolonged procedure and/or require additional medical intervention such as conversion from a minimally invasive surgery (MIS) to an open surgical procedure. Loss of visualization during the MIS procedure has the potential to lead to organ perforation requiring conversion to an open procedure. Failure to meet electromagnetic compatibility (EMC) of the standard IEC 60601-1-2 may affect other life supporting devices in the operating room, such as ventilators and monitoring equipment.

**Actions Required:**
Our records indicate that your facility is using one or more of the affected products. Quest is working on an update to correct the design in the coming months and will then contact you to coordinate the update for your unit(s). The foreseen time schedule is the first quarter of 2025.

In the meantime, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Quarantine and mark you Spectrum® 3 unit appropriately to prevent usage.
3. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification.
4. Acknowledge receipt of this letter through the Olympus recall portal:
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0456"
    c. Complete the form as instructed.
5. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report any complaints or any associated injuries to the Technical Assistance Center (TAC) at 1-800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
FCA Regional Lead, Americas