| Incident Report Form | PHOTONIC |
|---|---|
| **Luminaire / Suspension System** | Distributor form |

**Dear Customer, dear Distributor,**

This form is intended to report an incident which led or could have led to a serious adverse event. A serious adverse event is characterized by a serious deterioration of the state of health or even death of patients or operators which could be related to the malfunctioning of the medical device. Please report your information as precisely as possible, so that PHOTONIC can rapidly act to ensure further safe operation and work in close collaboration with the national health authorities.

| **Section 1: Administrative Information** | | | |
|---|---|---|---|
| **1.1** | **Distributor installing device** | | |
| **a** | **Organisation name** | **b** | **Photonic Certified Technician name** |
| **c** | **Email** | **d** | **Phone (international)** |
| **e** | **Street** | **f** | **Street number** |
| **g** | **Postal code / City** | **h** | **Country** |
| **1.2** | **Customer receiving device** | | |
| **a** | **Organisation name** | **b** | **Emergency contact name** |
| **c** | **Email** | **d** | **Phone (international)** |
| **e** | **Street** | **f** | **Street number** |
| **g** | **Postal code / City** | **h** | **Country** |

| **Section 2: Medical Device Information** | | | |
|---|---|---|---|
| **2.1** | **Luminaire identification** | | |
| **a** | **Device name** | **b** | **Serial number (SN)** |
| **c** | **Unique Device Identifier (UDI)** | **d** | **Reference number (REF)** |
| **2.2** | **Suspension system identification** | | |
| **a** | **Device name** | **b** | **Serial number (SN)** |
| **c** | **Unique Device Identifier (UDI)** | **d** | **Reference number (REF)** |
| **2.3** | **Location** | | |
| **a** | **Clinical department (f.e. Cardiology)** | **b** | **Type of facility (f.e. OR, ICU, …)** |

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| **Section 3: Incident details** | | | |
|---|---|---|---|
| **2.1** | **General informations** | | |
| **a** | **Date of incident (dd.mm.yyyy)** | **b** | **Number of patients involved** |
| **c** | **Current location of device** | **d** | **Number of operators involved** |
| **e** | **Has the national authority already been informed? If yes, please enter the report number.** | | |
| **2.2** | **Description of incident incl. adverse health effects (if applicable)** | | |
| | | | |
| **2.3** | **Immediate remedial actions taken by healthcare professional, patient or any other person** | | |
| | | | |
| **2.4** | **List any other devices or accesories which were connected or in close proximity to device** | | |
| | | | |

**Submission date:** **Signature of Distributor:**

*Please return this form immediately through the distributor portal or via meddev@photonic.at back to us!*