



Field Safety Notice, Follow Up Communication

iLED 7 Surgical Lights

FA-2024-035

Baxter Medical Systems GmbH + Co. KG (Single Registration Number: DE-MF-000005071)

Correction

October DD, 2024 (to be adapted locally)

Dear Sir/Madam (to be adapted locally),

**Problem
Description**

This is an update to a Baxter Healthcare Corporation Medical Device Correction letter regarding surgical light systems sent on June DD, 2024 (to be adapted locally). The updated information is in bold text. Baxter Healthcare Corporation is issuing a Medical Device Correction due to customer reports of thermal skin injuries when using the **iLED 7** surgical light system products listed below. The **iLED 7** surgical lights are intended to provide consistent illumination of the surgical field or the patient. Baxter identified that the customer reports are potentially related to a lack of awareness of surgical light safety. In addition, Baxter is continuing to investigate potential device inconsistencies.

Baxter has completed its investigation and is implementing additional actions to help mitigate the potential for thermal skin injuries. Actions include digitally accessible evidence-based clinical education, enrichment of the Instruction for Use (IFU), and further product enhancements.

Baxter Technical Service will call your facility to arrange the correction of our device; please be prepared to provide details of light head product codes and versions of all wall and mobile control units you may have. Baxter Technical Service may request photos of the iLED7 product label and the mobile control and/or wall control to ensure our Technical Service team can prepare for the correction with the appropriate tools/equipment.

**Affected Product
(to be adapted
locally)**

Product Code	Product Description	Serial Numbers	UDI Number
4068110	iLED 7 Ceiling Single Surgical Light	All	00887761968325
4068120	iLED 7 Mobile Surgical Light		00887761968318
4068140	iLED 7 Pendant Surgical Light		00887761968301
4068210	iLED 7 Ceiling Duo Surgical Lights		00887761968295



4068310	iLED 7 Ceiling Trio Surgical Lights		00887761968288
4068410	iLED 7 Ceiling Quad Surgical Lights		00887761968271

Hazard Involved Many factors may increase the risk of thermal injuries to the skin, organs, and tissue when using LED overhead surgical lights. The risk increases when multiple LED overhead surgical lights are overlapped and set at a high intensity during long exposure times. Thermal injuries may include skin burns and drying of tissue that may lead to scarring, infection, and/or internal organ damage. **Baxter has received 12 reports of serious injuries associated with this issue (to be adapted locally).**

- Action to be taken by the user**
1. Operators may continue to use the **iLED 7** surgical light systems by following the current instructions for use (IFU) cautions and warnings while considering the additional information below.
 - Utilize the lowest possible illumination level suitable for the procedure, especially in certain neurological or intestinal procedures on delicate, thin, dry, or abnormal tissue.
 - Avoid overlapping light fields that are set at high intensity (80% or higher).
 - If the light intensity of one light-head is set at 80% or higher the second light-head, if overlapping, should be set at 50% or lower.
 - If the light intensity of two or more light heads is set at 80% or higher, to minimize risk do not overlap them.
 - If a very high-intensity setting is temporarily required, reduce intensity as soon as the need passes.
 - Ensure the Adaptive Light Control (ALC) Plus sensor is activated and indicated on the wall or mobile control panel. If activation of the ALC Plus is not possible, please contact a technical service representative for further instructions.
 - If the ALC Plus is switched off, the light-head needs to be positioned at 100 centimeters (39.37 inches) from the surgical field. At other distances the illuminance and irradiance limits can be exceeded, which may result in thermal skin injuries.
 2. **Baxter highly recommends that all end users of the impacted product are made aware of essential educational information by visiting www.hillrom.com/iled-light-safety, or by scanning the QR code below to understand the changes Baxter has made to mitigate thermal skin injuries. As part of this action, a sticker with the QR code will be placed on the ILED 7**



wall control panel and/or mobile control units by Baxter Technical Service (to be adapted locally).

Your facility may contact Baxter Technical Support to request a complimentary paper version of the updated IFU. Please note that the printed updated IFU is not an alternative to visiting the iLED light safety web page listed above as the page consists of essential material such as in-service videos, LED safety whitepapers, etc.



3. If you received this communication directly from Baxter, please acknowledge receipt by responding on our customer portal at <https://BaxterFieldActionCustomerPortal.onprocess.com>. Log in to the portal using the account number located on the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgment, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification (to be adapted locally).
4. Please provide this information to all users of the impacted surgical light. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable in this situation. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.
6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Medical Device Correction in accordance with your customary procedures and check the associated box on the customer portal.

Further information and support (to be adapted locally)

For general questions regarding this communication or any product issue you are experiencing, contact Baxter at (insert local contact information), between the hours of (insert local information).



For Medical Information, please email medinfo@baxter.com and reference this recall notice. One of our agents will respond during our normal business hours of [\(insert local information\)](#)

The local Ministry of Health (MOH) has been notified of this action. [\(to be adapted locally\)](#)

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Name [\(to be adapted locally\)](#)

Title [\(to be adapted locally\)](#)

Baxter Healthcare Corporation [\(to be adapted locally\)](#)