

**New Field Safety Notice - Urgent Medical Device Correction**  
**da Vinci® 5 (dV5) System equipped with the Near Infrared (NIR)**  
**Handheld Camera (ISIFA2026-03-C)**

<p>1- Introduction and Reason for Field Action</p>	<p>Dear Intuitive Customer,</p> <p>This Field Safety Notice (FSN) is to advise you that Intuitive is initiating a Field Safety Corrective Action (FSCA) for the da Vinci® 5 (dV5) System equipped with the Near Infrared (NIR) Handheld Camera.</p> <p>The NIR Handheld Camera system is intended to be used for laparoscopic tasks within da Vinci procedures.</p> <p>Intuitive has identified a condition in which the NIR modes may remain active unintentionally when attempting to turn off visible white light illumination during normal clinical workflow transitions, notably when switching from the handheld camera to the robotic endoscope, which may result in thermal injury if the distal end of the light guide (detached) or assembled laparoscope contacts the patient, user, or sterile drapes while NIR mode is active.</p> <p>Due to the Camera Head button functionality, users may assume that they have turned off all illumination when the system is actually still operating in a near infrared imaging mode (NIR laser active). For example, the NIR FI Contrast mode emits only near-infrared laser light without visible white light. In this mode, only a faint magenta-colored glow may be visible from the distal tip of the light guide cable, which may cause the user to believe that all illumination has been deactivated even though the NIR laser remains active.</p> <p>When an NIR mode is active, the NIR Handheld Camera system provides the following indicators on the front panel of the Light Source (see Figure 2)</p> <ul style="list-style-type: none"> <li>• “LASER ON” status indicator</li> <li>• laser symbol on the LCD display</li> <li>• green-colored button backlights</li> </ul> <p>Depending on operating room configuration, the dV5 Tower monitor can be positioned such that these indicators are obstructed from view (see Figure 3), which may make it more difficult to visually confirm when NIR laser is active. When the NIR laser is active, only a dim magenta-colored glow may be visible from the distal tip of the Light Guide (see Figure 2).</p> <p>The components of the NIR Handheld Camera system are shown in Figure 1. An example of the Light Source with the NIR laser activated is shown in Figure 2.</p>
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Figure 1. da Vinci 5 NIR Handheld Camera System Components

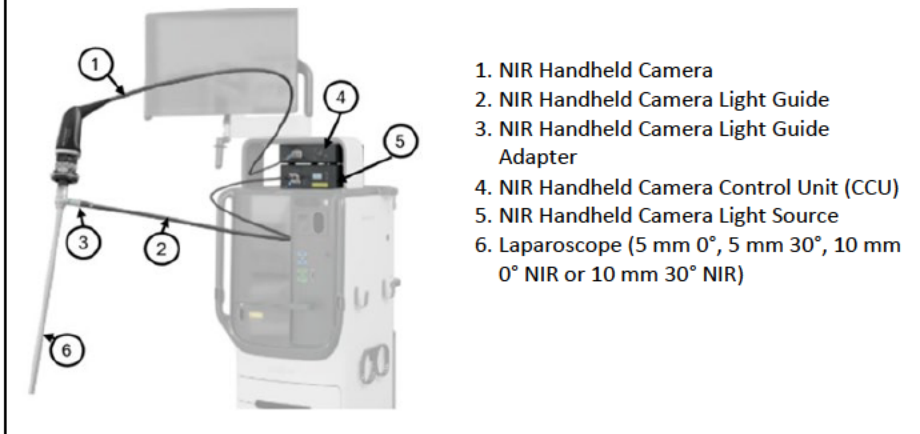
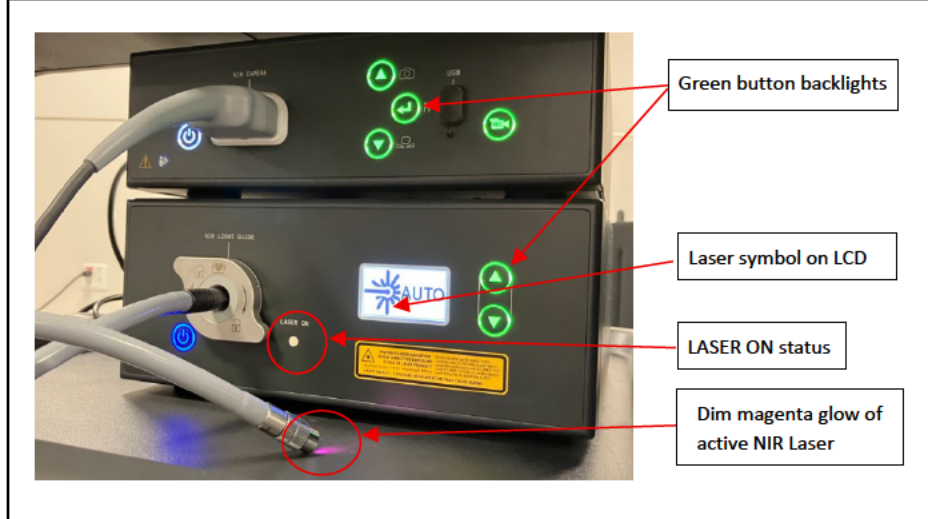


Figure 2. Light Source with NIR Laser Activated (Laser ON indicator illuminated)



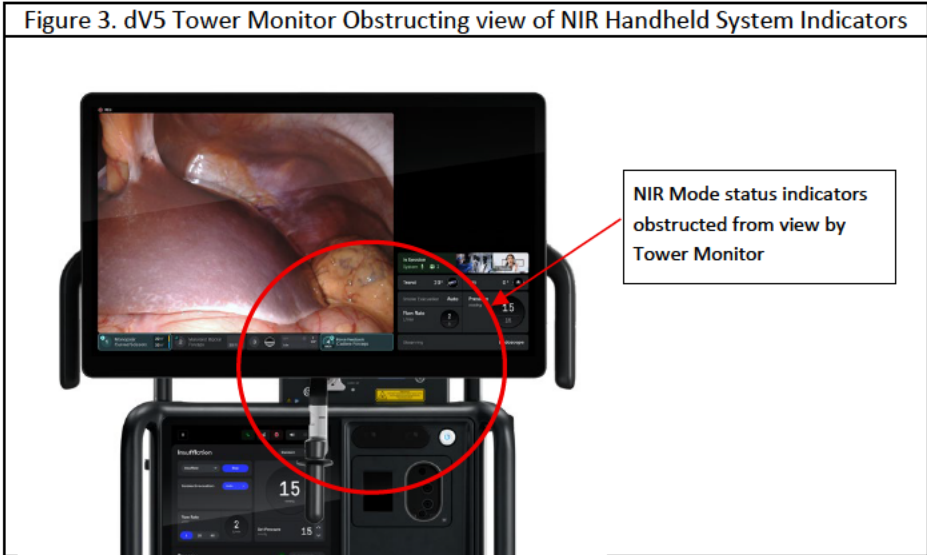
	<p>Figure 3. dV5 Tower Monitor Obstructing view of NIR Handheld System Indicators</p> 
<p>2 - Risk to Health</p>	<p>At this time, Intuitive has received forty-two (42) potentially relevant complaints worldwide. No serious incidents* associated with this issue were reported in Europe.</p> <p>Unintended activation of the NIR modes may result in external patient or user burn injury due to localized heating if the detached light guide cable is placed on the patient or sterile drapes while the NIR mode is active. Burn severity may range from minor superficial burns requiring minimal treatment to more serious burns requiring medical or surgical intervention.</p> <p>Localized heating may also damage or create holes in sterile drapes, potentially compromising sterility and increasing the risk of contamination and infection, which in severe cases could require medical or surgical treatment.</p> <p>Contact between the high-temperature distal tip of the light guide cable and flammable materials could result in ignition and / or combustion of those materials.</p>
<p>3. Affected Products</p>	<p><b>Product Name:</b> ASSY,DV5 TOWER,IS5000  <b>Product Number:</b> 380746  <b>UDI:</b> 00886874119662</p>
<p>4. Actions to be taken by the Customer/User</p>	<p><b>Actions required for Continued Use of dV5 Systems Equipped with the NIR Handheld Camera:</b></p> <ul style="list-style-type: none"> <li>• <b>Prior to each use</b>, ensure that the NIR Handheld Camera Light Source indicators remain visible to operating room staff so that the laser status can be confirmed. <b>Position</b> the dV5 Tower Monitor and other equipment so the Light Source indicators are not obstructed from view.</li> <li>• The Tower Monitor should be positioned to avoid obstructing the Light Source indicators to maintain clear visibility of the CCU during use. Monitor positioning may vary based on Operating Room configuration (see Figure 4 for an example). Refer to the Near Infrared Handheld camera System User Manual (PN 557076-03) for additional setup guidance</li> </ul>

Figure 4. Placement of CCU and light source (example)



1. **Tower monitor:** Images are displayed on this monitor.
2. **NIR handheld camera control unit (CCU):** Placed atop the NIR handheld camera light source.
3. **NIR handheld camera light source:** Placed on the accessory shelf of the Tower.
4. **Tower touchscreen:** Used to modify display settings.

- The indicators include:
  - “LASER ON” status indicator
  - Laser symbol on the LCD display
  - Green-colored button backlights
- Refer to the Near Infrared Handheld Camera System User Manual (PN 557076-03) for recommended placement of the NIR Handheld Camera system components.
- Prior to placing the device on the patient or sterile drapes, confirm that the Light Source is in **Standby Mode**, as indicated by white-colored button backlights and “Standby” on the LCD display.
- Press and hold the green “up arrow” button on the Camera Head for approximately **2.5 seconds** to deactivate the light source.
- As a reminder, please be aware of the following Cautions stated in the Handheld Camera Light Guide IFU (Schoelly’s reference: TPA037-460-176; Intuitive’s reference: PN 558610-01):
  - Do not touch light guide connections
  - Do not allow the distal end of the light guide to come into contact with patient tissue or with combustible or heat-sensitive materials
  - Do not leave light guide unsupervised while light is being transmitted from the light source

Please display this communication with your systems; ensure it is in a place likely to be seen/viewed by operators.

	<p><b>As part of this communication, please take the following standard actions:</b></p> <ol style="list-style-type: none"> <li>1. Review this notice with all surgeons, operating room personnel, robotics coordinators, and risk management staff.</li> <li>2. <b>Identify Affected Product:</b> Please inspect the product label on the CCU to confirm the Part Number and Serial Number.             <ol style="list-style-type: none"> <li>a. <b>Appendix A</b> provides an example label highlighting the location of the Part Number and Batch/Lot Number.</li> <li>b. <b>Appendix B</b> lists affected Part Numbers and Serial Numbers</li> </ol> </li> <li>3. Complete the attached Acknowledgement Form immediately and return it via email to Intuitive as instructed on the form.</li> <li>4. Please retain a copy of this letter and the acknowledgement form for your files.</li> <li>5. Inform Intuitive of any Serious Incidents* or quality problems concerning the use of the subject devices via the standard complaint process.</li> <li>6. Additionally, if Serious Incidents* or quality problems are experienced, please follow your standard reporting process to your health authority, if applicable.</li> </ol>
<p>5. Actions to be taken by Intuitive</p>	<p>To address the condition described in this notification, an Intuitive Field Service Engineer will schedule a site visit to your facility and implement the improved configuration update for the NIR Handheld Camera system. This update modifies the default button behaviors on the Camera Head to help to prevent the potential for NIR modes to remain active unintentionally during normal clinical workflow transitions.</p> <p>Upon completion of the configuration update, updated Instructions for Use (IFU) will also be provided to reflect the revised functionality.</p>
<p>6. Further Information &amp; Support</p>	<p>If you need further information or support concerning this Field Safety Notice, please contact your Clinical Sales Representative or contact Intuitive Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> <li>• Europe: <b>Confidential business information</b></li> </ul>

Please be informed that the appropriate Regulatory Authority for your region has been notified of this Field Safety Corrective Action (FSCA).

Sincerely,

**Confidential business information**



Definitions:

\*Serious Incident (EUMDR 2017/745) is defined as “any incident that directly or indirectly led, might have led or might lead to any of the following:

- a. the death of a patient, user or other person
- b. the temporary or permanent serious deterioration of a patient’s, user’s, or other person’s state of health,
- c. a serious public health threat

**ACKNOWLEDGMENT FORM**

**New Field Safety Notice - Urgent Medical Device Correction**  
**da Vinci® 5 (dV5) System equipped with the Near Infrared (NIR)**  
**Handheld Camera (ISIFA2026-03-C)**

Ship-to:  
Hospital Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
City, State, Zip: \_\_\_\_\_  
SFID: \_\_\_\_\_  
ATTENTION: \_\_\_\_\_

**PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY**

1. I have received and read this notice.
2. I have ensured all appropriate personnel are fully informed of the contents of this notice.
3. I will contact Intuitive if I have any questions.

Hospital name: \_\_\_\_\_

**Position:**

Name (print): \_\_\_\_\_

- Robotics Coordinator
- Operating Room Director

Signature: \_\_\_\_\_

Risk Manager

Phone Number: \_\_\_\_\_

Surgeon

Other: \_\_\_\_\_

Email: \_\_\_\_\_

Date: \_\_\_\_\_

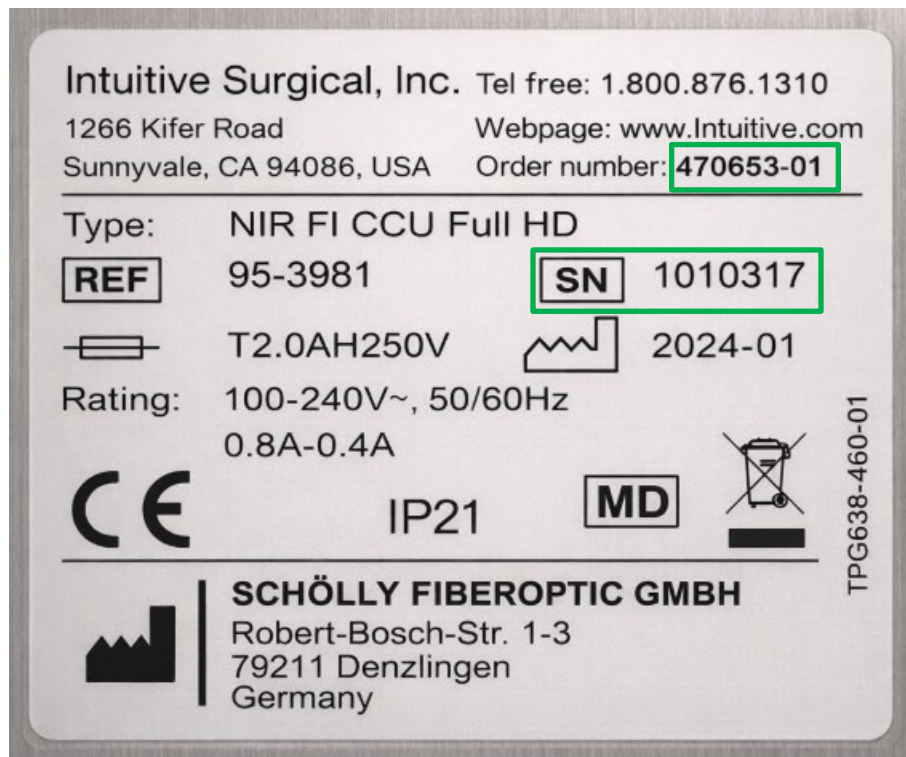
**PLEASE EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive**  
**ATTN: REGULATORY COMPLIANCE FIELD ACTIONS**  
**Subject line for email: Field Safety Corrective Action**  
**da Vinci® 5 (dV5) System equipped with the Near Infrared (NIR) Handheld Camera (ISIFA2026-03-C)**  
Email: Confidential business information

Customer Service: Confidential business information

## Appendix A: Example Product Label

The green boxes on the example label below specifically highlight the Part Number and Serial Number to assist you in locating these fields on your product.

**Affected Part Numbers:** 470653-01 and 470653-02



## Appendix B — Affected Product Part Number and Serial Numbers

Country	Part Number	Serial Number
Belgium	470653-03	1161059
Belgium	470653-03	1168931
Belgium	470653-03	1171068
France	470653-03	1159334
Germany	470653-03	1157750
Germany	470653-03	1157748
Germany	470653-03	1166282
Germany	470653-03	1157753
Germany	470653-03	1171021
Germany	470653-03	1168936
Germany	470653-03	1161053
Germany	470653-03	1157758
Germany	470653-03	1164454
Germany	470653-03	1166270
Germany	470653-03	1166278
Germany	470653-03	1171018
Greece	470653-03	1178566
Italy	470653-03	1164467
Italy	470653-03	1159327
Italy	470653-03	1159259
Italy	470653-03	1159329
Netherlands	470653-03	1157702
Netherlands	470653-03	1157757
Netherlands	470653-03	1159331
Netherlands	470653-03	1164548
Netherlands	470653-03	1157759
Netherlands	470653-03	1161060
Netherlands	470653-03	1159333
Netherlands	470653-03	1171024
Norway	470653-03	1171026
Norway	470653-03	1171037
Norway	470653-03	1171023
Poland	470653-03	1171066
Poland	470653-03	1161079
Poland	470653-03	1157756
Poland	470653-03	1159330
Poland	470653-03	1164457
Poland	470653-03	1159328

Poland	470653-03	1171067
Romania	470653-03	1168966
Romania	470653-03	1171064
Spain	470653-03	1164406
Spain	470653-03	1157751
Spain	470653-03	1168969
Spain	470653-03	1166266
Spain	470653-03	1161054
Switzerland	470653-03	1168951
Switzerland	470653-03	1159326
Switzerland	470653-03	1159332
Switzerland	470653-03	1159324
Turkey	470653-03	1200644
United Kingdom	470653-03	1157120
United Kingdom	470653-03	1166283
United Kingdom	470653-03	1178539
United Kingdom	470653-03	1179233
United Kingdom	470653-03	1168964
United Kingdom	470653-03	1171025
United Kingdom	470653-03	1171027
United Kingdom	470653-03	1195923
United Kingdom	470653-03	1197696
United Kingdom	470653-03	1197697
United Kingdom	470653-03	1197703