

Urgent Field Safety Notice

King Vision Video Laryngoscope Adapter Size ½
November 5th,2019
Return of Medical Devices to Supplier

P 317.776.6823
TF 800.642.5464
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November 8, 2019

Dear Risk Manager/Care Provider,

King Systems is initiating a voluntary recall of six (6) affected lots of its King Vision Video Laryngoscope Adapter Size 1/2 shipped between the dates of August 2nd and October 25th, 2019. Our records indicate that you have purchased one or more of the affected lots.

Affected Device(s) Details

| Part Number(s) | Lot Number(s) | Serial Number(s) |
|----------------|---------------|------------------|
| KVLVA12 | 010614 | LHXXXXXXXX10240 |
| | 010629 | LHXXXXXXXX10243 |
| | 010657 | LHXXXXXXXX10284 |
| | 010668 | LHXXXXXXXX10554 |
| | 010670 | LHXXXXXXXX10559 |
| | 010722 | LHXXXXXXXX10562 |
| | | LHXXXXXXXX10569 |
| | | LHXXXXXXXX10570 |
| | | LHXXXXXXXX10611 |
| | | LHXXXXXXXX10666 |

Description of the Problem

King Systems has received reports of some products exhibiting a reversed image, as illustrated below. Although the image may appear normal, the user's actions will be reversed on the display for left and right directions. Up and down directions are unaffected (Figure 1). Through investigation it was concluded that only the part number and lot numbers listed above are impacted. Use of an affected device may result in difficulties in navigation during intubation and/or delay in intubation. As of November 4th, 2019, King Systems has received no reports of adverse events resulting from this issue. Affected product can be identified by reviewing the

product packaging for Lot Number or individual devices for Serial Number. The Serial Number is located inside the Adapter (Figure 2).



Figure 1: KLVA12 exhibiting a reversed image. Although the image appears may appear normal, the user's actions will be reversed on the display for left and right directions. Up and down directions are unaffected.



Figure 2: KVLVA12 Serial Number location.

Action to be Taken by the User

Please review your current inventory and place any affected products in quarantine immediately. The affected products should NOT be used. Please note any affected quantity of product(s) on the attached form and return it within 30 days from the date of this letter by email to the local contact point described in the attached Recall Acknowledgment and Product Return Form

King Systems asks that you please return all affected product(s). Please contact Shelby Mitchell at +1 (410) 768-6464 or email shmi@ambu.com to arrange Return Authorization and credit/replacement.

Transmission of this Field Safety Notice

Please forward this notice to those who need to be aware within your organization, or to any organization where affected product(s) have been transferred, shipped, or sold. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We regret any inconvenience that this action may cause and thank you in advance for your cooperation. If you have any questions regarding this notice, please contact undersigned Kleve Heavin or Shelby Mitchell.

All relevant National Competent Authorities are being advised of this Field Safety Corrective Action.

Sincerely,



Kleve Heavin, Sr. Director, Quality, Regulatory & Development

Email: kleh@ambu.com

King Systems, 15011 Herriman Blvd., Noblesville, IN 46060

Attachment – Recall Acknowledgment and Product Return Form