For Immediate Release

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King Systems Issues Recall of King Vision Video Laryngoscope Video Adapter Size 1/2

Noblesville, IN – On November 5, 2019, King Systems initiated a voluntary recall of One-Hundred Seventy-One (171) units of its King Vision Video Laryngoscope Adapter Size 1/2. The affected products have been found to exhibit a reversed image, which could potentially result in difficulty navigating during intubation and/or delay in intubation.

The affected product(s) should NOT be used. All affected product(s) should be returned to King Systems.

Affected product was manufactured from April 2nd to September 19th, 2019 and distributed from August 2nd to October 25th, 2019.

The recall includes the following affected devices:

Part Number	Lot Numbers	Serial Numbers
KVLVA12	010614 010629 010657 010668 010670 010722	LHXXXXXXX10240 LHXXXXXXX10243 LHXXXXXXX10284 LHXXXXXXX10554 LHXXXXXXX10559 LHXXXXXXX10562 LHXXXXXXX10569 LHXXXXXXX10570 LHXXXXXXX10611 LHXXXXXXX10666

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 1).

King Systems voluntarily recalled the products after receiving reports of some products exhibiting a reversed image. 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 2). As of January 20th, 2020, King Systems has not received any reports of adverse events (no patient injuries) resulting from this issue. FDA has been notified of this action.

King Systems has notified impacted distributors and customers and is arranging for return and credit/replacement of all recalled product(s).

A total of One-Hundred and Seven (107) affected products were shipped to distributors and customers in the USA (AK, AL, CA, FL, IA, IL, KS, LA, MD, MN, MS, NC, NE, PA, SC, TX, WA, and WI) and Sixty-Four (64) were shipped internationally (Argentina, Australia, Belgium, Bolivia, Canada, Costa Rica, Germany, Hong Kong, India, Italy, Japan, Myanmar, Poland, Spain, and UK).

Consumers with questions may contact the company by phone at +1 (410) 768-6464 between the hours of 8:00am and 5:00pm EST or by emailing Shelby Mitchell at shmi@ambu.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
- Call FDA 1-800-FDA-1088

Figure 1: KVLVA12 Serial Number location.

Figure 2: KVLVA12 exhibiting a reversed image.