

ALERT: Potential for “Key Bounce” with Infusion Pumps

On August 25, 2006, at the request of the US Food and Drug Administration (FDA), US Marshals seized Alaris SE infusion pumps (formerly Alaris Signature Edition) from Cardinal Health’s manufacturing facility.¹ According to the FDA, the confiscated pumps have a design default called “key bounce” that may cause overinfusion of medications.¹ The Alaris SE pumps are in use in Canada, and this bulletin provides information to Canadian health care facilities about the potential problem. Event reports on key bounces have been received by ISMP (US)^{2,3} and the FDA.⁴ This issue was originally raised in an *ISMP Medication Safety Alert!* in early 2006. Of interest, ISMP (US) also received reports of key bounce errors with the SIGMA 8000 and 6000+ infusion pumps.³ An ECRI hazard and recall report indicates that their testing has demonstrated the potential for double-bounce errors on other infusion pump models and other medical devices with “membrane switches”.⁵ Practitioners need to be vigilant to the possibility of key bounce errors when programming infusion pumps.

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“Key bounce” (or “double-bounce”) occurs when a number on the pump is pressed once by the operator but registers twice.^{1,3} If not detected during programming verification, key bounce events may result in serious patient harm or death.⁶ For example, a patient received an overinfusion of oxytocin when an Alaris SE infusion pump was intended to be set for 36 mL/h but registered a rate of 366 mL/h.⁴ The facility reported 11 other similar events, including incidents involving insulin, magnesium sulfate, and intravenous hyperalimentation.⁴

The following recommendations to reduce potential key bounce errors resulting in medication overinfusion are derived from the *ISMP Medication Safety Alert!*³ and a Medical Device Recall letter issued by Cardinal Health⁶:

- **Use a proper stance.** When programming pumps, stand squarely in front of the keypad (ideally with the pump at eye level for best visibility) to facilitate proper depth of depression for each key.

- **Verify screen displays.** When programming pumps or changing settings, always compare the patient’s prescribed therapy on the medication administration record, original order, or bar code device with the displayed pump settings, for review and verification before starting or restarting an infusion.
- **Listen to pump tones.** Keep pump audible tones functional on all pumps and focus on listening to the number of beeps while programming IV pumps; each beep should correspond to a single digit entry. A double beep tone occurs with a key bounce.
 - **Observe the rate of infusion.** Before leaving the patient’s room, actually look at the IV tubing drip chamber to see if the observed rate of infusion looks faster or slower than expected. (A rate of 36 mL/h is visually much slower than an erroneous rate of 366 mL/h or 336 mL/h).
 - **Request an independent double check for high-alert medications.** Before starting or changing infusions with hospital-selected high-alert medications, require an independent double check of pump settings by another practitioner.
- **Institute dose alerts.** Use smart infusion pumps with software designed to reduce dosage errors by alerting the practitioner when safe doses and infusion rates have been exceeded during programming. This will help detect most double key bounces and double keying errors before the infusion begins.

Cardinal Health indicates that they are “currently testing a modification that reduces sensitivity of the key pad” but that this “will need to be validated on the product and approved by the FDA”⁷ for use in the United States. Cardinal Health has informed ISMP Canada that they have sent their Canadian customers a warning letter and alert labels (to be affixed to each Alaris SE infusion pump). Health Canada has been informed and is monitoring the situation; additionally, it will post information on its website (www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2006/index_e.html).

Practitioners are encouraged to report events related to infusion pumps when they occur to:

- Health Canada Hotline, medical device reporting at 1-800-267-9675;
- Infusion Pump Manufacturer (in addition to Health Canada);
- ISMP Canada that has a voluntary medication incident (includes near miss) reporting program. Share information on-line at www.ismp-canada.org/err_report.htm, by email: info@ismp-canada.org or by phone 416-733-3131 or 1-866-544-7672 (1-866-54-ISMPC).

References:

1. United States marshals seize defective infusion pumps made by Alaris products: pumps can deliver excess medication and harm patients [press release P06-119]. Rockville (MD): Food and Drug Administration (US); 2006 Aug 28 [cited 2006 Aug 30]. Available from: www.fda.gov/bbs/topics/NEWS/2006/New01437.html
2. Seeing (and hearing) double. *ISMP Med Saf Alert*. 2005;10(22):2.
3. Double key bounce and double keying errors. *ISMP Med Saf Alert*. 2006;11(1):1-2.
4. Manufacturer and user facility device experience database (MAUDE database). Rockville (MD): Food and Drug Administration (US); [cited 2006 Aug 29]. Available from: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm Information obtained using advanced search criteria "Alaris"; BrandName: "Signature"; ReportDateFrom: "07/24/2001"; ReportDateTo: "08/29/2006"
5. ALARIS/Cardinal Health SE Infusion Pumps: ECRI responds to FDA seizure. ECRI Healthcare Risk Control Alerts: Hazards and Recalls;2006 Sept 06.
6. Urgent medical device recall: Alaris SE pump (formally Signature Edition infusion pump) (all models). San Diego (CA): Cardinal Health; 2006 Aug 15 [cited 2006 Aug 30]. Available from: www.cardinal.com/alaris/brochure/20060804alarissealert.pdf
7. Cardinal Health suspends production of Alaris SE infusion pump following FDA actions. San Diego (CA): Cardinal Health; 2006 Aug 28 [cited 2006 Aug 30]. Available from: www.cardinal.com/alaris/brochure/AlarisSEAug282006.pdf

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ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

To report a medication error to ISMP Canada: (i) visit our website www.ismp-canada.org, or (ii) e-mail us at info@ismp-canada.org, or (iii) phone us at 416-733-3131. ISMP Canada guarantees confidentiality and security of information received. ISMP Canada respects the wishes of the reporter as to the level of detail to be included in our publications.

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