URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

10-28-2011

GE Ref: 35009

To: Materials Manager / Central Supply Coordinator

RE: **Vital Signs Broselow Pediatric Emergency System Kit** (distributed by Vital Signs and Armstrong Medical)

Vital Signs Devices, a GE Healthcare Company has become aware of a safety issue associated with Povidone Iodine Pad included in the Vital Signs Broselow Pediatric Emergency System Kit. The affected product is manufactured by H&P Industries. This is a safety issue, however, there have been no injuries associated with this issue to date. If you have any questions regarding this medical device correction or the identification of affected product, please contact Vital Signs Customer Service.

NOTE: The modules can be found in a Broselow/Hinkle cart, a Broselow/Hinkle EMS bag, separately in your clinical environment or in central supply.

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issues

The manufacturer of the Povidone Iodine Pad, H&P Industries, is conducting a field corrective action to address a potential contamination of these products with an objectionable organism, Elizabethkinga meningoseptica.

Safety Instructions

1. **DO NOT** use the Povidone Iodine Pads contained within the product numbers and lot codes listed below. The Povidone Iodine Pads are contained in the Busse IV Start Kits which are located in the Intra Venous Module of the Broselow Kit.
2. Please isolate and **discard** all affected products. Please fill out the attached Confirmation form and fax back per its instructions to obtain replacement Busse IV Start Kits.
3. Return the attached response form even if no recalled product is in inventory. When there is no product to be replaced, circle no affected product. This step is required for us to confirm communications with all customers.
4. If you have forwarded any affected lot numbers of this product to any other healthcare institutions, please forward a copy of this letter to those institutions.
5. Instructions for filling out the fax back Urgent Medical Device Correction Confirmation form:
    a. **Broselow Bag or Cart has been opened and in use:**
        i. Check for all of the Intra Venous Modules to verify their lot numbers. **Note:** Replacement product affected per this recall may have been inserted into these opened items so it is important to check all the Broselow bags to determine if there is an IV module that contains lot codes in the affected range.
        ii. Pull out any Busse IV Start Kits in these IV modules. Dispose of these affected kits.
        iii. On the fax back form, record only number of Busse IV Start Kits to discard.
        iv. Fax back to Customer Service at: **800-535-7923**.
    b. **Users that cannot break the Broselow kit seal**:
        i. Please look below for impacted Kit and lot codes. If you do not see your Kit code and associated lot code you are not affected. (If you do have an affected kit please, call Domestic Customer Service or International Customer Service at 800-932-0760 for further instructions.)

Affected Product Details

Product Codes affected:
Povidone Iodine Pads: The Povidone Iodine Pad is packaged in the Busse IV Start Kit that is included in the Intra Venous Module, which is contained in the Broselow products referenced below.

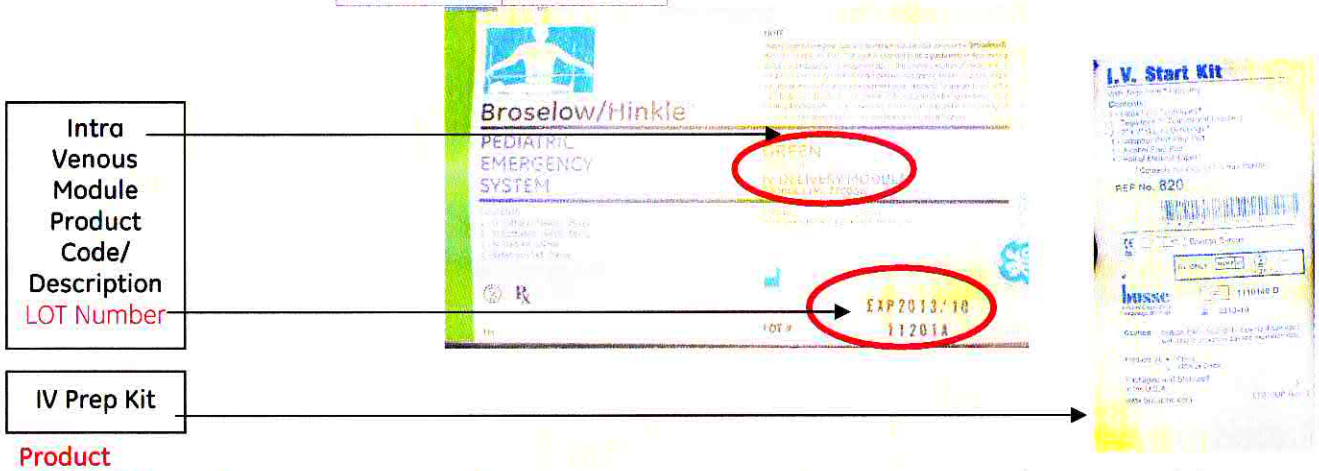
Affected Armstrong product numbers:
Kits: AE-4700, AE 4701, AE-4712, and PBL-PC-9A
Modules: 7700RIV, 7700PIV, 7700YIV, 7700WIV, 7700BIV, 7700OIV, 7700GIV, 7730RED, 7730PUR, 7730YEL, 7730WHI, 7730BLU, 7730ORG, and 7730GRN

Affected Vital Signs product numbers:
Kits: 7730ALS, 7730IALS, 7730FLY, 7730MOD
Modules: 7700RIV2, 7700PIV2, 7700YIV2, 7700WIV2, 7700BIV2, 7700OIV2, 7700GIV2, 7730RED5, 7730PUR5, 7730YEL5, 7730WHI5, 7730BLU5, 7730ORG5, and 7730GRN5
Sub-Assembly: 7700RIV, 7700PIV, 7700YIV, 7700WIV, 7700BIV, 7700OIV, and 7700GIV

Lot codes of the Broselow Kits and Intra Venous Modules that contain affected Povidone Iodine Pads:
2008: 228F-366F
2009: 010K-258K and 010L-258L

Lot codes of the Affected Busse IV Start Kits

Lot Code	Exp Date
0810822	9/30/11
0810822D	9/30/11
0810889	9/30/11
0810569D	6/30/11



Product Correction

Please discard all affected products and exchange with replacement products as stated above in the safety instructions of this notice.

Contact Information

If you have any questions or concerns regarding this notification, please contact Customer Service at +1-800-932-0760 (Domestic & International). Hours of Operation: 8:00 am EST to 6:00 pm EST. This information has been communicated to the appropriate National Competent Authorities.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Thank you,

James Dennison
Vice President QARA
GE Healthcare Systems

William Denman M.D., FRCA

William Denman, M.D., FRCA
Chief Medical Officer
GE Healthcare

URGENT MEDICAL DEVICE CORRECTION CONFIRMATION

1001 TECHNOLOGY PARK
ALBERTA BRANCH
GLEN ALLEN VA 23059
USA

RE: MEDICAL DEVICE CORRECTION

ATTN: Customer Service (email VitalSignsCustomerService@ge.com)

It is important that we confirm our customers have received this correction notice. As such, we require that you complete this confirmation form and **fax** it to: **800-535-7923. Once this step is complete, the process for shipping your replacement product commences. Please expect a 3-4 week timeframe for receiving replacement product.** Any questions, please call Customer Service: 800- 932-0760. Hours of Operation: 8:00 am EST to 6:00 pm EST.

Name of Account: _____ Account #_____

Contact Name: _____ Department: _____

Telephone Number: _____ Email: _____

Address #1: _____

Address # (room, etc.): _____

City: _____ State: _____ Zip Code_____

Do you have any affected product? **Yes/No**

Do you require a no charge PO for the replacement order, if so, please provide now: N/C PO #_____

Customer Support will contact you with the return details (if required) and the replacement order information.

	# of Busse IV Start Kits to discard	Busse Lot Codes
Busse IV Start Kit		0810822
		0810822D
		0810889
		0810569D

NOTE: Adding the replacement Busse IV Start Kit does not extend the life of the Intra Venous Module.