



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 32059

To: Nurse Manager, Labor & Delivery/ NICU
Manager, Respiratory Therapy/ Director of Risk Management
Manager Biomedical/Clinical Engineering

RE: Potential fall of certain Rotating IV pole used with Giraffe OmniBed Carestation, Giraffe Incubator Carestation Giraffe OmniBed, Giraffe Warmer, Panda Warmer, Giraffe Incubator, Care Plus Incubator, IWS, and Giraffe Shuttle.

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

Safety Issue GE Healthcare has recently become aware of the potential for the Rotating IV pole to fall. A fall could result in an injury to a bystander holding the patient or to the operator. There have been no injuries as a result of this issue.

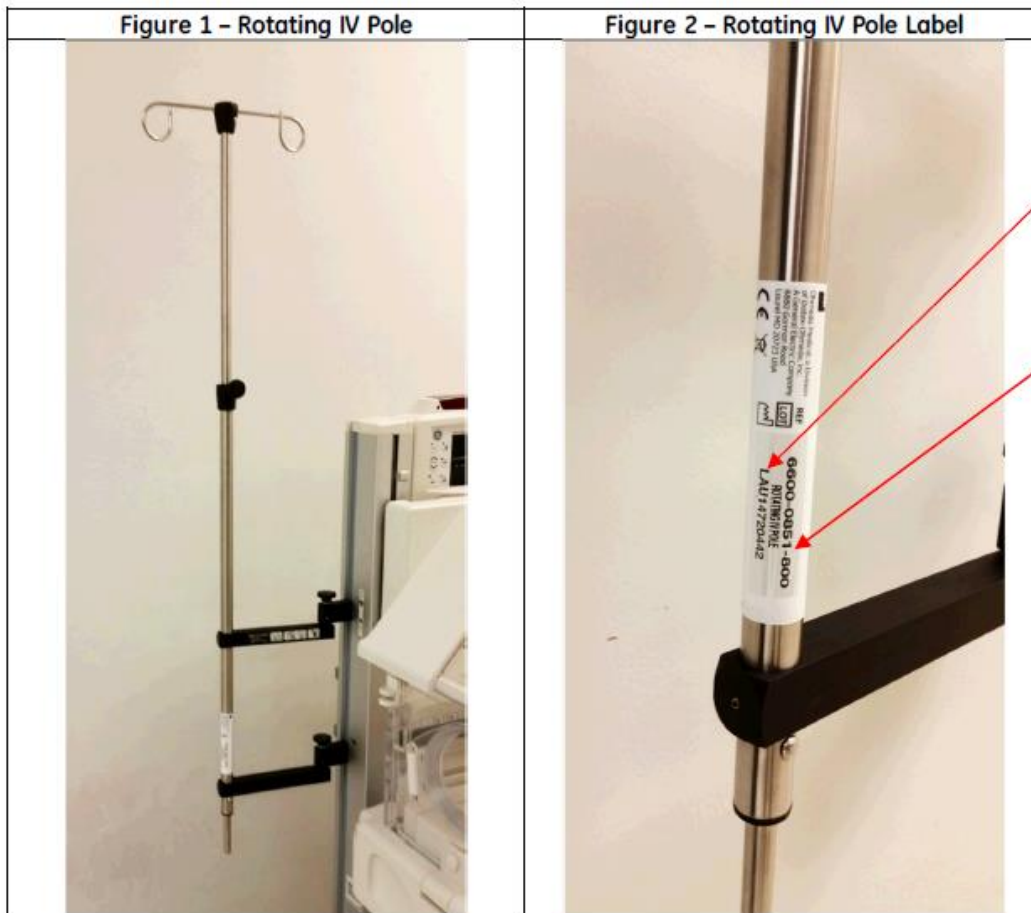
Safety Instructions Discontinue use of the affected Rotating IV poles and remove from Service. Place affected Rotating IV poles in a quarantine marked area. A GE Service Representative will contact you to arrange for the removal & replacement of a new IV pole.

Affected Product Details Rotating IV pole P/N 6600-0851-800 used with Giraffe OmniBed Carestation, Giraffe Incubator Carestation Giraffe OmniBed, Giraffe Warmer, Panda Warmer, Giraffe Incubator, Care Plus Incubator, IWS, and Giraffe Shuttle.

Affected Lot numbers

LAU13921134	LAU14256888	LAU14357933	LAU14491951	LAU14607719
LAU13921135	LAU14256889	LAU14357935	LAU14524883	LAU14607721
LAU14118204	LAU14256890	LAU14357936	LAU14524889	LAU14626923
LAU14118205	LAU14256891	LAU14357937	LAU14524893	LAU14626924
LAU14147284	LAU14275382	LAU14411516	LAU14524899	LAU14626925
LAU14147285	LAU14275383	LAU14411517	LAU14549831	LAU14684750
LAU14155643	LAU14289874	LAU14411518	LAU14549832	LAU14684751
LAU14155644	LAU14289875	LAU14475869	LAU14561083	LAU14713723
LAU14215249	LAU14289877	LAU14475870	LAU14561084	LAU14713724
LAU14215250	LAU14310716	LAU14475871	LAU14561085	LAU14720443
LAU14215251	LAU14348660	LAU14491943	LAU14606804	LAU14720444
LAU14215252	LAU14348663	LAU14491945	LAU14606807	
LAU14215255	LAU14348665	LAU14491948	LAU14607718	

On page 2, see the images of the affected lot & part number location on the label of the Rotating IV pole.



**Product
Correction**

GE Healthcare will replace all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the removal & replacement.

**Contact
Information**

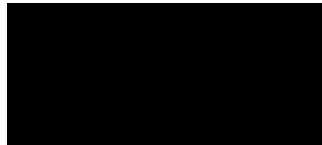
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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.

Sincerely,



James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer – Medical Safety
GE Healthcare