



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

[Date of letter deployment]

FMI 15132

To: Hospital Administrator / Risk Manager
Director/Manager of Radiology, Cardiology, Surgery
Director/Manager of Orthopedic Surgery, Pain Management

RE: Potential for uncommanded C-arm movement on certain GE Brivo OEC 715/785/865 systems

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

Safety Issue A board that controls vertical motion of the C-arm may fail, resulting in the C-arm moving up or down without command. There have been no injuries reported as a result of this issue. However, this issue could cause soft tissue damage if the C-arm were to move down during a surgical procedure and collide with medical instruments.

Safety Instructions Prior to starting a procedure, the operator should verify that the C-arm moves up and down normally and that the emergency stop button is functioning properly. If the C-arm moves up or down without command during a procedure, the user should press the emergency stop button to prevent the C-arm from colliding with medical instruments.

Affected Product Details

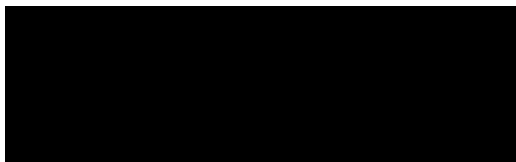
- GE Brivo OEC715: Serial Numbers B2S15158 to B2S15164; B2S15166 to B2S15171; B2S15173 to B2S15195; B2S15197; B2S15200; B2S15202; B2S16046; B2S16050; B2S16051;
- GE Brivo OEC785: Serial Numbers B3S15236; B3S15241; B3S15242; B3S15246; B3S15248; B3S15250; B3S15253 to B3S15257; B3S15259 to B3S15338; B3S15353; B3S15357 to B3S15359; B3S16152;
- GE Brivo OEC865: Serial Numbers B4S15063 to B4S15070; B4S15072; B4S15073; B4S15075; B4S16029

Product Correction GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

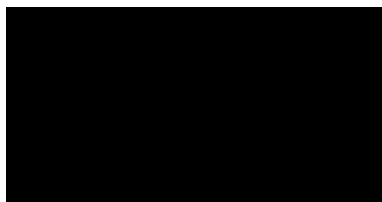
Contact Information If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,



Executive QA, DGS/Surgery
GE Healthcare



Chief Medical Officer
GE Healthcare