IMPORTANT PRODUCT INFORMATION

GE HealthCare

Apr 11,2024

GE HealthCare Ref. #15148

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

RE: **Update to Operator Manual Documentation – Correction to leakage radiation loading factor on GE HealthCare Brivo OEC 715/OEC Brivo Prime, Brivo OEC 785/OEC Brivo Essential, Brivo OEC 865/OEC Brivo Plus, OEC One and OEC One CFD systems**

Issue	GE HealthCare has become aware that the test conditions (loading factor) listed in the Operator Manual for performing radiation leakage testing are incorrect. This does not present any issues with the safety, operation, or performance of the system. Use of the incorrect loading factors during physics testing for leakage radiation will result in incorrect test results. There is no change to the product itself, only the documentation, and the system continues to function as intended.
Instructions	You can continue to use the system. If a test is needed for leakage radiation, use the corrected loading factors provided in the attached Addendum. Please keep a copy of the Addendum with your Operator Manual. Please ensure that all potential users in your facility are made aware of this notification and the recommended actions.
Affected Product Details	Brivo OEC 715/OEC Brivo Prime (GTIN: 00195278013453, 00840682115360) Brivo OEC 785/OEC Brivo Essential (GTIN: 00195278013446, 00840682115438) Brivo OEC 865/OEC Brivo Plus (GTIN: 00840682115377) OEC One (GTIN: 00840682125604) OEC One CFD (GTIN: 00840682145541)
Product Correction	GE HealthCare has provided the attached revised Addendum, which includes the corrected loading factors. This information supersedes the information in your current manual. Please keep a copy of the Addendum with your Operator Manual.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative. 奇異台灣免費客戶服務專線：0800-021-770

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

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

Addendum

This addendum is a replacement of information in the Operator Manual, the updated information for this version is identified in **Bold** text. Keep this addendum with the product's Operator Manual. To obtain the latest version of the Operator Manual, go to: "*https://customer-doc.cloud.gehealthcare.com*". Enter the document number in the search field. Launch the Search or use the Search By dropdown fields if the document number is not known.

Brivo Operator Manual Addendum, 6888006-199

12.3.2 X-Ray Source Assembly

Inherent Filter	2.55 mm Al @50KV with LOHMANN tube
Removable filter	3.5 mm Al @50kV
Maximum continuous heat dissipation rate	177W
Tube assembly dimension (length × Width × Height)	327mm × 132 mm × 238 mm
Tube assembly weight	17.5 kg
Maximum heat capacity	900,000HU
Maximum cooling rate	12,500HU/min
Cooling method	Natural cooling
Maximum symmetrical radiation field on the X-axis	100cm from the spot: Fluoro: 235 mm (diagonal) Film: 240mm (diameter)
Max. uninterrupted fluoro time (70KV/4.3mA, 8PPS)	> 1hr30min at 300W
Leakage radiation	Dose rate is less than **0.88mGy/h**, averaged over any area of 100 cm^2 of which no principal linear dimension exceeds 20 cm at 1 m from the focal spot under conditions of loading.
Leakage radiation loading factor	**110 kV, 0.5 mA (corresponding to Continuous Anode Input Power of 55W)**

OEC One Operator Manual, 6888000-1

15.3.2 X-Ray Source Assembly

Inherent Filter	2.55 mm Al @50KV
Maximum continuous heat dissipation rate	177W
Tube assembly dimension (length × Width × Height)	327mm × 132 mm × 238 mm
Tube assembly weight	17.5 kg
Maximum heat capacity	900,000HU
Maximum cooling rate	12,500HU/min
Cooling method	Natural cooling
Maximum symmetrical radiation field on the X-axis	100cm from the spot: Fluoro: 235 mm (diameter) Film: 240mm (diameter)
Max. uninterrupted fluoro time (70KV/4.3mA, 8PPS)	> 1hr30min at 300W
Leakage radiation	Dose rate is less than 0.88 mGy/h, averaged over any area of 100 cm^2 of which no principal

	linear dimension exceeds 20 cm at 1 m from the focal spot under conditions of loading.
Leakage radiation loading factor	**110 kV, 0.5 mA (corresponding to Continuous Anode Input Power of 55W)**

OEC One CFD Operator Manual Addendum, 6888006-199

15.3.2 X-Ray Source Assembly

Inherent Filter	2.55 mm Al
Maximum continuous heat dissipation rate	177W
Tube assembly dimension (length × Width × Height)	327mm × 132 mm × 246 mm
Tube assembly weight	17.5 kg
Maximum heat capacity	900,000HU
Maximum cooling rate	12,500HU/min
Cooling method	Natural cooling
Maximum symmetrical radiation field on the X-axis	100cm from the spot: Fluoro: 24cm (diameter)
Max. uninterrupted fluoro time (70KV/4.3mA, 8PPS)	> 1hr30min at 300W
Leakage radiation	Dose rate is less than 0.88 mGy/h, averaged over any area of 100 cm^2 of which no principal linear dimension exceeds 20 cm at 1 m from the focal spot under conditions of loading.
Leakage radiation loading factor	**110 kV, 0.5 mA (corresponding to Continuous Anode Input Power of 55W)**