



URGENT FIELD SAFETY NOTICE

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

Date of Letter Deployment

GEHC Ref# 32064

To: Director of Biomedical Engineering
Director of Clinical/Radiology
Risk Manager/Hospital Administrator

RE: **Giraffe OmniBed Carestation, Giraffe Incubator Carestation, Giraffe Warmer, Panda iRes Warmer, Panda Freestanding Warmer and Panda Wall Mount - Electrical Safety Testing Required**

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

Safety Issue

During an internal review of our manufacturing activities, we found an electrical safety test deficiency in some identified devices. The device design provides dual electrical safety protections. However, without performing the appropriate electrical safety test, the device could potentially lead to electric leakage affecting the user. There have been no complaints or injuries reported as a result of this issue.

Safety Instructions

You can continue to operate your device, consistent with good clinical practices. Until GE Healthcare performs the necessary testing, users should:

- 1) Disconnect devices that use the USB (Giraffe OmniBed Carestation and Giraffe Incubator Carestation only) and the RS232 Nurse call ports, see below pictures for location.
- 2) Inspect all power cords to ensure there is no damage to the cord or ground pin.

WARMERS RS232 PORT



CARESTATIONS RS232 PORT and USB PORT



Affected Product Details

Giraffe OmniBed Carestation, Giraffe Incubator Carestation, Giraffe Warmer, Panda iRes Warmer, Panda Freestanding Warmer and Panda Wall Mount. See the attached Appendix for affected serial numbers.

Product Correction GE Healthcare will perform necessary electrical safety test on all affected products and correct if required at no cost to you. A GE Healthcare representative will contact you to arrange for this test.

Contact Information If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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 Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

APPENDIX OF AFFECTED SERIAL NUMBERS

Giraffe OmniBed Carestation and Giraffe Incubator Carestation - 115V

TAAV60006	TAA62128	TAA62421	TABU67041	TABW63210	TABX62488
TAAV60007	TAA62132	TAA62422	TABU67043	TABX62211	TABX62489
TAAV60009	TAA62134	TAA62423	TABU67045	TABX62212	TABX62540
TAAV60011	TAA62136	TAA62424	TABU67047	TABX62360	TABX62541
TAAV60012	TAA62137	TAA62425	TABU67050	TABX62362	TABX62542
TAAV60015	TAA62138	TAA62426	TABU67053	TABX62363	TABX62665
TAAV60016	TAA62139	TAA62427	TABU67056	TABX62364	TABX63236
TAAV60017	TAA62140	TAA62428	TABU67058	TABX62365	TABX63252
TAAV60018	TAA62141	TAA62429	TABV60003	TABX62366	TABX63303
TAAV60019	TAA62142	TAA62430	TABV60013	TABX62367	TABX63304
TAAV60022	TAA62143	TAA62431	TABV60015	TABX62368	TABX63305
TAAV60029	TAA62144	TAA62432	TABV60016	TABX62369	TABX63306
TAAV60030	TAA62145	TAA62433	TABV60019	TABX62371	TABX63307
TAAV60032	TAA62146	TAA62434	TABV60022	TABX62373	TABX63309
TAAV60034	TAA62147	TAA62443	TABV60027	TABX62374	TABX63311
TAAV60037	TAA62155	TAA62444	TABV60028	TABX62376	TABX63312
TAAV60038	TAA62156	TAA62445	TABV60030	TABX62377	TABX63314
TAAV60039	TAA62157	TAA62446	TABV60033	TABX62431	TABX63315
TAAV60041	TAA62158	TAA62447	TABV60039	TABX62457	TABX63316
TAAV60042	TAA62159	TAA62448	TABV60053	TABX62458	TABX63318
TAAV60044	TAA62160	TAA62449	TABV60054	TABX62459	TABX63319
TAAV60047	TAA62161	TAA62450	TABV60055	TABX62460	TABX63320
TAAV60056	TAA62162	TAA62451	TABV60056	TABX62461	TABX63321
TAAV60057	TAA62174	TAA62452	TABV60060	TABX62462	TABX63322
TAAV60059	TAA62175	TAA62456	TABV60062	TABX62463	TABX63324
TAAV60062	TAA62176	TAA62458	TABV60065	TABX62476	

Giraffe Warmer					
GBWW60308	GBWW60328	GBWW60349	GBWX70170	GBWX70199	GBWX70239
GBWW60320	GBWW60330	GBWW70003	GBWX70171	GBWX70238	GBWX70242
GBWW60327	GBWW60331	GBWX70072			

Giraffe Bedded Warmer, Panda Ires Bedded Warmer, Panda Freestanding Warmer and Panda Wall Mount Warmer					
HDJL50310	HDJM50298	HDJM50672	HDJM51319	HDJQ50283	HDJT51188
HDJL50320	HDJM50299	HDJM50684	HDJM51320	HDJQ50285	HDJT51189
HDJL50321	HDJM50300	HDJM50688	HDJM51321	HDJQ50286	HDJT51190
HDJL50322	HDJM50301	HDJM50689	HDJM51322	HDJQ50333	HDJT51193
HDJL50323	HDJM50302	HDJM50693	HDJM51323	HDJQ50334	HDJT51195
HDJL50325	HDJM50305	HDJM50694	HDJM51324	HDJQ50342	HDJT51196
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HDJL50329	HDJM50309	HDJM50696	HDJM51327	HDJQ50372	HDJT51199
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HDJL50401	HDJM50313	HDJM50699	HDJM51330	HDJQ50434	HDJT51210
HDJL50402	HDJM50315	HDJM50700	HDJM51331	HDJQ50435	HDJT51230
HDJL50408	HDJM50316	HDJM50702	HDJM51332	HDJQ50437	HDJT51243
HDJL50412	HDJM50317	HDJM50703	HDJM51337	HDJQ50438	HDJT51247
HDJL50413	HDJM50319	HDJM50724	HDJM51338	HDJQ50461	HDJT51283
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HDJL50428	HDJM50351	HDJM50773	HDJM51404	HDJQ50581	HDJT51325
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HDJL50433	HDJM50353	HDJM50775	HDJM51426	HDJQ50588	HDJT51336
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HDJM50239	HDJM50635	HDJM51286	HDJP52181	HDJT50955	HDJT61189
HDJM50240	HDJM50636	HDJM51287	HDJP52571	HDJT50956	HDJT61335
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HDJM50277	HDJM50639	HDJM51290	HDJP52630	HDJT50961	HDJT61386
HDJM50278	HDJM50640	HDJM51291	HDJP52729	HDJT50962	HDJT61403
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HDJM50280	HDJM50642	HDJM51293	HDJP52845	HDJT50988	HDJT61421
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HDJM50286	HDJM50657	HDJM51301	HDJQ50071	HDJT51034	HDJT61530
HDJM50287	HDJM50658	HDJM51302	HDJQ50074	HDJT51037	HDJT61565
HDJM50288	HDJM50660	HDJM51309	HDJQ50092	HDJT51038	HDJT61566
HDJM50289	HDJM50661	HDJM51312	HDJQ50098	HDJT51040	HDJT61575
HDJM50290	HDJM50662	HDJM51313	HDJQ50106	HDJT51042	HDJT61604
HDJM50291	HDJM50663	HDJM51314	HDJQ50116	HDJT51060	HDJU60478
HDJM50293	HDJM50667	HDJM51315	HDJQ50126	HDJT51120	HDJU65781
HDJM50294	HDJM50668	HDJM51316	HDJQ50128	HDJT51124	HDJU66023
HDJM50295	HDJM50669	HDJM51317	HDJQ50146	HDJT51152	HDJU66024
HDJM50296	HDJM50670	HDJM51318	HDJQ50235	HDJT51187	
HDJM50297	HDJM50671				

Panda Ires Bedded Warmer, Panda Ires Warmer, Panda Freestanding Warmer					
PBWW60645	PBWW61248	PBWX60584	PBWX70570	PBWX70788	PBWX71165
PBWW61396	PBWW61249	PBWX70006	PBWX70575	PBWX70818	PBWX71170
PBWW60086	PBWW61250	PBWX70069	PBWX70582	PBWX70824	PBWX71183
PBWW60111	PBWW61252	PBWX70072	PBWX70636	PBWX70826	PBWX71184
PBWW60343	PBWW61263	PBWX70119	PBWX70644	PBWX70836	PBWX71186
PBWW60368	PBWW61268	PBWX70198	PBWX70656	PBWX70871	PBWX71236
PBWW60408	PBWW61269	PBWX70216	PBWX70685	PBWX70874	PBWX71427
PBWW60694	PBWW61295	PBWX70231	PBWX70701	PBWX70877	PBWX71435
PBWW60862	PBWW61297	PBWX70258	PBWX70706	PBWX70881	PBWX71437
PBWW60863	PBWW61298	PBWX70327	PBWX70709	PBWX70911	PFSV60114
PBWW60864	PBWW61299	PBWX70367	PBWX70714	PBWX70917	PFSW60069

PBWW60866	PBWW61304	PBWX70380	PBWX70715	PBWX71010	PFSW60070
PBWW61219	PBWW61349	PBWX70409	PBWX70725	PBWX71078	PFSW60071
PBWW61220	PBWW61351	PBWX70411	PBWX70735	PBWX71086	PFSW60072
PBWW61236	PBWW61681	PBWX70428	PBWX70736	PBWX71097	PFSX70050
PBWW61242	PBWW62015	PBWX70457	PBWX70738	PBWX71125	PFSX70059
PBWW61246	PBWW70003	PBWX70501	PBWX70749	PBWX71127	PFSX70067
PBWW61247	PBWW70005	PBWX70514	PBWX70772	PBWX71133	PFSX70081