



VIGTIG PRODUKTINFORMATION

GE Healthcare

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

GE Healthcare Ref: FMI 32064

6. November 2018

Til: Direktør for biomedicinsk teknik
Direktør for Klinisk/Radiologi
Risiko-manager/Hospitalsadministrator
Chef for Medicoteknisk afdeling

Vedrørende: **Giraffe OmniBed Carestation, Giraffe Incubator Carestation, Giraffe Warmer, Panda iRes Warmer, Panda Freestanding Warmer og Panda Wall Mount - Elektrisk sikkerhedstestning påkrævet**

De bedes sikre Dem, at alle potentielle brugere i Deres organisation gøres opmærksomme på denne sikkerhedsmeddelelse og de anbefalede handlinger.

Sikkerheds- Problem

Under en intern gennemgang af vores produktionsaktiviteter fandt vi en mangel på elektrisk sikkerhedstest i nogle identificerede enheder. Enhedsdesignet giver dobbelt elektrisk sikkerhedsbeskyttelse. Men udføres passende elektriske sikkerhedstest ikke, kunne enheden potentielt medføre lækstrøm, hvilket ville påvirke brugeren. Ingen klager eller skader er blevet rapporteret som følge af dette problem.

Sikkerheds- anvisninger

Du kan fortsætte med at bruge din enhed i henhold til god klinisk praksis. Indtil GE Healthcare udfører de nødvendige tests, bør brugere:

- 1) Afbryde strømmen til enheder, der bruger USB (Giraffe OmniBed Carestation og Giraffe Incubator Carestation) og RS232 Nurse Call Porte, se nedenstående billeder for placering.
- 2) Undersøg alle netledninger for at sikre, at ledningen eller jordstiften ikke er beskadigede.

Oplysninger om de påvirkede produkter

WARMERS RS232-PORT



CARESTATIONS RS232-PORT og USB-PORT



Giraffe OmniBed Carestation, Giraffe Incubator Carestation, Giraffe Warmer, Panda iRes Warmer, Panda Freestanding Warmer og Panda Wall Mount Se vedlagte Bilag for de påvirkede serienumre.

Produktrettelse

GE Healthcare vil udføre nødvendige elektriske sikkerhedstest på alle berørte produkter og udføre rettelser om nødvendigt uden omkostninger for dig. En GE Healthcare-repræsentant vil tage kontakt for at arrangere denne test.

Kontakt- oplysninger

Såfremt I har spørgsmål til denne vigtige produktinformation eller identifikation af berørt udstyr bedes I kontakte jeres lokale GE Healthcare service- eller salgsrepræsentant.
8040 4944

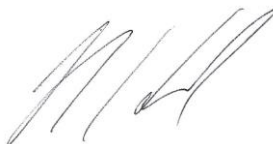
GE Healthcare bekræfter at Lægemiddelstyrelsen har modtaget denne meddelelse.

Vi garanterer, at vi prioriterer opretholdelse af et højt sikkerheds- og kvalitetsniveau meget højt. Hvis I har spørgsmål, bedes I straks kontakte os.

Mange tak.



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

BILAG MED PÅVIRKEDE SERIENUMRE

Giraffe OmniBed Carestation og Giraffe Incubator Carestation - 115V					
TAAW63144	TABV60433	TABW64046	TABX62149	TABX62229	TABX62270
TAAW63174	TABV60550	TABW64049	TABX62154	TABX62231	TABX62272
TAAW63176	TABW62153	TABW64059	TABX62156	TABX62232	TABX62276
TAAW63177	TABW63933	TABW64069	TABX62158	TABX62233	TABX62282
TAAW63178	TABW63937	TABW64078	TABX62159	TABX62234	TABX62283
TAAW63179	TABW63938	TABW64082	TABX62160	TABX62235	TABX62287
TAAW63180	TABW63940	TABW64084	TABX62161	TABX62236	TABX62290
TAAW63181	TABW63944	TABW64086	TABX62162	TABX62238	TABX62291
TAAW63183	TABW63948	TABW64087	TABX62163	TABX62239	TABX62292
TAAW63184	TABW63951	TABW64095	TABX62164	TABX62240	TABX62293
TAAW63186	TABW63952	TABW64096	TABX62165	TABX62242	TABX62295
TAAW63205	TABW63954	TABW64098	TABX62166	TABX62243	TABX62296
TAAW63206	TABW63959	TABW64099	TABX62168	TABX62244	TABX62300
TAAW63207	TABW63962	TABX62108	TABX62171	TABX62245	TABX62301
TAAW62053	TABW63964	TABX62109	TABX62173	TABX62246	TABX62319
TAAW62054	TABW63965	TABX62110	TABX62178	TABX62247	TABX62320
TAAW62075	TABW63966	TABX62113	TABX62188	TABX62248	TABX62324
TAAW62078	TABW63977	TABX62118	TABX62189	TABX62249	TABX62331
TAAW62079	TABW63982	TABX62120	TABX62193	TABX62250	TABX62332
TAAW62082	TABW63983	TABX62121	TABX62194	TABX62251	TABX62333
TAAW62088	TABW63987	TABX62128	TABX62196	TABX62252	TABX62335
TAAW62089	TABW63994	TABX62130	TABX62197	TABX62253	TABX62380
TAAW62092	TABW63995	TABX62131	TABX62198	TABX62254	TABX63175
TAAW62095	TABW63996	TABX62132	TABX62200	TABX62255	TABX63176
TAAW62096	TABW64000	TABX62135	TABX62206	TABX62257	TABX63177
TAAW62345	TABW64008	TABX62136	TABX62208	TABX62258	
TAAW62346	TABW64009	TABX62139	TABX62218	TABX62259	
TAAW62347	TABW64013	TABX62140	TABX62223	TABX62260	
TABV60078	TABW64023	TABX62141	TABX62226	TABX62264	
TABV60092	TABW64043	TABX62146	TABX62227	TABX62269	

Giraffe OmniBed Carestation og Giraffe Incubator Carestation - 230V					
TAAU67001	TAAV60093	TAAX62177	TABU67004	TABV60069	TABX62477
TAAU67002	TAAV62017	TAAX62178	TABU67011	TABV60072	TABX62478
TAAU67007	TAAV62075	TAAX62179	TABU67014	TABV60097	TABX62479
TAAU67008	TAAV62122	TAAX62180	TABU67021	TABV60102	TABX62480
TAAU67012	TAAV62229	TAAX62183	TABU67026	TABV61052	TABX62481
TAAU67014	TAAX62119	TAAX62184	TABU67028	TABV61236	TABX62482
TAAU67015	TAAX62120	TAAX62185	TABU67032	TABV62289	TABX62484
TAAU67016	TAAX62125	TAAX62409	TABU67034	TABV62294	TABX62485
TAAU67020	TAAX62126	TAAX62419	TABU67039	TABV62316	TABX62486
TAAU67021	TAAX62127	TAAX62420	TABU67040	TABW62598	TABX62487

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	TABX62336
TAAV60017	TAA62140	TAA62428	TABU67058	TABX62365	TABX62352
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
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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 og Panda Wall Mount Warmer					
HDJL50310	HDJM50298	HDJM50672	HDJM51319	HDJQ50283	HDJT51188
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HDJL50323	HDJM50302	HDJM50693	HDJM51323	HDJQ50334	HDJT51195
HDJL50325	HDJM50305	HDJM50694	HDJM51324	HDJQ50342	HDJT51196
HDJL50327	HDJM50306	HDJM50695	HDJM51326	HDJQ50367	HDJT51198
HDJL50329	HDJM50309	HDJM50696	HDJM51327	HDJQ50372	HDJT51199
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HDJM50141	HDJM50566	HDJM51046	HDJN50207	HDJS53484	HDJT51831
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HDJM50153	HDJM50585	HDJM51064	HDJN50606	HDJT50579	HDJT51866
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HDJM50155	HDJM50587	HDJM51098	HDJN50627	HDJT50620	HDJT51869
HDJM50156	HDJM50588	HDJM51120	HDJN50633	HDJT50622	HDJT51870
HDJM50157	HDJM50589	HDJM51144	HDJN50635	HDJT50628	HDJT51871
HDJM50158	HDJM50590	HDJM51145	HDJN50637	HDJT50664	HDJT51913
HDJM50159	HDJM50591	HDJM51146	HDJN50653	HDJT50676	HDJT51914

HDJM50160	HDJM50592	HDJM51147	HDJN50672	HDJT50683	HDJT51928
HDJM50161	HDJM50593	HDJM51148	HDJN50677	HDJT50694	HDJT51929
HDJM50162	HDJM50594	HDJM51177	HDJN50903	HDJT50702	HDJT51937
HDJM50163	HDJM50595	HDJM51178	HDJN51580	HDJT50722	HDJT51944
HDJM50164	HDJM50596	HDJM51179	HDJN51744	HDJT50732	HDJT51954
HDJM50165	HDJM50597	HDJM51180	HDJN51787	HDJT50739	HDJT51980
HDJM50166	HDJM50598	HDJM51188	HDJN52089	HDJT50740	HDJT60033
HDJM50167	HDJM50599	HDJM51189	HDJN52090	HDJT50752	HDJT60043
HDJM50168	HDJM50600	HDJM51192	HDJN52101	HDJT50777	HDJT60229
HDJM50170	HDJM50601	HDJM51214	HDJN52102	HDJT50781	HDJT60283
HDJM50171	HDJM50602	HDJM51215	HDJN52155	HDJT50797	HDJT60292
HDJM50172	HDJM50603	HDJM51216	HDJN52168	HDJT50805	HDJT60402
HDJM50173	HDJM50604	HDJM51217	HDJN52275	HDJT50810	HDJT60407
HDJM50174	HDJM50605	HDJM51218	HDJN52307	HDJT50818	HDJT60421
HDJM50175	HDJM50606	HDJM51219	HDJN52360	HDJT50821	HDJT60426
HDJM50176	HDJM50607	HDJM51220	HDJP50011	HDJT50826	HDJT60431
HDJM50177	HDJM50608	HDJM51221	HDJP50018	HDJT50832	HDJT60438
HDJM50178	HDJM50609	HDJM51222	HDJP50020	HDJT50838	HDJT60450
HDJM50179	HDJM50610	HDJM51223	HDJP50024	HDJT50839	HDJT60469
HDJM50180	HDJM50611	HDJM51224	HDJP50027	HDJT50842	HDJT60554
HDJM50181	HDJM50612	HDJM51225	HDJP50065	HDJT50843	HDJT60555
HDJM50182	HDJM50613	HDJM51226	HDJP50190	HDJT50875	HDJT60568
HDJM50183	HDJM50614	HDJM51227	HDJP50226	HDJT50887	HDJT60572
HDJM50184	HDJM50615	HDJM51237	HDJP51904	HDJT50912	HDJT60576
HDJM50185	HDJM50616	HDJM51238	HDJP51915	HDJT50914	HDJT60578
HDJM50186	HDJM50617	HDJM51239	HDJP51927	HDJT50916	HDJT60584
HDJM50187	HDJM50618	HDJM51242	HDJP51971	HDJT50917	HDJT60628
HDJM50188	HDJM50628	HDJM51282	HDJP52031	HDJT50918	HDJT60803
HDJM50236	HDJM50629	HDJM51283	HDJP52034	HDJT50948	HDJT60827
HDJM50237	HDJM50633	HDJM51284	HDJP52038	HDJT50951	HDJT61086
HDJM50238	HDJM50634	HDJM51285	HDJP52075	HDJT50953	HDJT61094
HDJM50239	HDJM50635	HDJM51286	HDJP52181	HDJT50955	HDJT61189
HDJM50240	HDJM50636	HDJM51287	HDJP52571	HDJT50956	HDJT61335
HDJM50242	HDJM50637	HDJM51288	HDJP52618	HDJT50958	HDJT61351
HDJM50276	HDJM50638	HDJM51289	HDJP52622	HDJT50960	HDJT61375
HDJM50277	HDJM50639	HDJM51290	HDJP52630	HDJT50961	HDJT61386
HDJM50278	HDJM50640	HDJM51291	HDJP52729	HDJT50962	HDJT61403
HDJM50279	HDJM50641	HDJM51292	HDJP52752	HDJT50987	HDJT61404
HDJM50280	HDJM50642	HDJM51293	HDJP52845	HDJT50988	HDJT61421
HDJM50281	HDJM50643	HDJM51294	HDJP52886	HDJT50989	HDJT61437
HDJM50282	HDJM50644	HDJM51295	HDJQ50005	HDJT51000	HDJT61440
HDJM50283	HDJM50654	HDJM51296	HDJQ50010	HDJT51008	HDJT61452
HDJM50284	HDJM50655	HDJM51299	HDJQ50065	HDJT51014	HDJT61471
HDJM50285	HDJM50656	HDJM51300	HDJQ50069	HDJT51015	HDJT61473
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