



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

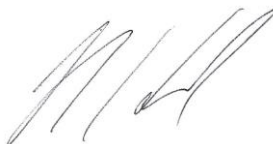
GE Healthcare bekræfter at Lægemiddelstyrelsen har modtaget denne meddelelse.

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

TAAV60006	TAA62128	TAA62421	TABU67041	TABW63210	TABX62488
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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					
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HDJM50288	HDJM50660	HDJM51309	HDJQ50092	HDJT51038	HDJT61566
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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