



VIGTIG PRODUKTINFORMATION

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 34076

6. april 2016

Til: Administrator for sundhedspleje/Risikoleder
Chef for anæstesi
Direktør for biomedicinsk/klinisk teknik
Chef for Medicoteknisk afdeling

Vedrørende: **Reduceret vakuum på ekstraudstyr til vakuumsugning for visse anæstesiprodukter i Aisys-serien**

GE Healthcare er blevet opmærksom på et potentielt sikkerhedsproblem med ekstraudstyret til vakuumsugning for visse anæstesiprodukter i Aisys-serien. **Sørg for, at alle potentielle brugere i Deres organisation gøres opmærksom på denne sikkerhedsmeddelelse og de anbefalede handlinger.**

Sikkerheds-Problem Slangerne til vakuumsugning kan være knækket inden i maskinen og forårsage et sug på mindre end 20 lpm, som er det påkrævede i følge ISO 10079-3. Hvis problemet ikke løses, kan det medføre utilstrækkelig sugning af luftvejene og utilstrækkelig ventilation af patienten. Der er ikke rapporteret om skader som følge af dette problem.

Sikkerheds-anvisninger Problemet påvirker kun ekstraudstyret til vakuumsugning på visse enheder i Aisys-serien. Andre egenskaber for anæstesimaskinens ydeevne påvirkes ikke.

Alle andre funktioner på anæstesenheden kan fortsat bruges. Ekstraudstyret til vakuumsugning kan fortsat bruges, under forudsætning af at dette er testet og opfylder minimumflow på 20 lpm som anført ovenfor og med henvisning til ydeevnespecifikationen på enhedens URM (registreret maksimumflow på ca. 39 lpm). Hvis enheden ikke består testen, bør det enkeltstående sugestyk straks gøres tilgængeligt.

Oplysninger om de påvirkede produkter Visse anæstesiprodukter i Aisys-serien med serienumre som anført i appendikset.

Produktrettelse GE Healthcare reparerer de berørte produkter uden beregning for Dem. De vil blive kontaktet af en repræsentant fra GE Healthcare med henblik på reparationen.

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 & Regulatory

Jeff Hersh, M.D.
Chief Medical Officer

Appendiks

Liste over serienumre på påvirkede anæstesimaskiner i Aisys-serien:

ANAU00102 ANAU00103

Liste over serienumre på påvirkede anæstesimaskiner i Aisys CS2-serien:

APWU00172	APWU00252	APWU00338	APWU00419	APWU00474	APWU00542	APWU00621	APWU00674
APWU00173	APWU00260	APWU00339	APWU00420	APWU00475	APWU00543	APWU00622	APWU00675
APWU00174	APWU00274	APWU00340	APWU00421	APWU00476	APWU00546	APWU00623	APWU00676
APWU00175	APWU00275	APWU00341	APWU00422	APWU00477	APWU00547	APWU00624	APWU00677
APWU00199	APWU00276	APWU00342	APWU00423	APWU00478	APWU00548	APWU00625	APWU00678
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APWU00201	APWU00278	APWU00352	APWU00425	APWU00480	APWU00550	APWU00627	APWU00680
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