



## HITNA SIGURNOSNA OBAVIJEST

GE Healthcare

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

GE Healthcare Ref: FMI 34093

7. August 2018

**Primatelj:** Voditelj anestezije  
Ravnatelj biomedicinskog/kliničkog inženjstva  
Administrator zdravstvene njege/ Upravitelj rizika

**Predmet:** **Potencijalni gubitak protoka svježeg plina - sustavi za anesteziju Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 i 9100c NXT**

**Molimo uvjerite se da su svi potencijalni korisnici u vašoj ustanovi upozoreni na ovu sigurnosnu obavijest i preporučeno ponašanje.**

**Sigurnosni problem** Kod sustava opremljenih pomoćnim zajedničkim plinskim izlazom (ACGO) postoji mogućnost da se pomoćni plinski prekidač neočekivano prebaci s položaja ACGO natrag u kružni položaj. Na sustavima opremljenima funkcijom Aux O2+Air prekidač se može neočekivano prebaciti sa položaja Aux O2 + Air na položaj kruga. Takve situacije mogle bi dovesti do hipoksije. I dalje bi bilo moguće ventilirati pacijenta s pomoću kružnog disajnog sustava u ručnom načinu ventilacije sa samonapuhujućom vrećom ili mehaničkim načinom ventilacije. Nema izvještaja o ozljedama vezanima za ovaj problem.

**Sigurnosne Upute** Možete i dalje upotrebljavati sustave anestezije navedene u detaljima zahvaćenih proizvoda ispod. Ako uočite prelazak prekidača sa ACGO/Aux na kružni položaj dok upotrebljavate ACGO ili Aux O2+Air, upotrijebite kružni disajni sustav kako biste ventilirali pacijenta. Na zaslonu je naznačeno ako su aktivni ACGO ili Aux O2+Air. Ako se prekidač prebaci u kružni položaj, može se primijetiti da indikator nestaje sa zaslona, prekidač se zakreće u kružni položaj i da se zaustavlja protok plina iz priključka ACGO ili Aux O2+Air. Ako primijetite bilo koji od ovih znakova, upotrijebite kružni disajni sustav za ventiliranje pacijenta. U bilo kojem trenutku, kliničar može upotrijebiti samonapuhujuću vreću kako bi ventilirao pacijenta i/ili se prebaciti na drugi uređaj za anesteziju.

**Detalji proizvoda na koje se obavijest odnosi** Sustavi za anesteziju Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 i 9100c NXT, pogledajte popis zahvaćenih serijskih brojeva u priloženom Dodatku:

Carestation 620 A1 (GTIN: 00840682103985)  
Carestation 650 A1 (GTIN: 00840682103947)  
Carestation 650c A1 (GTIN: 00840682103954)

**Korekcije proizvoda** GE Healthcare će besplatno popraviti sve zahvaćene proizvode. Predstavnik tvrtke GE Healthcare će Vas kontaktirati kako biste dogovorili popravak.

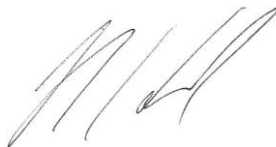
**Podaci za kontakt** Ako imate pitanja vezanih za ovaj problem, obratite se lokalnom servisnom predstavniku tvrtke GE Healthcare.

GE Healthcare potvrđuje da su o postojećem nedostatku obaviještene odgovarajuće regulatorne agencije. Održavanje visoke razine sigurnosti i kvalitete naš je glavni prioritet. Ako imate pitanja, odmah nam se obratite.

S poštovanjem,



James W. Dennison  
Vice President - Quality & Regulatory  
GE Healthcare



Jeff Hersh, PhD MD  
Chief Medical Officer – Medical Safety  
GE Healthcare

## Dodatak

### Popis zahvaćenih serijskih brojeva

#### Carestation 620/650/650c A1&A2 ACGO, zahvaćeni uređaji

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**Carestation 620/650/650c A1 Aux O2+Air, zahvaćeni uređaji**

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**Carestation 30 ACGO, zahvaćeni uređaji**

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**9100c NXT ACGO, zahvaćeni uređaji**

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