



STEIDZAMS DROŠĪBAS BRĪDINĀJUMS

GE Healthcare

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

GE Healthcare iekšējais kods: FMI 34093

2018. gada 7. augusts

Kam: Galvenajam anesteziologam
Biomedicīnisko/klīnisko lietu tehniskajam direktoram
Veselības aprūpes administratoram/risku pārvaldniekam

Temats: **Iespējami svaiga gāzes plūsmas zaudējumi — Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 un 9100c NXT anestēzijas sistēmās**

Lūdzu, nodrošiniet, ka visi iespējamie lietotāji Jūsu ārstniecības iestādē ir informēti par šo drošības paziņojumu un ieteicamajām darbībām.

Drošības problēma Sistēmu, kuras ir aprīkotas ar kopējo gāzes izslēgšanas palīgierīci (KGIP), palīgdzinēja gāzes pārslēgs var negaidīti pārslēgties no KGIP pozīcijas atpakaļ uz cirkulējošo pozīciju. Sistēmās, kuras ir aprīkotas ar O2 palīgierīces + gaisa funkciju, slēdzis var negaidīti pārslēgties no O2 palīgierīces + gaisa pozīcijas atpakaļ uz cirkulējošo pozīciju. Šādas situācijas var izraisīt hipoksiju. Arī tādos gadījumos ir iespējams elpināt pacientu, izmantojot cirkulējošo elpināšanas sistēmu manuālajā vai mehāniskajā elpināšanas režīmā. Ziņojumi par traumām, kas ir radušās šīs problēmas dēļ, nav saņemti.

Drošības Norādījumi Jūs varat turpināt lietot anestēzijas sistēmas, kuras ir minētas attiecīgo produktu detaļu sarakstā. Ja KGIP vai palīgierīces O2 + gaisa režīma lietošanas laikā novērojat slēdža pārslēgšanos no KGIP/palīgierīces uz cirkulējošo pozīciju, pacienta elpināšanai lietojiet cirkulējošo elpināšanas sistēmu. Kad KGIP vai papildierīces O2 + gaisa režīms ir aktivizēts, uz displeja parādās norāde. Ja slēdzis pārslēdzas uz cirkulējošo pozīciju, var novērot, ka norāde uz displeja pazūd, slēdzis pagriežas uz cirkulējošo pozīciju un gāze pārstāj izplūst no KGIP vai papildierīces O2 + gaisa režīma izejas porta. Ja novērojat kādu no šīm pazīmēm, lūdzu, pacienta elpināšanai lietojiet cirkulējošo elpināšanas sistēmu. Ārsts jebkurā brīdī pacienta elpināšanai var lietot pašpiepūšanas maisu un/vai mainīt anestēzijas ierīci.

Informācija par produktiem, uz kuriem attiecas problēma Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 un 9100c NXT anestēzijas sistēmas, sarakstu ar attiecīgajiem sērijas numuriem skat. pievienotajā pielikumā:

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

Izstrādājuma labojums Uzņēmums GE Healthcare bez maksas nodrošinās visu ietekmēto izstrādājumu labošanu. GE Healthcare pārstāvis sazināsies ar jums un vienosies par labojumu ieviešanu.

Kontakt - informācija Jautājumu vai šaubu gadījumā, lūdzu, sazinieties ar vietējo GE Healthcare servisa pārstāvi.

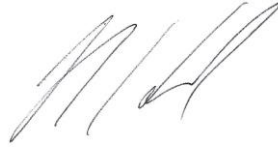
GE Healthcare apstiprina šī vēstule ir paziņota attiecīgajai regulēšanas aģentūra.

Lūdzu, ņemiet vērā, ka augsta drošības un kvalitātes līmeņa garantēšana ir mūsu prioritāte. Gadījumā, ja Jums rodas jautājumi, lūdzu, nekavējoties sazinieties ar mums.

Ar pateicību,



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



Jeff Hersh, PhD M.D.
Chief Medical Officer – Medical Safety
GE Healthcare

Pielikums

Attiecīgo sērijas numuru saraksts

Carestation 620/650/650c A1&A2 ACGO attiecīgās iekārtas

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Carestation 620/650/650c A1 Papildierīces O2+gaisa attiecīgās iekārtas

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Carestation 30 ACGO attiecīgās iekārtas

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9100c NXT ACGO attiecīgās vienības

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