



AVVISO URGENTE PER LA SICUREZZA NEL SITO

GE Healthcare

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

Rif. interno GE Healthcare: FMI 34093

7 agosto 2018

A: Primario anesthesiologia
Responsabile ingegneria biomedica / clinica
Direttore sanitario / Responsabile dei rischi

RIF: **Potenziale perdita di flusso di gas fresco - Sistemi di anestesia Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 e 9100c NXT**

Si raccomanda pertanto di comunicare a tutti i potenziali utenti presenti nella propria struttura sia il presente avviso, sia le relative azioni correttive raccomandate.

Problema di sicurezza Sui sistemi dotati di scarico di gas comune ausiliario (ACGO), esiste la possibilità che il selettore del gas ausiliario commuti in modo imprevisto dalla posizione ACGO alla posizione circuito rotatorio. Sui sistemi dotati della funzione Aux O2 + Air l'interruttore potrebbe improvvisamente passare dalla posizione Aux O2 + Air alla posizione circuito rotatorio. Queste situazioni potrebbero portare ad uno stato di ipossia. Sarebbe comunque possibile ventilare il paziente utilizzando il sistema di respirazione manuale o utilizzare la modalità di ventilazione meccanica. Ad oggi, non è stata riportata nessuna lesione dovuta a questo problema.

Istruzioni per la sicurezza È possibile continuare a usare i sistemi di anestesia elencati di seguito nei dettagli del prodotto interessato. Se si osserva che il selettore cambia dalla posizione ACGO/Aux a quella circuito rotatorio mentre si utilizza il sistema ACGO o Aux O2+Air, utilizzare il sistema di respirazione circuito rotatorio per ventilare il paziente. Quando è attiva la posizione ACGO o Aux o2+Air, sul display viene visualizzata un'indicazione. Se il selettore cambia in posizione circuito rotatorio si può osservare che l'indicazione sul display scompare e il flusso dei gas dalla porta ACGO o Aux O2 + Air smette di essere erogato. Se si osserva uno di questi segni, utilizzare il sistema di respirazione circuito rotatorio per ventilare il paziente. In qualsiasi momento, il clinico può utilizzare un pallone Ambu per ventilare il paziente e/o passare a un altro dispositivo di anestesia.

Dettagli del prodotto interessato Sistemi di anestesia Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 e 9100c NXT, vedere l'Appendice allegata per l'elenco dei numeri seriali interessati:

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

Correzione prodotti GE Healthcare apporterà le dovute modifiche senza addebitare alcun costo aggiuntivo al cliente. Per l'implementazione della correzione, un rappresentante dell'assistenza GE Healthcare provvederà a mettersi in contatto con l'utente.

Informazioni di contatto In caso di domande riguardanti questa azione correttiva 'sul campo' o le modalità di identificazione dei dispositivi coinvolti, contattate pure il vostro referente locale delle funzioni di vendita e/o assistenza tecnica.

Potete anche contattare il Supporto Tecnico di riferimento al numero : 226001500.

GE Healthcare vi conferma che questo avviso è già stato comunicato al Ministero competente. Il mantenimento di elevati livelli di sicurezza e qualità è la nostra massima priorità. Per eventuali domande, contattare immediatamente GE Healthcare.

Cordiali saluti,



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



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

Appendice

Elenco dei numeri di serie interessati

Unità interessate Carestation 620/650/650c A1&A2 ACGO

SM617220006WA	SM618040003WA	SM618040004WA	SM618050009WA	SM618050010WA	SM618060002WA
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Unità interessate Carestation 620/650/650c A1 Aux O2+Air

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Unità interessate Carestation 30 ACGO

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Unità interessate 9100c NXT ACGO

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