



AVISO URGENTE DE SEGURANÇA

GE Healthcare

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

3 de August de 2018

Refª interna da GE Healthcare: FMI 34093

Para: Anestesia Respiratória
Diretor de Engenharia Clínica

RE: Possível Perda de Fluxo de Gás Fresco - Sistemas de Anestesia Carestation 620/650/650c, Carestation 30 e 9100c NXT

Certifique-se de que todos os possíveis usuários de sua instalação estão cientes desta notificação de segurança e sobre as ações recomendadas.

Problema de segurança

Nos sistemas equipados com saída de gás comum auxiliar (ACGO), existe a possibilidade do comutador de gás auxiliar mudar inesperadamente da posição ACGO para a posição circular. Em sistemas equipados com a função Aux O2 + Ar, o interruptor pode alternar inesperadamente da posição Aux O2 + Ar para a posição circular. Essas situações podem levar à hipóxia. Ainda seria possível ventilar o paciente usando o sistema de respiração circular nos modos de bolsa manual ou de ventilação mecânica. Não houve nenhuma lesão relatada como resultado deste problema.

Instruções de segurança

Você pode continuar usando os sistemas de anestesia listados abaixo nos detalhes dos produtos afetados. Se você notar o interruptor mudar das posições ACGO/Aux para circular ao usar o ACGO ou o Aux O2 + Ar, use o sistema de respiração circular para ventilar o paciente. Quando o ACGO ou o Aux O2 + Ar está ativo, há uma indicação no visor. Caso o interruptor mude para a posição circular, pode-se observar que a indicação no visor desaparece, o comutador muda para a posição circular e que o fluxo de gás da porta ACGO ou Aux O2 + Ar para de fluir. Se você notar algum destes sinais, use o sistema de respiração circular para ventilar o paciente. Em qualquer momento o clínico pode usar um saco auto-inflável para ventilar o paciente e/ou para mudar para outro dispositivo de anestesia.

Detalhes do produto afetado

Para os sistemas de anestesia Carestation 620/650/650c, Carestation 30 e 9100c NXT, consulte o Apêndice em anexo para ver a lista de números de série afetados:

Carestation 620 (GTIN: 00840682103985)

Carestation 650 (GTIN: 00840682103947)

Carestation 650c (GTIN: 00840682103954)

Correção do produto

A GE Healthcare corrigirá todos os produtos afetados, sem nenhum custo para você. Um representante da GE Healthcare lhe contactará para agendar a correção.

Informações para contato

Se tiver dúvidas sobre este Aviso de Segurança ou sobre a identificação dos itens afetados, favor contactar o seu representante local de Vendas ou de Serviço da GE Healthcare. Favor ligar para um dos números a seguir:

Estados Unidos: 800 437 1171

Brasil: 3004 2525 (Capitais e regiões metropolitanas) / 0800 165 799 (Demais regiões)

Para outros países, entre em contato com o Serviço Técnico da GE Healthcare.

Esteja certo de que a nossa maior prioridade é manter um elevado nível de segurança e qualidade. Se tiver quaisquer dúvidas ou perguntas, por favor contacte-nos imediatamente.

Muito obrigado,

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

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

Apêndice

Lista dos números de série afetados

Unidades afetadas do Carestation 620/650/650c

SM617220006WA	SM618040003WA	SM618040004WA	SM618050009WA	SM618050010WA	SM618060002WA
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Unidades afetadas do Carestation 620/650/650c A1 Aux O2+Ar

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Unidades afetadas do 9100c NXT

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