

医疗器械召回事件报告表

(公司内部召回编号: FMI 36161)

提交: 企业所在地省级药品监督管理部门

器械注册/备案部门

产品名称	病人监护仪	注册证或备案 凭证编码	国械注进 20183072625 国械注进 20183072623
生产企业名称	通用电气医疗芬兰有限公司 GE Healthcare Finland Oy		
代理人名称	通用电气医疗系统贸易发展(上海)有限公司		
召回单位负责人和联系方式, 经办人和联系方式	负责人: 李延 010-57388736 经办人: 彭一苇 010-57388736		
产品的适用范围	见 附表 1 产品信息		
涉及地区和国家	中国、美国、欧盟等 国家和地区	召回级别	二级
涉及产品生产(或进口中国)批次、数量	1205 台	涉及产品 型号、规格	B850、B650
识别信息 (如批号)	见 附表 2 识别信息	涉及产品在中国的销售数量	1055 台
召回原因简述	<p>GE 医疗近期发现, 在更换 CPU 板时钟电池后, 如果在进行监护期间发生供电中断, 某些版本的 B850 和 B650 病人监护仪可能会失去监护功能。一旦发生这种情况, 可能会导致主电源恢复后监护仪仍无法打开, 这可能会导致在连接替代监护仪之前无法及时发现患者的病情变化。如果监护仪没有更换过 CPU 板时钟电池, 则不会出现上述问题。目前尚未收到由于该问题造成伤害的报告。</p> <p>GE 医疗中国未收到与该问题相关的国内市场反馈、国内投诉和不良事件相关信息。维护高标准的安全和质量是我们的首要任务, GE 医疗决定通过主动召回, 向客户提供更新的文本资料。</p>		
纠正行动简述(包括召回要求和处理方式等)	<p>1. GE 医疗将通知客户此问题和注意事项;</p> <p>2. GE 医疗将为客户提供相关的更新文本资料。</p> <p>注: 本次纠正行动不涉及受影响产品的停用及退回。</p>		

报告单位: 

报告人: 彭一苇

负责人: 李延

报告日期: 2024.5.8

附表 1 产品信息

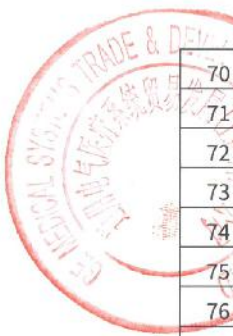
产品名称	型号	医疗器械注册证号	生产企业名称	产品适用范围
病人监护仪	B850	国械注进 20183072625	通用电气医疗芬兰有限公司 GE Healthcare Finland Oy	<p>该产品可在专业医疗机构内使用，适用于成人、小儿和新生儿患者，并且一次只能用于一名患者。该产品适合用于监护：</p> <ol style="list-style-type: none"> 1. 血液动力学（包括 ECG、ST 段、心律失常检测、ECG 分析和测量、有创血压、无创血压、脉搏血氧饱和度、心输出量（热稀释法和脉搏轮廓）、体温及混合静脉血氧饱和度，中心静脉氧饱和度，手术体积描记指数）。 2. 呼吸（阻抗呼吸、气道气体 [CO₂、O₂、N₂O 和麻醉剂]、肺功能测定和气体交换）。 3. 神经生理学状态（包括脑电图、熵指数、双频指数[BIS]和神经肌电传导）。 <p>该产品提供报警、趋势、快照、事件以及计算，并且可以连接到显示器，打印机和记录设备。该产品可以是独立的监护仪，也可以连接到其它设备。此外，还可以连接到其它监护仪进行远程查看，或者通过网络连接到数据管理软件设备。</p> <p>该产品应在执业医师的直接监控下进行使用，或由专业的医疗机构中接受过适当培训的人员使用。</p>
	B650	国械注进 20183072623	通用电气医疗芬兰有限公司 GE Healthcare Finland Oy	<p>该产品可在专业医疗机构内及院内转运使用，适用于成人、小儿和新生儿患者，并且一次只能用于一名患者。该产品适合用于监护：</p> <ol style="list-style-type: none"> 1. 血液动力学：ECG、ST 段、心律失常检测、ECG 分析和测量、有创血压、无创血压、脉搏血氧饱和度、心输出量（热稀释法和脉搏轮廓）、体温及混合静脉血氧饱和度，中心静脉氧饱和度，手术体积描记指数。 2. 呼吸：阻抗呼吸、气道气体（CO₂、O₂、N₂O 和麻醉剂）、肺功能测定和气体交换。 3. 神经生理学状态：脑电图、熵指数、双频指数（BIS）和神经肌电传导。 <p>该产品提供报警、趋势、快照、事件以及计算，并且可以连接到显示器，打印机和记录设备。该产品可以是独立的监护仪，也可以连接到其它设备。此外，还可以连接到其它监护仪进行远程查看，或者通过网络连接到数据管理软件设备。</p> <p>该产品应在执业医师的直接监控下进行使用，或由专业的医疗机构中接受过适当培训的人员使用。</p>

附表 2 识别信息

#	序列号	UDI	#	序列号	UDI
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3	SNR21070021HA	010084068214430821SNR21070021HA11211111	531	SNS22130044HA	010084068214380621SNS22130044HA11220331
4	SNR21070022HA	010084068214430821SNR21070022HA11211111	532	SNS22130045HA	010084068214380621SNS22130045HA11220331
5	SNR21070023HA	010084068214430821SNR21070023HA11211111	533	SNS22130046HA	010084068214380621SNS22130046HA11220331
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8	SNR21080057HA	010084068214430821SNR21080057HA11210519	536	SNS22130049HA	010084068214380621SNS22130049HA11220331
9	SNR21080059HA	010084068214430821SNR21080059HA11210517	537	SNS22130050HA	010084068214380621SNS22130050HA11220331
10	SNR21080061HA	010084068214430821SNR21080061HA11210517	538	SNS22130051HA	010084068214380621SNS22130051HA11220331
11	SNR21080062HA	010084068214430821SNR21080062HA11210517	539	SNS22130052HA	010084068214380621SNS22130052HA11220331
12	SNR21080064HA	010084068214430821SNR21080064HA11210517	540	SNS22130053HA	010084068214380621SNS22130053HA11220331
13	SNR21080065HA	010084068214430821SNR21080065HA11210519	541	SNS22130054HA	010084068214380621SNS22130054HA11220331
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18	SNR21110007HA	010084068214430821SNR21110007HA11210518	546	SNS22130059HA	010084068214380621SNS22130059HA11220331
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24	SNR21150113HA	010084068214430821SNR21150113HA11210519	552	SNS22130065HA	010084068214380621SNS22130065HA11220401
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28	SNR21230058HA	010084068214430821SNR21230058HA11211111	556	SNS22170004HA	010084068214380621SNS22170004HA11220428
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31	SNR21350007HA	010084068214430821SNR21350007HA11211027	559	SNS22170007HA	010084068214380621SNS22170007HA11220428
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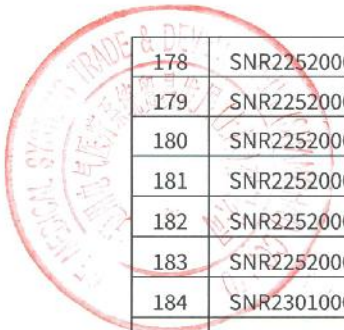
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36	SNR21440038HA	010084068214430821SNR21440038HA11211110	564	SNS22170012HA	010084068214380621SNS22170012HA11220428
37	SNR21440047HA	010084068214430821SNR21440047HA11211110	565	SNS22170013HA	010084068214380621SNS22170013HA11220428
38	SNR21440048HA	010084068214430821SNR21440048HA11211110	566	SNS22170014HA	010084068214380621SNS22170014HA11220428
39	SNR21440049HA	010084068214430821SNR21440049HA11211110	567	SNS22170015HA	010084068214380621SNS22170015HA11220428
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43	SNR21440057HA	010084068214430821SNR21440057HA11211110	571	SNS22170019HA	010084068214380621SNS22170019HA11220428
44	SNR21440058HA	010084068214430821SNR21440058HA11211110	572	SNS22170020HA	010084068214380621SNS22170020HA11220428
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46	SNR21440060HA	010084068214430821SNR21440060HA11211110	574	SNS22260001HA	010084068214380621SNS22260001HA11220628
47	SNR21440061HA	010084068214430821SNR21440061HA11211110	575	SNS22260002HA	010084068214380621SNS22260002HA11220628
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68	SNR21520073HA	010084068214430821SNR21520073HA11220105	596	SNS22290003HA	010084068214380621SNS22290003HA11220721
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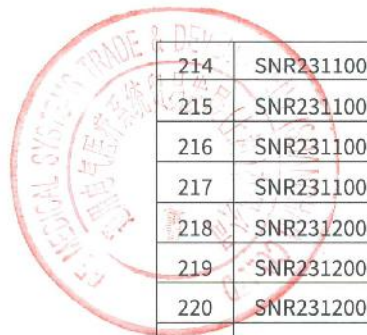
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83	SNR22020149HA	010084068214430821SNR22020149HA11220119	611	SNS22290018HA	010084068214380621SNS22290018HA11220721
84	SNR22020150HA	010084068214430821SNR22020150HA11220119	612	SNS22290019HA	010084068214380621SNS22290019HA11220721
85	SNR22020152HA	010084068214430821SNR22020152HA11220119	613	SNS22290020HA	010084068214380621SNS22290020HA11220722
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98	SNR22110155HA	010084068214430821SNR22110155HA11220329	626	SNS22320008HA	010084068214380621SNS22320008HA11220812
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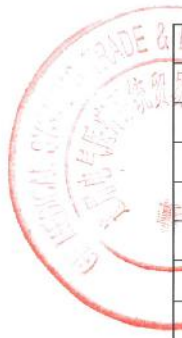
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514	SNS22130027HA	010084068214380621SNS22130027HA11220330	1042	SNS23410017HA	010084068214380621SNS23410017HA11231020
515	SNS22130028HA	010084068214380621SNS22130028HA11220330	1043	SNS23410019HA	010084068214380621SNS23410019HA11231020
516	SNS22130029HA	010084068214380621SNS22130029HA11220330	1044	SNS23410020HA	010084068214380621SNS23410020HA11231020
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518	SNS22130031HA	010084068214380621SNS22130031HA11220331	1046	SNS23410022HA	010084068214380621SNS23410022HA11231020
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521	SNS22130034HA	010084068214380621SNS22130034HA11220331	1049	SNS23440001HA	010084068214380621SNS23440001HA11231106
522	SNS22130035HA	010084068214380621SNS22130035HA11220401	1050	SNS23510030HA	010084068214380621SNS23510030HA11240103
523	SNS22130036HA	010084068214380621SNS22130036HA11220331	1051	SNS23510033HA	010084068214380621SNS23510033HA11240103
524	SNS22130037HA	010084068214380621SNS22130037HA11220331	1052	SNS23510034HA	010084068214380621SNS23510034HA11240103
525	SNS22130038HA	010084068214380621SNS22130038HA11220331	1053	SNS23510035HA	010084068214380621SNS23510035HA11240103
526	SNS22130039HA	010084068214380621SNS22130039HA11220331	1054	SNS23510037HA	010084068214380621SNS23510037HA11240103
527	SNS22130040HA	010084068214380621SNS22130040HA11220331	1055	SNS23510040HA	010084068214380621SNS23510040HA11240103
528	SNS22130041HA	010084068214380621SNS22130041HA11220331			-