



# 医疗器械召回事件报告表

(公司内部召回编号: FMI 36149)

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	安装在部分型号病人监护仪/患者监护仪上的患者数据模块 (PDM)	注册证或备案凭证编码	病人监护仪/患者监护仪注册证号: 国食药监械(进)字 2014 第 3212974 号; 国械注进 20193072135; 国食药监械(进)字 2013 第 3212417 号; 国食药监械(进)字 2014 第 3212922 号; 国械注进 20183072623; 国食药监械(进)字 2014 第 3212977 号; 国械注进 20183072625
生产企业名称	见 附表 1 产品信息		
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: 彭一革 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	556 件 PDM 模块	涉及产品型号、规格	病人监护仪/患者监护仪型号: B450、B650、B850
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	556 件 PDM 模块
召回原因简述	<p>本次召回实际涉及的产品为安装在部分型号病人监护仪/患者监护仪(型号: B450、B650、B850)上的患者数据模块(PDM)。GE 医疗近期发现,如果采用 Masimo SET® 技术的患者数据模块(PDM)超过 2 年未完全关闭电源,可能会显示不准确的冻结 SpO<sub>2</sub> 血氧饱和度,该值不再反映患者的临床变化状况。如果发生这种情况,可能会导致错过 SpO<sub>2</sub> 警报,延误对缺氧或过氧的诊断和治疗。</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 医疗决定主动召回受影响产品。</p>		
纠正行动简述(包括召回要求和处理方式等)	<ol style="list-style-type: none"> <li>1. GE 医疗发送客户信告知客户此问题以及注意事项;</li> <li>2. GE 医疗派工程师至现场对受影响的产品进行免费检查和修正;</li> </ol> <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: (盖章)

报告人: 彭一革

负责人: 李延

报告日期: 2021.6.28



附表 1 产品信息

产品名称	产品型号	注册证编号	生产企业名称	产品适用范围
病人监护仪	B450	国食药监械(进)字 2014 第 3212974 号	GE Healthcare Finland Oy	CARESCAPE 病人监护仪 B450、B650、B850 可在专业医疗机构内及院内转运使用; CARESCAPE 病人监护仪 B450、B650、B850 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;
	B650	国食药监械(进)字 2014 第 3212922 号	GE Healthcare Finland Oy	CARESCAPE 病人监护仪 B450、B650、B850 适合用于监护: <ul style="list-style-type: none"> <li>• 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)</li> <li>• 呼吸(阻抗呼吸、气道气体[CO<sub>2</sub>、O<sub>2</sub>、N<sub>2</sub>O 和麻醉剂]、肺功能测定)</li> <li>• 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)</li> </ul>
	B850	国食药监械(进)字 2014 第 3212977 号	GE Healthcare Finland Oy	<ul style="list-style-type: none"> <li>• 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)</li> <li>• 呼吸(阻抗呼吸、气道气体[CO<sub>2</sub>、O<sub>2</sub>、N<sub>2</sub>O 和麻醉剂]、肺功能测定)</li> <li>• 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)</li> </ul>
	B450	国械注进 20193072135	GE Healthcare Finland Oy 通用电气医疗芬兰有限公司	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;
	B650	国械注进 20183072623	GE Healthcare Finland Oy 通用电气医疗芬兰有限公司	适合用于监护: <ul style="list-style-type: none"> <li>• 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)</li> <li>• 呼吸(阻抗呼吸、气道气体[CO<sub>2</sub>、O<sub>2</sub>、N<sub>2</sub>O 和麻醉剂]、肺功能测定和气体交换)。</li> <li>• 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)</li> </ul>
	B850	国械注进 20183072625	GE Healthcare Finland Oy 通用电气医疗芬兰有限公司	<ul style="list-style-type: none"> <li>• 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)</li> <li>• 呼吸(阻抗呼吸、气道气体[CO<sub>2</sub>、O<sub>2</sub>、N<sub>2</sub>O 和麻醉剂]、肺功能测定和气体交换)。</li> <li>• 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)</li> </ul>
患者监护仪	B650	国食药监械(进)字 2013 第 3212417 号	GE Healthcare Finland Oy	该产品为多参数生理患者监护仪, 用于成人、小儿和新生儿患者, 旨在用于监护和记录血液动力学(ECG 测量、监护和分析、ST 段和心律失常检测、有创血压、无创血压、脉搏血氧、心排量、体温及混合静脉血氧饱和度)、阻抗呼吸、气道气体(CO <sub>2</sub> 、O <sub>2</sub> 、N <sub>2</sub> O 和麻醉剂)、呼吸功能测定、气体交换和神经生理(包括脑电图、熵指数、双频指数和神经肌电传导)状况, 并生成报警。该产品可作为独立的监护仪使用, 也可以连接到其他设备, 还可以连接到其他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。 该产品应在执业医师的直接监控下进行使用。



附表2 识别信息

序号	PDM 识别号	序号	PDM 识别号	序号	PDM 识别号
1	SA314211958GA	187	SA316121942GA	373	SA318320268SA
2	SA314211985GA	188	SA316121943GA	374	SA318320274SA
3	SA314336980GA	189	SA316121944GA	375	SA318320276SA
4	SA314337080GA	190	SA316121945GA	376	SA318320278SA
5	SA314337160GA	191	SA316121946GA	377	SA318320280SA
6	SA314337183GA	192	SA316121947GA	378	SA318320294SA
7	SA314347335GA	193	SA316121948GA	379	SA318320295SA
8	SA314347357GA	194	SA316121949GA	380	SA318320296SA
9	SA314347362GA	195	SA316121950GA	381	SA318320302SA
10	SA314347390GA	196	SA316121951GA	382	SA318320303SA
11	SA315037001GA	197	SA316121952GA	383	SA318320304SA
12	SA315037145GA	198	SA316121953GA	384	SA318320306SA
13	SA315091426GA	199	SA316121955GA	385	SA318320307SA
14	SA315133231GA	200	SA316121956GA	386	SA318320308SA
15	SA315133233GA	201	SA316121957GA	387	SA318320314SA
16	SA315133243GA	202	SA316121958GA	388	SA318320326SA
17	SA315144187GA	203	SA316121959GA	389	SA318320337SA
18	SA315154708GA	204	SA316121960GA	390	SA318320338SA
19	SA315154979GA	205	SA316121961GA	391	SA318320339SA
20	SA315155024GA	206	SA316121962GA	392	SA318320341SA
21	SA315155036GA	207	SA316121965GA	393	SA318320342SA
22	SA315155051GA	208	SA316121966GA	394	SA318320343SA
23	SA315155066GA	209	SA316121967GA	395	SA318330245SA
24	SA315155146GA	210	SA316121968GA	396	SA318420221SA
25	SA315155230GA	211	SA316121969GA	397	SA318420223SA
26	SA315155289GA	212	SA316121970GA	398	SA318420224SA
27	SA315155351GA	213	SA316121972GA	399	SA318420230SA
28	SA315165398GA	214	SA316121973GA	400	SA318420232SA
29	SA315165603GA	215	SA316121974GA	401	SA318420233SA
30	SA315165626GA	216	SA316121975GA	402	SA318420238SA
31	SA315165734GA	217	SA316121976GA	403	SA318420241SA
32	SA315165746GA	218	SA316121977GA	404	SA318420243SA
33	SA315165858GA	219	SA316121978GA	405	SA318420253SA

34	SA315165907GA	220	SA316121980GA	406	SA318420255SA
35	SA315165926GA	221	SA316121981GA	407	SA318420264SA
36	SA315165954GA	222	SA316121982GA	408	SA318420265SA
37	SA315166010GA	223	SA316121983GA	409	SA318420271SA
38	SA315166013GA	224	SA316121986GA	410	SA318420281SA
39	SA315166085GA	225	SA316121987GA	411	SA318420283SA
40	SA315166112GA	226	SA316121989GA	412	SA318420309SA
41	SA315176217GA	227	SA316121990GA	413	SA318420310SA
42	SA315176274GA	228	SA316121991GA	414	SA318420311SA
43	SA315176332GA	229	SA316121995GA	415	SA318420313SA
44	SA315176339GA	230	SA316121996GA	416	SA318420314SA
45	SA315176348GA	231	SA316121997GA	417	SA318420316SA
46	SA315176446GA	232	SA316121998GA	418	SA318420321SA
47	SA315176450GA	233	SA316122001GA	419	SA318420325SA
48	SA315176628GA	234	SA316122003GA	420	SA318420329SA
49	SA315176679GA	235	SA316122007GA	421	SA318420330SA
50	SA315176749GA	236	SA316122008GA	422	SA318420331SA
51	SA315176759GA	237	SA316122009GA	423	SA318420333SA
52	SA315176780GA	238	SA316122010GA	424	SA318420334SA
53	SA315176863GA	239	SA316122011GA	425	SA318460027SA
54	SA315176956GA	240	SA316122013GA	426	SA318460045SA
55	SA315176963GA	241	SA316122014GA	427	SA318460066SA
56	SA315176965GA	242	SA316122016GA	428	SA318460082SA
57	SA315187080GA	243	SA316122017GA	429	SA318460083SA
58	SA315187089GA	244	SA316122018GA	430	SA318460090SA
59	SA315187102GA	245	SA316122019GA	431	SA318460224SA
60	SA315187619GA	246	SA316122021GA	432	SA318460230SA
61	SA315198172GA	247	SA316122022GA	433	SA318460235SA
62	SA315208672GA	248	SA316122023GA	434	SA318460239SA
63	SA315208697GA	249	SA316122024GA	435	SPX19010115SA
64	SA315208732GA	250	SA316122025GA	436	SPX19010172SA
65	SA315208778GA	251	SA316122026GA	437	SPX19010192SA
66	SA315219028GA	252	SA316122027GA	438	SPX19020438SA
67	SA315219167GA	253	SA316122028GA	439	SPX19020441SA
68	SA315428127GA	254	SA316122030GA	440	SPX19020465SA
69	SA315428161GA	255	SA316122032GA	441	SPX19020523SA
70	SA315428163GA	256	SA316122033GA	442	SPX19030104SA





71	SA315428172GA	257	SA316122034GA	443	SPX19030107SA
72	SA315448426GA	258	SA316122035GA	444	SPX19030129SA
73	SA315448449GA	259	SA316122036GA	445	SPX19030136SA
74	SA315448453GA	260	SA316122037GA	446	SPX19030140SA
75	SA315448454GA	261	SA316152281GA	447	SPX19030147SA
76	SA315448456GA	262	SA316162329GA	448	SPX19030161SA
77	SA315448457GA	263	SA316162333GA	449	SPX19030186SA
78	SA315448460GA	264	SA316162338GA	450	SPX19030410SA
79	SA315448463GA	265	SA316162357GA	451	SPX19030426SA
80	SA315448464GA	266	SA316212862GA	452	SPX19030435SA
81	SA315448467GA	267	SA316212864GA	453	SPX19030452SA
82	SA315448469GA	268	SA316212878GA	454	SPX19030468SA
83	SA315448470GA	269	SA316212880GA	455	SPX19030484SA
84	SA315448473GA	270	SA316212881GA	456	SPX19030485SA
85	SA315448476GA	271	SA316212882GA	457	SPX19030492SA
86	SA315448478GA	272	SA316212883GA	458	SPX19030494SA
87	SA315448483GA	273	SA316212885GA	459	SPX19040416SA
88	SA315448574GA	274	SA316212886GA	460	SPX19040418SA
89	SA315448584GA	275	SA316212887GA	461	SPX19040421SA
90	SA315448590GA	276	SA316212892GA	462	SPX19040425SA
91	SA315448591GA	277	SA316212897GA	463	SPX19040440SA
92	SA315448597GA	278	SA316212899GA	464	SPX19040442SA
93	SA315448602GA	279	SA316212904GA	465	SPX19040444SA
94	SA315489978GA	280	SA316212942GA	466	SPX19040447SA
95	SA315490248GA	281	SA316212944GA	467	SPX19040448SA
96	SA315490378GA	282	SA316212945GA	468	SPX19040451SA
97	SA315490384GA	283	SA316212948GA	469	SPX19040452SA
98	SA315490390GA	284	SA316212949GA	470	SPX19040453SA
99	SA315490412GA	285	SA316212951GA	471	SPX19040454SA
100	SA315490436GA	286	SA316212953GA	472	SPX19040460SA
101	SA315500648GA	287	SA316212955GA	473	SPX19040461SA
102	SA315500653GA	288	SA316212956GA	474	SPX19040462SA
103	SA315500654GA	289	SA316212957GA	475	SPX19040463SA
104	SA315500655GA	290	SA316212958GA	476	SPX19040464SA
105	SA315500656GA	291	SA316212959GA	477	SPX19040465SA
106	SA315500658GA	292	SA316212961GA	478	SPX19040467SA
107	SA315500659GA	293	SA316212963GA	479	SPX19040468SA



108	SA315500669GA	294	SA316212964GA	480	SPX19040469SA
109	SA315500676GA	295	SA316212966GA	481	SPX19040470SA
110	SA315500682GA	296	SA316212967GA	482	SPX19040471SA
111	SA315500684GA	297	SA316212968GA	483	SPX19040472SA
112	SA315500687GA	298	SA316223036GA	484	SPX19040473SA
113	SA315500689GA	299	SA316223038GA	485	SPX19040474SA
114	SA315500692GA	300	SA316223040GA	486	SPX19040475SA
115	SA315500695GA	301	SA316223041GA	487	SPX19040476SA
116	SA315500700GA	302	SA316223046GA	488	SPX19040477SA
117	SA316041512GA	303	SA316223063GA	489	SPX19040478SA
118	SA316041516GA	304	SA316223070GA	490	SPX19040479SA
119	SA316041517GA	305	SA317040117SA	491	SPX19040480SA
120	SA316041518GA	306	SA317040119SA	492	SPX19040481SA
121	SA316041519GA	307	SA317040122SA	493	SPX19040482SA
122	SA316041520GA	308	SA317040126SA	494	SPX19040483SA
123	SA316041525GA	309	SA317040128SA	495	SPX19040485SA
124	SA316041526GA	310	SA317040134SA	496	SPX19040489SA
125	SA316041528GA	311	SA317040139SA	497	SPX19040491SA
126	SA316041529GA	312	SA317040143SA	498	SPX19050151SA
127	SA316081680GA	313	SA317090049SA	499	SPX19050168SA
128	SA316081754GA	314	SA317130332SA	500	SPX19050171SA
129	SA316111868GA	315	SA317460231SA	501	SPX19050308SA
130	SA316111869GA	316	SA317460242SA	502	SPX19050309SA
131	SA316111870GA	317	SA317460260SA	503	SPX19050310SA
132	SA316111871GA	318	SA317460331SA	504	SPX19050311SA
133	SA316111872GA	319	SA317460497SA	505	SPX19050312SA
134	SA316111873GA	320	SA317460506SA	506	SPX19050313SA
135	SA316111874GA	321	SA317460512SA	507	SPX19050319SA
136	SA316111875GA	322	SA317460518SA	508	SPX19050321SA
137	SA316111876GA	323	SA317460522SA	509	SPX19050366SA
138	SA316111877GA	324	SA317460535SA	510	SPX19050367SA
139	SA316111878GA	325	SA317460539SA	511	SPX19050370SA
140	SA316111879GA	326	SA317460555SA	512	SPX19050374SA
141	SA316111880GA	327	SA317460604SA	513	SPX19050387SA
142	SA316111881GA	328	SA317460629SA	514	SPX19050428SA
143	SA316111882GA	329	SA317460630SA	515	SPX19050446SA
144	SA316111883GA	330	SA317480228SA	516	SPX19050455SA



145	SA316111884GA	331	SA317480251SA	517	SPX19060082SA
146	SA316111885GA	332	SA317480258SA	518	SPX19060084SA
147	SA316111886GA	333	SA317480260SA	519	SPX19060085SA
148	SA316111887GA	334	SA317480266SA	520	SPX19060090SA
149	SA316111889GA	335	SA317480268SA	521	SPX19060093SA
150	SA316111890GA	336	SA317480273SA	522	SPX19060096SA
151	SA316111891GA	337	SA317480276SA	523	SPX19060098SA
152	SA316111892GA	338	SA317480285SA	524	SPX19060101SA
153	SA316111893GA	339	SA317490001SA	525	SPX19100310SA
154	SA316111894GA	340	SA317490002SA	526	SPX20250141SA
155	SA316111896GA	341	SA317490005SA	527	SPX20310136SA
156	SA316111897GA	342	SA317490006SA	528	SPX20310137SA
157	SA316111898GA	343	SA317490013SA	529	SPX20310150SA
158	SA316121909GA	344	SA317490022SA	530	SPX20310151SA
159	SA316121910GA	345	SA317490023SA	531	SPX20310156SA
160	SA316121911GA	346	SA317490025SA	532	SPX20310157SA
161	SA316121912GA	347	SA317490026SA	533	SPX20310158SA
162	SA316121913GA	348	SA317490027SA	534	SPX20310172SA
163	SA316121914GA	349	SA317490028SA	535	SPX20310233SA
164	SA316121915GA	350	SA318060673SA	536	SPX20310235SA
165	SA316121916GA	351	SA318070435SA	537	SPX20310237SA
166	SA316121917GA	352	SA318070450SA	538	SPX20310239SA
167	SA316121918GA	353	SA318070462SA	539	SPX20310351SA
168	SA316121919GA	354	SA318070465SA	540	SPX20310794SA
169	SA316121920GA	355	SA318070486SA	541	SPX20310878SA
170	SA316121921GA	356	SA318070487SA	542	SPX20311023SA
171	SA316121923GA	357	SA318070493SA	543	SPX20311051SA
172	SA316121925GA	358	SA318070541SA	544	SPX20311065SA
173	SA316121926GA	359	SA318080076SA	545	SPX20311072SA
174	SA316121927GA	360	SA318290235SA	546	SPX20311099SA
175	SA316121928GA	361	SA318290265SA	547	SPX20311138SA
176	SA316121929GA	362	SA318290299SA	548	SPX20311139SA
177	SA316121930GA	363	SA318320120SA	549	SPX20311167SA
178	SA316121931GA	364	SA318320132SA	550	SPX20311172SA
179	SA316121932GA	365	SA318320133SA	551	SPX20311173SA
180	SA316121933GA	366	SA318320141SA	552	SPX20311225SA
181	SA316121935GA	367	SA318320148SA	553	SPX20311232SA



182	SA316121936GA	368	SA318320151SA	554	SPX20330466SA
183	SA316121937GA	369	SA318320154SA	555	SPX20330805SA
184	SA316121938GA	370	SA318320157SA	556	SPX20330816SA
185	SA316121939GA	371	SA318320160SA	-	-
186	SA316121940GA	372	SA318320163SA	-	-

