



医疗器械召回事件报告表

(公司内部召回编号: FMI 36146)

提交: ☒ 企业所在地省级食品药品监督管理部门

☒ 器械注册/备案部门

产品名称	见 附表 1.产品信息	注册证或备案 凭证编码	见 附表 1.产品信息
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: 韦艺 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、加拿大、欧盟等国家或地区	召回级别	二级
涉及产品生产(或进口中国) 批次、数量	1522 件	涉及产品 型号、规格	见 附表 1.产品信息
识别信息 (如批号)	患者数据模块识别号 见 附表 2.识别信息	涉及产品在中国的 销售数量	1385 件
召回原因简述	本次主动召回实际涉及到的部件为安装在部分型号监护仪上的患者数据模块(PDM)。GE 医疗近期发现, 当患者数据模块(PDM) 与 B450/B650/B850 病人监护仪、Solar 8000M/8000i 患者监护仪一起使用时, 如果在监护仪上打开了 Pace(起搏)检测, 并且使用自动体外除颤仪(AED)来执行除颤的情况下, 则 AED 的低频信号将导致 PDM 发出错误的 ECG 信息, 在监护仪上显示心脏停搏并报警。这个问题可能延迟对于 ECG 心律失常的临床评估。 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。		
纠正行动简述(包括召回要求和处理方式等)	1. GE 医疗将通知受影响客户此问题及注意事项; 2. GE 医疗将免费为客户修复受影响的设备; 3. 本次纠正行动不涉及受影响产品的停用及退回。		

报告单位: (盖章)

报告人: 彭一苇



负责人: 韦艺

报告日期: 2020年6月8日

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
患者监护仪	Solar 8000i, Solar 8000M	国食药监械(进)字 2007 第 3211603 号	GE Medical Systems Information Technologies	用于医疗机构监测成人患者、儿童患者、新生儿患者的生理参数,参数包括心电、呼吸、体温、有创血压、无创血压、血氧饱和度、心排量、二氧化碳、成年和/或儿童患者的麻醉剂浓度。本次注册不包括脑电/意识深度参数的监测。
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; CARESCAPE 病人监护仪 B450、B650、B850 适合用于监护:
	B650	国食药监械(进)字 2014 第 3212922 号		- 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、中心静脉氧饱和度和手术体积描记指数) - 呼吸(阻抗呼吸、气道气体[CO₂、O₂、N₂O 和麻醉剂]、肺功能测定) - 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)
	B850	国食药监械(进)字 2014 第 3212977 号		
	B450	国械注进 20193072135		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; 适合用于监护:
	B650	国械注进 20183072623		- 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、中心静脉氧饱和度和手术体积描记指数) - 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)。 - 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)
	B850	国械注进 20183072625		





附表 2.识别信息

序号	识别号	序号	识别号	序号	识别号	序号	识别号
1	SA317420002SA	351	SA318480227SA	701	SPX19200157SA	1051	SPX19470311SA
2	SA317420005SA	352	SA318480273SA	702	SPX19200158SA	1052	SPX19470314SA
3	SA317420007SA	353	SPX18490410SA	703	SPX19200265SA	1053	SPX19470316SA
4	SA317420008SA	354	SPX18490411SA	704	SPX19200266SA	1054	SPX19470317SA
5	SA317420010SA	355	SPX18490423SA	705	SPX19200267SA	1055	SPX19470318SA
6	SA317420011SA	356	SPX18500006SA	706	SPX19200270SA	1056	SPX19470319SA
7	SA317420025SA	357	SPX18500294SA	707	SPX19200271SA	1057	SPX19470320SA
8	SA317420107SA	358	SPX18500295SA	708	SPX19200272SA	1058	SPX19470321SA
9	SA317420120SA	359	SPX18500296SA	709	SPX19200276SA	1059	SPX19470323SA
10	SA317460195SA	360	SPX18500298SA	710	SPX19200278SA	1060	SPX19470329SA
11	SA317460231SA	361	SPX18500299SA	711	SPX19200279SA	1061	SPX19470330SA
12	SA317460242SA	362	SPX18500300SA	712	SPX19200280SA	1062	SPX19470331SA
13	SA317460260SA	363	SPX18500301SA	713	SPX19200281SA	1063	SPX19470423SA
14	SA317460331SA	364	SPX18500303SA	714	SPX19200282SA	1064	SPX19470436SA
15	SA317460431SA	365	SPX18500305SA	715	SPX19200283SA	1065	SPX19480074SA
16	SA317460441SA	366	SPX18500306SA	716	SPX19200284SA	1066	SPX19480269SA
17	SA317460497SA	367	SPX18500307SA	717	SPX19200285SA	1067	SPX19480274SA
18	SA317460506SA	368	SPX18500308SA	718	SPX19200287SA	1068	SPX19480275SA
19	SA317460512SA	369	SPX18500309SA	719	SPX19200289SA	1069	SPX19480276SA
20	SA317460518SA	370	SPX18500313SA	720	SPX19200292SA	1070	SPX19480290SA
21	SA317460522SA	371	SPX18500314SA	721	SPX19200296SA	1071	SPX19480312SA
22	SA317460535SA	372	SPX18500316SA	722	SPX19200300SA	1072	SPX19480318SA
23	SA317460539SA	373	SPX18500317SA	723	SPX19200301SA	1073	SPX19480324SA
24	SA317460555SA	374	SPX18500318SA	724	SPX19200303SA	1074	SPX19480325SA
25	SA317460604SA	375	SPX18500320SA	725	SPX19200306SA	1075	SPX19480340SA
26	SA317460629SA	376	SPX18500321SA	726	SPX19200316SA	1076	SPX19480350SA
27	SA317460630SA	377	SPX18500322SA	727	SPX19200317SA	1077	SPX19480362SA
28	SA317460730SA	378	SPX18500323SA	728	SPX19200318SA	1078	SPX19480431SA
29	SA317460733SA	379	SPX18500324SA	729	SPX19200321SA	1079	SPX19480436SA
30	SA317460737SA	380	SPX18500325SA	730	SPX19200322SA	1080	SPX19480439SA
31	SA317460771SA	381	SPX18500326SA	731	SPX19200324SA	1081	SPX19480443SA
32	SA317460785SA	382	SPX18500327SA	732	SPX19200326SA	1082	SPX19480448SA
33	SA317460787SA	383	SPX18500328SA	733	SPX19200327SA	1083	SPX19480450SA
34	SA317460795SA	384	SPX18500330SA	734	SPX19200329SA	1084	SPX19480468SA
35	SA317470005SA	385	SPX18500332SA	735	SPX19200330SA	1085	SPX19480473SA
36	SA317470006SA	386	SPX18500334SA	736	SPX19200332SA	1086	SPX19480474SA
37	SA317470010SA	387	SPX18500335SA	737	SPX19200333SA	1087	SPX19480477SA
38	SA317470013SA	388	SPX18500337SA	738	SPX19200335SA	1088	SPX19480482SA
39	SA317470018SA	389	SPX18500338SA	739	SPX19200336SA	1089	SPX19480485SA
40	SA317470022SA	390	SPX18500343SA	740	SPX19200337SA	1090	SPX19480486SA
41	SA317470023SA	391	SPX18500345SA	741	SPX19200345SA	1091	SPX19480488SA
42	SA317470025SA	392	SPX18500347SA	742	SPX19200346SA	1092	SPX19480492SA
43	SA317470148SA	393	SPX18500348SA	743	SPX19200347SA	1093	SPX19480496SA
44	SA317470152SA	394	SPX18500349SA	744	SPX19200349SA	1094	SPX19480498SA

45	SA317470154SA	395	SPX18500350SA	745	SPX19200350SA	1095	SPX19480502SA
46	SA317470155SA	396	SPX18500351SA	746	SPX19200352SA	1096	SPX19480504SA
47	SA317470169SA	397	SPX18500352SA	747	SPX19200353SA	1097	SPX19480505SA
48	SA317480228SA	398	SPX18500353SA	748	SPX19200354SA	1098	SPX19480506SA
49	SA317480251SA	399	SPX18500354SA	749	SPX19200355SA	1099	SPX19480508SA
50	SA317480258SA	400	SPX18500355SA	750	SPX19200357SA	1100	SPX19480509SA
51	SA317480260SA	401	SPX18500356SA	751	SPX19200360SA	1101	SPX19480510SA
52	SA317480266SA	402	SPX18500357SA	752	SPX19200361SA	1102	SPX19480513SA
53	SA317480268SA	403	SPX18500358SA	753	SPX19200362SA	1103	SPX19480515SA
54	SA317480273SA	404	SPX18500359SA	754	SPX19200385SA	1104	SPX19480516SA
55	SA317480276SA	405	SPX18500360SA	755	SPX19200387SA	1105	SPX19480518SA
56	SA317480285SA	406	SPX18500361SA	756	SPX19200389SA	1106	SPX19480521SA
57	SA317490001SA	407	SPX18500362SA	757	SPX19200390SA	1107	SPX19480524SA
58	SA317490002SA	408	SPX18500363SA	758	SPX19200393SA	1108	SPX19480525SA
59	SA317490005SA	409	SPX18500364SA	759	SPX19200398SA	1109	SPX19480528SA
60	SA317490006SA	410	SPX18500365SA	760	SPX19200403SA	1110	SPX19480532SA
61	SA317490013SA	411	SPX18500366SA	761	SPX19200406SA	1111	SPX19480534SA
62	SA317490022SA	412	SPX18500367SA	762	SPX19200407SA	1112	SPX19480536SA
63	SA317490023SA	413	SPX18500368SA	763	SPX19200408SA	1113	SPX19480538SA
64	SA317490025SA	414	SPX18500369SA	764	SPX19200409SA	1114	SPX19480540SA
65	SA317490026SA	415	SPX18500370SA	765	SPX19200410SA	1115	SPX19480541SA
66	SA317490027SA	416	SPX18500371SA	766	SPX19200416SA	1116	SPX19480544SA
67	SA317490028SA	417	SPX18500373SA	767	SPX19200421SA	1117	SPX19480547SA
68	SA317510155SA	418	SPX18500374SA	768	SPX19200422SA	1118	SPX19480548SA
69	SA318060673SA	419	SPX18500375SA	769	SPX19200424SA	1119	SPX19480549SA
70	SA318070435SA	420	SPX18500376SA	770	SPX19200427SA	1120	SPX19480550SA
71	SA318070450SA	421	SPX18500377SA	771	SPX19200428SA	1121	SPX19480551SA
72	SA318070462SA	422	SPX18500378SA	772	SPX19200430SA	1122	SPX19480555SA
73	SA318070465SA	423	SPX18500379SA	773	SPX19200433SA	1123	SPX19480556SA
74	SA318070486SA	424	SPX18500380SA	774	SPX19200434SA	1124	SPX19480557SA
75	SA318070487SA	425	SPX18500381SA	775	SPX19200436SA	1125	SPX19480558SA
76	SA318070493SA	426	SPX18500382SA	776	SPX19200437SA	1126	SPX19480560SA
77	SA318070541SA	427	SPX18500383SA	777	SPX19200439SA	1127	SPX19480561SA
78	SA318080076SA	428	SPX18500384SA	778	SPX19200440SA	1128	SPX19480562SA
79	SA318150340SA	429	SPX18500385SA	779	SPX19200441SA	1129	SPX19480563SA
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81	SA318150747SA	431	SPX18500387SA	781	SPX19200444SA	1131	SPX19480570SA
82	SA318150755SA	432	SPX18500388SA	782	SPX19200446SA	1132	SPX19480571SA
83	SA318150756SA	433	SPX18500389SA	783	SPX19200449SA	1133	SPX19480573SA
84	SA318150758SA	434	SPX18500390SA	784	SPX19200450SA	1134	SPX19480574SA
85	SA318150768SA	435	SPX18500391SA	785	SPX19200451SA	1135	SPX19480575SA
86	SA318150775SA	436	SPX18500392SA	786	SPX19200453SA	1136	SPX19480579SA
87	SA318150791SA	437	SPX18500393SA	787	SPX19200455SA	1137	SPX19480581SA
88	SA318150797SA	438	SPX18500394SA	788	SPX19200458SA	1138	SPX19480583SA
89	SA318150798SA	439	SPX18500395SA	789	SPX19200459SA	1139	SPX19490001SA
90	SA318160003SA	440	SPX18500396SA	790	SPX19200461SA	1140	SPX19490004SA
91	SA318160005SA	441	SPX18500397SA	791	SPX19200463SA	1141	SPX19490010SA

92	SA318160011SA	442	SPX18500398SA	792	SPX19200464SA	1142	SPX19490011SA
93	SA318160014SA	443	SPX18500399SA	793	SPX19200465SA	1143	SPX19490019SA
94	SA318160025SA	444	SPX18500400SA	794	SPX19200469SA	1144	SPX19490021SA
95	SA318180409SA	445	SPX18500403SA	795	SPX19200470SA	1145	SPX19490042SA
96	SA318200016SA	446	SPX18500404SA	796	SPX19200471SA	1146	SPX19490052SA
97	SA318200257SA	447	SPX18500405SA	797	SPX19200472SA	1147	SPX19490055SA
98	SA318200466SA	448	SPX18500406SA	798	SPX19200474SA	1148	SPX19490059SA
99	SA318200473SA	449	SPX18500407SA	799	SPX19200476SA	1149	SPX19490204SA
100	SA318200474SA	450	SPX18500408SA	800	SPX19200477SA	1150	SPX19490206SA
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103	SA318200482SA	453	SPX19010115SA	803	SPX19200481SA	1153	SPX19490219SA
104	SA318200485SA	454	SPX19010172SA	804	SPX19200591SA	1154	SPX19490222SA
105	SA318200494SA	455	SPX19010192SA	805	SPX19200592SA	1155	SPX19490224SA
106	SA318200500SA	456	SPX19020432SA	806	SPX19200603SA	1156	SPX19490225SA
107	SA318200519SA	457	SPX19020438SA	807	SPX19200607SA	1157	SPX19490227SA
108	SA318200523SA	458	SPX19020441SA	808	SPX19200610SA	1158	SPX19490239SA
109	SA318200530SA	459	SPX19020465SA	809	SPX19200611SA	1159	SPX19490241SA
110	SA318200533SA	460	SPX19020523SA	810	SPX19200613SA	1160	SPX19490242SA
111	SA318200535SA	461	SPX19030017SA	811	SPX19200619SA	1161	SPX19490243SA
112	SA318200538SA	462	SPX19030104SA	812	SPX19200625SA	1162	SPX19490247SA
113	SA318200546SA	463	SPX19030129SA	813	SPX19200626SA	1163	SPX19490248SA
114	SA318200548SA	464	SPX19030136SA	814	SPX19200629SA	1164	SPX19490251SA
115	SA318200550SA	465	SPX19030140SA	815	SPX19200631SA	1165	SPX19490270SA
116	SA318200551SA	466	SPX19030141SA	816	SPX19200633SA	1166	SPX19490271SA
117	SA318200552SA	467	SPX19030147SA	817	SPX19200634SA	1167	SPX19490282SA
118	SA318200554SA	468	SPX19030161SA	818	SPX19200635SA	1168	SPX19490288SA
119	SA318200568SA	469	SPX19030168SA	819	SPX19200641SA	1169	SPX19500127SA
120	SA318200573SA	470	SPX19030186SA	820	SPX19200649SA	1170	SPX19500133SA
121	SA318210426SA	471	SPX19030200SA	821	SPX19200651SA	1171	SPX19500264SA
122	SA318210452SA	472	SPX19030373SA	822	SPX19200652SA	1172	SPX19510297SA
123	SA318210641SA	473	SPX19030410SA	823	SPX19200654SA	1173	SPX20020049SA
124	SA318210842SA	474	SPX19030412SA	824	SPX19200655SA	1174	SPX20040237SA
125	SA318210857SA	475	SPX19030423SA	825	SPX19200657SA	1175	SPX20040243SA
126	SA318210879SA	476	SPX19030426SA	826	SPX19200663SA	1176	SPX20040321SA
127	SA318210883SA	477	SPX19030435SA	827	SPX19200667SA	1177	SPX20040322SA
128	SA318210890SA	478	SPX19030452SA	828	SPX19200669SA	1178	SPX20040334SA
129	SA318210897SA	479	SPX19030468SA	829	SPX19200670SA	1179	SPX20040339SA
130	SA318210899SA	480	SPX19030484SA	830	SPX19200671SA	1180	SPX20040345SA
131	SA318210906SA	481	SPX19030485SA	831	SPX19200673SA	1181	SPX20040354SA
132	SA318210909SA	482	SPX19030492SA	832	SPX19200675SA	1182	SPX20040355SA
133	SA318210913SA	483	SPX19030494SA	833	SPX19200676SA	1183	SPX20040356SA
134	SA318210917SA	484	SPX19040359SA	834	SPX19200680SA	1184	SPX20040360SA
135	SA318210920SA	485	SPX19040363SA	835	SPX19200689SA	1185	SPX20040377SA
136	SA318210923SA	486	SPX19040366SA	836	SPX19200692SA	1186	SPX20040380SA
137	SA318210924SA	487	SPX19040384SA	837	SPX19200706SA	1187	SPX20040381SA
138	SA318210926SA	488	SPX19040388SA	838	SPX19200709SA	1188	SPX20040385SA

139	SA318210929SA	489	SPX19040416SA	839	SPX19200710SA	1189	SPX20040391SA
140	SA318210932SA	490	SPX19040418SA	840	SPX19200713SA	1190	SPX20040392SA
141	SA318210933SA	491	SPX19040421SA	841	SPX19200715SA	1191	SPX20040393SA
142	SA318210934SA	492	SPX19040425SA	842	SPX19200723SA	1192	SPX20040395SA
143	SA318210936SA	493	SPX19040440SA	843	SPX19200724SA	1193	SPX20040398SA
144	SA318210938SA	494	SPX19040442SA	844	SPX19200727SA	1194	SPX20040402SA
145	SA318210939SA	495	SPX19040444SA	845	SPX19200731SA	1195	SPX20040408SA
146	SA318210943SA	496	SPX19040447SA	846	SPX19200735SA	1196	SPX20040410SA
147	SA318220001SA	497	SPX19040448SA	847	SPX19200743SA	1197	SPX20040412SA
148	SA318220002SA	498	SPX19040451SA	848	SPX19200746SA	1198	SPX20040413SA
149	SA318220005SA	499	SPX19040452SA	849	SPX19200748SA	1199	SPX20040414SA
150	SA318220007SA	500	SPX19040453SA	850	SPX19200751SA	1200	SPX20050059SA
151	SA318220369SA	501	SPX19040454SA	851	SPX19220201SA	1201	SPX20050062SA
152	SA318230021SA	502	SPX19040459SA	852	SPX19230452SA	1202	SPX20050124SA
153	SA318230045SA	503	SPX19040460SA	853	SPX19240021SA	1203	SPX20050130SA
154	SA318230047SA	504	SPX19040461SA	854	SPX19240025SA	1204	SPX20050155SA
155	SA318230060SA	505	SPX19040462SA	855	SPX19240050SA	1205	SPX20050268SA
156	SA318230065SA	506	SPX19040463SA	856	SPX19240055SA	1206	SPX20050517SA
157	SA318230202SA	507	SPX19040464SA	857	SPX19240069SA	1207	SPX20050524SA
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