



医疗器械召回事件报告表

(公司内部召回编号: FMI 34126)

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	本次主动召回实际涉及的部件为安装在部分型号呼吸机上的 备用电池	注册证或备案凭证编码	呼吸机注册证号: 国械注进 20173081051 国械注进 20173541051
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、欧盟等国家或地区	召回级别	二级
涉及产品生产 (或进口中国) 批次、数量	1896 件	涉及产品型号、规格	中国境内可能受影响的呼吸机型号: CARESCAPE R860
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	1896 件
召回原因简述	本次召回实际涉及的产品为 安装在部分型号呼吸机 (中国境内可能受影响的呼吸机型号: CARESCAPE R860) 上的部分批次备用电池 。GE 医疗近期发现, 2019 年 4 月 1 日或之后生产的 CARESCAPE R860 呼吸机的内部备用电池, 及 2019 年 4 月 1 日或之后销售替换的用于这些呼吸机的备用电池, 其使用寿命可能达不到预期, 电池剩余运行时间的报警信息可能不准确。呼吸机使用此类备用电池运行时, 可能会在报警指示时间之前关机, 导致通气中断, 患者可能无法获得所需氧气。如果这种情况没有引起注意并给予及时治疗, 可能会危及患者生命。目前没有收到该问题造成伤害的报告。GE 医疗中国目前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的形式, 告知客户此潜在问题以及为客户免费修复受影响产品。		
纠正行动简述 (包括召回要求和处理方式等)	1. GE 医疗将通知客户此问题、使用注意事项以及相关检查测试方法; 2. GE 医疗将对受影响的产品进行免费检查和修正; 注: 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:

负责人:

报告日期:

2022.5.18

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
呼吸机	CARESCAPE R860	国械注进 20173081051	德恩欧美达公司 Datex-Ohmeda, Inc.	本呼吸机设计为体重不低于 0.25kg 的新生儿、儿童和成人患者提供机械通气或呼吸支持。本呼吸机是气动电控型呼吸机，可监测吸入氧浓度（FiO2）、气道压力、流速与容量，呼吸机上的 GE 患者监测模块选件还可对患者进行呼吸气体监测。受患者类型和选配件限制，呼吸机上的功能并非适用于所有患者类型或未选配相应附件的 CARESCAPE R860。CARESCAPE R860 呼吸机不是肺功能计算设备。该系统设计用于医院内使用，包括院内转运，而且只应在医疗人员指导下使用。
呼吸机	CARESCAPE R860	国械注进 20173541051	Datex-Ohmeda, Inc.	本呼吸机设计为体重不低于 0.25kg 的新生儿、儿童和成人患者提供机械通气或呼吸支持。本呼吸机是气动电控型呼吸机，可监测吸入氧浓度（FiO2）、气道压力、流速与容量，呼吸机上的 GE 患者监测模块选件还可对患者进行呼吸气体监测。受患者类型和选配件限制，呼吸机上的功能并非适用于所有患者类型或未选配相应附件的 CARESCAPE R860。CARESCAPE R860 呼吸机不是肺功能计算设备。该系统设计用于医院内使用，包括院内转运，而且只应在医疗人员指导下使用。



附表 2 识别信息

注 1: 以下为安装有可能会受影响的备用电池配件的 CARESCAPRE R860 呼吸机的识别信息。

注 2: UDI 编码目前均不适用于以下列明的所有可能受影响的 CARESCAPE R860 呼吸机。

序号	序列号	序号	序列号	序号	序列号	序号	序列号
1	CBRA00148	501	CBRY01273	1001	CBRZ00307	1501	CBRZ41371
2	CBRA00151	502	CBRY01274	1002	CBRZ00308	1502	CBRZ41373
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4	CBRA00165	504	CBRY01281	1004	CBRZ00310	1504	CBRZ41395
5	CBRA00177	505	CBRY01283	1005	CBRZ00311	1505	CBRZ41398
6	CBRA00182	506	CBRY01284	1006	CBRZ00312	1506	CBRZ41418
7	CBRA00189	507	CBRY01285	1007	CBRZ00313	1507	CBRZ41432
8	CBRA00192	508	CBRY01287	1008	CBRZ00314	1508	CBRZ41442
9	CBRA00197	509	CBRY01290	1009	CBRZ00315	1509	CBRZ41450
10	CBRA00201	510	CBRY01298	1010	CBRZ00316	1510	CBRZ41453
11	CBRA00203	511	CBRY01306	1011	CBRZ00318	1511	CBRZ41454
12	CBRA00204	512	CBRY01308	1012	CBRZ00320	1512	CBRZ41456
13	CBRA00205	513	CBRY01309	1013	CBRZ00321	1513	CBRZ41457
14	CBRA00207	514	CBRY01310	1014	CBRZ00322	1514	CBRZ41458
15	CBRA00208	515	CBRY01311	1015	CBRZ00323	1515	CBRZ41459
16	CBRA00209	516	CBRY01312	1016	CBRZ00324	1516	CBRZ41460
17	CBRA00210	517	CBRY01315	1017	CBRZ00325	1517	CBRZ41461
18	CBRA00211	518	CBRY01317	1018	CBRZ00326	1518	CBRZ41469
19	CBRA00212	519	CBRY01319	1019	CBRZ00327	1519	CBRZ41475
20	CBRA00213	520	CBRY01321	1020	CBRZ00328	1520	CBRZ41476
21	CBRA00214	521	CBRY01323	1021	CBRZ00329	1521	CBRZ41477
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25	CBRA00218	525	CBRY01327	1025	CBRZ00333	1525	CBRZ41491
26	CBRA00219	526	CBRY01328	1026	CBRZ00334	1526	CBRZ41493
27	CBRA00222	527	CBRY01329	1027	CBRZ00335	1527	CBRZ41500
28	CBRA00240	528	CBRY01333	1028	CBRZ00336	1528	CBRZ41546
29	CBRA00243	529	CBRY01335	1029	CBRZ00343	1529	CBRZ41564
30	CBRA00250	530	CBRY01336	1030	CBRZ00344	1530	CBRZ41598
31	CBRA00266	531	CBRY01337	1031	CBRZ00373	1531	CBRZ41600
32	CBRA00268	532	CBRY01338	1032	CBRZ00374	1532	CBRZ41609
33	CBRA00271	533	CBRY01339	1033	CBRZ00375	1533	CBRZ41610
34	CBRA00272	534	CBRY01340	1034	CBRZ00376	1534	CBRZ41615
35	CBRA00273	535	CBRY01341	1035	CBRZ00377	1535	CBRZ41617



36	CBRA00274	536	CBRY01342	1036	CBRZ00378	1536	CBRZ41681
37	CBRA00275	537	CBRY01343	1037	CBRZ00380	1537	CBRZ41688
38	CBRA00276	538	CBRY01344	1038	CBRZ00381	1538	CBRZ41702
39	CBRA00305	539	CBRY01345	1039	CBRZ00382	1539	CBRZ41705
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42	CBRA00415	542	CBRY01348	1042	CBRZ00385	1542	CBRZ41709
43	CBRA00637	543	CBRY01349	1043	CBRZ00386	1543	CBRZ41710
44	CBRA00647	544	CBRY01350	1044	CBRZ00387	1544	CBRZ41715
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46	CBRA00655	546	CBRY01353	1046	CBRZ00389	1546	CBRZ41718
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60	CBRA00672	560	CBRY01393	1060	CBRZ00404	1560	CBRZ42335
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63	CBRA00689	563	CBRY01396	1063	CBRZ00407	1563	CBRZ42375
64	CBRA00772	564	CBRY01397	1064	CBRZ00408	1564	CBRZ42376
65	CBRA00773	565	CBRY01398	1065	CBRZ00435	1565	CBRZ42378
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73	CBRA00781	573	CBRY01498	1073	CBRZ00444	1573	CBRZ42419
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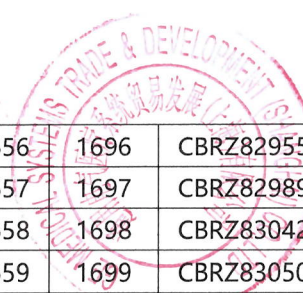


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81	CBRA00821	581	CBRY01548	1081	CBRZ00454	1581	CBRZ42598
82	CBRA00823	582	CBRY01549	1082	CBRZ00455	1582	CBRZ42599
83	CBRA00824	583	CBRY01555	1083	CBRZ00456	1583	CBRZ42601
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92	CBRA01182	592	CBRY01567	1092	CBRZ00465	1592	CBRZ42617
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94	CBRA01221	594	CBRY01570	1094	CBRZ00467	1594	CBRZ42619
95	CBRA01222	595	CBRY01571	1095	CBRZ00468	1595	CBRZ42620
96	CBRA01223	596	CBRY01572	1096	CBRZ00469	1596	CBRZ42623
97	CBRA01224	597	CBRY01573	1097	CBRZ00470	1597	CBRZ42624
98	CBRA01225	598	CBRY01574	1098	CBRZ00471	1598	CBRZ42625
99	CBRA01226	599	CBRY01575	1099	CBRZ00472	1599	CBRZ42629
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123	CBRA01386	623	CBRY01630	1123	CBRZ00496	1623	CBRZ81866
124	CBRA01387	624	CBRY01631	1124	CBRZ00497	1624	CBRZ81875
125	CBRA01388	625	CBRY01632	1125	CBRZ00498	1625	CBRZ81876
126	CBRA01389	626	CBRY01633	1126	CBRZ00499	1626	CBRZ81878
127	CBRA01390	627	CBRY01634	1127	CBRZ00500	1627	CBRZ81881
128	CBRA01391	628	CBRY01635	1128	CBRZ00501	1628	CBRZ81885
129	CBRA01392	629	CBRY01636	1129	CBRZ00502	1629	CBRZ81899
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142	CBRA01463	642	CBRY01691	1142	CBRZ00542	1642	CBRZ82110
143	CBRA01464	643	CBRY01692	1143	CBRZ00543	1643	CBRZ82113
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147	CBRA01468	647	CBRY01712	1147	CBRZ00602	1647	CBRZ82240
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154	CBRA01511	654	CBRY01969	1154	CBRZ00612	1654	CBRZ82405
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168	CBRA01525	668	CBRY02201	1168	CBRZ00626	1668	CBRZ82503
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173	CBRA01530	673	CBRY02222	1173	CBRZ00631	1673	CBRZ82519
174	CBRA01531	674	CBRY02223	1174	CBRZ00632	1674	CBRZ82523
175	CBRA01832	675	CBRY02224	1175	CBRZ00633	1675	CBRZ82560
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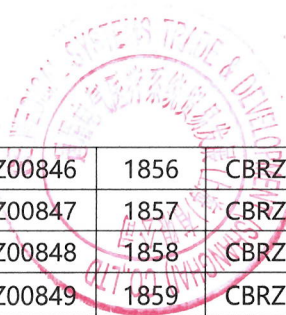
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411	CBRB00195	911	CBRY03458	1411	CBRZ00931		
412	CBRB00196	912	CBRY03459	1412	CBRZ00932		
413	CBRB00197	913	CBRY03460	1413	CBRZ00933		
414	CBRB00198	914	CBRY03461	1414	CBRZ00934		
415	CBRB02023	915	CBRY03466	1415	CBRZ00935		
416	CBRB02024	916	CBRY03475	1416	CBRZ00936		
417	CBRB02026	917	CBRY03514	1417	CBRZ00937		
418	CBRB02027	918	CBRY03520	1418	CBRZ00938		
419	CBRB02029	919	CBRY03521	1419	CBRZ00939		
420	CBRB02033	920	CBRY03522	1420	CBRZ00940		
421	CBRB02035	921	CBRY03523	1421	CBRZ00941		
422	CBRB02036	922	CBRY03524	1422	CBRZ00942		
423	CBRB02038	923	CBRY03525	1423	CBRZ00943		
424	CBRB02040	924	CBRY03526	1424	CBRZ00944		
425	CBRB02043	925	CBRY03527	1425	CBRZ00945		
426	CBRB02045	926	CBRY03529	1426	CBRZ00946		
427	CBRB02046	927	CBRY03530	1427	CBRZ00947		
428	CBRB02047	928	CBRY03531	1428	CBRZ00948		
429	CBRB02060	929	CBRY03532	1429	CBRZ00949		
430	CBRB02062	930	CBRY03533	1430	CBRZ00951		
431	CBRB02063	931	CBRY03534	1431	CBRZ00952		
432	CBRB02065	932	CBRY03539	1432	CBRZ00953		
433	CBRB02073	933	CBRY03540	1433	CBRZ00954		
434	CBRB02077	934	CBRY03541	1434	CBRZ00955		
435	CBRB02081	935	CBRY03542	1435	CBRZ00956		



436	CBRB02083	936	CBRY03770	1436	CBRZ07136
437	CBRB02128	937	CBRY03787	1437	CBRZ07140
438	CBRB02131	938	CBRZ00195	1438	CBRZ07141
439	CBRB02133	939	CBRZ00197	1439	CBRZ07142
440	CBRB02136	940	CBRZ00198	1440	CBRZ07143
441	CBRB02139	941	CBRZ00199	1441	CBRZ07144
442	CBRB02141	942	CBRZ00200	1442	CBRZ07145
443	CBRB02147	943	CBRZ00201	1443	CBRZ07146
444	CBRB02148	944	CBRZ00202	1444	CBRZ07147
445	CBRW01742	945	CBRZ00207	1445	CBRZ07148
446	CBRW02048	946	CBRZ00208	1446	CBRZ07149
447	CBRW02049	947	CBRZ00209	1447	CBRZ07150
448	CBRW02055	948	CBRZ00210	1448	CBRZ07152
449	CBRW02056	949	CBRZ00211	1449	CBRZ07154
450	CBRW02070	950	CBRZ00212	1450	CBRZ07155
451	CBRX00104	951	CBRZ00213	1451	CBRZ07202
452	CBRX01603	952	CBRZ00214	1452	CBRZ07207
453	CBRX03074	953	CBRZ00215	1453	CBRZ07564
454	CBRX03075	954	CBRZ00216	1454	CBRZ07604
455	CBRX03830	955	CBRZ00217	1455	CBRZ07631
456	CBRY00151	956	CBRZ00218	1456	CBRZ07633
457	CBRY00152	957	CBRZ00219	1457	CBRZ07635
458	CBRY00153	958	CBRZ00220	1458	CBRZ07645
459	CBRY00154	959	CBRZ00223	1459	CBRZ07646
460	CBRY00155	960	CBRZ00224	1460	CBRZ07647
461	CBRY00630	961	CBRZ00225	1461	CBRZ07648
462	CBRY00662	962	CBRZ00226	1462	CBRZ07649
463	CBRY00674	963	CBRZ00239	1463	CBRZ07650
464	CBRY00693	964	CBRZ00240	1464	CBRZ07659
465	CBRY00709	965	CBRZ00241	1465	CBRZ07661
466	CBRY00711	966	CBRZ00242	1466	CBRZ07662
467	CBRY00717	967	CBRZ00244	1467	CBRZ07670
468	CBRY00718	968	CBRZ00247	1468	CBRZ07671
469	CBRY00720	969	CBRZ00248	1469	CBRZ07672
470	CBRY00724	970	CBRZ00249	1470	CBRZ07673
471	CBRY00726	971	CBRZ00251	1471	CBRZ07676
472	CBRY00734	972	CBRZ00252	1472	CBRZ07679
473	CBRY00735	973	CBRZ00254	1473	CBRZ07683
474	CBRY00737	974	CBRZ00256	1474	CBRZ07684
475	CBRY00738	975	CBRZ00257	1475	CBRZ40003



476	CBRY00739	976	CBRZ00259	1476	CBRZ40005
477	CBRY00740	977	CBRZ00261	1477	CBRZ40007
478	CBRY00742	978	CBRZ00262	1478	CBRZ40008
479	CBRY00938	979	CBRZ00264	1479	CBRZ40009
480	CBRY00940	980	CBRZ00267	1480	CBRZ40937
481	CBRY00952	981	CBRZ00269	1481	CBRZ40938
482	CBRY00954	982	CBRZ00272	1482	CBRZ40939
483	CBRY00970	983	CBRZ00273	1483	CBRZ40954
484	CBRY00972	984	CBRZ00274	1484	CBRZ40958
485	CBRY00979	985	CBRZ00275	1485	CBRZ40959
486	CBRY00982	986	CBRZ00276	1486	CBRZ40960
487	CBRY00984	987	CBRZ00277	1487	CBRZ40961
488	CBRY00985	988	CBRZ00281	1488	CBRZ41183
489	CBRY01000	989	CBRZ00284	1489	CBRZ41279
490	CBRY01001	990	CBRZ00291	1490	CBRZ41294
491	CBRY01006	991	CBRZ00292	1491	CBRZ41333
492	CBRY01159	992	CBRZ00293	1492	CBRZ41360
493	CBRY01213	993	CBRZ00294	1493	CBRZ41362
494	CBRY01235	994	CBRZ00295	1494	CBRZ41363
495	CBRY01240	995	CBRZ00298	1495	CBRZ41364
496	CBRY01242	996	CBRZ00299	1496	CBRZ41366
497	CBRY01243	997	CBRZ00302	1497	CBRZ41367
498	CBRY01246	998	CBRZ00303	1498	CBRZ41368
499	CBRY01251	999	CBRZ00305	1499	CBRZ41369
500	CBRY01266	1000	CBRZ00306	1500	CBRZ41370