



YCV-QR-025a2 Medical Device Recall Reporting Form 医疗器械召回事件报告表 v1

医疗器械召回事件报告表

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	医用磁共振成像系统	注册证或备案凭证编码	国食药监械(进)字2013第3284026号; 国食药监械(进)字2012第3281132号.
生产企业名称	Philips Medical Systems Nederland B.V.		
代理人名称	飞利浦(中国)投资有限公司		
召回单位负责人和联系方式, 经办人和联系方式	后文琳 021-24128512 闫轲 021-24223802		
产品的适用范围	供临床MRI诊断。		
涉及地区和国家	全球	召回级别	一级召回
涉及产品生产(或进口中国)批次、数量	129台	涉及产品型号、规格	Achieva 1.5T; Achieva 3.0T.
识别信息(如批号)	请见附页	涉及产品在中国的销售数量	129台
召回原因简述	飞利浦发现 SENSE XL 躯干线圈(1.5T 和 3.0T)可能会在扫描过程中局部发热, 从而对患者造成潜在伤害。 (召回文件内部编号: Recall-2024-13)		
纠正行动简述(包括召回要求和处理方式等)	飞利浦将向受影响客户发放主动召回通知信函, 主动告知客户可以根据使用说明书(IFU)继续使用受影响的线圈。 1. 避免一级运行模式/高 SAR 扫描; 2. 使用随线圈提供的专用衬垫和床垫; 3. 避免线圈靠近孔, 确保线圈的上片与孔的距离大于2英寸(5cm)。 4. 单个患者的检查时间(不包括摆位时间)不超过45分钟。 飞利浦将在2024年底向受影响客户提供解决该问题计划的最新进展。		

报告单位: (盖章)

负责人: (签字)

报告人: (签字) 闫轲

报告日期: 2024年6月17日



后文琳



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129 台受影响系统的序列号:

系统型号	系统序列号	线圈型号	线圈序列号
Achieva 3.0T	38279	SENSE XL TORSO COIL 3.0T	446
Achieva 3.0T	38347	SENSE XL TORSO COIL 3.0T	560
Achieva 3.0T	38314	SENSE XL TORSO COIL 3.0T	521
Achieva 1.5T	33259	SENSE XL TORSO COIL 1.5T	988
Achieva 1.5T	33131	SENSE XL TORSO COIL 1.5T	1035
Achieva 3.0T	38252	SENSE XL TORSO COIL 3.0T	497
Achieva 3.0T	34247	SENSE XL TORSO COIL 3.0T	353
Achieva 1.5T	33365	SENSE XL TORSO COIL 1.5T	1055
Achieva 3.0T	38312	SENSE XL TORSO COIL 3.0T	515
Achieva 3.0T	38190	SENSE XL TORSO COIL 3.0T	386
Achieva 3.0T	38216	SENSE XL TORSO COIL 3.0T	369
Achieva 3.0T	38158	SENSE XL TORSO COIL 3.0T	253
Achieva 1.5T	32601	SENSE XL TORSO COIL 1.5T	411
Achieva 1.5T	33265	SENSE XL TORSO COIL 1.5T	968
Achieva 3.0T	34299	SENSE XL TORSO COIL 3.0T	571
Achieva 1.5T	8195	SENSE XL TORSO COIL 1.5T	586
Achieva 1.5T	33141	SENSE XL TORSO COIL 1.5T	885
Achieva 3.0T	38215	SENSE XL TORSO COIL 3.0T	503
Achieva 3.0T	38248	SENSE XL TORSO COIL 3.0T	389
Achieva 3.0T	38227	SENSE XL TORSO COIL 3.0T	360
Achieva 1.5T	33413	SENSE XL TORSO COIL 1.5T	1051
Achieva 3.0T	34272	SENSE XL TORSO COIL 3.0T	348
Achieva 1.5T	32788	SENSE XL TORSO COIL 1.5T	562
Achieva 3.0T	38267	SENSE XL TORSO COIL 3.0T	448
Achieva 3.0T	38284	SENSE XL TORSO COIL 3.0T	490
Achieva 1.5T	33531	SENSE XL TORSO COIL 1.5T	1113
Achieva 3.0T	34297	SENSE XL TORSO COIL 3.0T	556
Achieva 1.5T	33047	SENSE XL TORSO COIL 1.5T	773
Achieva 1.5T	33492	SENSE XL TORSO COIL 1.5T	1091
Achieva 3.0T	38338	SENSE XL TORSO COIL 3.0T	554
Achieva 3.0T	34234	SENSE XL TORSO COIL 3.0T	359
Achieva 3.0T	38350	SENSE XL TORSO COIL 3.0T	589
Achieva 3.0T	38349	SENSE XL TORSO COIL 3.0T	580
Achieva 3.0T	38330	SENSE XL TORSO COIL 3.0T	614
Achieva 1.5T	32789	SENSE XL TORSO COIL 1.5T	572
Achieva 1.5T	33741	SENSE XL TORSO COIL 1.5T	1238
Achieva 3.0T	38258	SENSE XL TORSO COIL 3.0T	403
Achieva 1.5T	33682	SENSE XL TORSO COIL 1.5T	1232
Achieva 3.0T	38307	SENSE XL TORSO COIL 3.0T	507
Achieva 3.0T	38124	SENSE XL TORSO COIL 3.0T	226





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Achieva 1.5T	33517	SENSE XL TORSO COIL 1.5T	1094
Achieva 3.0T	38282	SENSE XL TORSO COIL 3.0T	452
Achieva 1.5T	32290	SENSE XL TORSO COIL 1.5T	180
Achieva 1.5T	852	SENSE XL TORSO COIL 1.5T	1235
Achieva 1.5T	33161	SENSE XL TORSO COIL 1.5T	906
Achieva 3.0T	38361	SENSE XL TORSO COIL 3.0T	586
Achieva 1.5T	32991	SENSE XL TORSO COIL 1.5T	791
Achieva 3.0T	38298	SENSE XL TORSO COIL 3.0T	480
Achieva 1.5T	743	SENSE XL TORSO COIL 1.5T	244
Achieva 1.5T	297	SENSE XL TORSO COIL 1.5T	302
Achieva 1.5T	3099	SENSE XL TORSO COIL 1.5T	840
Achieva 1.5T	616	SENSE XL TORSO COIL 1.5T	982
Achieva 1.5T	248	SENSE XL TORSO COIL 1.5T	1207
Achieva 1.5T	845	SENSE XL TORSO COIL 1.5T	1229
Achieva 3.0T	678	SENSE XL TORSO COIL 3.0T	494
Achieva 3.0T	34312	SENSE XL TORSO COIL 3.0T	613
Achieva 1.5T	33422	SENSE XL TORSO COIL 1.5T	1074
Achieva 3.0T	38293	SENSE XL TORSO COIL 3.0T	482
Achieva 1.5T	33648	SENSE XL TORSO COIL 1.5T	1182
Achieva 3.0T	38358	SENSE XL TORSO COIL 3.0T	590
Achieva 3.0T	38210	SENSE XL TORSO COIL 3.0T	350
Achieva 1.5T	33645	SENSE XL TORSO COIL 1.5T	1184
Achieva 1.5T	33501	SENSE XL TORSO COIL 1.5T	1103
Achieva 1.5T	33689	SENSE XL TORSO COIL 1.5T	1202
Achieva 1.5T	32921	SENSE XL TORSO COIL 1.5T	674
Achieva 1.5T	33260	SENSE XL TORSO COIL 1.5T	960
Achieva 3.0T	38255	SENSE XL TORSO COIL 3.0T	465
Achieva 1.5T	32835	SENSE XL TORSO COIL 1.5T	606
Achieva 1.5T	33360	SENSE XL TORSO COIL 1.5T	1018
Achieva 3.0T	38287	SENSE XL TORSO COIL 3.0T	487
Achieva 1.5T	33112	SENSE XL TORSO COIL 1.5T	858
Achieva 3.0T	38249	SENSE XL TORSO COIL 3.0T	365
Achieva 3.0T	34260	SENSE XL TORSO COIL 3.0T	297
Achieva 1.5T	33322	SENSE XL TORSO COIL 1.5T	989
Achieva 1.5T	33637	SENSE XL TORSO COIL 1.5T	1259
Achieva 3.0T	38329	SENSE XL TORSO COIL 3.0T	549
Achieva 1.5T	33188	SENSE XL TORSO COIL 1.5T	878
Achieva 1.5T	33797	SENSE XL TORSO COIL 1.5T	1295
Achieva 1.5T	10016	SENSE XL TORSO COIL 1.5T	1080
Achieva 3.0T	34235	SENSE XL TORSO COIL 3.0T	196
Achieva 1.5T	33524	SENSE XL TORSO COIL 1.5T	1104
Achieva 3.0T	38318	SENSE XL TORSO COIL 3.0T	551
Achieva 1.5T	32628	SENSE XL TORSO COIL 1.5T	428





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Achieva 1.5T	33416	SENSE XL TORSO COIL 1.5T	1148
Achieva 3.0T	38257	SENSE XL TORSO COIL 3.0T	411
Achieva 1.5T	690	SENSE XL TORSO COIL 1.5T	140
Achieva 1.5T	2401	SENSE XL TORSO COIL 1.5T	375
Achieva 1.5T	2576	SENSE XL TORSO COIL 1.5T	460
Achieva 1.5T	185	SENSE XL TORSO COIL 1.5T	597
Achieva 1.5T	872	SENSE XL TORSO COIL 1.5T	1302
Achieva 1.5T	1302	SENSE XL TORSO COIL 1.5T	1303
Achieva 3.0T	125	SENSE XL TORSO COIL 3.0T	366
Achieva 3.0T	127	SENSE XL TORSO COIL 3.0T	382
Achieva 3.0T	38303	SENSE XL TORSO COIL 3.0T	499
Achieva 3.0T	38181	SENSE XL TORSO COIL 3.0T	320
Achieva 1.5T	33507	SENSE XL TORSO COIL 1.5T	1196
Achieva 3.0T	38327	SENSE XL TORSO COIL 3.0T	545
Achieva 1.5T	33455	SENSE XL TORSO COIL 1.5T	1064
Achieva 1.5T	33192	SENSE XL TORSO COIL 1.5T	894
Achieva 3.0T	38343	SENSE XL TORSO COIL 3.0T	566
Achieva 3.0T	34288	SENSE XL TORSO COIL 3.0T	495
Achieva 1.5T	33166	SENSE XL TORSO COIL 1.5T	916
Achieva 3.0T	34298	SENSE XL TORSO COIL 3.0T	552
Achieva 1.5T	33552	SENSE XL TORSO COIL 1.5T	1114
Achieva 3.0T	38245	SENSE XL TORSO COIL 3.0T	387
Achieva 1.5T	33256	SENSE XL TORSO COIL 1.5T	964
Achieva 3.0T	38238	SENSE XL TORSO COIL 3.0T	364
Achieva 1.5T	33329	SENSE XL TORSO COIL 1.5T	1028
Achieva 1.5T	33058	SENSE XL TORSO COIL 1.5T	998
Achieva 1.5T	33661	SENSE XL TORSO COIL 1.5T	1211
Achieva 1.5T	32930	SENSE XL TORSO COIL 1.5T	781
Achieva 3.0T	38372	SENSE XL TORSO COIL 3.0T	607
Achieva 1.5T	33163	SENSE XL TORSO COIL 1.5T	889
Achieva 1.5T	33170	SENSE XL TORSO COIL 1.5T	910
Achieva 1.5T	33687	SENSE XL TORSO COIL 1.5T	1209
Achieva 1.5T	33127	SENSE XL TORSO COIL 1.5T	852
Achieva 1.5T	33591	SENSE XL TORSO COIL 1.5T	1230
Achieva 1.5T	33554	SENSE XL TORSO COIL 1.5T	1118
Achieva 3.0T	34287	SENSE XL TORSO COIL 3.0T	450
Achieva 1.5T	33171	SENSE XL TORSO COIL 1.5T	926
Achieva 1.5T	33376	SENSE XL TORSO COIL 1.5T	1069
Achieva 1.5T	33086	SENSE XL TORSO COIL 1.5T	872
Achieva 1.5T	33534	SENSE XL TORSO COIL 1.5T	1100
Achieva 1.5T	33736	SENSE XL TORSO COIL 1.5T	1233
Achieva 1.5T	33731	SENSE XL TORSO COIL 1.5T	1240
Achieva 1.5T	33705	SENSE XL TORSO COIL 1.5T	1251

12/1/2011



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Achieva 1.5T	32705	SENSE XL TORSO COIL 1.5T	522
Achieva 1.5T	22311	SENSE XL TORSO COIL 1.5T	137
Achieva 1.5T	859	SENSE XL TORSO COIL 1.5T	1252

