

医疗器械召回事件报告表

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	呼吸机	注册证或备案凭证编码	国食药监械(进)字 2012第 3541252 号(更) 国械注进 20163542118
生产企业名称	Newport Medical Instruments, Inc.		
代理人名称	柯惠医疗器材国际贸易(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: 胡萍 021-20325859 经办人: 王迅飞 021-20325375		
产品的适用范围	适用于 5 公斤以上婴儿及儿童和成人。		
涉及地区和国家	美国、中国、日本等国家和地区	召回级别	1 级
涉及产品生产(或进口中国)批次、数量	见附页 1、190	涉及产品型号、规格	见附页 1
识别信息(如批号)	见附页 1	涉及产品在中国的销售数量	190
召回原因简述	柯惠全球对客户投诉调查时发现, 特定序列号的 HT70 呼吸机的电路板组件上的两个独立的电容器在故障情况下, 可能导致两种不同的结果: 一是呼吸机在使用过程中被关闭, 需使用其他通气方式; 二是警报被关闭且未能在关闭期间有效发出警报。目前尚未发生同一电路板上两个电容器同时故障的情况, 也不预期会发生, 因为导致每种结果的原因是独立且不重叠的。截至目前, 柯惠中国尚未收到由于该问题而导致患者伤害的投诉和不良事件。		
纠正行动简述(包括召回要求和处理方式等)	柯惠中国将采取下述纠正措施: 1. 柯惠中国将向所有受影响客户发送医疗器械主动召回通知函, 阐明此次召回的背景和要求, 并返回已签字确认函; 2. 要求客户立即停止经营和对使用中的产品转换为其他可替代通气方式后, 将受影响产品退回至我司仓库, 根据最终处置决定退回原厂或进行销毁。		

报告单位: 柯惠医疗器材国际贸易(上海)有限公司
报告人: 王迅飞

负责人: 胡萍
报告日期: 2025 年 06 月 17 日



附页 1 受影响呼吸机

产品型号	GTIN 识别码	序列号				
HT70M-CN-NA	10884521542044	N11HT700411320	N17HT700217730	N17HT700517788	N17HT700617843	N17HT701118049
		N11HT700511412	N17HT700217731	N17HT700517793	N17HT700617844	N17HT701118050
		N15HT700617417	N17HT700217732	N17HT700517798	N17HT700617845	N17HT701118051
		N15HT700617418	N17HT700217734	N17HT700517799	N17HT700617846	N17HT701118052
		N15HT700617419	N17HT700217735	N17HT700517801	N17HT700617847	N17HT701118053
		N15HT700917518	N17HT700217736	N17HT700617805	N17HT700617848	N17HT701118054
		N15HT700917520	N17HT700517754	N17HT700617806	N17HT700617849	N17HT701118055
		N15HT700917521	N17HT700517755	N17HT700617809	N17HT700617850	N17HT701118056
		N17HT700117684	N17HT700517756	N17HT700617810	N17HT700617851	N17HT701218057
		N17HT700117687	N17HT700517757	N17HT700617812	N17HT700617852	N17HT701218058
		N17HT700117688	N17HT700517758	N17HT700617813	N17HT700617853	N17HT701218059
		N17HT700117689	N17HT700517759	N17HT700617814	N17HT700717870	N17HT701218060
		N17HT700117690	N17HT700517760	N17HT700617816	N17HT700717875	N17HT701218061
		N17HT700117691	N17HT700517761	N17HT700617817	N17HT700717876	N17HT701218062
		N17HT700117693	N17HT700517762	N17HT700617818	N17HT700817941	N17HT701218063
		N17HT700117694	N17HT700517763	N17HT700617819	N17HT700817960	N17HT701218064
		N17HT700117697	N17HT700517765	N17HT700617820	N17HT701118024	N17HT701218065
		N17HT700117698	N17HT700517766	N17HT700617821	N17HT701118025	N17HT701218066
		N17HT700117701	N17HT700517767	N17HT700617822	N17HT701118026	N17HT701218067
		N17HT700117702	N17HT700517768	N17HT700617823	N17HT701118027	N17HT701218068
		N17HT700117703	N17HT700517769	N17HT700617824	N17HT701118028	N17HT701218070
		N17HT700117704	N17HT700517770	N17HT700617825	N17HT701118030	N17HT701218071
		N17HT700117705	N17HT700517771	N17HT700617826	N17HT701118031	N17HT701218072
		N17HT700117706	N17HT700517772	N17HT700617827	N17HT701118033	N17HT701218073
		N17HT700117707	N17HT700517773	N17HT700617828	N17HT701118034	N17HT701218074
		N17HT700117708	N17HT700517774	N17HT700617829	N17HT701118035	N17HT701218075
		N17HT700117713	N17HT700517775	N17HT700617830	N17HT701118036	N17HT701218076
		N17HT700117715	N17HT700517776	N17HT700617831	N17HT701118037	N18HT700318079
		N17HT700117716	N17HT700517777	N17HT700617832	N17HT701118038	N18HT700318086
		N17HT700117719	N17HT700517778	N17HT700617833	N17HT701118039	N18HT700318087
		N17HT700117720	N17HT700517779	N17HT700617834	N17HT701118040	N18HT700318090
		N17HT700117721	N17HT700517780	N17HT700617835	N17HT701118041	N18HT700318091
		N17HT700117722	N17HT700517781	N17HT700617836	N17HT701118042	N18HT700318095
		N17HT700217724	N17HT700517782	N17HT700617837	N17HT701118043	N18HT700318096
		N17HT700217725	N17HT700517783	N17HT700617838	N17HT701118044	N18HT700318101
		N17HT700217726	N17HT700517784	N17HT700617839	N17HT701118045	N18HT700318104
		N17HT700217727	N17HT700517785	N17HT700617840	N17HT701118046	N18HT700318106
		N17HT700217728	N17HT700517786	N17HT700617841	N17HT701118047	
		N17HT700217729	N17HT700517787	N17HT700617842	N17HT701118048	

HT70M- WW-NA	10884521542143	HT72160001	N11HT700411331	N15HT700517371	N15HT700716258	N15HT700817469
		HT72160002	N11HT700411341	N15HT700517410	N15HT700716259	N15HT700817472
		HT72160004	N11HT700411363	N15HT700517411	N15HT700716260	N15HT700817473
		HT72160005	N11HT700411365	N15HT700616204	N15HT700716263	N15HT700817474
		HT72160007	N11HT700511543	N15HT700616206	N15HT700716264	N15HT700817476
		HT72160011	N11HT700511548	N15HT700616207	N15HT700716267	N15HT700817477
		HT72160012	N11HT700611663	N15HT700616208	N15HT700717427	N15HT700817478
		HT72160017	N11HT700811830	N15HT700616210	N15HT700717428	N15HT700817479
		HT72160020	N11HT700811836	N15HT700616211	N15HT700717429	N15HT700817480
		HT72160023	N11HT700811867	N15HT700616212	N15HT700717430	N15HT700817481
		HT72160025	N11HT700910512	N15HT700616213	N15HT700717431	N15HT700817482
		N10HT700510066	N11HT700911939	N15HT700616214	N15HT700717435	N15HT700817483
		N10HT700710165	N11HT700911952	N15HT700616217	N15HT700717436	N15HT700817484
		N10HT700810184	N11HT701112548	N15HT700616219	N15HT700817441	N15HT700817485
		N11HT700111140	N12HT700112820	N15HT700616220	N15HT700817445	N15HT700817486
		N11HT700311180	N12HT700214024	N15HT700616222	N15HT700817446	N15HT700917502
		N11HT700311181	N12HT700412951	N15HT700716255	N15HT700817447	N15HT700917503
		N11HT700411323	N13HT700214668	N15HT700716256	N15HT700817468	N15HT700917508
		N15HT700917509	N15HT701117593			

