Class 2 Device Recall LIFEPAK CR Plus and/or LIFEPAK EXPRESS

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Class 2 Device Recall LIFEPAK CR Plus and/or LIFEPAK EXPRESS

See Related Information[22]

Recall Date	June 29, 2016
Recall Status[1]	Open
Recall Number	Z-2100-2016
Recall Event ID	74198[23]
510(K)Number	K033275[24]
Product Classification	Automated external defibrillators (non-wearable)[25] - **Product Code** MKJ[26]
Product	LIFEPAK CR Plus and/or LIFEPAK EXPRESS are Automatic External Defibrillator (s) and are non-wearable. LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are intended for use on patients in cardiac arrest.
Code Information	44036090, 44036091, 44036092, 44036094, 44036096, 44036123, 44036128, 44036132, 44036141, 44036144, 44036145, 44036148, 44036149, 44036150, 44036151, 44036152, 44036153, 44036154, 44036156, 44036157, 44036158, 44036159, 44065452, 44065616, and 44065619. ********Serial numbers of devices distributed OUTSIDE the US ********** 42900556, 42900677, 42900681, 42900682, 42900683, 42900684, 42900685, 42900686, 42900688, 42900690, 42900691, 42900692, 42900694, 42900695, 42900696, 42900699, 42900700, 42900702, 42900703, 42900705, 42900706, 42900708, 42900709, 42900710, 42900711, 42900712, 42900713, 42900714, 42900716, 42900717, 42900719, 42900720, 42900721, 42900722, 42900726, 42900727, 42900730, 42900731, 42900732, 42900733, 42900735, 42900736, 42900738, 42900739, 42900740, 42900741, 42900745, 42900747, 42900748, 42900749, 42900751, 42900753, 42900754, 42900758, 42900759, 42900761, 42900762, 42900764, 42900766, 42900775, 42900776, 42900777, 42900782, 42900784, 42900787, 42900788, 42900789, 42900797, 42900799, 42900802, 42900803, 42900804, 42900807, 42900808, 42900810, 42900811, 42900813, 42900828, 42900829, 42900830, 42900838, 42900839, 42900847, 42900848, 42900849, 42900850, 42900852, 42900853, 42900854, 42900855, 42900857, 42900858, 42900859, 42900860, 42900861, 42900862, 42900863, 42900864, 42900867, 42900869, 42900910, 42900911, 42900912, 42900913, 42900929, 42900932, 42900933, 42900934, 42900978, 42900979, 42900980, 42900981, 42900991, 42900994, 42900995, 42900996, 42900998, 42900999, 42901000, 42901001, 42901004, 42901005, 42901006, 42901010, 42901011, 42901012, 42901013, 42901046, 42901047, 42901048, 42901049, 42901050, 42901051, 42901052, 42901053, 42901062, 42901063, 42901064, 42901065, 42901067, 42901068, 42901069, 42901070, 42901071, 42901072, 42901073, 42901074, 42901075, 42901076, 42901078, 42901079, 42901080, 42901081, 42901083, 42901084, 42901085, 42901086, 42901087, 42901088, 42901089, 42901090, 42901091, 42901092, 42901093, 42901094, 42901095, 42901096, 42901097, 42901098, 42901099, 42901100, 42901101, 42901102, 42901103, 42901104, 42901105, 42901106, 42901110, 42901112, 42901113, 42901115, 42901116, 42901120, 42901121, 42901122, 42901123, 42901124, 42901125, 42901129, 42901131, 42901132, 42901134, 42901137, 42901141, 42901142, 42901145, 42901147, 42901148, 42901151, 42901152,

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Recalling Firm/ Manufacturer	Physio-Control, Inc. 11811 Willows Rd NE Redmond WA 98052-2003
For Additional Information Contact	800-442-1142
Manufacturer Reason for Recall	LIFEPAK CR Plus Automated External Defibrillators (AED) or LIFEPAK EXPRESS AED may fail to initiate voice prompts when the ON/OFF button is pressed and the lid is opened due to an internal component (reed switch) that can intermittently become fixed in the closed position. A defibrillator in this condition will fail to deliver a shock, with the potential result that therapy is not delivered and a patient is not resuscitated.
FDA Determined Cause [2]	Component change control
Action	The firm, Physio Control, sent an "URGENT MEDICAL DEVICE CORRECTION-ACTION REQUIRED"- LifePak CR Plus AE and LifePak Express AED letter and the Confirmation sheet, dated May 2016, to US customers on 5/25/16. Physio will notify international consignees during the week of 6/13/16. The letter described the product, problem and the actions to be taken. The customers were instructed to-URGENTLY bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your Automated External Defibrillators (AEDs); follow the instructions on the Confirmation Sheet that outline specific actions to take for the serial numbers listed, and if you have a routine check process, please continue this process. If you have not established a routine check process, please refer to section 5 of the Operating Instructions for recommended actions. In addition, customers should follow the instructions on the Confirmation Sheet and submit this form to Physio by: -Fax to: 1-866-448-9567 -Email to: rsrecall@physio-control.com -Mail to: Physio-Control, Inc. P.O. Box 970006, Dept. 15N Redmond, WA, 98073-9706 Physio-Control will contact customers with LIFEPAK CR Plus and LIFEPAK EXPRESS AEDs that contain the affected reed switch assembly. A device correction including provision of loaner devices and replacement of the reed switch component will be arranged for all affected devices. Customers who have any questions regarding this notification, please call Physio-Control at 1-800-442-1142, 6:00 a.m. to 4:00 p.m. (Pacific), Monday Friday.
Quantity in Commerce	25178 units (10,418 in US and 14,760 outside US)
Distribution	Worldwide Distribution-US (nationwide) including Guam and Puerto Rico and countries of: Argentina, Austria, Australia, Bahamas, Bangladesh, Belgium, Brazil, Brunei Darussalami, Canada, Chile, China, Croatia, Cyprus. Czech Republic, Denmark, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Kazakhstan, Kenya, Lithuania, Luxembourg, Malta, Mexico, Netherlands, Norway, Philippines, Poland, Portugal, Qatar, Russian Federation, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan (Province of China), Turkey, United Arab Emirates, United Kingdom, New Caledonia, and New Zealand,.
Total Product Life Cycle	TPLC Device Report[27]