Class 1 Device Recall Hudson RCI Neonate Manual Resuscitator

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Class 1 Recall
Hudson RCI Neonate Manual Resuscitator

Date Posted	June 24, 2015
Recall Status[1]	Open
Recall Number	Z-1809-2015
Recall Event ID	71254[24]
Premarket Notification 510(K) Number	K964719[25]
Product Classification	Ventilator, Emergency, Manual (Resuscitator)[26] - **Product Code** BTM[27]
Product	Lifesaver Single Patient Use Manual Resuscitator Product Usage: The Hudson RCI Lifesaver Single Patient Use manual resuscitator with pressure monitoring port is a disposable medical device intended for use on patients requiring temporary augmentation of ventilation with or without supplemental oxygen delivery during episodes of acute ventilatory failure or insufficiency.
Code Information	Product Code 5361 - 6 Digit Lot No. 140514 - 4 Digit Lot No. 1420; 6 Digit Lot No. 140616 4 Digit Lot No. 1425, 6 Digit Lot No. 140617 4 Digit Lot No. 1425; 6 Digit Lot No. 140621 4 Digit Lot No. 1425; 6 Digit Lot No. 140806 4 Digit Lot No. 1432; 6 Digit Lot No. 141103 4 Digit Lot No. 1445; 6 Digit Lot 141117 - No. 4 Digit Lot No. 1447; 6 Digit Lot No. 141201- 4 Digit Lot No. 1449; 6 Digit Lot No. 141224 - 4 Digit Lot No. 1452; 6 Digit Lot No. 141227 - 4 Digit Lot No. 1452; 6 Digit Lot No. 150112 - 4 Digit Lot No. 1503; Product Code 5362 - 6 Digit Lot No. 140504 - 4 Digit Lot No. 1419; 6 Digit Lot No. 140515 - 4 Digit Lot No. 1420; 6 Digit Lot No. 140517 - 4 Digit Lot No. 1420; 6 Digit Lot No. 140617 - 4 Digit Lot No. 1425; 6 Digit Lot No. 140621 - 4 Digit Lot 1425; No. 6 Digit Lot No. 140812 - 4 Digit Lot No. 1433; 6 Digit Lot No. 140819 - 4 Digit Lot No. 1434; 6 Digit Lot No. 140823 - 4 Digit Lot No. 1434; 6 Digit Lot No. 140929 - 4 Digit Lot No. 1440; 6 Digit Lot No. 141110 - 4 Digit Lot No. 1446; 6 Digit Lot No. 141115 - 4 Digit Lot No. 1446; 6 Digit Lot No. 141201 - 4 Digit Lot No. 1449; 6 Digit Lot No. 141214 - 4 Digit Lot No.1451; 6 Digit Lot No. 150112 4 Digit Lot No. 1503; Product Code 5364 6 Digit Lot No. 140507 - 4 Digit Lot No. 1419; 6 Digit Lot No. 140508 4 Digit Lot No. 1419; 6 Digit Lot No. 140514 - 4 Digit Lot No. 1420; 6 Digit Lot No. 140608 - 4 Digit Lot No. 1424; 6 Digit Lot No. 140614 - 4 Digit Lot No. 1424; 6 Digit Lot No. 140623 - 4 Digit Lot No. 1426; 6 Digit Lot No. 14628 - 4 Digit Lot 1426 - No. 6 Digit Lot No. 140714 - 4 Digit Lot No. 1429; 6 Digit Lot No. 140719 - 4 Digit Lot No. 1429; 6 Digit Lot No. 14806 - 4 Digit Lot No. 1432; 6 Digit Lot No. 140809 4 Digit Lot No. 1432; Product Code 5466 6 Digit Lot No. 140520 - 4 Digit Lot No. 1421; 6 Digit Lot No. 140923 - 4 Digit Lot No. 1439; 6 Digit Lot No. 140924 - 4 Digit Lot No. 1439; Product Code 45362 - 6 Digit Lot No. 140317 - 4 Digit Lot No. 1412; 6 Digit Lot No. 140630 - 4 Digit Lot No. 1427; 6 Digit Lot No. 141013 - 4 Digit Lot No. 1442.
Recalling Firm/ Manufacturer	Teleflex Medical 2917 Weck Dr Research Triangle Park, North Carolina 27709-0186
For Additional Information Contact	Jennifer E. Suh 610-378-0131
Manufacturer Reason for Recall	The intake port may be blocked which can cause the bag to fail to fill.
FDA Determined	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE):

Cause [2]	Nonconforming Material/Component
Action	Teleflex Medical sent an Urgent Medical Device Recall Notification letter dated May 14, 2015, to all consignees asking them to immediately discontinue distribution and quarantine the recalled product. The letter also requested a sub-recall of the product. The recall letter also included a response form which is to be returned to Teleflex by emailing it to recall@teleflex.com or fax it to 1-855-419-8507, Attn: Customer Service. Customers with questions were instructed to contact their local sales representative or Customer Service at 1-866-246-6990. For questions regarding this recall call 610-378-0131.
Quantity in Commerce	9,333 units
Distribution	Worldwide Distribution - US Nationwide in the states of AL, AK, AZ, AR, CA, CO, CT, FL, GA, IL, IA, KS, LA, MA, MI, MN, MS, MO, NE, NH, NY, NC, OH, OK, PA, RI, SD, TN, TX, VA, WA, including Puerto Rico and the countries of Australia, Bahamas, Canada, Guatemala, and Mexico.
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = BTM and Original Applicant = HUDSON RESPIRATORY CARE, INC.[30]

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