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**Class 2 Device Recall CareFusion**



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**Class 2 Recall  
CareFusion**



**Date Posted** September 23, 2014

**Recall Status<sup>1</sup>** Open

**Recall Number** Z-2689-2014

**Recall Event ID** 68955<sup>23</sup>

**Premarket Notification 510(K) Number** K915226<sup>24</sup>

**Product Classification** Heater, Breathing System W/Wo Controller (Not Humidifier Or Nebulizer)<sup>25</sup> - **Product Code BZE**<sup>26</sup>

**Product** CareFusion AirLife Heated Infant Breathing Circuit Product Usage: Respiratory breathing circuits are used with a ventilator when mechanical ventilation is administered to a patient.

**Code Information** All lots of the following products: 1) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 10127-4H1 ; 2) CIRCUIT RESP INFANT 4FT 30/CS , Product Code 10331N-4S2 ; 3) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 10351-4H2 ; 4) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 10387-4S2 ; 5) CIRCUIT RESP INFANT PV HTD 5FT 30/CS , Product Code 10392-503 ; 6) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 10485-4H2 ; 7) CIRCUIT INFANT INSP LINE HTD 8FT 30/CS , Product Code 10520-504 ; 8) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 10555-4S2 ; 9) CIRCUIT INFANT INSP LINE HTD 5FT 30/CS , Product Code 10680-504 ; 10) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 10706-4S2 ; 11) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 10790-4S2 ; 12) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 10814-4S2 ; 13) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 10849-4S2 ; 14) CIRCUIT RESP INFANT 3FT HTD 30/CS , Product Code 10865-4H2 ; 15) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 10868-4S2 ; 16) CIRCUIT RESP DISP INF HTD 30/CS , Product Code 1175-4H2 ; 17) CIRCUIT RESP INFANT DUAL DISP 30/CS , Product Code 1208-4H1 ; 18) CIRCUIT RESP INFANT DISP 30/CS , Product Code 1553-4H1 ; 19) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 1815-409 ; 20) CIRCUIT RESP INFANT 3FT HTD HI FI 30/CS , Product Code 1998-4H1 ; 21) INFANT RESP CIRC HTD 4 FT. , Product Code 2119-4S2G ; 22) INFANT RESP CIRC HTD 4 FT. , Product Code 2120-4S2G ; 23) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 4319-4H2 ; 24) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 4326-4H2 ; 25) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 4652-501 ; 26) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 4677-4H2 ; 27) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 4875-4H2 ; 28) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 5665-4H2 ; 29) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 5682-409 ; 30) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 5732-4H1 ; 31) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 5868-4H2 ; 32) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 6002-4H2 ; 33) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 6040-501 ; 34) CIRCUIT RESP INFANT PV HTD 5FT 30/CS , Product Code 6074-4H1 ; 35) CIRCUIT RESP PED 7FT HTD 20/CS , Product Code 6274-H12 ; 36) CIRCUIT RESP PED 7FT HTD 20/CS , Product Code 6301-H12 ; 37) INFANT RESP CIRC HTD 4 FT , Product Code 6313-501 ; 38) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 6459-4H2 ; 39) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 6485-4H2 ; 40) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 6588-4H2 ; 41) WYE KIT INFANT 30/CS , Product Code 6603-504 ; 42) CIRCUIT INFANT 6FT HTD INSP LINE 30/CS , Product Code 6862-504 ; 43) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 6921-4H2 ; 44) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 6942-4H2 ; 45) CIRCUIT INFANT 4FT HTD 30/CS , Product Code 7100-4S2 ; 46) CIRCUIT RESP

INFANT 4FT HTD 30/CS , Product Code 7147-4S2 ; 47) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 7156-4S2 ; 48) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 7184-4S2 ; 49) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 7206-4S2 ; 50) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 7213-4S2 ; 51) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 7354-4S2 ; 52) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 7395-4S2 ; 53) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 7407-4S2 ; 54) CIRCUIT RESP INFANT 3FT HTD 30/CS , Product Code 7431-4S2 ; 55) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 7441-4S2 ; 56) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 7483-4S2 ; 57) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 7526-4S2 ; 58) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 7575-4S2 ; 59) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 7582-4S2 ; 60) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 7588-4S2 ; 61) INFANT INSP LINE HTD 30/CS , Product Code 775687-101 ; 62) INFANT INSP LINE HTD 30/CS , Product Code 775687-102 ; 63) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 9052-4S2 ; 64) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 9053-4S2 ; 65) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 9054-4S2 ; 66) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code 9055-4S2 ; 67) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 9056-4S2 ; 68) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code 9058-4S2 ; 69) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code RC41-12010 ; 70) CIRCUIT RESP INFANT 40IN HTD 30/CS , Product Code RC41-12027 ; 71) CIRCUIT RESP INFANT 40IN HTD 30/CS , Product Code RC41-18039 ; 72) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code RC41-18052 ; 73) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code RC41-18060 ; 74) CIRCUIT INFANT INSP LINE HTD 5FT 30/CS , Product Code RC51-12002 ; 75) CIRCUIT RESP INFANT 5FT HTD 30/CS , Product Code RC51-12074 ; 76) CIRCUIT RESP INFANT 4FT HTD 30/CS , Product Code RC51-18004 ; 77) CIRCUIT NEONATE 4FT HTD W/ 30/CS , Product Code RT4851-00 ; 78) CIRCUIT NEO 4FT HTD W/12IN REMOTE 30/CS , Product Code RT4851-12 ; 79) CIRCUIT NEO 4FT HTD W/18IN REMOTE 30/CS , Product Code RT4851-18

<b>Recalling Firm/ Manufacturer</b>	Carefusion 2200 Inc 75 N Fairway Dr Vernon Hills, Illinois 60061-1845
<b>For Additional Information Contact</b>	CareFusion Customer Support 800-323-9088
<b>Manufacturer Reason for Recall</b>	The CareFusion AirLife Heated Infant Breathing Circuit is being recalled due to a regulatory compliance risk involving a material change. The changes to the gas pathway may potentially impact the safety of the device and quality of the gas condensates to the patient.
<b>FDA Determined Cause <sup>2</sup></b>	PREMARKET APPROVAL: No Marketing Application
<b>Action</b>	CareFusion sent an URGENT: PRODUCT RECALL letters dated July 31, 2014 to all affected customers. The letters instructed customers to: 1) perform a 100% physical inventory to verify if any of the affected product codes are in stock; 2) complete and return the attached Recall Response Form within 15 days; 3) notify any customers/parties that the recalled products were distributed to of the recall; 4) distributors should have all their customers return the products and a completed Recall Response Form to the distributor for credit; and, 5) customers should destroy the recalled products according to their disposal procedure. If a customers procedure(s) does not allow for the destruction of the recalled products, the customers was advised to contact CareFusion AirLife Customer Support at 800-323-9088 (Monday - Friday, 8:00 AM - 5:00 PM CST) for product return options. Customers will receive credit for all destroyed products. Direct accounts with questions about this recall should contact CareFusion AirLife Customer Support at 800-323-9088 (Monday - Friday, 8:00 AM - 5:00 PM CST) for additional information.
<b>Quantity in Commerce</b>	Approximately 318,280 devices
<b>Distribution</b>	Worldwide Distribution - US Nationwide in the states of AZ, CA, FL, IL, KY, LA, MI, MO, NE, NY, OH, OK, PA, RI, TN, TX, UT including Puerto Rico and the countries of Canada, China, Kuwait, Mexico, Saudi Arabia, and Switzerland.
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>27</sup>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>28</sup>](#)

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.