Class 2 Device Recall Mindray

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See Related Information[22]

Recall Date	August 30, 2016
Recall Status[1]	Open
Recall Number	Z-2689-2016
Recall Event ID	74758[23]
510(K)Number	K151954[24]
Product Classification	Gas-machine, anesthesia[25] - **Product Code** BSZ[26]
Product	A7 Anesthesia Delivery System, a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation. Part numbers 0632F-PA0000X (US domestic) and 0632B-00014 (international)
Code Information	P/N 0632F-PA0000X - (Domestic) and 0632B-PA00014 - (International) Serial numbers FR-5B000341, FR-5B000342, FR-5B000343, FR-5B000348, FR-5B000349, FR-51000148, FR-51000149, FR-51000150, FR-51000151, FR-51000152, FR-51000153, FR-51000154, FR-51000159 , FR-51000161, FR-51000162, FR-51000163, FR-51000164, FR-51000165, FR-51000166, FR-51000167, FR-51000168, FR-51000170, FR-51000171, FR-52000172, FR-52000173, FR-52000175, FR-52000176, FR-52000177, FR-52000178, FR-52000180, FR-52000181, FR-52000182, FR-52000183, FR-52000184, FR-52000185, FR-52000186, FR-53000187, FR-53000188, FR-53000189, FR-53000190, FR-53000191, FR-53000192, FR-53000193, FR-53000194, FR-53000197, FR-53000198, FR-53000199, FR-53000200, FR-53000203, FR-53000205, FR-53000206, FR-53000207, FR-53000209, FR-53000211, FR-53000212, FR-53000213, FR-53000214, FR-53000215, FR-53000216, FR-53000217, FR-54000218, FR-54000220, FR-54000221, FR-54000223, FR-54000224, FR-54000228, FR-54000229, FR-54000231, FR-54000233, FR-54000234, FR-54000235, FR-54000236, FR-54000237, FR-54000238, FR-54000239, FR-54000240, FR-54000241, FR-54000242, FR-54000243, FR-54000244, FR-56000245, FR-56000246, FR-56000247, FR-56000248, FR-56000249, FR-56000250, FR-56000251, FR-56000252, FR-56000253, FR-56000254, FR-56000255, FR-56000256, FR-56000257, FR-56000258, FR-56000259, FR-56000260, FR-56000261, FR-56000262, FR-56000265, FR-56000266, FR-56000267, FR-56000268, FR-57000269, FR-57000270, FR-57000271, FR-57000272, FR-57000274, FR-57000275, FR-57000276, FR-57000277, FR-57000278, FR-57000279, FR-57000280, FR-57000281, FR-57000282, FR-57000283, FR-57000284, FR-57000285, FR-57000286, FR-57000287, FR-57000288, FR-58000289, FR-58000290, FR-58000291, FR-58000292, FR-58000293, FR-58000294, FR-58000295, FR-58000296, FR-58000297, FR-58000298, FR-58000299, FR-58000300, FR-58000301, FR-58000302, FR-58000303, FR-58000304, FR-58000305, FR-58000306, FR-58000307, FR-58000308, FR-58000312, FR-58000313, FR-58000314, FR-58000315, FR-58000316, FR-58000317, FR-58000318, FR-58000319, FR-58000320, FR-58000321, FR-58000322, FR-58000323, FR-58000325, FR-59000330, FR-59000331, FR-59000333, FR-59000334, FR-59000335, FR-59000336, FR-59000338, and FR-59000339.
Recalling Firm/ Manufacturer	Mindray DS USA, Inc. dba Mindray North America 800 Macarthur Blvd Mahwah NJ 07430-2001
For Additional Information Contact	Ms. Diane Arpino 201-995-8407

Manufacturer Reason for Recall	Potential for a leak to occur on the back-up O2 and air e-size cylinder yokes on the A7 Anesthesia Delivery System.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	Mindray sent via certified mail with return receipt a recall letter dated June 15, 2016 to their affected customers. Mindray will replace the gasket on all e-size cylinder yokes on the affected A7 systems. Customer was instructed to contact their local Mindray Service Representative to arrange for this replacement. Customers can continue to use their A7 system while awaiting the replacement of the gasket(s). Customers can contact Ms. Diane Arpino, Director, Quality Operations and Regulatory Affairs via email to: d.arpino@mindray.com or via telephone to: (201)995-8407
Quantity in Commerce	167 units (165 units - US) and (2 units - International)
Distribution	US Nationwide Distribution to AL, MA, MD, MN, MO, NE, NJ, OK, OR, PA and VA; and Canada
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[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 = BSZ and Original Applicant = SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.[29]

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