### Class 2 Device Recall Mindray

#### Recall Information

**Recall Date:** August 30, 2016  
**Recall Status:** Open  
**Recall Number:** Z-2689-2016  
**Recall Event ID:** 7475823  
**510(K) Number:** K1519544  
**Product Classification:** Gas-machine, anesthesia - Product Code RSZ  
**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)  
**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

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=148395  
9/5/2016
<table>
<thead>
<tr>
<th>Manufacturer Reason for Recall</th>
<th>Potential for a leak to occur on the back-up O2 and air e-size cylinder yokes on the A7 Anesthesia Delivery System.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Determined Cause</td>
<td>Nonconforming Material/Component</td>
</tr>
<tr>
<td>Action</td>
<td>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: <a href="mailto:d.arpino@mindray.com">d.arpino@mindray.com</a> or via telephone to: (201)995-8407</td>
</tr>
<tr>
<td>Quantity in Commerce</td>
<td>167 units (165 units - US) and (2 units - International)</td>
</tr>
<tr>
<td>Distribution</td>
<td>US Nationwide Distribution to AL, MA, MD, MN, MO, NE, NJ, OK, OR, PA and VA; and Canada</td>
</tr>
<tr>
<td>Total Product Life Cycle</td>
<td>TPLC Device Report¹²⁷</td>
</tr>
</tbody>
</table>

¹ For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.56²⁸
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

Links on this page:

4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=74758
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K151954
