# Class 3 Device Recall BeneVision Series Telemetry Monitor



## Class 3 Device Recall BeneVision Series Telemetry Monitor

See Related Information[22]

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| **Date Initiated by Firm** | August 31, 2026 |
| **Date Posted** | October 07, 2026 |
| **Recall Status[1]** | Open[3], Classified |
| **Recall Number** | Z-0111-2027 |
| **Recall Event ID** | 99828[23] |
| **510(K)Number** | K242728[24] |
| **Product Classification** | System, network and communication, physiological monitors[25] - **Product Code** MSX[26] |
| **Product** | BeneVision Series Telemetry Monitor. Operator's Manuals: TM70/TM80 |
| **Code Information** | Part numbers of BeneVision Series Telemetry Monitor Operator's Manuals:<br>1. BeneVision TMS60 (TD60)/TM80 (no alarms) Operator's Manual up to and including revision 5.0; Part No. 046-011232-00<br><br>2. BeneVision TM70 Telemetry Monitor Operator's Manual up to and including revision 4.0; Part No. 046-019362-00<br><br>3. TM80 Telemetry Monitor Operator's Manual up to and including revision 9.0; Part No. 046-012662-00<br><br>4. TMS60 Telemetry Monitoring System Operator's Manual up to and including revision 4.0; Part No. 046-007056-00 |
| **FEI Number** | 2221819 |
| **Recalling Firm/ Manufacturer** | Mindray DS USA, Inc.<br><br>800 Macarthur Blvd<br><br>Mahwah<br>NJ<br>07430-2001 |
| **For Additional Information Contact** | James Clifford<br>+1-201-9958407 |
| **Manufacturer Reason for Recall** | Certain monitor operator's manuals contain descriptions that may be insufficient or may require clarification regarding selected physiological alarm functions |
| **FDA Determined Cause [2]** | Labeling design |
| **Action** | Mindray notified consignees on about 08/31/2026 via "URGENT: Medical Device Recall" letter. Consignees were informed that Mindray was providing updated instructions regarding physiological alarms in certain Mindray patient monitoring device Instructions for Use (IFU)/Operator s Manuals. This action is limited to updates to the IFU/Operators Manual content and does not require removal, return, repair, or replacement of the monitors.<br><br>Consignees were instructed to continue using the Mindray monitors associated with the affected operator s manual, ensure that applicable clinical staff are made aware of the content of this letter and the Operator s Manual Addendum, and if monitors have been distributed or transferred to another organization, please forward this notice to that organization. Additionally, consignees were instructed to complete and return the Acknowledgment and Receipt Form provided. Distributors were instructed to notify their customers.<br><br>Mindray provided the QR Code for the Operator s Manual Addendum - Addendum of the Arrhythmia Analysis Statement on their portal. |

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| **Quantity in Commerce** | 29,737 units |
| **Distribution** | Worldwide - Nationwide and the country of Canada. |
| **Total Product Life Cycle** | TPLC Device Report[27] |

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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| **510(K) Database** | 510(K)s with Product Code = MSX[29] |

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22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
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24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K242728
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MSX
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MSX
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=MSX
28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=MSX&knumber=&applicant=Shenzhen%20Mindray%20Bio%2DMedical%20Electronics%20Co%2E%2C%20L

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99828
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K242728
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27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=MSX
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