Class 3 Device Recall BeneVision N1 and NSeries Patient Monitor

Class 3 Device Recall BeneVision N1 and NSeries Patient Monitor

See Related Information[22]

Date Initiated by Firm	August 31, 2026
Date Posted	October 07, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-0110-2027
Recall Event ID	99828[23]
510(K)Number	K213799[24]
Product Classification	Monitor, physiological, patient(with arrhythmia detection or alarms)[25] - **Product Code** MHX[26]
Product	BeneVision N1 and N-Series Patient Monitor. Patient Monitor: N12/N15/N17/N19/N22.
Code Information	Part numbers of BeneVision N1 and N-Series Patient Monitors Operator's Manuals: 1. BeneVision N1 Operator's Manual up to and including revision 21.0; Part No. 046-011405-00. 2. BeneVision N-Series Operator's Manual up to and including revision 23; Part No. 046-011259-0.
FEI Number	2221819
Recalling Firm/ Manufacturer	Mindray DS USA, Inc. 800 Macarthur Blvd Mahwah NJ 07430-2001
For Additional Information Contact	James Clifford +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. 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. Mindray provided the QR Code for the Operator s Manual Addendum - Addendum of the Arrhythmia Analysis Statement on their portal.
Quantity in Commerce	44,651 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.

510(K) Database 510(K)s with Product Code = MHX[29]

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26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MHX
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=MHX
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=MHX&knumber=&applicant=Shenzhen%20Mindray%20Bio%2DMedical%20Electronics%20Co%2E%2C%20L

Page Last Updated: 10/27/2026

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
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