Class 3 Device Recall ePM Series Patient Monitors

Class 3 Device Recall ePM Series Patient Monitors

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-0109-2027
Recall Event ID	99828[23]
510(K)Number	K260098[24]
Product Classification	Monitor, physiological, patient(with arrhythmia detection or alarms)[25] - **Product Code** MHX[26]
Product	ePM Series Patient Monitor. Patient Monitor Series: ePM 10M/ePM 12M/ePM 12MA/ ePM 15M/ePM 10A
Code Information	Part numbers of ePM Series Patient Monitors Operator's Manuals: 1. Guardian Plus Operator's Manual (OEM, MDPro) up to and including revision 4.0; Part No. 046-026408-00 2. ePM 10A Operator's Manual up to and including revision 12.0; Part No. 046-019796-00 3. ePM 12MA Operator's Manual up to and including revision 13.0; Part No. 046-019797-00 4. ePM 10M, ePM 12M Operator's Manual up to and including revision 13.0; Part No. 046-019798-00 5. ePM 15M Operator's Manual up to and including revision 3.0; Part No. 046-028915-00
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	32,184 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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