Product Advisory (No disposition of product)
APM-26-06129

ForeSight™ Oximeter Cable Labels Switched
Affected Model Number: HEMFSM10

13 Aug 2026

Dear Valued Customers and Distributors,

Attention: Risk Management Department

CC : Chairman Medical Board and relevant Head of Departments

The purpose of this letter is to advise you that Edward Lifesciences is voluntarily notifying customers of a potential labeling issue affecting ForeSight Oximeter Cable.

Affected Product

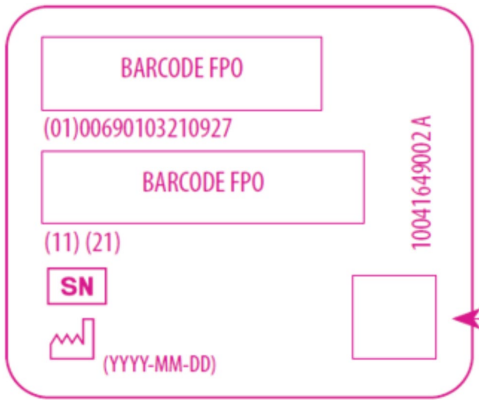
Product Name	Catalog No.	Dates of Manufacture	UDI-DI	Package Size
ForeSight Oximeter Cable	HEMFSM10	June 01, 2021, through June 30, 2026	00690103210927	1 ea.

**Please refer to Appendix A for impacted lot serial numbers.*

Note: There are other affected serial numbers that are affected globally, please check with product owner as needed.

Approved Description of the Problem

Based on customer feedback, Edwards Lifesciences has identified that during manufacturing, the laterality identification labels may be missing or inaccurately placed on the device. There is potential that the labels on the green cables may have been switched, with the channel 1 cable labeled as channel 2, and the channel 2 cable labeled as channel 1. This will lead to a mismatch as to the left and right values displayed on the monitor and what the labels indicate on the cables. This issue may affect certain devices manufactured between June 01, 2021, and June 30, 2026 (see below to identify the location of manufacturing date).



Approved Clinical Risk Statement

Should this potential issue occur during use, the values displayed on the monitor will be switched and will represent the opposite region being monitored. Therefore, there is a potential for incorrect diagnosis, leading to potential delay of appropriate treatment.

Diagnosis and treatment are not determined solely based on displayed hemodynamic values. However, in the case of unilateral desaturation and tissue oximetry cable labels that are mislabeled, correct diagnosis may be delayed while the clinician trouble shoots the monitoring device(s) and patient presentation. Although incidence rates are low, a worst-case scenario, may be unilateral cerebral desaturation, which may be indicative of an arterial dissection of the aorta, arch, or carotid artery(s). Once diagnosed, the clinical treatment would include assessment, cannulation, and surgical repair of the dissection. In this case, delayed treatment caused by assessment variation is inconsistent with the monitoring device, which may lead to the patient experiencing worse outcomes.

Complaint & Adverse Event Statement

To date, three complaints have been received about this issue worldwide, none of which resulted in adverse events.

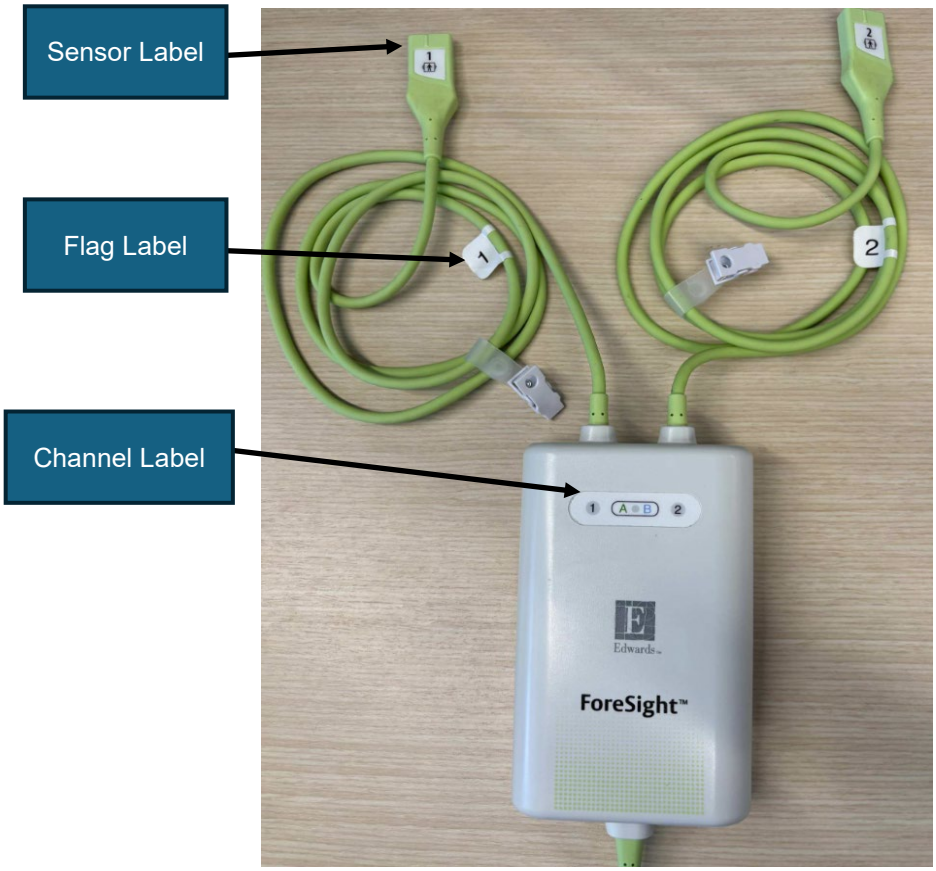
Actions for Clinical Users

Check devices in clinical use and in inventory:

1. Verify for the presence of the flag, sensor, and channel labels on the device.

2. Verify that the flag and sensor labels correspond to the correct channel label (A1 on left / B2 on right) on the housing (See picture below for correct label placement).

3. If either of the labels are missing, or the flag label and/or the sensor label do not match the channel label on the housing, contact : **APMTechServiceSEA@bd.com** Technical Support for further assistance.
4. If the flag and sensor labels correctly correspond to the channel labels, as seen in the picture below, there is no further action required.



Actions to be taken by customers and distributors.

1. Provide a copy of this notification to any customers and/or facilities you may have distributed devices to.

2. Post this notice on or segregate the impacted unit(s) until correction is completed. (regional requirements may be expanded for #2).

3. Complete the attached Customer Response Form and return it to the Edwards Lifesciences contact noted on the form whether or not you have any of the impacted

products so that Edwards Lifesciences may acknowledge your receipt of this notification.

4. E-mail completed form to Edward Lifesciences at CustomerService_MY@edwards.com within 15 days from receipt of this notification. Contact Edward Lifesciences Customer Service CustomerService_MY@edwards.com if you have further questions.

Actions by Edwards

Edwards has identified the root cause and is implementing appropriate corrective and preventative measures to prevent recurrence.

Sincerely,

Sunita Das

Digitally signed by Sunita Das
Reason: I am approving this document
Date: 2026.08.14 09:21:36 +05'30'

Sunita Das,

Sr Dir, Quality

Edwards

CUSTOMER RESPONSE FORM
APM-26-06129
ForeSight™ Oximeter Cable Labels Switched

Please assist Edwards by acknowledging this field action via Email: CustomerService_MY@edwards.com

Facility:_____
Please print full, current facility name. Do not use initials.

Street Address:_____

City:_____ **Province**: _____ **Postal Code**: _____

Response Form Completed By:	
Name:	
Title:	
Telephone No.	
Fax No.	
Email Address	

Please check all that apply:
☐ I have read and understood the attached notice and taken appropriate actions.
☐ We do not have any of the affected product(s) on hand

Product Name	Catalog No.	Lot No.	Quantity in Eaches

Please assist Edwards with assuring these communications are delivered to the appropriate person/function within your facility if that is not you.

Person/function responsible for the receipt and management of field actions at your facility:
Name: _____
Phone: _____
Email: _____
Fax #: _____

This response includes responses for the following locations as well:

Facility	Street Address	City	State	Zip

Edwards

Appendix A – List of Affected Serial Numbers

2nd Item Number	Lot Serial Number
HEMFSM10	21130845
HEMFSM10	21130846
HEMFSM10	21130310
HEMFSM10	21130311
HEMFSM10	21129199
HEMFSM10	21129571
HEMFSM10	21125987
HEMFSM10	21125988
HEMFSM10	21125989
HEMFSM10	21123138
HEMFSM10	21123343
HEMFSM10	21121943
HEMFSM10	21121932
HEMFSM10	21120665
HEMFSM10	21120263
HEMFSM10	21120274
HEMFSM10	21120276
HEMFSM10	21120277
HEMFSM10	21120279
HEMFSM10	21120281
HEMFSM10	21120663
HEMFSM10	21107527
HEMFSM10	21107528
HEMFSM10	21104442
HEMFSM10	21103560
HEMFSM10	21101061