**DATE:** 11th August 2026 **FSCA/FSN REF.: APM-26-06129**

# URGENT: FIELD SAFETY NOTICE (FSN)
# ForeSight Oximeter cable

**For Attention of:** **Clinical Personnel, Risk Managers, Biomedical Personnel, Purchasing Managers**

| Action Being Taken by the Manufacturer | | | |
|---|---|---|---|
| ☐ | Product removal | ☐ | On-site device modification/inspection |
| ☐ | Software upgrade | ☐ | IFU or labelling change |
| ☒ | Advisory | ☐ | Other |
| Provide further details of the action(s) identified | | N/A | |

## Information on Affected Devices

**Manufacturers SRN:** US-MF-000007139

| Product name | Product Code (REF) | Lot number / Serial number | UDI-DI |
|---|---|---|---|
| ForeSight Oximeter cable | HEMFSM10 | All serial numbers manufactured between June 01, 2021, through June 30, 2026 | 00690103210927 |

## Reason for Field Safety Corrective Action (FSCA)

**Description of the product problem**

Based on customer feedback, BD 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 labelled as channel 2, and the channel 2 cable labelled as channel 1 [CS4.1][KL4.2]. 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 Appendix 1 to identify date of manufacture).

**Note:** In September 2024, BD acquired the Edwards Lifesciences Critical Care business, including the product referenced in this Field Action. The transition process is currently ongoing, and Edwards Lifesciences remains the Legal Manufacturer until the transfer is fully completed. As agreed between the parties, BD is responsible for Post-Market Surveillance activities and is therefore conducting this Field Action.

**Hazard giving rise to the FSCA**

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 mislabelled, 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.

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

**Other information relevant to FSCA**

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

**Device Type(s)**

The white module with attached green cables that connects to the HemoSphere monitor and the ForeSight sensors.


**Primary clinical purpose of devices(s)**

The non-invasive ForeSight Oximeter Cable when used with HemoSphere Monitor, HemoSphere Alta monitor and HemoSphere Vita Monitor is intended to allow for the display of StO2 and ΔctHb.

The ForeSight Tissue Oximeter Module is a non-invasive device that measures absolute tissue oxygen saturation using near-infrared lights that are emitted and captured by an attached disposable sensor. It operates on the principle that blood contains two primary forms - oxygenated and de-oxygenated haemoglobin which absorb near-infrared light that can be measured. The disposable sensor emits near-infrared light (in five precise wavelength) through the target tissue and captures the reflected light for the module to calculate tissue oxygen saturation and haemoglobin oxygenation levels.

## General Information

**FSN type:** NEW
**For updated FSN, reference number and date of previous FSN:** N/A
**For updated FSN, key new information as follows:** N/A
**Further advice or information already expected in follow up FSN?** No

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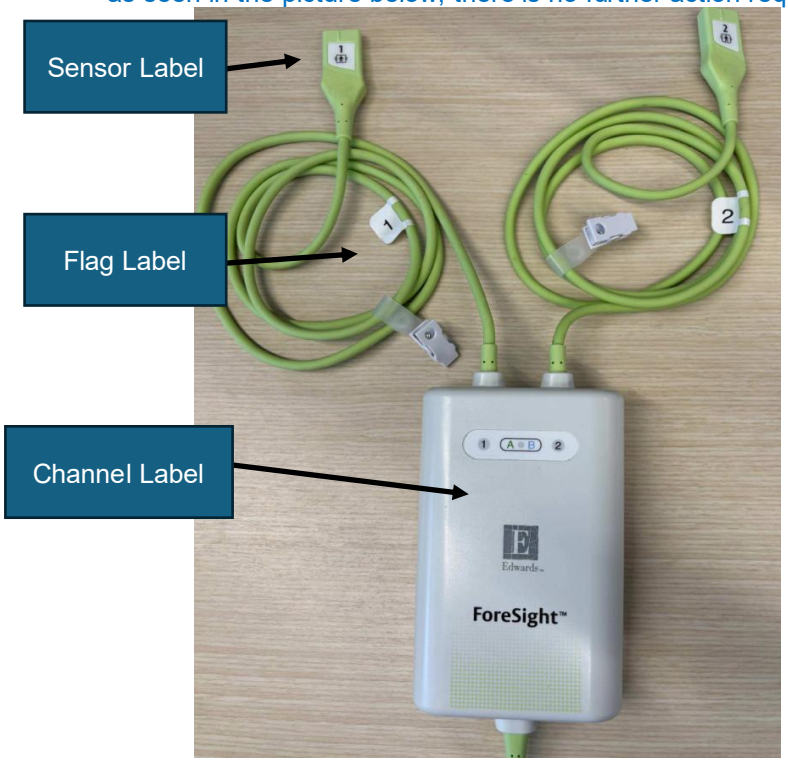
| Type of Action to mitigate the risk | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Action To Be Taken by the User** | | | | | | | |
| ☒ | Identify Device | ☒ | Quarantine Device | ☐ | Cease Use | ☐ | Return Device |
| ☐ | Destroy Device | ☒ | On-site device modification/inspection | ☐ | Follow patient management recommendation's | | |
| ☐ | Take note of amendment/reinforcement of Instructions for Use (IFU) | | | ☒ | Other | | |
| Provide further details of the action(s) identified | | | | 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, quarantine the device and return the completed response form to BD at BDFieldActions@bd.com for BD Technical Services to contact you. | | | |

**Particular considerations for:** 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, quarantine the device and return the completed response form to BD at BDFieldActions@bd.com for BD Technical Services to contact you.
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.



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| | |
|---|---|
| **Is follow-up of patients or review of patients' previous results recommended?** | No |
| **Provide further details of patient-level follow-up if required or a justification why none is required:** | No patient follow-up is required if the device has been used without any reported concerns. The ForeSight™ system is a monitoring device, not a diagnostic device, and is intended to provide supplementary information to support clinical assessment. |
| **Is customer Reply Required:** | Yes<br>If "yes"<br>Complete the form in its entirety and return the Customer Response Form even if you no longer have any inventory remaining in your facility by **31st August 2026.** |

| **Action To Be Taken by the Distributor** | | | | | | | |
|---|---|---|---|---|---|---|---|
| ☒ | Identify Device | ☒ | Quarantine Device | ☐ | Cease distribution | ☐ | Return Device |
| ☐ | Destroy Device | ☒ | On-site device modification/inspection | ☐ | Take note of amendment/reinforcement of Instructions for Use (IFU) | | |
| ☒ | Identify the facilities where you have distributed affected product and notify them immediately of this notice. | | | ☒ | Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes | | |
| ☒ | Complete and return the Customer Response Form following completion of your reconciliation activities | | | ☒ | Other | | |
| Provide further details of the action(s) identified | | | | 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, quarantine the device and return the completed response form to BD at BDFieldActions@bd.com for BD Technical Services to contact you. | | | |

| | **End User with Inventory** | **End User with ZERO inventory** | **Where to send completed form** |
|---|---|---|---|
| Purchased/distributed **directly** from BD | Complete the form in its entirety and ensure that all recommended actions have been implemented as required | Complete the form in its entirety and retain a copy of this notification for your records | BDFieldactions@bd.com |
| Purchased/distributed from a **distributor/3rd party** | Complete the form in its entirety and ensure that all recommended actions have been implemented as required | Complete the form in its entirety and retain a copy of this notification for your records | Return the form to your distributor |

**Contact details of local representative:** If you have any questions about this, please contact your local BD representative or the local BD office or e-mail BDFieldactions@bd.com

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## Transmission of this Field Safety Notice

- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred
- Transfer this notice to other organisations on which this action has an impact.
- Maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback

**The competent (Regulatory) Authority of your country has been informed about this communication to customers**

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## Appendix 1 – Manufacturing date identification

This issue may affect certain devices manufactured between June 01, 2021, and June 30, 2026. Refer to the following image to identify the location of manufacturing date.