



<Customer address>

## Field Safety Notice

### Name of the affected product:

3M™ Red Dot™ Monitoring Electrode with Foam Tape, reference 2228 and  
3M™ Red Dot™ Monitoring Electrode with 4mm Adapter, reference 2228BA

**FSCA-identifier:** FSN 2020-10 FSCA Red Dot

**Type of action:** Disposal of affected products

**Date:** October 9th, 2020

**Attention:** 3M Health Care Business Customers

Dear Customer,

3M is notifying all users of the above-mentioned **3M™ Red Dot™ Monitoring Electrodes** of a field safety corrective action.

### Details on affected devices:

The following lots of 3M™ Red Dot™ Monitoring Electrode with Foam Tape, reference 2228, and of 3M™ Red Dot™ Monitoring Electrode with 4mm Adapter, reference 2228BA, are affected by this field action:

| Affected Lots,<br>Reference Number 2228 |          |
|---|----------|
| 202204LK                                | 202204LS |
| 202204LL                                | 202204LX |
| 202204LM                                | 202204LZ |
| 202204LN                                | 202204MA |
| 202204LP                                |          |
| 202204LQ                                |          |
| 202204LR                                |          |

| Affected Lot,<br>Reference Number 2228BA |          |
|--|----------|
| 202204BA                                 | 202204BH |
| 202204BB                                 | 202204BI |
| 202204BC                                 | 202204BJ |
| 202204BD                                 | 202204BK |
| 202204BE                                 | 202204BL |
| 202204BF                                 | 202204BM |
| 202204BG                                 | 202204BN |

**Description of the problem and potential hazard and risk for the patient/user:**

This Field Safety Corrective Action has been initiated due to the risk of corrosion on the sensing element of the affected monitoring electrode product lots. In an emergency situation, where defibrillation is necessary, and where electrodes are already in use, the electrodes may not perform as intended resulting in the potential for a delayed trace response, poor trace response, or no trace response. 3M has received a very limited number of reports of corrosion, and no injuries or complications have been reported in association with this issue. However, in an abundance of caution, 3M is recalling these product lots in order to minimize patient risk associated with a potential delay in cardiac assessment and/or treatment.

Please note that only the lot numbers detailed above are subject to this Field Safety Corrective Action Notification.

**Action to be taken by the user:**

All users of the **3M™ Red Dot™ Monitoring Electrode** are being asked to take the following actions:

- Ensure all your internal and external customers are informed about this corrective action.
- **Discontinue use and dispose of** any affected 3M™ Red Dot™ Monitoring Electrode.
- Complete and return by e-mail to [meddev.de@mmm.com](mailto:meddev.de@mmm.com) the enclosed Acknowledgement Form, indicating that the corrective action was understood and executed. Please also indicate the number of devices you have disposed of.

**Transmission of this Field Safety Notice:**

Please pass on this notice immediately to all departments who might use the concerned products. In addition, ensure that the information is provided to any organisation where the concerned products potentially have been distributed.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this matter may cause.

**Contact reference person:**

If you have questions, please contact your local 3M representative.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Dr. Marie Isabel Cobbers  
Safety Officer  
3M Deutschland GmbH, Health Care Business  
Carl-Schurz-Strasse 1, 41453 Neuss, Germany  
Mail: [mcobbers@mmm.com](mailto:mcobbers@mmm.com)

**Acknowledgement Form – FSN 2020-10 FSCA Red Dot**Email completed form to: [meddev.de@mmm.com](mailto:meddev.de@mmm.com)

Please examine your inventory to determine if you have any stock of the affected monitoring electrodes indicated below. Note, this notification only applies to the indicated lots of 3M™ Red Dot™ Monitoring Electrode.

We have examined our inventory and identified and disposed of the following number of pouches of the affected lots of 3M™ Red Dot™ Monitoring Electrode, reference number 2228:

| Lot Number | Number of Pouches of 50 Electrodes in Inventory/To Be Disposed | Lot Number | Number of Pouches of 50 Electrodes in Inventory/To Be Disposed |
|------------|--|------------|--|
| 202204LK   |  | 202204LR   |  |
| 202204LL   |  | 202204LS   |  |
| 202204LM   |  | 202204LX   |  |
| 202204LN   |  | 202204LZ   |  |
| 202204LP   |  | 202204MA   |  |
| 202204LQ   |  |            |  |

We have examined our inventory and identified and disposed of the following number of pouches of the affected lots of 3M™ Red Dot™ Monitoring Electrode, reference 2228BA:

| Lot Number | Number of Pouches of 40 Electrodes in Inventory/To Be Disposed | Lot Number | Number of Pouches of 40 Electrodes in Inventory/To Be Disposed |
|------------|--|------------|--|
| 202204BA   |  | 202204BH   |  |
| 202204BB   |  | 202204BI   |  |
| 202204BC   |  | 202204BJ   |  |
| 202204BD   |  | 202204BK   |  |
| 202204BE   |  | 202204BL   |  |
| 202204BF   |  | 202204BM   |  |
| 202204BG   |  | 202204BN   |  |

**Acknowledgement Form – FSN 2020-10 FSCA Red Dot (continued)**

We have examined our inventory and do not have any above listed lot of 3M™ Red Dot™ Monitoring Electrode on stock.

I acknowledge that I have read and understood this letter and will complete the actions requested.

Email completed form to: [meddev.de@mmm.com](mailto:meddev.de@mmm.com)

Person completing this form:

|           |  |                      |  |
|-----------|--|----------------------|--|
| Name      |  | Company Name         |  |
| Signature |  | City, State, Country |  |
| Date      |  | Phone                |  |
|           |  | E-mail               |  |