



October 17, 2017

Subject: URGENT MEDICAL DEVICE RECALL of 3M™ Bair Hugger™ Temperature Monitoring Sensor, Model 36000, Formerly Known as 3M™ SpotOn™ Temperature Monitoring Sensors

Dear 3M Health Care Customer:

3M is conducting a recall of four (4) lots of the 3M™ Bair Hugger™ temperature monitoring sensor, Model 36000, formerly known as 3M™ SpotOn™ temperature monitoring sensors.

During a recent investigation, 3M confirmed that a programming translation error could occur in a small amount of the sensors that could lead to a temperature readout that is lower than the patient's actual temperature. If the impacted sensors are used as part of a system which is the only means of temperature monitoring, there is potential for improper or inadequate therapies to be given to a patient.

The following lot numbers are impacted:

- 17230
- 17233
- 17234
- 17241

Actions Required:

- 1) Please immediately identify the affected product listed above, remove from your inventory and DO NOT USE.
- 2) Follow the instructions on the attached Customer Product Recall Acknowledgement Form, complete the form and return it to 3M as indicated.
- 3) Please dispose of all affected product per your institutional protocol.

Once 3M has received your completed form, if you have indicated you have any remaining product from these lots, we will provide replacement product for affected product on hand.

We apologize for any inconvenience this may cause you. If you have questions regarding this matter, please contact the 3M Health Care Customer Helpline at 1-800-228-3957, option #6, Monday through Friday, 7:30 a.m. – 6:00 p.m. Central Daylight Time.

Thank you for your cooperation.

Sincerely,

Michael J. Besser, Division Quality Manger
3M Infection Prevention Division
3M Center, 270-5N-01
St. Paul, MN 55144

Customer Product Recall Acknowledgement Form
3M™ Bair Hugger™ Temperature Monitoring Sensor, Model 36000,
Formerly Known as 3M™ SpotOn™ Temperature Monitoring Sensors

Please examine your stock immediately to determine if you have any 3M™ Bair Hugger™ temperature monitoring sensor, Model 36000, formerly known as 3M™ SpotOn™ temperature monitoring sensors, lot numbers listed in the table below and complete this form.

Please indicate in the table below how many full (unopened) cases and/or individual sensors from partial (opened) cases of each listed lot you have and fill in your contact information. If you do not have inventory of the affected lots, please indicate in the second checkbox below. Email this form to 3Mhealthcare@montage72.com.

We have examined our inventory, identified the following products were found and have completed the table below with the quantity.

3M™ Bair Hugger™ Temperature Monitoring Sensor, Model 36000

Affected Lot	Count of Full (Unopened) Cases	Count of Individual Sensors from Partial (Open) Cases
17230		
17233		
17234		
17241		

We have examined our inventory and do not have the specified 3M products subject to recall.

By signing below, we certify we will fully dispose of the affected product.

Contact Information:

Name		Company Name	
Signature		Company Address	
Date		Phone	