67 Max Clinical Infrared Thermometer Recall and Replacement

Dear Customer:

The purpose of this letter is to advise you that Fluke Corporation is executing a voluntary field action of its **Fluke 67 Max Clinical Infrared Thermometer**. All devices are impacted *unless* a green mark has been placed on the label located in the battery compartment as show in Figure 1 below.

Figure 1: View of Label with Green Mark Located within the Battery Compartment

If you own a Fluke 67 Max Clinical Infrared Thermometer that does not contain a green mark as shown in Figure 1 and are experiencing any perceived accuracy (temperature measurement) issues, please stop using it and send it back to Fluke for a complimentary replacement unit. If you are not the primary user of the Fluke 67 Max Clinical Infrared Thermometer, please pass along this notice to the appropriate people within your organization to take action.

Description of the Issue:

Fluke identified that the following issues (whether occurring independently or at the same time) may cause the device to display a temperature reading (up to two (2) degrees Celsius) outside of its published specifications.

- Shorting of the electrical wiring near the battery terminals;
- Improper calibration of the device during the manufacturing process; and/or
- Drift in the calibration values in the product due thermal stabilization time issues encountered during the manufacturing process.

No adverse events have been reported to Fluke related to these issues. When used by a healthcare provider, no adverse health consequences are expected as the Fluke 67 Max would not be the only data point a health care provider would utilize to make a clinical decision. When used by a consumer / home care setting, minor inaccuracies in temperature measurements may go unnoticed and could potentially result in false positives or negatives with respect to elevated temperature. False positives are not expected to result in adverse health consequences; false negatives could potentially result in headaches, dizziness, cramps, confusion, nausea, and if prolonged, seizures because of a lack of appropriate antipyretic treatment within an appropriate timeframe.

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PO Box 9090 Everett WA 98206.9090 USA	425.347.6100	425.356.5116	www.fluke.com

Based on Fluke's investigation completed to date, the issues do not appear to be occurring throughout the entire device population (Fluke estimates that up to 7% of the devices may experience one of the issues noted above). Devices with a green mark on the label within the battery compartment as displayed in **Figure 1** were reworked to resolve the three (3) issues noted above and thus are not subject to this notice.

Immediate Action:

- If you are experiencing any perceived accuracy (temperature measurement) issues, please immediately stop using your affected 67 Max Clinical Infrared Thermometer.

- Contact your Fluke service number for information and to arrange for the return and replacement of your product: US: 1-888-993-5853

Additional Information:

Thank you very much for your continued loyalty to Fluke products. The quality of our product is our primary concern. Quality is important to Fluke. It is the foundation of our trust with you. We apologize for any inconvenience this issue may cause and appreciate your continued support of Fluke.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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Please contact Fluke Corporation via telephone or email as per below if you have any questions:

Telephone*: 1-888-993-5853
Email: fluke67max.feedback@fluke.com

* Hours of operation: 8:00AM to 5:00PM PST (Monday through Friday, excluding holidays)