April 28, 2021

PLEASE READ!
Important Product Removal Information
FLUKE-67 MAX Clinical Infrared Thermometer

Dear Fluke Distributor,

Given the state of the market related to fever screening solutions, Fluke Corporation has decided to discontinue the sale of the 67 Max Clinical Infrared Thermometer and will be reclaiming any existing / unsold inventory that may be in your possession. Please see below for instructions related to the discontinuation.

Separately, 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.

As a result, Fluke Corporation is executing a voluntary field action of its **Fluke 67 Max Clinical Infrared Thermometer** that are experiencing any perceived accuracy (temperature measurement) issues.

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.

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). Note that certain 67 Max Clinical Infrared Thermometers, which may have been distributed to you, were reworked during the manufacturing process to resolve the three (3) issues noted above. Devices that have been reworked have a green mark on the label located within the battery compartment as displayed in **Figure 1**. As noted below, we request that all 67 Max Clinical Infrared Thermometers within your inventory be returned to Fluke Corporation (including those with a green mark).

Fluke Corporation
PO Box 9090 Everett WA 98206.9090 USA

Telephone 425.347.6100
Facsimile 425.356.5116
Internet www.fluke.com

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

Immediate Actions:

- **STOP SELLING** the FLUKE-67 Max and **prepare the remaining units to be returned to Fluke,**
- Send an email to distribution.orders@fluke.com or fax request to (425) 446-5844 for an RMA for credit. Please ensure you include the following:
    - Contact Information
    - Email Address
    - Branch Locations that need to be credited (be sure to include the item / product # and quantity by branch location)
- Please note: This RMA will be for Credit Only.
- The Fluke order management team will follow up with the RMA # and UPS account details (shipment costs are paid by Fluke)
- Any backlog orders will be canceled.

Notification of Customers:

Fluke published a customer notice bulletin with includes instructions for requesting a replacement unit. A copy of the customer notice bulletin is attached to this letter and published on Fluke Corporation's website: www.fluke.com/67maxnotice

- Fluke Corporation requests that you:
    - Distribute the customer notice bulletin to your customers that may have purchased a 67 Max Clinical Infrared Thermometer.
    - Publish the customer notice bulletin on a location of your website where customers are expected to receive information regarding product recalls.
- Should any customer contact you with concerns regarding temperature measurement accuracy of their device, direct the customer to the customer notice bulletin.

Additional Information:

Fluke Corporation | Telephone | Facsimile | Internet
PO Box 9090 Everett WA 98206.9090 USA | 425.347.6100 | 425.356.5116 | www.fluke.com

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.

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

Telephone*: (425) 446-5844
Email: distribution.orders@fluke.com

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

Upon receipt, please email fluke67max.feedback@fluke.com confirming receipt of this notification as well as your understanding of the instructions.

Best regards,

Walter Hock
Vice President, Fluke Entity

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.

Fluke Corporation	Telephone	Facsimile	Internet
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.

***

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)