Testing Procedures for  
M4C Non-Contact Thermometer  
(DRAFT)

# Introduction

This paper summarizes the testing requirements from the FDA standards document *ASTM E-1965 – 98 (Reapproved 2003) Standard Speciﬁcation for Infrared Thermometers for Intermittent Determination of Patient Temperature*. We have access to this document, but there appears to be a later standard. We risk the FDA objecting to the marketing of our Non-Contact IR Thermometer (NCT) if we fail to meet the specifications in this standard. We must be open about conformance or non-conformance to these specifications.

# Device Classification

Our device is classified as a “skin IR thermometer” for the purposes of selecting applicable parts of the standard.

# Accuracy (Maximum Permissible Laboratory Error)

Any individual measurement taken during testing must be within 0.3C (0.5F) of the true temperature of the blackbody as measured by a calibrated contact thermometer imbedded or immersed in the blackbody. This applies to measurements under what we choose to publish as the allowable ambient operating conditions for the NCT.

# Clinical Accuracy

Clinical accuracy refers to the difference between NCT measurements of human subjects and internal body temperature measurements using an approved contact thermometer. There is no clinical accuracy requirement for skin IR thermometers.

# Ambient Conditions

The accuracy of the NCT must be maintained within the operating temperature range 16C to 40C (60.8F to 104.0F). A narrower operating range is allowed if labeled, but the high end of the range must be no lower than 35C (95F). The operating relative humidity range must be up to 95% noncondensing. We are allowed to specify a narrower operating humidity but must both disclose that in labeling and give the operator an indication that humidity is out of range.

Test measurements must be taken under the following ambient conditions at a minimum:

|  |  |
| --- | --- |
| Temperature | Humidity % |
| 16 to 18C (60 to 65F) | Less than 50 |
| 16 to 18C (60 to 65F) | 90 to 95 |
| 24 to 26C (75 to 80F) | 40 to 60 |
| 38 to 40C (100 to 104F) | Less than 25 |
| 38 to 40C (100 to 104F) | 75 to 85 |

# Mechanical Shock

The NCT with batteries installed must continue operating accurately after being dropped onto its “nose” from 1m onto a 20mm (2in) thick hardwood board on a hard (concrete) floor. The standards document shows the orientations that must be tested. Only a blackbody temperature of approximately 37C (98.6F) must be tested.

# Storage Conditions

We must test that the NCT will operate correctly when stored for 30 days at any temperature between -20 and 50C and at humidity up to 95% noncondensing.

# Cleaning and Sanitization

We must test that our device can be repeatedly cleaned and sanitized by our documented, approved methods. Based on reading of other technical papers, there is no expectation that out NCT must survive immersion in water or other liquid.

# Electromagnetic Immunity

Because our NCT is not intended for “professional” use, we appear to not be required to operate during and after exposure to electromagnetic interference.

# Electrostatic Discharge

We must test that the NCT give accurate measurements 5 seconds after being exposed to electrostatic discharge. The intensity of the discharge is not specified in the standard.

# Low Power Supply Operation

The NCT must give an indication of low battery. Tests must show that the NCT continues to operate at at least 0.1V lower than the point at which low battery indication is displayed.

# Operating Range Limits

We must test that the NCT displays an indication when ambient temperature, subject temperature, or power supply is outside our labeled operating ranges.

# Blackbody Testing

The blackbody used for testing must be accurate within 0.03C (0.05F).

Tests must be made within 1C (2F) of the following blackbody temperatures: 23, 30, 38C (73, 86, 100F).