

IFB #16945

Digital Data Loggers

10/13/16

Amendment 2

1. The amendment hereby replaces the **Required Product Specifications/Features** chart found in Section C, Item #3 (pages 6 and 7 of the IFB):

Original Language:

Required Product Specifications/Features
<i>Device</i>
a. Continuous temperature recording with sufficient memory to store at least 4,000 readings.
b. Records the date and time along with the temperature reading.
c. The ability to log temperatures at least once every 15 minutes
d. Displays temperatures on an active display that sits directly on the outside of the unit and allows reading temperatures without opening unit door.
e. Displays the current and minimum/maximum temperature of a refrigerator or freezer.
f. User can stop and start logging data via the device interface.
g. Device has a button or method to reset the minimum/maximum temperature displayed on at least a daily basis so that the most recent min/max temperatures are always displayed.
h. Device is exclusively powered by battery with a battery life of at least 2 years.
i. Data can be downloaded from the device to a computer.
j. Device has a low battery indicator.
k. Device has an alarm for out of range temperatures with the capability to program the alarm thresholds at: <ul style="list-style-type: none">• <36°F and >46°F (<2°C and >8°C) for the refrigerator• <-58°F and >5°F (<-50°C and >-15°C) for the freezer
<i>Probe and Buffer</i>
a. Device has a detachable probe buffered in a bio-safe glycol solution. The device probe is centered inside of a shatter-resistant glycol bottle, and does not touch the sides of the bottle.
b. The length of the detachable probe is at least 3 feet.
c. The glycol bottle has a method to secure it to maintain a fixed position in the center of the storage unit.
<i>Calibration</i>
a. Device is calibrated by a laboratory with accreditation from the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body <u>OR</u> to the standards set by the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025.
b. The device has a National Institute of Standards and Technology (NIST) Traceable Certificate of Calibration that has the logger's model number, serial number, date of calibration, and measurement results that indicate that the unit has passed the calibration test with accuracy or

uncertainty of +/- 1°F (0.5°C) or better and an operating range of -4 to 104°F (-20°C to 40°C) or better.
c. The device calibration is valid for a period of at least 2 years.
d. Devices are calibrated within one month of scheduled shipping date to ensure longest calibration life upon receipt by the healthcare provider.
<i>Data Download/Software and Hardware</i>
a. The device connects to PC for data downloads via USB and the USB hardware comes standard with the device.
b. The device allows the user to view data that shows logger temperature readings over time and shows the total number of minutes where readings were in the alarmed temperature ranges (via the device interface and through downloaded data).
c. Device data can be downloaded onto a computer in a comma separated values (CSV) file format.
d. User-attended software installation is not required to view/download data or to set preferences.

Revised Language: (changes in bold):

Required Product Specifications/Features
<i>Device</i>
a. Continuous temperature recording with sufficient memory to store at least 4,000 readings.
b. Records the date and time along with the temperature reading.
c. The ability to log temperatures at least once every 15 minutes
d. Displays temperatures on an active display that sits directly on the outside of the unit and allows reading temperatures without opening unit door.
e. Displays the current and minimum/maximum temperature of a refrigerator or freezer.
f. The specification that “User can stop and start logging data via the device interface” has been removed from the requirement list. It is no longer applicable.
g. Device has a button or method to reset the minimum/maximum temperature displayed on at least a daily basis so that the most recent min/max temperatures are always displayed.
h. Device is exclusively powered by battery with a battery life of at least 6 months.
i. Data can be downloaded from the device to a computer.
j. Device has a low battery indicator.
k. Device has an audible alarm and a visual alarm for out of range temperatures with the capability to program the alarm thresholds at:
<ul style="list-style-type: none"> • <36°F and >46°F (<2°C and >8°C) for the refrigerator • >5°F (>-15°C) for the freezer
<i>Probe and Buffer</i>
a. Device has a detachable probe buffered in a bio-safe glycol solution. The device probe is centered inside of a shatter-resistant glycol bottle, and does not touch the sides of the bottle.
b. The length of the detachable probe is at least 3 feet.
c. The glycol bottle has a method to secure it to maintain a fixed position in the center of the storage unit.

<i>Calibration</i>
a. Device is calibrated by a laboratory with accreditation from the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body <u>OR</u> to the standards set by the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025.
b. The device has a National Institute of Standards and Technology (NIST) Traceable Certificate of Calibration that has the logger's model number, serial number, date of calibration, and measurement results that indicate that the unit has passed the calibration test with accuracy or uncertainty of +/- 1°F (0.5°C) or better and an operating range of -4 to 104°F (-20°C to 40°C) or better.
c. The device calibration is valid for a period of at least 2 years.
d. Devices are calibrated within one month of scheduled shipping date to ensure longest calibration life upon receipt by the healthcare provider.
<i>Data Download/Software and Hardware</i>
a. The device connects to PC for data downloads via USB and the USB hardware comes standard with the device.
b. The device allows the user to view data that shows logger temperature readings over time and shows the total number of minutes where readings were in the alarmed temperature ranges (via the device interface and through downloaded data).
c. Device data can be downloaded onto a computer in a comma separated values (CSV) file format.
d. User-attended software installation is <u>not</u> required to view/download data or to set preferences.

2. The amendment hereby replaces IFB Attachment 4 (Technical Response Form) on pages 27 – 29 of the IFB with Attachment 4 Revised 10-13-16 (Technical Response Form).