Urgent: Medical Device Correction

Cardinal Health
15 Hampshire Street
Mansfield, MA 02048
800.292.9332 toll free
847.689.9101 fax
cardinalhealth.com

CardinalHealth

October 29, 2019

Dear Valued Customer:

The purpose of this letter is to notify our customers of an issue related to Genius 2 and Genius 3 Tympanic Thermometers.

Item code	Description	Affected Product
303000	Genius 2 Tympanic Thermometer	All product manufactured after October 1, 2016; Serial Numbers ≥ N16598087
303013	Genius 3 Tympanic Thermometer	All product manufactured after December 4, 2017; Serial Numbers ≥ N17700101

Reason for Notice:
The frequency of calibration for the Genius Tympanic Thermometer as stated in the operating manual may not ensure that thermometers always remain within the stated accuracy range (± 0.2°C for Genius 2 and ± 0.3°C for Genius 3 thermometers). The measurement readings drift upwards over time, which means that the thermometers could exceed the upper stated accuracy tolerance of +0.2°C for Genius 2 or +0.3°C for Genius 3. The potential patient harms include misdiagnosis and/or delay in treatment; however, the likelihood of harm occurring is low. There have been no reports of serious injury or harm to patients.

Cardinal Health is updating the operating manual to require thermometers to be calibrated at an increased frequency as stated in the table below. Copies of the updated documents can be found at:

- Genius 2 - https://www.cardinalhealth.com/content/dam/corp/web/documents/Manual/cardinal-health-genius-2-operating-manual.pdf
- Genius 3 - https://www.cardinalhealth.com/content/dam/corp/web/documents/Manual/cardinal-health-genius3-operating-manual.pdf

The Genius Checker/Calibrator (item codes 303096 and 303097) will need to receive a software update to tighten the calibration tolerance limit, which will ensure the Genius thermometers stay within the accuracy tolerance during the periods between calibration.

Thermometer Model	Current Calibration Frequency	Updated Calibration Frequency
Genius 2 and Genius 3	Once per year (52 weeks)	25 weeks from date of manufacture and every 25 weeks thereafter

The date of manufacture can be identified on the serial number sticker as shown below:

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Action Required:

1. **INSPECT** your inventory for the affected product code(s), serial number(s) and date of manufacture.

2. **IF YOU HAVE ACCESS TO A GENIUS CHECKER/CALIBRATOR:** Calibrate all affected Genius thermometers.
   - Following calibration, contact Cardinal Health Service & Repair to schedule and arrange for the software update on your Genius Checker/Calibrator.

     Monday – Friday between 8:00am - 8:00pm EST
     Service and Repair Line – 877-227-3462, Option 1

   - Once the updated Genius Checker/Calibrator has been returned to your facility, recalibrate all thermometers.

   IF YOU DO NOT HAVE ACCESS TO A GENIUS CHECKER/CALIBRATOR: Contact Cardinal Health Service & Repair to schedule and arrange for your thermometer(s) to be sent to one of our service centers.

   Monday – Friday between 8:00am - 8:00pm EST
   Service and Repair Line – 877-227-3462, Option 1

3. **RETURN** the enclosed acknowledgment form via fax to 614-652-4153 or email to GMB-GeniusFCA@cardinalhealth.com, whether you have affected product or not, indicating the product code, serial number, date of manufacture and quantity of product.

4. **NOTIFY** any customers to whom you may have distributed, or forwarded product affected by this correction. Your notification to your customers may be enhanced by including a copy of this correction notification letter.

If you did not purchase your thermometer(s) directly from Cardinal Health, please contact the supplier from which you purchased the product.

Cardinal Health has notified the U.S. Food & Drug Administration that we are taking this action.

The FDA can be contacted to report any adverse events experienced with the use of these products:

- Online @ http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or email) or call FDA 1-800-332-1088.

In the event you have experienced quality problems or adverse events related to the products listed above, send an email to: GMB-PRComplaints@cardinalhealth.com.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. Should you have any questions, or desire special assistance relating to this product, please feel free to contact Cardinal Health at 800-292-9332.

Sincerely,

Prajesh Patel
Director, QRA Management