URGENT: FIELD SAFETY NOTICE (CORRECTION)

Specific product codes and lots of:

- **Genius 2 & Genius 3 Thermometers**

Manufacturer's Reference: Event-2019-02412

30 October 2019

Attention: Risk Management Director and Materials Management

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 (discontinued)	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

- UK
  - https://www.cardinalhealth.co.uk/content/dam/corp/web/documents/Manual/cardinal-health-genius-2-operating-manual.pdf
- Germany
  - https://www.cardinalhealth.de/content/dam/corp/web/documents/Manual/cardinal-health-genius-2-operating-manual.pdf
- Spain
  - https://www.cardinalhealth.es/content/dam/corp/web/documents/Manual/cardinal-health-genius-2-operating-manual.pdf
- ALL OTHER COUNTRIES:
  - https://www.cardinalhealth.com/content/dam/corp/web/documents/Manual/cardinal-health-genius-2-operating-manual.pdf

Genius 3

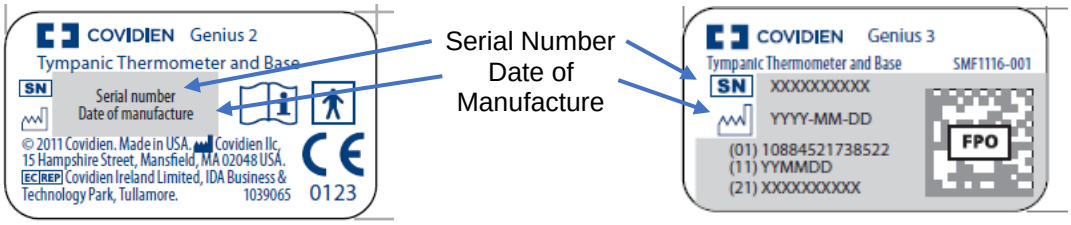
- UK
  - https://www.cardinalhealth.co.uk/content/dam/corp/products/professional-products/ous-patient-recovery/documents/cardinal-health-genius-3-user-manual-2.pdf
- Germany

- https://www.cardinalhealth.de/content/dam/corp/products/professional-products/ous-patient-recovery/documents/cardinal-health-genius-3-user-manual-2.pdf
- Spain
  - https://www.cardinalhealth.es/content/dam/corp/products/professional-products/ous-patient-recovery/documents/cardinal-health-genius-3-user-manual-2.pdf
- ALL OTHER COUNTRIES
  - https://www.cardinalhealth.com/content/dam/corp/products/professional-products/ous-patient-recovery/documents/cardinal-health-genius-3-user-manual-2.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:



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 your Cardinal Health Representative to schedule and arrange for the software update on your Genius Checker/Calibrator.

   - 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 your Cardinal Health Representative.

3. **NOTIFY** Share this communication with all those who need to be aware of it within your organization and to maintain awareness. Also share with any customers to whom you may have distributed, or forwarded product affected by this advisory. Your notification to your customers may be enhanced by including a copy of this advisory notification letter.

4. **RETURN** the enclosed acknowledgment form to your Cardinal Health representative.

The applicable regulatory agencies are being notified that Cardinal Health is voluntarily taking this action. We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions or concerns, please do not hesitate to contact your local sales representative or local sales office.

Sincerely,



Prajesh Patel
Director, QRA Management