Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

# Medical Device Alert

MDA/2020/009 Issued: 27 February 2020 at 14:00

## Tympanic thermometers – revision of the calibration frequency of Cardinal Health Genius 2 and Genius 3 models

## Summary

Manufactured by Cardinal Health – calibration period revised to 25 weeks instead of yearly to ensure these thermometers remain within their accuracy range and reduce the risk of misdiagnosis or delay in treatment.

## Action

- Inspect your inventory for the affected product codes, serial numbers and date of manufacture – see the manufacturer's Field Safety Notice for details.
- If you DO have access to a Genius checker/calibrator, calibrate all affected Genius thermometers.
- Following calibration, contact your Cardinal Health representative to arrange for a software update on your Genius checker/calibrator.
- Once the updated Genius checker/calibrator has been returned to your organisation, recalibrate all thermometers.
- If you DO NOT have access to a Genius checker/calibrator, contact your Cardinal Health representative.
- Amend your procedures to reflect the change in frequency of calibration and ensure that the latest versions of the instructions for use are available.
- Return the acknowledgment form in the Appendix to Cardinal Health.

**Action by**
Healthcare professionals who use these devices.

**Deadlines for actions**
Actions underway: 12 March 2020
Actions complete: 23 April 2020

**Medical Device Safety Officers** (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

**Remember**: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

## Device details

Device Identifier GTIN:

Genius 2 Tympanic Thermometer – 20884521099798

Genius 3 Tympanic Thermometer – 10884521738522

| Manufacturer item code | Description | Affected product |
|---|---|---|
| 303000 | Genius 2 Tympanic Thermometer (discontinued) | All product manufactured after 01 October 2016, Serial Numbers N16598087 and above |
| 303013 | Genius 3 Tympanic Thermometer | All product manufactured after 04 December 2017, Serial Numbers N17700101 and above |

## Background

Cardinal Health issued a Field Safety Notice but have had a poor response from end users acknowledging its receipt.

## Manufacturer contacts

Cardinal Health
Tel: 00800 844 77 384 option 2 / 020 3795 9970 option 2
GMB-CASHEL-RA@cardinalhealth.com

## Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

**Trusts (NHS boards in Scotland)**

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Ambulance services directors
- Ambulance staff
- Audiology departments
- Biomedical engineering staff
- Cardiac laboratory technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons

- Cardiothoracic surgery directors
- Clinical governance leads
- Colposcopy departments
- Community children’s nurses
- Community hospitals
- Community midwives
- Community nurses
- Coronary care departments
- Coronary care nurses
- District nurses
- EBME departments
- ENT departments
- ENT medical staff
- ENT services, directors of
- Equipment stores
- Equipment libraries and stores
- General surgery
- General surgical units, directors of
- Gynaecology departments
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health visitors
- Hospital at home units
- Immunisation co-ordinators
- Infection control departments
- Infection control nurses
- Infection prevention and control directors
- In-house maintenance staff
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maintenance staff
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical libraries
- Medical physics departments
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- NHS walk-in centres
- Nursing executive directors
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Occupational health departments

- Oncology nurse specialists
- Operating department practitioners
- Ophthalmic nurses
- Ophthalmology departments
- Ophthalmology, directors of
- Oral surgeons
- Orthopaedic surgeons
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Peritoneal dialysis units
- Radiation & medical oncology departments
- Renal medicine departments
- Renal medicine, directors of
- Risk managers
- School nurses
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments
- Walk-in centres

**NHS England area teams**

CAS liaison officers for onward distribution to all relevant staff including:

- General practice managers
- General practice nurses
- General practitioners

## *Independent distribution*

**Establishments registered with the Care Quality Commission (CQC) (England only)**

- Adult placement
- Care homes providing nursing care (adults)
- Clinics
- Domiciliary care providers
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

## Enquiries

**England**

Send enquiries about this notice to MHRA, quoting reference number **MDA/2020/009** or **2019/010/031/291/004**.

**Technical aspects**

Dr Philip Davenport or Andy Marsden, MHRA

Tel: 020 3080 6461 / 7205

Email: DSS-TM@mhra.gov.uk

**Clinical aspects**

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

**Northern Ireland**

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

**Scotland**

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

**Wales**

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).

Appendix to MDA/2020/009

# Urgent Field Safety Notice (Correction) (Event-2019-02412)

## Genius 2 & Genius 3 Tympanic Thermometers
## Product Codes 303000 & 303013
## Customer Acknowledgement Form

Cardinal Health is notifying its customers of an issue related to Genius 2 and Genius 3 Tympanic Thermometers. 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.

This action affects all Genius 2 and Genius 3 Tympanic Thermometers.

**Note: This is NOT a product removal.**

| | |
|---|---|
| **Customer Account No. and Name:** | |
| **Customer Contact Name:** | |
| **Customer Address:** | |
| **Sales Representative No. and Name:** | |
| **Sales Rep Contact Details:** | |

Our records indicate that your facility received product subject to the above field safety notice dated 30/Oct/2019.

**Part 1: Letter Acknowledgement (Customer)**
We are aware of the notification of the above Field Safety Notice. We have passed on, or will pass on, the Field Safety Notice to all those who need to be aware within our organization, or to any organization where potentially affected devices may have been transferred. Please select an option below.

_____ We confirm access to a Genius Checker/Calibrator and will calibrate all affected Genius thermometers. Following calibration, we will contact our 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 our facility, we will recalibrate all thermometers.

_____ We confirm that we do not have access to a Genius Checker/Calibrator. We will contact our Cardinal Health Representative.

Please enter quantities of product in Table 1.

_____ _____
Name/Signature: (Customer) Position: (Customer)

_____ _____
Contact Phone Number: (Customer) Date: (Customer)

Please return this completed acknowledgement form to your sales representative as per contact details above or e-mail to GMB-CASHEL-RA@cardinalhealth.com

**OR**

**Part 2: Letter Acknowledgement (Cardinal Health Sales Representative)**
I confirm that this Field Safety Notice has been communicated to the following person/department as the representative(s) of this customer.

_____ I confirm the customer has access to a Genius Checker/Calibrator and will calibrate all affected Genius thermometers. I will schedule and arrange for the software update on the customer's Genius Checker/Calibrator. I confirm that customer is aware that once the updated Genius Checker/Calibrator has been returned to their facility, customer will recalibrate all thermometers.

_____ I confirm the customer does not have access to a Genius Checker/Calibrator. I will schedule and arrange for the customer's thermometer(s) to be recalibrated.

Please enter quantities of product in Table 1.

_____

Customer Representative Name/Position or Customer Department

_____ _____
Name/Signature: Position:
(Cardinal Health Representative)

_____ _____
Contact Phone Number: Date:
(Cardinal Health Representative)

## Table 1

| Product Code | Quantity Requiring Correction per Field Safety Notice |
|---|---|
| 303000 (Genius 2) | |
| 303013 (Genius 3) | |