Urgent Field Safety Notice

Commercial name/Model: *VS-900, N12, N15, N17, N19 patient monitors*
FSCA-identifier: *CP1911-JH01049*
Type of action: *Safety Notice and Device modification*

January, 2020

Attention: [Hospital/Distributor Name]

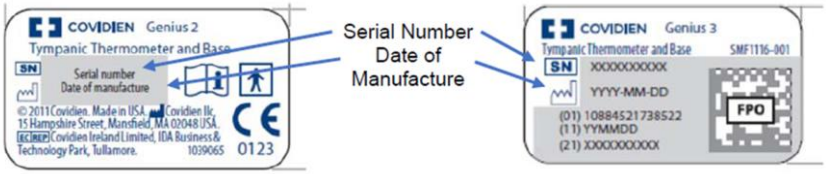
Dear Sir or Madam,

We have received our supplier Cardinal Health's correction notification regarding the issue related to Genius 2 Tympanic Thermometers which are integrated in Mindray*VS900, N17, N12, N15, N19* patient monitors. This letter is intended to provide you with the information. Cardinal Health's noitification letter has been attached in appendix for your reference.

Details on affected devices:

The affected Genius 2 Tympanic Thermometers are manufactured after October 1, 2016 which may distributed with Mindray VS-900 and N-Series (N12, N15, N17, N19) patient monitors or distributed separate as the monitors' accessary. The affected Mindray patient monitors or thermometers are listed in appendix 1 List of Affected devices. The date of Genius 2 Tympanic Thermometers manufacture can be identified on the serial number sticker of Genius 2 Tympanic Thermometers as shown below:

Item code	Description	Affected Product
303062	Genius 2 Tympanic Thermometer – OEM Tympanic	All product manufactured after October 1, 2016; Serial Numbers ≥ N16597907



Description of the problem:

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 which is ± 0.2° C for Genius 2 thermometers. The measurement readings drift upwards over time, which means that the thermometers could exceed the upper stated accuracy tolerance of +0.2° C. 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 has updated the OEM Integration Guide to require the thermometers to be calibrated at an increased frequency as stated in the table below.

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

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

Advise on action to be taken:

(Please be aware the below actions are related to the original manufacturer Cardinal Health.)

Follow the below instructions to calibrate the affected Genius 2 Tympanic Thermometer.

1) **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 Genius Checker/Calibrator has been updated, recalibrate all thermometers.

2) **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 the service centers.

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

The thermometer require to be calibrated every 25 weeks thereafter to ensure it remain within the stated accuracy range.

If you have any problems when calibrate or need further technical support，please contact our supplier Cardinal Health at 800-292-9332 or send an email to: GMB-PRComplaints@cardinalhealth.com.

Transmission of this Field Safety Notice:

This Notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We would be grateful if you could confirm receipt of this letter. Please fill in below Acknowledgement Form and return to Mindray via E-mail or Fax

Mindray Contact reference person:

We apologize for the inconvenience caused by this situation. If you have any other questions, you can also contact with your local Mindray Customer Service Engineer or designated Technical Support Engineer – Jia Liye

Organization: Shenzhen Mindray Bio-Medical Electronics Co., LTD
Tel: 0086-755-81885627

Fax: +86 755 26582680
Email: jialiye@mindray.com

This Notice has been notified the appropriate Regulatory Agency.

(Closing paragraph)

Signature:

Yang Funi
Representative of PMS Quality Center
SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD
Mindray building, Keji 12th Road South, High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R.China
Tel: 0086 755 8188 5627
Fax : 0086 755 26582680
Email : mr@mindray.com

Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

Affected Products : *VS-900, N12, N15, N17, N19 patient monitors*
FSCA : *CP1911-JH01049*
Type of action: *Safety Notice and Device modification*

Please fill in this form and return this confirmation by E-mail or Fax immediately.

Fax: +86 755 26582680
Email: jialiyang@mindray.com

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

_____

_____

Appendix 1 List of Affected Devices.

Country	Commercial name/Model	Serial Number	Distributor/End User	Contact person	Address	Telephone	Email

The commercial name is on the front housing，the serial number is on the main unit label which is on the back of the device. If you do not know how to identify the machine serial number, please refer to below picture:

Figure 1 Front housing（VS-900）

Figure 2 Main Unit Label（VS-900）

Figure 3 Front housing（N19）

Figure 3 Main Unit Label (N19)

Figure 3 Front housing（N12, N15,N17）

Figure 3 Main Unit Label（N12, N15,N17）

Appendix 2 Cardinal Health's noitification letter

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 25, 2019

Dear Valued Customer:

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

Item code	Description	Affected Product
303062	Genius 2 Tympanic Thermometer – OEM Tympanic	All product manufactured after to October 1, 2016; Serial Numbers ≥ N16597907
303063	Genius 2 Tympanic Thermometer – OEM Tympanic	All product manufactured after to December 10, 2017; Serial Numbers ≥ N17606406

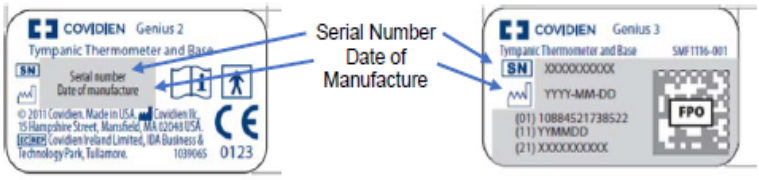
Reason for Notice:
The frequency of calibration for the Genius Tympanic Thermometer as stated in the operating manual may not ensure that thermometers always remain within the stated accuracy range which is ± 0.2°C for Genius 2 thermometers. The measurement readings drift upwards over time, which means that the thermometers could exceed the upper stated accuracy tolerance of +0.2°C. 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 has updated the OEM Integration Guide to require the thermometers to be calibrated at an increased frequency as stated in the table below. A copy of the updated OEM Integration Guide is included with this correction notice. Since the affected product is not a finished device and is further manufactured by your company, we advise that your organization assess the impact of this correction notice on the finished product you produce.

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

Thermometer Model	Current Calibration Frequency	Updated Calibration Frequency
Genius 2	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:



Urgent: Medical Device Correction

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

CardinalHealth

Action Required:

1. **INSPECT** your inventory for the affected product code, serial number 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