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*

Updated date: February, 2020

Attention: [Hospital/Distributor Name]

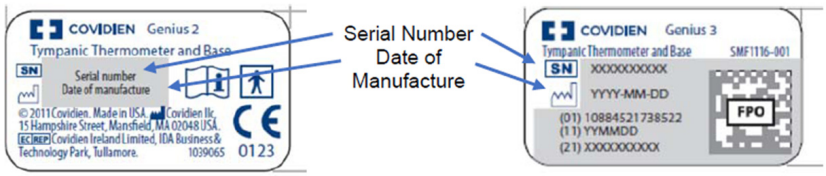
Dear Sir or Madam,

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.

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.

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:

1. Please pass this Notice to all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

2. If any device in your facility is on the affected list, please contact Mindray Service Representative to schedule and arrange for your thermometer to be calibrated.

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

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 questions，please 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: jialiye@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）

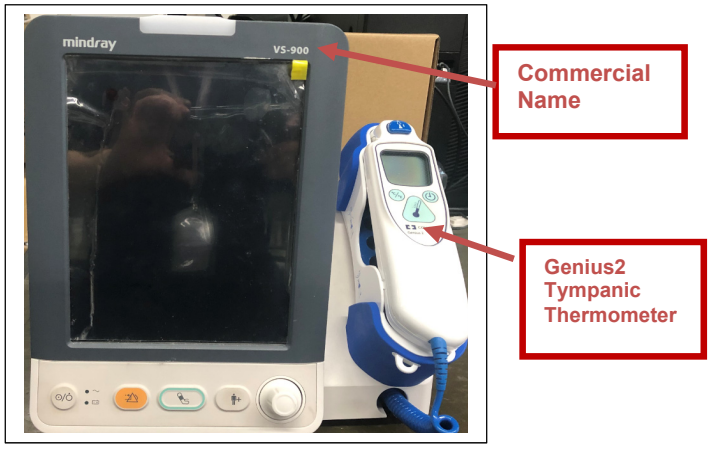

Figure 2 Main Unit Label（VS-900）

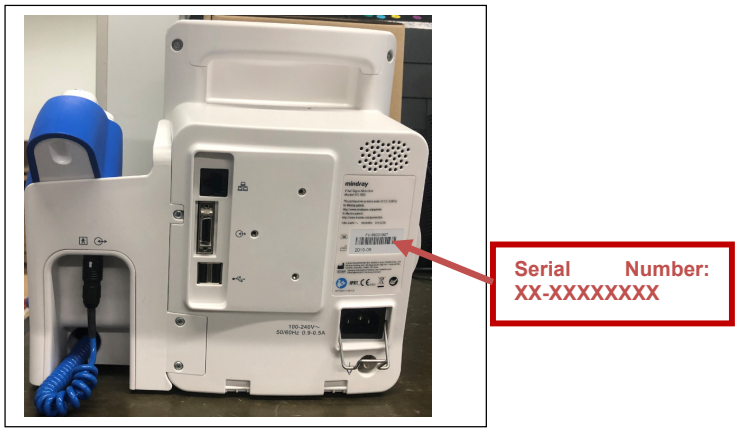

Figure 3 Front housing（N19）

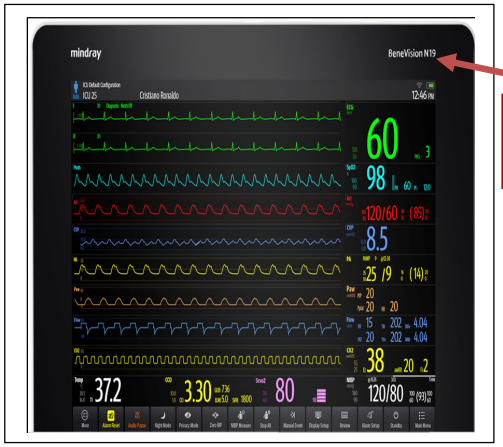

Figure 4 Main Unit Label (N19)

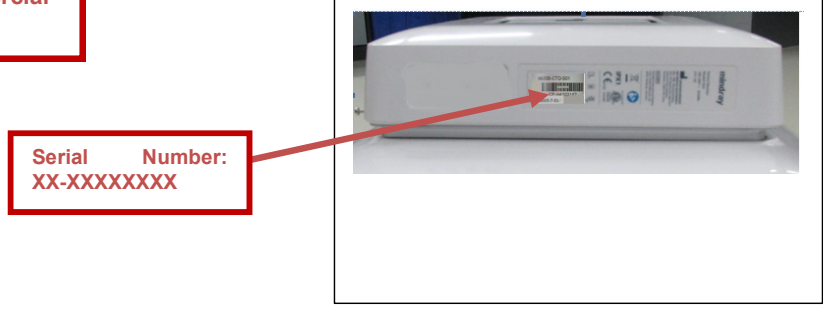

Figure 5 Front housing（N12, N15,N17）

Figure 6 Main Unit Label（N12, N15,N17）