



URGENT: V-SERIES MONITORING SYSTEM CORRECTIVE ACTION

May 19, 2014

Attention:

Please route this letter to all potential users of Mindray's V-Series Monitoring System within your facility.

Identification of the Problem

Mindray has identified issues with the V-Series Monitoring System 12-lead ECG interpretation feature. These issues impact the 12-lead ECG *interpretation* feature only; standard 12-lead ECG monitoring is not affected by these issues.

The following issues are identified:

- The 12-lead Standard and Extended Measurement Report will include false measurements when the P wave or QRS axis cannot be accurately determined by the algorithm.
- The Median Complex and Extended Measurement Report will display the representative beat as 25% larger than actual signal input.
- When a patient date of birth is imported into the V-Series from an external source, such as Mindray's Gateway, e-Gateway, Panorama Central Station or Panorama WorkStation, the age will not pass into the 12-lead ECG interpretation algorithm. The algorithm analysis will use the default adult criteria of "50 year adult" in which case the interpretive statements may be incorrect, depending on the actual age of the patient. Note: When the patient's date of birth is manually entered into the V-Series the correct age is accepted and the appropriate interpretation algorithm is applied.

Any output of the 12-lead ECG interpretation data (e.g. printed records, ECG management system, etc.) will include the issues described above.

There have been no reports of injuries associated with these issues. Mindray is proactively addressing the matter and recommends that you discontinue use of the 12-lead ECG interpretation feature until a software correction is available (anticipated in August 2014).

The V-Series Monitoring System equipped with 12-lead ECG interpretation capabilities distributed between January 31, 2014 and April 9, 2014 is affected by this corrective action.



Adverse Effects on the Patient:

These issues represent a low risk to patients since standard 12-lead ECG monitoring is not affected by these issues and is used as the primary input for ECG analysis; 12-lead ECG interpretation results are typically used secondarily, and in combination with physician review and additional diagnostic tests prior to initiating treatment.

Corrective Action:

Mindray recommends that you discontinue use of the 12-lead ECG interpretation feature until a software correction is available (anticipate in August 2014).

When the software correction is available, a Mindray Service Representative will contact you to schedule the upgrade of the V-Series System(s) in your facility.

In the interim, should you have any questions please contact me directly.

Sincerely,

A handwritten signature in black ink that reads "Diane Arpino". The signature is written in a cursive, flowing style.

Diane Arpino
Director, Regulatory and Clinical Affairs
d.arpino@mindray.com
201.995.8407