

Field Corrective Action

Inspiration® *i* Series Ventilator

Software Version 6.5.0

Details on affected devices:

All Inspiration *i* Series Ventilators running software version 6.5.0

Description of the problem:

eVent Medical has recently become aware that on the Inspiration *i* Series Ventilators running software version 6.5.0 only, during use of the mode PRVC-SIMV only, incorrect volume delivery may occur resulting in over or under patient ventilation.

This means that during use if the ventilation mode PRVC-SIMV is activated, the volume delivered to the patient may be greater than or less than the set tidal volume.

A solution for this issue has been identified and once validated, will be released for installation as an eVent Medical Field Corrective Action.

Advice on action to be taken by the user:

eVent Medical is requesting that all users of the Inspiration *i* Series Ventilator running software version 6.5.0 perform one of the following actions immediately.

