

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.

- **Disable Volume Targeted Ventilation (VTV) Modes** (see step A)

OR

- **Downgrade to Inspiration *i* Series Ventilator software version 6.4.1** (see step B)

Transmission of this Field Safety Notice:

Please pass this Field Safety Notice to all those who need to be aware of it within your organization and maintain awareness until all units with your organization have been upgraded with the new software.

The relevant national Competent Authorities have been advised of this notice.

Contact reference person:

Rick Waters, Vice President RA /QA

(949) 900-1917, x232

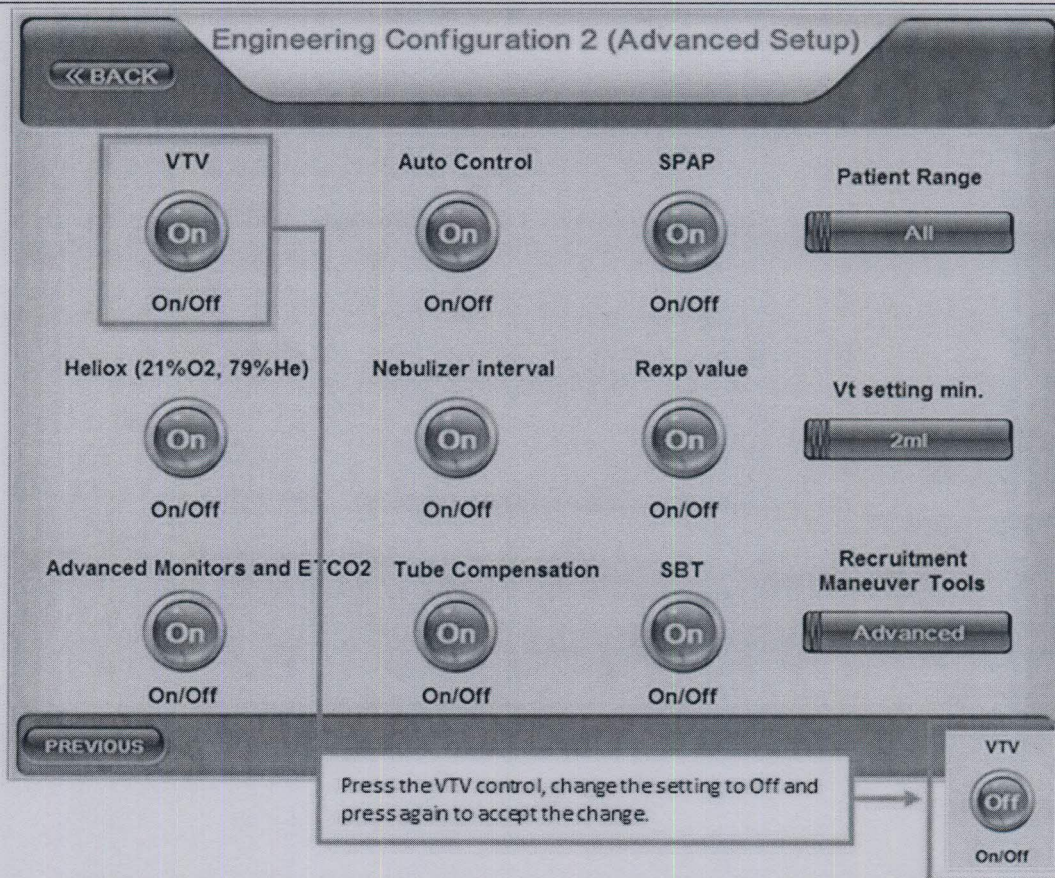
r.waters@event-medical.com

A. To Disable the Inspiration *i* Series Ventilator's VTV Modes follow these steps.

1. From the Patient Startup screen, press the "**Previous Patient**" button in the left panel.
 - Then press the green "**ACCEPT**" button in the right panel.
2. Press the Config. tab in the upper right part of the screen.
 - Then press the "**Technical**" Button in the left panel.
 - Then press the password field in the right panel.
 - Then enter the password 2634 and press the "**OK**" button.

A. To Disable the Inspiration *i* Series Ventilator's VTV Modes follow these steps.

3. Press the “**Engineering**” button in the Technical Settings left panel.
 - Then press the password field in the right panel.
 - Then enter the password 3455 and press the “**OK**” button.
4. From the Service Screens page, press the button labeled “**2.Advanced Setup**”.
 - Then enter the password 4284 and press the “**OK**” button.
 - The Engineering Configuration 2 (Advanced Setup) screen will load as shown below.



5. From the Engineering Configuration 2 (Advanced Setup) screen press the VTV control button.
 - Change the VTV control setting to Off.
 - Then press the VTV control button again to confirm the change.

A. To Disable the Inspiration *i* Series Ventilator's VTV Modes follow these steps.

6. Press the "<<BACK" button to return to the Service Screen page.
 - Then press the "<<BACK" button again to return to the Previous Patient Startup screen.
 - Then press the green "ACCEPT" button in the right panel.
7. From the Settings screen verify that the VTV modes (PRVC-CMV, PRVC-SIMV and VS) are not available as Mode Selection options on the left panel.
 - If the VTV modes are NOT available then the ventilator is ready for patient use and no further action is required at this time.
 - If the VTV modes are available as Mode Selection options, repeat steps 2 – 7.

B. To Downgrade Inspiration *i* Series Ventilator's software from version 6.5.0 to 6.4.1 follow these steps.

1. Verify the ventilator's Power Board software version before proceeding.
 - **If the ventilator's Power Board software version is 3.3.0,**
 - Do NOT downgrade the ventilator's system software to version 6.4.1. Power Board software revision 3.3.0 is not compatible with software version 6.4.1.
 - ✓ Instead, eVent Medical recommends disabling the ventilator's VTV modes as defined above in step A.
 - Please contact our Service department if your ventilator's Power Board software version is 3.3.0 and you wish to downgrade the ventilator's system software to version 6.4.1.
 - **If the ventilator's Power Board software version is 3.2.5, proceed to step 2 below.**
 - If the use of the ventilator's VTV modes is essential prior to the release of the software update which will correct the issue with PRVC-SIMV, then the ventilator's software must be downgraded to version 6.4.1.
 - Software version 6.4.1 is compatible ONLY with Power Board software version 3.2.5.
2. To downgrade Software 6.5.0/4.5.0 to 6.4.1/4.4.2:
 - Click [HERE](#) to download detailed installation instructions and all

B. To Downgrade Inspiration i Series Ventilator's software from version 6.5.0 to 6.4.1 follow these steps.

necessary software files.

- a. Connect the ventilator to your local Ethernet network with a standard Ethernet Cable
 - b. Ensure your PC is connected to the same Ethernet network
 - c. Turn the vent on. Go to the Config Screen and select Technical. Input the code 2634. Select 'Next'. Ensure that DHCP is enabled. You should see an IP Address. This is the IP address of the ventilator.
 - d. Open the Universal Download Tool on your computer. Select Ethernet Connection and input the IP address of the ventilator.
 - e. Next browse and find the Main Software file (.tim) on your computer. Click Next > twice.
2. To downgrade Software 6.5.0/4.5.0 to 6.4.1/4.4.2: *(continued)*
- f. The program will then attempt to connect to the ventilator. Once the connection has been established, the download will begin.
 - g. When the download has finished, do not turn off the ventilator. Close and reopen the Universal Download Tool.
 - h. Browse and find the Graphics Software file (.def) on your computer. Be sure to select the graphics file for your ventilator model (5i, 7i or LS)
 - i. Click Next > twice. The download will begin.
 - j. When the download has completed, restart the ventilator. Verify the software downloads by viewing either the System Information Screen or Fab Test 3