

# Vela® Ventilator

ECRI Response

**VIASYS®**  
HEALTHCARE  
Excellence For Life  
RESPIRATORY CARE

August 10, 2006

To Our Valued Customers:

It has come to our attention that some of our competitors may be presenting an incomplete picture of the Vela® Ventilator based on a recent ECRI evaluation of the ventilator. In the initial ECRI Evaluation of Intensive Care Ventilators, VELA received an unacceptable rating because of the default High Peak Pressure Alarm setting of 75 cmH<sub>2</sub>O. This is a User Selectable Alarm Setting that should be evaluated by the user and set appropriately before applying the ventilator to a patient.

**ECRI, in the same Intensive Care Ventilator Evaluation, also had the following comments about VELA**

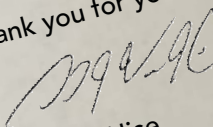
- Performance: **Good**
- Ease of Use: **Excellent**
- Monitoring and Communications: **Good**
- Reliability: **Good**

VELA complies with all local and national regulatory bodies in all 100 countries that it is sold. This includes the US FDA. The default value of 75 cmH<sub>2</sub>O has been present on VELA since its release in 2002. VIASYS has not received any reports regarding patient injury due to this default value. We have always asked users to please ensure that they check their Alarm Settings Screen before attaching the ventilator to a patient and set their alarm values appropriately.

In May 2006 VIASYS Respiratory Care released a software upgrade for VELA to change the default High Peak Pressure Alarm value from 75 to 40 cmH<sub>2</sub>O. This software is available for field installation upon customer request. All new VELA Comprehensive ventilators shipped from our factory since May have had this software installed.

Please note the Excellent and Good ratings that VELA received in this same ECRI evaluation for Ease of Use, Reliability, Quality of Construction and Monitoring. We are proud of the VELA and the units in the field working every day to support life.

Thank you for your support of VIASYS Healthcare's products.

  
Daniel VanHise  
Vice President of Marketing

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ECRI has upgraded the status of VELA to "Acceptable". This upgrade in status was published in their latest Ventilator Evaluation. They also addressed the fact that the software upgrade was done voluntarily by VIASYS and was not pending FDA approval

Monitoring & Communications rated **Good**

- Performance
  - Quality of Construction
  - Reliability
- all rated **Good**



User Interface rated **Excellent** for ease of use

Alarm Default Settings modified to 40 cmH2O High PPEAK

**ACCEPTABLE** reclassification printed in Health Devices, June 2006, Volume 35, Number 6

*ECRI welcomes any inquires into their evaluation of the VELA product line. For direct communications with ECRI please contact:*

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