## REPLY

Dr. Lee and his colleagues have correctly documented the design history of the means for attaching and sealing the bellows cylinder to the housing of the Air-Shields Ventimeter® Controller and Ventimeter® Ventilator. He has also correctly analyzed the consequences of leakage at the bond between the cylinder and the base of the cylinder assembly on the current model Ventimeter® Controller II and Ventimeter® Ventilator II, the effect on conventional low pressure alarms and the Air-Shields airway disconnect alarm, and the means to recognize the problem clinically.

Solvent welding Plexiglas® acrylic plastics is a recognized and accepted bonding means and typically results in a bond as strong as the plastic itself. Based on our investigation we believe the problem of incomplete bonding described by Lee et al. to be restricted to a relatively few units as a consequence of the use of solvent material beyond its rated shelf life. We have therefore imposed closer controls on the manufacturing materials used and have added an in-process bonding check to prevent recurrence of this problem.

While Lee et al. have not quantified the degree of risk, we trust they would agree that the likelihood of a significant increase in the leakage during a procedure is highly unlikely, as would be the failure to detect such an increase by routine monitoring of tidal volume, peak airway pressure and vital signs.

Thank you for this opportunity to comment.

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