

**URGENT – FIELD SAFETY NOTICE**  
**2009-11-16**

**PLEASE FORWARD THIS INFORMATION TO ALL RELEVANT USERS, BIOMEDICAL STAFF AND RISK MANAGEMENT DEPARTMENT IN YOUR FACILITY.**

**Subject: DO NOT USE A DEVICE SYSTEM THAT MAY GENERATE NEGATIVE PRESSURE BELOW -100 cmH<sub>2</sub>O (e.g., CLOSED SYSTEM SUCTIONING) WITH SV300/SV300A AND SV900C/D/E UNITS UNLESS THE VENTILATOR HAS BEEN EQUIPPED WITH NEW TYPE OF PRESSURE TRANSDUCERS**

Dear Customer,

The purpose of this letter is to inform users **not to use** a device system that may generate negative pressure below -100 cmH<sub>2</sub>O (e.g., Closed System Suctioning) with Servo Ventilator 300/300A (SV300) and Servo Ventilator 900C/D/E (SV900) due to the risk of damaging the ventilator's pressure transducers if applied improperly. This could lead to serious injury or death of a patient. The risks involved in such device systems were earlier communicated in a Safety Alert Letter issued in July 2002. Ventilators equipped with new type of pressure transducers are exempted.

**Products affected:**

Product	Serial Number (S/N)
Servo Ventilator 300/300A ("SV300")	00410-24999
Servo Ventilator 900C/D/E ("SV900")	010001-188499

Ventilators, within the above specified serial number range, that are marked with one of the following labels on the inside of the lid of the pneumatic unit are exempted since they have already been fitted with a new type of the pressure transducer:



Label 1 (SV300)



Label 2 (SV900)



Label 3 (SV300/SV900)

In addition, SV300 units with S/N higher than 24999 and SV900 units with S/N higher than 188499 are already equipped with the new type of pressure transducer.

Our records indicate that you have received one or more of these units.

### **Description of the problem**

A negative pressure in the breathing system (e.g. generated by an improper application of Closed System Suctioning) may impair the functionality of the pressure transducers in the ventilator. Such a pressure is created when the suctioning flow exceeds the flow delivered to the patient by the ventilator.

A negative pressure of -100 cmH<sub>2</sub>O or more can damage the pressure transducers in the ventilator and in the unlikely event of a failure of both transducers simultaneously, the ventilator may deliver a high positive pressure.

For the SV300 the maximum pressure delivered is limited by a safety valve opening at a pressure of 120 cmH<sub>2</sub>O. The maximum pressure delivered by the SV900 would correspond to the working pressure, which can be set to a maximum of 120 cmH<sub>2</sub>O, but is normally set to 60 cmH<sub>2</sub>O.

### **Indications**

In the case where both pressure transducers are damaged resulting in delivery of a high positive pressure, a Low Expiratory Minute Volume alarm will be generated.

### **Potential Hazard**

If both pressure transducers in the ventilator are damaged simultaneously the ventilator may deliver a high positive pressure, which can lead to serious injury or death.

### **Precautions**

- Before connecting the ventilator to patient, always perform a Function Check or Pre Use Check as described in the Operating Manuals of SV300 and SV900.
- Do not use any system (e.g. Closed System Suctioning) with the ventilator that may generate a negative pressure below -100 cmH<sub>2</sub>O, unless it is equipped with the new modified pressure transducers.

### **Disclaimer**

*MAQUET will not assume any liability for incidents caused wholly or partly by accessories and/or auxiliary equipment, which has not been manufactured or approved by MAQUET for use with their devices.*

**Corrective action**

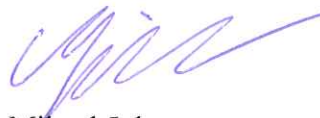
- Distribution of this Field Safety Notice. Please add this letter to all SV300 and SV900 Operating Manuals in your facility.
- Furthermore, an addendum to the Operating Manuals related to this topic will be added to the Preventive Maintenance kits for SV300 and SV900.

Should you have questions or require additional information related to this letter or more specifically to the new type of pressure transducers, please contact your local MAQUET representative.

Sincerely,



Thomas Wetterberg  
Product Manager Ventilation



Mikael Johansson  
Vice President  
Quality & Environment

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