

Medical Device Alert

Action

Ref: MDA(NI)2009-020 Issued: 25 March 2009 at 13:00

Device

All Servo ventilators 300 and 300A with automode function. Manufactured by Maquet Critical Care AB (previously Siemens).



Problem

Risk of inadequate ventilation of neonatal or paediatric patients without warning by any alarm.

Action by

All paediatric intensive care staff using these ventilators.

SABS deadlines

Action underway: 14 April 2009
Action complete: 05 May 2009

Action

Identify if you have any Servo 300 or 300A ventilators that have an automode function.

When using the automode function with either pressure control (PC) or pressure regulated volume control ventilation (PRVC) mode in the neonatal or paediatric patient range, ensure that:

- the set inspiratory rise time is in the range 7-10%
- the water level of the humidifier chamber is maintained according to the manufacturer's recommendations.

Ensure that users are aware of and act on Maquet's Field Safety Notice.

Contact

Manufacturer
Colin Moralee
Maquet Ltd

Tel: 0191 519 6200
E-mail: cmoralee@maquet.co.uk

Device

The Servo ventilators 300 (SV300) and 300A (SV300A) are intended for general and critical care ventilation of adult, paediatric and neonatal patients.

Affected ventilators are those with an automode function.

Automode is a function where two consecutive breathing efforts from the patient will shift the ventilator status from control mode to a support mode. The ventilator will remain in the support mode as long as the patient keeps breathing; if the patient stops breathing the ventilator will shift back to the control mode.

The Servo-I ventilator is not affected by this issue.

Problem

The MHRA is aware of an incident where a reduced inspiration time occurred, with no alarm, during ventilation of a neonate with a Servo ventilator 300A. The automode was on with the trigger level set to the minimum and the patient had no spontaneous breathing. The reduced inspiration time resulted in inadequate ventilation.

When pressure control (PC) or pressure regulated volume control (PRVC) ventilation is used with automode set to 'on' the ventilator cycles to expiration in the controlled mode if the airway pressure exceeds the set/calculated inspiratory pressure by more than 3 cm H₂O. The purpose of this cycle off criterion is to provide a smooth transition from controlled to supported ventilation when the patient starts to trigger the ventilator, since this increase in pressure is interpreted as the patient working against the ventilator.

This phenomenon only occurs with neonatal or paediatric patients with small tidal volumes and set, short inspiratory rise times during either PC or PRVC ventilation. The probability of occurrence increases with larger, compressible volumes in the tubing system (including humidifier chamber) and with a lower resistance of the patient's airways (including tracheal tube).

The manufacturer issued a Field Safety Notice on 15 December 2008 (see appendix).

Distribution

The NIAIC has sent this MDA via SABS to:

- HSC Trust, HSS Board, and Agency's Chief Executive's
- HSC Trust, HSS Board, and Agency's SABS Liaison Officer
- Selected members of the DPSSPSNI
- Hospitals in the independent sector
- Hospices

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Intensive care medical staff/paediatrics
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Paediatric theatres
- Risk managers
- Special care baby units
- Theatre/PICU managers

The Regulation and Quality Improvement Authority (RQIA) to:

Headquarters for onward distribution to:

- Independent treatment centres
- Nursing agencies

Boards to:

SABS liaison officers for onward distribution to:

- Risk manager

Central Services Agency (CSA) to:

SABS liaison officers for onward distribution to all relevant staff including:

- Staff with responsibility for purchasing

Contacts

Manufacturer

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NIAIC

Enquiries in Northern Ireland, please send enquiries about this notice to the NIAIC quoting reference number **MDA(NI)2009-020** and addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523868

Fax: 02890 523900

E-mail: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents

Incidents relating to medical devices in Northern Ireland must be reported to the Northern Ireland Adverse Incident Centre (NIAIC) as soon as possible.

Further information about reporting incidents can be found in DB(NI)2008-001; and downloadable report forms are available from the NIAIC's website (<http://www.dhsspsni.gov.uk/niaic>).

Alternatively, further information and printed incident report forms are available from: NIAIC at the address above.

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the NIAC website

Further information about SABS can be found at <http://sabs.dhsspsni.gov.uk>

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Addressees may take copies for distribution within their own organisations

APPENDIX

MAQUET

URGENT: FIELD SAFETY NOTICE
2008-12-15

PLEASE FORWARD THIS INFORMATION TO ALL RELEVANT USERS AND BIOMEDICAL STAFF IN YOUR FACILITY.

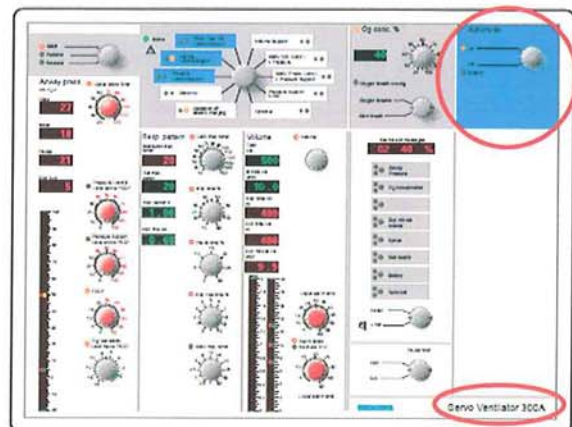
Subject: Short inspiratory times when using Servo Ventilator 300 Automode in Neonatal and Pediatric patient ranges

Dear Customer,

The purpose of this letter is to inform users of Servo Ventilator 300A (SV300A) to set a certain rise time when using the ventilation modes Pressure Control (PC) or Pressure Regulated Volume Control (PRVC) with the **Automode** function set to "On" in the Neonatal and Pediatric patient ranges to avoid potentially too short inspiration times.

Please note that the information in this letter is not applicable for the Automode function in the SERVO-i ventilators.

Products affected: Servo Ventilator 300A



Characteristic markings of the affected device SV300A

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

Description of the reported phenomenon

When PC or PRVC is used with Automode set to "On" the ventilator cycles to expiration in the controlled mode if the airway pressure exceeds the set/calculated inspiratory pressure by more than 3 cmH₂O. The purpose of this cycle off criterion is to provide a smooth transition from controlled to supported ventilation when the patient starts to trigger the ventilator, since this increase in pressure is interpreted as the patient is working against the ventilator.

One case has been reported where the patient was unintentionally hypoventilated in PC with Automode set to "On" (pediatric patient range). The patient had no spontaneous respiratory activity; still the cycle off criteria described above was continuously activated causing short inspiratory times. This case occurred in England (U.K.) and the Competent Authority in this country, MHRA, has received a Medical Device Vigilance (MDV) report from Maquet Critical Care AB and reviewed this Field Safety Notice.

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This phenomenon can only occur in the Neonatal and Pediatric patient categories with small tidal volumes together with set short inspiratory rise times (low end of the possible range 0-10%). The probability of occurrence increases with larger compressible volume of the tubing system (including humidifier chamber) and with lower resistance of the patient airways (including tracheal tube).

Indications

This phenomenon will normally not result in a ventilator generated alarm.

If oxygen saturation (SpO₂) or end tidal carbon dioxide concentration (etCO₂) are monitored the user will be alerted by changes in the patient's values.

Potential Hazard

If the cycle off criterion described above occurs repeatedly during a prolonged period the patient may be insufficiently ventilated which may lead to serious adverse health consequences if the patient is not attended to (i.e. too low ventilation that may cause hypoventilation / hypoxia). However, it is unlikely that this phenomenon will occur. Maquet Critical Care AB has only received one customer complaint regarding this issue since the introduction of Automode in SV300A on a world wide basis in 1996.

Actions to be taken by the hospital/user

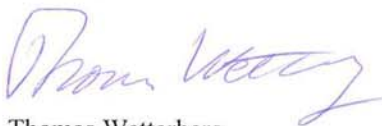
All concerned staff shall be informed about the instructions marked below.

When using the **Automode** function in the SV300A with either Pressure Control or Pressure Regulated Volume Control ventilation mode in the Neonatal or Pediatric patient range, the user shall:


- Set Inspiratory rise time in the range 7-10 %
- Maintain the humidifier chamber water level according to the manufacturer's recommendations

We apologize for any inconvenience this issue may have caused you. Should you have questions or require additional information related to this matter, please contact your local MAQUET representative.

Sincerely,



Thomas Wetterberg
Product Manager Ventilation



Mikael Johansson
Vice President
Quality & Environment

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