NSW HEALTH

Safety Alert 003/09

26 June 2009

Draeger Medical Babylog 8000 Plus Neonatal Ventilator

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

For response by:

- Directors of Clinical Governance

We recommend you also inform:

- Directors of Ambulance Services
- Directors of Neonate Emergency Transfer Services
- Directors of Anaesthesia & Surgery
- Directors of Biomedical Engineering
- Directors of Emergency Medicine
- Directors of Intensive Care
- Directors of Neonatal Intensive Care
- Directors of Paediatric intensive Care
- Directors of Medical Services
- Directors of Specialty Training Units
- Directors of Nursing and Midwifery
- Medical staff
- Nurses and Midwives

Deadline for completion of action

3 July 2009

Expert Reference Group

- Qld Health
- SA Department of Health
- Statewide Services NSW Health

Quality and Safety Branch

NSW Department of Health
Tel. 02 9391 9200
Fax. 02 9391 9556
Email: SAFETYALERTS@doh.health.nsw.gov.au
Website: http://www.health.nsw.gov.au/quality/sabs/index.html

Background

On 1 June 2009, Queensland Health released a Patient Safety Advisory relating to the Draeger Medical Babylog 8000 Plus. The advisory highlighted that there have been false alarms reported when the volume guarantee (VG) option is selected. The advisory alarm, "Flow sensor dirty? Please clean sensor" has also been noted to intermittently display even though the flow senor and associated circuitry may not be at fault. Queensland Health has advised they are liaising with Draeger Medical and the issue has been reported to the TGA.

Specific Incident

When the ventilation mode on a Draeger Babylog 8000 Plus ventilator was changed from SIPPV mode to SIPPV with volume guarantee, the ventilator produced a "Flow Sensor Dirty" alarm. At the time, the device did not register any breaths or VT when clearly the baby was receiving breaths and the chest wall was well expanded with each breath. The VT was set at 3.8mls, PIP at 24. The ventilator alarmed and suggested more PIP was required. The ventilator continued to alarm with various messages, dirty flow sensor; VT low; apnoea or tube obstructed when this was not the case. The ventilator was changed to an older Draeger model and it was noted that with the same settings (PIP 22 and VT 2.9mls) the ventilator only required a PIP of 6 - 7 to maintain the same VT.

Mandatory actions for Area Health Services

- Operators of the Babylog 8000 ventilator are aware of the reported issues as outlined in this notice and the reference documents issued by Queensland Health and South Australian Department of Health.
- Operators of the Babylog 8000 ventilator closely monitor the ventilator display, particularly when using volume guarantee.
- If the advisory alarm "Flow sensor dirty? Please clean sensor!" is displayed, please follow the manufacturer's recommendations in the Operators Manual of replacing the sensor.
- If the alarm continues following corrective action, the ventilator should be removed from clinical service for evaluation by local Biomedical Engineering Services.
- Any adverse events associated with this device are to be reported using the current NSW incident reporting system.

References

- Queensland Health Patient Safety Advisory, Number 4, 1 June 2009. http://www.health.qld.gov.au/patientsafety/documents/advis_0904.pdf
- SA Department of Health Safety Notice SN 07/09 Available on http://www.health.nsw.gov.au/quality/sabs/

Action required by Area Health Services

1. Ensure that this safety notice is distributed to all clinical staff involved in the use of Babylog 8000 Plus neonatal ventilators.
2. All Area Health Services with units currently using the Draeger Babylog 8000 Plus neonatal ventilator complete an inventory and testing to ensure all devices are in working order.
3. All Area Health Services with units currently using the Draeger Babylog 8000 Plus neonatal ventilator complete a risk assessment to ensure the availability of adequate ventilation devices to manage potential patient demand.
4. Any adverse events associated with this device are to be reported using the current NSW incident reporting system.

Made Obsolete September 2022
Note: Actions to be completed by 3 July 2009

Queensland Government
Queensland Health

patient safety ADVISORY

Advisory Number 4, 1 June 2009

Subject	*Babylog 8000 plus Neonatal Ventilator (Draeger)*
Issued by	*Patient Safety Centre*
Issue date	*1 June 2009*
Authority	*Queensland Health Patient Safety Executive Committee*
Issue	1. *False alarms have been reported in a number of Babylog 8000 plus ventilators when the volume guarantee (VG) option is selected. The VG option is available in the ventilation modes of Synchronized Intermittent Positive Pressure Ventilation (SIPPV), Synchronized Intermittent Mandatory Ventilation (SIMV) and Pressure Support Ventilation (PSV).* 2. *The advisory alarm "Flow sensor dirty? Please clean sensor!" has been noted to intermittently display where it has been observed by Biomedical Technology Services (BTS) and Draeger Medical that the*

Contact Us:

Patient Safety Centre
P O Box 152
RBWH HERSTON QLD 4029

Email: psc@health.qld.gov.au
Telephone: 3636 9711
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http://www.health.qld.gov.au/patientsafety

patientsafety centre

	flow sensor and associated circuitry may not be at fault.
Specific Incident	*When the ventilation mode on a Draeger Babylog 8000 plus ventilator was changed from SIPPV mode to SIPPV with volume guarantee, the ventilator produced a "Flow Sensor Dirty" alarm.* *At the time, the device did not register any breaths or VT when clearly the baby was receiving breaths and the chest wall was well expanded with each breath. The VT was set at 3.8mls, PIP at 24. The ventilator alarmed and suggested more PIP was required.* *The ventilator continued to alarm with various messages, dirty flow sensor; VT low; apnoea or tube obstructed when this was not the case.* *The ventilator was changed to an older Draeger model and it was noted that with the same settings (PIP 22 and VT 2.9mls) the ventilator only required a PIP of 6 - 7 to maintain the same VT.*
Requested Action	***Executive Directors of Medical Services and Directors of Neonatal Services/Neonatal Intensive Care Units**:-* 1. *Ensure operators of the Babylog 8000 plus ventilator are aware of the reported issues as outlined in this Advisory.* 2. *Ensure that operators of the Babylog 8000 plus ventilator closely monitor the ventilator display, particularly when using volume guarantee.* 3. *If the advisory alarm "Flow sensor dirty? Please clean sensor!" is displayed; please follow the manufacturer's recommendations in the Operators Manual of replacing the sensor.* 4. *If the alarm continues following corrective action, the ventilator should be removed from clinical service for evaluation by local Biomedical Technology Services.* 5. *Ensure any adverse events associated with this device are logged in PRIME Clinical Incidents.* 6. *Notify Linda McCormack A/Director Patient Safety Centre (07) 3636 6881 or Pete Losin, Director - Biomedical Policy and Planning telephone (07) 3131 6717 with any concerns about the device or instructions.* ***Queensland Health will ensure that:*** 1. *Biomedical Technology Service and the Patient Safety Centre liaise with the manufacturer and Therapeutic Goods Administration with regards to investigation and management of the Babylog 8000 plus ventilator.* 2. *Patient Safety Centre will notify District Chief Executive Officers of outcomes of above actions.*
Distribution List	***Action officers: -*** ▪ *Executive Directors of Medical Services and Directors Neonatal*

	Services /Neonatal Intensive Care:- o *Please read and distribute the advisory to all relevant medical staff.* ▪ *District Directors of Nursing Services* o*Please read and distribute the advisory to all relevant nursing staff.* ***Copies to – For information only:-*** ▪ *Director-General* ▪ *CEO Centre for Healthcare Improvement* ▪ *District Chief Executive Officers* ▪ *Biomedical Technology Services*
Contacts	▪ *Linda McCormack, A/Director Patient Safety Centre* *(07) 3636 6881; linda_mccormack@health.qld.gov.au* ▪ *Pete Losin, Director - Biomedical Policy and Planning* *(07) 3131 6717; pete_losin@health.qld.gov.au*
Advisory	"An **Advisory** communicates 'lessons learned' from serious adverse events to raise awareness"

Revision	Date	Author/s	Amendments
1.0	26 May 2009	Linda McCormack	Initial version (draft)
	2 June 2009	Dr Maarten Kamp	Approved

Government of South Australia
Department of Health

Safety Notice

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Issued by SA Department of Health, Quality and Safety Unit
Tel 08 8226 7454, Fax 08 8226 0725, http://www.safetyandquality.sa.gov.au

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24 June 2009

A patient **Safety Notice** strongly advises the implementation of particular recommendations or solutions to improve quality and safety.

We recommend you inform:

- Chief Executives
- General Managers
- Directors of Clinical Governance
- Biomedical Engineering
- Medical Directors
- Clinical Directors
- Nursing Directors
- Clinical Risk Managers
- Safety Managers

SAfety & quality

June 2009

Draeger Medical Babylog 8000 plus Neonatal Ventilator

Background

On 1 June 2009, Queensland Health released a Patient safety Advisory relating to the Draeger Medical Babylog 8000. The advisory highlighted that there have been false alarms reported when the volume guarantee (VG) option is selected. The advisory alarm, "Flow sensor dirty? Please clean sensor" has also been noted to intermittently display even though the flow senor and associated circuitry may not be at fault.

Queensland Health has advised they are liaising with Draeger Medical and the issue has been reported to the TGA.

Action Required by Health Services

Health services are required to ensure:

1. Operators of the Babylog 8000 ventilator are aware of the reported issues as outlined in this notice and the attached advisory issued by Queensland Health.

2. Operators of the Babylog 8000 ventilator closely monitor the ventilator display, particularly when using volume guarantee.

3. If the advisory alarm "Flow sensor dirty? Please clean sensor!" is displayed; please follow the manufacturer's recommendations in the Operators Manual of replacing the sensor.

4. If the alarm continues following corrective action, the ventilator should be removed from clinical service for evaluation by local Biomedical Engineering Services. Biomedical Engineering to notify the Safety & Quality Unit directly on evaluation outcomes.

5. Any adverse events associated with this device are logged in AIMS

Note: Actions to be completed by 3 July 2009

Notification of Compliance

Safety Alert Broadcast System (SABS) Officers are to:

1. Confirm receipt of this alert by email at SABS@health.sa.gov.au by Friday 26 June.

2. Report on whether or not your health service uses these Babylog 8000 ventilators?

   If yes, have the ventilators exhibited the described problems?

   Please report by Friday 3 July.

Attachment

Queensland Health Patient Safety Advisory, Number 4, 1 June 2009.