



Safety Notice 018/18

Newborn Self-Inflating Bag (SIB) resuscitators

27 November 2018

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Neonatology
- Neonatal Intensive Care Unit Managers/Staff
- Special Care Nursery Managers/Staff
- Midwifery Unit Managers/Staff
- Directors of Paediatrics
- Directors of Emergency
- Emergency Department Managers/Staff
- Ambulance Service NSW
- Newborn and Paediatric Emergency Transport Service
- Directors Medical Services
- Directors of Nursing/Midwifery

Expert Reference Group

Content reviewed by:

- Perinatal Services Network
- Maternity, Child, Youth and Paediatrics Department
- Office of the Chief Health Officer
- HealthShare NSW
- Director Patient Safety

Clinical Excellence Commission

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Internet Website:
<http://www.health.nsw.gov.au/sabs>

Intranet Website
<http://internal.health.nsw.gov.au/quality/sabs/>

Review date

November 2019

Situation

Newborn SIB resuscitators which have not passed all testing categories in a newly published research study are in use in NSW.

Background

In October 2018, University of Sydney researchers published an article on their results of newborn SIB resuscitator testing. In this research, 20 models of SIBs were bench tested with precision robotic testing of safety and reliability against four criteria (minimum average tidal volume delivered, variability in volume delivered, peak inflation pressure delivered and minimum compression required to deliver ventilation). Ten models did not pass all four testing criteria. These items had passed International Standards Organisation (ISO) criteria. Manufacturers of SIBs are guided by the ISO as to the performance required to provide effective ventilation of neonates.

A search of purchasing data from HealthShare NSW demonstrated that most sites stock newborn SIBs which passed testing in all categories, however, a small number of sites have purchased SIBs which failed testing methodology for peak inflation safety limits. These sites have been contacted directly.

There is potential that other sites may have SIBs which failed testing methodology without the knowledge of HealthShare NSW, if sites have purchased SIBs directly from vendors.

There have been no clinical adverse events reported in NSW related to the function of newborn SIBs in the Incident Information Management System (IIMS).

Assessment

Clinical experts have advised that SIB resuscitators which have not passed all testing criteria has the potential to cause harm to neonates.

Recommendation

NSW Health recommends that sites review products in view of this research and consider purchase of neonatal SIB resuscitators from manufacturers which have passed testing in all categories. The recommended manufacturers that currently supply NSW include:

- Laerdal
- Ambu
- Teleflex Medical (Galemed, Mayo)
- Intermed Medical (Headstar)

Please note: This information is only related to newborn SIBs. Paediatric and adult SIB resuscitators were not tested as part of this research.

Reference: Tracy MB, Halliday R, Tracy SK, et al. Newborn self-inflating manual resuscitators: precision robotic testing of safety and reliability. Archives of Disease in Childhood - Fetal and Neonatal Edition Published Online First: 18 October 2018
<https://fn.bmj.com/content/early/2018/10/18/archdischild-2018-315391>

Recommended actions by Local Health Districts/Networks

1. Forward information to appropriate areas for action.
2. Remove newborn SIB resuscitators which are not listed in the above recommended manufacturers list from use immediately once replacement stock is available.
3. If newborn SIB resuscitators not listed in the above recommended manufacturer's list are located, please notify CEC-Recalls@health.nsw.gov.au.
4. Report problems related to newborn self-inflated bag resuscitators systems and any related adverse clinical events to the Therapeutic Goods Administration at: [TGA](http://www.tga.gov.au) and via IIMS.
4. Document actions taken.