Australian Government

Department of Health

Therapeutic Goods Administration

Recall Action Notification

Babylog VN500, Evita V300 and Evita V500

Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- **Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.**
- **More information about Australian recall actions is available at <**http://tga.gov.au/safety/recalls-about.htm**>**
- **If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <**http://www.healthdirect.org.au/**>**

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989. Copyright restrictions apply to the System of Australian Recall actions (SARA) <http://tga.gov.au/about/website-copyright.htm>.

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2021-RN-01771-1
Product Name/Description[iii]	Babylog VN500, Evita V300 and Evita V500 Software version SW2.60 and lower. ARTG 92177 (Draeger Australia Pty Ltd Ventilator, adult) ARTG 158739 (Draeger Australia Pty Ltd - Ventilator, adult) ARTG 170141 (Draeger Australia Pty Ltd - Ventilator, intensive care, neonatal/pediatric)
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	25/08/2021
Responsible Entity[vii]	Draeger Australia Pty Ltd
Reason / Issue[viii]	Draeger have become aware of sporadic cases in which the ventilators restarted unintentionally. In the rare reported cases, an error in the data processing of the activated CO2 measurement caused the restart of the ventilation unit. Devices without integrated or with a disabled CO2 measurement function are not affected. During the restart, the ventilation is temporarily interrupted, and an audible alarm is activated by the auxiliary acoustic alarm system. The breathing system is opened to the ambient air during the restart to potentially allow the patient to breathe spontaneously. Opening the breathing system to ambient causes a loss of ventilation support from the ventilator including PEEP. The ventilation unit is restarted and after approximately 8 seconds automatically resumes ventilation at the identical settings prior to the restart. There have been no reports of injury in relation to this matter to date.
Recall Action[ix]	Product Defect Correction

Recall Action Instructions[x]	Customers are advised, if the information from this Product Defect Correction is considered, the devices can remain in operation. The behaviour can be effectively prevented by not activating the integrated CO2 measurement. If necessary, external CO2 monitoring can be used. Draeger has started to develop a software correction and global customers will be provided with an updated software version as soon as it becomes available. The release of a corrected software is expected to be available in Q4 of 2021. If an external CO2 monitoring device is not available, or if the use of the integrated CO2 measurement function is required, customers are advised to inspect your stock and quarantine the impacted device to prevent use, until the software correction has been implemented.
Contact Information[xi]	0459 956 368 - David Gladman (Draeger)

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- **Wholesale** - includes wholesalers and state purchasing authorities.
- **Hospital** - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- **Retail** - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- **Consumer** - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification**: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- **Class I** - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death.
- **Class II** - A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
- **Class III**- A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

[vi] Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action**: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation.

There are four distinct recall actions – recall, product defect correction, hazard alert and product defect alert.

- **Recall** - The permanent removal of an affected therapeutic good from supply or use in the market.
- **Product defect correction** - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- **Hazard alert** - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
- **Product defect alert** - Information issued to raise awareness about issues or deficiencies for a therapeutic good where a recall action will result in interruption of patient treatment or a medicine shortage, including advice to reduce potential risks of using affected goods.

[x] Recall Action Instructions: What customers with affected goods should do.

[xi] Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.

** These definitions are applicable to the 2017 URPTG (Implemented from Jan 15 2018). Recall Action types and Recall Action Classifications prior to 15 Jan 2018 can be found at:
https://www.tga.gov.au/sites/default/files/recalls-urptg-170412.pdf