Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2016-RN-00143-1
Product Name/Description[iii]	Carestation 620 A1, 650 A1, and 650c A1 Anaesthesia devices and service kits Serial Numbers: Carestation 620 A1 (GTIN: 00840682103985): SM615020004WA to SM616010008WA Carestation 650 A1 (GTIN: 00840682103947): SM715020005WA to SM716010008WA Carestation 650c A1 (GTIN: 00840682103954): SM815020001WA to SM815500001WA Service kits affected 2071003-001-S , BTV SWITCH ASSEMBLY 2081000-001-S , ASSY BOTTOM BC 2082466-001-S, ASSY BOTTOM BC AUS FEMALE 22 ARTG Number: 93955
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	4/02/2016
Responsible Entity[vii]	GE Healthcare Australia Pty Ltd
Reason / Issue[viii]	GE Healthcare has recently become aware of a potential safety issue with the BTV switch of certain Carestation 600 Series Anaesthesia systems. The BTV switch could become difficult to move between mechanical ventilation and manual bag modes or remain in a position where it is not possible to ventilate the patient using the anaesthesia system. This issue could result in loss of patient ventilation potentially resulting in hypoxia. There have been no customer complaints or injuries reported as a result of this issue.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	GE Healthcare is advising users that the systems can continued to be used. However users should ensure back up ventilation, independent of the anaesthesia machine is available. GE is advising users all affected devices will be corrected.
Contact Information[xi]	1800 659 465 - GE National Call Centre

Footnotes

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

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