# Recall detail

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|---|---|
| **Type of Product**[i] | Medical Device |
| **TGA Recall Reference**[ii] | RC-2014-RN-01266-1 |
| **Product Name/Description**[iii] | Defibrillation Electrode for Children (Leonhard Lang) used with GE defibrillators<br><br>Product Codes: 2059144-001 & 2059144-005 (DF69, 50461)<br><br>Lot numbers: 21003-0770, 21113-0777 & 21220-0771<br><br>ARTG number: 208134 |
| **Recall Action Level**[iv] | Hospital |
| **Recall Action Classification**[v] | Class I |
| **Recall Action Commencement Date**[vi] | 4/12/2014 |
| **Responsible Entity**[vii] | GE Healthcare Australia Pty Ltd |
| **Reason / Issue**[viii] | Following an internal investigation triggered by reports in the field, it was identified that during the use of these defibrillation electrodes a possibility for arcing and a resulting malfunction exists. This could lead to a situation, in which a patient who is in a life threatening situation requiring a defibrillation can receive such therapy only with a delay or not at all. In such a situation the inability to defibrillate or a delay in doing so can as a consequence lead to the death or severe injury of the patient. This potential malfunction can occur with these electrodes after a duration of storage of about 2 years or more. |
| **Recall Action**[ix] | Recall |
| **Recall Action Instructions**[x] | Customers are advised to quarantine affected lot numbers and return for replacement |
| **Contact Information**[xi] | 1800 659 465 - GE Healthcare National Call Centre |

# 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