

## Recall detail

Type of Product <sup>i</sup>	Medical Device
TGA Recall Reference <sup>ii</sup>	RC-2015-RN-00266-1
Product Name/Description <sup>iii</sup>	Harris Oxygen Flowmeter  Model Numbers: 86630LOX and 86630LAIR (labelled as "Model 866")  All Lot Numbers  ARTG No. 140296
Recall Action Level <sup>iv</sup>	Hospital
Recall Action Classification <sup>v</sup>	Class II
Recall Action Commencement Date <sup>vi</sup>	15/04/2015
Responsible Entity <sup>vii</sup>	HGEA Pty Ltd
Reason / Issue <sup>viii</sup>	Fisher & Paykel Healthcare Pty Ltd is issuing this recall for product correction on behalf of the Harris Products Group as there have been two reports of confusion due to mislabelled measurement lines on the model 86630LOX flowmeter. The measurement lines are labelled for ArCO <sub>2</sub> gas and not Oxygen gas. There have been no reports of injury to date, however there is potential to set up an incorrect flow of Oxygen or Air gas to a patient.  Note: even though there have been no reports involving the air flow meter, it is being included in this recall as it also uses an ArCO <sub>2</sub> labelled tube.
Recall Action <sup>ix</sup>	Recall for Product Correction
Recall Action Instructions <sup>x</sup>	Harris Products Group is supplying the correction labels to all affected customers. This label is to be affixed to the flow meter to correctly read the flow of Oxygen or Air gas
Contact Information <sup>xi</sup>	03 9879 5022 - Fisher & Paykel Healthcare

## Footnotes

<sup>i</sup> Type of Product: Medicine, Medical Device, or Biological

<sup>ii</sup> TGA Recall Reference: Unique number given by the TGA

<sup>iii</sup> 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.

<sup>iv</sup> 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.