Medical Safety Information
Pharmaceuticals and Medical Devices Agency

Pmda No.2 November, 2007

Recall of Resuscitators

POINT Key points for safe use

1 Request for cooperation in the voluntary recall of resuscitators

- Among manual resuscitators (commonly known as "Ambur bags"), there are some products in which the expiratory valve becomes occluded when ventilation is operated under high oxygen flow. Therefore, the voluntary recall of resuscitators is currently being conducted and your cooperation is requested.
- The Ministry of Health, Labour and Welfare (MHLW) has already issued a notification on this matter. If you possess a resuscitator which is not listed in the notification, please contact the Pharmaceutical and Food Safety Bureau of the MHLW.

HPB/GAD Notification No. 0914001 issued by the General Affairs Division of the Health Policy Bureau, MHLW, and PFSB/SD notification No. 0914001 issued by the Pharmaceutical and Food Safety Bureau, MHLW on September 14, 2007
"Voluntary Recall of Manual Resuscitators (Request)"

The notification on this matter has been uploaded onto the Pharmaceuticals and Medical Devices Information website (http://www.info.pmda.go.jp/mdevices/md2007-0914003.html) (in Japanese).

2 Products targeted for recall

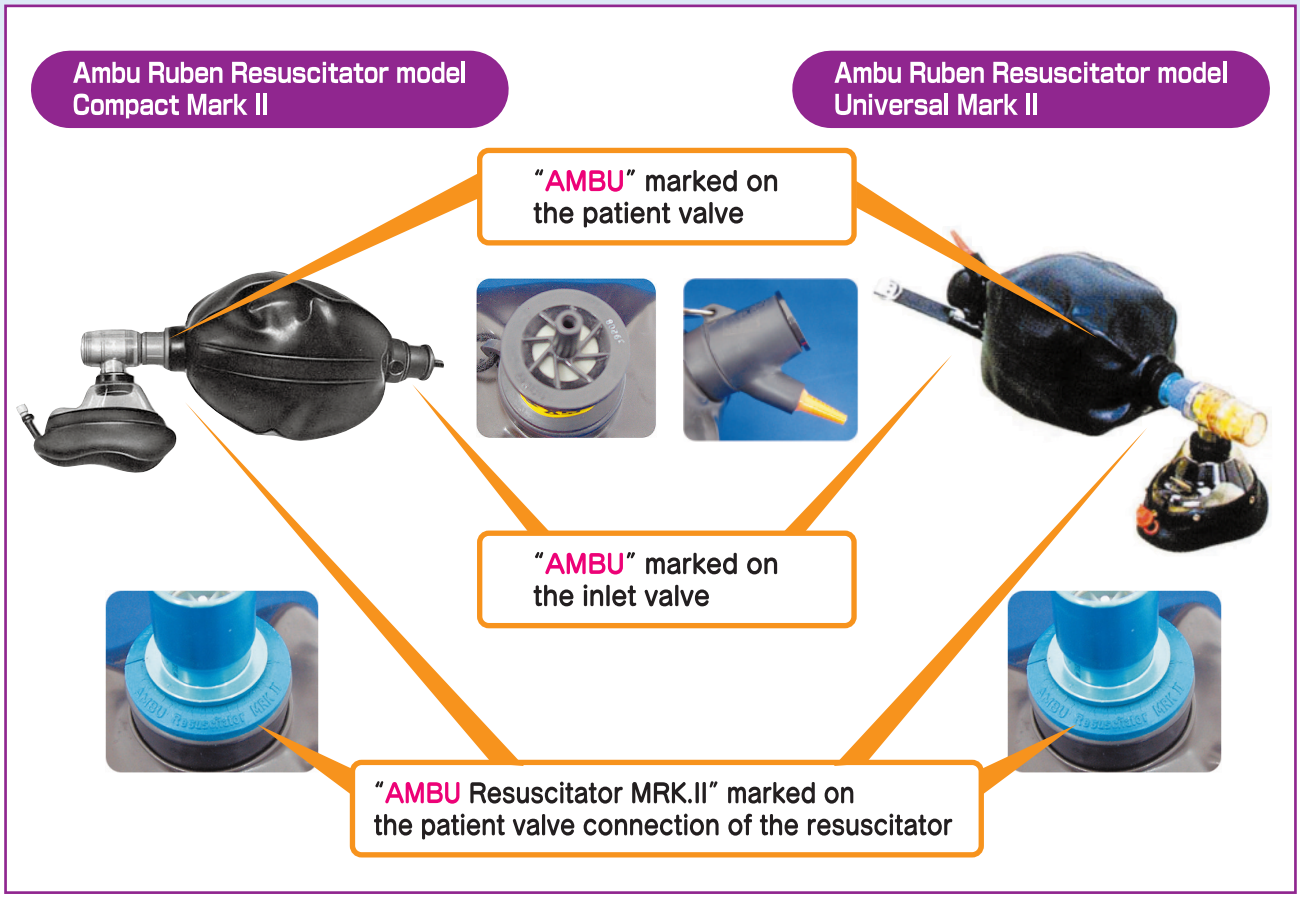
- Products targeted for recall are listed and shown in the following table and pictures. Please contact the relevant manufacturer/distributor, if you possess any of these products.

For more information on the voluntary recall, please see the Pharmaceuticals and Medical Devices Information website:
http://www.info.pmda.go.jp/kaisyuu/kaisyuu2007-1-538.html
http://www.info.pmda.go.jp/kaisyuu/kaisyuu2007-1-539.html
http://www.info.pmda.go.jp/kaisyuu/kaisyuu2007-1-540.html (in Japanese).

List of Products Targeted for Voluntary Recall

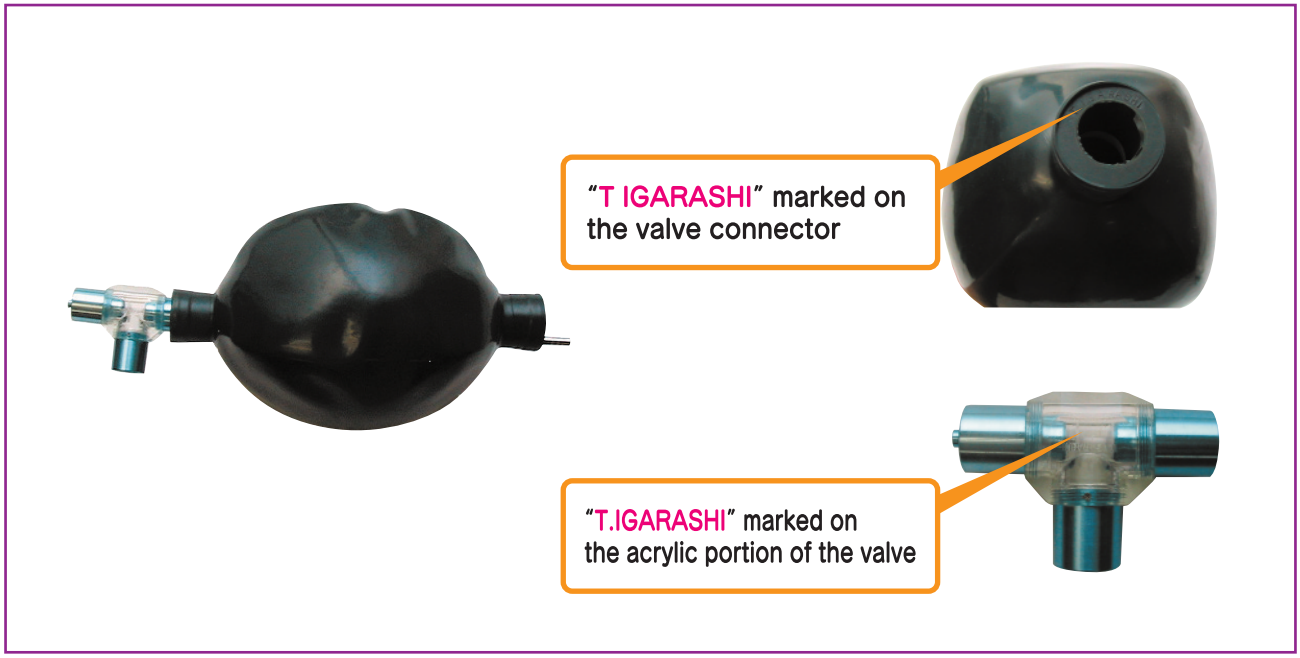
Manufacturer/ Distributor	Brand Name (Name written on the certificate of approval)	Maximum Oxygen Flow
Ambu A/S / IMI Co., Ltd. <Picture 1>	Ambu Ruben Resuscitator model Compact Mark II Period of Sale: November 1970 - December 1997	up to 8 L/min
	Ambu Ruben Resuscitator model Universal Mark II Period of Sale: November 1970 - December 1997	up to 8 L/min
	Ambu Emergency Set Period of Sale: November 1977 - December 1997	up to 8 L/min
	Casualty Rescue Set (Ambu Casualty Rescue Kit) Period of Sale: February 1978 - December 1997	up to 8 L/min
Igarashi Ikakogyo Co., Ltd. <Picture 2>	Pana Bag (Constituents: "Pana Bag main body" and "TI valve") Period of Sale: December 1977 - June 2001	up to 10 L/min
Blue Cross Emergency Co., Ltd. <Picture 3>	Blue Cross Silicone Resuscitator Period of Sale: August 1985 - January 2006 (Note: Old products before design change sold during the above period of sale.)	up to 12 L/min (for adults) / up to 6 L/min (for newborn infants)
	Emergency Medical Set with Oxygen Inhalation Set Oxygen Inhalation Emergency Resuscitation Kit Emergency Oxygen Artificial Resuscitator Emergency Oxygen Resuscitator Period of Sale: December 1990 - June 2006 (Note: Old products before design change sold during the above period of sale.)	up to 12 L/min (for adults) / up to 6 L/min (for newborn infants)
	Emergency Medical Set Emergency Resuscitation Set Emergency Artificial Resuscitator Emergency Resuscitator Period of Sale: December 1990 - June 2006 (Note: Old products before design change sold during the above period of sale.)	up to 12 L/min (for adults) / up to 6 L/min (for newborn infants)

Picture 1: IMI Co., Ltd. Products



For product inquiries contact: IMI Co., Ltd. +81-48-988-4410, +81-48-988-4440

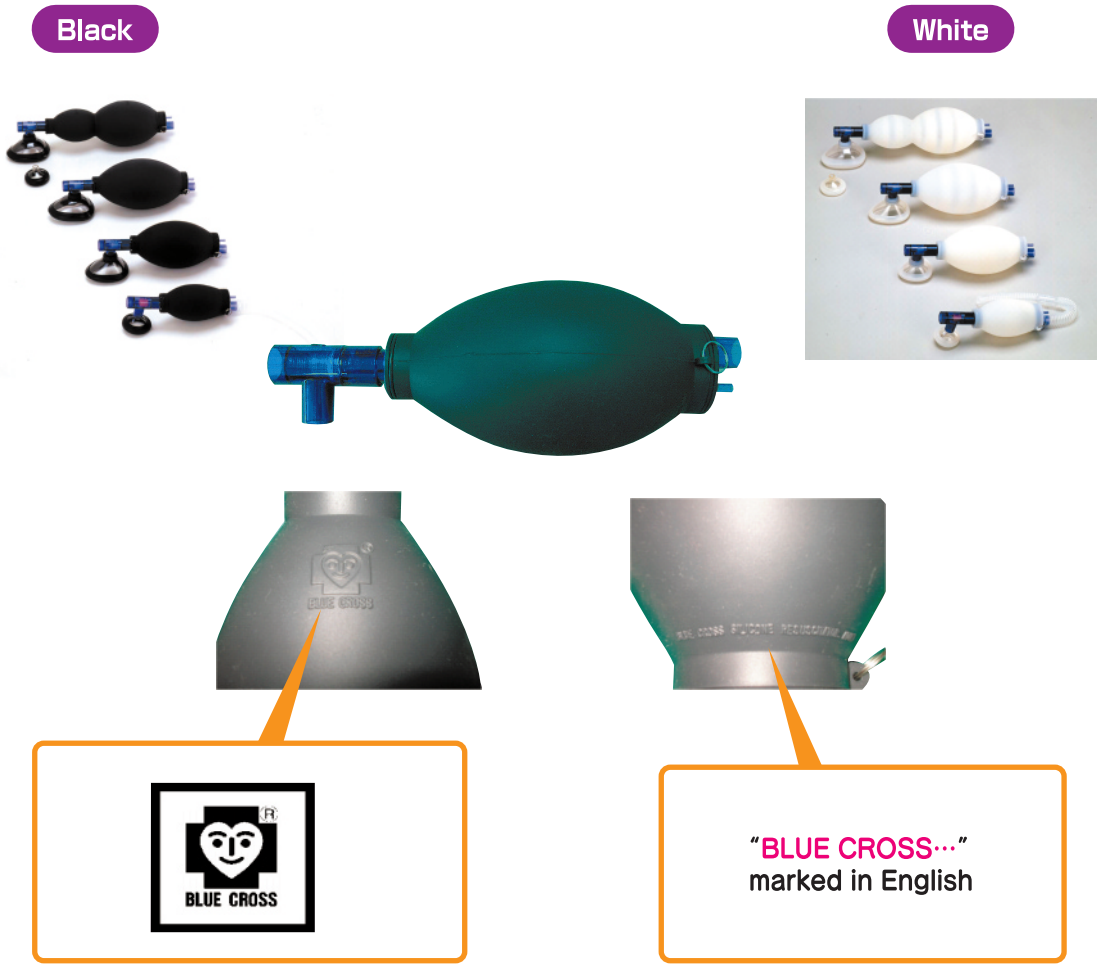
Picture 2: Igarashi Ikakogyo Co., Ltd. Products



For product inquiries contact: Igarashi Ikakogyo Co., Ltd. +81-3-3815-1474

Picture 3: Blue Cross Emergency Co., Ltd. Products

There are different types of bag colours (white and black) for the same product.



Blue Cross Emergency Co., Ltd. Logo

For product inquiries contact: **Blue Cross Emergency Co., Ltd. +81-49-243-9966**

About this information

* PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Pharmaceutical Affairs Law.
* We have endeavored to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy into the future.
* This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.

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