

October 12, 2009

## Unomedical Issues Worldwide Recall of Certain Manual Pulmonary Resuscitators

FOR IMMEDIATE RELEASE - October 06, 2009 - Unomedical Inc., a manufacturer of medical devices, today announced that it is conducting a voluntary recall of certain units of the single-patient use Manual Pulmonary Resuscitator (MPR).



The recall only impacts MPRs manufactured from July 2002 – March 2008 and matching the lot numbers listed on the following Unomedical web page: <http://www.unomedical.com/?pageid=H3160>.

This recall is being conducted because of a potential malfunction of certain units of the MPR, which may impair the ability of the device to generate the positive pressure necessary to function properly. The occurrence of such a malfunction may create a situation in which the use of the product could potentially cause serious adverse health consequences or death. This recall does not impact any MPRs manufactured after March 2008.

Unomedical is contacting customers to arrange for the return and credit of all MPR units subject to this recall by sending notification letters to distributors and customers. In addition, the company has set up a web page with a list of affected lot numbers, guidance (diagram and photos) to allow customers to identify products subject to the recall in the event that the customer has already removed the primary product packaging, and instructions on what actions to take.

In order to distinguish between the recalled product and unaffected product, customers may examine the patient valve housing immediately below the right-angle exhalation port, where the retention ring should be visible. MPR units with a clear or transparent ring, as well as those where no ring can be seen, should be returned to Unomedical as instructed. MPR units with a clearly visible blue retention ring are not affected and do not need to be returned.

The MPR is a single-patient use device used by healthcare professionals. It is intended for patients requiring total or intermittent ventilatory support.

Customers with questions are urged to contact Unomedical at 1-800-634-6003. Any adverse reactions experienced with the use of this product, and/or quality problems can also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF- 2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### Customer Contacts:

Raymond Mendoza, 1-800-634-6003 (8:00am – 5:30pm, Mon-Thurs, 8:00am – 1:00pm Fri (CST))

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[www.kcercoalition.com/alerts.htm](http://www.kcercoalition.com/alerts.htm)