

Covidien Pedi-Cap End-Tidal CO2 Detector

Audience: Anesthesiology healthcare professionals, hospital risk managers, surgical service managers

[Posted 09/10/2009] FDA notified healthcare professionals of a Class I recall of Pedi-Cap End-Tidal CO2 Detector (Pedi-Cap and Pedi-Cap 6), because the device may increase the resistance of the flow of air into the lungs, resulting in ineffective ventilation and the inability to verify the correct placement of a breathing tube when inserting it into the windpipe. This device is used in pediatric patients, weighing 2.2-33 pounds, during the process of exchanging oxygen for carbon dioxide (ventilation) in healthcare settings. There is a reasonable probability that use of the recalled PediCap will cause serious adverse health consequences or death. Covidien informed their distributors and customers to stop selling/using the affected devices and to return them to the company.

Any adverse events or quality problems that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program online, by phone [1-800-332-1088], or by returning the postage-paid FDA Form 3500 by mail