



VITALS

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A Weekly Safety Newsletter For Medical Transport Professionals

Warnings And Recalls



These Medical Device and Drug issues are all serious. If you use any of these items, were you aware of this information? If not, why? On the other hand, even if these particular items are not pertinent to your service, maybe it's a good idea to review how you handle Warnings and Recalls, store your equipment and update your drug protocols.

Smiths Medical has issued an Urgent Device Recall of its Portex Pediatric-Sized tracheal tubes made before September, 2009. These are 2.5, 3.0 and 3.5 mm tubes. Some of them were made with internal diameters slightly smaller than that which was indicated on the labeling. Consequently, a clinician may be unable to remove secretions which could result in an airway obstruction. The smaller diameter may also increase airway resistance which could make it more difficult to ventilate the patient. For questions regarding the recall, contact Charlotte Veysey at Charlotte.veysey@smiths-medical.com.

The FDA has issued a Class I Recall (Class I is the most serious recall and involves the risk of serious injury or death.) for the Covidien Pedi-Cap End-Tidal Carbon Dioxide Detector (Pedi-Cap and Pedi-Cap 6), because the device may increase the resistance of the flow of air into the lungs. Both ineffective ventilation and the inability to verify correct placement of the endotracheal tube may occur. The device is designed for pediatric patients weighing between 2.2 to 33 pounds. Covidien's Technical Services Group may be reached at 1-800-635-5267, option 3, then option 1.

Physio-Control has issued a Class I Recall for a number of their LIFEPAK CR Plus Automatic External Defibrillators (AEDs). Apparently, when placed in an extremely humid environment the AED may improperly analyze the cardiac rhythm and delay or fail to deliver proper electrical therapy.

Physio-Control Customer Care is available from 6AM to 4PM Pacific Time at 1-800-442-1142.

The FDA has issued a Boxed Warning and required the revision of the Dosage and Administration Section of Prescribing Information for Promethazine Hydrochloride marketed as Phenergan. Perivascular infiltration, unintentional intra-arterial injection and intraneuronal or perineuronal infiltration may result in irritation, tissue damage and gangrene. Some cases of tissue injury following intravenous administration of Phenergan have been so severe that amputation was required. The FDA indicates that deep IM injection is the preferred way to administer promethazine. The 50mg/ml concentration is to be used only for deep IM injection. The 25 mg/ml concentration may be used for deep IM injection or intravenous administration. It should be noted the maximum recommended concentration of promethazine for IV use is 25 mg/ml, which should be given at 25 mg per minute through the tubing of an IV infusion set that is known to be functioning properly. If you carry this drug it's important that you go to www.fda.gov/drugs, get the information and discuss it in detail with your Medical Director. If necessary, modify your protocols and re-educate your personnel. Document your actions in great detail.