MEDICAL DEVICE SAFETY ALERTS

LINAK JUMBO BATTERY PACKS – RISK OF FIRES

DIR 12012

LINAK Jumbo rechargeable battery packs contain two 12-volt gel-cell lead-acid batteries to provide a total of 24 VDC to power medical devices such as electric patient lifters and electric beds.

The Medical Device Incident Report Investigation Scheme (IRIS) recently received a report that a LINAK Jumbo Rechargeable Battery Pack spontaneously caught fire while sitting on a shelf in an Intensive Care Unit. The battery was still in its packaging as supplied by the local agent. The local supplier had routinely replaced the internal batteries, re-assembled the pack and re-packed it in bubble-wrap inside a cardboard carton.

The local supplier verified to IRIS that an operator had fitted the replacement batteries according to the diagram within the pack and had accidentally crushed two of the wires during re-assembly. A foam packing piece was also missing from inside the pack. This normally stops the batteries moving about. The insulation on the wires eventually broke down and a short-circuit occurred within the pack that caused the subsequent fire. There have been only two reports of this problem in Australia and one overseas, out of 95,000 packs sold to date, which is an incidence of approximately 0.003%.

An affected pack examined in the TGA Laboratories showed several faults. The wiring diagram did not match the actual wiring layout and the length of the red wire was insufficient to be correctly routed in the battery pack. As the pack was wired, the red wire passed close to all four battery terminals and a white wire connecting the two batteries. The potential existed for this wire to provide a direct path across the terminals on one or both batteries. As a result a high current could flow sufficient to melt and ignite the battery pack case. The internal fuse could not limit this current, as it is further along the circuit.

The manufacturer, LINAK A/S, Denmark, has agreed to change the wiring layout and rubber spacers within their packs to reduce the possibility of short-circuit. They will also alter the wiring diagram to reflect the correct layout.

The Australian agent, LINAK Australia, has agreed to produce an upgrade kit consisting of a new wiring diagram, new longer red connecting wire, printed-circuit fuse board and instructions for fitting all items. This will be distributed to all 62 distributors of Linak battery packs. Linak Australia will also issue a Service Information Bulletin to all distributors.

Recommendation

All users of LINAK Jumbo Battery Packs should contact their local supplier or LINAK Australia on 03 9753 2200 if they require further information about the upgrade kit or the Service Information Bulletin.

Product Notification on Innovo Insulin Injectors

DIR 12282

On 11 September 2000, the TGA received notification from the Australian sponsor about an increasing number of complaints of defective release buttons on Innovo® dosers distributed in Japan. The cumulative frequency of the problem was 2.5% (verified complaints, 3.6% reported) compared to an overall frequency of 0.2% in the rest of the world.

Investigations pointed to the high number of complaints in Japan being related to the unusually hot and humid weather experienced there during their summer. Laboratory tests showed that hot humid conditions resulted in a softening of the release mechanism. Up until this point the complaint was usually regarded to be caused by the user not closing the cartridge holder properly, a situation which also prevents the push button from being released (this is a safety feature).

There was some concern about the problem because Australia is approaching its own hot season and patients may experience difficulties if a doser failed and the patient did not have alternative means of delivering the insulin.

A Product Notification was sent to all users of the doser, diabetes care professionals and pharmacists regarding the problem. The notification explains the problem, the precautions necessary (to have an alternative device available), and an offer to supply, free of charge, an alternative device, the NovoPen3®. Novo Nordisk is working to correct the problem with Innovo® through design modifications. Innovo® distribution will cease in Australia until those design changes are in effect. The TGA considers that this action is a better alternative to a recall of the Innovo®. In this way, the patients would be informed, they would be able to keep their device of preference, and they would all have an opportunity, at no charge to them, to get a backup device. Most (97%) Innovo dosers are expected to behave normally even if Australian Innovo® users experience the same difficulties experienced in Japan.

The Product Notification was sent on 20 September 2000 to approximately 1300 pharmacists, endocrinologists, diabetes care professionals and patients. The Australian summer is not yet over, however, Novo Nordisk has not received the same rates of reports of failures as in Japan, even after the Product Notification. The total number of complaints (unconfirmed) is far below that of the observed rate of release button malfunction failure experienced last year in Japan. The TGA will monitor the performance of the doser and consider further action if necessary.

Recommendations

If you are a diabetes care professional or pharmacist or use an Innovo® doser, but did not receive the Product Notification letter from Novo Nordisk dated 20 September 2000 explaining the problem, you should contact Novo Nordisk Pharmaceuticals as soon as possible on 1800 224 321.

Never expose either your insulin or your self-administration equipment to extreme temperature and humidity conditions such as those found in a car glove box or dashboard.

Always have some alternative backup equipment for the delivery of your insulin in case your preferred device malfunctions.

Always prime your injection device prior to every injection. Priming is not merely a process through which air bubbles are eliminated. It should be regarded as a pre-injection check to ensure that the injector is working normally before each injection. Most problems become apparent during the priming procedure.

Always use your injector in accordance with the manufacturer's instructions for use.

Please report any device malfunctions to the manufacturer and/or the Therapeutic Goods Administration.

Toshiba Radiographic Screening Table - Risk of Patient or Operator Injury

DIR 12036

Toshiba Australia National Service Manager, Mr Raymond Saich, has reported to the TGA an adverse incident involving a Toshiba Radiographic Screening Table. The Spot Film Holder fell on the patient when the wire rope supporting it gave way. Fortunately, the wire rope failed slowly and the 120-kilogram spot film device fell slowly on to the patient. The radiographer and radiologist were injured when they removed the spot film device from the patient.

Toshiba engineers inspected the device and concluded that the cable broke because of wear and tear. The wire rope was found to have several broken wires or "whiskers" when it was inspected in May 1998, but it was not replaced. The Preventive Maintenance Manual clearly stated that the rope should be regularly inspected for "whiskers". If a single broken wire is found then the entire rope should be replaced for continued patient and operator safety.

Toshiba recommend that the Radiographic Screening Table be serviced and inspected every six months. This particular unit had not been serviced for two years and was 14 years old. Services on reported problems over the years had not required opening of the panel that covered the cable supporting the spot film device. The cable, therefore, may not have been inspected for many years.

This type of unit has been on the market for over 14 years and is still being sold. Users generally regard it as electrically and mechanically reliable and tend to service the machine when something goes wrong. This report highlights the need for regular inspection and maintenance of critical components in line with manufacturer's recommendations.

Action Required

Owners of Toshiba Radiographic screening tables should ensure that their units are inspected and serviced regularly for continued electrical and mechanical safety of patients and operators. For details of maintenance, please read the "Toshiba Preventive Maintenance Manual" or contact Mr Raymond Saich, Toshiba Australia, on 02 9887 8051.

Drager 8000 Incubators

DIR 12116

The TGA became aware of incidents involving the Drager 8000 Incubators from a Hazard Alert distributed by the Medical Devices Agency (MDA) in Great Britain.

The alert relates to the failure in the skin temperature sensor system, which caused the skin temperature probe to heat up resulting in a serious burn to a neonate.

A disposable skin temperature probe on the Drager 8000 incubator became very hot causing the serious burn. This was due to a fault in the incubator's skin temperature sensor system. The skin temperature system is common to all Drager 800 series incubators with optional skin temperature module or thermal monitoring.

Recommendations

The manufacturer recommends that the following precautions be taken to prevent this problem from happening:

- Use the air temperature or manual mode
- If appropriate, use a different temperature monitoring system
- If the decision is made to use the device in skin temperature mode, maintain vigilance as you would do to monitor transcutaneous temperature probe measurement, for any evidence of overheating.

The Drager 8000 incubator series, Babytherm 8000 open care systems and Radiant Heater RH 600 are the only units affected by this problem. Babytherm 8004, Babytherm 8010 and Babytherm WB are not affected by this problem.

If users have any concerns or would like further information, they are advised to contact Jim Collins at the Drager head office in Australia on 03 9265 5000.

INCIDENT REPORTING AND INVESTIGATION SCHEME STATISTICS REPORT

Device Incident Reports 01/10/2000 to 31/12/2000

Number received: 138

Cause of Problem		Effect		Source Category	
Biocompatibility	10	Death	4	Medical Administrator	5
Component failure	26	No Injury	95	Specialist	9
Contamination	4	Serious Injury	8	Coroner	1
Design	2	Temporary Injury	31	TGA	3
Electrical	8			Nurse	22
Inadequate Instructions	3			Blood Bank	12
Labelling	6	**Result of Investigation**		Competitor	4
Maintenance	5	Bulletin Article	2	Hospital Supply Service	13
Manufacture	12	No Further Action	45	Other	6
Material/Formulation Deficiency	16	Not Investigated	62	Patient/User	6
Mechanical	4	Other	4	Sponsor	44
Not Device Related	20	Problem Not Confirmed	4	Overseas Advice	5
Other	20	Product Improvement	8	Pharmacist	2
Packaging/Sterility	3	Recall/Hazard Alert	9	Biomed Engineer	6
Quality Assurance	9	Refer to GMP	3		
Unknown	25	Safety Alert	4		
Wear/Deterioration	6	User Education	13		