IRISH MEDICINES BOARD
SAFETY NOTICE

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Oxy-Top 5 / Oxy-Tec 5 Oxygen Concentrator

IMB Safety Notice: SN2009(12)
Circulation Date: 9th December 2009

MANUFACTURER/SUPPLIER
YSM Medical & Rehabilitation Equipment Ltd, Israel.

TARGET GROUPS
Chief Executive Officers
Medical Directors
Hospital Risk Managers
Purchasing Managers
Clinical Engineering / Medical Physics departments
Medical, Nursing, Technical and Portering staff in all wards and departments
General Practitioners
Practice Nurses
Medical device distributors
Medical device wholesalers
Medical device retailers
General Public

ISSUE
Risk of ignition of Oxy-Top 5 / Oxy-Tec 5 oxygen concentrators.

BACKGROUND
The Irish Medicines Board (IMB) has been advised of two incidents of ignition of Oxy-Top 5 / Oxy-Tec 5 oxygen concentrators that were reported in Germany. The ignition is reported to have been caused by defective capacitors in the circuitry of the oxygen concentrator.

It is believed that the Israeli manufacturer YSM Medical & Rehabilitation Equipment Ltd is no longer trading.

As a result of the incidents that occurred in Germany, the German Competent Authority for Medical Devices has recommended that these devices should no longer be used.

The IMB has been unable to obtain confirmation that these products are not on the Irish market. The devices have been sold in Germany, but marketing in other countries cannot be excluded at this time.

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ACTION OR RECOMMENDATIONS

Advice for Retailers and Wholesalers

(1) Retailers and wholesalers should examine their stock to determine if they have any medical devices branded Oxy-Top 5 / Oxy-Tec 5 oxygen concentrators.

(2) If you have these devices, cease sale of these devices immediately and quarantine all stock. Contact the IMB immediately to obtain further instruction and guidance.

(3) Ensure the appropriate personnel are made aware of this notice.

Advice for Healthcare Institutions / Consumers

(1) Check your oxygen concentrator to determine if it is branded Oxy-Top 5 / Oxy-Tec 5.

(2) Examine the information for use provided with the device to determine if either the name or manufacturer details match those provided above.

(3) If you find that you have one of these devices, discontinue use immediately and seek an alternative. Please quarantine the device and contact the IMB to obtain further instruction and guidance.

(4) Ensure the appropriate personnel are made aware of this notice.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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