U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

JUN 1 6 2008

Ms. Carroll Martin
Regulatory Affairs Manager
Invacare Corporation
One Invacare Way,
Elyria, OH 44035

Ref. No.: 08-0032

Dear Ms. Martin:

This is in response to your January 30, 2008 letter and subsequent conversation with Ben Supko of my staff regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 100-180) to a device that your company calls the Invacare Portable Oxygen Concentrator XPO100 and an external battery module.

On August 9, 2007, PHMSA amended the HMR to tighten the safety standards for transportation of lithium batteries, including both primary (non-rechargeable) and secondary (rechargeable) lithium batteries (HM-224C & HM-224E; 72 FR 44929). A copy of the rulemaking is enclosed. Effective January 1, 2008, the Pipeline and Hazardous Materials Safety Administration revised and relocated the 8-gram exception for small lithium batteries formerly found under § 173.185(b)(2) of the HMR. New requirements applicable to the Invacare XPO100 and external battery module, described in your letter, are provided in Special Provision 188 (§ 172.102).

In your letter, you indicate that the Invacare XPO100 portable oxygen concentrator and external battery module meet the following criteria:

(1) the pressure of the oxygen in the device does not exceed 40.6 psia at 20 °C;
(2) the cells contain not more than 1.5 grams of lithium equivalent content;
(3) the lithium ion batteries contain an aggregate equivalent lithium content of not more than 8g;
(4) the device contains no other materials subject to the HMR; and
(5) the batteries are fully contained in equipment and packaged in a manner to preclude sparks or the generation of a dangerous quantity of heat.

Based on the information provided, the Invacare XPO100 portable oxygen concentrator and external battery module meet Special Provision 188. Provided they continue to meet the requirements established by Special Provision 188, you are not otherwise subject to the HMR.

You should also note that Federal Aviation Administration (FAA) approval is required before these electronic devices may be used by passengers on board aircraft. The FAA published a final rule in the Federal Register regarding these devices on July 12, 2005 (70 FR 40156). A copy of the rulemaking is enclosed.

In addition, even with FAA approval the air carrier ultimately determines what may or may not be carried on its aircraft. We suggest that you check with the air carrier to ensure that the Invacare XPO 100 portable oxygen concentrator and external battery module may be carried.

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

Edward T. Mazzullo

Edward T. Mazzullo
Director
Office of Hazardous Materials Standards

Supko
173.115
173.185
173.10
Battery + Air
08-0032

January 30, 2008

Ms. Hattie Mitchell
Chief, Regulatory Review and Reinvention
U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Standards
1200 New Jersey Avenue, SE East Building, 2nd Floor
Washington, DC 20590

RE: Invacare Portable Oxygen Concentrator

Dear Ms. Mitchell:

Invacare is requesting written confirmation from the Pipeline and Hazardous Materials Safety Administration that the Invacare Portable Oxygen Concentrator XPO100 is not subject to the U.S. hazardous materials regulation under HMR; 49 CFR Parts 100-180 after review of all appropriate information.

The Invacare XPO100 Portable Oxygen concentrator is a lightweight device that separates nitrogen from room air through the pressure swing adsorption (PSA) process and stores the resultant concentrated oxygen gas for delivery to patients who need supplemental oxygen therapy (see Exhibit A). The XPO100 device delivers the oxygen to a patient through the pulse dose delivery method for maximum effectiveness and operational time. This means that the XPO100 delivers oxygen only when a breath is detected. If no breath is detected (i.e. the cannula detaches from the device or the patient takes the cannula off), no oxygen is delivered. This feature of delivering oxygen only when a breath is detected prevents oxygen saturation of the surrounding area or materials when the cannula is not connected to the concentrator or the patient.

The maximum internally attainable pressure during the PSA cycle of the Invacare XPO100 is 23.5 PSIG (38.2 PSIA) over an operating temperature range of 5°C to 40°C. As this maximum operating pressure is lower than the 40.6 PSIA at 20°C for a Division 2.2 gas in 49 CFR 173.115(b)(1), Invacare feels the XPO100 device is not subject to the U.S. HMR regulations for oxygen gas.

The XPO100 device can be powered by an internally captive lithium ion battery pack that is not customer removable or replaceable, an external AC to DC power adapter, an external DC to DC power adapter, or an external accessory lithium ion battery pack. This

allows for maximum flexibility and operational time with multiple power sources. Recharging is only available with the use of the AC/DC or DC/DC power adapters.

The internally captive lithium ion battery pack (see Exhibit F) consists of 8 cylindrical 2.6 amp-hour lithium ion cells (see Exhibits B and C) with a total lithium equivalent content of 6.24 grams of lithium. The internally captive battery pack is not user accessible and not replaceable by a patient/user. It is securely captured in the product and has passed all applicable UN Manual of Tests and Criteria requirements for lithium battery packs (see Exhibits D and E). The internally captive mechanism of the Invacare XPO100 also prevents any user from generating sparks or short-circuiting as it is not externally accessible. The battery pack terminals are not exposed to any outside contact by virtue of being totally integrated into the product. (see Exhibit A)

The external accessory battery module (see Exhibit I) for extended operating time is a self-contained power accessory for the Invacare XPO100 device. The external battery module contains a separate battery pack that consists of 8 cylindrical 2.6 amp-hour lithium ion cells with a total lithium equivalent content of 6.24 grams of lithium (see Exhibit G). The lithium battery pack is not user accessible and is not replaceable by a patient/user. It is securely captured in the external module and has passed all applicable UN Manual of Tests and Criteria requirements for lithium battery packs (Exhibits D and E). The captive mounting mechanism of the external battery module also prevents any user from generating sparks or short-circuiting the lithium battery pack. The battery pack terminals are not exposed to any outside contact as they are connected to an intervening power switching and charging circuit board (see Exhibit K) that interfaces to the Invacare XPO100 device. The external battery module connection cable (see Exhibit J) contains a connector that prevents accidental shorting or generation of sparks during handling or storage.

Invacare feels that based on the requirements of 49 CFR 173.185(c)(2), both the internally captive lithium battery pack and the lithium battery pack in the external battery module are exempt from the HMR requirements. The individual cells do not contain more than 5 grams of lithium equivalent grams and each battery pack does not contain more than 25 grams of lithium equivalent grams. Each battery pack has been tested and approved to the UN Manual of Tests and Criteria for all appropriate lithium cell/pack testing. In addition, both the internally captive and external battery packs are packed securely within the respective product case and are prevented from short-circuiting and spark generation.

Invacare believes that all the other materials used in the device are not subject to the U.S. hazardous materials regulation under HMR 49 CFR Parts 100-180 (Exhibit H).

With all of the preceding information, Invacare asks that the PHMSA confirm that the Invacare Portable Oxygen Concentrator XPO100 is not subject to the U.S. hazardous materials regulation under HMR; 49 CFR Parts 100-180.

If you need any additional information or wish to speak with me regarding this submission, please feel free to contact me by phone at 440-329-6356 or by e-mail at Carroll.Martin@invacare.com.

You may contact us in either of the following ways with your decision:
Mail: Carroll Martin, One Invacare Way, Elyria, Ohio 44035
E-Mail: Carroll.Martin@invacare.com
Fax: 440-326-3458

Respectfully submitted,

Carroll L. Martin
Regulatory Affairs Manager
Invacare Corporation