



U.S. Department
of Transportation

1200 New Jersey Avenue SE
Washington, DC 20590

**Pipeline and Hazardous
Materials Safety
Administration**

JAN 11 2012

Mr. Jim Parker
Quality Manager
Precision Medical, Inc.
300 Held Drive
Northampton, PA 18067

Ref. No.: 11-0295

Dear Mr. Parker:

This is in response to your November 29, 2011, letter regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to a portable oxygen concentrator (POC). According to your letter, the POC (common name Easy Pulse) is a portable device that produces an oxygen enriched gas mixture by removing nitrogen from the air. The maximum operating pressure of the POC is 14.5 psi. The POC is powered by multiple sources, including AC or DC power, and a rechargeable lithium-ion battery pack with less than 6.24 g aggregate equivalent lithium content. The lithium-ion battery pack is a type proven to meet the appropriate tests in the United Nations Manual of Tests and Criteria, and the battery pack is packaged in a manner to prevent short circuits when offered for transport or carried onboard passenger aircraft. You ask whether this device is regulated under the HMR.

Based on the information provided in your letter, the Easy Pulse POC is currently not subject to the HMR because: (1) the pressure of the oxygen in the device does not exceed 200 kPa gauge (29.0 psig/43.8 psia) at 20 °C (68 °F); (2) the lithium-ion battery pack used to operate the device is excepted from the HMR under § 172.102(c)(1), Special provision 188; (3) the POC contains no other materials subject to the HMR; and (4) the battery pack is packaged in a manner to preclude it from creating sparks or generating a dangerous quantity of heat (e.g., by the effective insulation of exposed terminals).

Although the exception in § 175.10(a)(18) of the HMR would apply to a passenger carrying an Easy Pulse POC as described above, approval by the Federal Aviation Administration (FAA) is required before it may be used by a passenger onboard an aircraft. The FAA published a final rule on July 12, 2005 (70 FR 40155) regarding these devices. For further assistance, you may contact Mr. Dave Catey, Aviation Safety Inspector for the FAA Air Carrier Operations Branch

(AFS-220) by phone at (202) 267-3732 or email at david.catey@faa.gov. In addition, even with FAA approval, an air carrier ultimately determines what may or may not be carried on its aircraft. We suggest that you contact the airlines to ensure that the Easy Pulse POC may be carried.

I hope this information is helpful. If you have further questions, please contact this office.

Sincerely,

A handwritten signature in black ink, appearing to read "Ben Supko". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Ben Supko
Acting Chief, Standards Development
Office of Hazardous Materials Standards

Drakeford, Carolyn (PHMSA)

Leary
§ 175.10

Portable Oxygen Concentrator
11-0295

From: Betts, Charles (PHMSA)
Sent: Tuesday, November 29, 2011 4:13 PM
To: Drakeford, Carolyn (PHMSA)
Subject: FW: Precision Medical POC
Attachments: example_oxus.pdf; request_for_assist_phmsa.pdf; PHMSA letter dated 82311.pdf; scandocs@precisionmedical.com_20110727_093213.pdf; FAA letter072711.doc; 506640 Rev0 062811.pdf

Carolyn -

Please log and assign to Kevin for handling.

Thanks,
Charles

-----Original Message-----

From: Lawson, Eleanor (PHMSA)
Sent: Tuesday, November 29, 2011 1:46 PM
To: Betts, Charles (PHMSA)
Subject: FW: Precision Medical POC

This has been bouncing around for quite awhile. James Parker needs to have the FAA Rule (SFAR 106) amended to add Precision Medical Inc Portable oxygen concentrator to the list of oxygen concentrator allowed on aircraft. However, before FAA can act on his request, they require a clarification or review from PHMSA. Apparently, there was a similar request which resulted in a review from Standards and this review resulted in a letter of clarification issued by Standards. This letter is attached.

Eleanor Lawson
U.S. Department of Transportation
PHMSA/OHMS/AP Div./Approvals
1200 New Jersey Avenue, SE
East Building, 2nd Floor, Rm. E23-443
Washington, DC 20590
Tel: 202-366-3987
Fax: 202-366-3753
Email: Eleanor.Lawson@dot.gov

-----Original Message-----

From: DK.Deaderick@faa.gov [<mailto:DK.Deaderick@faa.gov>]
Sent: Tuesday, November 29, 2011 12:44 PM
To: Lawson, Eleanor (PHMSA)
Subject: Fw: Precision Medical POC

Eleanor,

It was good talking with you today. Thanks for your offer to assist this petitioner. Here's the pdf notes and letters that we discussed. I have provided an example of a PHMSA letter from the Oxus rule making project to amend SFAR

106

(See attached file: example_oxus.pdf)(See attached file:

request_for_assist_phmsa.pdf)

Let me know if I can assist further. I feel that I owe this manufacturer an apology because he asked for coaching with the rulemaking process and I've been working with him since July.

----- Forwarded by D K Deaderick/AWA/FAA on 11/29/2011 12:34 PM -----

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| "James Parker" <jparker@precisionmedical.com>
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| To:        |
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| D K Deaderick/AWA/FAA@FAA
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| Precision Medical POC
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Hi DK,
Attached are the documents, I originally sent.
Let me know if you need anything else.

Thanks for your help.

Best Regards,

Jim Parker
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Precision Medical Inc.
300 Held Drive
Northampton, Pa 18067
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Phone: 610-262-6090 ext 228
Fax:610-262-6080
Cell : 610-762-9673

(See attached file: PHMSA letter dated 82311.pdf)(See attached file:
scandocs@precisionmedical com_20110727_093213.pdf)(See attached file: FAA
letter072711.doc)(See attached file: 506640 Rev0 062811.pdf)