

R-Team DACH

An: alle Vertriebspartner

Von: Antje Männich

Date: 22.10.2012

Betreff: Flugzulassung SimplyGo



Liebe Vertriebspartner,

Hiermit teile ich mit Ihnen die freudige Meldung, dass der tragbare Sauerstoffkonzentrator eine Flugzulassung der FAA- Behörde erhalten hat.

Durch diese Zulassung ist der SimplyGo der erste tragbare Sauerstoffkonzentrator mit einem Gewicht von nur 4,5 kg und der Auswahl zwischen einem atemzuggesteuerten Flow und einem Dauerflow bis zu 2 l/min, der eine solche Flugzulassung besitzt.

Diese Zulassung gilt für alle SimplyGo- Konzentratoren; auch für die, die schon vor diesem Schreiben ausgeliefert wurden. Besuchen Sie die Seite von der FAA- Behörde: <http://www.gpo.gov/fdsys/pkg/FR-2012-10-16/html/2012-25412.htm>

Alle neuen Geräte sind produktionsseitig mit dem Sticker über die FAA- Zulassung ausgestattet. Wenn Sie diesen nachrüsten möchten, können Sie ihn mit folgender Bestellnummer über den Customer Service beziehen:

SimplyGo FAA Sticker	
einzeln	1102514
20 er Pack	1102515

Wenn Sie weitere Fragen haben, können Sie mich oder Ihren Ansprechpartner jederzeit kontaktieren.

Viele Grüße,

Antje Männich

[Federal Register Volume 77, Number 200 (Tuesday, October 16, 2012)]
[Rules and Regulations]
[Pages 63217-63221]
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[\[www.gpo.gov\]](http://www.gpo.gov)
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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No. FAA-2012-0928; Amdt. No. 121-361]
RIN 2120-AK18

Use of Additional Portable Oxygen Concentrators on Board Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the FAA's rules for permitting limited use of portable oxygen concentrator systems on board aircraft, to allow for the use of additional portable oxygen concentrator (POC) devices on board aircraft, provided certain conditions in the SFAR are met. This action is necessary to allow all POC devices deemed acceptable by the FAA for use in air commerce to be available to the

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traveling public in need of oxygen therapy. Passengers will be able to carry these devices on board the aircraft and use them with the approval of the aircraft operator.

DATES: Effective October 31, 2012.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact DK Deaderick, Air Transportation Division, AFS-200, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone 202-167-8166; email DK.Deaderick@faa.gov.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA is authorized to issue this final rule pursuant to 49 U.S.C. 44701. Under that section, the FAA is authorized to establish regulations and minimum standards for other practices, methods, and procedures the Administrator finds necessary for air commerce and national security.

Background

On July 12, 2005, the FAA published Special Federal Aviation

Regulation 106 (SFAR 106) entitled, ``Use of Certain Portable Oxygen Concentrator Devices Onboard Aircraft'' (70 FR 40156). SFAR 106 is the result of a notice the FAA published in July 2004 (69 FR 42324) to address the needs of passengers who must travel with medical oxygen. Before publication of SFAR 106, passengers in need of medical oxygen during air transportation faced many obstacles when requesting service. Many aircraft operators did not provide medical oxygen service aboard flights, and those that did often provided service at a price that travelers could not afford. Coordinating service between operators and suppliers at airports was also difficult, and passengers frequently chose not to fly because of these difficulties.

Medical oxygen technologies approved by the Food and Drug Administration (FDA) reduce the risks typically associated with compressed oxygen and provide a safe alternative for passengers who need oxygen therapy. Numerous manufacturers have developed small portable oxygen concentrators (POC) that work by separating oxygen from nitrogen and other gases contained in ambient air and dispensing it in concentrated form to the user with an oxygen concentration of about 90%. The POCs operate using either rechargeable batteries or, if the aircraft operator obtains approval from the FAA, aircraft electrical power.

In addition, the Pipeline and Hazardous Materials Safety Administration (PHMSA) has determined that the POCs covered by this amendment are not hazardous material. Thus, they do not require the same level of special handling as compressed oxygen, and are safe for use on board aircraft, provided certain conditions for their use are met.

SFAR 106 permits passengers to carry on and use certain POCs on board aircraft if the aircraft operator ensures that the conditions specified in the SFAR for their use are met. The devices initially determined acceptable for use in SFAR 106, published July 12, 2005, were AirSep Corporation's LifeStyle and Inogen, Inc.'s Inogen One POCs. SFAR 106 has been amended several times to allow passengers to use additional devices. This final rule adds additional POC devices, including AirSep Corporation's Focus, AirSep FreeStyle 5, Inogen One G3, Inova Labs, Inc.'s LifeChoice Activox, Phillips Respironics Simply Go, Precision Medical Inc.'s EasyPulse and SeQual Technologies, Inc.'s SAROS that may be carried on and used by a passenger on board an aircraft.

In addition, on January 27, 2012 (77 FR 4219), the FAA published a Technical Amendment to update the names of two approved POC manufacturers due to business changes. The LifeChoice POC is currently being manufactured by Inova Labs, Inc. and the RS-00400 POC is currently being manufactured by Oxus, Inc. In the technical amendment, the FAA inadvertently removed the previous manufacturer's names from the list of approved POCs in SFAR 106. People still have POCs marked with those manufacturer's names. In this final rule, the FAA will add those previous manufacturer's names (International Biophysics Corporation's LifeChoice and Delphi Medical Systems' RS-00400) back to the list of approved POCs in SFAR 106.

Aircraft operators can meet certain conditions and allow passengers to carry on and use one of the POC devices covered in SFAR 106. SFAR 106 is an enabling rule, which means that no aircraft operator is required to allow passengers to operate these POC devices on board its aircraft, but it may allow them to be operated on board. If one of these devices is allowed by the aircraft operator to be operated on board, the conditions in the SFAR must be met.

When SFAR 106 was published, the FAA committed to establishing a single performance standard for all POCs so the regulations wouldn't apply to specific manufacturers and models of device. Whenever possible, the FAA tries to regulate by creating performance-based standards rather than approving by manufacturer. In the case of SFAR

106, the most efficient way to serve both the passenger and the aircraft operator was to allow the use of the devices determined to be acceptable by the FAA in SFAR 106 in a special, temporary regulation. As the FAA stated in the preamble discussion of the final rule that established SFAR 106, ``while we are committed to developing a performance-based standard for all future POC devices, we do not want to prematurely develop standards that have the effect of stifling new technology of which we are unaware.'' The FAA developed and published SFAR 106 so passengers who otherwise could not fly could do so with an affordable alternative to what existed before SFAR 106 was published.

The FAA continues to pursue the performance-based standard for all POCs. This process is time-consuming, and the FAA intends to publish a notice in the Federal Register and offer the public a chance to comment on the proposal when it is complete. In the meantime, manufacturers continue to create new and better POCs, and manufacturers have requested that their product also be included as an acceptable POC in SFAR 106. Precision Medical, Inc., Inogen, Inc. and AirSep Corporation have formally submitted petitions for exemption to the FAA that would allow their POCs to be used on aircraft. In addition, SeQual Technologies, Inc., Inova Labs, Inc., and Phillips Respironics have submitted requests for approval and addition to SFAR 106, with all required documentation for their POCs, to the Department of Transportation's Docket Management System.

Additionally, as stated in Section 2 of SFAR 106, no covered device may contain hazardous materials as determined by PHMSA (written documentation necessary), and each device must also be regulated by the FDA. All manufacturers have included technical specifications for their devices in each request for approval, as well as the required documentation from PHMSA and the FDA.

The Rule

This amendment to SFAR 106 will include the AirSep Focus, AirSep FreeStyle 5, Inogen One G3, Inova Labs LifeChoice Activox, **Respironics Simply Go**, Precision Medical EasyPulse and SeQual SAROS devices in the list of POC devices authorized for use in air commerce. The FAA has reviewed these devices and accepted the

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documentation provided by the manufacturers. That documentation includes letters provided to the manufacturer by PHMSA and the FDA affirming the status of the device as it applies to the requirements stated in SFAR 106. After reviewing the applicable FDA safety standards and the PHMSA findings, the device was determined by the FAA to be acceptable for use in air commerce.

Additionally, in the January 27, 2012 technical amendment to SFAR 106, while updating manufacturer's names due to business changes, the FAA inadvertently removed the previous manufacturer's names from the list of approved POCs. Even though these POCs are manufactured under new manufacturer's names, people still have POCs marked with the previous manufacturer's names. In this final rule, the FAA will add those previous manufacturer's names (International Biophysics Corporation's LifeChoice and Delphi Medical Systems' RS-00400) back to the list of approved POCs in SFAR 106.

Waiver of Notice of Proposed Rulemaking and Delay in Effective Date

Section 553 of the Administrative Procedure Act, 5 U.S.C 553(b) (3) (B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing

notice and an opportunity for public comment. We have determined that there is good cause for making the rule final without prior proposal and opportunity for comment because the issues related to the use of POC devices on board aircraft have already been discussed as part of an earlier rulemaking. More specifically, on July 14, 2004, the FAA issued a notice of proposed rulemaking on the use of portable oxygen concentrator devices on board aircraft (69 FR 42324). Then, on July 12, 2005, after reviewing public comments received, the FAA published Special Federal Aviation Regulation 106 (SFAR 106) entitled, ``Use of Certain Portable Oxygen Concentrator Devices on Board Aircraft.'' (70 FR 40156) Therefore, it is unnecessary and contrary to the public interest to publish a notice requesting comments on this amendment.

Moreover, pursuant to 5 U.S.C.553(d)(3), we find that good cause exists for making this rule effective in less than 30 days. This rule is being made effective 15 calendar days after its publication in the Federal Register to prevent unnecessary delay in acceptance of these devices as authorized for use on board aircraft by airlines while still providing airlines adequate notice and time to ensure the devices can be used safely on board aircraft. We believe, based on information the Department has received from airlines, that fifteen calendar days is sufficient amount of time for an airline to ensure/confirm that an FAA-approved POC does not cause interference with avionics system on that carrier's aircraft and convey this information to the appropriate airline personnel in order to accept these devices on board aircraft for use by passengers who need oxygen therapy for air travel. As such, the FAA believes that good cause exists for making this rule effective 15 calendar days after its publication in the Federal Register.

Regulatory Notices and Analyses

Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96-39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows:

This action amends SFAR 106 to allow for the use of additional POC devices on board aircraft, provided certain conditions in the SFAR are

met. This action is necessary to allow additional POC devices deemed acceptable by the FAA to be available to the traveling public in need of oxygen therapy, for use in air commerce. When this rule becomes effective, there will many different POC devices the FAA finds acceptable for use on board aircraft, and passengers will be able to carry these devices on board the aircraft and use them with the approval of the aircraft operator. As the rule increases the number of acceptable POC devices on board aircraft, the rule does not increase costs and provides additional benefits. The FAA has, therefore, determined that this final rule is not a ``significant regulatory action'' as defined in section 3(f) of Executive Order 12866, and is not ``significant'' as defined in DOT's Regulatory Policies and Procedures.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96-354) (RFA) establishes ``as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to ``solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the

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factual basis for this determination, and the reasoning should be clear.

This final rule adds additional POC devices to the list of authorized POC devices in SFAR 106. This economic impact is minimal. Therefore, as the Acting FAA Administrator, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of \$100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ``significant regulatory action.'' The FAA currently uses an inflation-adjusted value of \$143.1 million in lieu of \$100 million. This final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

Paperwork Reduction

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

Information collection requirements associated with this final rule have been approved previously by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) and have been assigned OMB Control Number 2120-0702. This final rule requires that if a passenger carries a POC device on board the aircraft with the intent to use it during the flight, he or she must inform the pilot in command of that flight. Additionally, the passenger who plans to use the device must provide a written statement signed by a licensed physician that verifies the passenger's ability to operate the device, respond to any alarms, the extent to which the passenger must use the POC (all or a portion of the flight), and prescribes the maximum oxygen flow rate. The Paperwork Reduction Act paragraph in the final rule that established SFAR 106 still applies to this amendment. The availability of a new POC device will likely increase the availability and options for a passenger in need of oxygen therapy, but the paperwork burden discussed in the original final rule is unchanged. Therefore, the OMB Control Number associated with this collection remains 2120-0702.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96-39), as amended by the Uruguay Round Agreements Act (Pub. L. 103-465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this final rule and determined that it will have only a domestic impact and therefore will not create unnecessary obstacles to the foreign commerce of the United States.

Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical

exclusion identified in paragraph 312f and involves no extraordinary circumstances.

Executive Order Determinations

Executive Order 13132, Federalism

The FAA has analyzed this immediately adopted final rule under the principles and criteria of Executive Order 13132, Federalism. The agency determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have Federalism implications.

Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this immediately adopted final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a ``significant energy action'' under the executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

How To Obtain Additional Information

Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the Internet--

1. Search the Federal eRulemaking Portal (<http://www.regulations.gov>);
2. Visit the FAA's Regulations and Policies Web page at http://www.faa.gov/regulations_policies/or
3. Access the Government Printing Office's Web page at <http://www.gpo.gov/fdsys/>.

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-9680.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the FOR FURTHER INFORMATION CONTACT heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit <http://>

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www.faa.gov/regulations--policies/rulemaking/sbre--act/.

List of Subjects in 14 CFR Part 121

Air carriers, Aircraft, Airmen, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends SFAR No. 106 to Chapter I of title 14, Code of Federal Regulations as follows:

PART 121--OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS

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1. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(g), 1153, 40101, 40102, 40103, 40113, 41721, 44105, 44106, 44111, 44701-44717, 44722, 44901, 44903, 44904, 44906, 44912, 44914, 44936, 44938, 46103, 46105.

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2. Amend SFAR 106 by revising sections 2 and 3(a) introductory text to read as follows:

Special Federal Aviation Regulation 106--Rules for Use of Portable Oxygen Concentrator Systems on Board Aircraft

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Section 2. Definitions--For the purposes of this SFAR the following definitions apply: Portable Oxygen Concentrator: means the AirSep FreeStyle, AirSep LifeStyle, AirSep Focus, AirSep FreeStyle 5, Delphi RS-00400, DeVilbiss Healthcare iGo, Inogen One, Inogen One G2, Inogen One G3, Inova Labs LifeChoice, Inova Labs LifeChoice Activox, International Biophysics LifeChoice, Invacare XP02, Invacare Solo2, Oxlife Independence Oxygen Concentrator, Oxus RS-00400, Precision Medical EasyPulse, Respironics EverGo, Respironics SimplyGo, SeQual Eclipse and SeQual SAROS Portable Oxygen Concentrator medical device units as long as those medical device units: (1) Do not contain hazardous materials as determined by the Pipeline and Hazardous Materials Safety Administration; (2) are also regulated by the Food and Drug Administration; and (3) assist a user of medical oxygen under a doctor's care. These units perform by separating oxygen from nitrogen and other gases contained in ambient air and dispensing it in concentrated form to the user.

Section 3. Operating Requirements--

(a) No person may use and no aircraft operator may allow the use of any portable oxygen concentrator device, except the AirSep FreeStyle, AirSep LifeStyle, AirSep Focus, AirSep FreeStyle 5, Delphi RS-00400, DeVilbiss Healthcare iGo, Inogen One, Inogen One G2, Inogen One G3, Inova Labs LifeChoice, Inova Labs LifeChoice Activox, International Biophysics LifeChoice, Invacare XP02, Invacare Solo2, Oxlife Independence Oxygen Concentrator, Oxus RS-00400, Precision Medical EasyPulse, Respironics EverGo, Respironics SimplyGo, SeQual Eclipse and SeQual SAROS Portable Oxygen Concentrator units. These units may be carried on and used by a passenger on board an aircraft provided the aircraft operator ensures that the following conditions are satisfied:

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Issued in Washington, DC, on October 2, 2012.

Michael P. Huerta,
Acting Administrator.

[FR Doc. 2012-25412 Filed 10-15-12; 8:45 am]

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