Subject

(d) Air Transport Association (ATA) of America Code 57: Wings.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

Several cases of aileron terminal quadrant support brackets that were manufactured using sheet metal have been found cracked on DHC–8 Series 300 aircraft. Investigation revealed that the failure of the support bracket was due to fatigue. Failure of the aileron terminal quadrant support bracket could result in an adverse reduction of aircraft roll control.

These conditions could result in loss of control of the airplane.

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Actions

(g) For airplanes with an aileron terminal quadrant support bracket having part number (P/N) 85711569: At the applicable times specified in paragraph (g)(1) or (g)(2) of this AD, install a new aileron input quadrant support bracket by incorporating MODSUM 8Q101250, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 8–57–43, Revision B, dated October 7, 2009.

(1) For airplanes that have accumulated 30,000 total flight hours or more as of the effective date of this AD: Within 3,000 flight hours after the effective date of this AD.

(2) For airplanes that have accumulated less than 30,000 total flight hours as of the effective date of this AD: Before the accumulation of 33,000 total flight cycles or within 6,000 flight hours after the effective date of this AD, whichever occurs first.

(h) Doing the installation by incorporating MODSUM 8Q101250 is also acceptable for compliance with the requirements of paragraph (g) of this AD if done before the effective date of this AD in accordance with Bombardier Service Bulletin 8–57–43, dated August 9, 2002; or Bombardier Service Bulletin 8–57–43, Revision A, dated January 17, 2003.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(i) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York, 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(j) Refer to MCAI Canadian Airworthiness Directive CF–2009–45, dated December 11, 2009; and Bombardier Service Bulletin 8–57–43, Revision B, dated October 7, 2009; for related information.

Issued in Renton, Washington, on August 18, 2010.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010–21064 Filed 8–24–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0845; Directorate Identifier 2010–CE–044–AD]

RIN 2120–AA64

Airworthiness Directives; Diamond Aircraft Industries GmbH Models DA 40 and DA 40F Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Diamond Aircraft Industries GmbH Models DA 40 and DA 40F airplanes. This proposed AD would change the emergency open doors procedure by incorporation of a temporary revision into the FAA-approved airplane flight manual for all airplanes. This proposed AD would also require replacement of the passenger door retaining bracket with an improved design retaining bracket for certain airplanes. This proposed AD results from several reports of the rear passenger door departing the airplane in flight. We are proposing this AD to change the emergency open doors procedure and retrofit the rear passenger door retaining bracket, which if not corrected could result in the rear passenger door departing the airplane in flight.

DATES: We must receive comments on this proposed AD by October 12, 2010.

ADDRESSES: Use one of the following addresses to comment on this proposed AD:

- *Federal eRulemaking Portal: Go to http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Diamond Aircraft Industries GmbH, N.A. Otto-Straße 5, A–2700 Wiener Neustadt, Austria, telephone: +43 2622 26700; fax: +43 2622 26780; e-mail: *office@diamond-air.at*; Internet: *http://www.diamond-air.at.*

FOR FURTHER INFORMATION CONTACT: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; e-mail: *mike.kiesov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments regarding this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number, "FAA–2010–0845; Directorate Identifier 2010–CE–044–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each

substantive verbal contact we receive concerning this proposed AD.

Discussion

We have received information from Diamond Aircraft Industries GmbH that the Models DA 40 and DA 40F airplanes have had an estimated 31 rear passenger doors depart the airplane while in flight. They also estimate an additional 18 doors have been replaced because of damage to the hinge, primarily due to wind gust conditions while the airplane is parked. Diamond Aircraft Industries GmbH conducted a structural test to determine the root cause of the door opening in flight. The test concluded that the locking mechanism provided adequate strength to react the loads in flight. They determined that the root cause was the crew not properly securing the rear passenger door prior to flight.

Models DA 40 and DA 40F airplanes do have a secondary safety latch design feature. The initial intended design function of this latch was to hold the rear passenger door in the "near closed" position while on the ground, protecting the door from wind gusts. However, the original retainer bracket might not hold the door in this "near closed" position while in flight. Diamond Aircraft Industries GmbH has designed an improved retainer bracket to prevent the passenger rear door fully opening in flight. In addition, they have revised the emergency door open procedure.

This condition, if not corrected, could result in the rear passenger door departing the airplane in flight.

Relevant Service Information

We have reviewed Diamond Aircraft Industries GmbH Mandatory Service Bulletin NO. MSB 40–070/NO. MSB D4–079/NO. MSB F4–024, dated April 30, 2010; and Diamond Aircraft Industries GmbH Work Instruction WI–MSB 40–070/WI–MSB D4–079/WI–MSB F4–024, dated April 30, 2010.

The service information describes procedures for replacement of the passenger door retaining bracket with an improved design retaining bracket.

FAA's Determination and Requirements of the Proposed AD

We are proposing this AD because we evaluated all information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design. This proposed AD would require a retrofit of the rear passenger door retaining bracket for certain airplanes. This proposed AD would also change the emergency open doors procedure by incorporation of a temporary revision into the FAA-approved airplane flight manual for all airplanes.

Costs of Compliance

We estimate that this proposed AD would affect 699 airplanes in the U.S. registry.

We estimate the following costs to do the proposed revision to the airplane flight manual:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
.5 work-hour × $85 per hour = $42.50	Not Applicable	$42.50	$29,707.50

We estimate the following costs to do the proposed retrofit of the passenger door retaining bracket. We estimate that this would affect 428 airplanes in the U.S. registry:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
2 work-hours × $85 per hour = $170.00	$75.00	$245.00	$104,860.00

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket that contains the proposed AD, the regulatory evaluation, any comments received, and other information on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone (800) 647–5527) is located at the street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Diamond Aircraft Industries GmbH: Docket No. FAA–2010–0845; Directorate Identifier 2010–CE–044–AD.

Comments Due Date

(a) We must receive comments on this airworthiness directive (AD) action by October 12, 2010.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Diamond Aircraft Industries GmbH Models DA 40 and DA 40F airplanes, all serial numbers (S/N), that are certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 52: Doors.

Unsafe Condition

(e) This AD results from several reports of the rear passenger door departing the airplane in flight. We are proposing this AD to change the emergency open doors procedure and retrofit the rear passenger door retaining bracket, which if not corrected could result in the rear passenger door departing the airplane in flight.

Compliance

(f) To address this problem, you must do the following, unless already done:

Actions	Compliance	Procedures
(1) *For all serial numbers:* Incorporate Diamond Aircraft Temporary Revision TR–MÄM 40–428, page 3–37b, dated April 30, 2010, into the FAA-approved airplane flight manual.	Within 6 months after the effective date of this AD.	Follow Diamond Aircraft Temporary Revision TR–MÄM 40–428, Cover Page, dated April 30, 2010.
(2) *For Model DA 40, S/N 40.006 through 40.009, 40.011 through 40.081, 40.084, and 40.201 through 40.749; and Model DA 40F S/N 40.FC001 through 40.FC009:* Replace the rear passenger door retaining bracket with an improved design retaining bracket.	Within 6 months after the effective date of this AD.	Follow Diamond Aircraft Industries GmbH Mandatory Service Bulletin NO. MSB 40–070/NO. MSB D4–079/NO. MSB F4–024, dated April 30, 2010; and Diamond Aircraft Industries GmbH Work Instruction WI–MSB 40–070/WI–MSB D4–079/WI–MSB F4–024, dated April 30, 2010.

Alternative Methods of Compliance (AMOCs)

(g) The Manager, Small Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; e-mail: *mike.kiesov@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Related Information

(h) To get copies of the service information referenced in this AD, contact Diamond Aircraft Industries GmbH, N.A. Otto-Straße 5, A–2700 Wiener Neustadt, Austria, telephone: +43 2622 26700; fax: +43 2622 26780; e-mail: *office@diamond-air.at*; Internet: *http://www.diamond-air.at.* To view the AD docket, go to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, or on the Internet at *http://www.regulations.gov.*

Issued in Kansas City, Missouri, on August 18, 2010.

John R. Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010–21068 Filed 8–24–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870, 884 and 892

[Docket No. FDA–2010–N–0412]

RIN 0910–AG51

Effective Date of Requirement for Premarket Approval for Four Class III Preamendments Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following four class III preamendments devices: Ventricular bypass (assist) device; pacemaker repair or replacement material; female condom; and transilluminator for breast evaluation. The agency is also summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA is announcing the opportunity for interested persons to request that the agency change the classification of any of the aforementioned devices based on new information. This action implements certain statutory requirements.

DATES: Submit written or electronic comments by November 23, 2010. Submit requests for a change in classification by September 9, 2010. FDA intends that, if a final rule based on this proposed rule is issued, anyone who wishes to continue to market the device will need to submit a PMA within 90 days of the effective date of the final rule. Please see section XIII of this document for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0412 and/or RIN number 0910–AG51, by any of the following methods:

Electronic Submissions