DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0326; Directorate Identifier 2013–CE–051–AD]

RIN 2120–AA64

Airworthiness Directives; Rockwell Collins, Inc. Transponders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Rockwell Collins TDR–94 and TDR–94D Mode select (S) transponders that are installed on airplanes. This proposed AD was prompted by instances where the TDR–94 and TDR–94D Mode S transponders did not properly respond to Mode S Only All-Call interrogations when the airplane transitioned from a ground to airborne state. This proposed AD would require inspecting the setting of the airplane type code category strapping and require either modifying the airplane type code category setting or installing the software upgrade to convert the affected transponders to the new part number. We are proposing this AD to correct the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by July 7, 2014.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Rockwell Collins, Inc., Collins Aviation Services, 350 Collins Road NE., M/S 153–250, Cedar Rapids, IA 52498–0001; telephone: 888–265–5467 (U.S.) or 319–265–5467; fax: 319–295–4941 (outside U.S.); email: *techmanuals@rockwellcollins.com;* Internet: *http://www.rockwellcollins.com/Services_and_Support/Publications.aspx.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0326; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Ben Tyson, Aerospace Engineer, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Room 100, Wichita, Kansas 67209; phone: 316–946–4174; fax: 316–946–4107; email: *ben.tyson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2014–0326; Directorate Identifier 2013–CE–051–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because 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 about this proposed AD.

Discussion

We were notified that Bombardier CL604 airplanes in Eurocontrol airspace were not transmitting the appropriate Mode S replies. In at least one case, the flight crews switched to the other installed transponder, resulting in normal operation. Rockwell Collins, Inc. confirmed that other types of airplane could exhibit this same unsafe condition. As a result of the issue in Eurocontrol airspace, EASA issued Airworthiness Directive 2010–0003R1, effective date January 11, 2010.

The TDR–94 and TDR–94D Mode S transponder internal software does not correctly implement the air/ground override function when the airplane type code strapping is set to any value other than (1) or (0) and the airplane rotation speed is greater than 100 knots. The error in the air/ground override function inhibits the Mode S Only All-Call replies. This condition, if not corrected, could result in increased pilot and air traffic controller workload as well as reduced separation of airplanes.

Relevant Service Information

We reviewed Rockwell Collins, Inc. Service Information Letter 07–2, Revision No. 1, 523–0810069–101000, dated September 2, 2008; Service Bulletin 505, 523–0816034–001000, dated September 2, 2008; Service Bulletin 507, 523–0816423–301000, dated Revision 3, dated December 5, 2011; Service Bulletin 508, 523–0817821–001000, dated September 16, 2009; and Service Bulletin 509, 523–0817822–001000, dated September 16, 2009. The service information describes procedures for verifying the airplane type category strapping is correctly set and installing the software upgrade to convert the affected transponders to the new part number.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require inspecting the setting of the airplane type code category strapping and require either modifying the airplane type code category setting or installing the software upgrade to convert the affected transponders to the new part number.

Costs of Compliance

We estimate that this proposed AD affects 8,000 products installed on airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect the setting of the airplane type category strapping.	1 work-hour × $85 per hour = $85.	Not applicable	$85	$680,000

We estimate the following costs to do any necessary corrections that would be required based on the results of the proposed inspection. We have no way of determining the number of airplane that might need these corrections:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Modify the airplane type code category strapping	1 work-hour × $85 per hour = $85.	Not applicable	$85.
Convert the part number of the equipment	2 work-hours × $85 per hour = $170.	See conversion parts cost table.	Varies depending on applicable part number or service bulletin.

CONVERSION PARTS COST TABLE—TDR–94 AND TDR–94D

Starting part number	Service Bulletin 505	Service Bulletin 507	Service Bulletin 508	Service Bulletin 509
–007	N/A	$5,886	$12,636	$18,465
–008	$2,323	5,886	3,414	9,429
–108	2,323	N/A	N/A	6,816
–207	N/A	5,886	9,234	15,057
–308	2,323	5,886	3,414	9,429
–309	N/A	5,886	3,414	9,429
–310	N/A	N/A	N/A	6,183
–408	2,323	N/A	N/A	3,414
–409	N/A	N/A	N/A	3,414

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 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 this 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),

(3) Will not affect intrastate aviation in Alaska, and

(4) 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.

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 airworthiness directive (AD):

Rockwell Collins, Inc.: Docket No. FAA–2014–0326; Directorate Identifier 2013–CE–051–AD.

(a) Comments Due Date

We must receive comments by July 7, 2014.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to the following Rockwell Collins, Inc. part number (P/N) Mode S transponders that are known to be installed on but not limited to the airplanes listed in paragraphs (c)(2)(i) through (c)(2)(xiv) of this AD, except for those airplanes listed in paragraphs (c)(3)(i) through (c)(3)(vi) of this AD, that have been modified in-production or in-service:

(i) TDR–94: CPN 622–9352–008, 622–9352–108, 622–9352–308, 622–9352–408; and

(ii) TDR–94D: CPN 622–9210–008, 622–9210–108, 622–9210–308, 622–9210–408.

(2) The products listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this AD may be installed on but not limited to the following airplanes featuring weight-on wheels input to the transponder, certificated in any category:

(i) ATR42 and ATR72;

(ii) Bombardier (Canadair) CL–600–2B16 (604 Variant);

(iii) Bombardier CL–600–2B19 (RJ100 and RJ200);

(iv) Cessna 525, serial numbers (S/N) 525–0600 through 525–0684 (CJ1);

(v) Cessna 525A, S/N 525A–0300 through 525A–0438 (CJ2);

(vi) Cessna 525B, S/N 525B–0001 through 525B–0293 (CJ3);

(vii) Cessna 560, S/N 560–0751 through 560–0802 (Citation Encore);

(viii) Cessna 560XL, S/N 560–6001 and subsequent;

(ix) Dassault Aviation Mystere-Falcon 50;

(x) Dassault Aviation Mystere-Falcon 900;

(xi) Dassault Aviation Falcon 2000;

(xii) Dassault Aviation Falcon 2000EX;

(xiii) Piaggio Aero Industries P.180 (Avanti and Avanti II); and

(xiv) SAAB 2000.

(3) This AD action does not apply to the excepted airplane models, identified in paragraphs (c)(3)(i) through (c)(3)(vi) of this AD, that have been modified in-production or in-service. They do not have the unsafe condition described in this AD.

(i) Dassault airplanes that have been modified in-service or in-production following the applicable Dassault Aviation service information as listed in table 1 of paragraph (c)(3)(i) of this AD.

TABLE 1 OF PARAGRAPH (C)(3)(I) OF THIS AD: EXCEPTED DASSAULT AIRPLANES

Airplane models	Service Bulletin	Modification(s)
Mystere-Falcon 50	F50–457	M2966 and M2968.
Mystere-Falcon 900	F900–354	M3896.
Falcon 900EX	F900EX–239	M3896.
Falcon 2000	F2000–312	M2624 and M2632.
Falcon 2000EX	F2000EX–043	M2624.

(ii) Model ATR 42 airplanes or ATR 72 airplanes that had P/N 622–9210–108 transponders installed in production using ATR modification 05614 or installed in-service using ATR Service Bulletin ATR42–34–0167 or ATR Service Bulletin ATR72–34–1094, as applicable.

(iii) SAAB Model 2000 airplanes that had P/N 622–9210–008 transponders installed in production using SAAB modifications 6231, 6243, and 6249 or installed in-service using SAAB Service Bulletins 2000–34–066, 2000–34–072, and 2000–34–076.

(iv) Bombardier Aerospace (Canadair) airplanes Model CL–600–2B16 (604 Variant) that had P/N 622–9210–008 transponders installed and incorporated the corrective actions recommended in the Bombardier Advisory Wire AW 604–34–0078 using the instructions in Bombardier Aerospace Service Bulletin 604–34–054 (drawing 604–70482 Engineering Order, Revison D–1) or using a service request for product support. Bombardier Aerospace (Canadair) airplanes Model CL–600–2B19 (RJ100 and RJ200) that had P/N 622–9210–008 transponders installed in production using Bombardier Aerospace Modification TC601R16789 or in service using Bombardier Aerospace Service Bulletin 601R–34–142 (Modification TC601R16790).

(v) Cessna Aircraft Company Models 525, 525A, and 525B airplanes that had P/N 622–9352–008 transponders installed in production using Cessna Engineering Change Records (ECRs) 55298, 58654, and 59567; and Model 525B airplanes that had P/N 622–9352–008 transponders installed in service using Cessna Aircraft Company Service Bulletin SB525B–34–03 or SB525B–34–08. Cessna Aircraft Company Models 525, 525A, 525B, 560, and 560XL airplanes that had P/N 622–9210–008 transponders installed in production using Cessna ECRs 55298, 58654, 59567, 56135, and 58032; and Model 525B airplanes that had P/N 622–9210–008 transponders installed in service using Cessna Service Bulletin SB525B–34–03 or SB525B–34–08.

(vi) Piaggio Aero Industries Model P.180 (Avanti) airplanes that had P/N 622–9210–008 transponders installed in production using Piaggio modification 80–0773 or in service using Piaggio Service Bulletin SB–80–0227. Piaggio Aero Industries Model P.180 (Avanti II) airplanes that had P/N 622–9210–008 transponders installed in production using Piaggio modification 80–0588 and 80–0598.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by instances where the TDR–94 and TDR–94D Mode S transponders did not properly respond to Mode S Only All-Call interrogations when the airplane transitioned from a ground to airborne state. We are issuing this AD to detect and correct Mode S transponders that do not respond correctly to Mode S Only All-Call interrogations, which could result in increased pilot and air traffic controller workload as well as reduced separation of airplanes.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection

Within the next 2 years after the effective date of this AD, inspect the airplane type code category strapping setting for a value of zero (0) or one (1) following Rockwell Collins, Inc. Service Information Letter 07–2, 523–0810069–101000, Revision 1, dated September 2, 2008. If the airplane type code category strapping is set to a value of zero (0) or one (1), no further action is required by this AD.

(h) Modification

If the airplane type code category strapping is not set to a value of zero (0) or one (1), within two years after the effective date of this AD, do the actions required in either paragraph (h)(1) or (h)(2) of this AD.

(1) Modify the airplane type code category strapping setting to a value of zero (0) or one (1) following Rockwell Collins, Inc. Service Information Letter 07–2, 523–0810069–101000, Revision 1, dated September 2, 2008.

(2) Install a software upgrade to convert the part numbers of the transponders to the new part numbers using the following service information, as applicable:

Note 1 to paragraph (h)(2) of this AD: More than one of the bulletins may apply to your particular P/N transponder, but each bulletin brings different capabilities and associated costs. We recommend reviewing each bulletin to determine the optimal choice for your installation.

(i) Service Bulletin 505, 523–0816034–001000, dated September 2, 2008;

(ii) Service Bulletin 507, 523–0816423–301000, Revision 3, dated December 5, 2011;

(iii) Service Bulletin 508, 523–0817821–001000, dated September 16, 2009; or

(iv) Service Bulletin 509, 523–0817822–001000, dated September 16, 2009.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (j)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

(1) For more information about this AD, contact Ben Tyson, Aerospace Engineer, Wichita ACO, FAA, 1801 Airport Road,

Room 100, Wichita, Kansas 67209; phone: 316–946–4174; fax: 316–946–4107; email: *ben.tyson@faa.gov.*

(2) For service information identified in this AD, contact Rockwell Collins, Inc., Collins Aviation Services, 350 Collins Road NE., M/S 153–250, Cedar Rapids, IA 52498–0001; telephone: 888–265–5467 (U.S.) or 319–265–5467; fax: 319–295–4941 (outside U.S.); email: *techmanuals@rockwellcollins.com;* Internet: *http://www.rockwellcollins.com/Services_and_Support/Publications.aspx.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on May 16, 2014.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–11846 Filed 5–21–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2014–N–0440]

Microbiology Devices; Reclassification of Influenza Virus Antigen Detection Test Systems Intended for Use Directly With Clinical Specimens

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify antigen based rapid influenza virus antigen detection test systems intended to detect influenza virus directly from clinical specimens that are currently regulated as influenza virus serological reagents from class I into class II with special controls and into a new device classification regulation.

DATES: Submit either electronic or written comments on the proposed order by August 20, 2014. See section XI for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2014–N–0440, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/*Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2014–N–0440 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stefanie Akselrod, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5517, Silver Spring, MD 20993–0002, 301–796–6188.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the FD&C Act, FDA clears or approves the three classes of medical devices for commercial distribution in the United States through three regulatory processes: Premarket approval (PMA), product development protocol, and premarket notification (a premarket notification is generally referred to as a ''510(k)'' after the section of the FD&C Act where the requirement is found). The purpose of a premarket notification is to demonstrate that the new device is substantially equivalent to a legally marketed predicate device. Under section 513(i) of the FD&C Act, a device is substantially equivalent if it has the same intended use and technological characteristics as a predicate device, or has different technological characteristics but data demonstrate that the new device is as safe and effective as the predicate device and does not raise different issues of safety or effectiveness.

FDA determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807). Section 510(k) of the FD&C Act and the implementing regulations in part 807, subpart E, require a person who intends to market a medical device to submit a premarket notification submission to FDA before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use.

In accordance with section 513(f)(1) of the FD&C Act, devices that were not in commercial distribution before May 28, 1976, the date of enactment of the 1976 amendments, generally referred to as postamendment devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless FDA classifies the device into class I or class II by issuing an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval or the device is reclassified into class I or class II. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807 of FDA's regulations.

Section 513(f)(2) of the FD&C Act establishes procedures for ''de novo'' risk-based review and classification of postamendment devices automatically classified into class III by section