



SAIB: HQ-12-07R1

Date: March 2, 2012

SUBJ: Emergency Equipment – Contaminated Iodine Wipes

This is information only. Recommendations aren't mandatory.

Introduction

This Special Airworthiness Information Bulletin is intended to alert owners and operators of all aircraft of the potential that first aid kits sold by Avox Systems, Inc. may contain contaminated iodine wipes (labeled as Applicator, Antiseptic and also referred to as iodine or povidine prep pads). This revision reflects new service information which allows for easier identification of affected wipes. The applicability and recommendations remain unchanged.

Background

14 CFR 91.513, 14 CFR 121.803, 14 CFR 125.207, and 14 CFR 135.177 require aircraft operated under those parts to have certain emergency equipment. This includes first aid and emergency medical kits. The FAA has been notified by Avox Systems, Inc., of potential contamination of certain iodine wipes. The wipes are included as antiseptic swabs as part of first aid kits. Additionally, these wipes were also sold individually and as replacement parts. The manufacturer of the wipes has issued a recall.

Recommendations

Owners and operators are encouraged to inspect their first aid or emergency medical kits for Avox Systems, Inc. part number 70135-00. These parts are known to be included in Avox kit numbers including, but not limited to, 70001-00, 70002-00, 70003-00, 70004-00, 74050-00, 74051-00, 74052-00, 74052-01, and 73777-01. The packages may be marked as North PVP Iodine Wipe.

Check the package for the lot number. See attached Avox Systems Inc. Service Information Letter, SIL-25-01, Revision 2, dated December 2, 2011, for more information, including pictures, on how to identify the lot number. Lot numbers W349999 and lower are suspect and should be replaced. Lot numbers W350000 and higher are not suspect and are acceptable as is.

For Further Information Contact

Rob Romero, Aerospace Engineer, 2601 Meacham Blvd., Fort Worth, TX 76137; phone: (817) 222-5102; fax: (817) 222-5960; e-mail: Robert.A.Romero@faa.gov.

AIRCRAFT SYSTEMS
Oxygen Systems

Date: June 13, 2011

To: All Aircraft Operators, Airframe OEMs, Distributors, Zodiac Services Locations,
that may be in possession of suspect Applicator, Antiseptic AVOX P/N 70135-00

From: AVOX Systems Inc.

Subject: Recall Notification Povidine Prep Pads, (Applicator, Antiseptic, AVOX P/N 70135-00)

AVOX Systems was recently notified by the Food and Drug Administration (FDA) and our supplier (H&P Industries Inc.) of a recall for Povidine Prep Pads, (Applicator, Antiseptic AVOX P/N 70135-00).

This recall has been initiated due to concerns expressed by the FDA regarding the potential contamination of these products with an objectionable organism, *Elizabethkingia meningoseptica*. H&P Industries Inc. internal investigation also concluded a raw material component as the potential source of this contamination.

Use of contaminated Povidine Prep Pads, (Applicator, Antiseptic, AVOX P/N 70135-00) could lead to life threatening infections, especially in at risk populations, including neonates, immune suppressed patients, and surgical patients. Treatment options are limited for *Elizabethkingia meningoseptica infections*. To date we have not received any reports of adverse events.

This recall extends to all lots of PVP -Iodine Prep Pads (Applicator, Antiseptic AVOX P/N 70135-00) remaining within their labeled expiration dating (three years), including all lot numbers beginning with the digits 8, 9, 0 or 1. PVP -Iodine Prep Pads packages (AVOX P/N 70135-00) identified with and expiration dates between March - 2011 and April 2014 are affected.

The above mention item may have been delivered to your facility in two forms:

- a) Delivered as a detailed component of a First Aid Kit 1st (see Appendix I)
- b) Delivered as a detailed component Applicator, Antiseptic AVOX P/N 70135-00 (see Appendix II)

Please immediately examine your inventory and quarantine product subject to the recall.

To secure replacements go to <http://www.avoxsys.com/website>.

Complete the form located under heading "**Customer Support**"

Titled: Recall - PVP - Iodine Prep Pads. (AVOX PN # 70135-00)

Please email your completed form to: ***Carol Messina – AVOX Customer Service Representative***

E-mail: carol.messina@zodiac aerospace.com

AVOX apologizes for all inconveniences caused by this situation and pledges its full resources towards a quick resolution.

Sincerely,

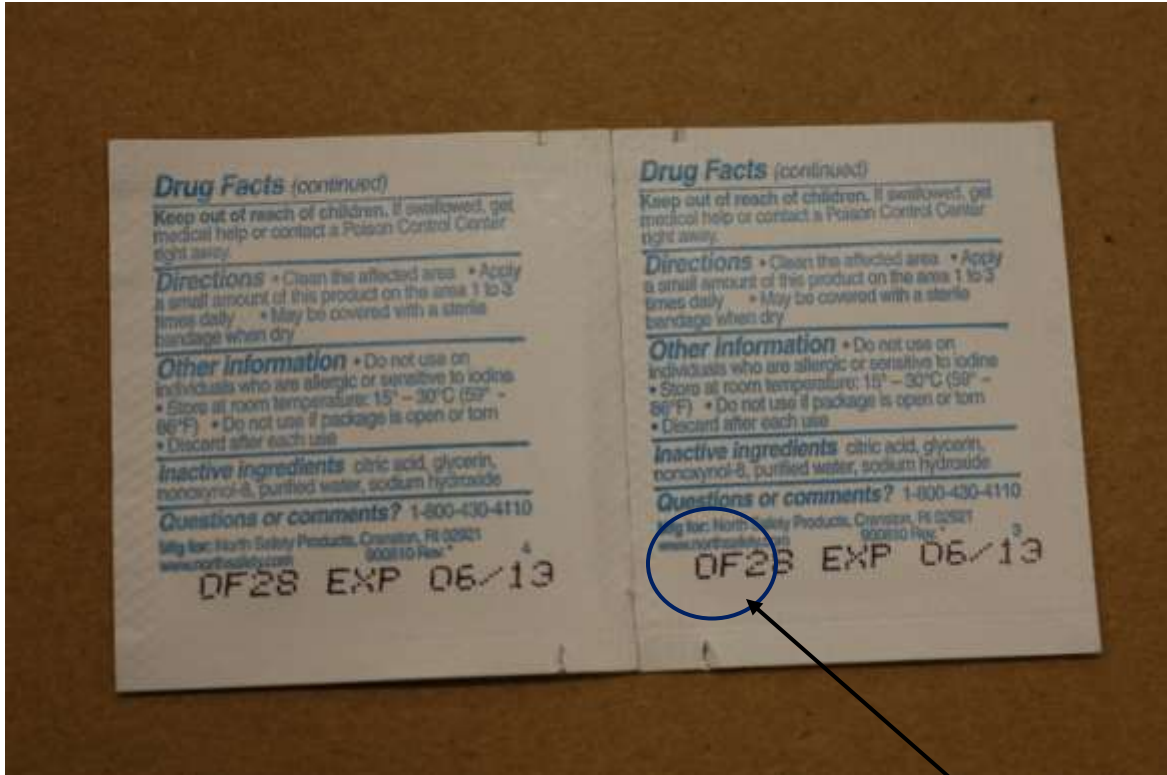
Deborah Rindfuss Ellis
Director of Quality Assurance
716-686-1562
Deborah.Ellis@zodiac aerospace.com

Appendix I

First Aid Kit PN #	Qty of PVP- Iodine Prep Pads AVOX P/N 70135-00 per Kit	Range of Expiration Dates Effected
70001-00	2 boxes containing (10 each)	March -2011 and April 2014
70002-00	4 boxes containing (10 each)	
70003-00	6 boxes containing (10 each)	
70004-00	6 boxes containing (10 each)	
74050-00	2 boxes containing (10 each)	
74051-00	4 boxes containing (10 each)	
74052-00	6 boxes containing (10 each)	
74052-01	2 boxes containing (10 each)	
73777-01	2 boxes containing (10 each)	



Appendix II



The example that appears above would be included in the recall .
Individual PVP -Iodine Prep Pads identified with lot numbers beginning with the digits 8, 9, 0 or 1 are affected.



SERVICE INFORMATION LETTER

AVOX Systems Inc., 225 Erie Street, Lancaster NY 14086-9502 USA
Tel: 716-683-5100 • Fax: 716-681-1089 • Vendor Code: 53655

EQUIPMENT/FURNISHINGS - ATA CHAPTER 25

MANUFACTURER VOLUNTARILY RECALLS POTENTIALLY CONTAMINATED POVIDONE IODINE PREP PADS THAT MAY BE CONTAINED IN AVOX SYSTEMS FIRST AID KITS

WARNING: USE OF CONTAMINATED POVIDONE IODINE PREP PADS MARKED AS AVOX SYSTEMS ANTISEPTIC APPLICATOR PADS PART NUMBER (PNR) 70135-00 AND POTENTIALLY CONTAINED IN AVOX SYSTEMS FIRST AID KITS COULD LEAD TO LIFE THREATENING INFECTION ESPECIALLY IN POPULATIONS AT RISK, INCLUDING NEONATES, IMMUNE-SUPPRESSED AND SURGICAL PATIENTS.

1. BACKGROUND

H&P Industries, Inc. has issued a voluntary recall of Povidone Iodine Prep Pads. These pads are potentially contaminated by Elizabethkingia meningoseptica which is a bacterium that can cause serious infection and death.

Some of these pads were packaged by H&P Industries for North Safety Products, then re-identified by AVOX Systems as Antiseptic Applicators PNR 70135-00 (see Table 1 and Figure 1). These antiseptic applicators are contained in the AVOX Systems first aid kits identified in Table 2.

2. DESCRIPTION

These wipes are packaged 10 to a box by North Safety Products, re-identified by AVOX Systems and included in AVOX Systems first aid kits. The quantities of boxes (AVOX PNR 70135-00) in each AVOX first aid kit are listed by PNR in Table 2.

It is necessary to inspect all AVOX Systems first aid kits listed in Table 2 to determine if any contain the affected lots of PVP iodine wipes identified in Table 3. Figures 1, 2 and 3 show where the lot number appears on the box.

All affected units must be properly disposed of. Replacement units will be provided by AVOX Systems free of charge.

You are authorized to make copies of this SIL and give them to other persons. If you copy this SIL, you must copy all of the SIL.

3. EFFECTIVITY

A. Aircraft

AVOX Systems first aid kits can be installed in any commercial, corporate or general aviation aircraft.

B. Spares

This SIL also applies to all units held in spares.

Table 1
Relationship of Products by Company

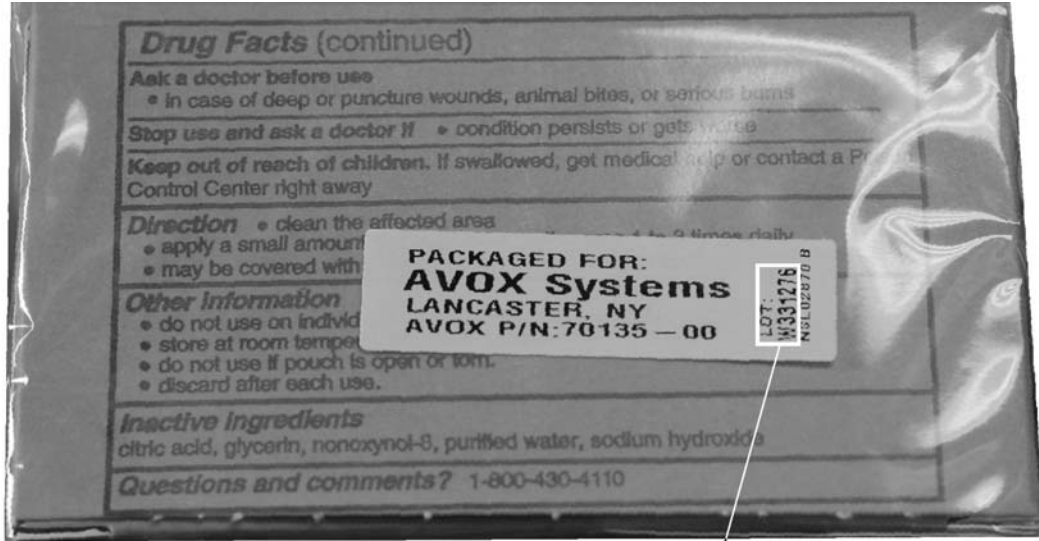
Company	Nomenclature	PNR
H&P Industries, Inc.	Povidone Iodine Prep Pads	N/A
	PVP Iodine Wipe	N/A
AVOX Systems	Antiseptic Applicator	70135-00

Table 2
Part Numbers of Affected First Aid Kits

AVOX Part Number	Qty of Pads PNR 70135-00 per Kit
70001-00	2 boxes containing (10 each)
70002-00	4 boxes containing (10 each)
70003-00	6 boxes containing (10 each)
70004-00	2 boxes containing (10 each)
74050-00	2 boxes containing (10 each)
74051-00	4 boxes containing (10 each)
74052-00	6 boxes containing (10 each)
74052-01	2 boxes containing (10 each)
73777-01	2 boxes containing (10 each)

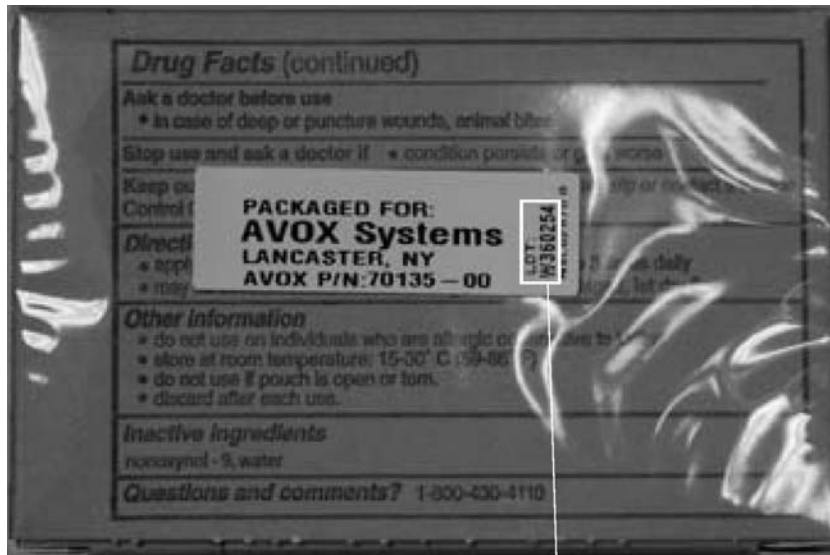
Table 3
Affected Lot Numbers
(See Figures 1, 2, 3)

AFFECTED Lot Numbers	NOT Affected Lot Numbers
W349999 and lower	W350000 and higher



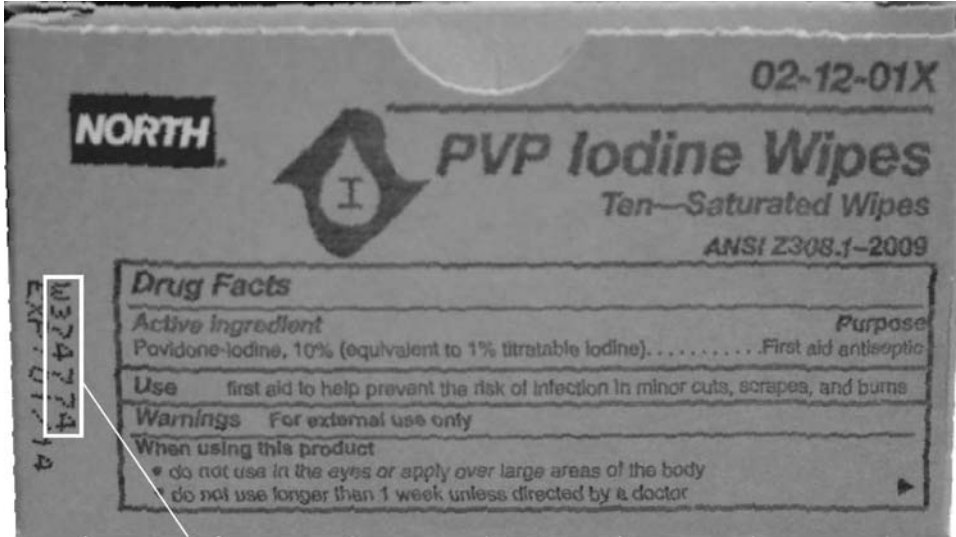
LOT NUMBER ON LABEL ON CLEAR WRAP (W331276 = AFFECTED)

AFFECTED Example Box of PNR 70135-00 Antiseptic Applicators
Figure 1



LOT NUMBER ON LABEL ON CLEAR WRAP (W360254 = NOT AFFECTED)

NOT Affected Example of PNR 70135-00 Box with Lot Number on Label on Wrap
Figure 2



LOT NUMBER ON BOX (W374774 - NOT AFFECTED)

NOT Affected Example of PNR 70135-00 Box with Lot Number on Box
Figure 3

4. Action

- A. Immediately examine all AVOX Systems first aid kits (Table 2) on your fleet or in your stores.
- B. Quarantine all items affected by this SIL (see Table 2 and Figure 1).
- C. Complete the form in the appendix of this SIL and email it to AVOX Systems to obtain replacement antiseptic applicators PNR 70135-00.
- D. Replace all units removed from first aid kits on aircraft and in stores with new antiseptic applicators obtained from AVOX Systems.
- E. The PVP Iodine Wipes have been designated as non- hazardous and can be disposed of through conventional methods.

5. APPENDIX

A. To get technical aid, contact a Zodiac Services location:

ZODIAC SERVICES EUROPE	ZODIAC SERVICES ASIA	ZODIAC SERVICES AMERICAS
<p>Celine Melloul Product Support Manager 7, avenue du Parana BP 303 91958 COURTABOEUF cedex FRANCE Phone: +33 1 64 86 53 33 Fax: +33 1 64 86 69 85 celine.melloul@zodiac aerospace.com www.zodiac aerospace.com</p>	<p>Cyril Coutou Product Support Engineer 36 Loyang Drive SINGAPORE 508949 Phone : +65 6579 2251 Cell: +65 9770 5059 Fax: +65 6579 2231 cyril.coutou@zodiac aerospace.com www.zodiac aerospace.com</p>	<p>Ruben Membrila Technical Support Engineer 6734 Valjean Ave. Van Nuys, CA 91406 USA Phone: +1 818 435 0928 x2928 Fax: +1 818 435 0960 ruben.membrila@zodiac aerospace.com www.zodiac aerospace.com</p>

B. To buy spares or to have a cylinder assembly serviced, contact an Authorized Distributor:

EUROPE: ZSE	UNITED KINGDOM: ZAU	USA: ZSU
<p>ZODIAC SERVICES EUROPE 7, avenue du Parana BP 303 91958 COURTABOEUF Cedex FRANCE Phone: +33 1 64 86 69 69 AOG: +33 1 49 75 45 73 Fax: +33 1 64 86 69 79</p>	<p>ZODIAC Aerospace UK Unit 9, Blackwell Drive Springwood Industrial Estate BRAINTREE Essex CM72QJ England Phone: +44 (0)1376 329 194 Fax: +44 (0)1376 340 734</p>	<p>ZODIAC SERVICES AMERICAS 4900 St Joe Boulevard Building 200, Suite 400 COLLEGE PARK, GA 30337 USA Phone: +1 678 228 8153 AOG: +1 800 879 0411 Fax: +1 818 994 7901</p>
MIDDLE EAST: ZSM	ASIA: ZSA	
<p>IN-SERVICES MIDDLE EAST Abu Dhabi International Airport Cargo Village Area P.O. Box 106675 ABU DHABI UNITED ARAB EMIRATES Phone: +(971)-2575 7088 AOG: +(971)-5064 20034 Fax: +(971)-2575 8482</p>	<p>ZODIAC SERVICES ASIA 36, Loyang Drive SINGAPORE 508949 Phone: +65 6546 9792 AOG: +65 9770 5061 Fax: +65 6579 2231</p>	

Notice of Destruction

PRODUCT DESIGNATED FOR DESTRUCTION

Product Description: PVP -Iodine Prep Pads (AVOX P/N 70135-00 Applicator, Antiseptic)

Item Number:	AVOX P/N 70135-00	If Applicable, NCR No.:	
Lot Code:			
Quantity/unit:			

Reason for Destruction:

Product Location:

Replacements shall be shipped to :

Name:

Address:

City:

State:

Zip Code:

Phone:

Email:

Contact Name:

NOTE:

**FIRST AID KITS (see notification letter) IDENTIFIED WITH LOT NUMBERS:
W350000, RW350000, VW350000
OR HIGHER CONTAIN PVP -Iodine Prep Pads (AVOX P/N 70135-00 Applicator, Antiseptic)
THAT ARE "ACCEPTABLE" FOR USE.**

CERTIFICATE OF DESTRUCTION

THIS PRODUCT HAS BEEN DESTROYED IN A MANNER RENDERING IT INCAPABLE OF USE.

Method of Destruction:

- Deface and dispose of in accordance with local regulations.
- Other _____

Note: The PVP Iodine Wipes have been designated as Non- hazardous and can be disposed of through conventional methods.

Destroyed By:

Title:

Verified By:

Title:

Please email your completed form to Carol Messina, AVOX Customer Service Representative:

E-mail: carol.messina@zodiac aerospace.com