USAFSAM-TP-89-6

EVALUATION OF THE BIOMED SPRING-ACTUATED INFUSION PRESSOR AND THE MIGADA EMERGENCY AND MILITARY INFUSION SYSTEM

Rufino U. Navalta, Jr., Master Sergeant, USAF

August 1989

Interim Report for Period January 1988 - July 1988

USAF SCHOOL OF AEROSPACE MEDICINE
Human Systems Division (AFSC)
Brooks Air Force Base, TX 78235-5301

NOTICES

This interim technical paper was submitted by personnel of the Chemical Defense Branch, Crew Technology Division, USAF School of Aerospace Medicine, Human Systems Division, AFSC, Brooks Air Force Base, Texas, under job order 7930-16-12.

When Government drawings, specifications, or other data are used for any purpose other than in connection with a definitely Government-related procurement, the United States Government incurs no responsibility or any obligation whatsoever. The fact that the Government may have formulated or in any way supplied the said drawings, specifications, or other data, is not to be regarded by implication, or otherwise in any manner construed, as licensing the holder or any other person or corporation; or as conveying any rights or permission to manufacture, use, or sell any patented invention that may in any way be related thereto.

The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

This report has been reviewed and is approved for publication.

RUFINO U. NAVALTA, JR., MSgt, USAF
Project Scientist

F. WESLEY BAUMGARDNER, Ph.D.
Chief, Chemical Defense Branch

GEORGE E. SCHWENDER, Colonel, USAF, MC, CFS
Commander

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

1a. REPORT SECURITY CLASSIFICATION: Unclassified	1b. RESTRICTIVE MARKINGS
2a. SECURITY CLASSIFICATION AUTHORITY	3. DISTRIBUTION/AVAILABILITY OF REPORT: Approved for public release; distribution is unlimited.
2b. DECLASSIFICATION/DOWNGRADING SCHEDULE	
4. PERFORMING ORGANIZATION REPORT NUMBER(S): USAFSAM-TP-89-6	5. MONITORING ORGANIZATION REPORT NUMBER(S)
6a. NAME OF PERFORMING ORGANIZATION: USAF School of Aerospace Medicine; 6b. OFFICE SYMBOL (If applicable): USAFSAM/VNC	7a. NAME OF MONITORING ORGANIZATION
6c. ADDRESS (City, State, and ZIP Code): Human Systems Division (AFSC), Brooks Air Force Base, TX 78235-5301	7b. ADDRESS (City, State, and ZIP Code)
8a. NAME OF FUNDING/SPONSORING ORGANIZATION: HQ, Military Airlift Command; 8b. OFFICE SYMBOL (If applicable): MAC/SGNL	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER
8c. ADDRESS (City, State, and ZIP Code): Scott Air Force Base, IL 62225	10. SOURCE OF FUNDING NUMBERS

PROGRAM ELEMENT NO.	PROJECT NO.	TASK NO	WORK UNIT ACCESSION NO
62202F	7930	16	12

11. TITLE (Include Security Classification): Evaluation of the Biomed Spring-Actuated Infusion Pressor and the Migada Emergency and Military Infusion System

12. PERSONAL AUTHOR(S): Navalta, Rufino U., Jr.

13a. TYPE OF REPORT	13b. TIME COVERED	14. DATE OF REPORT (Year, Month, Day)	15. PAGE COUNT
Interim	FROM 88/01 TO 88/07	1989, August	8

16. SUPPLEMENTARY NOTATION

17. COSATI CODES		
FIELD	GROUP	SUB-GROUP
23	01	
23	05	

18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number): Test and evaluation; Intravenous (I.V.) bag pressor; Biomed and administration set; Migada; Aeromedical evacuation

19. ABSTRACT (Continue on reverse if necessary and identify by block number)

The Israeli Defense Forces (IDF) developed an infusion administration system consisting of a foldable spring-actuated infusion bag pressor and an administration set with a nonoriented air-trap drip chamber. This system enables medical personnel to perform intravenous (I.V.) infusion even when limited space restricts the use of gravitational force, and/or when fast administration of fluid is indicated. In both cases, continuous monitoring of flow is possible, while the risk of air emboli is avoided. The system includes the Biomed Spring-Actuated Infusion Pressor (S.A. Pressor), (Cat. 51787), and the Emergency and Military Infusion System (EMIS). The S.A. Pressor and the EMIS were found acceptable for use on board aeromedical evacuation aircraft. This technical paper presents the results of the United States Air Force School of Aerospace Medicine/Chemical Defense Branch, Aeromedical Research Function evaluation of the S.A. Pressor and the EMIS.

20. DISTRIBUTION/AVAILABILITY OF ABSTRACT	21. ABSTRACT SECURITY CLASSIFICATION
☒ UNCLASSIFIED/UNLIMITED ☐ SAME AS RPT. ☐ DTIC USERS	Unclassified

22a. NAME OF RESPONSIBLE INDIVIDUAL	22b. TELEPHONE (Include Area Code)	22c. OFFICE SYMBOL
Rufino U. Navalta, Jr., Master Sergeant, USAF	(512) 536-2937	USAFSAM/VNC

DD Form 1473, JUN 86 — Previous editions are obsolete. — SECURITY CLASSIFICATION OF THIS PAGE

EVALUATION OF THE BIOMED SPRING-ACTUATED INFUSION PRESSOR AND THE MIGADA EMERGENCY AND MILITARY INFUSION SYSTEM

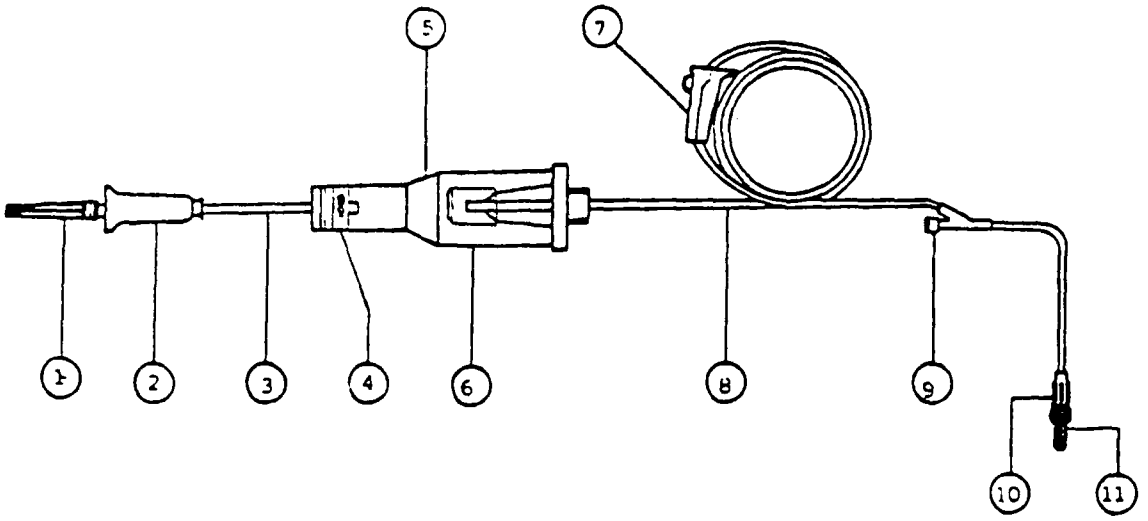
INTRODUCTION

The Israeli Defense Forces (IDF) developed an infusion administration system consisting of a foldable spring-actuated infusion bag pressor and an administration set with a nonoriented air-trap drip chamber. This system enables medical personnel to perform intravenous (I.V.) infusion even when limited space restricts the use of gravitational force, and/or when fast administration of fluid is indicated. In both cases, continuous monitoring of flow is possible, while the risk of air emboli is avoided (1). This technical paper presents the results of our evaluation of the IDF developed infusion administration system for possible use in the U. S. Air Force (USAF) aeromedical evacuation environment

The system includes the Biomed Spring-Actuated Infusion Pressor (S.A. Pressor) (Cat. 51787), manufactured by Biomedical Instruments Ltd, P.O. Box 26100, Tel Aviv 61260, Israel; and the Emergency and Military Infusion System (EMIS) (Fig. 1), manufactured by Migada, Science Based Industrial Park, P.O. Box 211, Rehovot 7601, Israel.

The S.A. Pressor allows quick infusion administration from a collapsible plastic bag without the need to hang the bag over the patient. The S. A. Pressor consists basically of 6 curved, hardened steel plates. The plates, in 2 groups of 3, are covered by a strong synthetic fabric; the 6 plates form 2 large curved plates, fastened at one edge to a common hinge, around which they revolve. A sleeve made from the same synthetic fabric is also attached to this hinge. A long strap is riveted to the free edge of the opposite plate. By pulling the strap, the 2 groups of 3 plates are pivoted to the closed position. The other pairs of steel plates can be closed together by clamps. Because of the elasticity, when closed, the plates apply a continuous squeezing force to the bag inserted in the sleeve, and the squeezing force is exercised until the infusion bag is empty (2). The S. A. Pressor can be used an estimated 1,000 times and has a minimum shelf life of 10 years when left in the unopened package.

The dominant factor differentiating the EMIS set from the regular set is the design of the drip chamber which serves as a trap for air bubbles at the same time. The EMIS drip chamber is made of a rigid transparent material. This configuration ensures that after the chamber is partially filled with fluid, there is no contact between the outlet opening and the air bubble in any possible position of the chamber. Thus the small amount of air left in the drip chamber enables monitoring of the flow when the drip chamber is held in the upright position, but the air does not escape into the circulatory system (1). The EMIS has a drop/volume ratio of 20 drops/ml (cm^3) and an accuracy of ±10 %.



1. Protector (spike cover)
2. Spike
3. Plastic tubing
4. Filter
5. Conical zone
6. Drip chamber
7. Control (roller) clamp
8. Plastic tubing
9. Injection site
10. Male Luer lock
11. Protector

Note: Except for items 4,5, & 6, all other parts of the EMIS are identical to a regular administration set

Figure 1. Emergency and Military Infusion System (EMIS) (1).

METHODS

The Aeromedical Equipment Evaluation Laboratory (AEEL) develops test procedures that cover safety and human factors issues regarding the equipment to be tested. Specifically, a "performance check" is developed; this check is a procedure that verifies proper functioning of the equipment under various conditions. Before our evaluation, an initial inspection is performed by a biomedical equipment maintenance technician (BEMT) to verify conformance to manufacturer specifications.

When the device passes the initial inspection, it is subjected to various "referee tests" to check its performance under various anticipated operational conditions. The "referee tests" generally involve a repetition of the performance check under the specified conditions. Each "referee test" also includes any special measurements or procedures necessary due to the peculiarities of the testing conditions.

Performance Check

The S.A. Pressor and EMIS were prepared in accordance with manufacturer's literature. A 1,000 ml 0.9% sodium chloride solution I.V. bag, an Arm-A-Flow I. V. Flow Regulator and an 18-gauge catheter were used in the different setups. Pressure was measured using a Gould pressure transducer, series P23 and preamplifier (Model 13-461550I), and recorded on a Grant Squirrel Data Logging System. The pressure of the I.V. fluid was continuously measured at the I.V. bag injection port during maximum I.V. fluid flow. During the other tests when the flow was adjusted for a certain rate, pressure was measured by momentarily occluding the I.V. fluid flow at a 3-way stopcock placed in-line before the catheter. Drip rate was adjusted using the EMIS clamp

or the Arm-A-Flow regulator, and measured at the EMIS drip chamber. The S.A. Pressor was at a horizontal position and at the same plane as the EMIS, catheter, and pressure transducer.

Initial Inspection

The following tests were performed:

1. Maximum flow.
2. Flow at 93 drops/min or 279 ml/h using EMIS.
3. Flow at 93 drops/min or 279 ml/h using EMIS and Arm-A-Flow regulator.
4. Human factors and physical characteristics.

Vibration

The main purpose of this test was to observe if the EMIS passed any air bubbles to the administration site when subjected to the vibrational forces encountered during aeromedical transport (3). The test setup was the same as in the initial inspection, but flow was set at 75 drops/min or 225 ml/h. The EMIS was taped to the vibration table and was on the same horizontal plane as the S.A. Pressor and catheter.

Altitude

The test setup was the same as in the maximum I.V. flow test in the initial inspection. During the initial altitude test, the I.V. fluid in the EMIS chamber receded below the normal level once we were at altitude. As a follow-up test, two other test setups were done to observe the effects of underfilling and overfilling the EMIS chamber by 1.7 ml (cm^3) from the normal level.

Tests Not Performed

Our evaluation routinely includes electromagnetic compatibility (EMC), environmental, and clinical tests. However, our staff judged these tests are unnecessary due to the design and construction of the S.A. Pressor and the EMIS. We should note that operating the EMIS or any unheated fluid-filled device in freezing temperatures (0° C (32° F)) will render the device unusable. In-flight feasibility testing was not necessary because data from the initial, vibration, and altitude tests were sufficient to support our results and conclusions.

RESULTS

The S.A. Pressor performed as stated in the product literature. Its simple design, operation, and rugged construction make the S.A. Pressor ideal for field use. However, a small amount of dexterity and strength is needed to close the S.A. Pressor clamps. Another drawback is the inability of the care provider to visually determine how much fluid is left in the I.V. bag because of the opaque construction of the S.A. Pressor.

The S.A. Pressor was designed for unattended and fast infusion of large quantities of fluid. During the maximum flow test, the S. A. Pressor delivered a 1,000 ml 0.9 % sodium chloride solution in 17 min. The Flow Performance Testing literature of the manufacturer stated it can deliver 800 ml (from a 1,000 ml bag) 0.9 % sodium chloride solution in 14 min. The I.V.

flow and the I.V. fluid pressure decreased as the I.V. solution was delivered. Consequently, the care provider must monitor and adjust the drip rate as necessary if the S.A. Pressor is used for other than a maximum flow. The use of an Arm-A-Flow I.V. fluid regulator helped stabilize the drip rate even when the I.V. fluid pressure decreased as the I.V. solution was delivered.

Altitude caused a minor change in flow. Air expansion within the EMIS chamber caused the fluid at the chamber to recede but not enough to pass air bubbles. Overfilling and underfilling the EMIS chamber do not affect the flow.

The vibration tests produced some interesting results. Low (5-35 Hz) vibration frequencies produced small air bubbles at the EMIS chamber. As the vibration frequency went beyond 35 Hz, these small air bubbles grouped into bigger bubbles and were passed to the administration site. The amount of air bubbles passed was minimal and did not pose a medical threat.

During the sinusoidal (Z-axis) vibration test, the EMIS chamber filled up by 1.6 ml (cm^3) past the normal level. The vibration action mimicked the EMIS chamber fill-up procedure, which instructs the user to shake the chamber horizontally while filling the chamber with I.V. fluid. However, this overfill condition did not affect the flow.

CONCLUSIONS

Based on the data and observations gathered during our evaluation and testing, we conclude both the S.A. Pressor and the EMIS are acceptable for use in the aeromedical evacuation environment.

ACKNOWLEDGMENTS

I wish to thank the following individuals for their support during the performance phase of this report:

Major Garye D. Jensen, Chief Nurse Aeromedical Research Function; 2Lt Rebecca B. Schultz, Research Biomedical Engineer; TSgt Ernest G. Roy, Biomedical Equipment Maintenance Technician; and TSgt Robert J. Van Oss, Aeromedical Evacuation Technician.

REFERENCES

1. Gasko, Oded D., et al, A Battle-Tested New System for Handling Shock, Medical Corps International, 1/1987.

2. The Biomed Spring-Actuated Infusion Pressor, Cat 51787, Description and Operating Manual, Tel Aviv, Israel: Biomedical Instruments Ltd.

3. MIL-STD-810-C, Environmental Test Methods and Engineering Guidelines, 19 Jul 1983 and supplemental letters.

☆ U.S. GOVERNMENT PRINTING OFFICE: 1989– 761-051 9-00061