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EVALUATION OF THE ARM-A-FLOW INTRAVENOUS FLOW REGULATOR

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USAF SCHOOL OF AEROSPACE MEDICINE
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NOTICES

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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.

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The Arm-A-Flow intravenous flow regulator is a gravity-flow infusion device that uses a pressure-sensitive component in addition to a valve to control intravenous (I.V.) flow. When this regulator is placed between the I.V. administration set and the catheter, it is simply a more accurate way of controlling the I.V. flow instead of using the administration set I.V. tube clamp. In contrast to electronic flow controllers which control the flow by counting the drops, the Arm-A-Flow regulator controls flow by monitoring changes in pressure. The Arm-A-Flow regulator has a pressure-sensitive diaphragm in addition to a valve. This diaphragm automatically readjusts the orifice opening when there is a change in flow so that the difference is accommodated for, and the solution continues to be dispensed at the set rate. The Arm-A-Flow regulator was 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 Arm-A-Flow regulator.

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EVALUATION OF THE ARM-A-FLOW INTRAVENOUS FLOW REGULATOR

INTRODUCTION

The 375th Aeromedical Airlift Wing (MAC/SGNL), Scott AFB, Illinois, requested an evaluation of the Arm-A-Flow Intravenous Flow Regulator for possible use in the aeromedical evacuation environment. This technical paper presents the results of our evaluation of the Arm-A-Flow regulator , manufactured by Armour Pharmaceutical Company, Kankakee, Illinois 60901.

The Arm-A-Flow regulator is a gravity flow infusion device that uses a pressure sensitive component in addition to a valve to control intravenous (I.V.) flow (Fig. 1). When this regulator is placed between the I.V. administration set and the catheter, it is simply a more accurate way of controlling the I.V. flow instead of using the administration set I.V. tube clamp. In contrast to electronic flow controllers which control the flow by counting the drops, the Arm-A-Flow regulator controls flow by monitoring changes in pressure. The Arm-A-Flow regulator has a pressure-sensitive diaphragm in addition to a valve. This diaphragm automatically readjusts the orifice opening when there is a change in flow so that the difference is accommodated for, and the solution continues to be dispensed at the set rate (1). The regulator is made of plastic, is disposable and portable, and does not require a power supply. The Arm-A-Flow regulator does not generate a pressure capable of infusion; therefore, maintaining the height of the I.V. bag (60.96 cm (24 in.) - 91.44 cm (36 in.)) and the administration site is essential in a gravity-dependent system.

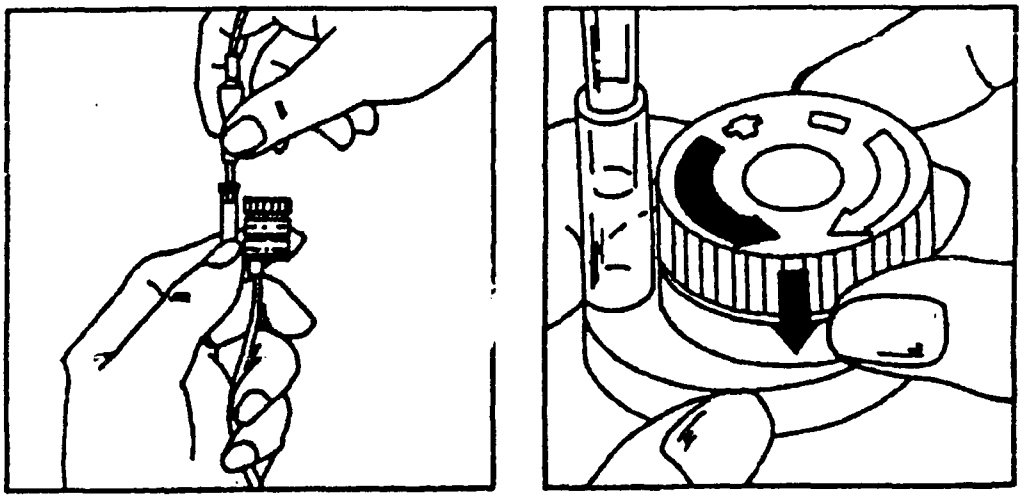

Figure 1. Arm-A-Flow I.V. flow regulator.

METHODS

The A· omedical 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" that 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 Arm-A-Flow regulator was set up in accordance with the product literature. A 1,000 ml 0.9 % sodium chloride solution I.V. bag, Emergency and Military Infusion System (EMIS) administration set, and an 18-gauge catheter were used. Height of the I.V. bag was measured from the top of the I.V. fluid in the I.V. bag to the administration site. Drip rate was measured at the EMIS drip chamber. Pressure was measured using a Gould pressure transducer, Series P23 and Preamplifier (Model 13-461550), and recorded on a Grant Squirrel Data Logging system. Pressure was measured by momentarily occluding the I.V. fluid flow at a 3-way stopcock before the catheter. The Arm-A-Flow regulator, pressure transducer, and the catheter were on the same horizontal plane.

Initial Inspection

The following tests were performed:

1. Comparing drip rate accuracy between an I.V. bag with an Arm-A-Flow regulator and an I.V. bag without an Arm-A-Flow regulator as the I.V. bag height was changed from 91.44 cm (36 in.) to 76.2 cm (30 in.) and 60.96 cm (24 in.)

2. Performance of an Arm-A-Flow regulator when used with an I.V. Stat Constant Pressure Infuser. Same test setup as in Test 1, except the I.V. bag with the I.V. Stat infuser was at a horizontal position and at the same plane as the Arm-A-Flow regulator, catheter, and pressure transducer.

3. Performance of an Arm-A-Flow regulator when used with a Biomed Spring-Actuated Infusion Pressor (S.A. Pressor). Same test setup as in Test 1, except the I.V. bag with the S.A. Pressor was at a horizontal position and at the same plane as the Arm-A-Flow regulator, catheter, and pressure transducer.

4. Drip rate accuracy with varying venous pressures. Venous pressures were simulated by immersing the tip of the catheter in 8 cm (3.2 in.) and 15 cm (6 in.) of water. The height of the I.V. bag from the tip of the catheter was maintained at 91.44 cm (36 in.).

5. Human factors and physical characteristics.

Vibration

The main purposes of these tests were to determine the accuracy of the Arm-A-Flow regulator to maintain a drip rate and to observe if any air bubbles pass to the administration site when subjected to vibrational forces encountered during an aeromedical transport (2).

The I.V. bag was adjusted to maintain a height of 76.5 cm (30 in.) during the entire vibration test series. Drip rate was set at 75 drops/min or 225 ml/h at the start of the first vibration test. Thereafter, only the I.V. bag was changed; the Arm-A-Flow regulator, EMIS, and the drip rate setting were not changed.

Altitude

This test verified the ability of the Arm-A-Flow regulator to maintain drip rate with changes in altitude. The altitude tests were conducted in a hypobaric chamber. The rate of altitude change in the hypobaric chamber during ascent to 10,000 ft and descent to ground level was 500 ft/min. The performance of the regulator at ground level before the altitude test was used as a reference in comparing the performance of the regulator at altitude and at ground level after the altitude test.

As previously stated, the Arm-A-Flow regulator maintains a drip rate by monitoring changes in pressure. This change in pressure is a major concern during an aeromedical evacuation flight because with an increase in altitude, the pressure acting on the I.V. fluid decreases and therefore the drip rate decreases.

A graduated cylinder filled to the top lip with water was used to simulate the venous back pressure which is normally encountered in an I.V. setup (3). The catheter tip was lowered 8 cm (3.2 in.) into the graduated cylinder, measured from the lip of the graduated cylinder to the tip of the catheter. Overflow from the graduated cylinder during the delivery of the I.V. solution was then measured to approximate the volume of I.V. solution delivered. Drip rate was measured at the EMIS drip chamber.

The test setup was the same as in the initial inspection when flow accuracy was compared between an I.V. bag with an Arm-A-Flow regulator and an I.V. bag without an Arm-A-Flow regulator . However, the height of the I.V. bag was not changed in increments of 91.44, 76.2, and 60.96 cm (36, 30, and 24 in.); instead the height of the I.V. bag was adjusted to maintain a height of 76.2 cm (30 in.) during the test.

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 Arm-A-Flow regulator . Note that operating the Arm-A-Flow regulator 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

All initial inspection test setups resulted in an enhanced flow accuracy with the use of the Arm-A-Flow regulator as compared to a similar I.V. setup without the regulator, even with a decrease in I.V. fluid pressure as the I.V. solution is delivered. During the initial test when the

I.V. bag height was adjusted from 91.44 cm (36 in.) to 76.2 cm (30 in.) the I.V. set with the Arm-A-Flow regulator had a change of 2 drops/min (6 ml/h) or 1.1 % and from 91.44 cm (36 in.) to 60.96 cm (24 in.) a change of 4 drops/min (12 ml/h) or 4.4 % . In contrast, the I.V. set without the Arm-A-Flow regulator had a change of 20 drops/min (60 ml/h) or 21.7 % when the I.V. bag height was adjusted from 91.44 cm (36 in.) to 76.2 cm (30 in.) and from 91.44 cm (36 in.) to 60.96 cm (24 in.) a change of 33 drops/min (99 ml/h) or 35.8 %. The Arm-A-Flow regulator compensated for changes in venous pressure and maintained the drip rate. The I.V. set without the regulator had a change of 8 drops/min (24 ml/h) or 8.8 % with venous pressure of 8 cm of water and 7 drops/min (21 ml/h) or 7.7 % with venous pressure of 15 cm of water.

At altitude, the Arm-A-Flow regulator compensated for changes in pressure thereby maintaining the volume delivered. The flow of the I.V. bag without the regulator decreased and thereby delivered less volume. Figures 2 and 3 illustrate the results of these tests. Small air bubbles which formed on the I.V. line did not have an effect on the flow as these air bubbles passed through the Arm-A-Flow regulator . The amount of air bubbles was minimal and did not pose a medical threat.

During the vibration tests, flow variation before vibration and during vibration was 2.6 %. Some air bubbles traveled up the I.V. bag especially after two-thirds of the I.V. fluid had been delivered. The amount of air bubbles was minimal and did not pose a medical threat.

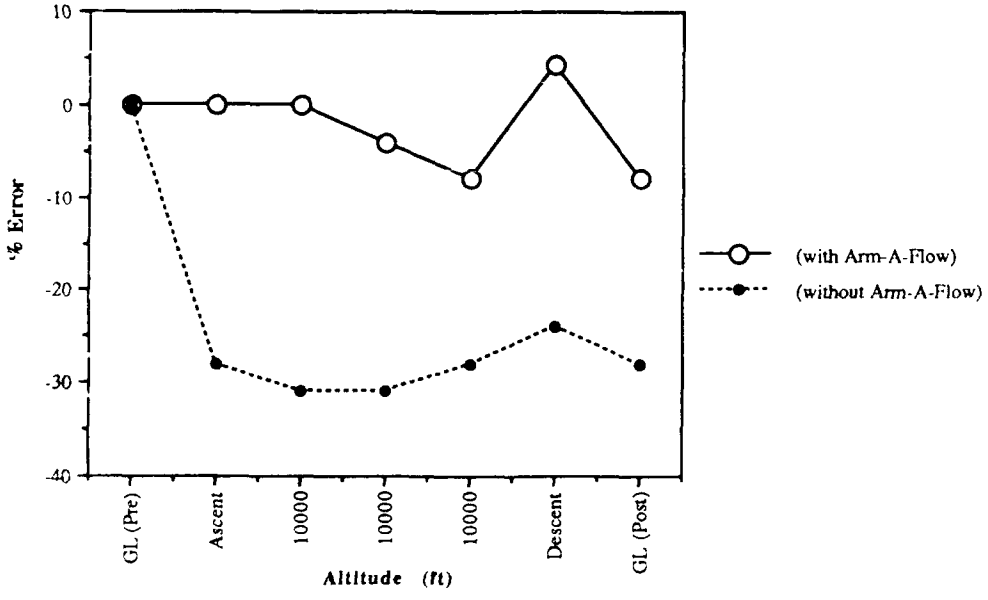

Figure 2. Comparison of % error of volume delivered at altitude. Percent error averages: with Arm-A-Flow regulator, 1.0 ml or 4.2%; without Arm-A-Flow regulator, 8.0 ml or 27.3%. (Note: Each volume measurement taken at 10,000 ft is for a period of 5 min.)

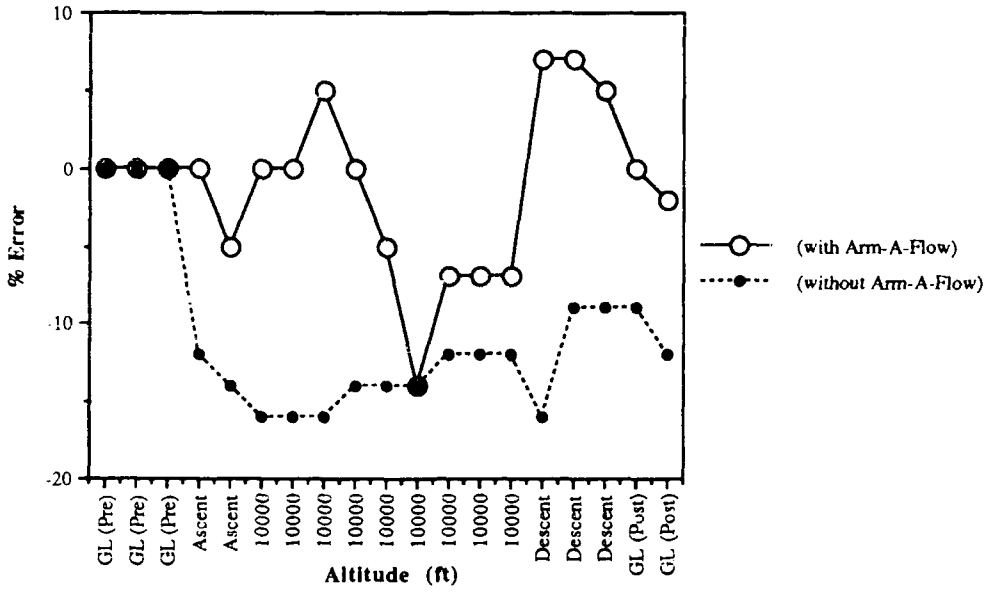

Figure 3. Comparison of % error of drip rate at altitude. Percent error averages: with Arm-A-Flow regulator, 2.9 drops/min (8.7 ml/h) or 3.3 %; without Arm-A-Flow regulator, 10.5 drops/min (31.5 ml/h) or 12.3 %. (Note: Three drip rate measurements were taken at 10,000 ft for every 5 min volume measurement period.)

CONCLUSIONS

The Arm-A-Flow regulator performed in accordance with the product literature. The regulator is a very simple device, both in design and operation. The regulator provides a more reliable means of controlling I.V. drip rate especially during field operations, when transporting patients, and when a power supply is not available. However, the regulator is not a replacement for an electronic infusion pump which should be used if one is available. As previously stated, the height of the I.V. bag to the administration site must be maintained if the Arm-A-Flow regulator is used in a gravity-dependent I.V. setup. Based on the data and observations gathered during our evaluation and testing, we conclude the Arm-A-Flow regulator is acceptable for use in the aeromedical evacuation environment.

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