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SHUTTLE ORBITER MEDICAL SYSTEM EQUIPMENT/SUPPLIES EVALUATION

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FLIGHT DATE:	May 3 and 25, 1990

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GOAL:

To evaluate the effectivity in zero gravity of several medical equipment and supply items flown in the Shuttle Orbiter Medical System (SOMS). Several procedures listed in Medical Operations Medical Checklist, JSC 1732 were also evaluated.

BACKGROUND:

A reevaluation of the SOMS kits was initiated in January 1990. The effectivity in microgravity of several items was in question so they were drawn out of the kits and tested on the KC-135. Two different KC-135 flights were dedicated to this procedure; FLIGHT ONE on May 3,1990, and FLIGHT TWO on May 25,1990. In these flights, the following elements were examined:

1. **Measuring IV Flow**

   The Cutter brand Primary Additive Nonvented IV Set is flown in the SOMS medical kit. The set contains all of the necessary components for successful zero gravity operation, however, the set also contains extraneous components. Although the set has proven effective in one G, effectivity in microgravity was placed in question following an equipment evaluation by Dr. James Bagian on STS-29. The set includes the following components in series:

   - spike for IV bag penetration
   - drip chamber

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- one way check/flow valve
- upper medicinal entry with swab pad injection site
- 0.22 micron filter for air/fluid separation (referred to hereafter as the air/fluid separator)
- safticlamp roller clamp
- ower medicinal entry with swab pad injection site
- luer adapter
- 86" of tubing length

In zero gravity, air contained in the IV bag becomes evenly distributed throughout the fluid. The air must be removed prior to IV administration. The effectiveness of the Cutter set in zero gravity is based on the operation of three components:

Drip Chamber:

- not necessary in zero-gravity

One Way Flow Valve

- The effectiveness of the valve is questionable when located above the air/fluid separator due to the compressibility of the air/fluid mixture flowing through this region.

- If the valve is ineffective, the force applied to the IV bag must be adequate to overcome central venous pressure (CVP) at the patient end of the IV line. If pressure is not maintained, blood flows into the IV tubing.

Air/fluid Separator:

- The efficacy in microgravity is in question following evaluation on STS-29.

- The necessity of this feature has been questioned when alternative IV administration techniques are used.

On STS-29, Dr. James Bagian set up the IV infusion set and reported a blockage of flow at the air/fluid separator. The equipment was tested postflight and performed within expectations. Dr. Bagian also attempted an administration technique which eliminates the necessity of an air/fluid separator. Dr. Bagian swung the IV bag over head in a circular

motion to separate the air out of the IV fluid. The weight of the IV fluid causes it to travel to the outer portion of the bag forcing the air to the inner portion where the bag opens to the tubing. When flow was initiated, the air travels out of the bag first, leaving the fluid behind to be administered intravenously.

To further evaluate the failure experienced in STS-29, during STS-32, mission Bonnie Dunbar set up the IV administration set. The IV set operated successfully.

2. **Chemstrip Protocol for Urine Analysis in Zero-gravity**

   Although the effectivity of the chemstrips is not altered in zero gravity, the technique of liquid application must be altered.

   Under "Bladder Infection" in the medical checklist, p.2-13, chemstrip use is suggested, however, no urine application technique is listed. To develop a technique suitable for zero gravity, several different application materials were tested on the KC-135. All materials were drawn from the SOMS kits.

3. **Tamper Resistant Seals for Injectable Medications**

   The use of tamper resistant seals for injectable medications has recently been suggested.

   The appropriate product produced by United States Clinical Products (USCP) was selected and the ease of use in microgravity was tested on the KC-135.

OBJECTIVES:

This experiment was designed to:

1. **Measure IV Flow Rate**

   The effectiveness of the Cutter brand Primary Non-vented IV administering set was analyzed by observing the following:

Drip Chamber

- flow through the chamber in correspondence with the resultant flow from the terminal end of the IV line
- how the initial condition of a full or empty drip chamber effected the IV flow
- project how removing this component would alter IV flow

One Way Flow Valve

- flow immediately before and after the valve
- project how removing this component would alter IV flow
- project how altering the location of the valve would alter IV flow

Air/fluid Separator

- the effectiveness of the air/fluid separator by monitoring the fluid flow immediately before and after the component
- alternative methods of air/fluid separation

The experiment was also designed to test the procedure listed in the Medical Checklist for IV use and alter if need be. The experiment measured flow rates produced by using the procedure listed in the Medical Checklist (see appendix B).

2. **Chemstrip Protocol**

Several techniques designed for chemstrip use were tested with the intention of incorporation into the Medical Checklist. The following materials were analyzed:

- cotton balls
- gauze pads
- calgiswabs

3. **Tamper Resistant Seals**

USCP tamper resistant seals were tested using the following criterion for evaluation:

- surface tension:was it relatively easy to puncture the seal with the Tubex injector
- did the seals inhibit injectable removal from the kit , impacting emergency situations

4. **Identify other components of the SOMS kits that should be reevaluated.**

MATERIALS:

1. Measuring IV Flow

- Cutter brand Pureflo IV Filtration System 86" Primary Additive Nonvented IV Set (described in the background),located in the Emergency Medical Kit (EMK) D1-8
- blood pressure cuff, EMK C1-1
- 250cc saline pouches (dyed for video purposes), EMK D1-8
- receiving bags, saline bags emptied
- towels
- duck tape
- dermacil tape, Medications and Bandage Kit (MBK) F1-4, EMK B1-8
- stop watch
- 2x3 foot table
- scissors

2. Chemstrip Protocol

- Urine Test Package, containing 12 chemstrips, EMK B2-2
- 60cc syringes
- colored water for urine simulation
- calgiswabs, MBK F1-1
- cotton balls, EMK C1-2
- gauze pads, MBK F2-1, MBK F2-2, EMK P1
- towels

- ducktape
- absorbant field

3. **Tamper Resistant Seals**

- Tubex injector syringes
  - prefilled
  - partially filled
- metal Tubex injector
- USCP tamper resistant seals
- cotton wad to absorb the discharged liquid

PREFLIGHT PROCEDURES:

Flight One

1. **Measuring IV Flow**

This portion of the experiment was designed to measure the flow through the air/fluid separator.

Four different set ups were used, each consisting of:

- 250 cc saline bag, injected with blue dye for video purposes
- Cutter IV administration set
- blood pressure cuff
- 3 liter receiving bag attached to the terminal end of the IV line

A single IV administration set was setup preflight and it was determined that in order to prevent preflight wetting of the filter, the IV line needed to be clamped before the air/fluid separator as well as having the pinch roller valve closed.

The following saline bag masses were recorded preflight(in gms):

#1 298.14
#2 297.14
#3 297.68
#4 298.55

The following equations were suggested to measure flowrate postflight:

- inflight flow time = t
- change in mass = preflight mass - postflight mass = m (gms)
- flow volume = v (ml), v= m*specific volume of the fluid where the specific volume is defined as the volume per unit weight, for water =1 ml/gm = m*1ml/gm.
- flowrate = volume/time = ml/sec

2. **Tamper Resistant Seals**

Partially filled and prefilled Tubex syringes were obtained and USCP tamper resistant seals were placed over the end of the syringe. Preflight analysis proved the seals to be an adequate product. Hypobaric chamber testing was also conducted to evaluate the seals in low pressure situations. Results are described in appendix B. Offgassing tests were also performed prior to the flight, see appendix C.

Flight Two, May 25,1990

1. **Measuring IV Flow**

Three set ups identical to those used in flight were used, however, two set ups used a presaturated air/fluid separator.

Preflight saline bag masses were recorded as (in gms):

#1	568.9
#2	298.6
#3	297.2

2. **Chemstrip Protocol**

To simulate urine flow, a 60cc syringe used. To saturate the chem strip, two techniques were proposed:

- "controlled method"
  - wetting the material with approximately 5cc of fluid

- holding the syringe approximately 3mm away

- "free flowing method"
  - holding the syringe at least 6 cm away
  - a large amount of fluid was directed toward the material to simulate conditions in which a urine sample is obtained during a space shuttle mission.

The following materials were used to apply the liquid to the chemstrip:

- cotton balls
  - one and two cotton balls

- gauze pads
  - one and two gauze pads

- calgiswabs
  - one and two calgiswabs

The water in the syringe was dyed blue for video purposes. All materials were tested before flight, the calgiswabs had the best results.

POSTFLIGHT PROCEDURES:

Flight One

Measuring IV Flow

All four sets were laid out on a table and analyzed separately. Dr. Schulz recorded flow time during the flight, giving the "GO" when zero gravity was obtained during each parabola. Ms. Maidlow controlled the pinch roller valve, and Dr. Lloyd observed flow through the air/fluid separator making oral observations on a micro casette recorder.

During the first two sets of parabolas (1-20), a quantitative and qualitative analysis of IV flow was done on all four sets.

IV Set #1 - Pre-zero gravity conditions

- filter inadvertently saturated when the pre-air/fluid separator clamp fell off

- this set was set aside for later observation

IV Set #2 - Pre-zero gravity conditions

- air vent of the air/fluid separator pointed upward in relation to the table
- 250cc saline bag
- Drip chamber contained approximately 5ml's of fluid, 75% empty
- Pressure cuff inflated to 40mmHg, had difficulty maintaining pressure with the cuff, through out the flight had to keep pumping up the cuff
- air/fluid separator dry prior to flow initiation
- IV line clamped off prior to the air/fluid separator and at the roller clamp
- Ms. Maidlow controlled the pinch roller valve

Inflight observations

Parabola #1

- drip chamber took a long time to fill
- extremely slow flow
- a lot of air in the air/fluid separator
- 21.79 seconds flow time recorded

Parabola #2

- Air/fluid flowing into the air/fluid separator,fluid flowing out
- 20.57 seconds flow time recorded

Parabola #3

- continuous fluid flow post air/fluid separator despite excessive air coming from the IV bag

- continuous flow for the duration of the parabola
- 21.58 seconds flow time recorded

IV Set #1 - Pre-zero gravity conditions

- air vent of the air/fluid separator pointed downward
- 250cc saline bag
- drip chamber approximately 1/2 full prior to flow initiation and remained at this level during flow
- blood pressure cuff inflated to 150 mmHg

Inflight observations

Parabola #4

- 19.96 seconds flow time recorded

Parabola #5

- 23.00 seconds flow time recorded

Parabola #6

- 23.15 seconds flow time recorded

IV Set #3 - Pre-zero gravity observations

- air/fluid separator oriented in a vertical plane with the north side of the filter pointed upward

Inflight observations

Parabola #7

- 23.68 seconds flow time recorded

Parabola #8

- flow initiation slow due to difficulty in opening the pinch roller valve
- 23.34 seconds flow time recorded

Parabola #9

- 24.54 seconds flow time recorded

IV Set #4 - Pre-zero gravity conditions

- air/fluid separator oriented in a north south plane with the north side of the filter pointed downward

Inflight observations

Parabola #10

- 17.3 seconds recorded flow

Parabola #11

- 24.84 seconds recorded flow

Parabola #12

- 23.39 seconds recorded flow

Parabola #13

- 22.38 seconds recorded flow

Parabola #14

- qualitative analysis was done on IV set up #4 for the remainder of the IV flow portion of the experiment
- flow consistent, air/fluid flowing into the air/fluid separator, fluid flowing out

Alternative IV Administration Technique

Part I - Deployment of the IV Administration Equipment

During the third set of parabolas, the IV line was modified to test the air/fluid separation technique used by Dr. Bagian in STS-29. This was done by cutting the air/fluid separator off the IV line and moving the pinch roller clamp valve to the end of the remaining portion. Holding the roller clamp, the IV bag was swung overhead.

Preflight conditions

The IV administration set, saline bag, and blood pressure cuff was deployed from the SOMS medical kits during this portion of the experiment.

Inflight observations

Parabolas# 15-20

- IV administration set, saline bag, and blood pressure cuff were deployed from the SOMS kits
- difficult to get into the kits and deploy the medical items in the time frame of one parabola
- difficulty getting the protective pouch around the saline bag open causing the bag to be shaken up quite a bit, evenly distributing the air bubbles
- flow started immediately after the spike of the IV set was inserted into the saline bag
- following Medical Checklist procedures, the blood pressure cuff was wrapped around the saline bag and inflated to 160 mmHg pressure found it very difficult to inflate the cuff to 300 mmHg and maintain that pressure
- pressure of the blood pressure cuff was increased to 170 mmHg pressure
- it took a full 10 parabolas to deploy the IV set, saline bag, and set up for IV administration (estimated 230 seconds or approximately 4 minutes)

- after flow was initiated, the pressure was increased to 300 mmHg, the bag seemed fine
- flow appeared similar to the other three sets

Part II: Attempting the Technique

Pre-zero gravity conditions

- the air/fluid separator was cut off of the IV line
- pinch roller clamp moved up just below the air/fluid separator

Inflight observations

Parabolas#21-30

- Dr. Schulz attempted the technique with success
- air displaced from the liquid, moved to the interior portion of the IV bag
- as roller clamp valve was opened, the air traveled out of the bag mixed with a small portion of liquid
- time limitations prohibited removal of all of the air, however, it appeared as thought a majority of the air had been removed from the IV bag

During the fourth and finial set of parabolas, the tamper resistant seals were analyzed along with other items in the SOMS kits.

Flight Two

Measuring IV Flow

The first set of parabolas was dedicated to measuring IV flow both quantitatively and qualitatively. Ms. Maidlow recorded flow and made oral observations in a micro cassette recorder. Ms. Breeding controlled flow by the pinch roller clamp valve.

IV SET #1 - Pre-zero gravity conditions

- 500cc saline bag
- Drip chamber totally full
- Pressure cuff inflated to 40mmHg
- air/fluid separator presaturated
- IV line clamped off at the roller clamp

Inflight observations

- Observable flow did not start until the third parabola(visible by air bubble movement into the air/fluid separator)
- Flow appeared considerably slower than in the previous flight
- By the fifth parabola, flow increased somewhat
- Total flow time 1 minute 52.11 seconds

IV Set #2 - Pre-zero gravity conditions

- 250cc saline bag
- Drip chamber half full
- Air/fluid separator saturated
- IV line clamped off at the pinch roller clamp

Inflight observations

- Set was tested for 4 parabolas only, the remainder of which were lost due to difficulty keeping the blood pressure cuff on the IV bag, however 250cc bag much easier than 500cc bag.
- Air/fluid separator vent port facing north
- Air and fluid flowing into the filter, fluid flowing out.
- Total flow time 1 minute, 41.39 seconds

IV Set # 3 - Pre-zero gravity conditions

- The IV line was clamped off before the air/fluid separator, keeping the filter dry until flow was initiated.
- The line was also clamped off at the roller valve.
- Drip chamber one third full.

Inflight observations

- Flow appeared much greater than in the first two sets.
- Flow rate was consistent throughout the entire set of parabolas.
- Total flow time 35.17 seconds

Chemstrip Protocol

The second set of parabolas was dedicated to analyzing techniques appropriate for urine sample application in zero gravity. Each material was tested for two parabolas. The material with the best results was then tested for the four remaining parabolas in the second set.

Pre-zero gravity conditions

- urine test package taped on testing table which was covered with absorbant material
- 60cc syringe taped to table leg
- Ms. Breeding holding chemstrip
- Ms. Maidlow applying sample

Inflight observations

- The urine test assembly provided extremely easy access to the chemstrips.

Cotton Balls

Controlled Method

- One cotton ball was thoroughly saturated to the point where the fluid was on the verge of escaping from the cotton ball.
- The cotton ball was then passed over the chemstrip and was found to saturated the test strip totally.
- Excess liquid fell out of the cotton ball as it was passed over the chem strip.

- Two cotton balls held the liquid better then the single cotton ball.
- Excess liquid fell out of the balls when passed over the chemstrip.

Free Flowing Method

- One cotton ball became heavily saturated
- When passed over the chem strip, free fluid was released
- The chemstrip was thoroughly saturated
- Two cotton balls became heavily saturated
- When passed over the chemstrip, free fluid was released
- The chemstrip was thoroughly saturated.

Gauze Pads

Controlled Method

- One gauze pad did not hold liquid, the excess was taken up by the absorbant pad.
- The gauze was found to be totally inappropriate for the use intended. Two gauze pads were not tested.

Free Flowing Method

- This was not tested due to the inadequacy of the material.

Calgiswabs

Controlled Method

- One swab was saturated by the syringe, did not hold the entire 5 cc's of liquid
- The single swab wet the chemstrip, however, several passes were

necessary to thoroughly wet the strip. A rubbing motion was necessary.

- Two swabs held the 5 cc's of fluid
- The two swabs thoroughly wet the strip when gently passed over the test area.

Free Flowing Method

- After the syringes were saturated, they were passed over the chemstrips with the same results as in the controlled method.

RESULTS

1. Measuring IV Flow

SET UP #	TOTAL FLOW VOLUME (ml)	TOTAL FLOW TIME (sec)	FLOW RATE (cm3/sec)
FLIGHT ONE			
1	57.95	66.11	.8766
2	46.70	63.94	.7303
3	51.68	71.56	.7220
FLIGHT TWO			
1	60.89	112.11	.5432
2	50.91	101.39	.5021
3	27.76	35.17	.7906

2. Tamper Resistant Seals

Seals did not interfere with Tubex syringe operation.

3. Chemstrip Protocol

Two calgiswabs proved the best material for liquid application on the chemstrips in microgravity.

DISCUSSION AND RECOMMENDATIONS

1. Measuring IV Flow

Results from both flights proved constant operation of the Cutter brand Primary Nonvented IV Administration Set. In all instances, the filter removed all of the air that was visible. The filter removed air regardless of the duration of flow. The pinch roller valve was easy to operate in all portions of the experiment. Injection sites were not tested.

Flow rates varied from .5021 cm^3/sec to .8766 cm^3/sec. Dr. John Schulz concurred this as an acceptable range. The flow did not seem to vary with the blood pressure cuff pressure. In both flights, 86" of tubing length was excessive. Reduction of the tubing length is desired.

From both flights, the following recommendations have been made:

- reduce tubing length
- move one way flow valve to follow the air/fluid separator
- move both injection sites to follow the air/fluid separator
- eliminate the drip chamber

Cutter is unable to custom produce an IV administration set. However, Baxter Travenoll has expressed an interest in accommodating the needs of Medical Operations. A new set is currently in design, this set will include(in order):

- IV bag spike
- approximately 36" IV tubing
- air/fluid separator
- oneway flow valve
- pinch roller clamp
- two medicinal entry sites
- luer adapter

See appendix D for the proposed design. When the prototype is obtained,testing will occur on the KC-135.

2. Chemstrip Protocol

The two calgiswab method of wetting the chemstrip appears to be the

best technique for on orbit urine analysis. Although the cotton balls held sufficient liquid and saturated the chemstrip, surgical gloves would be necessary with this technique. With the calgiswabs, the 7" wooden handle would allow the flight crew member to hold the hand clear of the urine stream. The technique is appropriate for males and females alike .

The swabs can be placed in the wet trash when the urine analysis is been complete. This technique has been incorporated into the Medical Checklist.

To facilitate urine sample collection, we recommend the placement of a velcro square on the back of the urine test assembly. The velcro could then be mounted to the velcro in the WCS compartment. Currently, the crew member has to hold on to the assembly which understandably could be quite cumbersome when gathering a sample.

3. Tamper Resistant Seals

Results from the hypobaric chamber proved the tamper resistant seals inappropriate for partially filled Tubex syringes. Results from microgravity testing were satisfactory. The surface tension of the seals did not pose a problem for actual Tubex operation. The benefit of using tamper resistant seals is substantial. A request has been made to the pharmaceutical company that manufactures the medications in the partially filled Tubex to produce 1ml syringes. The company has not given an answer to this request at this time.

SUMMARY OF PHOTOS AND VIDEO

NASA Photo Description

S90-36902 *IV flow analysis set up, flight one*

- blood pressure cuff inflated around set numbers 3&4
- flow just started in set #4
- Ms. Maidlow holding air/fluid separator in N/S orientation in relation

to the table

- flow had been initiated in all 4 sets

S90-36904 ***Air/fluid separator, flight one***

- IV set up #4
- drip chamber totally full, air/fluid mixture flowing into the air/fluid separator, fluid flowing out
- air/fluid separator containing a great deal of air

S90-36905 ***Air/fluid separator, flight one***

- IV set up #4
- air/fluid separator in N/S plane of orientation
- drip chamber filled with air and fluid
- air/fluid separator filled primarily with fluid
- pinch roller clamp open

S90-36912 ***SOMS Kit evaluation***

- Ms. Maidlow holding MBK
- Dr. Lloyd holding Tubex syringe with tamper resistant seal
- Dr. Schulz holding IV set with inflated blood pressure cuff getting ready for the swinging air removal method

S90-36913 ***SOMS Kit evaluation***

- Ms. Maidlow holding the MBK
- Dr. Lloyd holding Tubex syringe
- Dr. Schulz holding IV set prior to swing method modification

S90-36894 *SOMS Kit evaluation*

S90-36914

- Ms. Maidlow holding Norgestrel/ethinyl/estradiol pills
- Dr. Lloyd holding Tubex syringe and receiving bag
- Dr. Schulz holding IV administration set

S90-39743

- Chemstrip protocol for urine analysis, flight two
- Ms. Breeding holding chemstrip
- Ms. Maidlow holding 60cc syringe and applying sample to the chemstrip with calgiswab

NASA Video Reference Master 117583

Title: STS-32 Onboard ID#18
Work Order: 01060
Date: 3/21/90

On board video of mission specialist Bonnie Dunbar operating the Cutter brand IV Administration Set.

APPENDIX A

HYPOBARIC ANALYSIS OF USCP TAMPER RESISTANT SEALS

Partially filled Tubex syringes pose a problem during Shuttle missions when the cabin is depressed to 10.2 psia during EVA preparation. Gasses trapped within the syringe expand which causes plunger movement. If the movement is prohibited, a pressure chamber within the syringe results. When the protective covering is removed from the needle, it is projected that the medication would shoot out of the needle.

To simulate 10.2 psia cabin operations preflight testing protocol included a hypobaric chamber run using partially and prefilled Tubex syringes. To examine the force exerted on the syringe stopper by the seals, 10 syringes were observed. Morphine and meperidine are the only partially filled Tubex syringes flown in the SOMS medical kits. Three of each were taken into the chamber along with 4 prefilled sodium chloride syringes for generic observation.

10.2 psia is equivalent to 9700 ft. on an altimeter.

The following results were obtained:

Morphine Sulfate

syringe #1

- at 8,8000 ft., stopper began moving toward the end of the syringe
- 15,000 ft could not move any further, it had hit the seal

syringe #2

- began moving at 10,10,000 ft.

syringe #3

- began moving at 6,6000 ft.

Stoppers on all syringes stopped moving at 15,15,000 ft., they had reached the limit of the tamper resistant seal. When the protective covering was removed from one of the syringes, the medication shot out in a projectile motion. During descent, all stoppers retracted slightly. but not enough to overcome the pressure built up in the syringe.

Meperidine

syringe #4

- stopper began moving around 9,9000 ft.
- stopper hit tamper resistant seal at 9700 ft.

syringe #5&6

- stopper hit tamper resistant seal at 9700 ft.

Sodium chloride

syringe #6-10

- stopper movement was not apparent

APPENDIX B

IV ADMINISTRATION TECHNIQUE LISTED IN THE MEDICAL CHECKLIST

p. 4-8 Medical Checklist

Intravenous Fluid Infusion

1. Unstow:
   - IV fluid bag (D1-8)
   - IV administration set (D1-8)
   - Tape, Dermacil (F1-4)
   - Blood Pressure Cuff (C1-1)

2. Tear off four 4-in. strips Dermicil tape

3. Assemble IV setup:
   - Remove IV bag from package
   - Remove caps and plug IV tubing spike into IV bag

NOTE: Make sure IV line roller clamp in CLOSED

4. Remove cap from patient end of tubing save finial cap

5. Open roller clamp and squeeze bag to prime IV line and purge air: close clamp

6. Re-cap patient end of line

7. Wrap blood pressure cuff tightly around bag and inflate to 300mmHg