IN-FLIGHT DEMONSTRATION OF THE SPACE STATION FREEDOM HEALTH MAINTENANCE FACILITY FLUID THERAPY SYSTEM (E300/E05)

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The Space Station Freedom (SSF) Health Maintenance Facility (HMF) will provide medical care for crew members for up to 10 days. An integral part of the required medical care consists of providing intravenous infusion of fluids, electrolyte solutions, and nutrients to sustain an ill or injured crew member. In terrestrial health care facilities, intravenous solutions are normally stored in large quantities. However, due to the station's weight and volume constraints, an adequate supply of the required solutions cannot be carried onboard SSF. By formulating medical fluids onboard from concentrates and station water as needed, the Fluid Therapy System (FTS) eliminates weight and volume concerns regarding intravenous fluids. The first full-system demonstration of FTS in continuous microgravity will be conducted in Spacelab-Japan (SL-J).

The FTS evaluation consists of two functional objectives and an in-flight demonstration of intravenous administration of fluids. The first is to make and store sterile water and IV solutions onboard the spacecraft. If intravenous fluids are to be produced in SSF, successful sterilization of water and reconstituting of IV solutions must be achieved (Figure 1). The second objective is to repeat the verification of the FTS infusion pump, which had been performed in Spacelab Life Sciences - 1 (SLS-1). During SLS-1, the FTS IV pump was operated in continuous microgravity for the first time. The pump functioned successfully, and valuable knowledge on its performance in continuous microgravity was obtained. Finally, the technique of starting an

IV in microgravity will be demonstrated. The IV technique requires modifications in microgravity, such as use of restraints for equipment and crew members involved.

Hardware for use in the experiment was developed in conjunction with manufacturers in the medical devices field and other fields. Modified available terrestrial hardware was used whenever possible. There are nine major components in the FTS experiment: Source Water Container (SWC), Sterile Water for Injection Assembly (SWI), Intravenous Reconstituting Device (IRD), Large Volume Parenteral Bags (LVP), Intravenous Fluid Infusion Pump (IV Pump), Payload and General Support Computer (PGSC), Fluid Administration Set (FAS), Sample Containment Device (SCD), and Flight Infusion System Test (FIST) equipment. Following is a detailed description of each component and its role in FTS.

The SWC is a steel tank containing pressurized water for use throughout the experiment. Tap water will be used for the experiment. Water from the SWC passes to the SWI (Figure 3), which is a cartridge designed to purify water to USP XXI specifications. Purification of the water will be accomplished by first passing it across a bed of activated carbon, followed by a bed of 50:50 activated carbon and deionizing resin, then several beds of 100% deionizing resin, and finally through an ultrafilter. This process is intended to remove organic and halogenated contaminants and contaminants larger than 10,000 molecular weight. In addition, the fluid will then pass through a sterilizing microfilter to remove particles larger than 0.22 micron in size. A conductivity indicator is used to indicate when the desired purity level has been reached (Figure 3).

After water sterilization has been completed, water is stored in a polyvinyl chloride (PVC) LVP bag. If intravenous fluids are to be formulated, the IRD is used. The IRD is a flow-through pouch containing the constituents (liquid concentrates) of the solution which are to be mixed with the sterile water to reconstitute single units of intravenous fluids. Quick-disconnect fittings and drippless valves allow for easy removal and change of the IRDs and LVPs with fresh supplies.

The pump used in the verification phase is a modified commercially available and widely-used IV pump. It has two pumping channels which allow for the simultaneous infusion of two separate solutions at different rates. This feature also provides redundancy in the event either pump channel fails. The IV pump will deliver fluid solutions via the FAS (made of PVC connecting tubing) to the SCD, which contains a series of ten bags that will be used to hold the samples. The PGSC, a portable personal computer, will control the operation of the IV pump during this part of the experiment. In the FIST phase of the experiment, a crew member will demonstrate the technique of initiating an intravenous infusion on a manikin arm (Figure 2).

Different component configurations will be used for each portion of the experiment. In the sterile water for injection portion, the FTS will be configured only with the following equipment: SWC, SWI, and LVP (Figure 1). Water will be dispensed from the SWC and will pass through the SWI for purification. Sterile water will then pass into a LVP bag until the bag fills. A total of 9 liters of sterile water will be produced throughout the experiment.

Of the 9 liters formed, 5 liters will be used to reconstitute the intravenous solutions. For this part, the IRD will be placed between the SWI and the LVP bag (Figure 4). For the

Spacelab-J mission, solutions of sodium chloride (0.9%) and dextrose (5.0%) will be reconstituted. The volume of fluid in the LVP is controlled by the use of a volumetric assurance enclosure over the LVP bag. Production of sterile water and solutions will be performed concurrently.

The next step in the experiment is the verification of the IV pump (Figure 2). Two bags, one containing sodium chloride solution and one containing dextrose solution, will be attached to the IV pump using the FAS. Since IV pump operation is controlled by the PGSC, the crew member may continue to monitor the filling of the LVP bags in the sterilization and reconstitution part of the experiment, while the computer commands the IV pump to perform the verification tasks. The solutions will be automatically pumped into the SCD. The crew member will interact with the IV pump at 20-minute intervals, but no data will be lost if the crew member is delayed, because the PGSC controls start, stop, and data collection functions.

The final step in the experiment is the demonstration of intravenous infusion in continuous microgravity (Figure 2). A manikin arm designed for practicing the initiation of an IV solution will be used, along with the required supplies. The manikin arm is equipped with venous channels to simulate a patient arm. The IV pump will operate at several infusion rates, and intentional failures will be produced to determine effective methods for coping with the failures.

Only one crew member will be required to perform all of the tasks previously described. The experiment will be performed once during the mission. Shortly before initiating the in-flight

experiment, the crew member will notify the ground team so that a ground control experiment may be performed simultaneously.

Post-flight, the samples will be collected at the landing site and immediately returned to Johnson Space Center for analysis. The Johnson Space Center Biomedical Operations and Research Branch will perform the necessary analyses and tests on the flight and ground control samples to determine if the sterile water and IV solution production parts of the experiment were successful.

In conclusion, this experiment will determine if intravenous solutions can be successfully produced by mixing concentrates and water sterilized onboard a spacecraft. The experiment will also demonstrate the performance of the IV pump in continuous microgravity, and finally, the technique of starting an IV in microgravity will be demonstrated.

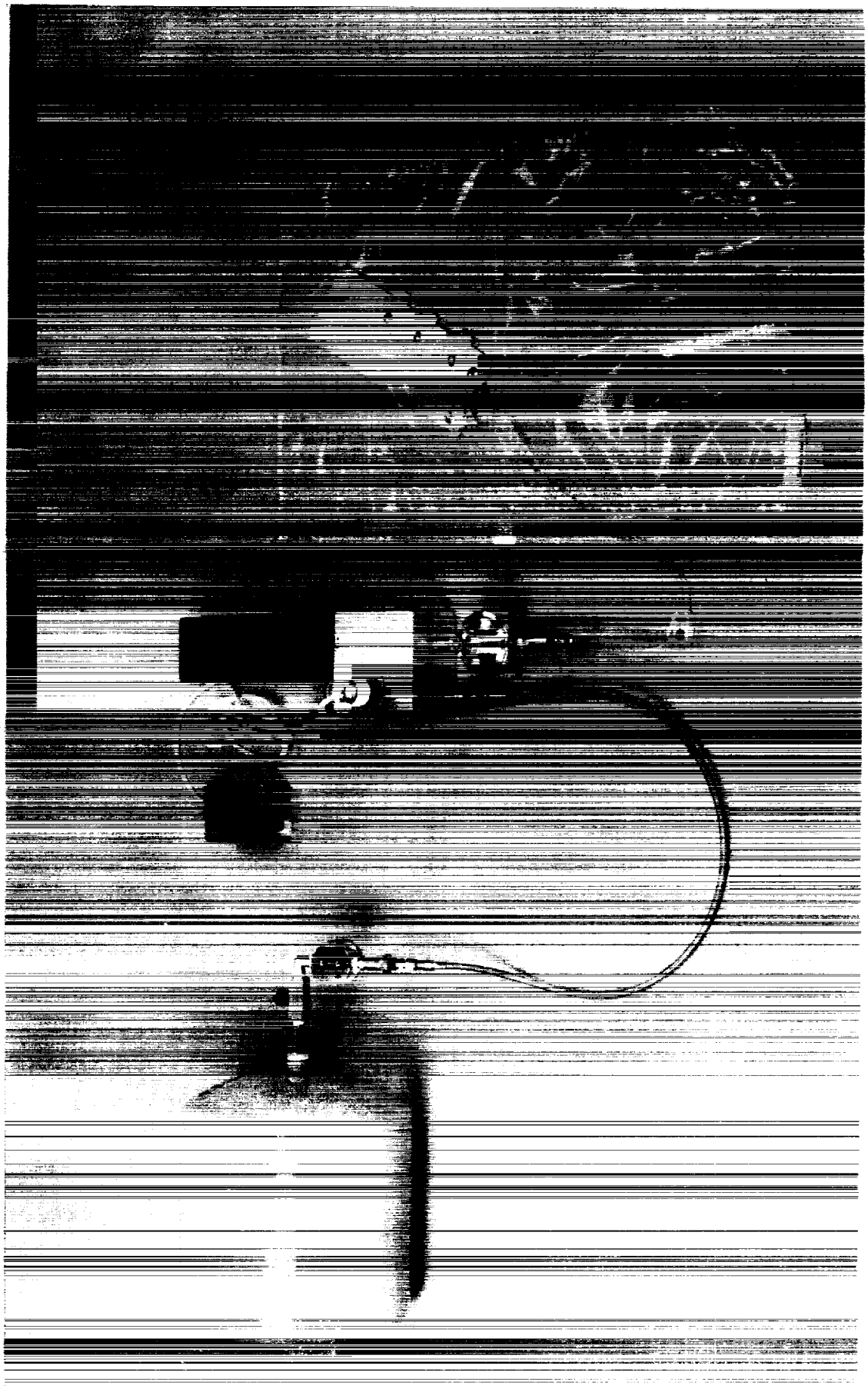

Figure 1. FTS with IV Adaptor to make sterile water for injection.

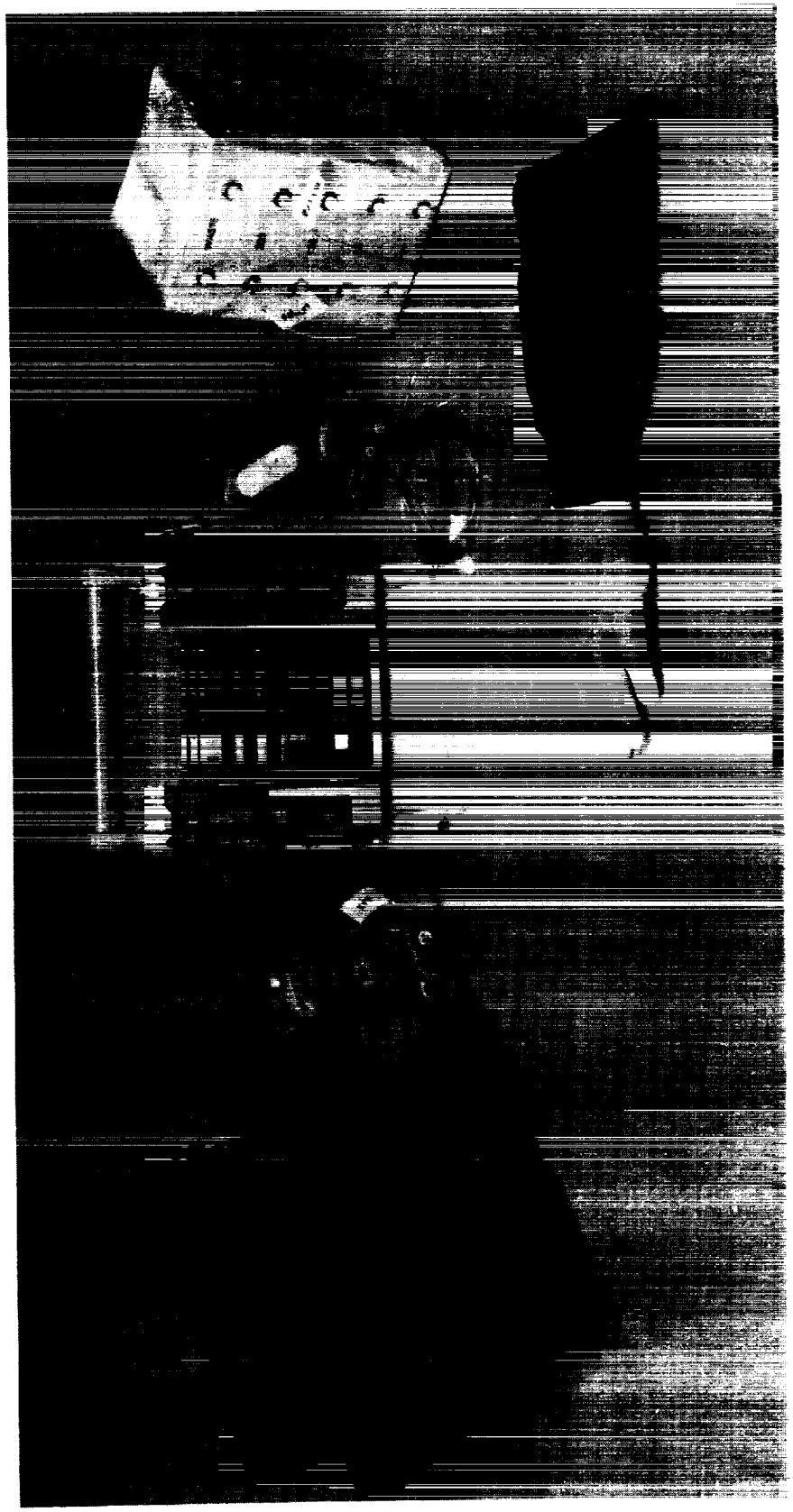

Figure 2. FTS showing the PGSC and the SCD with the FIST.

Figure 3. Close-up of the SWI cartridge.

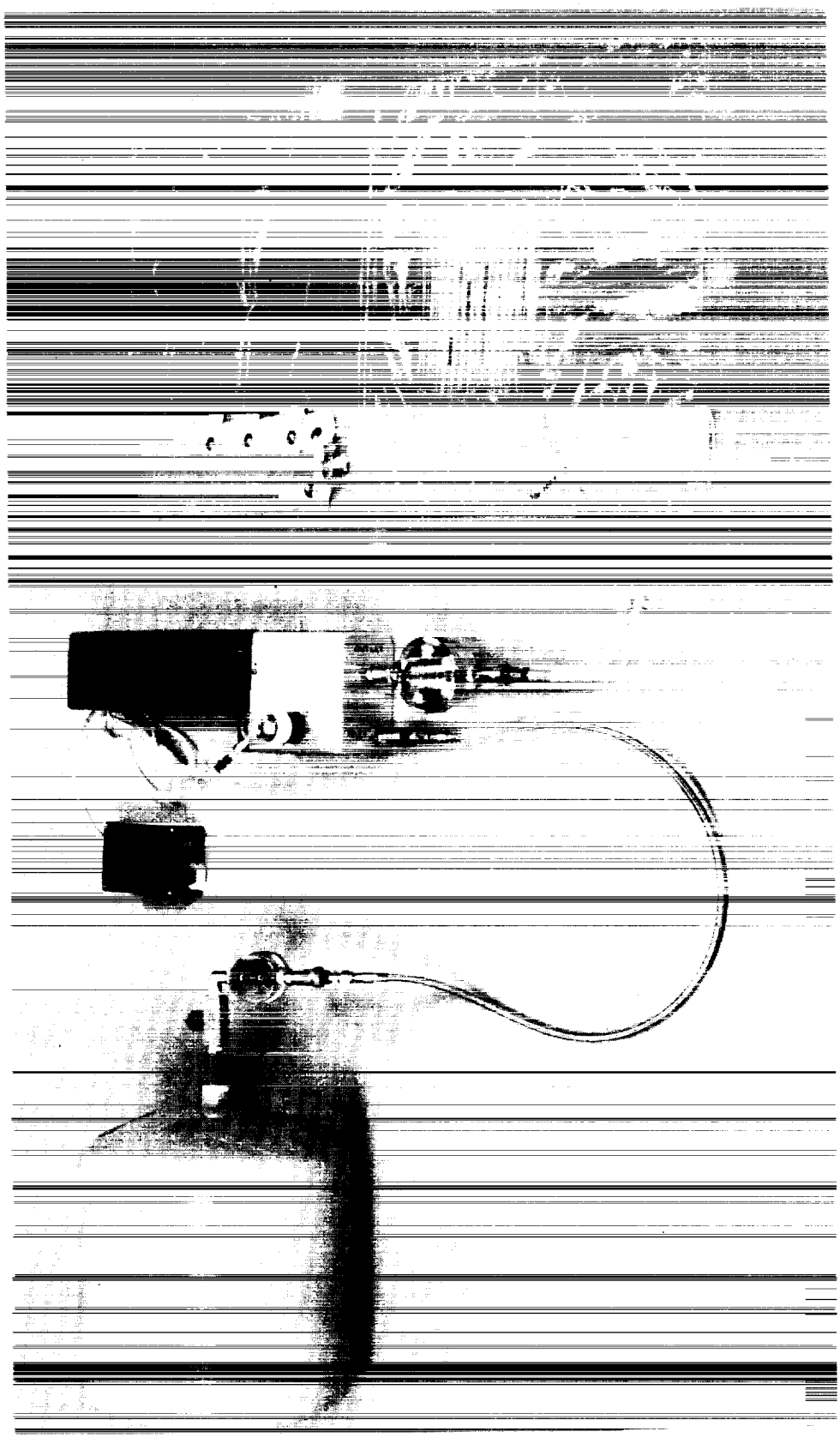

Figure 4. FTS with IV reconstitution bag in place for making either normal saline or dextrose 5%.

☆ U.S. GOVERNMENT PRINTING OFFICE 1993—733-050/80102

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	August 1993	**Technical Memorandum**

4. TITLE AND SUBTITLE

Spacelab J Experiment Descriptions

5. FUNDING NUMBERS

6. AUTHOR(S)

Teresa Y. Miller, Editor

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

George C. Marshall Space Flight Center
Marshall Space Flight Center, AL 35812

8. PERFORMING ORGANIZATION REPORT NUMBER

M-725

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

National Aeronautics and Space Administration
Washington, D.C. 20546

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

NASA TM- 4517

11. SUPPLEMENTARY NOTES

Prepared by Space Science Laboratory, Science and Engineering Directorate.

12a. DISTRIBUTION / AVAILABILITY STATEMENT

Unclassified--Unlimited
Subject Category: 29

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

This document contains brief descriptions of the experiment investigations for the Spacelab J Mission which was launched from the Kennedy Space Center aboard the Endeavour in September 1992.

14. SUBJECT TERMS

Spacelab Missions, Life Sciences, Microgravity Science, Spacelab J

15. NUMBER OF PAGES

271

16. PRICE CODE

A12

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	**Unclassified**	**Unclassified**	**Unlimited**

END DATE NOV 4, 1993