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FINAL REPORT

Modification of NASA Urine Collecting System

May 1, 1966 through April 1, 1968

PREPARED

by

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FORWARD

This is the final report on the Project # NAS 9-6206 concerned with development of an improved method of inflight urinary collection. The research was collected by Russell Scott, Jr., M. D.; Professor and Head, Division of Urology, Baylor University College of Medicine for the National Aeronautics Space Administration, Houston, Texas, under Contract No. NAS 9-6206. This report covers the period May 1, 1966 through April 1, 1968. The project monitors at the Manned Spacecraft Center have been Dr. Richard Boster and Mr. Richard Sauer.

Personnel who contributed to the research effort include Russell Scott, Jr., M. D., Charles Homsy, Sc. D., J. L. Walkup, M. D., Paul Mani, M. D., and David L. Mutchnik, M. D.

Respectfully submitted,

Russell Scott, Jr., M. D.
Professor and Head
Divison of Urology
Baylor University College of Medicine

ABSTRACT

This project involves four areas of research in development of an improved system of in-flight urinary collection.

External Urinary Collecting Device

Anatomical form fitting condoms have been developed to reduce potential leakage and improve comfort. Methods of production are described and photographs provided. Prototypes of the condoms produced in various sizes have been delivered to NASA. A design has been proposed for a urine collection system close-coupled to the suit of the astronaut.

Bacteriostasis and Precipitate Control

Bacterial and precipitate control in the urinary collection system is necessary for safety and comfort of the astronaut as well as proper functioning of the system. Observations on bacterial growth, turbidity, and alkalinity of initially sterile urine are discussed. Recommendations are made for an additive solution for control of these factors.

Skin Protection

Skin irritation from leaked urine is a potential in-flight problem. Upon advice from dermatologic consultants, a suitable commercial product is recommended to avoid this complication.

Urinary Protection Garment

·The possibility of urine leakage within the suit exists regardless of external catheter design. Developmental concepts are discussed regarding a garment which would provide for absorption of leaked urine. Suitable sources for further development in this area are suggested.

Modification of NASA Urine Collecting System

Introduction

Evaluation of data by NASA of the recent Gemini flights elucidated several problems attendant to the existing system of in-flight urine collection, storage and disposal. Post-flight criticism by astronauts and NASA systems evaluation officials indicated difficulties in the following areas:

A. Urine leakage around poorly fitting external collecting devices

B. Bacterial growth, and precipitate formation in the stored urine with clogging of valves in the device

C. Skin irritation from leaked urine

This project had as its objectives development of an improved system with specific attention to the following:

A. Development of an improved external penile urine collecting device

B. Bacteriostasis and control of precipitation in the stored urine

C. Protection of skin from urine irritation

D. Development of an undergarment for absorption of the urine that might leak

Because our progress reports on this project have contained detailed descriptions of our experimental work, this report briefly reviews our early studies and concentrates on the final outcome of our work in these areas.

External Collecting Device

Anatomical External Catheters (AEC) for Astronaut Use

Background

The primary interface between the astronaut and his in-suit urine collection reservoir is a condom-like receptacle or "external catheter" (EC). The distal end of the EC is close-coupled to the external check-valve of the reservoir. In use, this collection arrangement has allowed back-leakage of urine between EC and shaft of the penis. The objective of the work here reported was the development of a technique for fabrication of anatomically appropriate external catheters which would be formfitting. It was hoped that better fit would correct the back-leakage problem.

Procedure and Results

The method of AEC fabrication described below provides both for custom fitting of catheter for each astronaut or production of a range of sizes scaled from a given anatomical configuration. In the latter case, the best fitting catheter could be selected by trial.

Preparation of Penile Replicates

A technique has been developed for rapid preparation of penile replicates. The procedure provides three significant features: (1) it requires only a few minutes; (2) it does not cause skin irritation or other trauma; and (3) it provides an accurate replicate.

This technique involves the following steps:

1. An impression slurry is prepared by rapidly mixing (less than one minute mix time) 80 cc of water with two standard flat measures of dental impression pwoder. The powder used in this work was obtained from Lange Dental Manufacturing Company, Chicago, Illinois, and the standard measure is supplied with the powder. While other brands of powder would no doubt be suitable, the above ratio of powder to water is probably specific to the Lange product.

2. The impression slurry is poured into a small paper cup, providing a fill depth of about two inches and a total cup height of about five inches.

3. The urethral meatus should be covered with a small tab of adhesive. Subject should assume a position 20-30 degrees from vertical (by leaning on a wall or other suitable support). In this way, the penis assumes an equivalent angle from the axis of the body and is more easily admitted to the slurry. The subject inserts his penis into the slurry which at this stage provides little resistance.

4. Approximately three minutes after insertion (total of four to five minutes after slurry was prepared), the slurry will set to a firm gel. At this time, the penis may be removed without discomfort providing air is allowed to leak along the shaft of the penis by gentle lateral pressure there on.

5. A replicate of the penis may be cast immediately, using any suitable mold material such as plaster of Paris/water or RTV Silicone Rubber.

Preparation of Penile Molds

Replicates of plaster of Paris were used to develop equivalent molds. RTV-634[1] silicone rubber was found to be very suitable for this procedure. The rubber was prepared with curing catalyst according to manufacturer's specification. The catalyzed rubber was poured into a slightly tapered polyethylene beaker; the taper is important for easy removal of the cured rubber.

It is important to heed manufacturer's instructions for deaeration of the rubber immediately after catalyst addition. This prevents development of voids proximal to the article from which the mold is to be patterned. Deaeration was conveniently carried out by placing the tapered beaker within a laboratory vacuum bell jar. Sequential evacuation of the jar was necessary to prevent excessive frothing of the rubber.

The plaster penile replicates were suspended within the catalyzed, deaerated rubber. Curing of rubber was accomplished at room temperature over a 48-hour period. More rapid cure cycles at elevated temperatures may be used e.g., 65 degrees centigrade for four hours, 100 degrees centigrade for one hour.

---

(1) RTV-634 silicone rubber was obtained from General Electric Company, Silicone Products Department, Waterford, New York.

Casting of External Catheter Forms

The silicon rubber molds were used directly for casting the external catheter forms. These forms were cast from Hetron 197[2] polyester resin; two grams of methylethylketone peroxide [3] catalyst were used per 200 grams of the resin. At this catalyst level, the polyester resin cured within 12 hours. The surface finish of the finished forms was smoothed by light rubbing with a solvent such as benzene or chloroform.

Scaled Size Forms

A family of forms scaled down in size from a given master form was also prepared. In this instance, molten beeswax [4] was used in place of the polyester resin as described above. The master beeswax form was then reduced in size by removing successive layers of wax with a hot spatula. Anatomical similtude was well preserved by maintaining ratios of characteristic lengths, e.g., ratio of diameter of corpora cavernosa penis to the anterior distance between the neck of the glans and meatus.

Each size of form in beeswax was then used to prepare an equivalent silicon rubber mold. The procedure followed was that outlined above with one important exception. The beeswax was found to inhibit cure of the silicon rubber. However, a good cure at the interface between

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(2) Hooker Chemical Corp., North Tonawanda, New York

(3) Lupersol DDM, Lucidol Division. Wallace and Ternan Corp., Buffalo, N. Y.

(4) L. D. Caulk Co., Milford, Delaware

silicon rubber and beeswax was obtained by painting the beeswax form with the silicon rubber catalyst prior to insertion of the form into the catalyzed rubber.

The silicon rubber molds thus produced were then used to cast polyester resin forms as described above. The necessity for developing a polyester form stems from the elevated temperature of latex solutions from which the external catheters were made. The beeswax forms would have distorted at these temperatures.

Preparation of External Catheters

External catheter prototypes were prepared from the polyester forms by dip coating from rubber latex solutions. This work was carried out by the Anode Rubber Plating Company, 5801 Green Ash, Houston, Texas.

Three formulations of latex were used: (1) natural rubber; (2) a blend of natural rubber (90 vol %) and nitrile rubber (10 vol %); and (3) a second blend of natural rubber (70%) and nitrile rubber (30%). The catheters prepared wholly from natural rubber were less resistance to oxidation and to urine than those prepared from the blend recipes. The nitrile rubber contributes importantly to developing resistance to the oxidation and the deteriorating effects of urine.

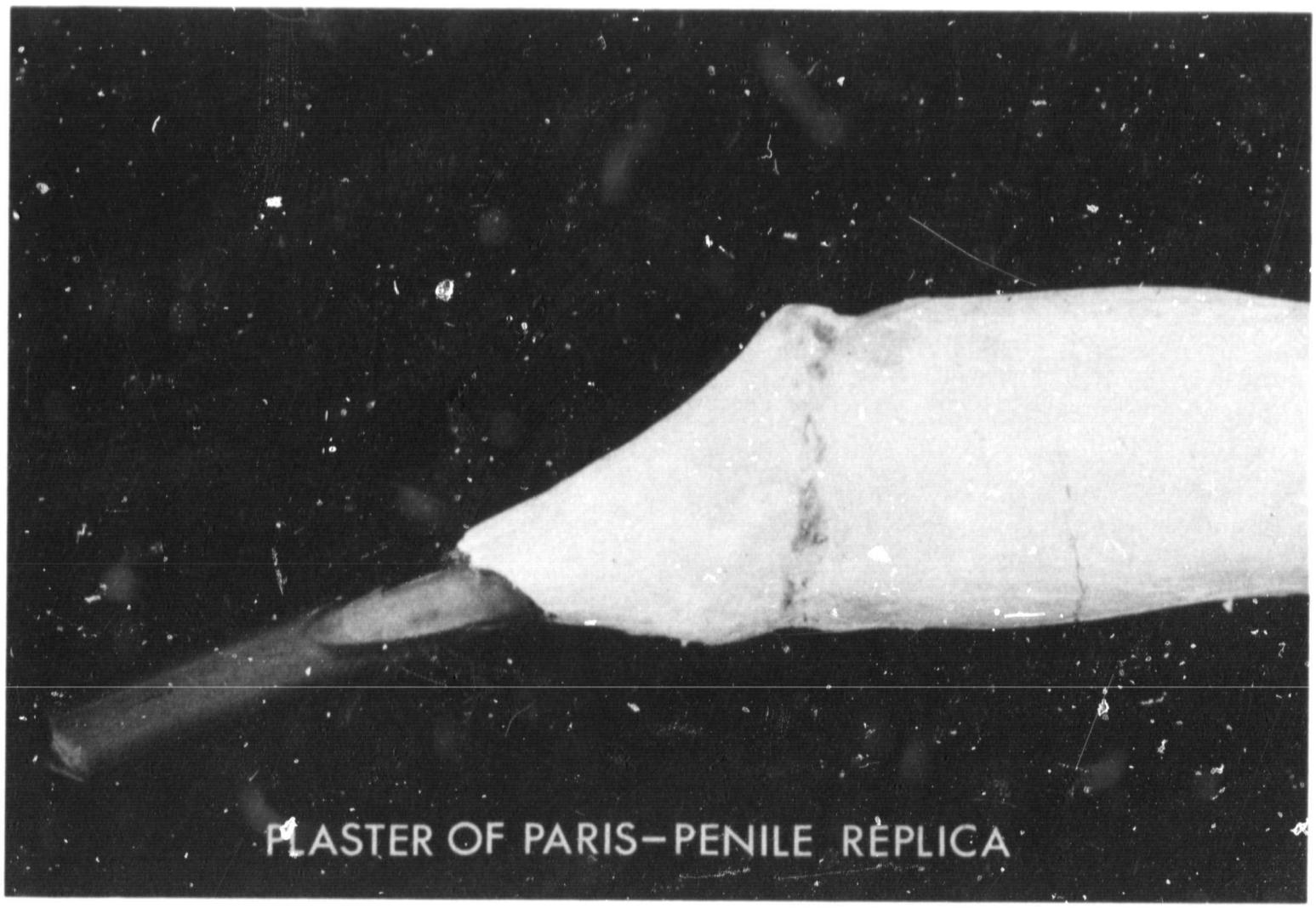
Six scaled sizes of external catheter made with each of the above recipes were transmitted to the Manned Spacecraft Center for evaluation as to ease of use.

Conclusions

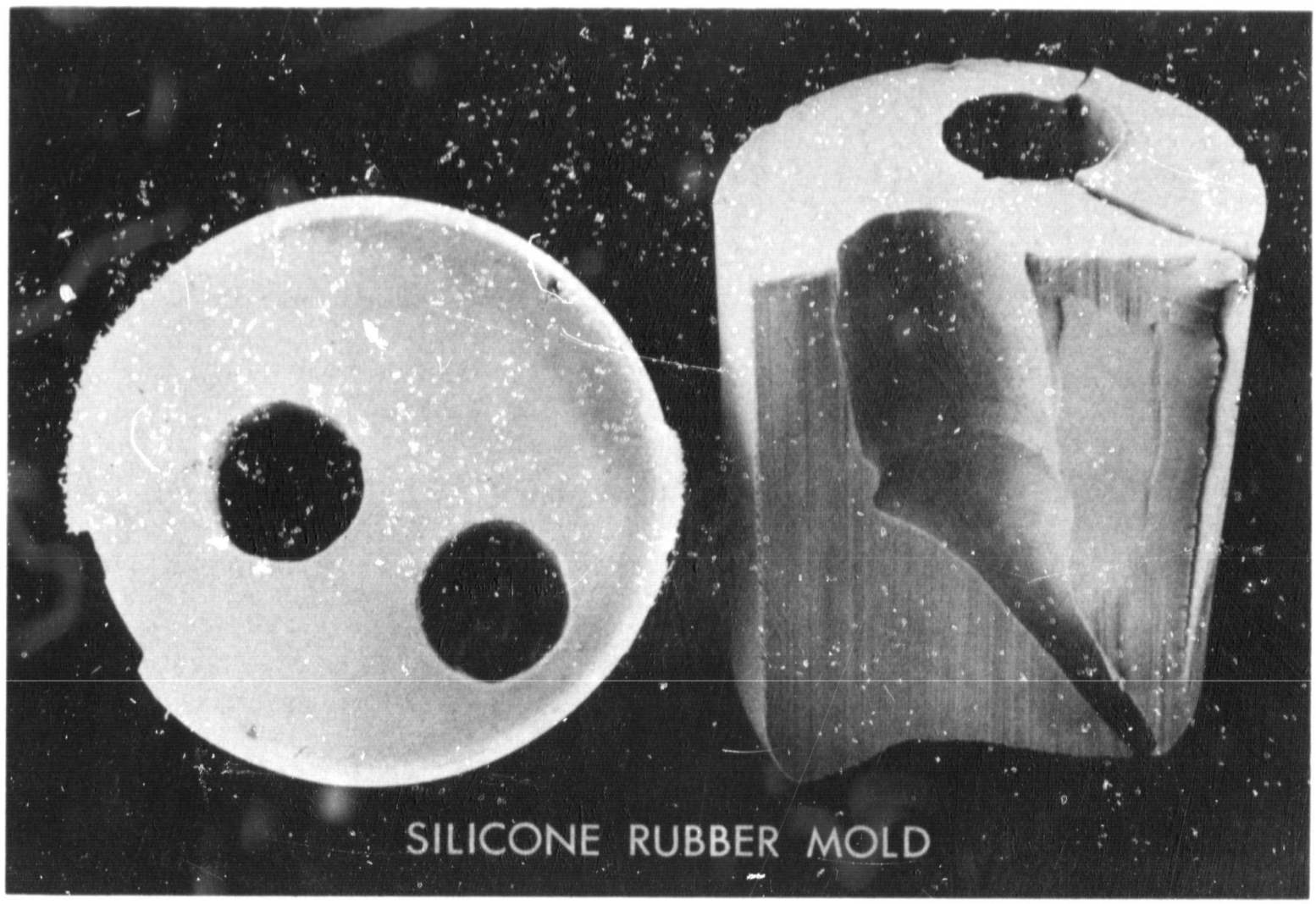
1. Techniques have been developed for manufacture of custom-fitting external catheters which may be close-coupled to the astronaut's in-suit urine reservoir.

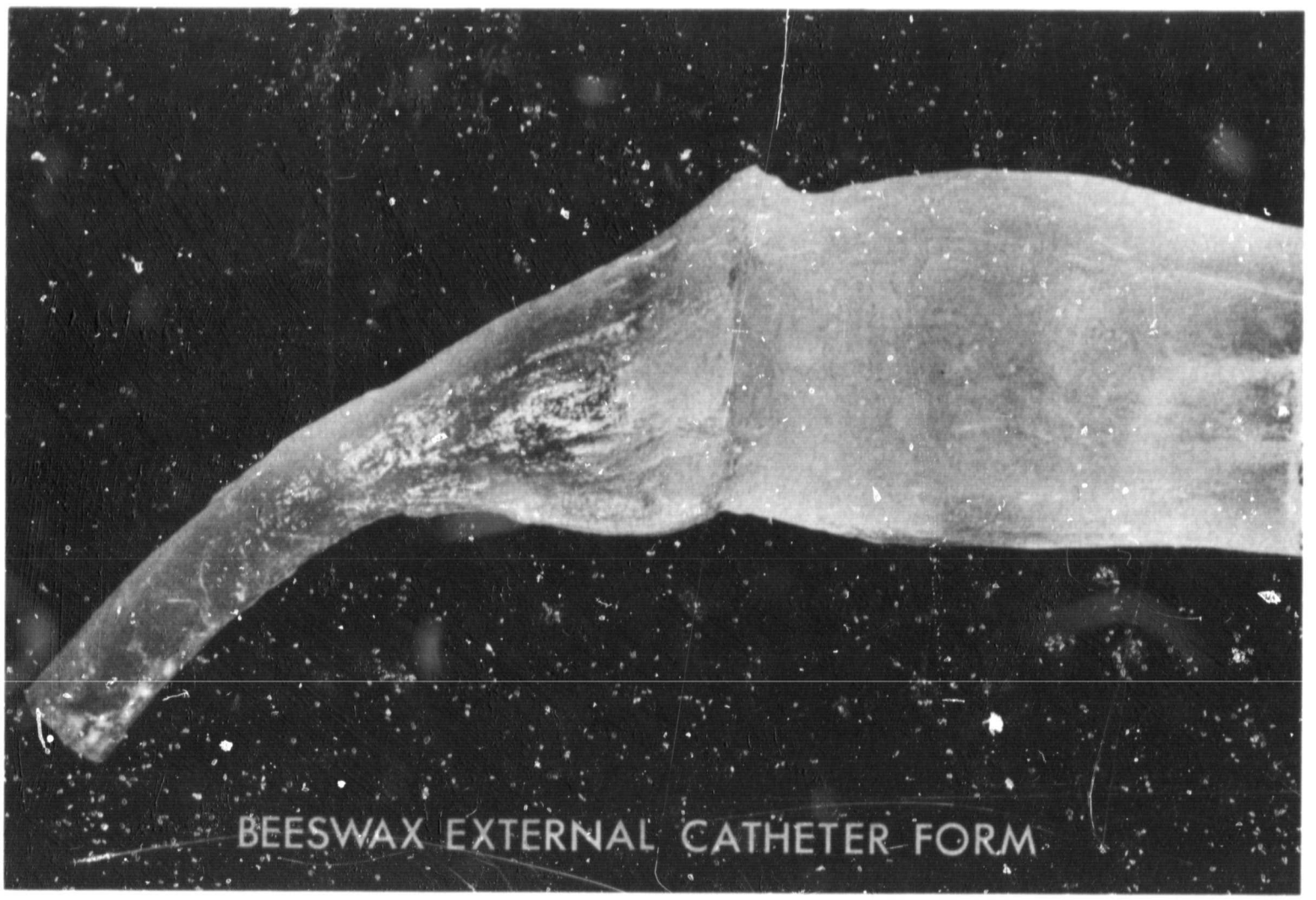
2. Methodology has been developed which allows preparation of a range of sizes based on a given anatomical configuration.

3. Prototypes of external catheters suitable for close-coupling to the in-suit urine reservoir were transmitted to MSC. These prototypes were in six scaled sizes and were fabricated from three candidate latex rubber formulations.

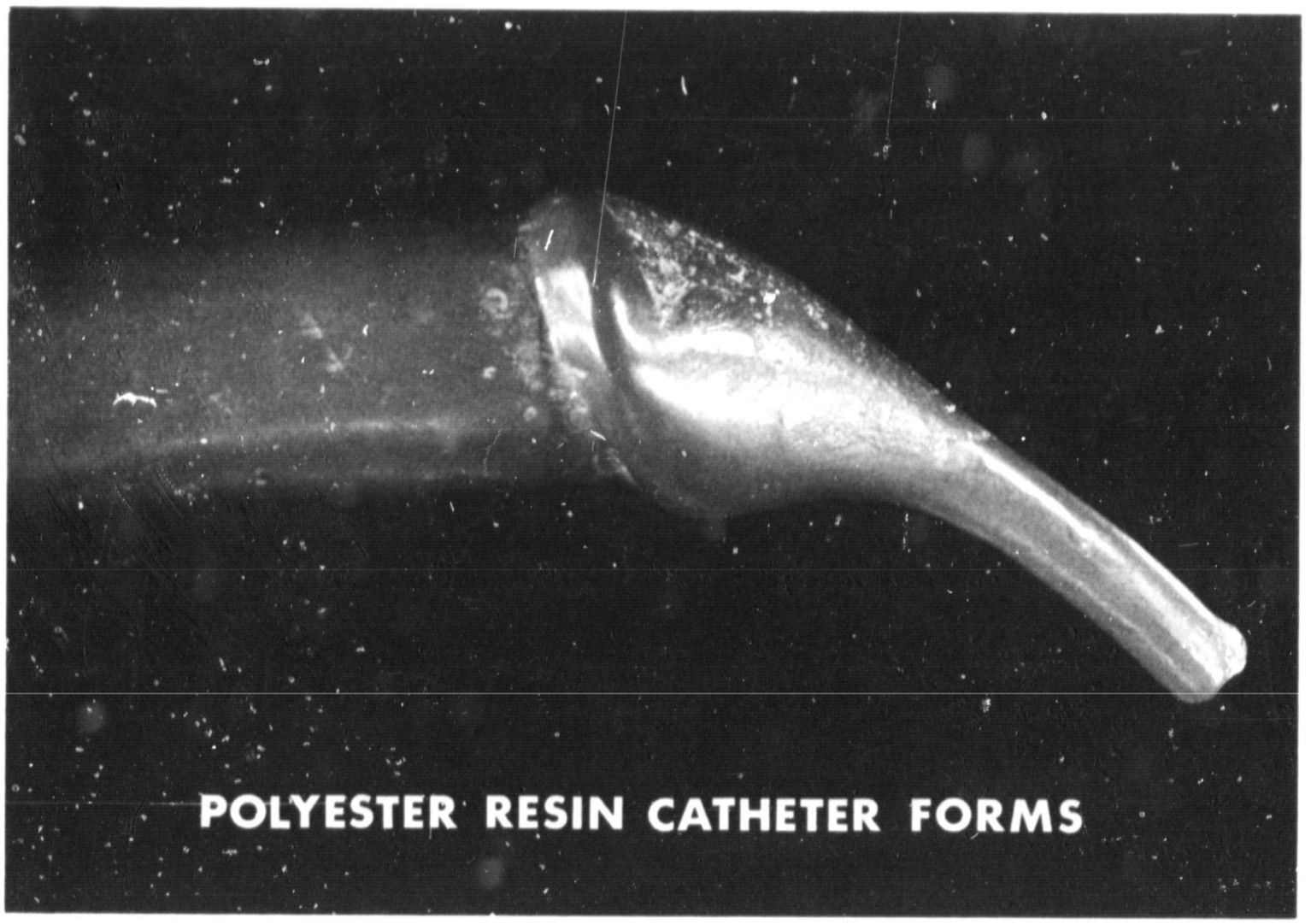


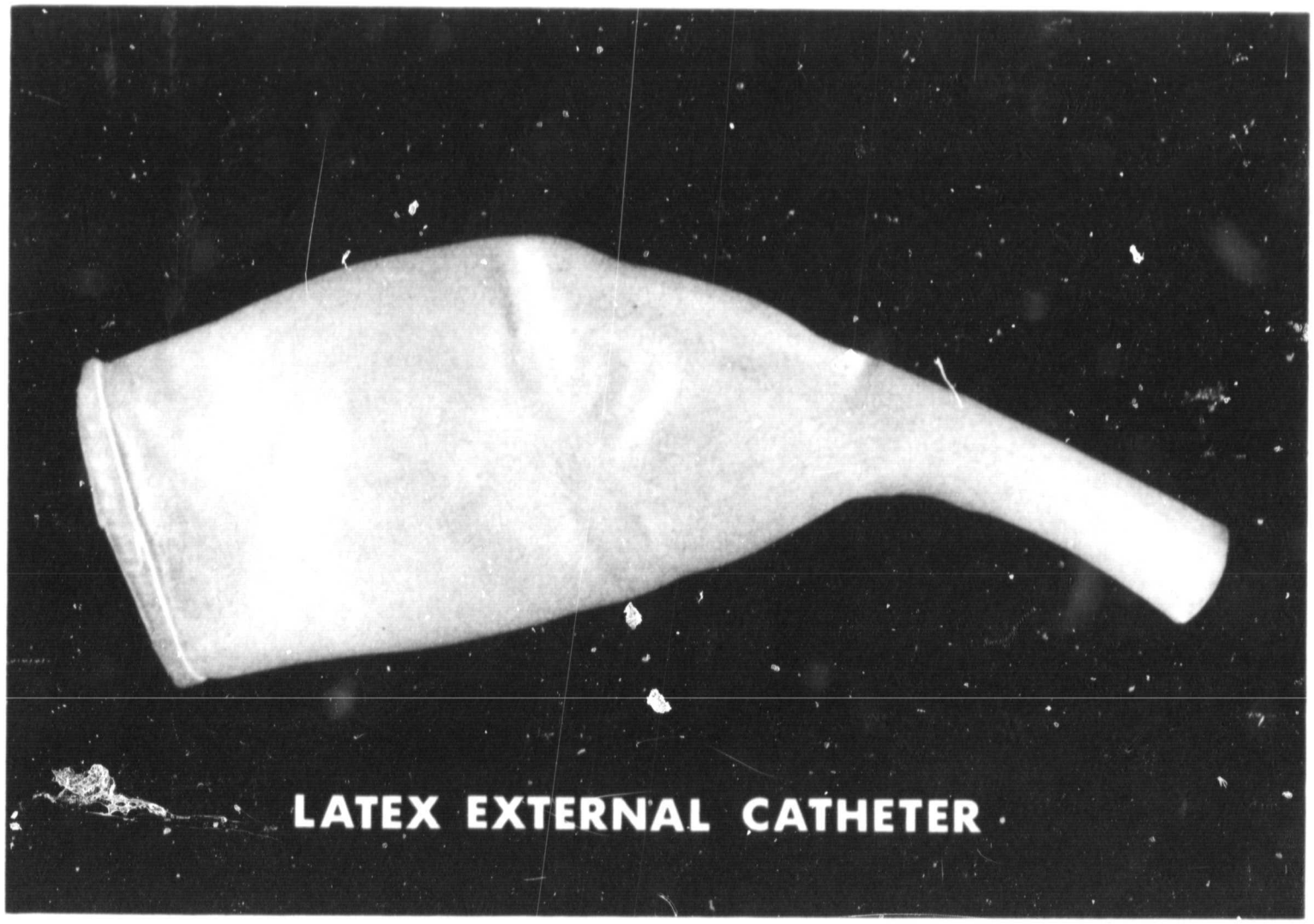
PLASTER OF PARIS–PENILE REPLICA


SILICONE RUBBER MOLD



BEESWAX EXTERNAL CATHETER FORM


POLYESTER RESIN CATHETER FORMS


LATEX EXTERNAL CATHETER

Proposal for Urine Collection System External to and Close-Coupled to Astronaut's Suit

The present in-suit urine collection and holding system appears deficient in several aspects:

1. Movement of the reservoir has tended to dislodge the external catheter. Although mechanical attachment technique for the latter devised by individual astronauts and the anatomical external catheter discussed in Section I reduce this problem, potential for the occurrence remains.

2. When the astronaut must remain in a supine position for extended periods, the attendant compression of the collection reservoir develops backpressure during urination.

3. In a contingency situation when the astronaut may have to remain within his pressure suit for as long as 115 hours, the reservoir capacity would be completely inadequate.

Discussion

The following proposal is for a urine collection and holding system which would eliminate the above problems, generally improve astronaut's comfort, and not interfere with astronaut's mobility. The system is external to but directly coupled to the astronaut's suit; that is, it is part of the suit sub-system and moves with the suit. It provides for greater holding capacity and semi-automatic disposal of collected urine at the astronaut's convenience.

Form Fitting Condom

A schematic diagram, not to scale, of the proposed system is presented in Exhibit I, Page 18 ;also shown is a sketch of the system as worn by the astronaut. (Exhibit II, Page 19)

In design of this system, we may presume that astronaut's intra-bladder super-ambient pressure is controlled by bladder muscle contracture and transurethral flow resistance; this is consistent with the super-atmospheric bladder pressures observed during voiding of normal subjects. Moreover, we can presume that this intra-bladder pressure increment will not be substantially affected by the reduced pressure environment (approximately 250 mm of mercury abs.) within the space suit.

In the absence of flow but with relaxed urethral sphincter, pressure available at the urethral meatus should be approximately the same as intra-bladder pressure. Therefore, at sphincter relaxation we take Pm (pressure at the meatus) to be equal to intra-bladder pressure; and, a value of 30 mm of mercury gauge is taken for this pressure on the basis of clinical data. Actually, system function does not depend on positive bladder pressure.

The form-fitting condom (A) includes about a four (4) inch extension, 1/4" diameter (B) around which is a light spiral spring. The function of the spring is to prevent mechanical pinching of the relatively flexible and collapsible extension. The extension connects to a relatively more rigid

and collapse-resistant tubing (such as 1/4" wall Tygon tubing) which leads to a suitable through-suit connector. A check valve III ought to be located proximal to this connector.

The urine collection unit (F) would be close-coupled to the through-suit connector as shown in the figure and manual valves I and II located as indicated. The collection unit could be a metal or plastic (Teflon FEP for non-flammability) container within which a collapsible bladder (E) is positioned as shown. The unit could be directly fabricated to NASA specification developed for hydrazine and nitrogen tetroxide fuel tanks used on rocket engines. (NASA supplier - Dilectrix Corporation, Farmingdale, Long Island, New York.)

Operation of the collection system would proceed as follows:

At attachment of the collection unit (F), pressure within the plenum reservoirs has been pre-set at about 50 mm of mercury abs. and the flexible bladder (E) is in its collapse position providing about 900 cc of plenum volume. The volume of the reservoir (D) is about 100 cc at this time with pressure something less than 50 mm of mercury abs. Valves I and II are closed, of course.

When the astronaut elects to urinate, he would open valve I. This would reduce the pressure within conduit (C) and condom extension (B) to below 250 mm of mercury abs.; extension (B) would be collapsed, thereby, protecting the meatus from exposure to pressure much below 250 mm of mercury.

As micturition begins, the urine pressure at the meatus of 280 mm of mercury abs. would easily re-open extension (B), and urine flow would proceed into reservoir (D) under a pressure driving force of 280 mm of mercury less about 50 mm of mercury (the pressure within the plenum reservoir). As voiding proceeds, the flexible bladder (E) will extend. If void volume is 300 cc, the plenum pressure (Pr) will rise to 75 mm of mercury abs.

At completion of voiding, the condom extension would collapse and both remove urine from the meatus proximity and prevent exposure to the meatus to pressure below about 250 mm of mercury abs. Astronaut would then close valve I. At all times during micturition, pressure within the condom extension (B) and conduit (C) would be less than 250 mm of mercury ambient pressure, thereby, eliminating leakage between penis and condom.

A second voiding of about 300 cc would be carried out as above and accommodated by urine reservoir (D) with plenum pressure rising only to 150 mm of mercury abs. This may be a practical limit for easy suction of the urine from the meatus. Theoretically, when plenum pressure reaches 250 mm of mercury, leakage between the penis and condom could occur depending on the compression of the condom.

The collection unit (F) may be readily emptied for re-use by opening valve II to space vacuum or on-ship urine handling gear. The flexible bladder (E) will collapse and plenum reservoir pressure will return to 50 mm of mercury abs.

Overall dimensions of the collection unit (F) would be about 5 cm by 20 cm by 10 cm. This system should greatly increase astronaut in-suit comfort, minimize or eliminate in-suit urine leakage, not add a net weight increment to the spacecraft, and not interfere with astronaut mobility during extra-vehicular activities.

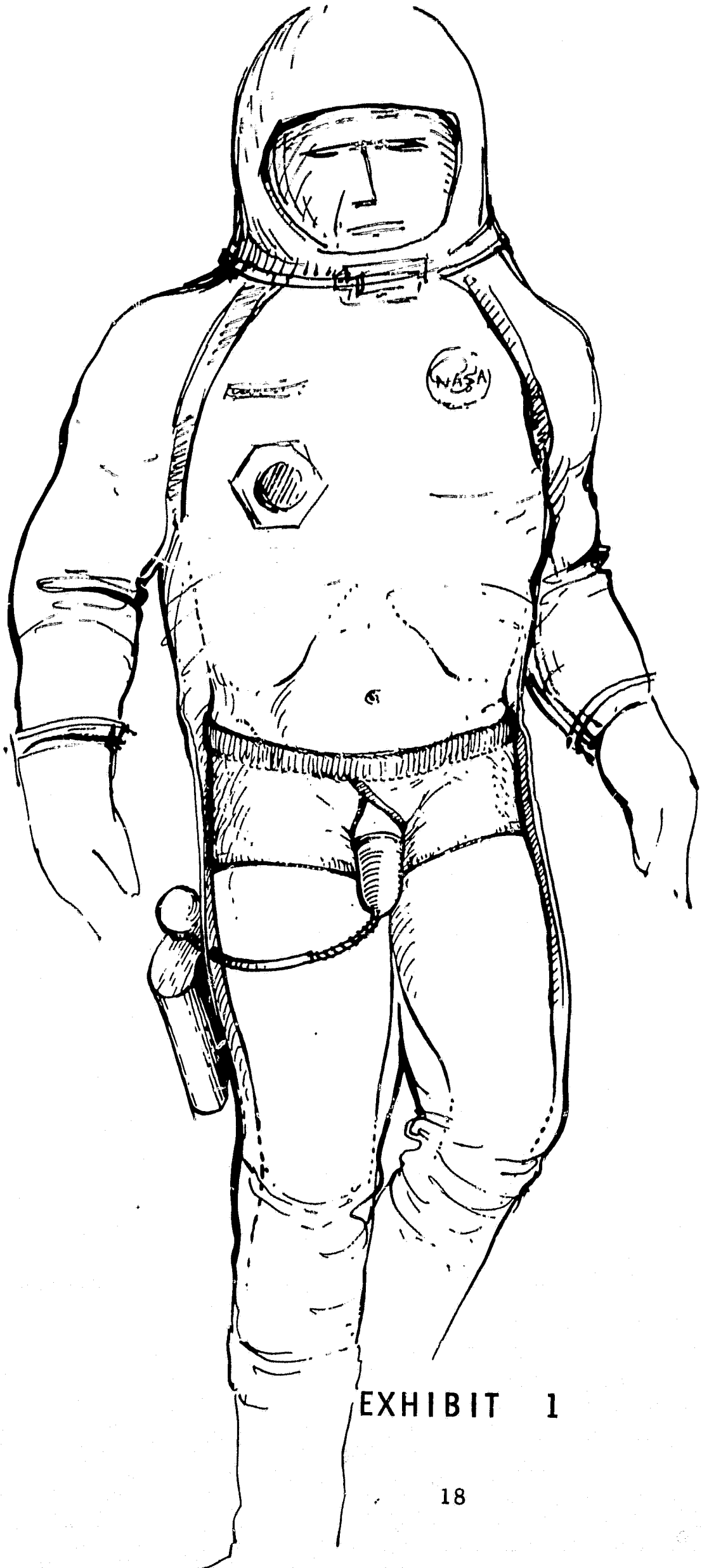


EXHIBIT 1

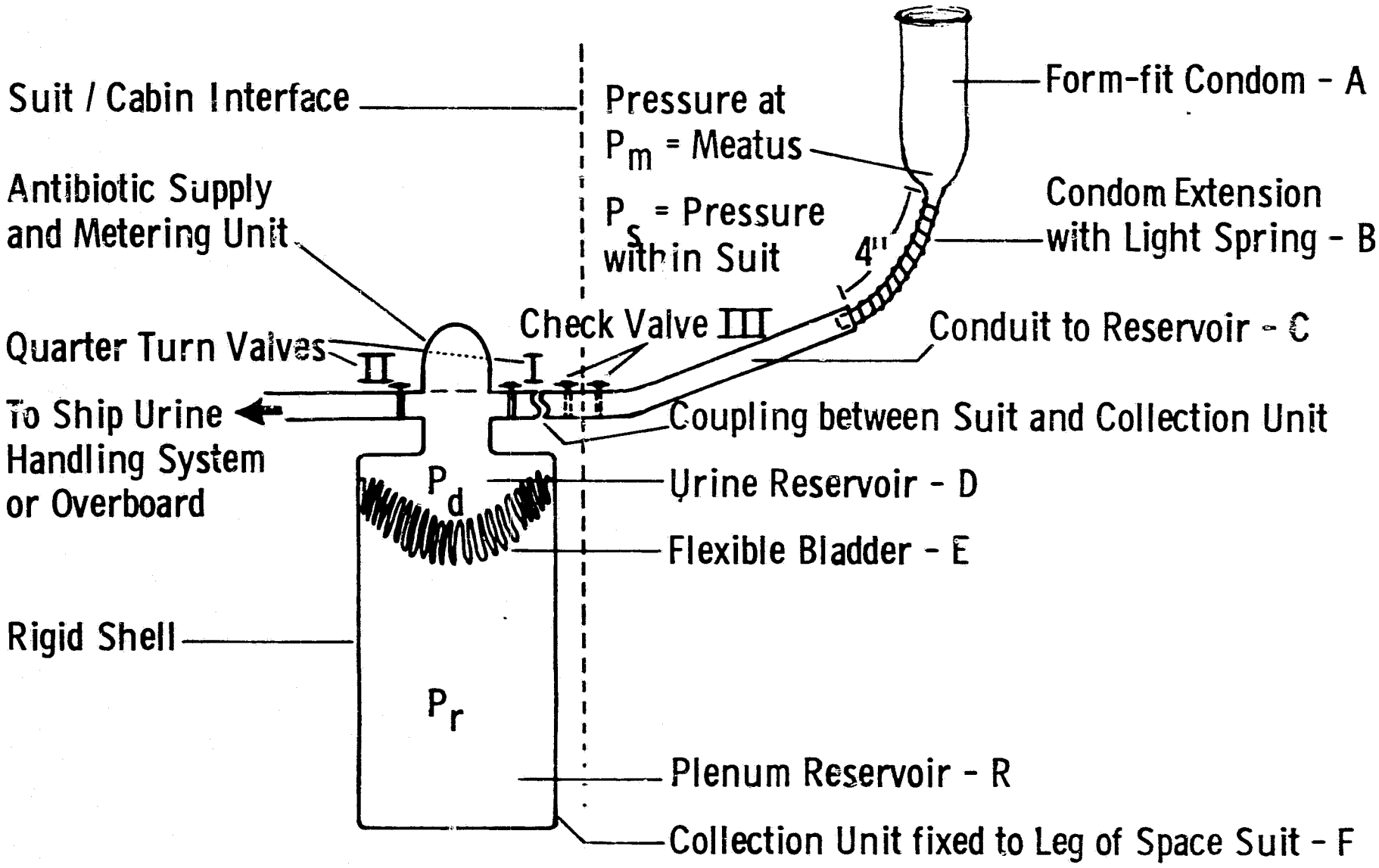

Suit / Cabin Interface
Pressure at
P_m = Meatus
P_s = Pressure within Suit
Form-fit Condom - A
Condom Extension with Light Spring - B
4"
Antibiotic Supply and Metering Unit
Quarter Turn Valves
II
I
Check Valve III
Conduit to Reservoir - C
To Ship Urine Handling System or Overboard
Coupling between Suit and Collection Unit
P_d
Urine Reservoir - D
Flexible Bladder - E
Rigid Shell
P_r
Plenum Reservoir - R
Collection Unit fixed to Leg of Space Suit - F

EXHIBIT II

Bacteriostasis and Precipitation Control

The Problem

NASA evaluation of the existing urinary collection system has indicated concern about several aspects relevant to bacterial growth in the system. It is felt that uncontrolled bacterial growth might at some point become a health hazard to the astronaut. Consequent odor formation could be a problem. Comment has also centered on obstruction of the various filtering mechanisms in this system by precipitates in the urine following prolonged usage.

Our research in this area centered mainly on finding a suitable agent or agents which might be added to the system for control of both bacterial growth and precipitate formation. It is anticipated that such an additive may be injected in small quantities to the system after each voiding and may, in addition, be used in larger quantities to "flush" the system at intervals. For use under the prescribed conditions, several requirements are mandatory. Such an agent must be :

1. Non toxic - Because of potential for exposure to cabin atmosphere and contact of leaked urine with the astronaut's skin, major consideration must be given to skin and eye toxicity of any additive.

2. Potent - Due to space and weight limitations, such additives must be potent enough for use in small quantities.

3. Inert - Extensive biochemical determinations are to be performed on the stored urine. Thus, the ideal additivie must neither influence the determination or chemically change the urine composition.

Methods and Materials and Results

Initial observations were made on aliquots of untreated sterile voided stagnant urine to determine the natural sequency of bacterial growth precipitate formation, and pH changes. It was found that bacterial contamination readily occurs with proteus and E. coli species as the usual predominating organisms. Rapid bacterial multiplication ensues, reaching a maximum of greater than 10^{12} at about the 10th day in our experiments. This maximum is apparently determined by the nutrient available. Essentially this is a ratio of the volume of stagnant urine per concentration of bacteria. When the available nutrient is exhausted, bacterial death ensues and the urine again becomes sterile. Sterile cultures were obtained in our studies by the 14th day. (See Page 27, Table I)

Consequent to this bacterial growth, rapid elevation of the urine pH occurs reaching a pH of 8.0 as early as 48 hours. This is a result of biochemical degradation of urine urea to ammonia by the enzyme urease produced by the proteus bacilli. Alkalinization once achieved remains unchanged. Concomitant with development with bacterial contamination and progressive alkalinity of the urine, large amounts of precipitable material are formed. These precipitations consist mainly of mycelial (fungal) overgrowth, dead bacteria and insoluable calcium and ammonium

phosphates. Accumulation of these substances produced a markedly cloudy urine as early as the 7th day in our studies.

Although a strictly closed stagnant situation is not encountered in the urine collection and drainage system, it is readily appreciated that the above observations are applicable as urine is expected to remain for extended periods in the collection bags, various testing devices, connection tubing and etc., allowing ample opportunity for bacterial overgrowth and development of precipitate formation to occur.

Attempts were subsequently made to determine a suitable additive which would adequately control bacterial growth and precipitate formation and also comply with the mandatory requirements of non toxicity, potency and biochemical inertia. Upon advice from the Baylor University College of Medicine, Department of Microbiology, a neomycin solution was tested. It was found that a concentration of 100 mg/500 cc of urine adequately controlled bacterial growth. Larger concentrations did not appear to significantly improve this effect. Despite adequate bacterial control with this agent, progressive alkalinization and precipitate formation occurred as before, apparently unaffected by bacteriostasis. A possible explanation of this phenomenon is production of significant amounts of urease by the few surviving bacteria or its accumulation before adequate bacterial control is attained. Neomycin does not appear to inhibit mycelial growth, further contributing to a continued precipitate formation with use of this agent alone.

Attempts were then made to find a suitable acidifying agent which might be combined with neomycin. Formic acid in a concentration of 3% was found to adequately control bacterial growth, acidity, and precipitate formation. Potency was adequate as a small volume of 2.5 cc of a 60% solution could be added to 500 cc of urine to attain the desired results. Consultation with the Baylor Department of Ophthalmology, Dermatology and Pharmacology, however, indicated that its toxicity to skin and eyes would preclude its use under the required conditions.

Attention was then turned to less toxic acidifying agents. Sodium metabisulfite appears to be satisfactory. Titration studies indicated that a concentration of less than one percent adequately maintained pH at 6.5 or less when bacterial growth was sufficiently controlled. Potency of this agent is indicated by adequate acidification with use of as little as 0.2 cc of a 40% solution sodium metabisulfite with 100 cc urine or 1.0 cc per 500 cc of urine.

Another agent, hexadecyltrimethyl ammonium bromide, was then tested for use to control mold growth. The agent potency in very low concentration was seen to be suitable for use in our studies. It also appeared to be a useful agent for bacterial control as is seen in Table III in which bacterial growth and precipitate formation are inhibited by use of a combination of sodium metabisulfite and this agent in very low concentration. Doubling the concentration of this agent does not appear to improve its effect. It is seen from Table V, however, that optimal

control of all perimeters of bacterial and mycelial growth, precipitate formation, and alkalinity is best achieved by a combination of all three agents. Our studies have indicated that 0.4 cc of this solution containing these agents in the following concentration is adequate for control of approximately 100 cc of urine:

1. Hexadecyltrimethyl ammonium bromide, 4% ----------	0.1 cc
2. Neomycin sulfate, 200 mg/ml ----------	0.1 cc
3. Sodium metabisulfite, 40% ----------	0.2 cc
Total	0.4 cc

Odor of urine treated with these agents appears to be adequately controlled.

Baylor Dermatology consultants indicate the possibility of Neomycin skin sensitization and are unsure as to skin sensitivity of the other agents. They suggest that skin testing may be advisable. The Baylor Pharmacology and Ophthalmology have indicated a lack of toxicity of these agents at the stated concentration. (See consultation reports Page 30-33).

The possibility exists of interference of this combination of agents with the biochemical agents that are to be done on the samples of urine. It is also possible that these agents may in some way change the chemical constitution of the urine so that the determinations may be erroneous. Evaluation of these possibilities has not been explored in this project. As this is likely to be a rather formidable and technical undertaking, it is recommended that such evaluation be carried by commercial research laboratory.

Recommendations

Our final recommendation of an additive suitable for control of bacterial and fungal growth, alkalinity and precipitate control is a solution containing hexadecyltrimethyl ammonium bromide, neomycin sulfate, and sodium metabisulfite. Although the final decision has not been reached as to the method of insertion of the desired additive, it is anticipated that injection of a small quantity of this solution may be done with each voiding and may in addition be used in larger quantities to "flush" the system at intervals.

Voided volumes of less than 500 cc are to be expected. However, the suggested agents are recommended in concentrations to provide adequate coverage for volumes of this size. Recommended concentrations of these agents are:

1.	Hexadecyltrimethyl ammonium bromide, 4% ----------	0.5 cc
2.	Neomycin sulfate, 200 mg/cc ----------	0.5 cc
3.	Sodium metabisulfite, 40 % ----------	1.0 cc
	Total	2.0 cc

Two milliliters of this solution may be added to this system with each voiding at some location yet to be determined.

Baylor Pharmacology and Ophthalmology consultants have indicated that these agents should be safe for use under the prescribed conditions. Baylor Dermatology consultants have indicated the possibility of Neomycin skin sensitivity and the need for possible skin testings of the other agents.

Evaluation of the possible biochemical interference with determinations to be done on a sample urine would best be done by a commercial research laboratory.

Comparison of Various Concentration of Agents in Bacteriostasis and Precipitate Control of Stagnant Voided Urine

The following study was done using 100 cc alignots of clean catch, midstream voided urine. Initial pH determination and bacterial culture were done. Following addition of the various agent combinations, serial pH determinations were made at the 7th, 10th, 14th and 23rd day. Cultures were made initially, and on days 7, 10 and 14. Microscopic examination results at the 23rd day are shown. Determination of pH was made by use of pHydrion papers. (Microessential laboratory, Brooklyn 10, New York).

The following agents were used:

(Hexa)	Hexadecyltrimethyl ammonium bromide	4% & 8%
(Neo)	Neomycin sulfate	200 mgm/ml
(Acid)	Sodium metabisulfite	40%

TABLE I

		Day	pH	Culture	Appearance
Urine	100.0	Initial	6.0-6.4	No growth	
Saline	.4	7	8.0	E. coli $3x10^8$ Proteus $51x10^{10}$	Cloudy with ppt.
		10	8.0	E. coli $5.2x10^{12}$ Proteus $2.1x10^{12}$	
		14	8.0	No growth	Foul smell, turbid with ppt.
		23	8.0		Turbid (4+) Microscopic Exam: Uric acid crystals and dead bacteria

TABLE II

		Day	pH	Culture	Appearance
Urine	100.0	Initial	6.0-6.4	No growth	Clear
Neo	0.2	7	6.0-6.4	No growth	Clear
Acid	0.2	10	6.0-6.4	No growth	
		14	7.6	No growth	Cloudy with mold growth
		23	7.6		Turbid (3+)
					Microscopic Exam: Mycelia

TABLE III

		Day	pH	Culture	Appearance
		Initial	6.0-6.4	No growth	Clear
Urine	100.0	7	6.0-6.4	No growth	Clear with sl. cloudy sediment
Hexa.	4% 0.2	10	6.0-6.4	No growth	
Acid	0.2	14	6.0-6.4	No growth	Clear with sl. cloudy sediment
		23	6.0-6.4		Slightly cloudy (1+)
					Microscopic Exam: Very small amount amorphous material

(Hexa) Hexadecyltrimethyl ammonium bromide
(Neo) Neomycin sulfate
(Acid) Sodium metabisulfite

TABLE IV

		Day	pH	Culture	Appearance
Urine	100.0	Initial	6.0-6.4	No growth	Clear
Hexa	8%				
	0.1	7	6.0-6.4	No growth	Clear with sl. Cloudy ppt. sediment
Acid	0.2	10	6.0-6.4	No growth	
Neo.	0.1	14	6.0-6.4	No growth	sl. cloudy sediment
		23	6.0-6.4		sl. cloudy (1+)
					Microscopic Exam: Very small amount amorphous material

TABLE V

		Day	pH	Culture	Appearance
Urine	100.0	Initial	6.0-6.4	No growth	Clear
Hexa	4%				
	0.1	7	6.0-6.4	No growth	Clear
Acid	0.2	10	6.0-6.4	No growth	Clear
Neo	0.1	14	6.0-6.4	No growth	Clear
		23	6.0-6.4		Clear
					Microscopic Exam: No sediment

(Hexa) Hexadecyltrimethyl ammonium bromide
(Neo) Neomycin sulfate
(Acid) Sodium metabisulfite

Baylor University College of Medicine
Texas Medical Center
Houston, Texas 77025
Department of
Pharmacology

December 21, 1967

Dr. Jim L. Walkup
Resident in Urology
Baylor University College of Medicine
Houston, Texas

Dear Dr. Walkup:

I am very sorry for the delay in responding to your letter of December 7. I now have had the opportunity to speak to three of my associates about your question and hasten to assure you that we do not find any potential harm in the preparation you propose.

Some of my colleagues have asked why not add a thymol crystal to prevent a mold growth in urine or a small monomolecular layer of toluene above the urine sample as is commonly done. These are our only suggestions.

Sincerely,

Harris Busch, M.D., Ph.D.
Professor of Pharmacology
Chairman of the Department

HB:cc

Baylor University College of Medicine
Texas Medical Center
Houston, Texas 77025
Department of
Ophthalmology

December 15, 1967

James L. Walkup, M. D.
Division of Urology
Baylor University College of Medicine
Houston, Texas

Dear Doctor Walkup:

The concentration of the three agents you have described would be well below the minimum toxic levels to the eye and surrounding skin. I would think the urine itself would cause more eye irritation than the bacteriostatics.

Sincerely,

Louis J. Girard, M. D.
Professor and Chairman

LJG/cg

Baylor University College of Medicine
Texas Medical Center
Houston, Texas 77025
Department of
Dermatology

December 15, 1967

Jim L. Walkup, M. D.
Resident in Urology
Department of Surgery
Baylor University
College of Medicine
Houston, Texas 77025

Dear Doctor Walkup:

Your letter was circulated to three other members of our faculty. May I suggest that you contact Dr. W. Christopher Duncan, who is the M.D. in charge of our Infectious Disease Section. We would be happy to assist in any way possible.

Actually, no one in our group was very familiar with any of the agents except Neomycin Sulfate. Neomycin is a skin sensitizer and, therefore, could cause trouble if it is constantly or periodically in contact with skin or mucous membrane. We do not know enough about the other agents to comment. If they are to be in contact with the skin, the manufacturing company probably has toxicology, sensitivity index and irritancy potential data that could be examined. You would probably want to obtain this material before talking to Doctor Duncan, if you need his advice in regard to skin safety.

Sincerely,

John M. Knox, M. D.
Professor and Chairman
Department of Dermatology

JMK:pjm
Transcribed: 12-18-67

MEMORANDUM

BAYLOR UNIVERSITY
COLLEGE OF MEDICINE

FROM: W. Christopher Duncan, M. D.

TO: Jim L. Walkup, M. D.

DATE: January 5, 1968

Without benefit of the information from the company supplying the material in question, I really have nothing to add beyond what Doctor Knox's letter of 12/15/67 said.

If no information is available, the only way to answer the question is to perform patch tests both for primary irritancy and allergenic potential. Neither of the two chemicals are listed in a new text on contact dermatitis. Do they have some trade name?

If you have any specific questions, please do not hesitate to call on me.

WCD

Skin Protection from Urine Irritation

Problem

Astronaut evaluation of the urine collection system used in the Gemini flights indicated that leakage of urine around the condom brought about minor local skin irritation. This problem could become a significant one when prolonged flights or contingency situations are involved in which the astronaut might not have access to the device inside the suit. Opportunity for urine leakage exists regardless of modification or improvements made in condom design.

Materials and Methods

Advice was sought from the Department of Dermatology, Baylor University College of Medicine regarding suitable skin protection.

Results

Their recommendation has been a Dow-Corning product "Protective Hand Cream". We considered "pre conditioning" of the skin in this area with the application of various solutions for 21 days prior to flight. This can still be considered, and appropriate solutions evaluated for astronaut known to have sensitive skin, dilute acetic acid might be considered.

Recommendations

Although actual testing of "Protective Hand Cream" has not been done by us, it is felt that application of this cream in the pubic, groin, and scrotal areas prior to application of the external collection device and

and perhaps again at regular periodic intervals will provide adequate skin protection should urine leakage occur. Until leakage is found to be more of a problem it would be our recommendation not to use any skin protecting cream.

Urinary Protection Undergarment

Problem

Leakage of urine between the external collection device and the penile shaft has proven a problem in the previous Gemini flights. Potential for leakage exists regardless of condom design. Attendant to this problem and the consequent skin irritation caused by leaked urine, astronauts have expressed an interest in an absorbent undergarment which might be worn inside the suit. The purpose of this garment would be to absorb leaked urine in an effort to prevent pooling within the suit and consequent problems with skin irritation and odor.

Methods and Materials

Our investigation of such an undergarment has been limited to development of concepts which might prove useful should later production be desired. In an effort to obtain expert advice in this area, we have contacted Mr. J. N. Masci, Vice President of Advanced Technology, Johnson and Johnson Company. (Makers of disposable diapers and similar devices)

Results

Mr. Masci has suggested that the most absorbent substance for use under these conditions might be a hydrocolloid produced by Dow Chemical Company. Granules of this hydrocolloid could be incorporated in the fibrous matrix surfaced with a dacron or nylon fabric and backed by a

plastic film so that it would feel dry even if wet. This garment could be shaped to fit the area of expected leakage inside the suit. An appropriate hole in the garment would be necessary to accommodate the collecting device. Mr. Masci suggests that such a garment could be designed to absorb up to 300 ml of leaked urine. It was Mr. Masci's recommendation that the fiber of the inner layer be so constructed that it would absorb and conduct the urine away from the area of spill in a matter of seconds. The chemical substances within the garment can be produced to specification so that it would not be "activated" until a given volume of fluid had been picked up by the garment (30 cc) and that once "activated", the chemical substances would attract and bind all additional liquid up to a specified volume. Disposability would be an additional desirable feature. (See correspondence on Page 38)

Recommendations

Although Johnson and Johnson Company is not interested in production of a garment prototype of this description at the present, Mr. Masci indicated that Dow Chemical Company has active research in the problems of urine absorption and retention. It would be advisable to seek their assistance should NASA desire to pursue further development in this area. (See correspondence on Page 39)

Johnson & Johnson

DOMESTIC OPERATING DIVISION — NEW BRUNSWICK NEW JERSEY

December 30, 1966

Dr. Russell Scott
Department of Urology
College of Medicine
Baylor University
Texas Medical Center
Houston, Texas 77025

Dear Dr. Scott:

I have reviewed the results of our discussion in Houston with my colleagues and we have concluded that it is possible to construct a device capable of absorbing at least 300 ml. of urine by the use of hydrocolloids. The object would be to have most or all of the urine imbibed by the granules of colloid to result in a minimum of free liquid.

This material would be contained in a fibrous matrix, surfaced with a nylon or dacron fabric so that it would feel dry, and backed by plastic film. The entire absorbing device would be shaped to fit inside the urine collection device and have a hole to accommodate the catheter coupling.

If you would like to have us do so, we will proceed immediately to prepare some product prototypes for your examination and critique.

Sincerely,

J. N. Masci
Vice-President
Advanced Technology

JNM/gk

Johnson & Johnson

DOMESTIC OPERATING COMPANY NEW BRUNSWICK, N J.

February 6, 1968

Russell Scott, Jr., M.D.
Division of Urology
Baylor College of Medicine
Texas Medical Center
Houston, Texas 77025

Dear Dr. Scott:

I apologize for the delay in responding to your letter of January 8, 1968, but I have been exploring ways in which we could accommodate the needs of your program.

Although we are very interested in the program I find that the R & D groups which have competence in the field of design of urine retentive garments are so committed to urgent programs of their own that they are reluctant to undertake an additional program.

Under the circumstances I have another suggestion to make. The hydrogel products which we have been using are the product of the Dow Chemical Company. Their laboratories have also worked on the problem of urine absorbtion and retention. In the interest of getting your program underway, I would be glad to explore the possibility of interesting them in the proposal and getting them to estimate time and cost for you.

Would this be of interest to you?

With personal regards,

Sincerely yours,

J. N. Masci
Vice-President
Advanced Technology

JNM/gk