Final Report for Intravenous Fluid Generation (IVGEN) Spaceflight Experiment

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Level of Review: This material has been technically reviewed by technical management.

Contents

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Summary

NASA designed and operated the Intravenous Fluid Generation (IVGEN) experiment onboard the International Space Station (ISS), Increment 23/24, during May 2010. This hardware was a demonstration experiment to generate intravenous (IV) fluid from ISS Water Processing Assembly (WPA) potable water using a water purification technique and pharmaceutical mixing system. The IVGEN experiment utilizes a deionizing resin bed to remove contaminants from feedstock water to a purity level that meets the standards of the United States Pharmacopeia (USP), the governing body for pharmaceuticals in the United States. The water was then introduced into an IV bag where the fluid was mixed with USP-grade crystalline salt to produce USP normal saline (NS). Inline conductivity sensors quantified the feedstock water quality, output water purity, and NS mixing uniformity. Six 1.5-L bags of purified water were produced. Two of these bags were mixed with sodium chloride to make 0.9 percent NS solution. These two bags were returned to Earth to test for compliance with USP requirements.

On-orbit results indicated that all of the experimental success criteria were met with the exception of the salt concentration. Problems with a large air bubble in the first bag of purified water resulted in a slightly concentrated saline solution of 117 percent of the target value of 0.9 g/L. The second bag had an inadequate amount of salt premeasured into the mixing bag resulting in a slightly deficient salt concentration of 93.8 percent of the target value. The USP permits a range from 95 to 105 percent of the target value.

The testing plans for improvements for an operational system are also presented.

1.0 Introduction and Background

The Vision for Space Exploration (Ref. 1) outlined a new direction for NASA, consisting of missions to return astronauts to the Moon and test the technologies required for Mars missions. The International Space Station (ISS) will also be used as a test bed for some of these new technologies. NASA's Exploration Systems Architecture Study (Ref. 2) presented several Design Reference Missions (DRMs) that were used to facilitate the derivation of various requirements for the essential technologies such as the Environmental Control and Life Support Systems (ECLSS), spacecraft power and propulsion, and communications. These DRMs included ISS expeditions, Lunar Sorties lasting 7 days, a Lunar Outpost with crew exchanges once every 6 months, and various options for a trip to Mars. With the exception of the ISS expeditions, there is limited capability for emergency medical evacuations because of the distance from Earth and their associated return timelines. The ability to stabilize and treat patients on exploration missions will depend on access to needed consumables. IV fluids have been identified as required consumables. Miller et al. (Ref. 3) reviewed the ISS Patient Condition Database (PCDB), which lists over 400 medical conditions that could require treatment during ISS missions. These conditions are a subset of possible conditions that could be encountered during long-duration, Extravehicular Activity (EVA) intensive, exploration missions. Of the 442 conditions, approximately 115 could require medical

Figure 1.—Advanced life support pack.

fluids during the course of treatment. Terrestrial treatment would typically include fluids such as normal saline (NS, 0.9 percent NaCl), 5 percent dextrose, Lactated Ringer's, or blood products. Watkins (Ref. 4) provided a condition list, the Space Medicine Exploration Medical Condition List (SMEMCL), for the Exploration Medical Capabilities Element of the Human Research Program that examined seven DRMs and listed the breakdown of various medical conditions and treatment priorities.

Currently, the ISS stocks a large complement of diagnostic medical equipment and supplies for the purpose of both biomedical research and treatment of injuries and illnesses among the crewmembers. The philosophy for life-threatening and severe cases is to provide initial treatment to stabilize the patient and evacuate the patient back to Earth in a timely fashion. To implement this philosophy, the Advanced Life Support Pack (ALSP), shown in Figure 1, contains IV fluid of 0.5-L bags of dextrose solution and 0.5- and 1-L bags of 0.9 percent NS solution for a total of 4.5 L. Due to shelf life considerations, each of the contents of the ALSP is replaced at least every 18 months (Ref. 5).

Operational constraints such as mass limitations and lack of refrigeration may limit the type and volume of such fluids that can be carried onboard the spacecraft. Consequently, the objective of the IVGEN experiment was to develop, design, and validate the necessary methodology to purify spacecraft potable water into a NS solution thus reducing the amount of IV fluids that are included in the launch manifest.

1.1   Standards

The United States Pharmacopeia (USP) is the authoritative source for medicine and healthcare product standards. These standards are in place to improve public health by ensuring the quality and safety of products. As such, the USP has developed monographs detailing standards for drug products, including various types of water to be used for pharmaceutical purposes. The monographs for these water products include a cascade of multiple techniques and requirements as illustrated in Figure 2. The classification for the final products depends not only on the preparation method, but the usage and packaging as well. For example, "Sterile Water for Irrigation" (SWFI) and "Sterile Water for Injection" (SWI) may be prepared identically, but SWFI is packaged "in bulk" or in sterile containers that hold more than 1 L of fluid while SWI must be packaged in containers no larger than 1 L.

Some monographs include process-oriented descriptions, that is, they describe a series of operations or procedures that are not verified directly via measurements of quantifiable values, such as a concentration, for all possible contaminants. As an example, the USP standard for purified water requires that source water meet Environmental Protection Agency (EPA) National Primary Drinking Water Regulations (NPDWR). To meet USP requirements for water for irrigation (WFI) distillation, reverse osmosis, or an equivalent or superior process is acceptable; however, there are no quantifiable values for assessment.

Drinking Water
(Complying with US EPA NPDWR or drinking water regulations of EU or Japan or WHO Guidelines for Drinking Water)

↓

Typical Treatment Steps could include:

Distillation	De-ionization
Reverse osmosis	Prefiltration
Dechlorination	Softening
De-ammonification	Ultrafiltration
Organic scavenging	UV Light

↓

Purified water

↓

Distillation, reverse osmosis or equivalent/superior process for removing chemicals and micro-organisms

↓

Water for injection

↓

Packaging and sterilization

↓

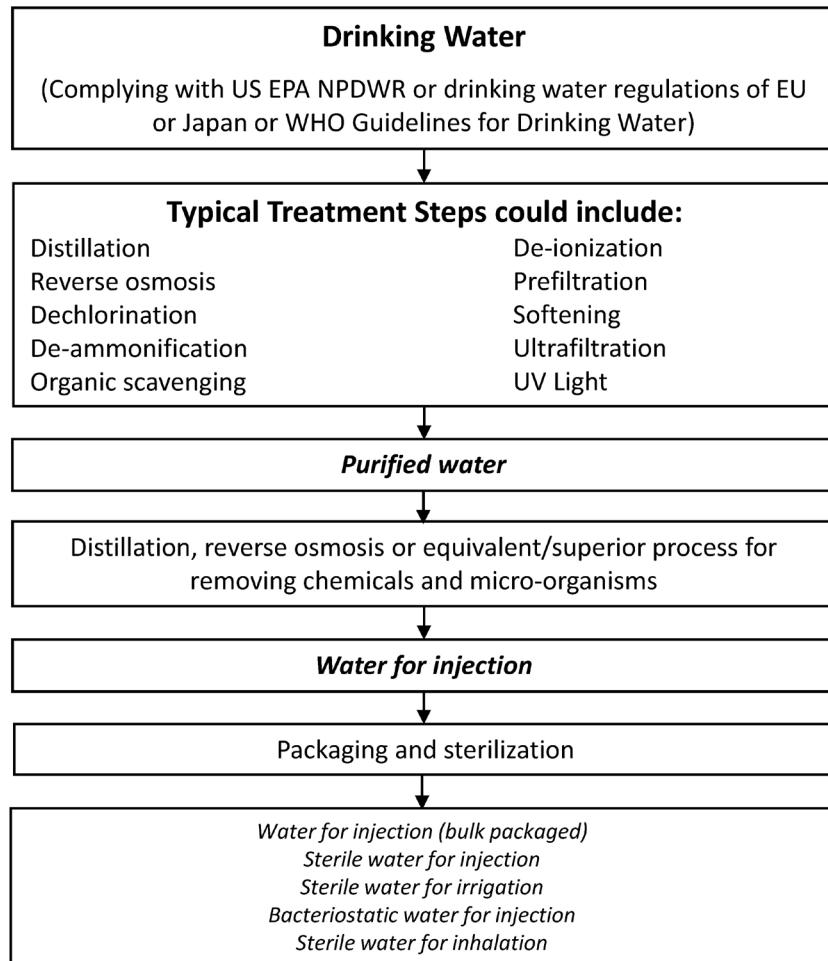| *Water for injection (bulk packaged)*
Sterile water for injection
Sterile water for irrigation
Bacteriostatic water for injection
Sterile water for inhalation |
| :---: |

Figure 2.—Process for manufacturing water for injection.

The EPA does not have limits on all possible contaminants, such as iodine and silver because these biocides, which are generally used in space vehicle water, are not normally present in public water systems. Biocides are not allowed in SWI and must be removed. Bagdigian et al. (Ref. 6) discuss in detail the various agencies and regulations governing water quality and allowed contaminant levels in water to be used for different purposes.

It should also be noted that there are additional stipulations listed within the USP National Formulary (Ref. 7) that are imposed upon these processes that are not readily apparent otherwise. For example, with regards to distillation, provisions need to be incorporated that eliminate the possibility of evaporator flooding and mist carryover. Furthermore, during periods of system nonusage, provisions need to incorporate the ability to drain and dry the distillation apparatus to minimize the possibility of microbial infiltration and growth. Finally, there needs to be a process to validate and periodically inspect the process to assure that quality standards are being met.

Cascading requirements and procedures are not limited only to the preparation of WFI. Per the USP National Formulary, the specification for NS solution, "Sodium Chloride Injection," is 0.9 weight percent concentration of sterile sodium chloride in WFI. Therefore, a NS solution must meet the EPA requirements for potable water; and the USP requirements for purified water, WFI, sodium chloride injection and sterility. The USP monographs may be found at their online website.

1.2   Spacecraft Potable Water

NASA potable water must meet requirements defined in the Spacecraft Water Exposure Guidelines (SWEGs) (Ref. 8) in NASA Space Station Program (SSP) 41000 (Ref. 9) and CxP 20024 (Ref. 10), if they are different than EPA NPDWR standards. While there is some overlap in the two standards, NASA's standards cover contaminants specific to spacecraft water. Furthermore, the SWEGs establish limits based on exposure durations that include 1, 10, 100, and 1000 days. These standards reduce the acceptable concentration as the exposure duration increases. Some contaminant standards, such as manganese salts, are not addressed by the NPDWR, while the SWEGs establish a limit.

While using the vehicle's potable water for the SWI source is an obvious choice, other potential sources do exist. Short-duration missions could use fuel cells, such as those in the shuttle, to generate high-purity water. Moderate-duration missions feed potable water into an additional deionizing bed to remove the iodine biocide before feeding the water into an electrolysis unit to generate oxygen. The feed water into the electrolysis unit could also be used to generate SWI. A generic emergency water source to be used for oxygen generation, medical emergencies, or replenishing potable water stores may be a viable option for moderate- to long-duration missions. Water obtained from in situ resource utilization would presumably go through processing to bring quality up to potable water standards. In addition, other sources of nonpotable water (SSP 57020 (Ref. 11)), such as the ISS technical water, which is water generated from fuel cells without any effective biocide additive, exist and might be usable provided sufficient treatment could be assured of the water supply.

During initial phases of assembly for the ISS, water was either supplied directly from terrestrial sources or the shuttle fuel cells. Water from the space shuttle or Space Transportation System (STS), was stored in multiple Contingency Water Containers (CWCs) and emptied as needed. The CWCs were treated with a silver biocide and could store 44 L of fluid, much larger than the 1 L of fluid required for a normal IV bag. CWCs were replaced by Contingency Water Container Iodine (CWC–I) that used iodine as the biocide. While shuttle fuel cells do have the ability to provide relatively high purity water, additives were used to adjust the taste and prevent bacterial growth. Subsequently, as part of the ECLSS, the Water Processing Assembly (WPA) was launched. Drinking water for the astronauts from the WPA is dispensed via the Potable Water Dispenser (PWD). Samples from both the STS potable water source and the WPA were periodically returned to Earth and their water quality was tested. Some results (Ref. 12) are presented in Table 1 and show that the purity standards that are required are met with ample margin.

TABLE 1.—ISS WPA POTABLE WATER SAMPLING RESULTS

	Parameter						
	Total organic carbon, mg/L	Ethanol, mg/L	Acetone, mg/L	Conductivity, μmhos/cm	Nickel, mg/L	pH	Iodine, mg/L
Maximum contaminant level (MCL)	4	----	--------	--	0.3	4.5 to 8.5	6/0.2
Maximum contaminant level source	41000	----	--------	--	SWEG and 41000	41000	[b]41000
November 22, 2008[a]	1.05	<0.1	0.174	6	1.69	7.7	0.21
November 25, 2008	0.35	<0.1	0.031	3	0.42	7.48	1.40
November 26, 2008	0.23	<0.1	0.011	3	0.05	7.06	1.89
November 26, 2008	0.19	<0.1	0.009	3	0.13	7.43	1.90
December 8, 2008	0.23	<0.1	0.016	9	0.10	7.79	2.41
February 9, 2009	0.12	<0.1	<0.002	3	0.11	6.91	2.54
February 27, 2009	0.12	<0.1	<0.002	3	0.25	6.82	2.70
March 10, 2009	0.09	<0.1	<0.002	3	0.12	6.49	2.70
March 25, 2009	0.09	<0.1	<0.002	3	0.04	6.03	2.71

[a]Represents primarily residual water in the WPA at launch, not processed water
[b]Total I max/total I at point of consumption

2.0   Previous Spaceflight Experiment: Sterile Water for Injection System

In the late 1980s and early 1990s, NASA conducted a detailed investigation to determine the possibility of producing IV fluids on orbit as part of the Health Maintenance Facility for the Space Station Freedom Program. The NASA Johnson Space Center (JSC) led this effort, which included contracts with Krug International, Sterimatics, and Baxter, and culminated in a flight experiment on STS–47 from September 12, 1992, through September 20, 1992. Part of that decision was based on the ability to rapidly return ill crewmembers to Earth, an option that becomes increasingly more difficult as the time duration of exploration missions and the distance from Earth increases.

As part of the SWIS effort, Creager of Krug Life Sciences (Ref. 13) evaluated six scenarios requiring fluids for medical treatment. Fluid volumes were calculated for each scenario using seven types of solutions. The volume required to treat a particular scenario ranged from 11 to 90 L, averaging 37 L. The total volume required to treat all individual scenarios envisioned for a mission and the minimum volume required to any single scenario in a mission were also calculated. The total volume of the seven types of solutions required to cover one incident of all of the scenarios was 220 L, while 141 L was the maximum required to cover any single scenario. (The report suggested that the minimum was 123 L but there was an 18 L error in the calculations for the minimum amount of NS required.)

Krug International, as lead contractor for the Health Maintenance Facility on Space Station Freedom, subcontracted with Sterimatics Corporation to develop a Sterile Water for Injection System (SWIS) to produce IV fluids. The SWIS was a filter/adsorption-based technology to produce SWI. The design goal was to convert ISS "hygiene water," which has a lower quality than ISS potable water, to SWI. System requirements included producing at least 6 L of SWI at 6 L/hr with a sterile shelf life of 90 days utilizing a filter with a minimum shelf life of 1 year. As developed, the SWIS had a dry mass of 2 kg and produced 9 L of SWI from water-containing contamination levels 10 times the ISS potable water specification. Testing indicated that at least 20 L of SWI could be produced from potable water.

As part of the SWIS project, Baxter worked on developing methods to mix both powders and concentrates, but was unable to overcome problems in mixing powders (Ref. 14) even in a normal gravity environment. The development was constrained by a requirement to mix "passively" by utilizing only water pressure. Baxter conducted experiments with a dyed concentrate and observed a low degree of mixing, with the heavier, dyed concentrate located on the bottom of the bag in 1g testing. No quantitative mixing studies were completed in normal or microgravity. Subsequent analysis and tests have demonstrated that these mixing techniques can easily be gravity-driven and care must be taken not to interpret those results as a testament to their effectiveness in microgravity (Ref. 15).

The SWIS was flown on STS–47 in September 1992 as part of the Fluid Therapy System (FTS) on the Spacelab–J (Spacelab–Japan). The test plan called for a purge sample of approximately 350 to 400 mL of liquid to purge the SWIS cartridge, followed by an assortment of 1-L bags of four sterile water samples, three 5 percent dextrose samples, and three NS solution samples. Problems were encountered with the system including the following (Ref. 16):

- Small bubbles were present in all of the filled bags.
- Air was detected in the IV line.

While post-flight microbiological analysis indicated that all of the samples were sterile (Ref. 17), there were some problems that the chemical analysis detected (Ref. 18):

- The saline concentration for two of the three bags was slightly higher than allowable tolerances per the USP specifications.
- The Total Organic Carbon (TOC) content for both ground testing and spaceflight testing was considerably above USP specifications.

Based on these results and vehicle constraints, NASA decided not to produce sterile water or IV fluids on Space Station, but to use prepackaged IV fluids. No flight-ready hardware was fabricated for sterile water production.

3.0   IVGEN Trade Studies

Several trade studies were performed as part of the effort to develop the IVGEN experiment to evaluate different aspects for the design. Mixing techniques were evaluated in a manner in normal gravity that minimized natural convection due to density differences between the solvent and the solution mixture. The selected mixing technique was then verified in low gravity aboard the C–9 aircraft.

A second series of trade studies were performed to select water purification techniques and included both analysis and testing. After the selection of the water purification technique, a secondary study was performed to size the cartridge.

3.1   Mixing Studies

In their 2006 trade study, Niederhaus and Miller (Ref. 15) evaluated several different mixing techniques. Their evaluation criteria were qualitative and included the following:

- Efficiency or minimal power consumption
- Ability to maintain sterility
- Flexibility to accommodate both powders and concentrates
- Overall system mass
- Confidence that the technique could be adapted to use in the microgravity environment
- Amount of crew time required to set up and operate the system coupled with degree of difficulty

The mixing techniques included the following:

- Recirculation within the IV bag that is generated via a peristaltic pump attached to a tubing appendage on the IV bag
- Mixing cartridge with the powdered pharmaceutical placed in the inlet flow path to IV bag; dissolution and/or mixing would occur as the water passes through the cartridge and enters the bag
- Magnetic stir bar prepositioned within the bag
- Impeller mixing with a rotating shaft that penetrates the IV bag walls
- A rod that penetrates the IV bag walls and vibrates ultrasonically
- IV bag deformation or kneading
- Vibrating surface in external contact with IV bag wall
- High frequency acoustic emitter placed in external contact with IV bag wall

Niederhaus and Miller assessed each mixing technique an adjectival rating of "High," "Medium," or "Low" for every evaluation criteria listed above. Numerical scores were assigned to the adjectival rating and summed and then ranked in Table 2 (Ref. 15). Based on their results, the magnetic stir bar and vibrating wall methods were selected for normal gravity testing. They used Planar Laser-Induced Fluorescence (PLIF) and schlieren were used to determine mixing times.

PLIF utilizes a laser beam shaped to be narrow in one dimension and 5 to 6 centimeters wide in the orthogonal direction, thus illuminating a plane. In this case, Niederhaus and Miller doped the fluid with particles that would fluoresce under laser illumination. A video camera perpendicular to the plane of illumination captures a time sequence of images of the particles in the flow, thus mapping out the mixing process as a function of time.

TABLE 2.—EVALUATION OF MIXING METHODS ACCORDING TO SELECTION CRITERIA

	Efficiency	Sterility	Flexibility	Equivalent system mass	µg confidence	Operations	Development ease	Unweighted score	Relative ranking
Recirculation loop	H	M	H	H	M	M	M	17	4
Inline mixer	M	H	L	M	L	M	L	12	8
Magnetic stirrer bar	H	H	H	M	H	H	M	19	1
Shaft with impeller	H	M	H	M	H	M	M	17	4
Vibrating rod	M	M	H	M	L	M	L	13	7
Shape change	L	H	H	M	M	M	M	15	6
Vibrating surface	M	H	H	H	H	H	M	19	1
Acoustic streaming	M	H	H	H	H	H	L	18	3

A schlieren system passes collimated light from a point source through a test section of interest, where the object under test must have refractive index differences, which in the case of mixing, are produced by density differences. After passing through the test section, the light is focused with a knife edge in the focal plane obscuring half of the focal spot. A camera that is focused on the test section is placed after the focal spot. By using this arrangement, the camera records images of density differences in the test section that appear as shadows moving across the field of view. This system records the mixing process without the need to dope the fluid. Alternatively, the optical configuration for schlieren is much more complicated and less compact than PLIF, so each has its advantages. By using both techniques, Niederhaus and Miller were able to ensure that they had the best possible technique to collect the mixing data.

While Niederhaus and Miller demonstrated that both mixing techniques showed promise, the presence of an air bubble in the IV bag greatly enhanced the mixing efficiency for the vibrating wall technique whereas the stir bar technique did not require such assistance. Tests of the vibrating wall technique that were conducted in single phase liquid with no air bubble exhibited mixing times that approximated mixing by diffusion, which means that the vibrating walls were producing essentially no mixing.

As shown in Figure 3, using 30- by 3-mm (length by diameter) and 35- by 3-mm stir bars at various angular velocities, mixing times were well under the 20 min target. For example, the data revealed that the 30-mm stir bar at 700 rpm could achieve a homogeneous solution for liquid-liquid mixing in less than 2 min. The 30-mm stir bar at 700 rpm could aid in the dissolution of a solid and achieve thorough mixing in under 8 min (Ref. 19).

Following the 1g testing, Niederhaus and Miller conducted preliminary microgravity experiments in the Glenn Research Center (GRC) 2.2-Second Drop Tower. Results indicated that faster spinner velocities are required to move bubbles away from the bag wall to prevent possible "dead zones" of no flow; however, not enough time was available to achieve a "steady-state" condition. Longer duration experiments were then performed aboard the NASA C–9 to examine concerns such as whether powder granules would collect in bag corners, and whether large bubbles would interfere with the mixing process.

Small nonsoluble polymer spheres (250 and 500 µm in diameter) were used as surrogates for pharmaceutical powders to track and analyze particle motion within various bag geometries during the mixing process. The use of a surrogate eliminates the regulatory issues associated with using actual pharmaceutical. These tests revealed that small particles do not become lodged in dead zones within the bag, such as fill ports and corners within the IV bag, and that bag shape does not prevent particles from being uniformly distributed. In microgravity, the mobility of the particles greatly increased as particles "rose" into the bulk fluid, rather than resting on or against, the bag "floor" as occurs in 1 g. Experiments demonstrated that air bubbles, some as large as 100 mL, did not interfere with the mixing process as the bubbles were sheared apart when contacting the rotating stir bar.
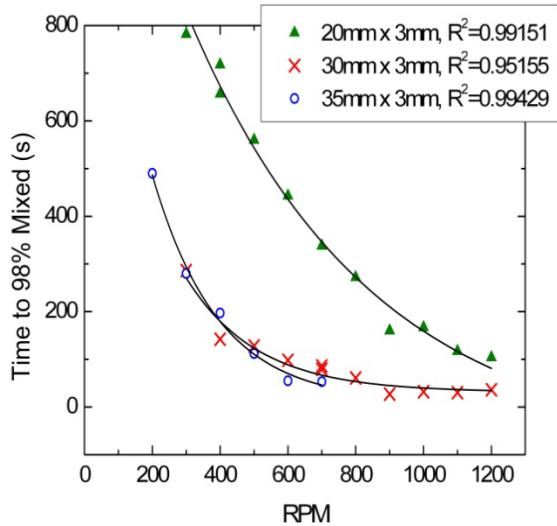
Figure 3.—Mixing times from stir bars, sized 20 to 35 mm, at various rpms.

Bag filling tests were also conducted in microgravity. High liquid fill rates (1700 mL/min) produced a turbulent jet that dissolved the salt almost completely by the time the bag was full. However, low flow rates (~20 mL/min) did not aid rapid salt dissolution. Furthermore, the stir bar did not rotate easily when the bag contained very little water, and the stir bar became trapped within solid salt crystals. The dissolution of these salts crystals was limited because of the small amount of water within the bag. As the bag filled with water, the salt that trapped the stir bar dissolved and the stir bar would begin rotating.

3.2   Water Purification Studies

The USP specifies both requirements and processes for generating SWI based on the concept that "the nature and robustness of the purification process is directly related to the resulting purity (Ref. 20)." As specified by the USP, distillation and reverse osmosis (RO) are the "acceptable" means of producing SWI; however, provisions are included to utilize other processes, provided that these processes deliver water of equivalent quality.

In addition to mixing, Niederhaus et al. (Ref. 21), examined several sterilization processes including the following:

- *Distillation*—Purification by phase change and collection of steam. Special provisions are needed to negate any liquid carryover in the form of droplet mists or boilover surges.
- *Reverse osmosis*—Osmotic pressure removes the contaminants by applying a pressure gradient across a semipermeable membrane.
- *Adsorption*—Impurities are chemically absorbed onto a packing material.
- *Ultrafiltration*—Water is purified by flowing through a filter medium with very small pore diameters that physically block the passage of impurities.

In addition, three recently developed techniques were examined as part of the current effort:

- *Microwave*—UMPQUA, Research Company, under a Small Business Innovative Research (SBIR) contract, examined the use of microwaving the water under pressure to kill any microorganisms. This technique would still need to be coupled with some filtering mechanism to remove impurities such as ions, organic carbon, and endotoxins.

- *Artificial kidney*—Dr. Shuvo Roy, formerly an Assistant Staff member in the Department of Biomedical Engineering, Lerner Research Institute, Cleveland Clinic Foundation, and currently with the University of California, San Francisco, demonstrated the performance of a nanodevice prototype that should filter all impurities from input potable water.
- *Forward osmosis*—Several manufacturers now offer a device that can take unpurified and untreated water, pass it through an osmotic membrane in the forward direction and generate a sports drink from a syrup. The physical principles governing that process can be directly applied to generating a pharmaceutical mixture for IV administration.

Further discussion of these techniques, including analysis and some experimental evaluations, is discussed below.

3.2.1 Distillation

Purification by distillation relies on the evaporation and/or boiling of water and the flow of the water vapor to a separate location where the vapor is condensed. Sterilization is achieved by subjecting the water to sufficiently hot temperatures to kill any bacteria. Purification is accomplished by collecting the water condensate over a narrow range of temperature and pressure conditions whereby any compound that is more volatile than water is vented prior to collection and any compound less volatile than the water never vaporizes and flows into the condenser. Historically, this technique was the first acknowledged purification method and is still used today especially for the purification of large quantities of water.

It should be noted, however, that within the USP, there are several additional constraints placed upon the purification technique. Among these constraints are the following:

- Provisions must be made to demist the vapor flow, that is, liquid droplets cannot be present within the vapor stream as they are likely to contain impurities that would have remained behind.
- Provisions must be made to eliminate "boil-over." A rapid increase in the amount of vaporization can result in the pockets of liquid mass drops and globules being carried over from the boiler/evaporator to the condenser as the vapor surges in. These liquid slugs would be carrying impurities with it.
- The distillation system must be periodically inspected, drained, and cleaned for mineral deposits.
- During periods of nonusage, the system must be drained and dried.

Distillation is a purification technique that relies heavily on buoyancy forces to achieve separation between the purified vapor and the source liquid. Aboard the ISS, the Urine Processing Assembly (UPA) utilizes a centrifuge operated at low pressure to achieve the evaporation and phase separation (Ref. 6). Consequently, this ISS hardware is heavy and power intensive.

Given that some medical conditions within the SMEMCL involve burns, there is a possibility that the same event that caused the injury may have also damaged the spacecraft and thus limited the power production capability of the spacecraft.

Therefore, because of the numerous gravitational complications, large power demands, and mass and volume requirements incompatible with constraints on system size, distillation was discounted as a method to generate purified water in an emergency situation.

3.2.2 Osmosis

Osmosis is the process of a solvent diffusing across a semipermeable membrane from a region of low concentration to a region of higher concentration. This movement results in the dilution of the more concentrated region, and as a result, the local pressure adjacent to the membrane is higher on the concentrated side of the membrane. This process is known as forward osmosis. These membranes have a filtering capacity for removing particles larger than 0.1 μm. Filters that can sterilize water typically have a particle removing capacity of 0.2 μm or smaller.

By applying a higher pressure to the concentrated solution side of the membrane, it is possible to reverse the flow and drive the solvent fluid from the solution side to the solvent side of the membrane purifying it in the process. This technique is known as RO and was the other standard process recognized by the USP for purifying water.

Both osmotic processes, forward and reverse, will be discussed.

3.2.2.1 Reverse Osmosis

When reverse osmosis is used to purify water within a terrestrial application, typically the system is configured in a manner whereby only a portion of the feed stream is purified as it passes through the membrane (permeate) while some of the feed solution becomes more concentrated and exits the device without passing through the membrane (concentrate also known as retentate) (Ref. 22 and EPA/625/R–96–009) as shown in Figure 4. Consequently, there is a significant amount of feed water that is "rejected" from the system. Nonetheless, it was decided to test the effectiveness of this technology at nearly complete conversion of the feed water.

For this testing, a thin-film composite (TFC) membrane, similar to that used in NASA Kennedy Space Center's (KSC's) Clearwater device (Refs. 23 and 24), was tested. Testing revealed that the RO filter (manufactured by General Electric's Osmonics Desal, model 18 GPD TFC RO Membrane) failed to remove sufficient quantities of endotoxins, chloride ions, carbon dioxide, and oxidizable substances and failed sterility. It should be noted though, that the RO filter was included in the Clearwater system to meet the USP requirements at that time. The Clearwater system is discussed in greater detail in Section 3.2.5.

Ultimately, RO technology was rejected since it demonstrated that it was not possible to achieve the necessary purity without a substantial effluent flow of water.
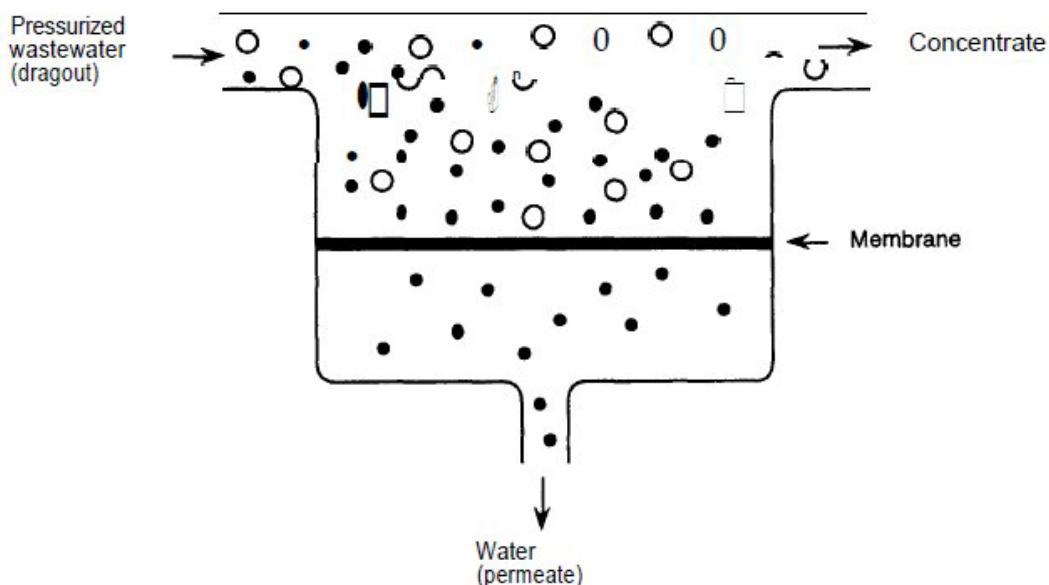

Figure 4.—Simplified flow schematic of reverse osmosis process.

3.2.2.2   Forward Osmosis

Osmostic membranes are used within sports drink bags that are marketed for those participating in outdoor wilderness activities that may not have access to a potable water source. Hydration Technology Innovation LLC's X-pack can provide 1-L increments of a sports drink from a syrup and "muddy" water. The syrup is poured into the concentrate side of the X-pack and the water is poured into the other side. Analysis showed that the X-pack was able to meet the USP requirements; however, the flow rate was substantially lower than the requirements for the IVGEN experiment. Furthermore, there were concerns about the impact of liquid positioning within the X-pack in a low-gravity environment and its impact on X-pack performance. Specifically, if the liquid were in poor contact with the membrane, there would be insufficient transfer of purified liquid across the semipermeable membrane especially during the latter stages of purification.

3.2.3   Deionization

Deionization (DI) or demineralization uses ion-exchange resin particles to bind with mineral salts. A combination of different resin particles are used to remove cations such as sodium, potassium, etc., and anions, such as chloride and fluoride. Two different DI cartridges were tested: cartridges from the KSC Clearwater system and Prismedical Corporation's MainStream (Ref. 25) device.

Two identical cartridges, Pentek Part Number PCF1–10MB, are used in the KSC Clearwater system. These cartridges contain a "semiconductor-grade" deionizing resin. The cartridges are constructed with a hollow core so that flow through the resin beads is directed radially. The cartridges are typically installed in filter housings that permit flow through the annular region outside the cartridge, through the resin cartridge, and out the central core region inside the cartridge. Performance testing demonstrated that the cartridge was able to meet USP purity requirements for SWFI; however, because of the cartridge geometry, challenges were encountered with bubbles and unusual hydraulic characteristics during normal gravity testing as the flow direction with respect to the gravity vector was changed. This cartridge and its resin were not selected though, primarily due to a shelf life of 6 months that was posted on its package.

Prismedical developed for the Army, as part of the SBIR program, the MainStream system, Figure 5. The entire system was sealed within a foil-barrier envelope and contained a source water bag, the purification module, and a sterile receiver bag. The purification module contained both hydrophilic and hydrophobic filter material, as a means of removing any gas that either entered or was trapped in the system, and a ResinTech, Inc., deionizing resin. The system had a shelf life of 5 years. The MainStream could use any available source water, ranging from potable to contaminated, and produce up to 3 L of SWFI. The MainStream device did pass the USP requirements for SWFI but did not work when attempting to flow against gravity. The team conducted this test in an effort to identify gravity-related performance issues. An investigation revealed that an internal hydrophilic membrane did not allow the trapped gas present within the interstitial volume in the device to exit through the purified water exit port during the initial filling. The gas vent port is located adjacent to the water inlet port. The device was removed from consideration because of concerns with regards to flow in microgravity: the gas will co-flow with the liquid and attempt to exit through the liquid exit port. Gas has not been observed to counter-flow through porous media in microgravity.

3.2.4   Microwave

Under a SBIR contract to the NASA Glenn Research Center (GRC), UMPQUA Research Company, developed a system to produce medical-grade water using microwaves. The system immersed a microwave generator within a flow loop that sterilized and pyrolyzed the source water (Figure 6 and Ref. 26). Analyses and tests were conducted over a range of flow rates and power levels to determine the temperatures equivalent to autoclave conditions and sterilize the source water to meet acceptable standards. For example, typical steady-state operating conditions in experiments on this system included a

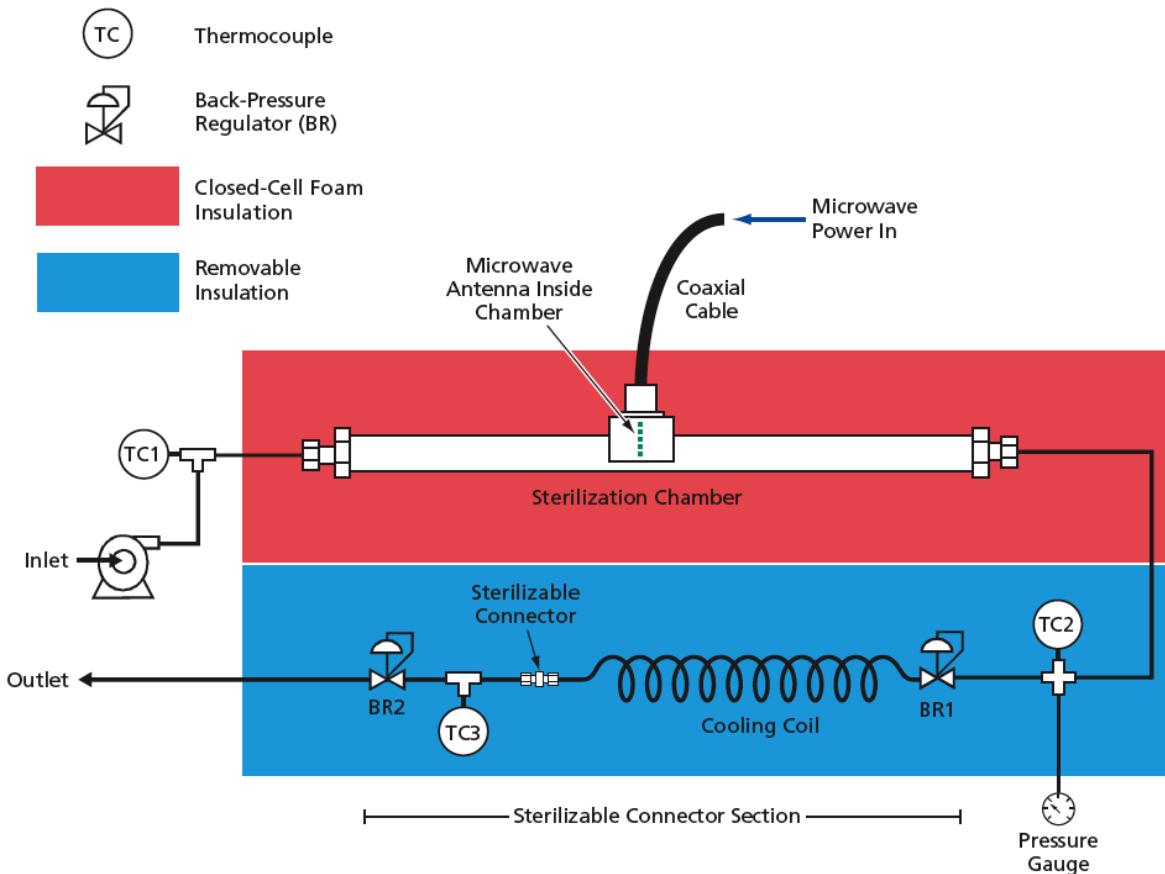Figure 5.—Prismedical's MainStream Device.

Figure 6.—UMPQUA's Microwave Medical Water Generation System.

single-phase liquid flow rate of 13 mL/min and a microwave power of 150 W, resulting in a sterilization temperature between 155 and 158 °C. Under these conditions, the system demonstrated effective sterilization and inactivation of endotoxins. While the technique was successful, this technique was discounted from further evaluation based on power consumption and the system mass and volume.

3.2.5 KSC Clearwater System

Components of the KSC Clearwater system, namely the RO and DI filters, were mentioned earlier. The system as a whole was developed by NASA KSC with Tiger Purification Systems (Figure 7) using multiple filters to produce up to 300 L of WFI. The system features its own pumps, valves, and redundant flow paths (Figure 8). Source water first entered 5-μm sediment filters to remove particulate matter so that it would not burden filter elements downstream. A KDF–55 heavy metal and chlorine filter was used to remove some of the ions, particularly chloride ions, to prevent premature depletion of the reverse osmosis membrane that was located downstream. Waste water from the RO membrane was recycled back into the source water, but eventually all water was processed by the system. A deionizing resin filter was followed by a Posidyne ELD filter (Pall Corporation) primarily to remove any air bubbles from the flow. While the system could produce up to 300 L of WFI at a rate of 5.3 L/hr, the Clearwater system was removed from consideration for several reasons including the size of the system (52.5- by 28.4- by 23.2-cm), dry weight of the system (19.5 kg) and the need for an electrically driven pump to supply the flow. Furthermore, each parallel leg could only be used once to generate the WFI for no more than 100 L. Once each leg had been used, the flow through that leg could not be reestablished without violating sterility protocols for Pall filter.

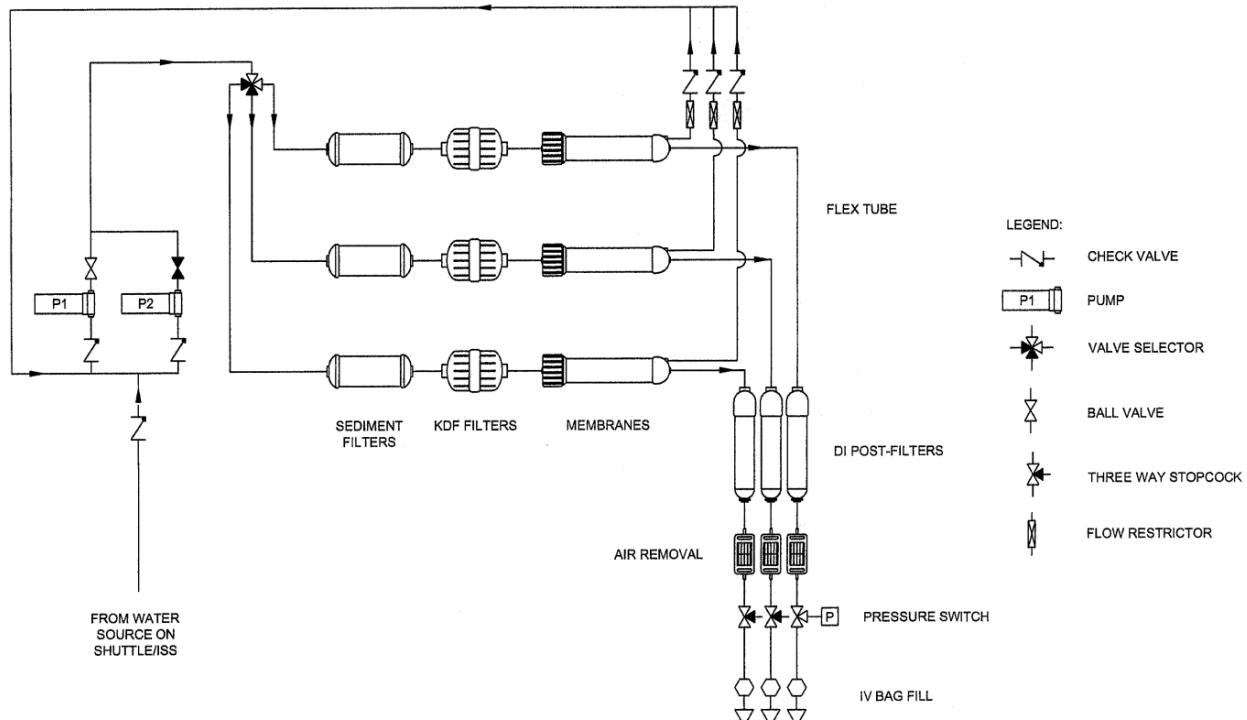Figure 7.—Prototype Clearwater IV-Grade Water Filtration System.

Figure 8.—Flow schematic of the KSC Clearwater System.

3.2.6 Cartridge Sizing for IVGEN

After completing the testing associated with the IVGEN trade study, the project team determined that DI resin bed technology augmented with ultrafiltration would best meet medical operations, USP, and spaceflight requirements. As a result of that decision, the next tasks were to identify the best DI resin to produce USP WFI, and to determine the appropriate storage technology to ensure a resin lifetime long enough for exploration missions. During the course of this effort, system-level requirements needed to be established. Among these requirements included the following:

- Production rate of the WFI: It was assumed that a few bags of NS solution would be available for immediate use in the event of an emergency. After discussions, it was determined that a production of approximately 1 L/hr—would be sufficient to replenish consumed supplies.
- Production per cartridge: Terrestrially, the treatment protocol for a severe burn requires up to 16 L per patient for the first 24 hr (Ref. 27). Additional amounts may be required during the subsequent days. However, 1 to 2 L per day may only be required for infusions of certain medications for treatment of infections and dehydration. Given that the USP requires that the distribution system be drained and dried during periods of prolonged nonuse, a balance between producing small quantities of fluid for slow consumption rates versus large quantities for faster consumption must be achieved. Furthermore, while only the DI resin is depleted during the purification, the packaging of the DI resin, the tubing, fittings, etc., consume the significant portion of the cartridge mass and size. It was decided to size the cartridge to produce up to 6 L of WFI from the shuttle potable water supply.
- Shelf life of DI resin: IV fluid is typically rotated through the ISS every 18 months, which corresponds roughly to recommended shelf life of most producers of IV fluid. The DRMs to Mars were as short as 18 months; however, some were projected to last up to 3 years.

The volume of the DI resin is one of the principal variables in determining the total amount of water that can be purified. The water flow rate into the cartridge also determines the amount of water that can be

purified as well as the level of purity achieved. The amount of time that the water spends in contact with the resin beads is known as the resonance time and is directly proportional to both the amount of water purified and the purity level. The resonance time is calculated by dividing the volume of the cartridge bed by the flow rate.

In normal gravity, packed bed reactors have been known to suffer from bed occlusion, in which a portion of the packing is blocked by the gas phase from reacting with the liquid phase. Motil et al. (Ref. 28) found that two-phase flow through a packed bed of spherical beads in a microgravity environment tended to be well dispersed throughout the entire volume. They were operating at much higher flow rates than Holder and Parker (Ref. 29) who found regions of occlusion where there were no flow and liquid interaction with the nonspherical packing shapes, thus implying that there would be no chemical reaction or absorption in these regions. The required volumetric flow rates for this system are similar to that of Holder and Parker, but the packing material is similar to Motil et al. Given the purification efficiency of the selected resin, the packing material density similar to Motil et al. is used and the inner diameter of the cartridge (1.27 cm) was sized to yield a "superficial" or empty tube velocity that was closer to Motil et al. than Holder and Parker.

The IVGEN hardware would ideally be manufactured and stored in such a way that a 5-year shelf life would be possible. As the deionizing resin degrades when exposed to oxygen, the storage would likely involve storing the hardware in a sealed manner to prevent such exposure. Initially, ResinTech Resin type MBD–10–NG or nuclear grade was purchased and tested because it met MIL–SPEC–DTL–24119D(SH). This MIL-SPEC outlines a storage standard for resin, which allows a life of at up to 5 years; however, the method of storage prescribed within the MIL–SPEC does not correspond to the desired method of storage for this NASA technology development. The MIL–SPEC is subject to export control laws; therefore, a more detailed description of the method outlined within the document will not be disclosed in this report. A second resin, Resin type MBD-10-Ultra, was purchased because the manufacturer had determined a method of storage that allowed for a storage life of up to 5 years. The method included using a heat-sealing technique to enclose the resin a film with low permeability. As the outer most resin in a stored volume degrades the quickest, the shelf life is likely dependent on the volume of resin stored. Consequently, a test program was devised and is being implemented to evaluate the storage techniques for the both the MBD–10–NG and MBD-10-Ultra.

4.0   Design of IVGEN

The objective of the IVGEN experiment was to verify in a microgravity environment the ability to produce WFI and mix it with a predetermined amount of salt to produce a 0.9 percent NS solution. It should be noted that to verify the performance of this system, diagnostic instrumentation was placed in critical locations to measure hydraulic and purification characteristics. Thus, the design of an operational system should be much simpler with minimal diagnostics. Figure 9 shows the flow schematic for the system to verify the operational concept. The primary components include the accumulator, the purifier module, the mixing stand that holds both the mixing bag and transfer bag, and an avionics box. These components will be discussed in greater detail in the sections that follow. The design utilized video cameras, pressure transducers, thermocouples, conductivity sensors, and a flow meter to characterize on-orbit system performance and provide forensic data, if needed. While these sensors characterized the relative mixing uniformity, demonstrating the compliance of the solution produced with USP requirements would have required such an extensive array of tests so two transfer bags of mixed saline were returned to Earth for USP testing by a certified laboratory.

4.1   Accumulator

The accumulator was designed to receive potable water from either the shuttle fuel cells via the CWCs or the ISS WPA (Figure 10). Two hoses that met the requirements for connecting to each water supply were fabricated with identical connections to the accumulator. The accumulator consisted of a
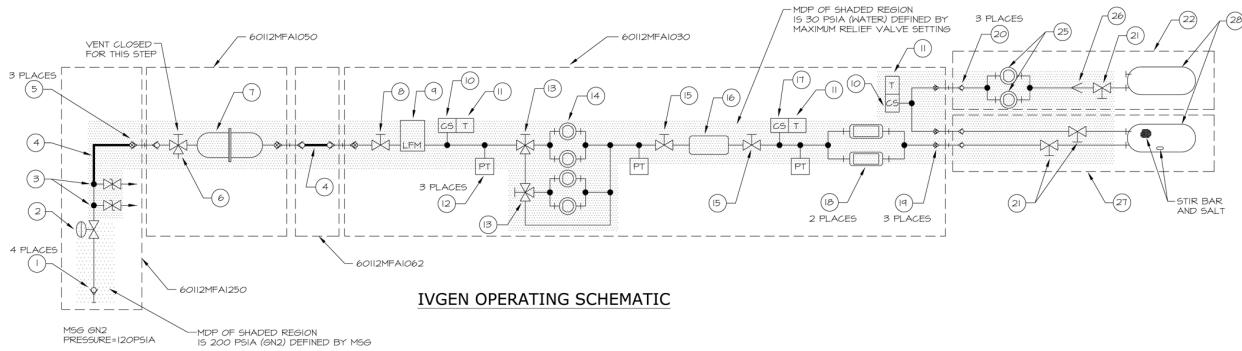
Figure 9.—IVGEN purification, mixing, and transfer flow schematic.

Figure 10.—Accumulator.

polycarbonate housing and an internal bag, or bladder that was filled with the liquid and was sized to accommodate 1.5 L of water. To pump the water from the bladder, the housing was pressurized using the gaseous nitrogen source provided within the Microgravity Science Glovebox (MSG). In the event that pressurized sources are not available or operational in a space vehicle, other pressure sources, such as a hand pump, may be used in an operational system.

To meet the concentration specification for NS solution, the liquid fill needed to be within 19 mL of the specified amount of water provided that the amount of salt was accurately measured to within 0.67 g. Estimates were made to account for the volume of the empty liquid transfer line between the WPA or CWC and the bladder. However, in the very late stages of flight hardware build and verification activities, ECLSS required that a filter be added to the IVGEN Accumulator Fill Hose for WPA (IVGEN Drawing Number 60112MFA1191) to prevent back-contamination into the WPA. The filter added significant air volume (55 mL) to the system. That air volume meant 55 mL less water in the saline solution resulting in a 3.8 percent increase in salt concentration. While the addition of the filter did not guarantee an out-of-specification sample, it drastically reduced the allowable tolerance of other factors such as the amount of dry salt in the bag, air bubbles introduced by the WPA, and completeness of accumulator filling. This dramatically reduced the acceptable uncertainties required to meet the USP tolerance bound for salt concentration in the final product. Prior to the addition of the filter, the IVGEN system could tolerate a reasonable amount of error while still producing saline within USP specification. Consequently, the amount of residual air in this transfer line was larger than expected and the first filling of the accumulator did not have sufficient water.

The final flight configuration was tested prior to launch. Schedule constraints only allowed for the generation and analysis of two saline bags. One bag passed all USP tests while the other passed all but the saline concentration. The test results indicated that while the final flight configuration was capable of

producing USP NS, there was very little margin for error when it came to meeting the concentration specification. Due to the amount of time required to send the solution for test, testing time, and reporting time, the IVGEN team was not aware of the failure until after the hardware had been launched. Section 6.3 provides a detailed summary of the post-flight investigation to determine the cause of the anomalies.

4.2   Purifier

The purifier module was the core of the experiment. It included the DI resin cartridge, air removal filters, and the instrumentation. An aluminum box with a transparent top housed the components in two layers (Figure 11). A Coriolis flow meter was used to provide the necessary accuracy to track the total amount of water that had passed through the system and the liquid flow rate for the hydraulic measurements, and also measured the density of the fluid flowing through the meter. Using this density measurement, it was possible to track whether gas or liquid was flowing from the accumulator into the purifier. A dual-ring conductivity probe was used to measure the baseline conductivity of the source water prior to purification. Because of the lack of conductivity for air, the probe also was able to detect bubble passage into the purifier.

Two pairs of Supor filters (Pall Corporation) were used primarily to prevent air from entering the DI cartridge. These filters had a polyethersulfone membrane with a pore diameter of 1.2 μm in a 0.7 mL housing. As water began to flow through the system, the membrane would wet, thus permitting water passage while venting air bubbles through openings in the housing. In the event that the filters would plug due to particulate accumulation, each pair of filters had an isolation valve that could be used to divert flow from one pair of filters to the other pair or to a bypass line.

The DI cartridge was machined from medical-grade polycarbonate into a hollow cylinder that had an outer diameter of 21.3 mm and an inner diameter of 15.9 mm with a length of approximately 170 mm. The outer diameter at each end was machined with threads to accept stainless steel end caps.
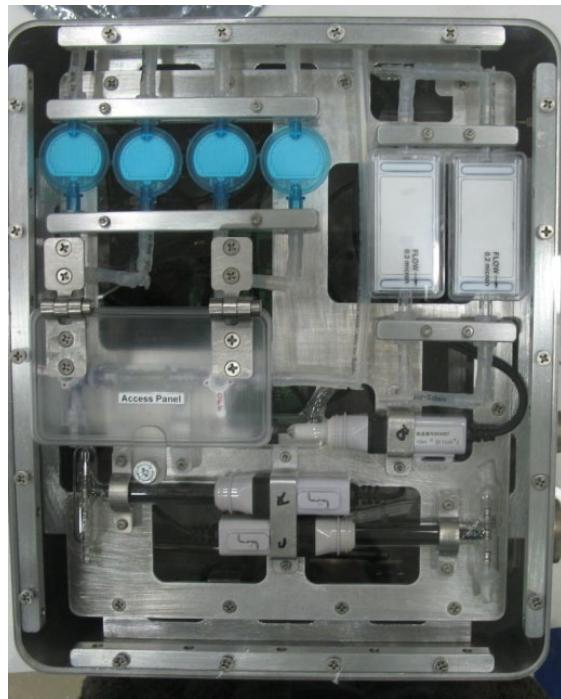

Figure 11.—Top level of purifier module.

The cartridge was loaded with DI resin from ResinTech. The specific resin used was MBD–10–ULTRA and has the following characteristics:

- 60 percent anion
  - Hydroxide form
  - Type 1 strong-base gel
  - R4N+OH (type 1 gel)
  - 1.40 meq/mL min capacity (Clform)
- 40 percent cation
  - Hydrogen form
  - Strong acid
  - Sulfonated gelular polystyrene
  - RSO3-H+ (gel)
  - 1.95 meq/mL min capacity (Na+ form) permit volume

This resin was certified by ResinTech to have a 5-year shelf life in a terrestrial environment. A space environment could impact the shelf life because of radiation, but this assessment was beyond the scope of this effort. The resin is retained in the cartridge by polyester felt filter discs that were positioned at each end of the cartridge and extended across the cross-sectional area of the tube. The discs had an average pore diameter of 1 μm.

To minimize settling of the resin particles, a procedure was developed to fill the cartridge with small amounts of resin beads and periodically compress the interstitial volume by gently tapping on the beads with a blunt rod. To prevent the formation of voids or empty spaces within the resin bed, a compressed spring was positioned between the upstream cap and filter disc. If additional compaction occurred due to vibrations, such as those imposed by launch, the spring would maintain a constant level of pressure on the bed to minimize the formation of voids. The spring was positioned between the end cap and the upstream filter disc so that any decomposition of the spring could be absorbed by the DI resin.

A series of Posidyne ELD filters were used primarily to prevent air from entering the collection or saline bags. These filters use a nylon membrane with a pore diameter of 0.2 μm and also provide particle, bacteria, and endotoxin retention. This filter, like the Supor filter, permits water passage while air bubbles are vented through openings.

A flat plate sensor measured the conductivity of the purified water and also could provide an indication of the efficiency of the Pall filters in removing air bubbles. Using this and the inlet conductivity sensor, it is possible to determine the purification efficiency of DI cartridge.

Three absolute pressure transducers were plumbed into the system to measure the pressure loss across the two types of Pall filters and the DI cartridge and to provide a means of determining the density of any gas that would be present within the system.

The water would flow through the purifier out to the mixing assembly. After the salt dissolution was completed, the water would flow back into the purifier into a third conductivity sensor. This sensor was used to measure the uniformity of the salt concentration within the mixture before the solution flowed into the sterilized collection bag.

4.3   Mixer Assembly

The mixer assembly, Figure 12, consisted of two flat aluminum plates, a mixer motor and its controller, and the saline and collection bags. The mixer used two samarium cobalt rare earth magnets on a rotor driven by a direct current (DC) motor. The motor had a maximum speed of 900 rpm. The motor could be activated and its speed controlled remotely by the Data Acquisition and Control Unit (DACU), but there were provisions to locally control via a dial and switch. The rotor was visible through the bags to verify its functionality.

Figure 12.—Mixer assembly
(without bags).

Both the collection and saline bags were multilayer bags manufactured from ethyl vinyl acetate. To prevent over-pressurization of the system, the accumulator was designed to supply only 1.5 L of water and the collection, saline, and transfer bag volumes were 2.0 L. Each bag had three ports: liquid inlet and outlet ports and a filling port. The filling port was used to place the salt and stir bar into collection bag and the port was then sealed. A 13.5 ± 0.67 g of USP-grade NaCl was specified to be introduced into each saline bag.

The stir bar was Teflon (DuPont) resin coated and octagonal shaped. The bar measured 28.6 by 7.9 mm and featured a molded-on pivot ring. The mixing tests conducted by Barlow indicated that the complete mixing could be achieved in shorter time periods using stir bars 30 mm or longer (see Figure 3). However, during prototype testing, the longer stir bars would snag on the ethyl vinyl acetate bag walls and decouple from the rotation of the stirring motor. It was necessary to shut off the stirring motor to reengage the stir bar. Additional prototype testing revealed that the 28.6-mm bar did not exhibit similar behavior within the ethyl vinyl acetate bag.

Isolation valves were installed on the inlet and outlet bag ports and were used to maintain the integrity of the collection bag contents. The valves were opened and closed to accept or drain liquid into or from the bags as needed.

The transfer bags were constructed in a similar fashion as the collection bags; however, the transfer bags were gamma irradiated as part of the sterilization process and needed to be manufactured from polyethylene (PE) to avoid degradation due to the irradiation process.

Isolation valves were also used on the inlet and outlet ports of the transfer bags; however, a Pall Pediatric IV filter was spliced between the bag and the valves. This filter uses a Supor membrane with a pore diameter of 0.2 μm which is retentive of B. diminuta and meets USP 25/NF 20 requirements for a sterilizing-grade filter per American Society for Testing and Materials (ASTM) F838–83 test methods. Thus, as the salt solution flowed through this filter into the transfer bag, it was sterilized. The filters also vented any air that was entrained in the liquid from the collection bag to the transfer bag.

5.0   Procedure

The MSG is a single rack facility onboard the ISS that provides power, thermal control, command and control, and imaging to scientific investigations (Ref. 30). The IVGEN hardware was designed to operate autonomously after the system was configured. IVGEN was installed into the MSG on May 4, 2010. The installation included mounting the accumulator, the purifier module, and the mixer assembly to the MSG baseplate and the power converter and DACU to the MSG back wall. Cabling was connected for power, command, and control functions, and data between the MSG facilities and IVGEN. A hose to the MSG nitrogen port was installed to provide the pressurant to the accumulator housing to drive the flow of the water during the purification process from the accumulator bladder, through the purifier into the collection bag mounted on the mixing assembly. In addition, liquid hoses were installed between the accumulator and purifier, the purifier and the collections bag on the mixing stand and the purifier and the transfer bag on the mixing stand for each test.

Cameras were provided by MSG. One camera was focused on the parallel plate conductivity cell to verify that the cell was properly primed as flow through the purifier was initiated and later repositioned to view the Posidyne filters in the purifier. Another camera was positioned to view the Pall 1.2-μm Supor filters in the purifier module, and the last camera imaged the collection bag side of the mixer assembly.

Potable water was supplied from the WPA. IVGEN was required to install a sterilizing filter between the receiving container and the potable water reservoir (PWR) to prevent back contamination of the WPA via the PWR. After ensuring that the nitrogen supply was closed, the nitrogen hose was disconnected from the accumulator. The water hose between the accumulator and the purifier was also disconnected. The accumulator was removed from the MSG and transported to the WPA where the accumulator was connected to the PWR. Potable water was transferred into the accumulator until it was filled. The accumulator was disconnected from the PWR and carried back to the MSG where the nitrogen and water hoses were reconnected to it.

Prior to the start of each test generating saline, the crewmember installed a new collection bag on the mixing stand, along with a new transfer bag. For those tests that did not generate saline, but merely tested filter capacity, the crewmember only installed a collection bag. The crewmember annotated unused videotapes with the recorder designation and date and loaded them into recorders in the MSG video drawer.

To flow water from the accumulator through the purifier to the collection bag, the accumulator was pressurized with nitrogen from the MSG gas supply. At the initiation of a test, the shutoff valve for the gaseous nitrogen supply in MSG was opened; however, the accumulator hand valve was left closed. Thus, the accumulator was not yet pressurized. To avoid degradation of the DI resin, the DI cartridge was isolated from the rest of the system by shutoff valves. The potable water shutoff valve on the purifier was also opened. After these steps had been completed, the hand valve on the accumulator was opened and liquid began to flow through the system.

During the purification, the astronaut crewmember watched for leaks and tracked the progression of liquid through the system. After about 1 min, the liquid had flowed to the collection bag inlet valve. Gas was vented through a Posidyne filter. The collection bag inlet valve was opened and liquid filled the bag. The system was periodically surveyed for trapped bubbles and leaks.

The system was operated for six purification cycles. For the first two cycles, the purified water flowed into one of the collection bags containing the premeasured salt to test the mixing capability and to generate NS solution. For the remaining four cycles, the purified water flowed into empty collection bags to test the capacity of the DI resin cartridge. Two cycles were performed each day with no changeout of the DI cartridge.

For the NS generation cycles, after approximately 500 mL of liquid had been purified (based on flow meter readings), the magnetic stirrer was remotely started via the DACU. The operator would periodically check that the stir bar was still centered adjacent to rotor.

Figure 13.—Collection bag inserted into blood pressure cuff.

For all cycles, after the water supply in the accumulator was exhausted, the operator verified that the collection bag was full. The MSG gaseous nitrogen supply valve, collection bag inlet valve, the purifier's potable water shutoff and DI cartridge isolation valves were closed.
Mixing continued for 20 min after the purification was completed for the first saline bag and only 5 min for the second saline bag. The actual mixing began shortly after purified water began to flow into the bag, thus the total mixing time was at least 30 min.

After mixing was completed, the operator verified that the stir bar had ceased rotating. The collection bag was removed from the mixer assembly and inserted into a blood pressure cuff (Figure 13). The outlet line was connected to the saline port on the purifier. The valves on the outlet port of the collection bag and the inlet port of the transfer bag were opened. The blood pressure cuff was inflated to pump water from the collection bag, through the conductivity sensor in the purifier and the 0.2-μm Supor sterilizing filter into the transfer bag. Periodically, the operator would check the flow and reinflate the blood pressure cuff if necessary to ensure that the liquid would continue to flow. After the liquid transfer had been completed, the valves on both bags were closed and the tubing ends were capped. The bags were stowed and returned to Earth for analysis on STS–132 in May 2010.

For the remaining four collection bags of purified water that were produced, there was no liquid transfer to other bags. The crew emptied these collection bags by transferring the water back into the ISS water reservoir. These bags and the saline bags were returned to Earth.

Upon return to Earth, the transfer bags containing NS were inspected, weighed, and photographed. They were shipped to Pace Analytical Services, Inc., Life Sciences for compliance with USP testing requirements. The collection bags were also inspected and were placed into bonded storage.

6.0   Results

During operation of the IVGEN experiment, conductivity, temperature, flow rate, and pressure data were measured and recorded by the DACU via the appropriate sensors. These data were analyzed to assess the purification effectiveness, hydrodynamic performance, and the gas bubble removal effectiveness. For the sake of brevity, some representative plots will be shown here, with a tabulation of results from all the samples generated on the ISS within the body of this text. Plots of the remaining data are shown in Appendix B.

Video imaging provided evidence of the proper priming of the flat plate conductivity sensor and the type of flow into the collection bag. The video imaging also provided a qualitative assessment of the gas bubble removal in the Pall filters and the mixing process in the collection bag.

6.1 Hydrodynamic Characterization

The characterization of the flow loop is quantified via the flow meter and the pressure losses across the Pall filters and the DI resin cartridge. A time trace of the flow rate through the system and corresponding pressure drops are shown in Figure 14 and Figure 15. The flow and pressure spike at the start of this purification cycle was due to the initial opening of valves that resulted in an inrush of fluid. Flow and pressure oscillations at the end of this cycle were due to air bubbles that entered the system from the accumulator. The Coriolis flow meter has the capability to measure the density of the fluid passing through it and registered significant fluctuations. These fluctuations were also recorded in the inlet conductivity sensor and confirm the presence of air bubbles prior to the Pall 1.2-μm Supor filters.
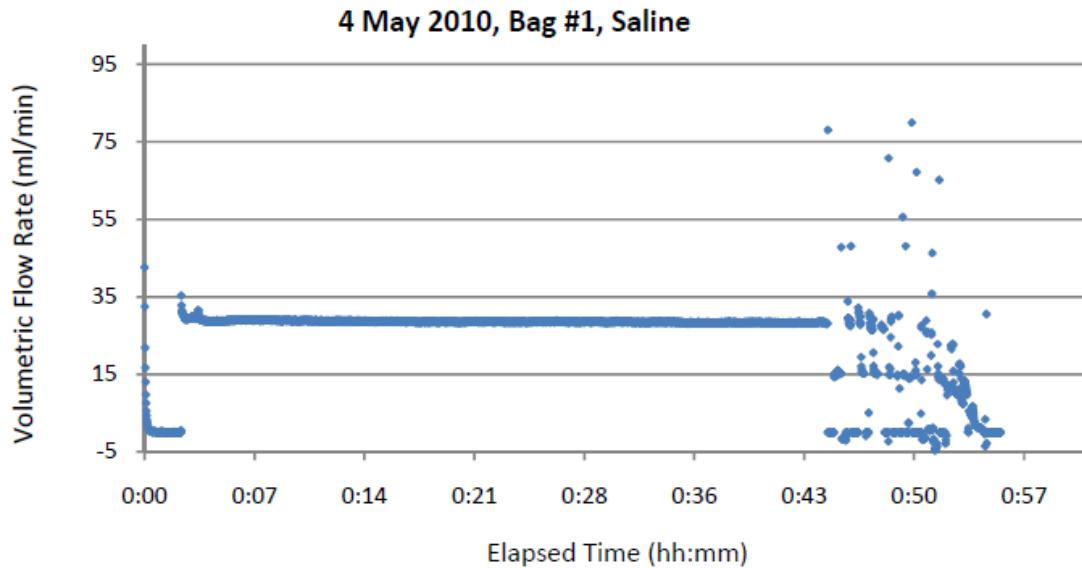
Figure 14.—Time trace of flow rate through IVGEN system.
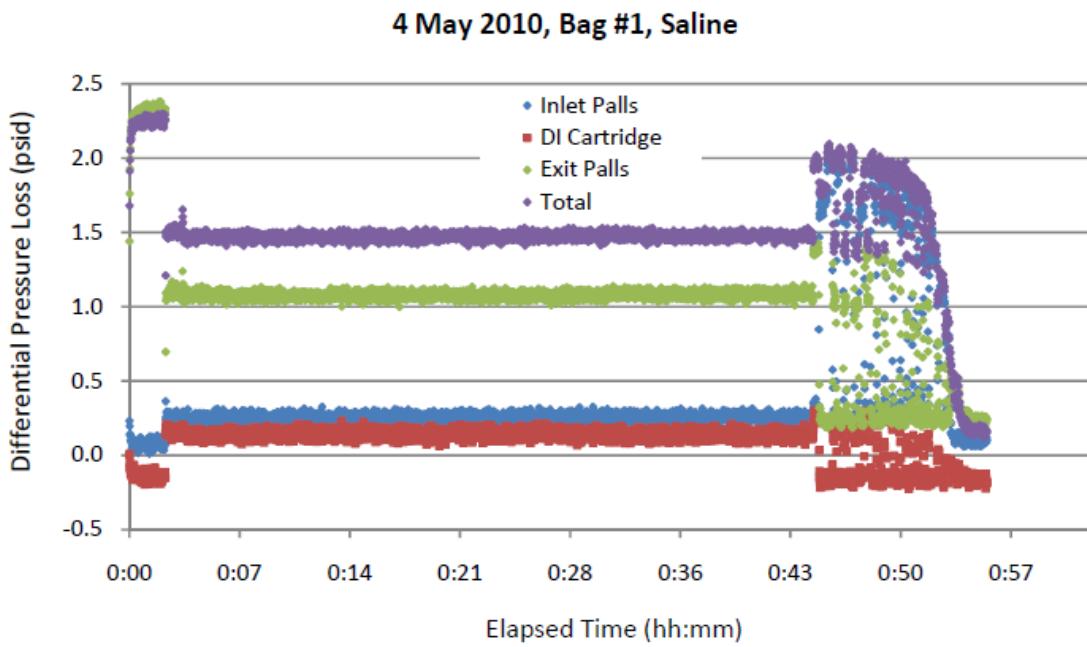
Figure 15.—Time traces of pressure losses through IVGEN system.

The method of characterizing flow through a packed bed is the Darcy equation:

$$Q = -\frac{kA}{\mu}\frac{\Delta P}{L} \tag{1}$$

where
Q	volumetric flow rate
k	Darcy constant
A	cross-sectional area
ΔP	pressure difference
L	length of the packed bed

This equation may be applied to flow through the Pall filters; however, given that the parameters of the cross-sectional area and the length, or thickness, of the hydrophilic membrane are fixed quantities, this is combined with the Darcy constant to yield the following:

$$Q = -C\frac{\Delta P}{\mu} \tag{2}$$

with C being defined as

$$C = \frac{kA}{L} \tag{3}$$

Due to the costs and constraints of the spaceflight experiment, the IVGEN system was tested for only one set of Pall filters and DI resin cartridge at nominally the same flow rate. This set of data can be compared to normal gravity data obtained over a wider range of flow rates and system temperatures and tabulated.

The results of the spaceflight tests are shown in Table 3. The NS–1 and NS–2 collection samples were generated on the first day of test operations. WFI–3 and WFI–4 collection samples were generated on the second day of operations and WFI–5 and WFI–6 were generated on the third and final day of operations. Overall, while the liquid flow rate was slightly faster than desired, it was acceptable, because the conductivity data suggested that the DI cartridge was providing acceptable purification. The total pressure loss through the system showed a 7 percent increase from the first sample to the last samples produced. The pressure loss within the DI cartridge increased by 30 percent through the course of the experiment. While it is plausible that the DI cartridge may have captured additional particulate matter that contributed to the gradual increase, the Inlet Pall filters should have captured this matter. Other possibilities remain: Swelling of the resin beads due to continued exposure to the water or a shifting, settling of the resin beads over time due to vibrations encountered either during flow or exposure to low gravity, or crushing and crumbling of the particles and subsequent plugging of interstitial flow paths within the cartridge.

The maximum pressure drop is encountered when the flow valve between the accumulator and the purifier is opened. The first sample had the lowest maximum pressure drop among all of the samples generated. This may be because the system was relatively dry at this point and the pressure required to pass single-phase air through the system is much lower than single-phase liquid or a two-phase gas and liquid mixture. Minor differences in the timing of opening the valves on the purifier unit may also contribute to the differences in the maximum pressure loss encountered.

After the first day of operations, the components with the most significant contribution to the maximum pressure drop were the exit Pall filters. While there may be slight differences in the purity of the potable water supply, it is more likely that the exit Palls were becoming plugged with particulate matter. These filters have a life of 96 hr which fell within the operational parameters of the experiment.

TABLE 3.—HYDRODYNAMIC TEST RESULTS FROM SPACEFLIGHT EXPERIMENT

Parameter		Collection bag					
		NS 1	NS–2	WFI–3	WFI–4	WFI–5	WFI–6
Average flow rate, mL/min		28.6	28.8	28.0	28.6	26.8	27.5
Average pressure drop	Inlet Palls, psi	0.25	0.27	0.28	0.27	0.26	0.26
	DI cartridge, psi	0.14	0.15	0.14	0.14	0.19	0.18
	Exit Palls, psi	1.08	1.09	1.10	1.09	1.11	1.10
	Total, psi	1.47	1.50	1.51	1.50	1.55	1.55
Maximum pressure drop	Total, psi	2.09	3.61	3.48	3.62	4.13	2.45
	Major contributor	Inlet Palls	Inlet Palls	Exit Palls	Exit Palls	Exit Palls	Exit Palls

TABLE 4.—FLOW CONSTANTS FOR
CRITICAL COMPONENTS OF IVGEN

Component	$-C$, cm^3/s^2
Inlet Palls	0.00256
DI cartridge	0.00433
Exit Palls	0.00062

Referring back to Equations (2) and (3), the values of the constant $-C$ are shown in Table 4. It should be noted that these values can easily be adjusted for a number of reasons. First, there are additional flow system components, namely the isolation valves and the conductivity sensors, which were lumped into these calculations and add flow resistance or pressure loss. In addition, both sets of Pall filters were plumbed into the system in parallel, the net effect being to reduce the pressure loss. Nevertheless, these values may be used as an approximation for an operational system.

From a hydrodynamic standpoint, the IVGEN system did not exceed the maximum pressure drop within the system, which was 10 psi. The average pressure drop was 1.5 psi and the peak value encountered was less than 5 psia. The average flow rate for the IVGEN system was 28 mL/min which was very close to meeting the target flow rate range of 17 to 25 mL/min. This range was selected to meet the minimum production rate required for the system (approximately 1 l/hr) and to provide sufficient residence time, or exposure, for the liquid within the DI cartridge. Even with the slightly faster flow rate, the IVGEN system was able to meet the purification requirements.

6.2   Conductivity

As was noted earlier, conductivity sensors were positioned within the purifier to measure the effectiveness of the DI cartridge in purifying the water and to determine the mixing effectiveness. All six samples were evaluated for the purification effectiveness, but only two samples, NS–1 and NS–2, were evaluated for the uniformity of solution concentration after the mixing was completed.

6.2.1   Purification

The time trace for NS–1 sample is shown in Figure 16. Both the potable water input and the purified water output are shown. It should be noted that there is an initial spike in both the input and output streams that is partially attributable to a temperature effect on conductivity (Figure 17) and to bed "rinsing." As liquid stagnates within the bed, the DI resin leaches some of its contents into the water. Bed rinsing flushes this solution from the bed. Towards the end of the time trace, there are several points where the conductivity for the potable water drops below the average value. These values are most likely

attributable to bubble passage through the conductivity sensor. Similar drops in the density measurement and widely fluctuating flow rate measurements from the Coriolis flow meter were recorded during this time period. Further analysis included calculating the mass flow rate based on the volumetric flow rate and density and integrating the mass flow rate over the experiment duration to obtain a total mass collected. The total mass was in agreement with the post-flight weight of the NS–1 collection bag. These results revealed that the IVGEN system processed an insufficient amount of liquid.

4 May 2010, Bag #1, Saline
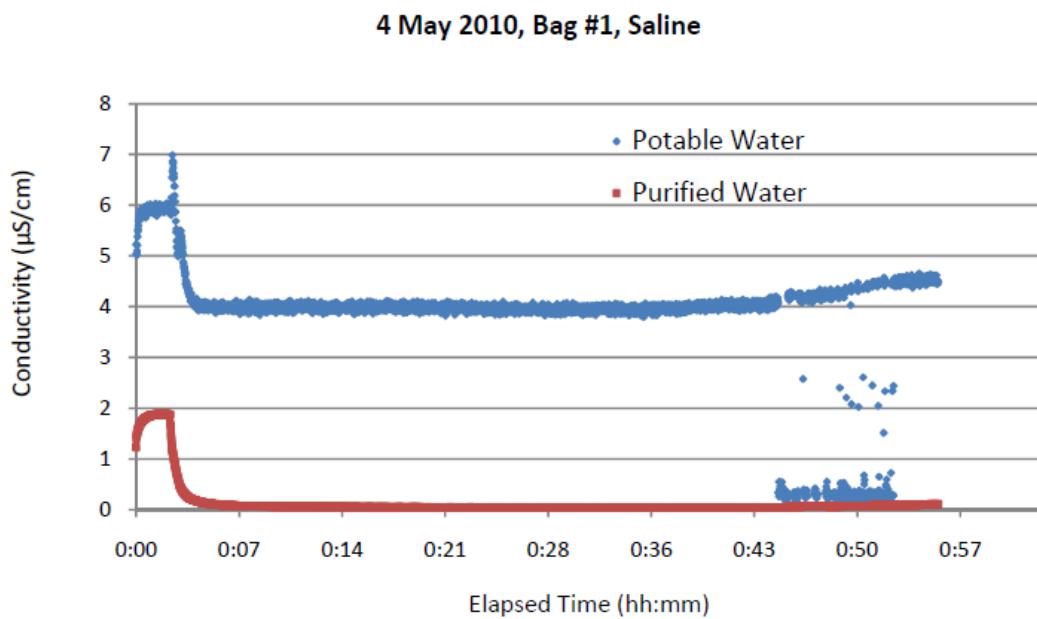
Figure 16.—Time history trace for DI cartridge purification capability.

4 May 2010, Bag #1, Saline
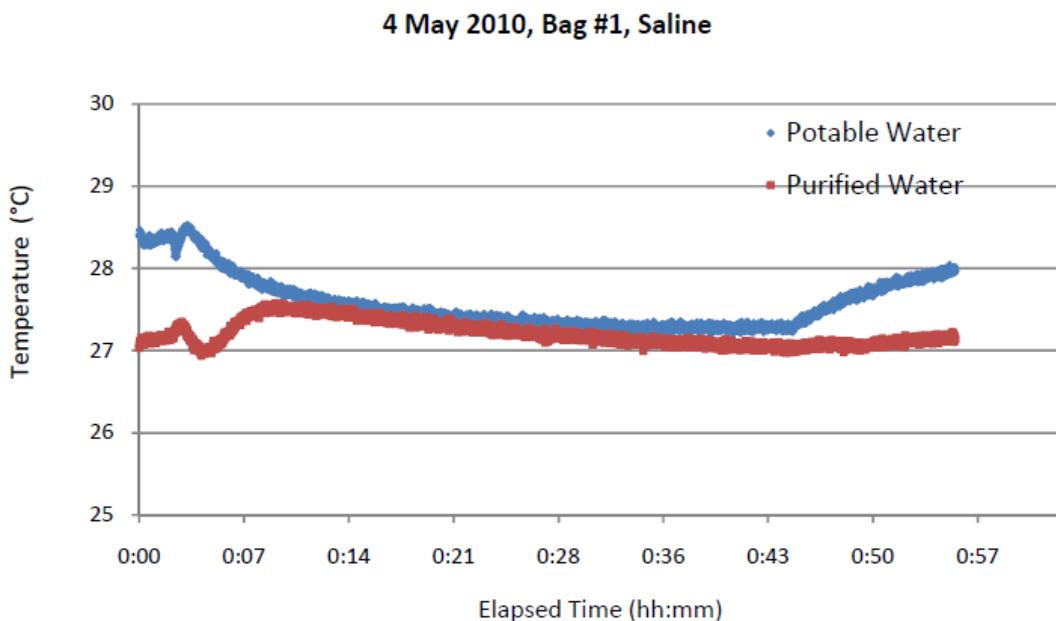
Figure 17.—Time history trace for water temperature in conductivity sensors.

As was stated earlier, the conductivity sensors provided a limited verification that the purified water produced would meet USP standards for WFI. Solution sterility and other contaminants, such as endotoxins, oxidizable substances, and particulate matter, could not be measured in a timely and cost-effective manner on orbit, but the contents of NS bags were tested by a Food and Drug Administration (FDA)-certified lab after these bags were returned from the ISS on STS–132. It should be noted that the USP does adjust the maximum acceptable conductivity levels for temperature as shown in Table 5 (Ref. 20). As can be seen from the table, the maximum acceptable conductivity for WFI is between 1.3 and 1.4 µS/cm for the test conditions.

TABLE 5.—TEMPERATURE CORRECTED
ACCEPTABLE CONDUCTIVITY
VALUES FOR WFI

Temperature, °C	Conductivity, µS/cm
15	1.0
20	1.1
25	1.3
30	1.4
35	1.5

To provide additional margin, for this data analysis the maximum acceptable concentration was taken to be 1.0 µS/cm. While the initial spike in the potable water supplied to the IVGEN may be due to warming of the liquid within the MSG, ionic impurities leaching from the DI resin beads into the stagnant water are the probable culprit. This conductivity spike was noted each time flow through the DI cartridge was initiated. The DI resin manufacturer specifies that within seven "bed volumes," the output water will have flushed these impurities away (Ref. 31). For the IVGEN experiment, a bed volume was approximately 30.1 mL.

Average purification was defined as the percentage change in the instantaneous conductivity between the input (potable water) and output (purified water) from the DI cartridge:

$$\overline{P} = 100\% \frac{C_{\text{Potable}} - C_{\text{Purified}}}{C_{\text{Potable}}} \tag{4}$$

Table 6 presents a synopsis of the purification capability of the DI cartridge from the two conductivity probes in the purifier assembly. Overall, average purifications of about 98 percent were achieved for each bag of potable water that was processed. It should be noted that the WPA supplied a very clean water supply that had an average conductivity of about 4 µS/cm with no maximum value greater than 7 µS/cm. The minimum values for the instantaneous conductivity data for the potable water were most likely due to the passage of air bubbles from the accumulator into the purifier. The first set of Pall filters, which removed large particulate matter and air bubbles, were located downstream of both the flow meter and the inlet conductivity sensor. As was discussed earlier, the Coriolis flow meter is capable of measuring the fluid flow rate and the fluid density. Comparison of the sample volume and the sample mass appears consistent with the exception of NS–1. For this sample, there is approximately a 2:1 discrepancy between the volume and mass measured. A closer examination of Figure 16 reveals at the end of the time trace, significant fluctuations in the conductivity for the potable water input. Again, this was most likely due to the presence of air within the source water. This discrepancy has repercussions later in the experiment, during the generation of the NS solution.

With regards to the purified water produced, with the exception of the startup spike for NS–1 and WFI–3, all samples fall well within the criteria for the maximum acceptable conductivity. For these two samples, the flushing of a single bed volume of liquid (30 mL) through the DI cartridge brings the volume averaged conductivity measurement to within specifications. The remaining samples also had startup spikes; however, the spikes did not exceed the USP threshold of 1.3 µS/cm, but as an academic exercise, a much lower threshold was chosen (0.2 µS/cm), and the rinse volumes for these samples were calculated.

TABLE 6.—SYNOPSIS OF PURIFICATION CONDUCTIVITY DATA

Parameter			NS–1	NS–2	WFI–3	WFI–4	WFI–5	WFI–6
					Collection bag			
Volume, mL			2621	1516	1520	1521	1501	1488
Volume, g			1392	1498	1500	1498	1482	1465
Potable water input	Instant	Average, µS/cm	4.02	3.87	3.57	3.57	3.32	3.36
		Maximum, µS/cm	6.99	6.49	4.96	4.24	4.09	3.78
		Minimum, µS/cm	3.80	0.48	2.06	2.20	2.72	2.94
	Volume averaged	Average, µS/cm	4.20	3.98	3.65	3.63	3.28	3.37
		Maximum, µS/cm	6.08	5.32	5.89	4.92	3.55	3.74
		Minimum, µS/cm	4.03	3.02	3.59	3.59	2.77	3.35
Purified water output	Instant	Average, µS/cm	0.068	0.058	0.065	0.050	0.067	0.050
		Maximum, µS/cm	1.636	1.013	1.107	0.436	0.967	0.040
		Minimum, µS/cm	0.034	0.040	0.046	0.041	0.048	0.232
	Volume averaged	Average, µS/cm	0.171	0.116	0.065	0.070	0.119	0.060
		Maximum, µS/cm	1.440	0.769	0.084	0.390	0.660	0.052
		Minimum, µS/cm	0.074	0.072	1.105	0.057	0.079	0.190
Averaged purification			98.4	98.5	97.8	98.4	98	98.3
Rinse volumes		Threshold conductivity, µS/cm	1.0	0.2	1.0	0.2	0.2	0.2
		Instant, mL	10.4	42.5	9.8	22.2	32.8	13.3
		Average, mL	21.7	181.1	16.7	58.0	171.6	0.0

It should be noted that a single DI cartridge easily produced about 9 L of purified water and showed no signs of exhausting the purification capability. However, ground-based testing using tap water that had an average conductivity ranging from 250 to 300 µS/cm would show cartridge exhaustion within 6 L of processed water. Again, this is due to the high purity of the WPA water used as a source for IVGEN.

6.2.2 Mixing Uniformity

For samples NS–1 and NS–2, software activated the magnetic stirrer after the collection bag had received one-half of the total filtered liquid volume. After purification ceased and flow into the collection bag had stopped, a crewmember closed the valve between the collection bag and the purification assembly. Stirring continued for 20 min for sample NS–1 and only 5 min for NS–2.

Prior to the fill, all sample/collection bags had some residual air content. This was particularly true for the two bags containing the premeasured quantity of salt and stir bar. Consequently, as purified water entered the bag, a large air bubble was trapped inside the bag. When mixing was initiated, the large air bubble would periodically encounter the rotating stir bar and have a portion shear off into smaller bubbles (Figure 18).

Per the procedure, the collection bag was removed from the mixing assembly and placed in a blood pressure cuff that was inflated to pressurize the collection bag. The collection bag was connected to the purifier assembly that was connected to the sterile transfer bag assembly. This arrangement permitted the measurement of the solution conductivity as it flowed from the collection bag to the transfer bag.

As can be seen from Figure 19 and Figure 20, with the exception of the conductivity dropouts, due to the passage of air bubbles through the conductivity sensor, the upper bound of the conductivity is fairly flat with some minor variations that coincide with temperature fluctuations within the solution.

Referring to Figure 19, the time-averaged conductivity measurement is 18.5 ± 0.4 mS/cm from the time flow is initiated until after 43 min have elapsed. However, if conductivity readings associated with the passage of bubbles through the conductivity cell are discounted from the averaging routine, the average is 20.2 ± 0.4 mS/cm, which corresponds nicely with Figure 20.

Similarly, the same averaging methodology is applied to sample NS–2 in Figure 20. This time, however, the time average for the first 25 min of the fluid transfer is 16.3 ± 0.4 mS/cm while an average

over the entire transfer period that discounts the readings associated with bubble passage yielded a value of 16.5 ± 0.4 mS/cm. For this case, good agreement is obtained between both values.

It should be noted; however, that while both mixtures appear to be uniform, there is considerable difference in these baseline conductivity measurements even though the target salt concentration was 0.9 g/L of water. This discrepancy will be discussed in more detail in the next section.

Figure 18.—Collection bag for NS–1 prior to (left) and during mixing (right).
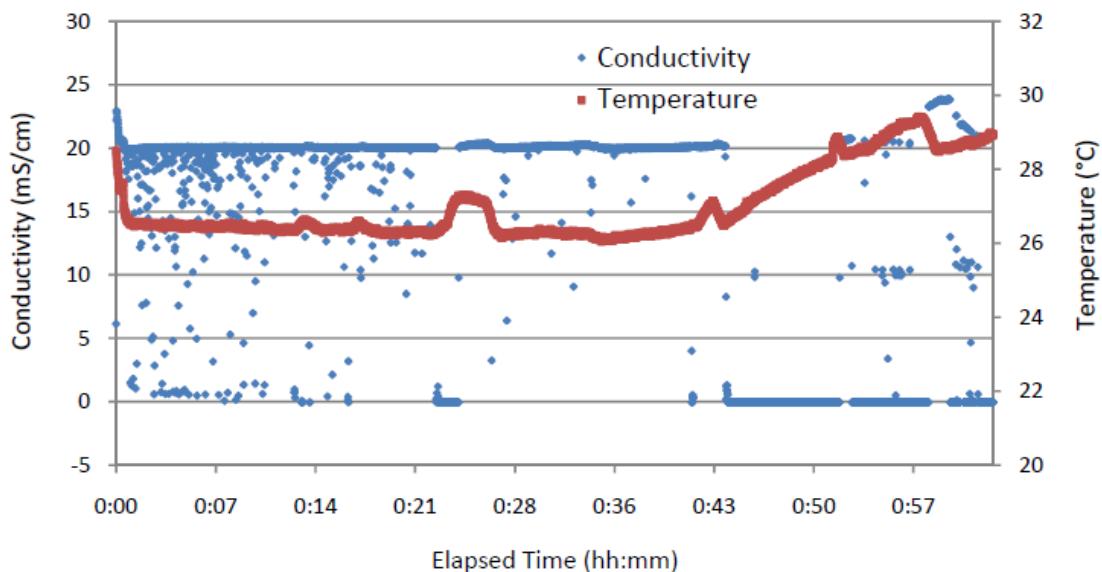
Figure 19.—Mixing uniformity results for NS–1.
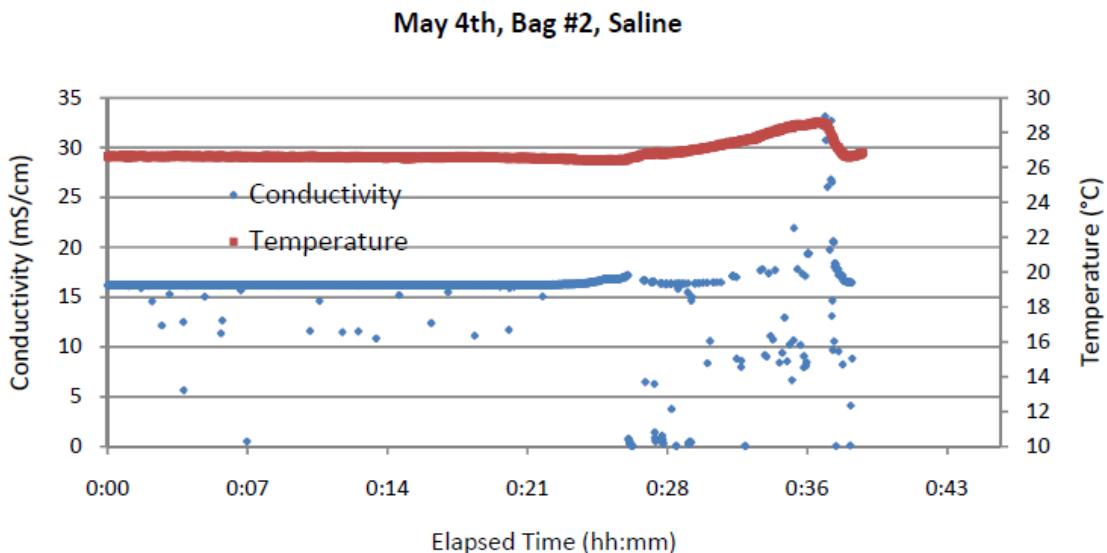
Figure 20.—Mixing uniformity results for NS–2.

6.3 Post-Flight Analysis

Upon sample return, the NS–1 and NS–-2 sample bags were inspected, photographed, and weighed. These bags were then shipped to Pace Analytical Services, Inc., an FDA-certified laboratory, to evaluate the contents for compliance with USP standards for sterile sodium chloride solution for injection. The types of tests and results are shown in Table 7.

As was stated earlier, the experiment requirements called for 13.5 ± 0.67 g of sodium chloride to be measured and preloaded into each of the two collection bags. The requirements also called for flow rate measurements that were within ± 1 percent of the full-scale measurement range to ensure that a tolerance of 25 ml in the total volume was collected.

Several potential causes for the failure were identified and evaluated. Among these causes are the following:

- Incorrect amount of water introduced into the collection bag
- Incorrect amount of salt introduced into the mixing bag
- Insufficient mixing that did not sufficiently dissolve salt crystals or homogenize solution
- Evaporation from the bag

TABLE 7.—USP TESTING RESULTS

Test	Specification	NS–1 result	NS–2 result
Sterile sodium chloride for injection	95.0 to 105.0% of target	117.0% Fail	93.8% Fail
Endotoxin concentration	<0.0050 EU/mL	Pass	Pass
Heavy metals by USP <231>	Not more than (NMT) 0.001%	Pass	Pass
Identification sodium by USP <191>	Sample responds to tests for sodium	Pass	Pass
Identification chloride by USP <191>	Sample responds to tests for chloride	Pass	Pass
Iron by USP <241>	NMT 2 ppm	Pass	Pass
Particulate analysis by USP <788>	≤25 particles per mL larger than 10 μm ≤3 particles per mL larger than 25 μm	3.40 Pass 0.00 Pass	1.20 Pass 0.00 Pass
Sterility by USP <71>	No growth	Pass	Pass
pH testing by USP <791>	4.5 to 7.0	5.4 Pass	5.4 Pass

Reviewing the sensor data from the orbital operations, it was highly likely that an insufficient amount of water was purified and charged into collection bag NS–1. This was confirmed by post-flight weight NS–1 bag assembly of 1371 g, which is significantly less than the specified mass of water of 1500 g. Nevertheless, additional analyses were conducted to decisively eliminate other potential causes. The water volume in the NS–2 bag was within acceptable margins, based on both sensor data and the post flight weight.

With regards to insufficient mixing time, per Barlow (Ref. 19), a time of 4 min for a smaller stir bar at 900 rpm should have been sufficient to achieve the necessary homogeneity within the solution. Even at a revolution rate of 50 percent of the target value, 10 min should have been sufficient. Actual mixing times ranged from 5 to 20 min after the collection bag had been filled and did not account for the 34 min of mixing time while NS–1 was filling. Furthermore, the conductivity sensor during the fill of the transfer bag indicated a relatively consistent level. There was still concern that residual salt crystals may have been trapped inside the fill port of collection bag and did not get immersed by the water and thus dissolved during the mixing process.

While it was not the original plan, the collection bags for NS–1 and NS–2 were returned from the ISS. A procedure was developed to take advantage of this opportunity by analyzing the residual contents of the bags to better determine the cause of the saline discrepancy. It was decided to use a technique called inductively coupled plasma optical emission spectrometry (ICP/OES). Sodium was chosen since ICP/OES has a sensitivity of 50 μg/L while ion chromatography is used for chloride content but has a detection limit of 50 mg/L. However, the sample needed to be diluted since the technique required at least 100 mL of sample, and there was only an estimated 10 to 20 mL of residual solution within each bag. Details of this procedure and test results can be found in Appendix C, Investigation Results for Out-of-Specification Saline Concentration.

Each bag was weighed and approximately 100 mL of ASTM Type I water (highly purified) was added to the bag and the bag was reweighed. The water was sloshed around the bag in various orientations to ensure that any undissolved salt crystals would contact the water. The contents were drained into clean sample containers and sent to Precision Analytical, Inc., for the ICP/OES analysis. The "empty" bag was weighed, dried with gaseous nitrogen, and reweighed.

The samples were analyzed and the results were 1.36 g/L of sodium for NS–1 and 0.568 g/L for NS–2. This concentration equates to 13.78 g for NS–1 and 12.59 g for NS–2. As stated earlier, each collection bag should have been filled with 13.5 ± 0.67 g of sodium chloride, thus NS–1 was filled with an acceptable amount of salt while NS–2 had an insufficient amount of salt. The completed test plan, the results from the chemical analysis performed by Precision Analytical, and an analysis that converts these findings into the salt mass loaded into each bag is in Appendix C.

Additional collection bags were prepared with stir bars and salt, but were placed in bonded storage and not used. During this anomaly investigation, the contents of three of these bags were evaluated. The bags had an "extracted" salt mass of 13.34, 13.23, and 12.76 g. This measurement was simply based on the salt that was removed from the bag. To negate the possibility of sample loss during this process, a second set of measurements were also made. The bags were weighed initially before the salt extraction. After the salt was extracted, the bags were rinsed to remove any residual salt and then reweighed. The difference between these weights yielded a calculated salt mass of 13.595, 13.449, and 12.773 g, respectively. Thus, while two of the bags were within the specification, at least one additional bag did not meet the requirement. To summarize the findings:

- NS–1's salt concentration was too high. The cause was that an insufficient amount of purified water was supplied to the collection bag because a significant amount of air had entered the accumulator during the filling process. Consequently, the estimate for the amount of residual air in this transfer line was larger than expected and the first filling of the accumulator did not have sufficient water. One potential resolution is to place a bubble separator at the accumulator inlet.
- NS–2's salt concentration was too low. The cause was that an insufficient amount of salt was placed into the collection bag during the bag assembly process. While certificates of conformance

received with the salt-filled bags indicated that the salt quantity met the tighter manufacturing specification of 13.5 ± 0.5 g. Each individual bag was not tested directly for salt quantity. However, initial lot testing—conducted prior to the full-up flight system configuration tests—was performed in which several bags were filled with a known quantity of water (1500 mL) and analyzed for salt concentration. The salt concentration was found to be within an acceptable range for all tested bags. Performing a pre-salt and post-salt mass analysis on all bag assemblies should be done rather than lot testing, but this would have significantly affected the flight hardware delivery schedule for IVGEN.

7.0   Plans

Although the spaceflight experiment was conducted and test results evaluated, there is still a significant amount of work that should be completed, both with regards to testing and the design of an operational system.

7.1   Testing

Two types of testing and the subsequent data analysis are in the process of being performed. Data have been obtained but need additional analysis to assess the effect of temperature on the system. In the event that an IVGEN operational system is needed to address a spaceflight medical emergency, the chances are that the environmental control and life support system may not be functioning optimally. One result of this may be that the cabin and or potable water supply temperature may be either very warm or very cold. A series of tests were performed to assess the DI cartridge's performance with input water at temperatures of 4, 15, 25, and 35 °C. The performance with regards to the cartridge purification ability and the pressure loss as a function of the flow rate through the cartridge is being evaluated. In addition, given that some DRMs have durations of at least 2 or 3 years, the packaging technique and the effect of shelf life on the DI resin are also being evaluated. As received from the manufacturer, the resin has a moisture content of about 60 percent and the storage container prevents direct contact with the atmosphere. The storage technique is important because the resin is degraded by both desiccation and exposure to carbon dioxide, which it absorbs. Exposure to the atmosphere produces both of these negative outcomes and, therefore, must be avoided by proper packaging.

To validate the IVGEN storage technique, two sets of cartridges have been prepared and are undergoing shelf life testing. The first set of cartridges contains ResinTech's MBD–10–NG resin within a polycarbonate tube that is capped with stainless steel fittings at each end. The second set of cartridges contains ResinTech's MBD–10–ULTRA resin also within a polycarbonate tube that is capped with stainless steel fittings at each end, but in a hermetically sealed bag. It was learned early in the program that vacuum sealing these bags was detrimental to the DI resin purification performance as it dried the resin. Once every 6 months, one cartridge from each set will be removed from storage and tested. Pending the results of these tests, it may be necessary to reevaluate the storage technique and restart testing.

7.2   Operational System Design

The operational IVGEN system will not be identical to the experimental system. The experiment included conductivity sensors and temperature sensors to verify purity of water. However, with the use of either a color-indicating DI resin to indicate capacity or by certifying that a DI cartridge cannot produce more than a given quantity of purified water, it is not necessary to use these sensors. A flow meter was used to identify flow-induced causes for anomalies, such as the air bubble. The Pall filters performed as advertised; however, an additional set of filters should be placed on the inlet of the accumulator. If that step were to be taken, the user could be confident of an appropriate saline concentration. Pressure transducers were used to determine the scalability of the system in terms of cartridge length versus quantity of purified water produced.

Based on the experiment results, though, the following should be addressed:

- Shelf life and storage techniques: Testing is ongoing and needs to be continued to verify that the components of the system can be stored for up to 5 years and maintain desired capability.
- Accurate metering of water volume: Based on the results from NS–1 testing, the amount of water that is introduced into the salt bag is critical to producing an NS solution of acceptable concentration. There are several technologies that may be used to address this concern including the use of more bubble separators or traps in strategic locations within an operational system or the use of a microgravity-rated, liquid-only, volumetric flask.
- Testing of purification "challenges": In determining the final spaceflight experiment hardware, the IVGEN team worked closely with a pharmaceutical consultant to develop a pharmaceutical process validation plan. Execution of this test plan with the final system should be performed to document the maximum capacity of the system for each known contaminant. These challenges should include preparing and testing samples of purified water with known concentrations of particulate matter, endotoxins, sucrose, ammonia, and representative water meeting the NASA's SWEG, 41000 and CxP 20024 guidelines by flowing it through the system.
- Depletion of purification capability: The ISS already provides highly purified water courtesy of the WPA. Future exploration systems may not provide potable water of such quality. Consequently, either the cartridges will have to be rated for the potable water supply of each spacecraft system or some method, such as either conductivity probes or color-indicating, purity-sensitive DI resin will need to be used to ensure a quality product.

8.0   Conclusion

Intravenous Fluid Generation (IVGEN) experiment was operated onboard the International Space Station (ISS) during May 2010. This hardware demonstrated the capability to generate intravenous (IV) fluid from ISS Water Processing Assembly (WPA) potable water using a water purification technique and pharmaceutical mixing system. Six 1.5-L bags of purified water were produced. Two of these bags were mixed with sodium chloride to make 0.9 percent normal saline (NS) solution. These two bags were returned to Earth to test for compliance with USP requirements.

On-orbit results indicated that all of the experimental success criteria were met with the exception of the salt concentration. Problems with a large air bubble in the first bag of purified water resulted in a slightly concentrated saline solution of 117 percent of the target value of 0.9 g/L. This problem can be resolved by placement of a gas-liquid separator filter immediately upstream of the liquid inlet to the accumulator. The second bag had an inadequate amount of salt premeasured into the mixing bag resulting in a slightly deficient salt concentration of 93.8 percent of the target value. The United States Pharmacopeia (USP) permits a range from 95 to 105 percent of the target value.

The testing plans for improvements for an operational system were also presented and included shelf life testing of the storage technique for the DI resin cartridge and challenging the purification ability of the DI resin cartridges.

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Appendix A.—Acronyms and Abbreviations

ALSP   Advanced Life Support Pack

ASTM   American Society for Testing and Materials

CEV   Crew Exploration Vehicle

CHeCS   Crew Health Care System

CWC   Contingency Water Container

DACU   Data Acquisition and Control Unit

DC   direct current

DI   deionization

DRM   Design Reference Mission

ECLSS   Environmental Control and Life Support Systems

EPA   Environmental Protection Agency

EVA   Extravehicular Activity

FDA   Food and Drug Administration

FTS   Fluid Therapy System

GRC   Glenn Research Center

ICP/OES   inductively coupled plasma optical emission spectrometry

ISS   International Space Station

IV   intravenous

IVGEN   Intravenous Generation

JSC   Johnson Space Center

KSC   Kennedy Space Center

MCL   maximum contaminant level

MDL   Shuttle Middeck Locker

MSG   Microgravity Science Glovebox

NASA   National Aeronautics and Space Administration

NMT   not more than

NPDWR   National Primary Drinking Water Regulations

NS   normal saline

OGS   Oxygen Generation System

PCDB   Patient Condition Database

PE   polyethylene

PLIF	Planar Laser-Induced Fluorescence
PWD	Potable Water Dispenser
PWR	Potable Water Reservoirs
RO	reverse osmosis
SAL	Sterility Assurance Level
SBIR	Small Business Innovative Research
SM	Service Module
SMEMCL	Space Medicine Exploration Medical Condition List
SSP	Space Station Program
STS	Space Transportation System (Space Shuttle)
SWEG	Spacecraft Water Exposure Guideline
SWFI	Sterile Water for Irrigation
SWI	Sterile Water for Injection
SWIS	Sterile Water for Injection System
TFC	thin-film composite
TOC	Total Organic Carbon
UPA	Urine Processing Assembly
USP	United States Pharmacopeia
WFI	water for irrigation
WPA	Water Processing Assembly

Appendix B.—Test Results

B.1   Bag 1, Normal Saline

4 May 2010, Bag #1, Saline
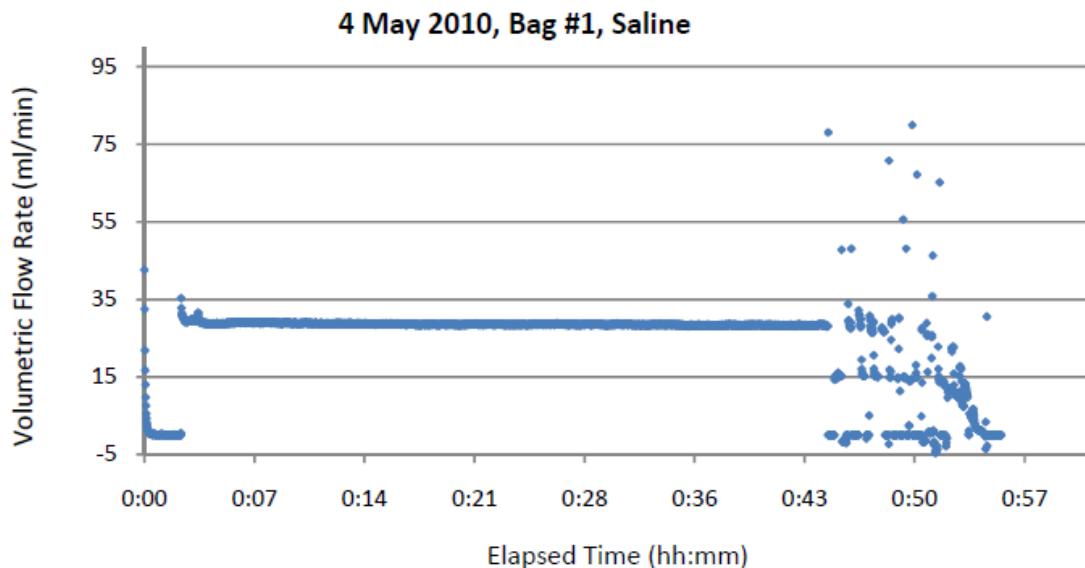
Figure B.1.—Bag 1, time trace of volumetric flow rate.

4 May 2010, Bag #1, Saline
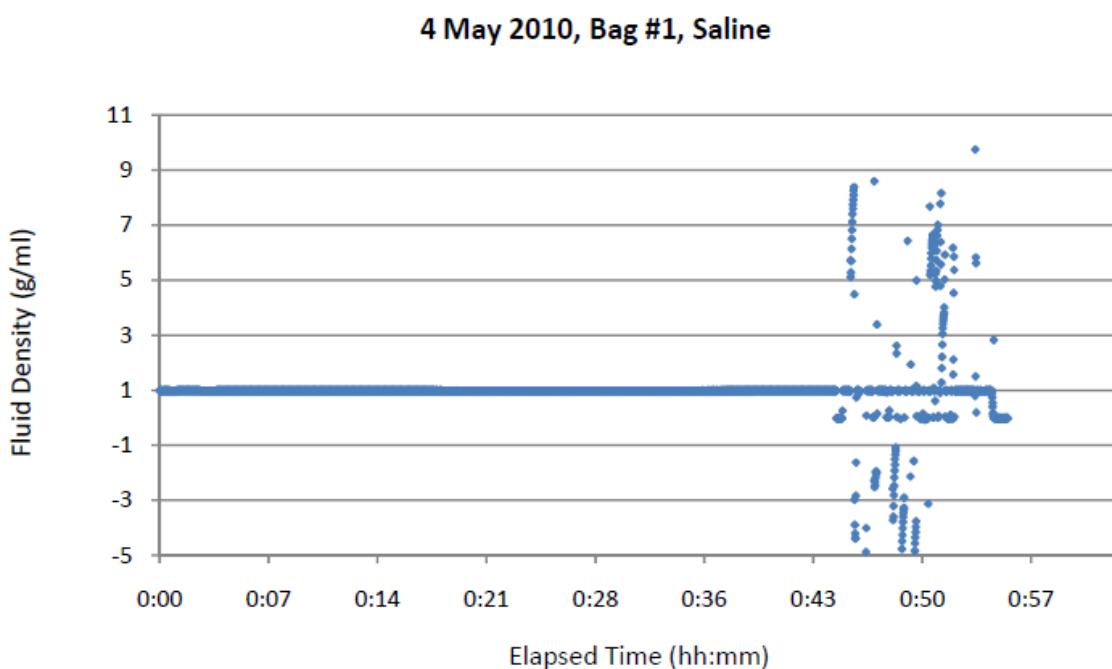
Figure B.2.—Bag 1, time trace of fluid density.
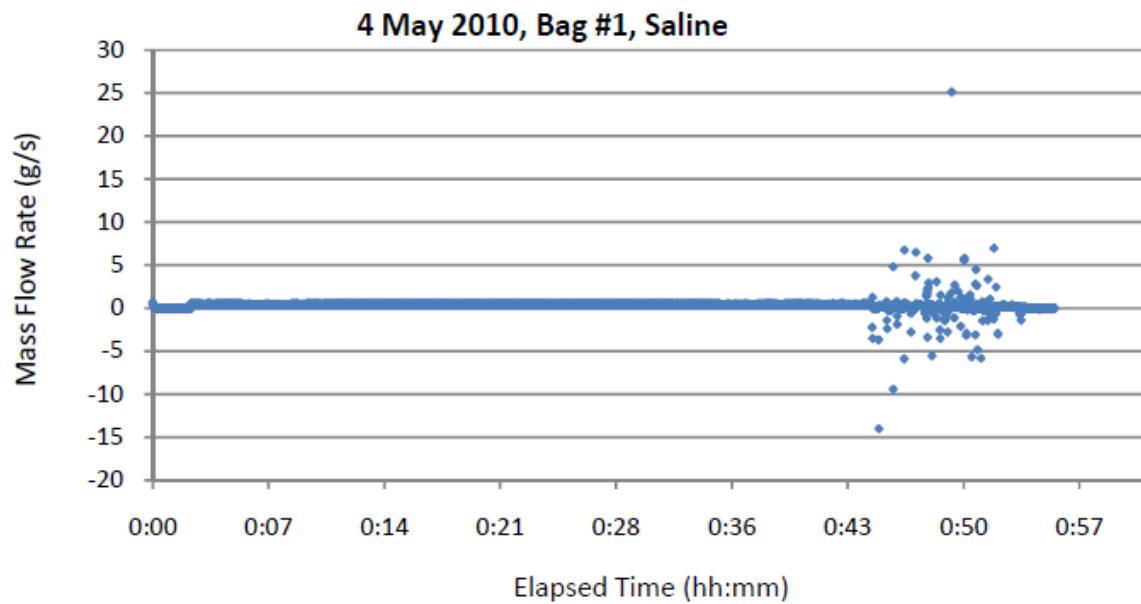
Figure B.3.—Bag 1, time trace for mass flow rate.
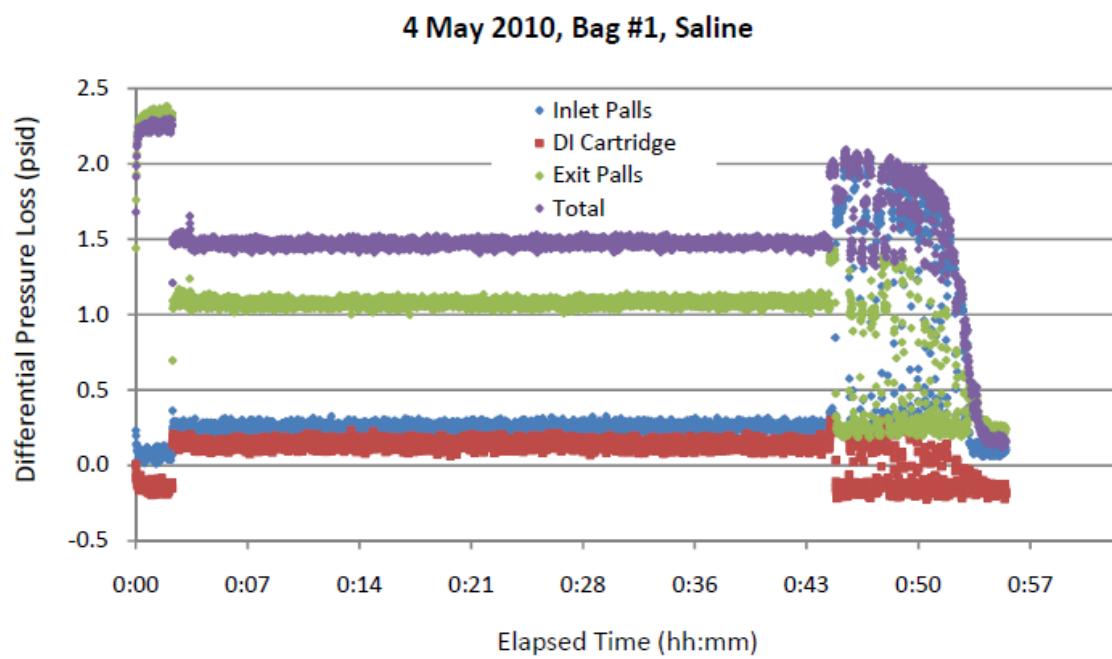
Figure B.4.—Bag 1, time trace of pressure drop.

4 May 2010, Bag #1, Saline
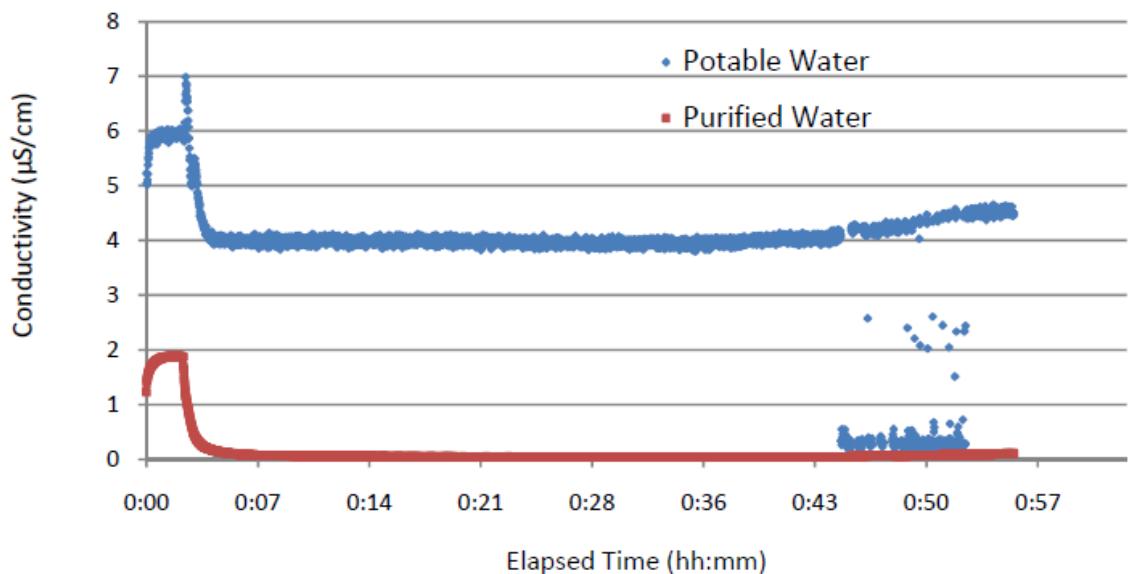
Figure B.5.—Bag 1, time trace on conductivity for potable water input and purified water output from DI Cartridge.

4 May 2010, Bag #1, Saline
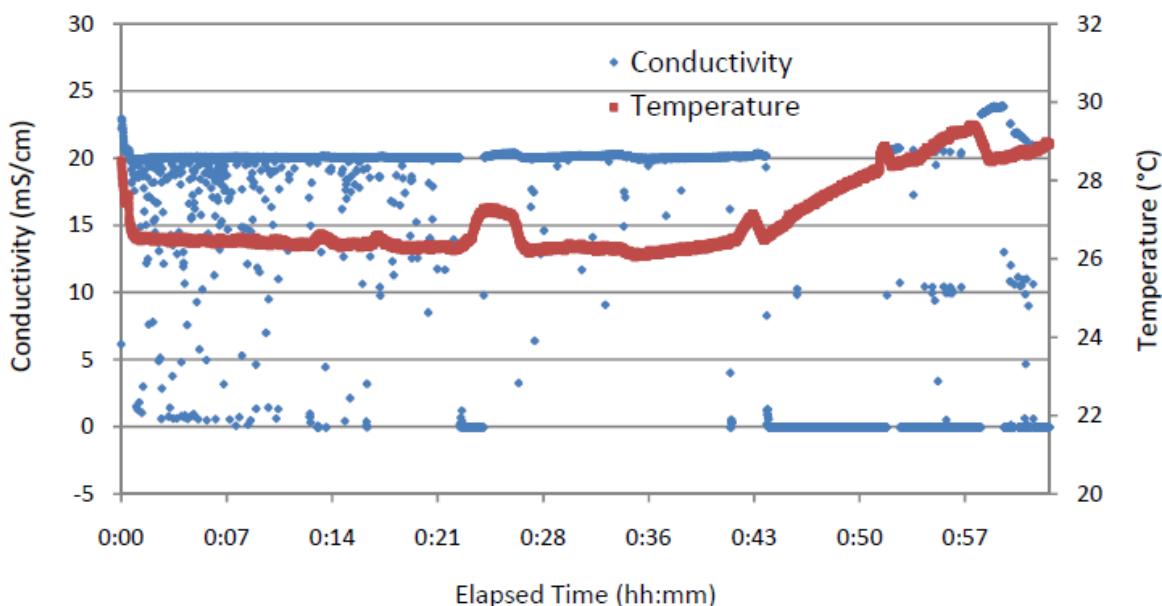
Figure B.6.—Bag 1, time trace of conductivity and temperature during transfer of saline solution to sterile bag.

4 May 2010, Bag #1, Saline
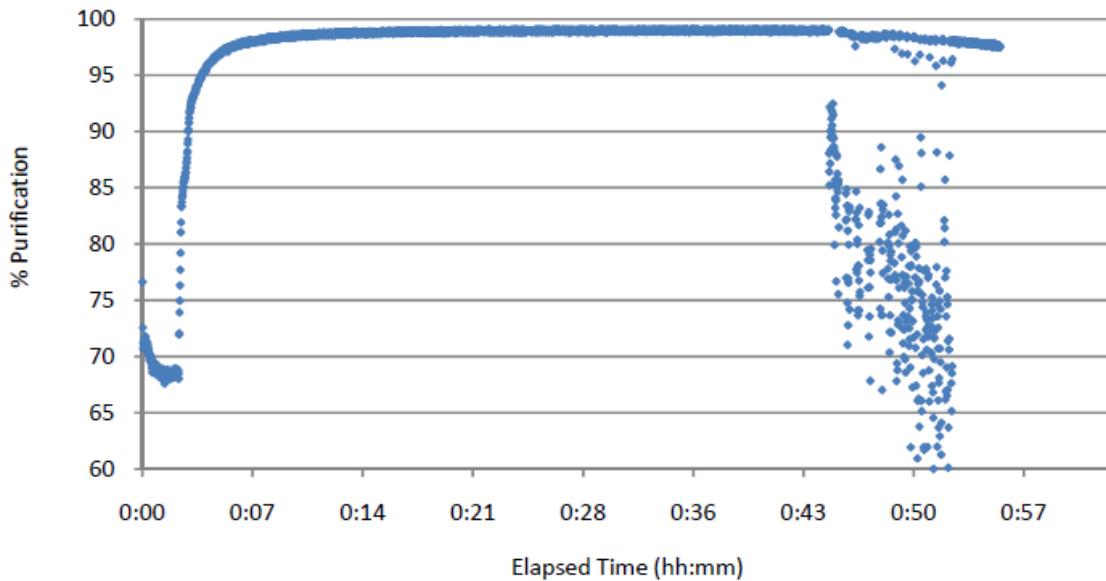
Figure B.7.—Bag 1, time trace for purification efficiency.

4 May 2010, Bag #1, Saline
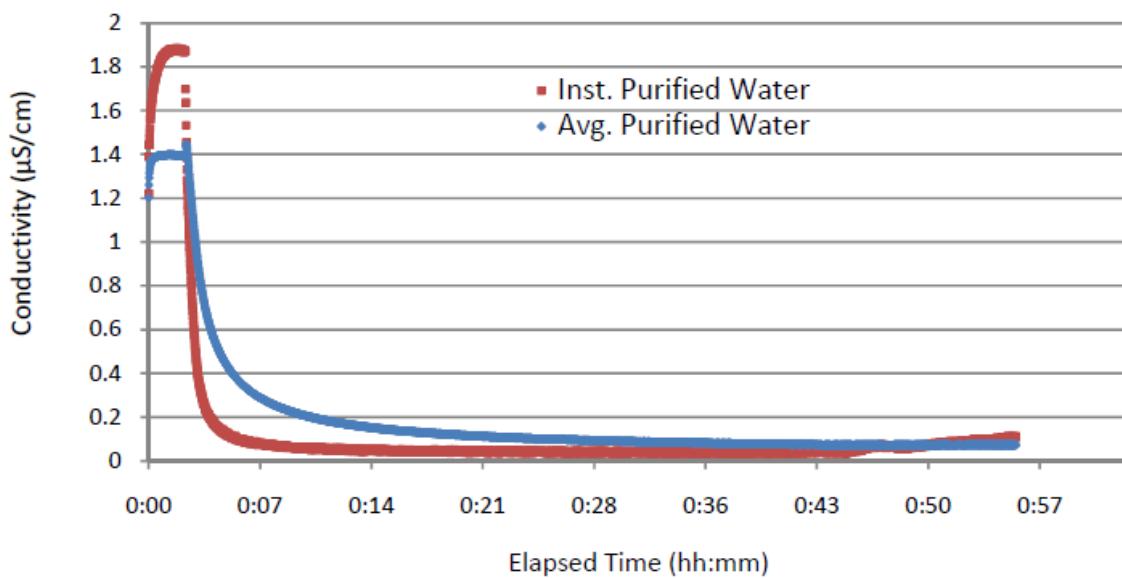
Figure B.8.—Bag 1, time trace for instantaneous and average conductivity for the purified water output from DI Cartridge.

B.2   Bag 2, Normal Saline

May 4th, Bag #2, Saline
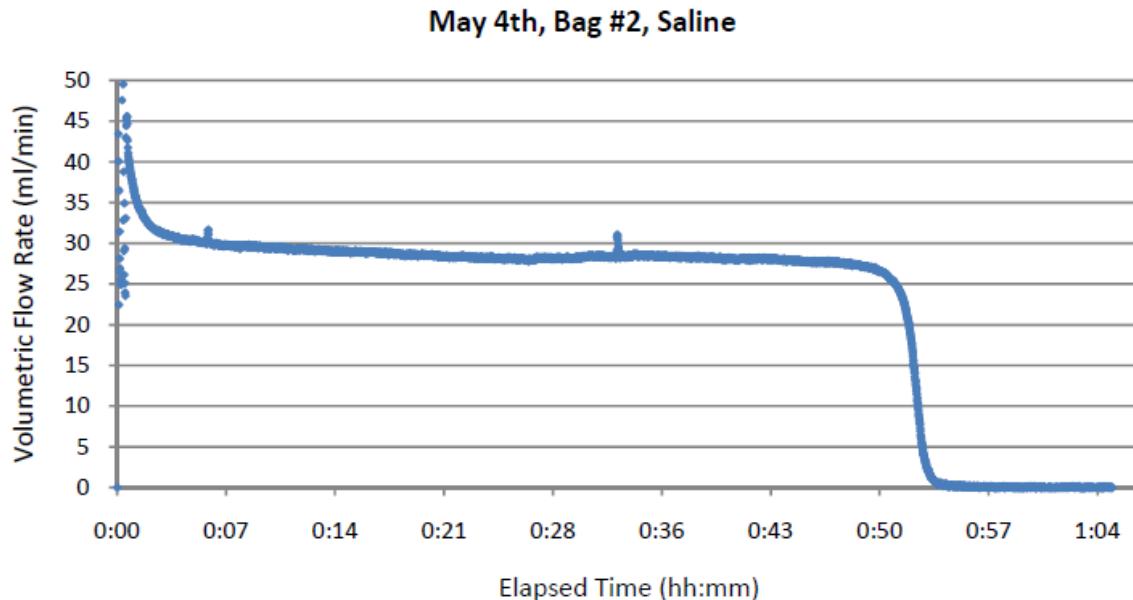
Figure B.9.—Bag 2, time trace of volumetric flow rate.
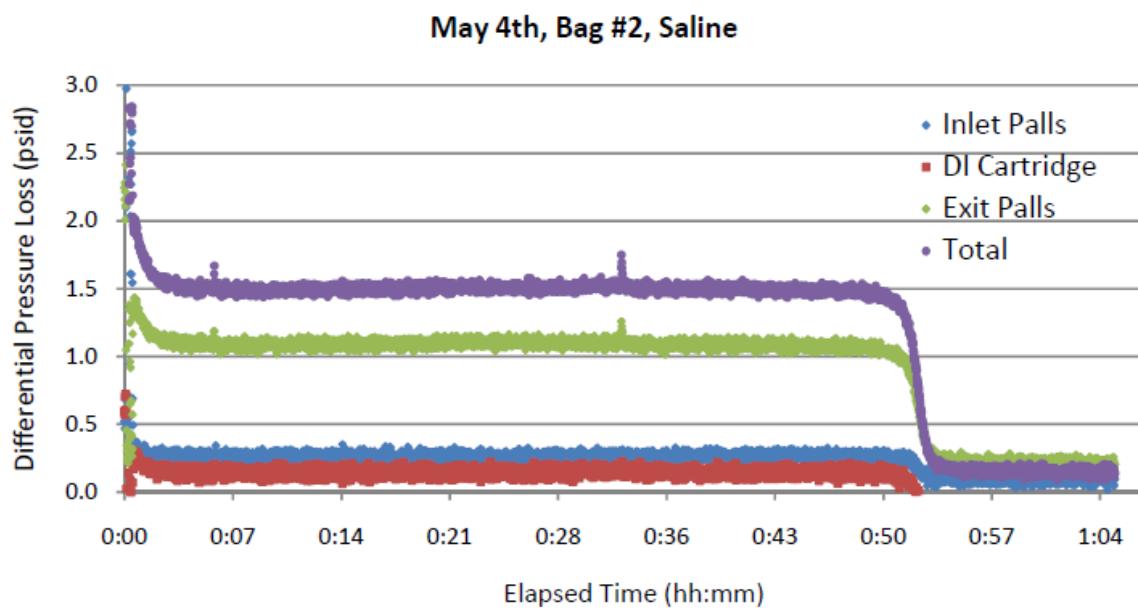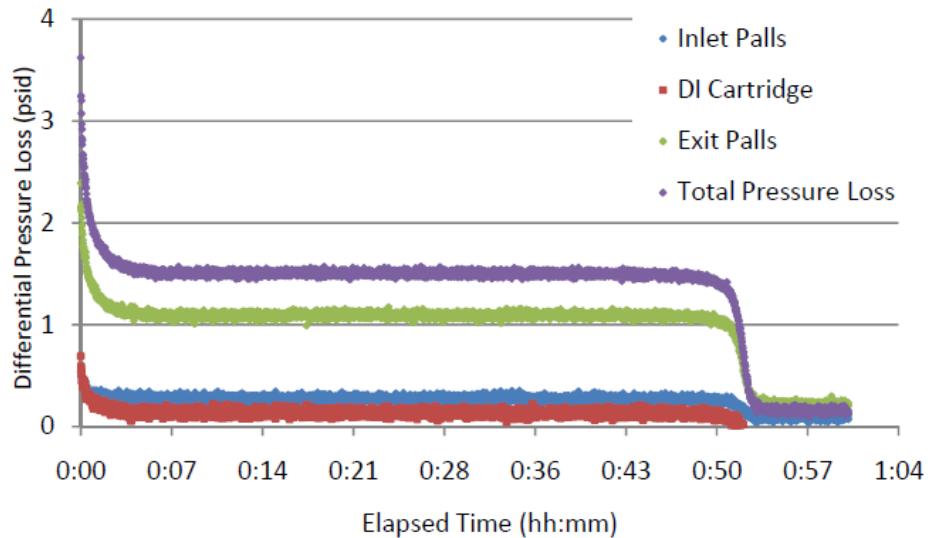
May 4th, Bag #2, Saline

Figure B.10.—Bag 2, time trace of pressure drop.
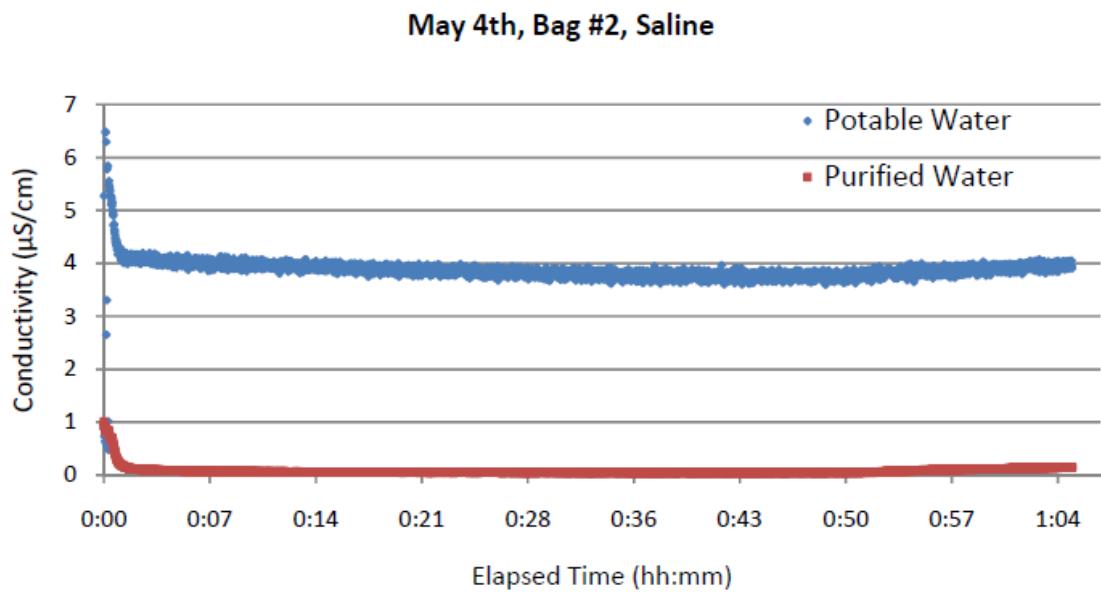
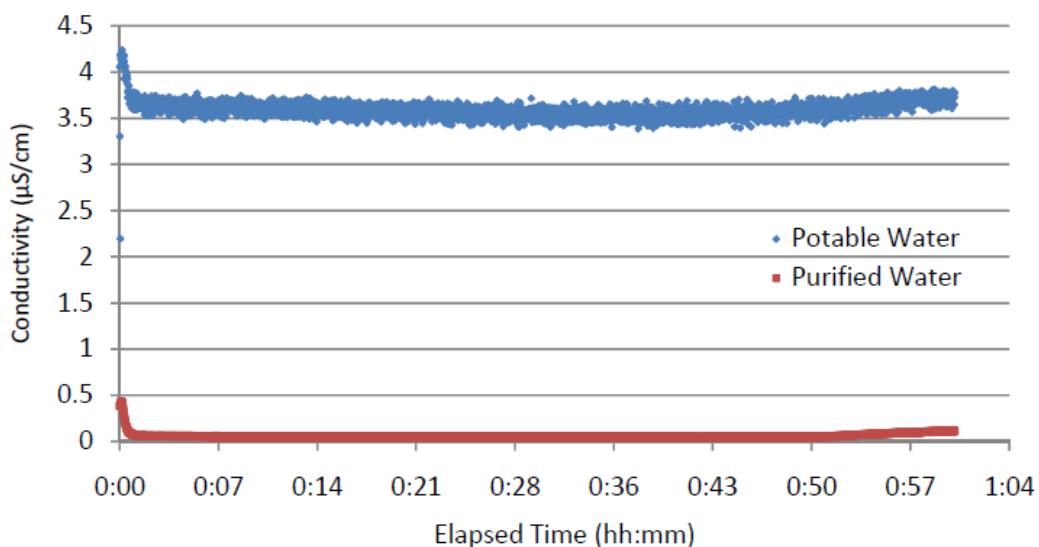## May 4th, Bag #2, Saline

Figure B.11.—Bag 2, time trace on conductivity for potable water input and purified water output from DI Cartridge.
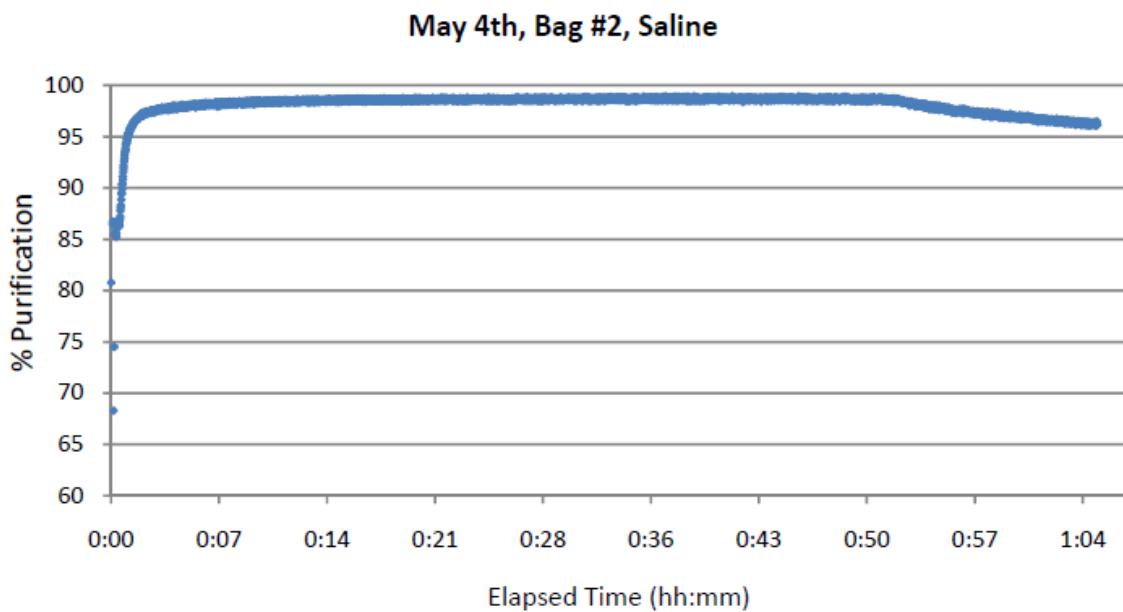
May 4th, Bag #2, Saline

Figure B.12.—Bag 2, time trace for purification efficiency.

May 4th, Bag #2, Saline
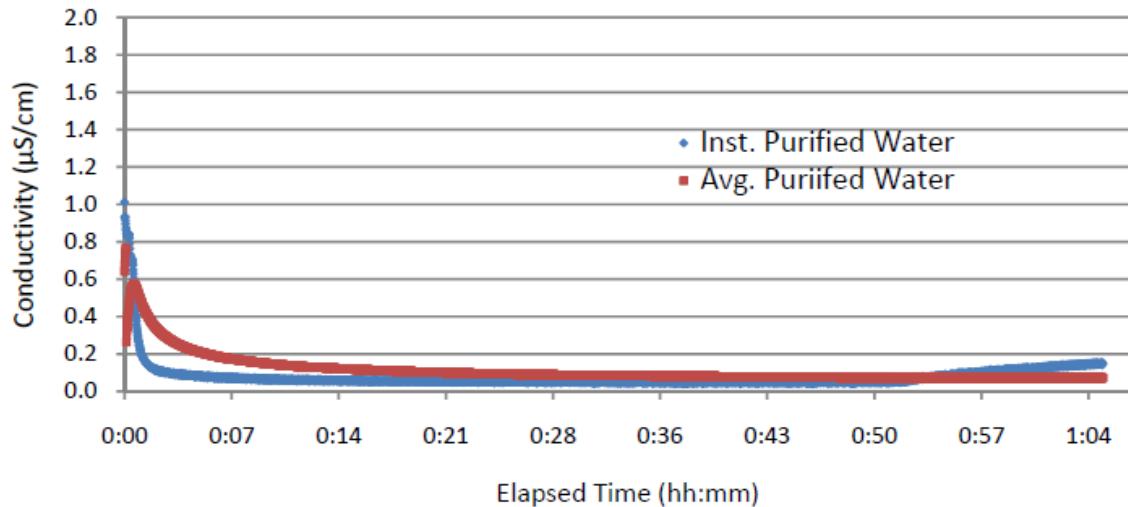
Figure B.13.—Bag 2, time trace for instantaneous and average conductivity for the purified water output from DI Cartridge.

May 4th, Bag #2, Saline
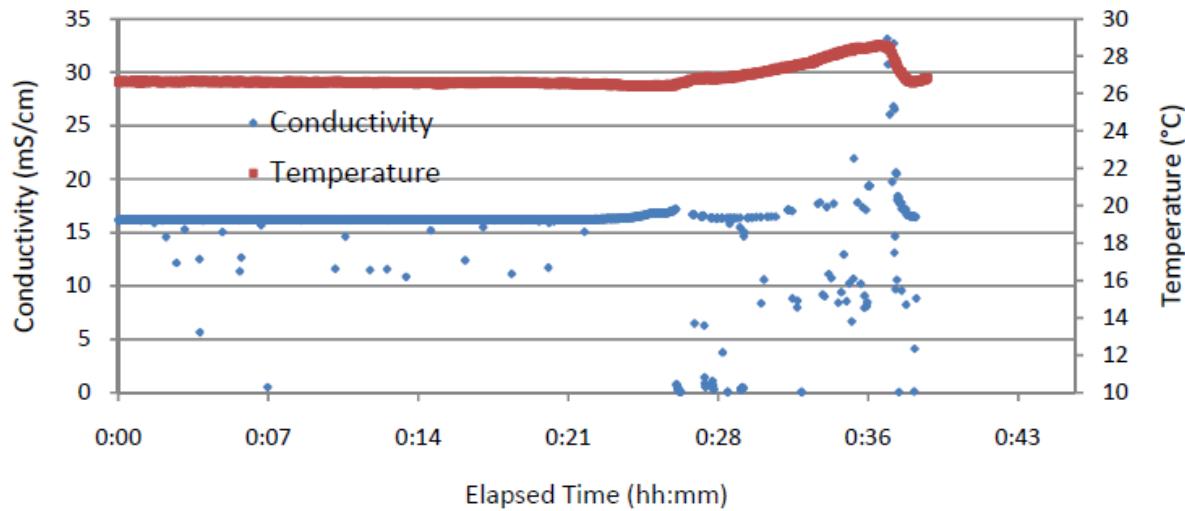
Figure B.14.—Bag 2, time trace of conductivity and temperature during transfer of saline solution to sterile bag.

B.3 Bag 3, Purified Water
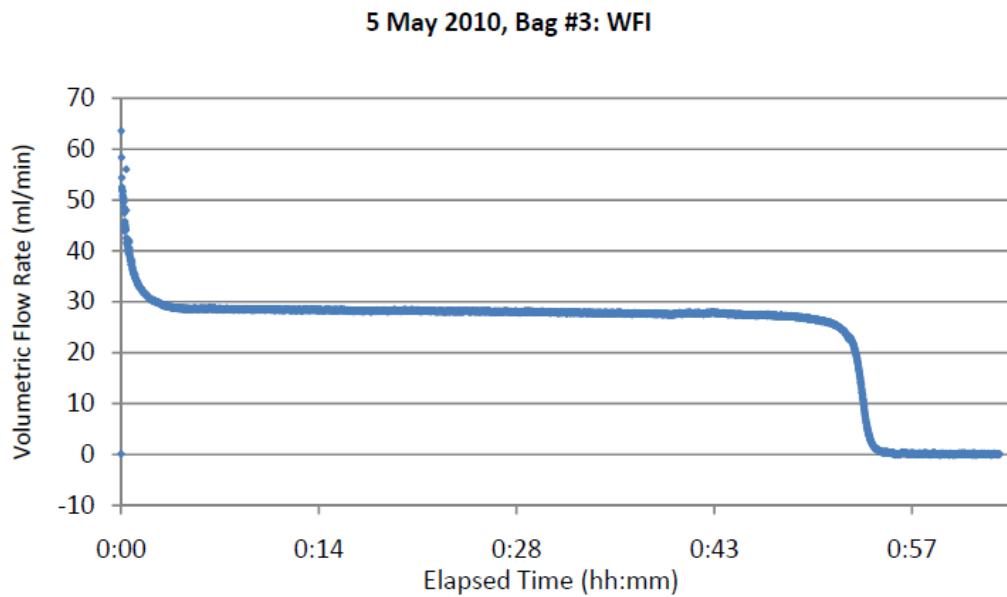
5 May 2010, Bag #3: WFI

Figure B.15.—Bag 3, time trace of volumetric flow rate.
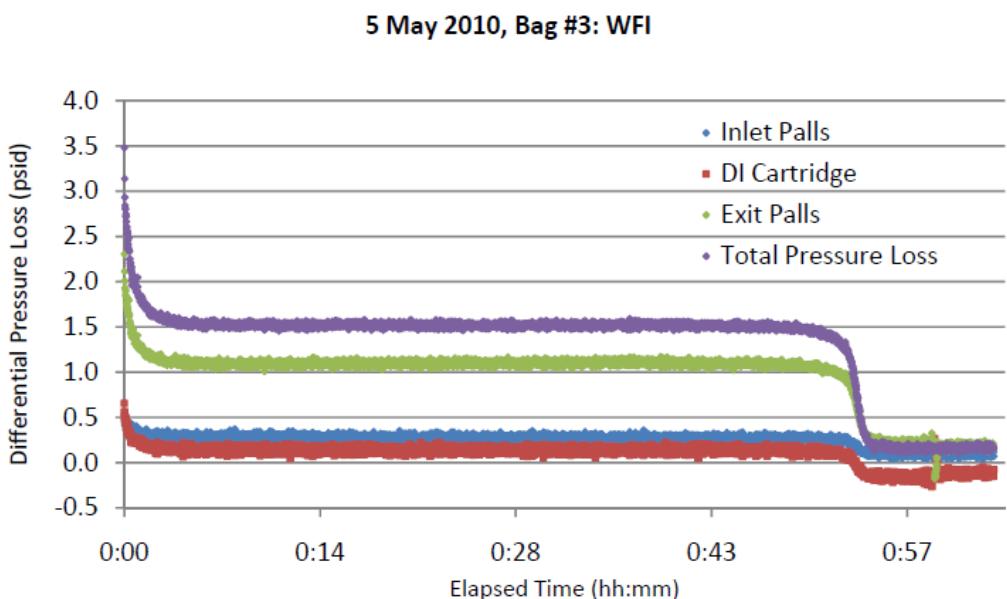
5 May 2010, Bag #3: WFI

Figure B.16.—Bag 3, Time Trace of Pressure Drop.

5 May 2010, Bag #3: WFI
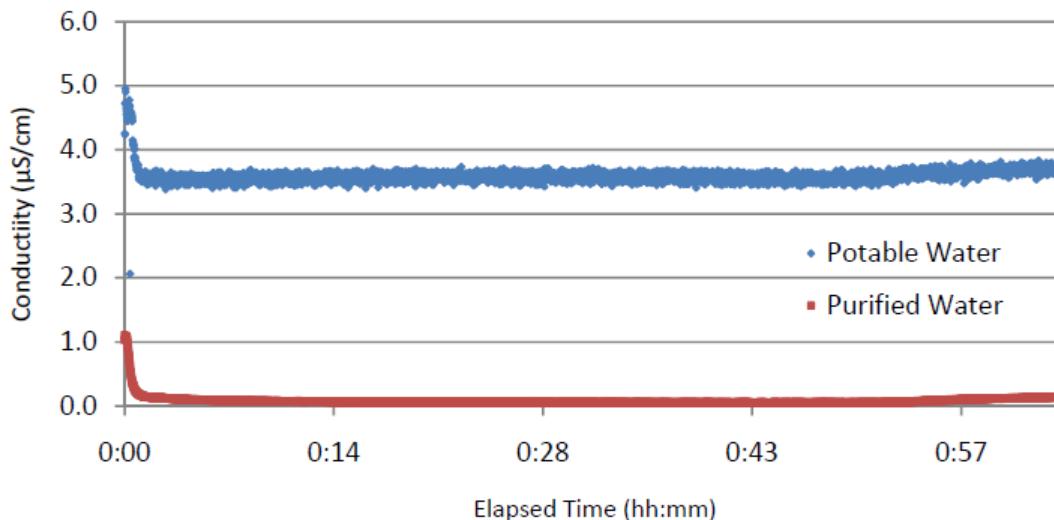
Figure B.17.—Bag 3, time trace on conductivity for potable water input and purified water output from DI Cartridge.
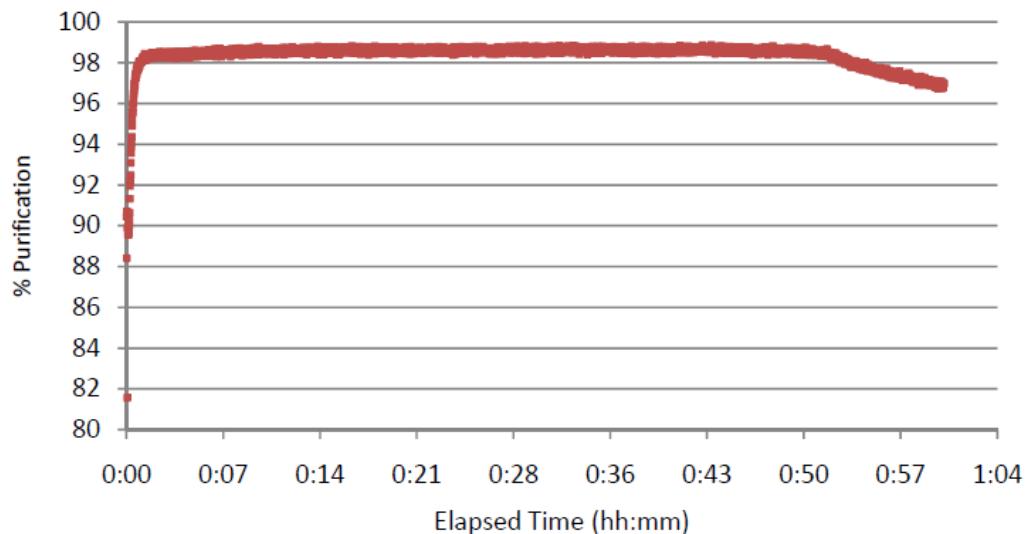
5 May 2010, Bag #3: WFI
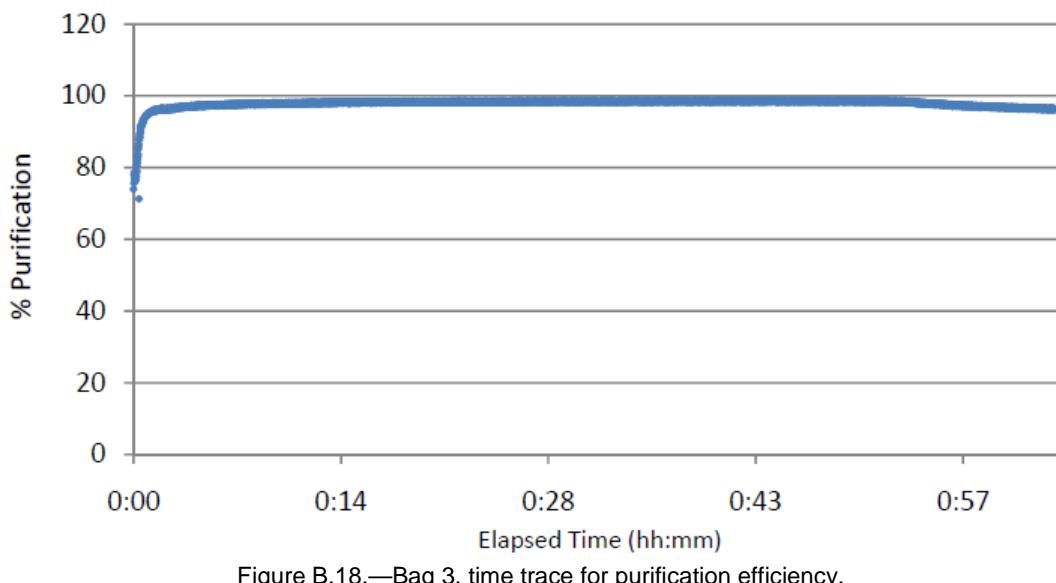
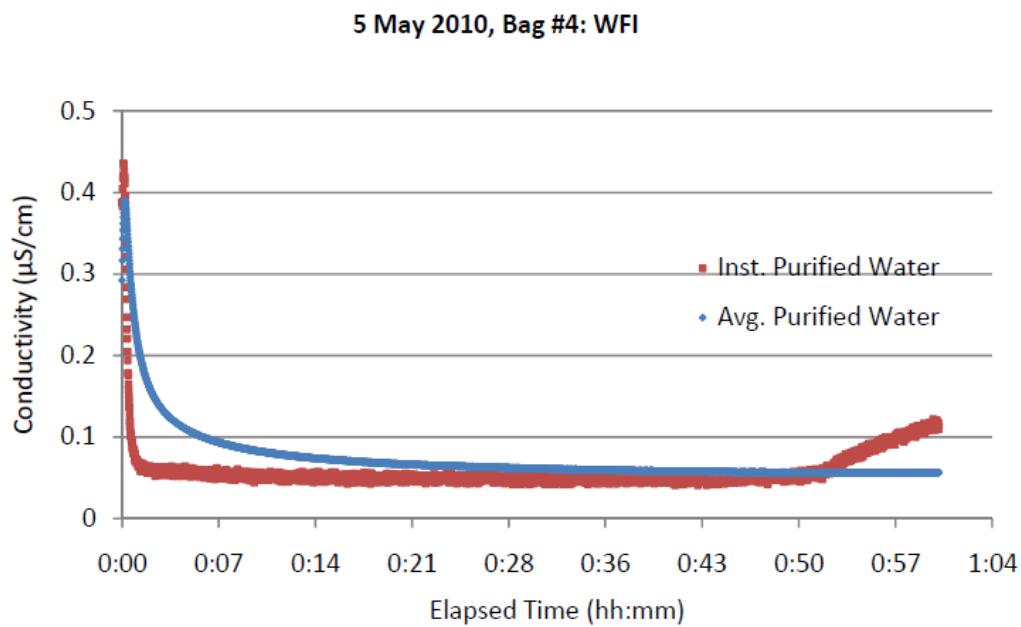Figure B.18.—Bag 3, time trace for purification efficiency.

5 May 2010, Bag #3: WFI
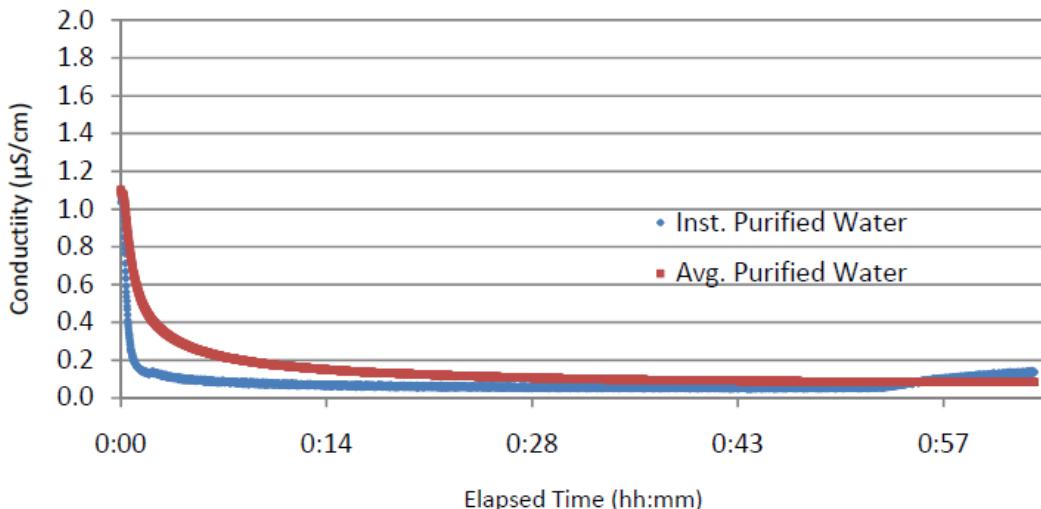
Figure B.19.—Bag 3, time trace for instantaneous and average conductivity for the purified water output from DI Cartridge.
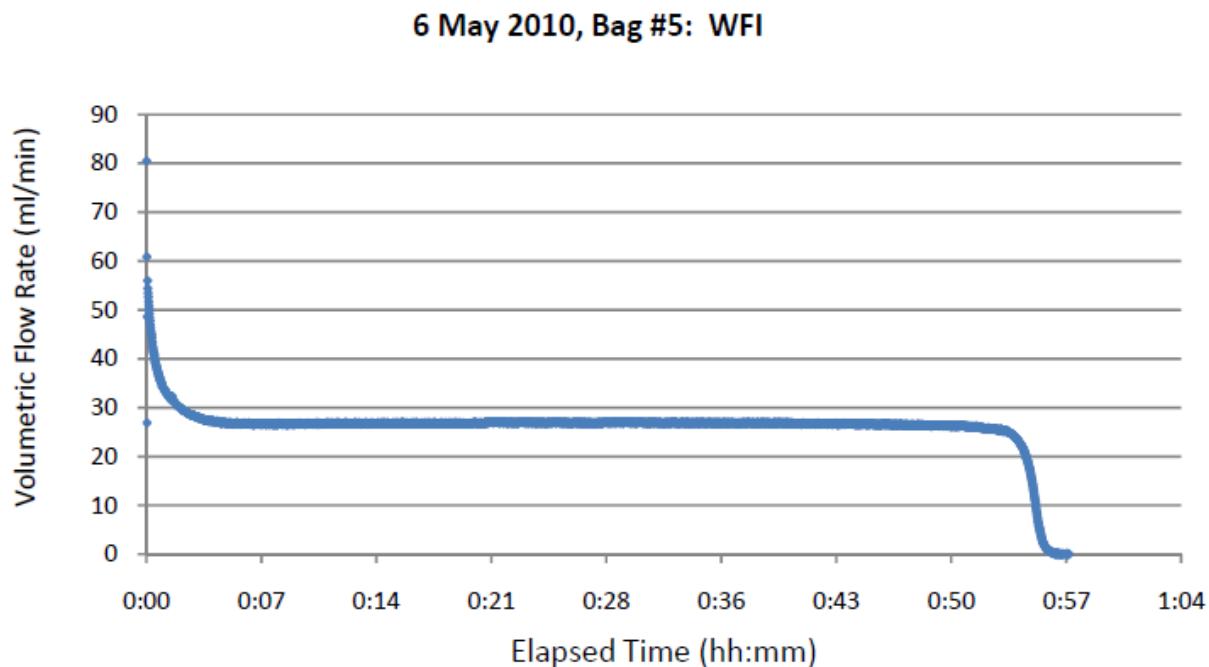
B.4   Bag 4, Purified Water
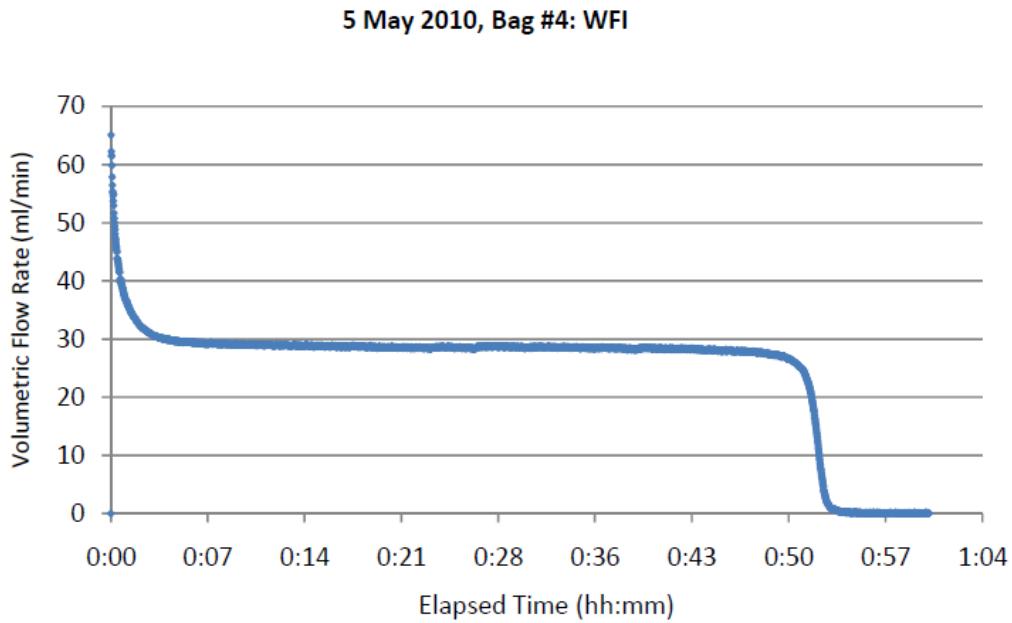
5 May 2010, Bag #4: WFI

Figure B.20.—Bag 4, time trace of volumetric flow rate.
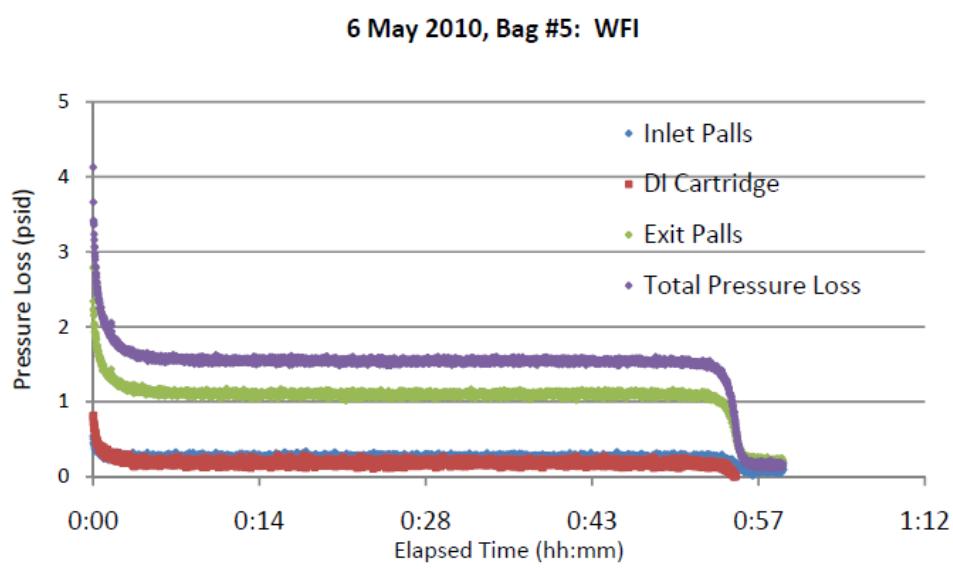
5 May 2010, Bag #4: WFI

Figure B.21.—Bag 4, time trace of pressure drop.

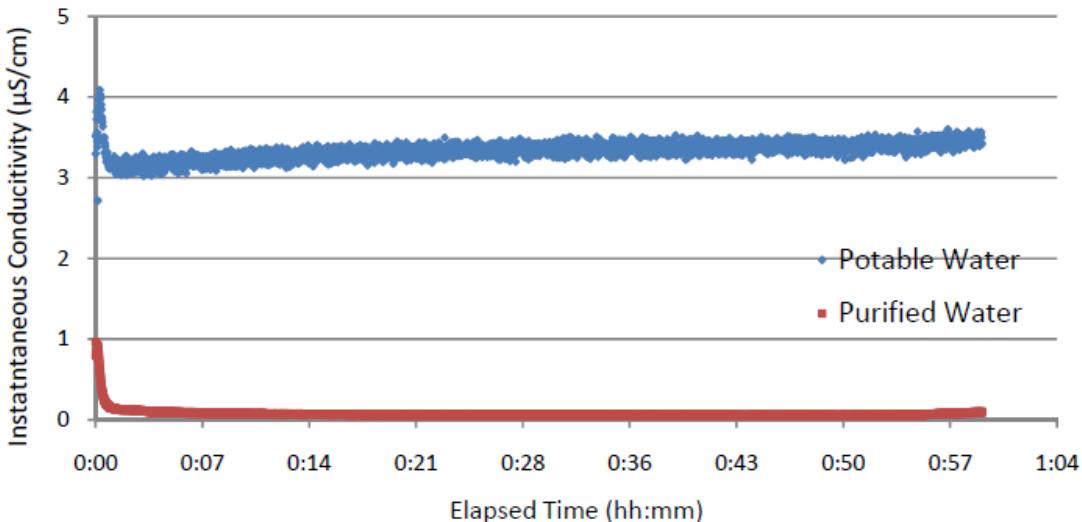## 5 May 2010, Bag #4: WFI

Figure B.22.—Bag 4, time trace on conductivity for potable water input and purified water output from DI Cartridge.
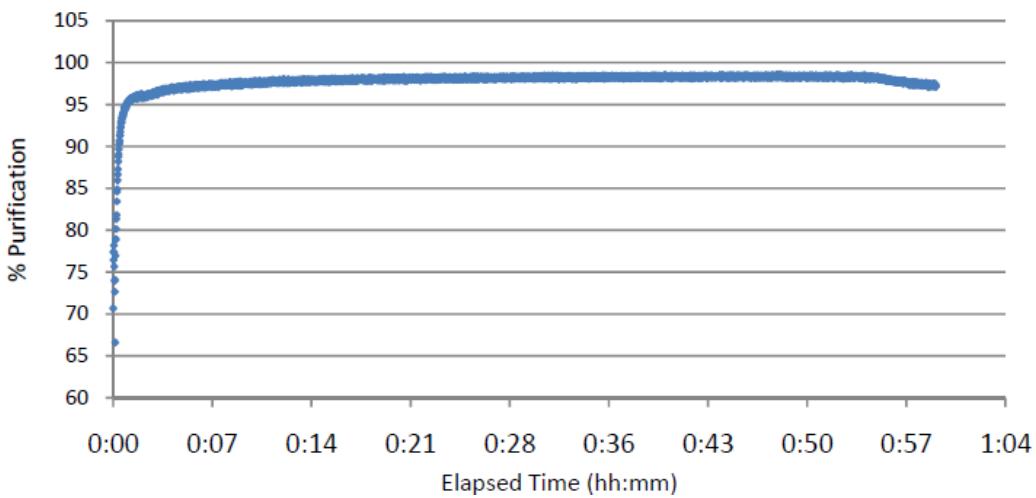
5 May 2010, Bag #4: WFI

Figure B.23.—Bag 4, time trace for purification efficiency.
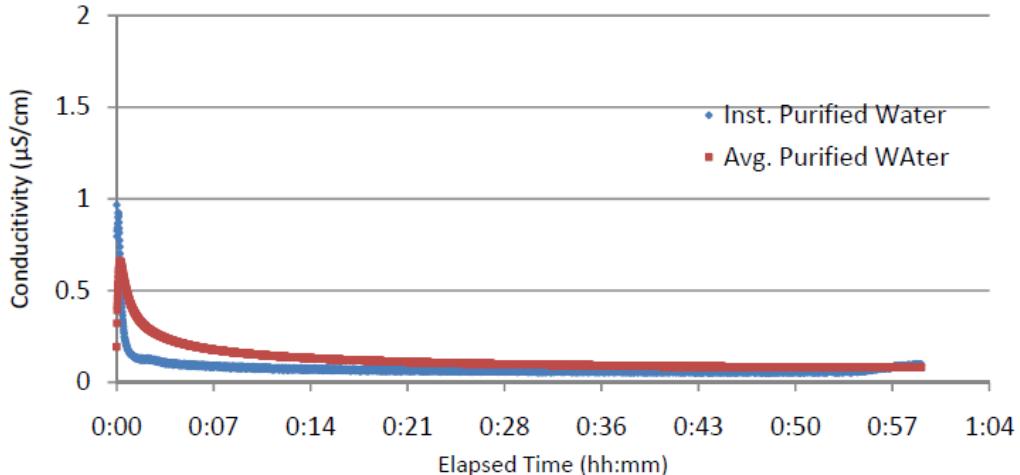
5 May 2010, Bag #4: WFI

Figure B.24.—Bag 4, time trace for instantaneous and average conductivity for the purified water output from DI Cartridge.

B.5   Bag 5, Purified Water

6 May 2010, Bag #5: WFI

Figure B.25.—Bag 5, time trace of volumetric flow rate.

6 May 2010, Bag #5: WFI

Figure B.26.—Bag 5, time trace of pressure drop.

6 May 2010, Bag #5: WFI

Figure B.27.—Bag 5, time trace on conductivity for potable water input and purified water output from DI Cartridge.

6 May 2010, Bag #5: WFI

Figure B.28.—Bag 5, time trace for purification efficiency.

Figure B.29.—Bag 5, time trace for instantaneous and average conductivity for the purified water output from DI Cartridge
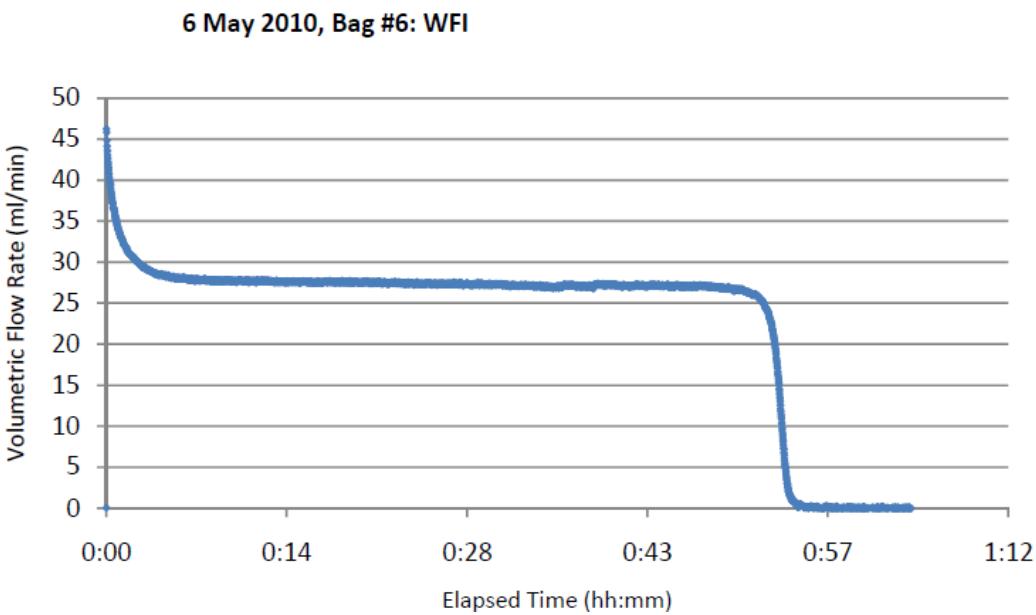
B.6   Bag 6, Purified Water

Figure B.30.—Bag 6, time trace of volumetric flow rate.
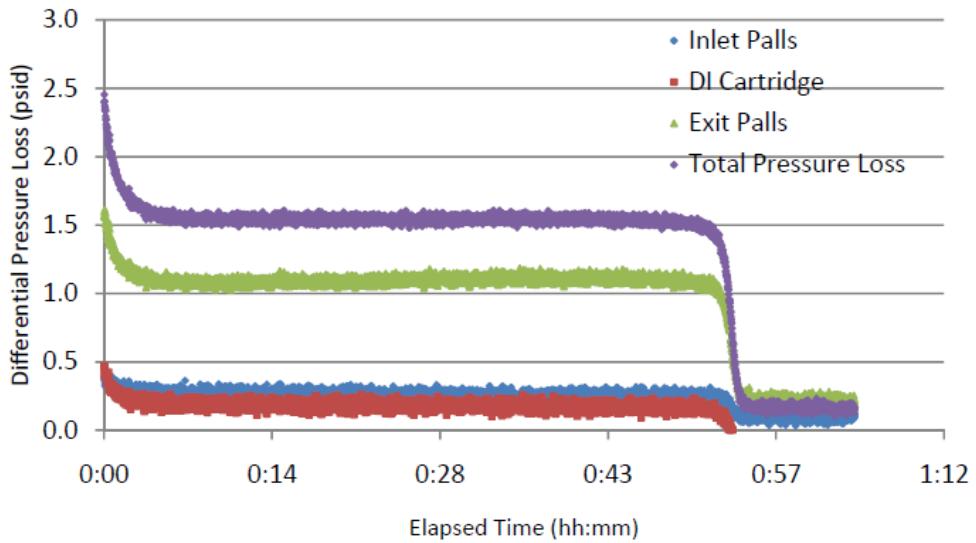
6 May 2010, Bag #6: WFI

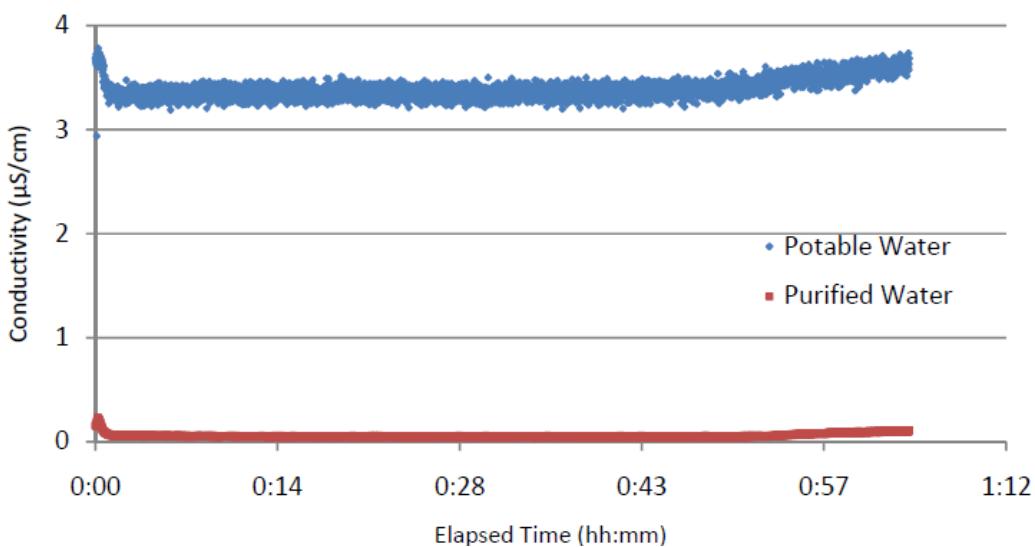Figure B.31.—Bag 6, time trace of pressure drop.

6 May 2010, Bag #6: WFI

Figure B.32.—Bag 6, time trace on conductivity for potable water input and purified water output from DI Cartridge.
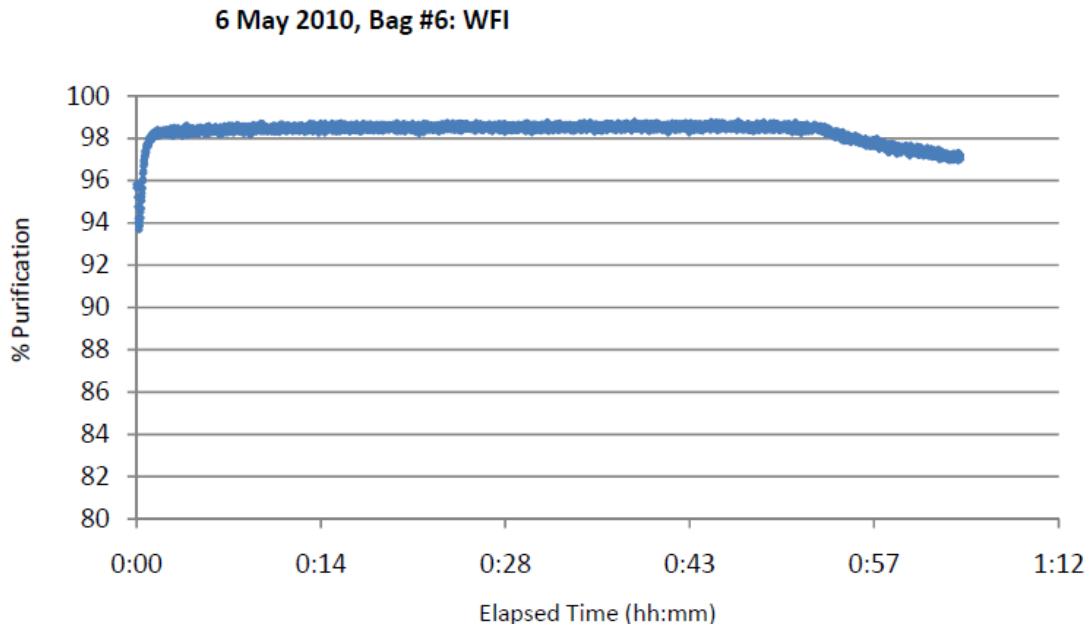
6 May 2010, Bag #6: WFI

Figure B.33.—Bag 6, time trace for purification efficiency.
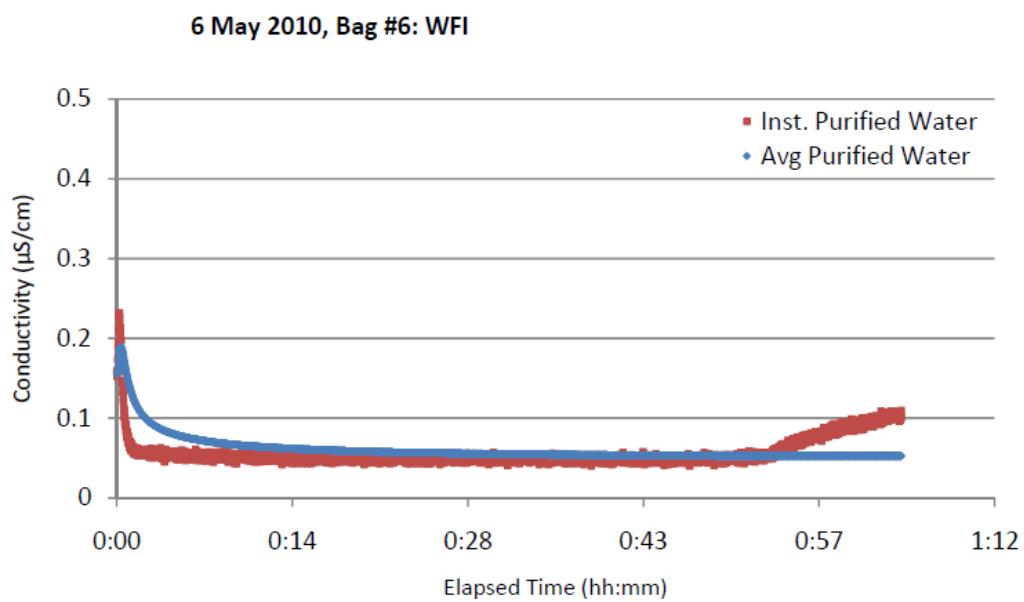
6 May 2010, Bag #6: WFI

Figure B.34.—Bag 6, time trace for instantaneous and average conductivity for the purified water output from DI Cartridge.

**Appendix C.—Investigation Results for
Out-of-Specification Saline Concentration**

C.1   Completed Test Plan

Out of Specification Salinity Root Cause Analysis Test Plan
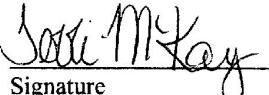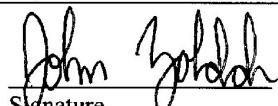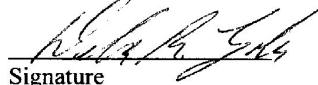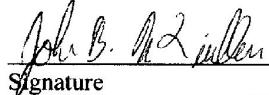# And Procedure For The Intravenous Fluid Generation
(IVGEN) Experiment

November 9, 2010

National Aeronautics and Space Administration
Glenn Research Center
Cleveland, Ohio

SIGNATURE PAGE

Date: November 9, 2010
Revision: 1.0

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Project Manager DeVon W. Griffin	*[signature]* Signature	*11/15/2010* *Date*
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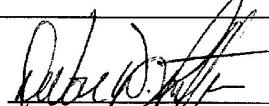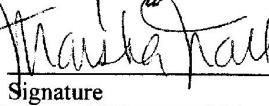
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DOCUMENT SUMMARY:

The purpose of this test plan is to define the analysis that will be conducted on the returned mixing bags from the IntraVenous fluid GENeration (IVGEN) flight project. The goal of this effort is to provide insight into the out of specification concentration results for both flight experiment saline samples.

REVISION HISTORY:

Initial Release: November 9, 2010

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1.0   Introduction

This test plan documents the procedure and analysis which will be used to investigate the saline concentration results of the samples returned from the IVGEN flight experiment. This will include evaluation and testing of each of the two samples for salt remaining in the saline bags which were used for mixing.

1.1   Background

The IntraVenous Fluid Generation (IVGEN) experimental hardware was flown and tested onboard the International Space Station (ISS) in May 2010. The IVGEN experiment aimed to demonstrate the capability to purify ISS potable water and mix the water with salt to produce a normal saline fluid *in situ* that met the United States Pharmacopeia (USP) standards required for intravenous injection. The two samples that were produced met all of the specifications listed in the current USP monograph for Sodium Chloride Injection except for the specification for Sodium Chloride concentration of 95.0 – 105.0% of the labeled amount of NaCl.

IVGEN operations involved, first filling the IVGEN accumulator from the pressurized potable water source onboard the ISS. Once filled, the accumulator was connected to the purifier and pressurized. The pressure forced water through the IVGEN purifier, which housed multiple filters and diagnostic instruments, and then into the saline bag. The saline bag contained a premeasured amount of salt to make a 0.9% sodium chloride solution, as well as a magnetic stir bar. After the bag was filled, the stir bar mixed the solution. Mixing occurred concurrently with the bag fill. The first bag that was generated was then mixed for an additional 20 minutes after filling was complete. The second bag was mixed for an additional 5 minutes after filling was complete. Following mixing, the fluid passed out of the mixing bag, through a conductivity sensor to measure uniformity, and into a final sterile collection bag which was returned to Earth for USP testing. The assembly drawing for the collection bags and a schematic of the IVGEN hardware can be found in Appendix B.

The target specification for concentration was 0.9% Sodium Chloride in Sterile Water for Injection (SWI) with an acceptable range of 95% to 105% of that specification. This equates to dissolving 13.5 grams into 1500 mL of water. The first bag that was generated was at 117.0% of the target range. The second bag that was generated was at 93.8% of the target range. The USP test facility's Standard Operating Procedure (SOP) requires an investigation for all Out Of Specification (OOS) results. The initial investigation involved assessment of: sampling and sample integrity, method and process used, data, calculations, equipment and materials, samples, standards, reagents, media, cultures, and analyst training. As no definitive error was determined from the initial investigation, both samples were retested by two separate analysts. The result of the retest confirmed the original OOS results. Results for both samples as well as the OOS investigation form can be found in Appendix C.

Multiple hypotheses have been developed to explain the OOS results. The first bag that was generated was more concentrated than expected. The possibilities for this occurring that have been identified are as follows:
- An error in the salt measurement may have resulted in too much salt in the mixing bag.
- A bubble may have been trapped in the accumulator during the accumulator fill which would have resulted in less water than expected being delivered to the bag.
- The accumulator may not have been completely filled which would have resulted in less water than expected being delivered to the first bag generated.

- The holdup volume of the dry system may have been higher than anticipated which would result in less water than expected being delivered to the bag. Holdup volume is defined as the volume in the plumbing components between the accumulator and the mixing bag. The first bag was generated using a dry system and therefore the holdup volume was estimated from measurements based on the qualification unit.

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Electronic data, obtained during IVGEN operations aboard the ISS, from the flow meter indicated that between 1309 and 1329 grams of water flowed through the IVGEN experiment to mix with the predetermined amount of salt. The first value was determined by summing the mass output from the flow meter. The second value was determined by summing the volumetric output and dividing by the instantaneous density of the liquid. Each bag was also weighed at the USP testing facility. The first bag weighed 1371.6 grams (which includes tubing and filters).

The saline concentration in the second bag was less than expected. The possibilities for this occurring that have been identified are:
- An error in the salt measurement may have resulted in too little salt in the bag.
- The decreased mixing time may have resulted in incomplete mixing. If mixing were incomplete, some salt may have remained in the mixing bag resulting in a lower than expected salt concentration.
- Salt may have been trapped in the port that was used for adding the salt to the bag which would have resulted in a lower than expected salt concentration.

Electronic data obtained from the flow meter for the second bag indicated that between 1499 and 1518 grams of water flowed through the IVGEN experiment to mix with the predetermined amount of salt. The bag was also weighed at the USP testing facility. The second bag weighed 1576.5 gram (which includes tubing and filters). In order to thoroughly eliminate the possibility of an error in salt measurement or incomplete mixing due to the shortened mixing duration, it is necessary to analyze the residual salt concentration in the bag

1.2 Test Summary

The purpose of this test is to determine the amount of salt remaining in the mixing bags after the transfer to the collection bags was completed on orbit. From this information and the results obtained from the analytical test facility, a mass balance calculation will be performed to determine whether the correct amount of salt was in the mixing bag. It may also be possible to determine whether or not the anomalous results were due to incomplete mixing. The test plan pertains specifically to generating a sample from each mixing bags to be sent out to a test lab for quantitative analysis. The test lab will analyze the sample for sodium using Inductively Coupled Plasma Mass Spectrometry (ICP-MS). The reporting limit for this method is 50 μg/L and requires a 100 mL sample. The concentration of sodium chloride will be calculated based on the sodium concentration results.

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2.0 Test Sample Description

The residual contents of the saline bags used for mixing during the IVGEN space flight experiment will be analyzed. The saline bags (60112MFA1120 SN1 and SN2) were returned after the IVGEN experiment was conducted in May 2010. The assembly drawing for these bags is shown in Figure 2.1.
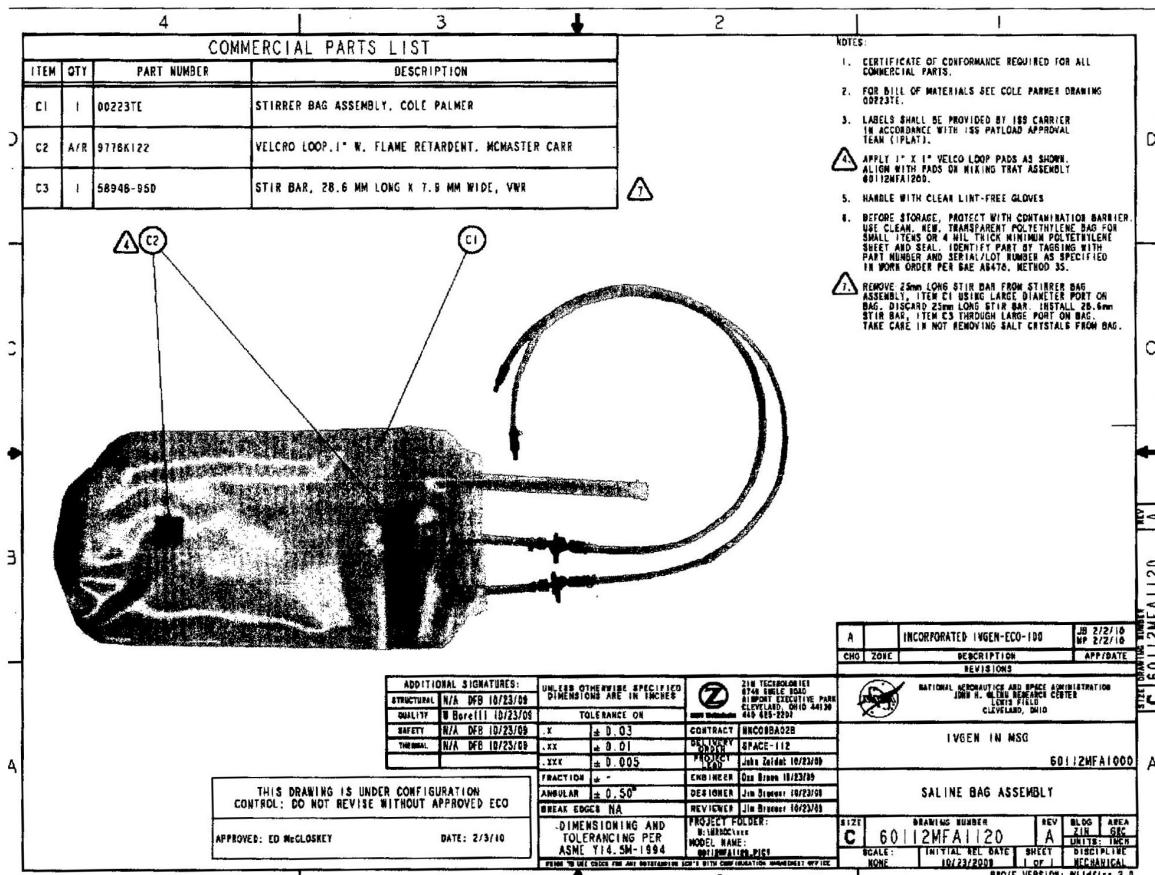
Figure 2.1 Saline Bag

3.0 Test Procedure

3.1 General Guidelines

1. A 100 ± 2 ml sample from each saline bag shall be submitted.

2. A control sample of the reagent grade water used to dilute the samples and contained in containers identical to the sample containers shall also be submitted.

3. All test activities shall be documented, including dates and signatures. Photo documentation of the bags before and after sample extraction is required.

    a. The mass of each bag, before and after sample extraction, shall be measured and recorded.

    b. The mass of each sample container, before and after sample introduction, shall be measured and recorded.

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4. Environmental conditions for sample dilution and extraction shall satisfy standards specified in ASTM 4453, Standard Practice for Handling of Ultra-Pure Water Samples.

5. Reagent grade, ASTM Type I water, shall be used for sample dilution to ensure the sample will not be contaminated by the dilutant.

6. Containers and transfer equipment, which will be in contact with the dilutant or sample, shall satisfy standards in ASTM 4453, Standard Practice for Handling of Ultra-Pure Water Samples. In particular the container material recommendations and procedure specified in 5.2.2 of ASTM 4453 for the Analysis of Other Trace Ions shall be followed.

7. Sample containers for storage and submission of the samples for ICP analysis shall be obtained from the analytical test facility. http://www.precisionanalytical.com/

8. Samples should be submitted to the test facility on the day of extraction. Samples shall be submitted to the test facility within 24 hours of extraction.

9. The test procedure checklist in Appendix A shall be used for sample extraction and post-sample extraction steps.

10. Either the IVGEN PI or PS shall be present during sample extraction and post-extraction steps.

3.2 Post-analysis

1. Calculate grams of dissolved salt in undiluted solution based on analysis results.

2. Compare undiluted residual concentration of salt bags to concentration results obtained from initial USP analysis.

4.0 Test Facility

The test facility shall be Precision Analytical of Cleveland, Ohio.

http://www.precisionanalytical.com/

5.0 Test Description

As the test for Sodium is significantly more sensitive than the test for chloride (50 µg/L versus 50 mg/L), the samples will only be tested for Sodium. The NaCl concentration will then be calculated based on the sodium concentration. Precision Analytical tests for Sodium using ICP-MS. See Appendix D for salt concentration calculations based on 100 mL extracted samples.

6.0 Test Report

Results will be documented in a Test Report.

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7.0 Appendix A: Test Procedure Checklist

☑ Don nitrile gloves.

☑ Photograph the front and back of each saline bag including labels. Photograph using white, black and gray background.

☑ Label the three sample containers which will be used to submit the samples for analysis. Include:

   1. Sample ID - For extraction samples, reference mixing bag label (SN1 or SN2). For control sample, the sample ID should be ASTM Type I water.

   2. Date

☑ Carefully inspect both bags and record any relevant findings below.

Notes: _BAG SN1 APPEARED TO CONTAIN MORE RESIDUAL SALINE AND ALSO HAD A SIGNIFICANT_

AMOUNT OF AIR BUBBLES IN THE OUTLET TUBE. COMPARED TO BAG SN2 (AFB 11-19-10)

BAG SN2 HAD BASICALLY NO LIQUID IN OUTLET TUBE.

☑ Record the scale model, part number, serial number, and calibration date below.

Scale Manufacturer: _SARTORIUS ISO CAL_

Part/Model Number: _LC 3201 A - 00MS_

Serial Number: _50404813_

Calibration Date: _MAR 15, 2010 DUE MAR 15, 2011_

☑ Tare the scale. Record Value displayed: _0.000 g_

☑ Record the mass (± 0.01 gram) of each bag (including tubing and fittings) and each of the three empty sample containers (with lids) below.

Saline Bag SN1 Mass: _141.794g_

Saline Bag SN2 Mass: _128.930g_

Saline SN1 Sample Container: _27.021 g_

Saline SN2 Sample Container: _28.006 g_

ASTM Type I Water Container: _26.936 g_

☑ Add 100 ± 3 ml of reagent grade, ASTM Type I water, to each saline bag. Add the water through the port which saline flowed out of during the IVGEN experiment.

☑ Close Port

☑ Record the mass (± 0.01 gram) of each bag (including tubing and fittings) to verify that the water specification was met.

Saline Bag SN1 Mass: _240.888 g_

Saline Bag SN2 Mass: _228.225 g_

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☑ Ensure water enters bag ports and dilutant mixes with residual sample:

1. Orient bag with ports down, let liquid set for 10 minutes.

Time Started: ___10:34___

Time Finished: ___10:44___

2. Rotate bag in planar direction 6 times at a rate no faster than 1 rotation per 2 minutes with agitation. DFB 11-19-10

Time Started: ___~~10:57~~ 10:45___

Time Finished: ___10:57___

3. Rotate bag in orthogonal direction 6 times at a rate no faster than 1 rotation per 2 minutes with agitation.

Time Started: ___10:57___

Time Finished: ___11:09___

☑ Extract atleast 100 ± 2 ml of liquid from each bag into labeled sample containers provided by the test facility. Extract sample through same port that was used for adding the reagent grade water.

☑ Add 100 ± 3 ml reagent grade, ASTM Type I water to the control sample container.

☑ Again, record the mass (± 0.01 gram) of each bag (including tubing and fittings) and each of the three sample containers below.

Saline Bag SN1 Mass: ___130.536 g___

Saline Bag SN2 Mass: ___127.566 g___

Saline SN1 Sample Container: ___137.255 g___

Saline SN2 Sample Container: ___128.040 g___

ASTM Type I Water Container: ___127.345 g___

☑ Record date and time of sample extraction completion.

Date: ___11-19-10___   Time: ___11:35 AM EST___

☑ Verify sample container lids are secure and attach QA label to verify seal.

☑ Pass dry nitrogen through saline bags to evaporate any remaining visible water.

☑ Record mass (± 0.01 gram) of each bag (including tubing and fittings).

Saline Bag SN1 Mass: ___120.700 g___

Saline Bag SN2 Mass: ___119.281 g___

☑ Again, photograph front and back of each saline bag including labels . Use white (or black background?).

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SN1 - 120.700 g
SN2 - 119.281

☑ Record mass displayed by empty scale pan: ___0.000 g_____

☑ Send all three samples to the analytical lab for analysis. Record date and time of sample pick-up.

Date: ___11-19-10_____   Time: ___1:15 PM EST_____

☑ Witnesses sign and date below.

ZIN Analyst   Signature: _~D4 fn Bol_____   Date: __11-19-2010___

ZIN QA   Signature: _Darryl Suley_____ (ZIN-Test QA-006) Date: _11-19-2010____

GRC PS or PI   Signature: _Jerri McKay_____   Date: __11-19-2010___

7

C.2 Chemical Analysis Results of Bag Contents (Performed by Precision Analytical)

PRECISION
ANALYTICAL, INC.

November 23, 2010

Dan Brown
ZIN Technologies, Inc.
6745 Engle Rd.
Middleburg Hts., Ohio 44130
TEL: (440) 625-2219
FAX: (440) 625-2354

RE: IVGEN   Order No.: 1011516

Dear Dan Brown:

Precision Analytical, Inc. received 3 sample(s) on 11/22/2010 for the analyses presented in the following report.

There were no problems with the analytical events associated with this report unless noted in an attached Case Narrative. Quality control data is within laboratory defined or method specified acceptance limits except if noted. Note that sample results reported relate only the samples as received at the laboratory.

Solid samples are reported in ug/Kg or mg/Kg as received, unless specified in the units as dry weight. Unless otherwise noted, results have not been background or blank corrected.

If you have any questions regarding these tests results, please feel free to call.

Certifications: Ohio EPA - 4041; NELAC NY - 11167; NELAC PA - 68-00434;
                        W.Va DEP - 245; KY UST - 69

Sincerely,

Scott Bolam

Scott Bolam
QA/QC Manager

Page 1 of 4

PRECISION ANALYTICAL, INC.

Precision Analytical, Inc.
4450 Johnston Parkway Unit B
Cleveland, OH 44128
TEL: 216 663 0808 FAX: 216 663 0656
Website: www.precisionanalytical.com

Analytical Report
(consolidated)

WO#: **1011516**

Date Reported: **11/23/2010**

CLIENT:	ZIN Technologies, Inc.		**Collection Date:**	11/19/2010 11:35:00 AM
Project:	IVGEN			
Lab ID:	1011516-001		**Matrix:**	AQUEOUS
Client Sample ID	SN1			

Analyses	Result	RL	Qual	Units	DF	Date Analyzed
METALS ANALYSIS BY ICP				**E200.7**		Analyst: **STB**
Sodium	1,360,000	5,000		µg/L	100	11/23/2010 1:06:29 PM

Analytical Report

(consolidated)

WO#: **1011516**

Date Reported: **11/23/2010**

CLIENT:	ZIN Technologies, Inc.	**Collection Date:**	11/19/2010 11:35:00 AM
Project:	IVGEN		
Lab ID:	1011516-002	**Matrix:**	AQUEOUS
Client Sample ID	SN2		

Analyses	Result	RL	Qual	Units	DF	Date Analyzed
METALS ANALYSIS BY ICP				**E200.7**		Analyst: **STB**
Sodium	568,000	5,000		µg/L	100	11/23/2010 1:06:29 PM

Qualifiers:						
	*/X	Value exceeds Maximum Contaminant Level		B	Analyte detected in the associated Method Blank
	DF	Dilution Factor		H	Holding times for preparation or analysis exceeded
	J	Analyte detected below quantitation limits		M	Manual Integration used to determine area response
	MDL	Method Detection Limit		N	Tentatively identified compounds
	ND	Not Detected at the Reporting Limit		PL	Permit Limit
	RL	Reporting Detection Limit (PQL)		S	Spike outside acceptance limits

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Precision Analytical, Inc.
4450 Johnston Parkway Unit B
Cleveland, OH 44128
TEL: 216 663 0808 FAX: 216 663 0656
Website: www.precisionanalytical.com

PRECISION
ANALYTICAL, INC.

CLIENT:	ZIN Technologies, Inc.			**Collection Date:**	11/19/2010 11:35:00 AM	
Project:	IVGEN					
Lab ID:	1011516-003			**Matrix:**	AQUEOUS	
Client Sample ID	ASTM Type 1 Water					

Analyses	Result	RL	Qual	Units	DF	Date Analyzed
METALS ANALYSIS BY ICP				E200.7		Analyst: **STB**
Sodium	ND	50.0		µg/L	1	11/23/2010 1:06:29 PM

Qualifiers:	*/X	Value exceeds Maximum Contaminant Level	B	Analyte detected in the associated Method Blank
	DF	Dilution Factor	H	Holding times for preparation or analysis exceeded
	J	Analyte detected below quantitation limits	M	Manual Integration used to determine area response
	MDL	Method Detection Limit	N	Tentatively identified compounds
	ND	Not Detected at the Reporting Limit	PL	Permit Limit
	RL	Reporting Detection Limit (PQL)	S	Spike outside acceptance limits

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PRECISION ANALYTICAL, INC.
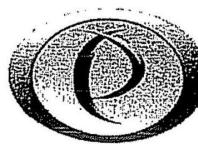
4450 JOHNSTON PARKWAY, UNIT B • CLEVELAND, OH 44128
(216) 663-0808 • FAX (216) 663-0656

LABORATORY WORK ORDER # 101516

REPORT TO: CONTACT & COMPANY	ZIN TECHNOLOGIES, INC. (DAN BROWN)
ADDRESS	6745 ENGLE RD
CITY	MIDDLEBURG HTS OH	STATE OH	ZIP CODE 44130

PHONE NO. 440-625-2219 FAX NO. 440-625-2354

EMAIL: DANIEL.BROWN@ZIN-TECH.COM PROJECT NAME/NUMBER: IVGEN

☑ Check if same as Report To

INVOICE TO: NAME
ADDRESS
CITY STATE ZIP CODE
PHONE NO. FAX NO.
PO#: 26,262 QUOTE #: STD

Turnaround Time: ☐ Std. **Rush:** ☐ 24 hr. ☐ 48 hr. ☐ 72 hr. Authorizing signature

Special Instructions & QC Requirements (additional charge for QC):
ICP ANALYSIS OF SODIUM CONTENT
LEVEL 4 QUALITY CONTROL

TEMP (°C) N/A
VISIBLE ICE (circle) YES (NO)

Sample Disposal (A fee will be assessed if samples are retained longer than 1 month & disposed of by lab)
☐ Return To Client ☐ Disposal By Lab ☐ Archive For _____ Months

ANALYSIS REQUESTED

NO.	CUSTOMER SAMPLE IDENTIFICATION	SAMPLE DATE	SAMPLE TIME	Comp/Grab	NO. OF CONT.	MATRIX			
1	SN1	11-19-10	11:55 AM		1	1.1	X	-1	
2	SN2	11-19-10	11:55 AM		1		X	-2	
3	ASTM TYPE 1 WATER	11-19-10	11:55 AM		1		X	-3	
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									

Samplers: (Signature)	Relinquished by: (Signature)	Date 11-19-10	Time 1:15 PM	Received by: (Signature)
Received by: (Signature)	Relinquished by: (Signature)	Date	Time	Received in laboratory by: (Signature)

Relinquished by: (Signature) Date 11/22/10 Time 12:20

Date 11/22/10 Time 12:20

PRECISION
ANALYTICAL, INC.

Sample Receipt Checklist

Work Order No. 1011516

RUSH: ☐ Yes ☒ No ☐ NA

Date & Time Received: 11/22/10 11:20 Received By: CRe

Date & Time Logged In: 11/22/10 14:47 Logged In By: JLG

Date & Time Reviewed: 11/23/10 940 Reviewed By: GM

Carrier Name: ☒ PAI ☐ UPS ☐ FedEx ☐ Client ☐ Other _____

Samples Analyzed In House? ☒ Yes ☐ No Subbed To _____

Is Chain Of Custody Present?	☒ Yes	☐ No
Is Chain Of Custody Properly Filled Out?	☒ Yes	☐ No
Does Chain Of Custody Match Sample Labels?	☒ Yes	☐ No

Are Samples Past Hold Time? ☐ Yes ☒ No ☐ NA

Are Samples In Proper Containers? ☒ Yes ☐ No Intact? ☒ Yes ☐ No

No. Of Containers? 3 ☐ Glass ☒ Plastic ☐ Baggie ☐ VOA ☐ Micro ☐ Other _____

When Applicable, Is Headspace Present? ☐ Yes ☐ No

Matrix: ☒ Aqueous ☐ Liquid ☐ Sludge ☐ Solid ☐ Oil ☐ Drinking Water ☐ Soil ☐ Other _____

On Ice? _____ °C ☒ Yes ☐ No ☒ NA

Are Samples Preserved? ☒ Yes ☐ No ☒ NA

pH Results:

Metals 2 Hardness _____ ☒ HN03	CN _____ ☐ NaOH

COD _____ NH3 _____ Phenol _____ TOC _____ TKN/TON _____ Phos _____ No2No3 _____ ☐ H2S04

Sulfide _____ ☐ NaOH & ZnAcetate	Other _____

Field Data: ☐ pH ☐ Temp ☐ Flow ☐ TRC ☐ TRC Low ☐ Color ☐ Odor ☐ Turbidity ☐ Other _____

Explanation of Comments & Problems:

_____
_____
_____
_____
_____
_____
_____

IV-Gen: Post-Flight Salt Concentration Analysis

Mathematica **V5.1 by Wolfram Research, www.wolfram.com**

Experiment operations were conducted aboard the International Space Station (ISS) for the IntraVenous fluid GENeration (IV-Gen) experiment during May 2010. Two bags of Normal Saline (NS) solution were produced and returned to Earth for analysis by a United States Pharmacopeia (USP) certified testing facility. While both samples passed several of the tests, they both failed to be within tolerances (±5%)for the salt concentration.

The salt concentration for first bag was at 117% of the target value, while the salt concentration for second bag was at 93.8%.

Ideal Case

```
IdealVolume (*ml H20*) = 1500.0 (*ml H20*)
```

1500.

```
IdealSaltMass (*g NaCl*) = 13.5 (*g NaCl*)
```

13.5

Although a tolerance was specified of ±0.5 g NaCl, it is still possible to meet the USP requirements if a tolerance of 0.75 g was used.

```
SaltTolerance (*g NaCl*) = 0.75 (*g NaCl*)
```

0.75

$$\text{IdealConcentration} \left(* \tfrac{g\ NaCl}{ml\ H_2 0} *\right) = \frac{\text{IdealSaltMass } (*g\ NaCl*)}{\text{IdealVolume } (*ml\ H_2 0*)}$$

0.009

$$\text{MinimumConcentration} \left(* \tfrac{g\ NaCl}{ml\ H_2 0} *\right) = \frac{\text{IdealSaltMass } - \text{SaltTolerance } (*g\ NaCl*)}{\text{IdealVolume } (*ml\ H_2 0*)}$$

0.0085

$$\text{MaximumConcentration} \left(* \tfrac{g\ NaCl}{ml\ H_2 0} *\right) = \frac{\text{IdealSaltMass } + \text{SaltTolerance } (*g\ NaCl*)}{\text{IdealVolume } (*ml\ H_2 0*)}$$

0.0095

```
NSDensity (*g/ml*) = 1.0046(* g/ml -- Reported in CRC Handbook of Chemistry and Physics*)
```

1.0046

```
DilDensity (*g/ml*) = 0.9989
  (* g/ml -- Reported in CRC Handbook of Chemistry and Physics*)
```

0.9989

Bag #1

■ Saline Solution

There was no direct measure of the flight sterile saline bag weights. Therefore, an estimate was made based on the average bag weight of 5 of the 12 bags in bonded storage. This weight was adjusted to include the weight of the flight labels, Kapton tape, and the blue hose clamp, see Dan Brown's email dated September 3, 2010, 2:55PM.

```
SterileBag1EmptyWt (*g*) = 96.4 (*g*)
```

96.4

An analysis was performed by Pace Analytical to verify compliance with the United States Pharmacopeia (USP) for a Normal Saline Solution.

```
SterileBag1FullWt (*g*) = 1371.6(*g -- measured by Pace *)
```

1371.6

```
PerCentOver (* % *) = 117.0 (* %-- measured by Pace *)
```

117.

```
SterileBag1LiqVol (*ml*) =
  (SterileBag1FullWt (*g*) - SterileBag1EmptyWt (*g*)) / NSDensity (* g/ml *)
```

1269.36

However, review of the water flow rate data from the IV-Gen DACU and adjusting it for the passage of bubbles yields a total water mass of 1309 g passed through the purifier. While approximately 13 g of salt can be added to the water weight, there is still a discrepancy of a 50g of water. Nonetheless, the value of 1371.6 g will be used.

```
SterileBag1Conc (* g NaCl/ml H20 *) =
  PerCentOver (* % *) * ────────── IdealConcentration (*g NaCl/ml H20*)
                        100 (* % *)
```

0.01053

```
SterileBag1SaltMass (*g NaCl*) =
  SterileBag1Conc (* g NaCl/ml H20 *) * SterileBag1LiqVol (*ml*)
```

13.3664

■ Residuals Analysis

The residual analysis refers to the liquid that was retained within the mixing bag. This bag contained the premeasured abount of salt, the stir bar, and had some tubing. The amount of residual liquid was determined by weighing the bag, emptying, drying and then reweighing the bag.

```
SaltBag1Dry (*g*) = 120.700 (*g*)
```

120.7

```
SaltBag1LiqRes (*g*) = 141.794 - SaltBag1Dry(*g*)
```

21.094

It should be noted that about four months ago, this bag, with the residual liquid, weighed 143.835 g.

Precision Analytical was contracted to perform a quantitative analysis on the amount of sodium in residual water. However, in order to do this, they needed at least 100 ml sample. Therefore, approximately 100 ml of ASTM Type I (distilled/deionize/purified) water was added to dilute the sample.

```
Dilution1Vol (*g*) = 240.888 - SaltBag1Dry (*g*)
```

120.188

Precision Analytical used a techique call ICP or inductively coupled plasma optical emission spectrometry (ICP-OES), is an analytical technique to detect the sodium. This technique is a type of emission spectroscopy that uses the inductively coupled plasma to produce excited atoms and ions that emit electromagnetic radiation at wavelengths characteristic of a particular element. The result obtained was $1,360,000 \frac{\mu g}{l}$.

$$\text{PostBag1Conc } (*\tfrac{g\ NaCl}{l}*) = 1360000 (*\tfrac{\mu g\ Na}{l}*) * \frac{1\ (*g\ Na\ *)}{1*10^6\ (*\mu g\ Na\ *)} * \frac{58.5 (*g\ NaCl\ *)}{23\ (*g\ Na\ *)}$$

3.45913

The amount of salt left in the mixing bag was

$$\text{Bag1ResSaltMass}(*g\ NaCl*) =$$
$$\text{PostBag1Conc } (*\tfrac{g\ NaCl}{l}*) * \frac{\text{Dilution1Vol } (*\ g\ *)}{\text{DilDensity } (*\tfrac{g}{ml\ Solution}*)} * \frac{1\ (*\ l\ *)}{1000\ (*\ ml*)}$$

0.416204

Adding together the salt in sterile saline bag and the salt left in the mixing bag yields

```
Bag1TotalSaltMass(*g NaCl*) =
 Bag1ResSaltMass(*g NaCl*) + SterileBag1SaltMass (*g NaCl*)
```

13.7826

This quantity falls within the acceptable limit.

For yucks, the concentration of the salt left in the mixing bag with the residual liquid yields a value of

$$\texttt{ResidualConc1} = \frac{\texttt{Bag1ResSaltMass(*g NaCl*)}}{\frac{\texttt{SaltBag1LiqRes (*g*)}}{\texttt{NSDensity (*g/ml*)}}}$$

0.0198217

This is over twice the concentration in the sterile saline bag. Either the mixing was incomplete or there was another source of sodium that contributed to this analysis.

Bag #2 Saline Solution

Again, since there was no direct measure of the actual weight of the flight sterile saline bag, an average was used

```
SterileBag2EmptyWt (*g*) = 96.4 (*g*)
```

96.4

Results from Pace Analytical are as follows:

```
SterileBag2FullWt (*g*) = 1576.5 (*g -- measured by Pace *)
```

1576.5

```
PerCentUnder (* % *) = 93.8 (* % -- measured by Pace*)
```

93.8

```
SterileBag2LiqVol (*ml*) =
 (SterileBag2FullWt (*g*) - SterileBag2EmptyWt (*g*)) / NSDensity (*g/ml*)
```

1473.32

For this case, review of the water flow rate data from the IV-Gen DACU and adjusting it for the passage of bubbles yields a total water mass of 1499 g passed through the purifier. While approximately 13 g of salt can be added to the water weight, there is still a discrepancy of a 50g of water. Nonetheless, the value of 1480.1 g will be used.

```
SterileBag2Conc (*g NaCl/ml H2O*) =
 PerCentUnder (* % *) * ──── IdealConcentration (*g NaCl/ml H2O*)
                        100 (* % *)
```

0.008442

$$\text{SterileBag2SaltMass } (*g*) = \text{SterileBag2Conc } (*\tfrac{g\ NaCl}{ml\ H20}*) * \text{SterileBag2LiqVol } (*ml*)$$

12.4378

■ Residuals Analysis

Similar to the first mxing bag, the residual analysis refers to the liquid that was retained within the mixing bag. This bag also contained the premeasured abount of salt, the stir bar, and had some tubing.

$$\text{SaltBag2Dry } (*g*) = 119.281(*g*)$$

119.281

$$\text{SaltBag2LiqRes } (*g*) = 128.93 - \text{SaltBag2Dry}(*g*)$$

9.649

It should be noted that about four months ago, this bag, with the residual liquid, weighed 143.835 g.

Approximately 100 ml of ASTM Type I (distilled/deionize/purified) water was added to dilute the sample.

$$\text{Dilution2Vol } (*g*) = 228.225 - \text{SaltBag2Dry } (*g*)$$

108.944

ICP was used on this sample to detect the sodium content, and the result obtained was $568{,}000\,\tfrac{\mu g}{l}$.

$$\text{PostBag2Conc } (*\tfrac{g\ NaCl}{l}*) = 568000(*\tfrac{\mu g\ Na}{l}*) * \frac{1\ (*g\ Na\ *)}{1*10^6\ (*\mu g\ Na\ *)} * \frac{58.5(*g\ NaCl\ *)}{23(*g\ Na\ *)}$$

1.4447

The amount of salt left in the mixing bag was

$$\text{Bag2ResSaltMass}(*g\ NaCl*) =$$
$$\text{PostBag2Conc } (*\tfrac{g\ NaCl}{l}*) * \frac{\text{Dilution2Vol } (*\ g\ *)}{\text{DilDensity } (*\tfrac{g}{ml\ Solution}*)} * \frac{1\ (*\ l\ *)}{1000\ (*\ ml*)}$$

0.157564

Adding together the salt in sterile saline bag and the salt left in the mixing bag yields

$$\text{Bag2TotalSaltMass}(*g\ NaCl*) =$$
$$\text{Bag2ResSaltMass}(*g\ NaCl*) + \text{SterileBag2SaltMass } (*g\ NaCl*)$$

12.5954

This quantity falls below the acceptable limit and explains the likely cause as to why the bag failed the USP requirements for normal saline solution

For yucks, the concentration of the salt left in the mixing bag with the residual liquid yields a value of

$$\texttt{ResidualConc2} = \frac{\texttt{Bag2ResSaltMass(*g NaCl*)}}{\frac{\texttt{(SaltBag2LiqRes (*g*)-Bag2ResSaltMass(*g NaCl*))}}{\texttt{DilDensity (*}\frac{\texttt{g}}{\texttt{ml Solution}}\texttt{*)}}}$$

0.0165824

This is also nearly twice the concentration in the sterile saline bag. Either the mixing was incomplete or there was another source of sodium that contributed to this analysis.

Conclusions:

From the combined chemical analyses performed by Pace Analytical on the sterile saline bags and by Precision Analytical on the mixing bags, the following statements can be made:
1. For Mixing Bag 1, the amount of salt loaded into the bag was acceptable. The most likely cause for the unacceptable high normal saline concentration is that the insufficient water was loaded into the bag.
2. For Mixing Bag 2, the amount of salt loaded into the bag was below the acceptable range and is the most likely cause of the abnormal low saline concentration.
3. Both mixing bags had a residual sodiumt concentration that was about double of that found in the sterile saline bags. While this finding is disturbing, it is inconsequential on the amount of salt loaded into each bag.

REPORT DOCUMENTATION PAGE

1. REPORT DATE (DD-MM-YYYY)	2. REPORT TYPE	3. DATES COVERED (From - To)
01-07-2011	Technical Memorandum	

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
Final Report for Intravenous Fluid Generation (IVGEN) Spaceflight Experiment	
	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)	5d. PROJECT NUMBER
McQuillen, John, B.; McKay, Terri, L.; Griffin, DeVon, W.; Brown, Dan, F.; Zoldak, John, T.	
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER WBS 444543.01.02.01

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)	8. PERFORMING ORGANIZATION REPORT NUMBER
National Aeronautics and Space Administration John H. Glenn Research Center at Lewis Field Cleveland, Ohio 44135-3191	E-17731

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSORING/MONITOR'S ACRONYM(S)
National Aeronautics and Space Administration Washington, DC 20546-0001	NASA
	11. SPONSORING/MONITORING REPORT NUMBER NASA/TM-2011-217033

12. DISTRIBUTION/AVAILABILITY STATEMENT
Unclassified-Unlimited
Subject Categories: 34 and 52
Available electronically at http://www.sti.nasa.gov
This publication is available from the NASA Center for AeroSpace Information, 443-757-5802

13. SUPPLEMENTARY NOTES

14. ABSTRACT
NASA designed and operated the Intravenous Fluid Generation (IVGEN) experiment onboard the International Space Station (ISS), Increment 23/24, during May 2010. This hardware was a demonstration experiment to generate intravenous (IV) fluid from ISS Water Processing Assembly (WPA) potable water using a water purification technique and pharmaceutical mixing system. The IVGEN experiment utilizes a deionizing resin bed to remove contaminants from feedstock water to a purity level that meets the standards of the United States Pharmacopeia (USP), the governing body for pharmaceuticals in the United States. The water was then introduced into an IV bag where the fluid was mixed with USP-grade crystalline salt to produce USP normal saline (NS). Inline conductivity sensors quantified the feedstock water quality, output water purity, and NS mixing uniformity. Six 1.5-L bags of purified water were produced. Two of these bags were mixed with sodium chloride to make 0.9 percent NS solution. These two bags were returned to Earth to test for compliance with USP requirements. On-orbit results indicated that all of the experimental success criteria were met with the exception of the salt concentration. Problems with a large air bubble in the first bag of purified water resulted in a slightly concentrated saline solution of 117 percent of the target value of 0.9 g/L. The second bag had an inadequate amount of salt premeasured into the mixing bag resulting in a slightly deficient salt concentration of 93.8 percent of the target value. The USP permits a range from 95 to 105 percent of the target value. The testing plans for improvements for an operational system are also presented.

15. SUBJECT TERMS
Microgravity applications; Water treatment; Separation; Fluid flow; Medical equipment

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON STI Help Desk (email:help@sti.nasa.gov)
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	UU	85	19b. TELEPHONE NUMBER (include area code) 443-757-5802