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EVALUATION OF INTRAVENOUS THERAPY DEVICES IN THE HYPERBARIC CHAMBER

Navy Experimental Diving Unit

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19. ABSTRACT:
Ventilators, cardiac monitors, intravenous (IV) pumps, and other equipment are being evaluated to meet a U.S. Navy–identified need to improve patient care levels in the hyperbaric environment. Though the MTP MILITARY is currently the only IV pump that has been found suitable for use in the hyperbaric chamber, a search of the market has identified three pumps that afford increased capability for patient care. This report presents results from a series of tests conducted to increase the IV pump options available to commands operating hyperbaric chambers. The pumps evaluated each have capabilities that may make them appealing in different operational scenarios.

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INTRODUCTION

Since the U.S. Navy has identified a need to improve its level of patient care in hyperbaric environments, ventilators, cardiac monitors, intravenous (IV) pumps, and other equipment are being evaluated to meet this need.

The only IV pump currently found suitable for use in the hyperbaric chamber is the MTP® Military Transport Infusion Pump (Medical Technology Products, Inc.; Huntington Station, NY). After researching the market and contacting several clinical hyperbaric facilities, the Navy Experimental Diving Unit (NEDU) has identified three intravenous pumps with features that may provide fleet commands with options that meet their varied needs: the IMED Gemini PC-1®, the ALARIS Medsystem III®, and the Infusion Dynamics Power Infuser. This report presents test results on and documents the safety and performance of these three pumps, and, on those bases, evaluates what and how each might contribute to fulfilling Navy needs for such units in hyperbaric settings.

METHODS

GENERAL

Testing was conducted both on the surface and at various depths in the NEDU treatment chamber. The units were reviewed in several phases to evaluate their

1. technical information,
2. physical characteristics,
3. surface functioning at atmospheric pressure, and
4. test depth functioning.

EXPERIMENTAL DESIGN AND ANALYSIS

Following a search of military and civilian organizations to identify standards for operating ventilators in a hyperbaric chamber, the *U.S. Navy Diving and Manned Hyperbaric System Safety Certification Manual* was found to define such standards for U.S. Navy hyperbaric chambers.[1] The National Fire Protection Association (NFPA), in its *NFPA 99 Health Care Facilities*, also provides standards for electronic devices used in oxygen-enriched environments,[2] a standard specifying current flows for operating medical devices in O_2-enriched environments.

Test Parameters

1. To determine whether the pumps could be safely exposed in the hyperbaric environment, NEDU engineers inspected the units per *NFPA 99* and the *U.S. Navy Diving and Manned Hyperbaric System Safety Certification Manual*.[1,2]

2. Unmanned pressure testing to a depth of 247 feet of seawater (fsw) was conducted to ensure that increased pressures would not damage electrical components of the units. Results were documented and reviewed.

3. If a unit had an internal battery, that battery was tested per NEDU Test Plan 01-23.[3]

4. Function testing was conducted on the surface to establish unit operating characteristics and baseline operating parameters. The following measurements of pump function and settings were taken:

   For the ALARIS Medsystem III® and the IMED Gemini PC-1®

   a. Flow rate at 20 mL/h (KVO), with total volume 20 mL

   b. Flow rate at 100 mL/h, with total volume 100 mL

   c. Flow rate at 400 mL/h, with total volume 400 mL

   For the Infusion Dynamics Power Infuser*

   a. Flow rate at 200 mL/h, with total volume 200 mL

   b. Flow rate at 1000 mL/h, with total volume 1000 mL

   c. Flow rate at 2000 mL/h, with total volume 2000 mL

*** The Power Infuser is designed as a high-volume rehydration pump and cannot be set to the levels of the other two pumps.**

5. The IV pumps and calibrated containers were set up in the NEDU treatment chamber, and results from the parameter settings were recorded at 30, 60, and 165 fsw.

Test Parameters at Treatment Depths in the Chamber

On the surface, the IV pumps were set at one setting within their operating ranges. The chamber was then compressed to 30, 60, and 165 fsw. Upon reaching each depth, the inside tender monitored the units for one hour and measured each pump's output in the calibrated cylinders. Each test was repeated four times at each setting at each depth, and all results were recorded and reviewed.

EQUIPMENT AND INSTRUMENTATION

- Infusion Dynamics Power Infuser
- ALARIS Medsystem III®
- IMED Gemini PC-1®
- Three (3) 1000-mL calibrated cylinders
- NEDU treatment chamber

RESULTS

The batteries, tested per NEDU Test Plan 01-23, were found to be safe. Their discharge times are listed in Table 1.

Table 1.
Operation after 24-hour charge

Pump	Predive Duration	Postdive Duration
IMED Gemini PC-1®	7 hours, 30 minutes	8 hours, 10 minutes
ALARIS Medsystem III®	8 hours, 10 minutes	8 hours, 0 minutes
Power Infuser	10 hours, 15 minutes	N/A

The pumps were set up in the NEDU treatment chamber and operated at the specified settings (see **EXPERIMENTAL DESIGN AND ANALYSIS**, Test Parameters, 4), and pump outputs were measured and documented as shown in Table 2.

Table 2.
Pump output volume as measured by calibrated cylinder

IMED Gemini PC-1®	DEPTH (fsw)	SETTING	cycle 1	cycle 2	cycle 3	cycle 4	Standard Deviation
	0	20 mL/h	20 mL	20 mL	21 mL	20 mL	0.5
	30	20 mL/h	20 mL	20 mL	20 mL	20 mL	0
	60	20 mL/h	22 mL	22 mL	20 mL	20 mL	1.15
	165	20 mL/h	20 mL	20 mL	20 mL	24 mL	2.0
	0	100 mL/h	100 mL	102 mL	100 mL	100 mL	1.0
	30	100 mL/h	100 mL	102 mL	102 mL	102 mL	1.0
	60	100 mL/h	102 mL	102 mL	102 mL	102 mL	0
	165	100 mL/h	103 mL	104 mL	104 mL	100 mL	1.90
	0	400 mL/h	410 mL	405 mL	400 mL	415 mL	6.45
	30	400 mL/h	430 mL	425 mL	415 mL	425 mL	6.29
	60	400 mL/h	425 mL	415 mL	425 mL	425 mL	5.0
	165	400 mL/h	400 mL	410 mL	412 mL	446 mL	20.03

ALARIS Medsystem III®	DEPTH (fsw)	SETTING	cycle 1	cycle 2	cycle 3	cycle 4	Standard Deviation
	0	20 mL/h	20 mL	19 mL	20 mL	20 mL	0.5
	30	20 mL/h	19 mL	20 mL	20 mL	Alarm	0.58
	60	20 mL/h	22 mL	20 mL	20 mL	20 mL	1.0
	165	20 mL/h	20 mL	20 mL	20 mL	20 mL	0
	0	100 mL/h	102 mL	102 mL	100 mL	102 mL	1.0
	30	100 mL/h	100 mL	100 mL	100 mL	100 mL	0
	60	100 mL/h	102 mL	100 mL	102 mL	102 mL	1.0
	165	100 mL/h	102 mL	104 mL	100 mL	104 mL	1.91
	0	400 mL/h	405 mL	410 mL	405 mL	405 mL	2.5
	30	400 mL/h	400 mL	400 mL	410 mL	Alarm	5.77
	60	400 mL/h	410 mL	415 mL	425 mL	425 mL	7.5
	165	400 mL/h	420 mL	410 mL	400 mL	412 mL	8.23

Power Infuser	DEPTH (fsw)	SETTING	cycle 1	cycle 2	cycle 3	cycle 4	Standard Deviation
	0	200 mL/h	206 mL	208 mL	210 mL	198 mL	5.26
	30	200 mL/h	168 mL	189 mL	184 mL	170 mL	10.34
	60	200 mL/h	205 mL	198 mL	210 mL	200 mL	5.38
	165	200 mL/h	200 mL	200 mL	200 mL	200 mL	0
	0	1000 mL/h	890 mL	890 mL	950 mL	950 mL	34.64
	30	1000 mL/h	1015 mL	1000 mL	1020 mL	1000 mL	10.31
	60	1000 mL/h	910 mL	910 mL	920 mL	Alarm	5.77
	165	1000 mL/h	950 mL	960 mL	940 mL	960 mL	9.57
	0	2000 mL/h	2000 mL	2050 mL	1990 mL	2000 mL	27.08
	30	2000 mL/h	2050 mL	1980 mL	1850 mL	1900 mL	88.13
	60	2000 mL/h	1925 mL	2000 mL	2050 mL	1870 mL	79.62
	165	2000 mL/h	1950 mL	1800 mL	1700 mL	1820 mL	102.75

DISCUSSION

Technical review of supporting documentation for each of the three IV pumps found no components that caused significant concern about their use in the hyperbaric chamber. When batteries were removed and evaluated, all were found to be safe and functional. The IMED Gemini PC-1® and the ALARIS Medsystem III® pumps were placed on their respective chargers for 24 hours to ensure that their batteries were fully charged. The Power Infuser operates on AAA batteries, which already are authorized for chamber use and do not require charging.

Each pump was operated until its battery discharge was low enough to cause a low power alarm. The pumps were then pressurized 11 times, after which they were reexamined. The IMED Gemini PC-1® and ALARIS Medsystem III® batteries were recharged and operated until a low power alarm was given (see Table 1).

During testing at depth, low power alarms from the IMED Gemini occurred on two occasions. Once, 30 minutes into the fourth cycle of 100 mL/h at 30 fsw, the alarm sounded, but the pump continued to operate until the end of the test, with no apparent change in the flow rate. The unit had been in operation for five hours at the time of this alarm. The second alarm occurred 45 minutes into the fourth cycle of 11 mL/h at 60 fsw; again, the pump completed the cycle with no change in its flow rate.

To assess the functional characteristics and establish the performance accuracy of the units, each IV pump was operated at the surface. As the results of Table 2 show, the Power Infuser is designed as a rehydration pump and is unable to deliver the small volumes that the other pumps can. The ranges set during the testing represent low-, mid-, and high-output ranges for each of the pumps.

Once the accuracy of the pumps was established, the chamber was compressed to 30 fsw, and the pumps were operated through four one-hour runs at each of the given drip rates. The amounts collected in their calibrated cylinders were measured, and these cylinders were emptied at one-hour intervals. After the cycles at 30 fsw were completed, the chamber was compressed to 60 fsw, and all tests were repeated. Because of concerns about the decompression status for the inside tenders, the first cycles were for one hour, and the following three cycles at 165 fsw were shortened to 30 minutes, with the measured volume then doubled for charting purposes.

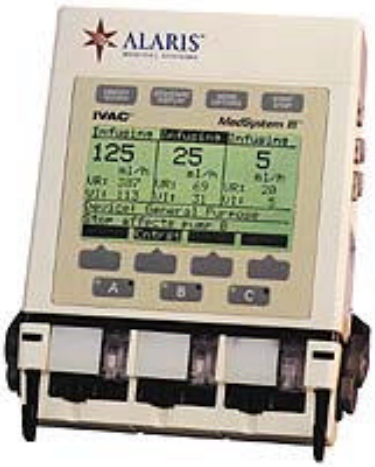
CONCLUSIONS/RECOMMENDATIONS

All three pumps completed all testing with satisfactory results. Each of the three units has particular features that address specific needs:

Infusion Dynamics Power Infuser. This small (9.8 cm x 7.0 cm x 5.0 cm), light (330-g) infusion pump powered by six AAA batteries rated to last approximately eight hours under typical operation can deliver fluids at rates from 0.2 to 6.0 L/h. It uses a scuttle mechanism pump and can deliver fluids to the patient even when the bag and unit are level with or below the patient. Tested by the U.S. Army, the Power Infuser is certified for air medivac use[4,5] and is well adapted to facilities and units with limited available space, particularly to commands with transportable recompression chamber systems (TRCS). Its small size allows the unit to meet space limitations of deploying units. Medications, however, cannot be delivered by this unit: the filter system in its infusion set will easily clog if any substance other than IV solution is passed through it.

Infusion Dynamics Power Infuser

ALARIS Medsystem III®. This medium-sized unit (20.0 cm x 15.2 cm x 5.3 cm) weighs 1828 g and is powered by a nickel cadmium battery with an expected operating time of six hours or more when all three channels are operating. As a hospital intensive care–level IV pump, the Medsystem III can deliver three different medications or solutions simultaneously and can do so with great precision, at rates from 0.01 to 9.9 L/h. Its dose rate calculation function is also capable of delivering complex doses of medication. The pump is sensitive to air in the lines, however, and is often difficult to clear and restart if air or occlusions cause alarms to resound. This unit is a good choice for a hospital-based chamber expected to treat patients with multiple and complex medical problems.



ALARIS Medsystem III®

IMED Gemini PC-1®. As a large unit (8.4 inches x 10.8 inches x 6.5 inches) weighing 11.2 lb, this pump is rugged and versatile. Under normal rates of operation, an internal lead acid battery can power the Gemini for five hours. This unit, which is simple to operate and the least expensive of the pumps tested, can deliver fluids and medications at rates from 0.01 to 9.9 L/h. As a hospital-level pump with enough resilience to be transported to remote locations and into adverse conditions, it is well suited for multifunction hyperbaric treatment units. The pump worked well in all attitudes, both above and below the patient, and since it has been used extensively in military medical facilities throughout the world, most military healthcare providers as well as established biomedical repair and maintenance personnel are familiar with it.

IMED Gemini PC-1®

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