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## **AMXD: A New Extended-Wear Bladder Relief System Developed for the U.S. Air Force**



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## **Abstract**

Omni Measurements Systems, Inc. has developed extended-wear, semi-automatic bladder relief systems for female and male aircrew for the U.S. Air Force. The Advanced Mission Extender Device (AMXD) is designed for extended flights in aircraft without toilet facilities. Use of other bladder relief devices including male piddle packs and female diapers require unstrapping, partial undress, and excessive movement within the cockpit.

Three accidents (two F-16s and one A-10) have been reported involving male piddle packs, resulting in loss of life and aircraft. Some aircrew members also dehydrate prior to long missions in order to avoid relieving their bladders while in flight. Dehydration impairs performance and can lead to serious health problems. Recognizing this problem, the Air Force made aircrew bladder relief the Number Two priority for Life Support in 2004.

The self-powered AMXD improves aircrew members' combat readiness and permits them to concentrate on mission objectives without distractions or interruption. No unbuckling, undressing or maneuvering is required.

The AMXD has undergone extensive laboratory and human testing at Omni's facility, human ground trials at Seymour Johnson and Luke Air Force Bases, and altitude and vibration testing at Brooks-City Air Force Base. The U.S. Air Force is conducting in-flight Safe-To-Fly certification testing during Spring 2006, and the AMXD systems will be available for procurement after completion of this testing.

The AMXD includes a small, battery-operated pump unit, a disposable urine collection bag, a disposable, inflatable cup for males, and a disposable, inflatable pad for females. The lightweight cup and pad are discretely worn under the flight suit and remain in a deflated state when not in use. A small hose is attached to the front end of the cup and pad. To activate the system, the aircrew member retrieves the hose from the flight suit and plugs the hose and a collection bag into the pump unit. The pump inflates the cup or pad to create a reservoir for urine. The aircrew member pushes a button on the pump to extract the urine into the collection bag. Upon completion, the aircrew member detaches the cup/pad hose from the pump unit and places the hose back into the flight suit.

The AMXD system can be used multiple times during a mission. After the mission, the aircrew member disposes of the cup or pad and collection bag. Between flights, a cleaner unit sanitizes the pump unit in seconds, and a charger unit recharges the battery pack.

The AMXD is being repackaged for Chemical-Biological (CB) use so that the entire system can be worn comfortably and unobtrusively inside the CB suit. This capability will allow soldiers to relieve their bladders safely without breaking the seal of their protective suit.

## **The Company**

Omni Measurement Systems, Inc. is a research, development and production company located in South Burlington, Vermont. Mark Harvie, Omni's president and the inventor of the AMXD bladder relief system, has been involved in research, design and development of mechanical and electromechanical systems for the past 25 years. He has successfully commercialized 35 products of his own design through his companies. Omni currently manufactures ten of these products, including compression load cells, digital scale indicators and remote displays. Omni also designs cutting-edge test equipment to evaluate new microchips for IBM, Infineon, Motorola, and Lucent.

# Introduction

Omni has developed safe, odor free, self-powered, semi-automatic bladder relief systems that increase the safety of aircrew members and preserve the integrity of their multi-million dollar, high performance aircraft. These systems permit aircrew to concentrate on mission objectives without distractions or interruption.

Since the attacks on the World Trade Towers on September 11, 2001, both female and male pilots are flying much longer missions (up to 14 hours), and more frequent missions. With normal hydration, the body produces approximately 50 to 100cc of urine per hour. The reflex that prompts the physiologic need to void urine begins when about 200cc of urine has accumulated in the bladder. Therefore, within two to four hours after voiding, the need to urinate recurs.

## Existing Bladder Relief Systems

There are no acceptable bladder relief systems for aircrew members flying long missions in single and dual seat aircraft. Current commercially-available devices were not developed for use in limited spaces or in the sitting position typical of ejection seat aircraft. Most of these devices require the user to unbuckle his or her seat belt and harness, partially undress, and physically move up above the seat to urinate. During this time the user is distracted, jeopardizing control of the aircraft.

To avoid having to urinate, aircrew members will dehydrate themselves before long missions, resulting in mission degradation and long-term adverse health risks. Dehydration can cause headaches, impair mental alertness, lower blood pressure, and increase heart rate. Dehydration is especially serious for aircrew because it reduces tolerance to G forces experienced in high performance flight and increases the risk of G-induced loss of consciousness. (Three percent dehydration reduces G tolerance by 40 percent.) Chronic episodes of dehydration result in concentrated urine, which increases the risk of urinary tract stones that can cause sudden, incapacitating pain.

### Male Aircrew

The piddle pack, a plastic bag containing a urine-absorbing powder, is the bladder relief method most commonly used by male aircrew in the U.S. military. To use a piddle pack, the aircrew member has to loosen or unbuckle his seat belt and harness and use both hands to open the bag and hold it in place. This procedure is distracting, making the pilot vulnerable to sudden changes in weather and other aircraft. The piddle pack can be dangerous to use if the pilot needs to eject from the aircraft while urinating because he is not securely fastened into the ejection seat while urinating. There have been three mishaps caused or contributed to by piddle pack usage. These have occurred in F-16s and an A-10 and have involved loss of life and aircraft. Source: Air Force Safety Center. The average cost of an F-16 is \$16M (FY98 constant dollars) Source: <http://www.af.mil/factsheets/factsheet.asp?fsID=103>

### Female Aircrew

Female aircrew cannot use the piddle packs or catheter/tubing/bag assemblies designed for males. Some female aircrew use adult diapers, which have a number of drawbacks. If the female aircrew member wears the diaper throughout a flight, high G maneuvers can force her downward into her seat, displacing urine from the diaper and leaving her to sit in a wet flight suit for the duration of the flight. The diapers do not have the capacity to hold the amount of urine produced during long flights, so instead of wearing one, she may insert a number of diapers into her flight suit during the flight. To insert the diaper, the female has to unbuckle her seat belt and harness and unzip her flight suit.

Similarly, the female-designed Flight Extender and Lady J devices require the user to unbuckle her seat belt and harness and physically move up above the seat.

## Development of a Solution

Recognizing this problem, the U.S. Air Force approved an Operational Requirement Document (ORD) for a Female Aircrew Member Bladder Relief Capability (FAMBRC) on 10 February 1997 (CAF (USN) 003-94-I-A). The objective of the FAMBRC program was to develop an extended-wear device that provided bladder relief for female aircrew. In May 2002, Omni received a contract through the government-funded Small Business Innovative Research (SBIR) program to develop a bladder relief system for female aircrew for the U.S. Air Force.



Phase I AMXD System



Phase II AMXD System



Phase II Enhancement Male AMXD



Phase II Enhancement Female AMXD

During Phase I (May 2002 through January 2003) Omni designed, developed and tested prototypes of the system. During Phase II (May 2003 through May 2005) Omni refined these prototypes, and conducted in-house human testing and aircrew ground trials at two Air Force bases. Phase II Enhancement, which began in June 2005, is funded by Air Warfare Battlelab, the SBIR program and Air Combat Command. Phase II Enhancement includes safety and environmental testing which was completed in December 2005, Interim Safe-To-Fly certification, which was awarded in January 2006, and Safe-To-Fly testing, scheduled for March 2006. The AMXD will be available for procurement following Safe-To-Fly certification. The U.S. Congress has allocated \$2.1 million in funding for initial procurement of the systems by the U.S. military. The US Air Force requirement is for more than 20,000 bladder relief systems. Omni is developing a Phase III work plan with the U.S. Air Force to modify the AMXD for use by aircrew wearing Chem Bio gear.

# The AMXD System

The AMXD includes a small, battery-operated pump unit, a disposable urine collection bag, a disposable, inflatable cup for males, and a disposable, inflatable pad for females. The lightweight cup and pad are discretely worn under the flight suit and remain in a deflated state when not in use. The aircrew member carries the small pump unit and collection bag in her helmet bag.

A small hose is attached to the front end of the cup and pad. To activate the system, the aircrew member retrieves the hose from the flight suit and plugs the hose and a collection bag into the pump unit. The pump inflates the cup or pad to create a reservoir for urine. The aircrew member pushes a button on the pump to extract the urine into the collection bag. Upon completion, the aircrew member detaches the cup/pad hose from the pump unit, places the hose back into the flight suit, and the pump and bag back in the helmet bag.

The AMXD system can be used multiple times during a mission. After the mission, the aircrew member disposes of the cup or pad and collection bag. Between flights, a cleaner unit sanitizes the pump unit in seconds, and a charger unit recharges the battery pack.



## System Components

### **Control Unit (Pump Unit)**

The Control Unit removes urine from the Female Pad and Male Cup. When the aircrew member is ready to urinate, she or he attaches the hose from the Pad/Cup to one end of the Control Unit, and a Collection Bag to the other end of the Control Unit. The Pad or Cup automatically inflates. She or he then pushes a button on the Control Unit, which pumps the urine out of the pad or cup through the Control Unit and into a Collection Bag. The Control Unit is powered by a detachable Battery Pack.



**Control Unit**



**Battery Packs**

### **Non-Rechargeable Battery Pack**

The Non-Rechargeable Battery Pack provides the power to operate the AMXD. It uses six AAA alkaline batteries. The battery pack slides and locks into place on the Control Unit.

### **Rechargeable Battery Pack**

The Rechargeable Battery Pack provides the power to operate the AMXD. It uses six NiMH (nickel metal hydride) batteries. The battery pack slides and locks into place on the Control Unit.

### **Female Pad**

The disposable, inflatable Female Pad is worn under the aircrew member's flight suit. When the aircrew member is ready to urinate, she retrieves the pad's hose from the flight suit and plugs it into one end of the Control Unit, and plugs a Collection Bag into the other end of the Control Unit. The pad inflates to create a reservoir for urine, which is pumped out of the cup by the Control Unit and into the Collection Bag. The pad has two models: an F-15 and F-16 model. Each model has two sizes.



**Female Pad**



**Male Cup**



**Collection Bag**

### **Female Undergarment**

The Female Undergarment is worn over the Female Pad to keep it in place. It has two sizes.

### **Male Cup**

The disposable, inflatable Male Cup is worn under the aircrew member's flight suit. When the aircrew member is ready to urinate, he retrieves the cup's hose from the flight suit and plugs it into one end of the Control Unit, and plugs a Collection Bag into the other end of the Control Unit. The cup inflates to create a reservoir for urine, which is pumped out of the cup by the Control Unit and into the Collection Bag. The Male Cup comes in one size.

### **Male Undergarment**

The Male Undergarment is worn over the Male Cup to keep the cup in place. It has two sizes.

### **Collection Bag**

The Collection Bag is a disposable urine collection bag that connects to one end of the Control Unit. Inside the bag, a sheet of super absorbent polymer gels the urine on contact. The standard bag is designed to hold 25 ounces (800 mL) of liquid.

## Disinfectant Cleaner Kit

The Cleaner Kit cleans and sanitizes the Control Unit.



The two parts of the Cleaner Kit (shown left) attach to either end of the Control Unit (center). A Disinfectant Pack (shown right) is poured into the right end of the Cleaner Kit to clean the Control Unit.

## Power Unit

The Power Unit charges the Control Unit batteries between uses.



Power Unit



Power Unit attached to Control Unit

## Testing and Test Results

The AMXD has undergone extensive laboratory and human testing at Omni's facility, human ground trials at Seymour Johnson and Luke Air Force Bases, and altitude and vibration testing at Brooks-City Air Force Base. The U.S. Air Force is conducting in-flight Safe-To-Fly certification testing during Spring 2006, and the AMXD systems will be available for procurement after completion of this testing.

## In-House Comfort and Functionality Testing

Human testing is necessary to provide Omni with data and information regarding the dryness of the pad and cup after voiding, as well as comfort, fit, and potential side effects. The human testing conducted at Omni's facility during Phase II was under the supervision of board-certified urologist Dr. Mark Plante. Dr. Plante is the Director of Urologic Research at the University of Vermont College of Medicine. Through the university's Urology Research Center, founded in 2000, he oversees basic research in bladder outlet obstruction funded by the National Kidney Foundation, as well as clinical research in genital-urinary cancer. He has also authored and co-authored numerous publications.

Four rounds of comfort and functionality testing were conducted with human subjects between April 2004 and January 2005. Female and male test subjects wore and used the AMXD devices for periods of up to eight hours. Modifications and improvements were made to the device between each round of testing. These tests significantly contributed to the development of the device. There were no injuries or health problems reported as a result of the testing.

## **Comfort Testing**

In comfort testing, the test subjects wore the AMXD under a flight suit for up to eight hours at a time. During this time, the subjects sat in a simulated ejection seat, walked and ran. Several modifications were made as a result of the comfort testing:

1. It was determined that the material used to cover the male cup and female pad needed to be softer.
2. The length of the female pad was increased by two inches and the interior of the cup was made larger.
3. The hose connected to the pad was repositioned so it comes out of the pad at a right angle instead of out of the top of the pad, so that it will fit better under a G suit.

## **Functionality Testing**

In functionality testing, the test subjects wore the AMXD under a flight suit for up to eight hours, and used the device when they needed to urinate. As a result of the functionality testing:

1. The pump rate was increased by redesigning the pump to increase its capacity and adding a second tube to the inside of the male cup and female pad.
2. The number of holes in the female pad was increased to allow better drainage of urine into the collection area beneath the holes.
3. The number of buttons on the control unit was reduced to eliminate confusion about which button to push to activate the system.
4. The LCD display was redesigned to be easier to read and provide more information.
5. The method of securing the pump unit on the aircrew member's leg with Velcro was redesigned to be more secure.
6. The size and weight of the pump unit was reduced to make it easier to hold and use.
7. The urine collection bag was changed from clear to opaque, to make it more discrete when used in the presence of others and when disposed of after use.
8. A faster-absorbing polymer was added in the collection bag.

The trials contributed to the final development of the assets to be used in Air Force OUA safe-to-fly testing. Omni then shifted to Air Force ground trials and safe-to-fly testing.

# Air Force Ground Trials

## 1. Seymour Johnson Air Force Base

Aircrew ground trials were held in October 2004 at Seymour Johnson Air Force Base in North Carolina, USA. At the suggestion of the Seymour Johnson participants, several modifications were made to the AMXD:

1. More urine collection holes were added to the female pad.
2. The size of the hose and hose connector were reduced for a better fit below the G-suit.
3. The display on the control unit was improved to provide more information through full graphic characters, bar graphs and symbols.
4. Simplification of the push button that inflates the female pad/male cup and activates the control unit.

## 2. Luke Air Force Base

Additional ground trials were held in February 2005 at Luke Air Force Base in Glendale, Arizona, USA with five female and two male aircrew members. Following these trials, additional improvements were made:

1. Velcro was added to the hose and to the front of the under garment, to hold the hose and hose connector in place when not in use.
2. An adhesive strip was added to the bottom of the female pad to hold the pad securely in place in the undergarment.
3. Absorbent material was added to the wings of the pad to absorb any possible residual moisture.
4. The pad was fabricated in two models (F-15 and F-16) and two sizes, to accommodate the seat angles of the aircraft and female aircrew anatomy.



## Safety and Environmental Testing

The AMXD underwent numerous tests to ensure that the system would be capable of properly functioning over a wide range of environments. The AMXD was tested in its packaging configuration over a temperature range of -20°C to +70 °C, and in active operation over a temperature range of -10 °C to +50 °C. The system was exposed to a humidity range of 10 percent to 90 percent humidity.

Military standard vibration profiles were used to evaluate the AMXD system's performance in randomized and constant vibration environments typically encountered in jet aircraft. Normal operation was observed after exposure to these vibration environments. Vibration testing on the AMXD was completed at Brooks-City Air Force Base in Texas.

To ensure correct operation of the device within high performance aircraft, Omni tested the AMXD according to Air Force altitude test requirements (MIL-STD-810F), in high altitude and rapid decompression scenarios. Additionally, the AMXD was tested in an explosive environment according to MIL-STD-810F.

The AMXD was not a source of ignition in an explosive gas mixture across the temperature and pressure ranges outlined in that specification.

The AMXD was evaluated for electrical interference and was found to comply with electrical interference standards including electromagnetic interference standard MIL-STD-461E and electrostatic discharge standard EN61000-4-2.

Drop testing was performed on a production-equivalent AMXD control unit. OMSI designed the internal pump assembly of the control unit so that the unit would successfully pass drop testing. The control unit successfully survived repeated drops onto each of its axes from a maximum height of three feet.

OMSI evaluated the cockpit compatibility of the AMXD to ensure that the system would not interfere with any cockpit or aircrew systems in high performance aircraft. This testing was done using F-16 cockpit simulators at the Vermont Air National Guard Base Vermont, in addition to in-house testing in a simulated ejection seat. The AMXD was found to be compliant with existing aircrew ensembles and non-interfering with cockpit exit procedures.



Explosive Atmosphere Testing



Collection Bag Capacity Testing

## **Future Applications for Omni's Bladder Relief System**

The company is currently seeking funding to develop the AMXD for use by ground troops wearing Chem Bio gear.

Potential civilian applications for the Omni Bladder Relief System include female and male urgency incontinence patients; incontinent elderly; civilian pilots and passengers in aircraft without toilet facilities; glider pilots; astronauts; rescue workers in hazmat suits; long-distance truckers and race car drivers; armored car drivers; long distance train staff; security forces, and surgeons performing extended operations.

## **Biography of Author/Presenter**

Jerry Reid is a Consultant to Omni Measurements Systems, Inc. on the Advanced Mission Extender Device (AMXD). Mr. Reid retired from the U.S. Air Force in 2000 as Chief, Aircrew Life Support where he was responsible for the planning, development, fielding and system maintenance of more than 10,000 U.S. Air Force Life Support items and the execution of 11 life support acquisition programs valued at over \$300M. He has over twenty-eight years of government-related operations and program management with emphasis on business development and execution in the aerospace and logistics industries. He has Masters Degrees in Business and Aviation, in addition to certifications in Program Management, Contracting and Acquisition Logistics.