

CASE STUDY

ABRD - AMXDmax Bladder Relief System Testing and Trials

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ABRD – Advanced Bladder Relief Device

AMXD – Advanced Mission Extender Device

AMXDmax – Advanced Mission Extender Device GEN II

ABSTRACT: Omni answered an Air Force request to develop a bladder relief device for aircrew, such as fighter pilots, who are without facilities for missions of longer duration. Mark Harvie, President of Omni Medical Systems, was awarded the Air Force sponsored *Small Business Innovative Research* grant to develop the bladder relief device.



Case study subject testing the AMXDmax with Air Force issued cold weather and dry suit ensembles.

INTRODUCTION: Ken Hurd, Director of Research & Development at Omni Medical Systems joined Omni early in the program, working closely with Mark Harvie to develop a comfortable, effective system of bladder relief. The device was developed to be deployed to aircrew in a variety of aircraft, including F15, F16, F22, A10, helicopters, etc. The system has progressed to a smaller, refined device making it a viable, hands-free, urine collection system for military use. The case study has longevity testing for the product, which is the focus of this case study. The case study resulted in no adverse events when using the ABRD (AMXDmax) for extended periods of time, such as rashes or irritation.

RESULTS:

CASE 1: AMXD INITIAL DEVELOPMENT TESTING

As the product evolved into a functioning handheld device, a bladder relief log spreadsheet was kept. This spreadsheet was created to manage critical testing and development. It also provided notes to identify product improvements. Data includes times, dates, clothing worn, AMXD System description, urination amounts and other key information. As most entries are documenting System use by the case study subject, there are also entries from Mark Harvie and female test subjects.

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228 urination events were logged from November 2004 through March 2006. The AMXD System testing was performed with a variety of Air Force Flight ensembles, including warm and cold weather suits; Chem Bio suits; and a poopy (dry) suit. The System was also tested in different types of cockpit seating. Omni Medical Systems used an ACCIS II Ejection seat for most of its testing; however configured the tilt for all airframes from A-10, F-15, F-16, F-18, F-22, Apache and UH-60 Seats. Omni also fabricated wooden mock-up seats for the F-35 and Eurofighter. Omni borrowed Bell 222, Black Hawk UH-60, CH-47 Chinook and Civilian 206B III, R 22 Robinson. The System was again refined, and design iterations were tested by wearing the device in everyday activities, which were often more vigorous than being buckled into an ejection seat.

The case study subject was able to discretely wear the system and test it on a daily basis. This contributed to additional product improvements and led to modifications in cup design and undergarments to ensure comfort and proper fit. The AMXD was tested walking, climbing stairs and ladders, and sitting in a variety of seats. These seats included ejection seats, wheelchairs, executive conference chairs, automobiles, and a downhill ski chairlift. The case study and other engineering test subjects spent numerous hours wearing and using the AMXD and AMXDmax while at their desk, driving, skiing, snowboarding, and laying on their backs. The System did not restrict any activity.



Case Study Subject using the AMXD while motocross racing and pond skimming

CASE 2: AMXDmax URINATION LOG FILES

Longevity human testing with case study subject using autosensing AMXDmax:



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Formula Ford, (test day) at Cherry Hill Track Case Study Subject seated in Formula Ford



Case Study Subject field testing the 1st AMXDmax sensor activated fully automatic System

The case study subject was able to wear the cup during race testing, while urinating comfortably without leaking, in a seated stationary position with a safety harness. The System was hands-free, being that this early generation of the AMXDmax was equipped with automatic urine detection. Urination while racing was not convenient on this track, as there was no “level and steady” time to urinate. The track was made up of mostly corners and the car cornered at 1.6G’s.

In February 2010 Omni started trials on six case study subjects. The case study subjects wore the AMXDmax system for 42 consecutive days with an average use of 12 to 16 hours per day. The testing started February 2, 2010 and concluded on March 23, 2010.



AMXDmax System



Case study subject mono-skiing while testing the AMXDmax

The tests included driving, skiing, snowboarding, mono-skiing, auto repair, and working in an office (where the subject frequently used the stairs to access different parts of the building). During the testing stages, Omni was asked if the System would provide bladder relief for an interested (Tampa Florida VA) physician while mono-skiing. Omni then arranged with Bolton Valley Adaptive Ski Center in Vermont to test a System while mono-skiing (mono-skiing is what is used by paraplegics). The case study subject used the AMXDmax System strapped on the mono-ski as a paraplegic, immobilizing his torso and legs, while being guided by an instructor. The AMXDmax System worked as intended; the case study subject was able to urinate and stay dry, all while doing strenuous activity. The instructor that accompanied the subject was unaware that the subject had urinated while mono-skiing. There was no wetness (leaking), discomfort or skin irritation using the System.

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The AMXDmax significantly increases the amount of time spinal cord injury patients are able to ski. This is yet another demonstration on how easy the system is to use and adapt to normally difficult situations.

Between January 2009 and January 2011, the case study subject logged another 238 urination events using the RS232 port on the AMXDmax. These records include date, time, sensor, and pump and battery data. (Some of the test runs used simulated urine).



Subject ejection seat testing



Subject pond-skimming at Bolton Valley Ski Area in VT

Example Log Entries:

March 9: used from 8:30AM to 1:00AM at office.

March 13: used from 10:30AM to 11:59PM (14 hours). Used for 3 hours while skiing.

March 14: used from 10AM to 11PM (13 hours). Used while on the ski lift.

March 20: used during 3 hours of snowboarding.

March 22: used from 8:30AM to 12:30AM (16 hours).



Case study subject testing the AMXDmax System in environmental chamber temp -10C to 55C

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CASE STUDY RESULT CONCLUSION:

The case study subject estimates usage of the AMXDmax System over 600 times with 350+ hours logged, including 42 consecutive days of use in a human testing trial. This 42 day period had an average usage time of 12 hours. There were also days when the case study subject used the System for 16 hours. The case study subject did not experience any incidence of rash or skin irritation. The subject was not restricted from any activities while wearing the System, short of wearing a bathing suit. The subject urinated while using the AMXD System skiing, snowboarding, mono-skiing, driving, sitting in a race car, walking, lying down (slightly reclined), and various everyday activities, such as working in an office setting. The subject's most notable uses with the AMXD System were several rides in the car, when he urinated successfully and comfortably with no adverse events.

Omni received a PHASE I SBIR contract with the ARMY and developed several concept versions of the AMXDmax for use by ARMY Warfighter in Chemical Biological protective gear for both on the ground and in the air. Unfortunately, SBIR funding was not available for PHASE II.



Case study subject in Chem Bio suit testing Omni's proof of concept AMXDmax (ABRD) for Army SBIR Waste Management Contract.

With the success of the AMXDmax being used with the active duty military, a similar need was met, with the ever growing incontinent civilian population. Omni Medical Systems has spiral developed a product for civilian use as well and has been extremely successful in providing an alternative approach to bladder management for patients who suffer from complications of Urinary Incontinence.