

MARKET AND TECHNOLOGY OPPORTUNITY ASSESSMENT

prepared for

PRECISION DESIGN, INC.
Weatherford, OK

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PROJECT OVERVIEW AND ASSESSMENT SUMMARY

Client: Precision Design, Inc.
Weatherford, OK

Request: Technology assessment
Assessment of market opportunity
Creation of promotional market opportunity document

Contact: Mr. Craig Easter

Technology: Vacuum Assisted Relief System (VARS) for the collection and removal of urine (and other waste).

Overview of Method and Deliverables:

Deliverable 1: Market characterization and technology assessment

Deliverable 2: One page 'Market Opportunity' document

Research using private and public database resources via the internet was conducted to determine the characteristics and size of the market opportunity. Determination of the *potential* or market size was developed using reliable statistical databases and reputable industry and professional journals. Statistics were gathered from various US census and allied databases.

A report characterizing the Medically Needy market opportunity was prepared. This report includes the discovery or recognition of a silent and growing market niche for VARS technology. These are included in Deliverable 1.

A brief 'Market Opportunity' document was prepared using the market and technology assessment information developed in the preparation of Deliverable 1. The document was developed in close conference with Mr. Easter to suit his specific needs. New intellectual property was created in the form of graphs to illustrate the findings.

Summary Conclusion:

The VARS technology offers a unique approach to the management of urine collection for both the targeted population of confined users such as pilots or hazardous materials workers and the incontinence markets. The VARS technology has market niche opportunities for the institutional markets (hospitals and nursing homes) and the 'vital' males and females for whom few real alternatives exist. The market opportunity for incontinence products is a \$12-Billion per year industry. The work for this document has lead to the identification of potential commercialization partners and methods of production and manufacture that will become part of the commercialization planning process.

THE TECHNOLOGY

The Vacuum Assisted Relief System (VARS) provides a unique and revolutionary solution to the management of urine for both males and females engaged in long-duty confined assignments in aviation, space travel, and hazardous industries. The technology also has important opportunities for commercial, institutional and individual personal applications.

The patent applied for technology consists of a specially designed state-of-the-art fabric sandwich of advanced materials and a proprietary collection, aggregation and liquid removal system. A distinguishing characteristic of the VARS is its unisex design that can be worn under existing uniforms, flight suits or typical business or casual clothing by either male or female users. This is important not only to the military and space applications but for civilian, institutional and personal hygiene markets.

VARS has been developed in response to United States Department of Defense (DOD) need for urine collection for pilots and others on long continuous duty missions under DOD contract at a combined state and federal investment of \$125,000.00 and is the first advanced system of urine management offered to these several communities of users in more than 50 years. Precision Design, Inc. of Weatherford, Ok owns the intellectual property and controls all commercialization opportunities for the product.

Background

Devices or systems that attempt to fill the need for urine collection and management are referred to as UCD's or Urine Collection Devices. Other government agencies and organizations have personnel with the same or similar needs. One similar technology developed by the National Aeronautical and Space Administration (NASA) was discussed in a press release in the March 30, 2003 issue of *Medical Devices & Surgical Technology Week* (1). The NASA device is described as a urine collection device for males. This is important because like many other devices of this kind they are tailored specifically and solely for males. It is also important to note that while NASA is seeking to commercialize the product to recoup its investment it is simultaneously seeking better solutions for the problem

The VARS technology was evaluated for both 'government' and civilian market opportunities. We will discuss aspects of both these markets under the "MARKET" section of this report. With respect to validation of the technology this has been established by the award of Phase I SBIR funding and the invitation by the DOD to re-apply for a Phase 2 award. The federal government acting through the Department of Defense has demonstrated their validation of the technology by their willingness to fund further development of this product. The question then becomes "Are there other valid opportunities for this technology?" We believe that the answer to this is a strong, "Yes" as we will define in this report.

The status of the intellectual property of PDI's technology is presently "patent pending" with a full patent application being prosecuted with the United States Patent and

Trademark Office (USPTO) by Robert Platt Bell, Registered Patent Attorney,
Alexandria, VA.

Ease of Manufacture

The technology utilizes off the shelf components combined in a proprietary way to create a new and novel device. For instance, the advanced textiles used to capture and 'wick' urine in VARS was designed for use in human applications and is being used to perform that function in this new device. Likewise, micro vacuum pumps and tubing are being used in the same kind of applications only in a new configuration or device. Anticipated model improvements for targeted niche applications such as wetness alarms also utilize existing technology. From a purely technological point of view this may make the invention appear pedestrian; however, in this case we believe that this is a potentially disruptive technology that presents limited manufacturing challenges. The manufacture or fabrication of this device should encounter few major manufacturing obstacles. There are several paths available to market for this device which include but are not limited to complete device manufacture, contract manufacture of components with assembly and licensing without manufacture. (2)

THE MARKET

The market opportunity for this product is any situation or individual that requires the collection and management of urine. The market is divided into targeted segments as follows -

- Military and Commercial aircraft pilots
- Space transportation and space industry
- Medically needy
 - Male Incontinence
 - Female Incontinence
 - Children and Teen Incontinence
- Special applications
 - Nuclear Biological Chemical (NBC) responder gear
 - Long duty assignments – truck drivers
 - Extreme environment
 - Entertainment / News confined assignments

The Medically Needy segment is significant in terms of size and growth potential.

THE ADULT MEDICALLY NEEDY MARKET

VARs vs. The Competition

The products offered to this population include catheters, an invasive, uncomfortable device prone to infection; and diapers, which are a larger version of infant diapers.

The Foley catheter was first marketed in 1934 by C. R. Bard and catheter technology has not improved significantly since. It is still an invasive procedure where a flexible tube is inserted to provide a channel for the removal of waste liquids with the target of product improvements directed toward reducing discomfort and infection.

The disposable diaper was invented in 1950 by Marion Donovan, and while there have been minor changes with advances in textiles and materials, it is still an infant's diaper intended to absorb liquid and creates a damp, uncomfortable and inadequate alternative for adults.

VARs, on the other hand, is a novel approach to the problems faced by adults who have need for urine management. As describe earlier it utilizes state-of-the-art technology to deliver a product that eliminates the damp and unconformable aspects of a diaper by moving liquid away from the wearer and significantly minimizes the potential for infections because it is not invasive.

The Aging Population

While we are all aware of the growth of the ageing population it is important to look at the actual data and projections which we believe further support the need and opportunity for VARs.

The following table is based on US Bureau of the Census projection of the age 65 and over population (3) :

Age 65 + Population Projections in Millions					
Year	1995	2000	2010	2030	2050
Millions	33.5	34.7	39.4	69.4	78.9

Table 1

The US Census Bureau and Agency on Aging (3) estimates that 5 % of the aged population suffer from one form or another of incontinence. These data have been combined in a new graph below. We can see in Chart 1 that the projected over age 65 incontinent customers for the technology reaches 2-million by 2010.

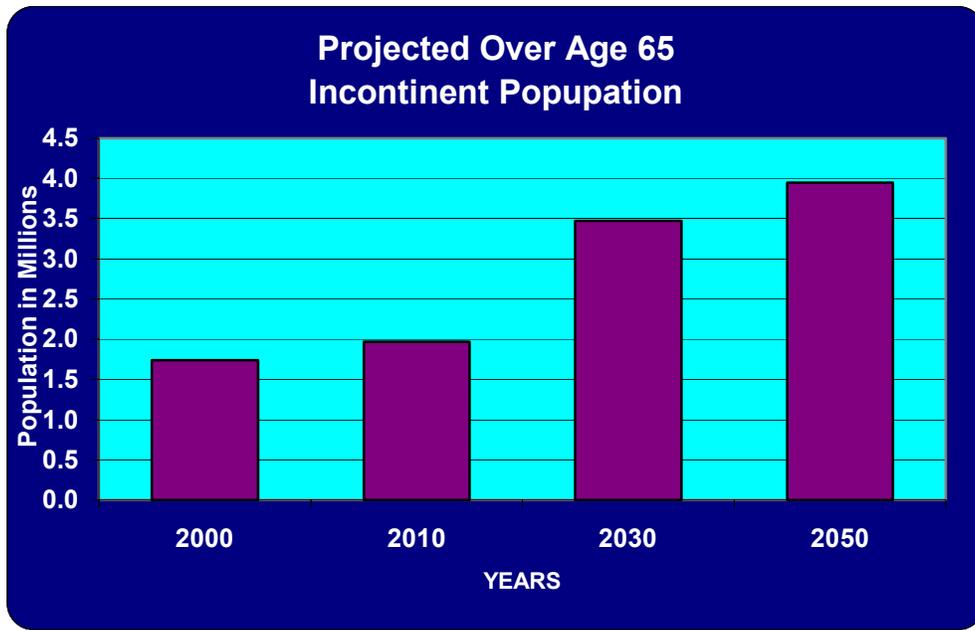


Chart 1
 Copyright Precision Design, Inc. 2003

The Institutional Market

Incontinence is managed in two distinct settings or modalities – institutional and personal or retail. The following chart is based on data from the US Bureau of Census and the Agency for Aging and depicts the rising costs of caring for the incontinent in institutional settings (hospitals, nursing homes):

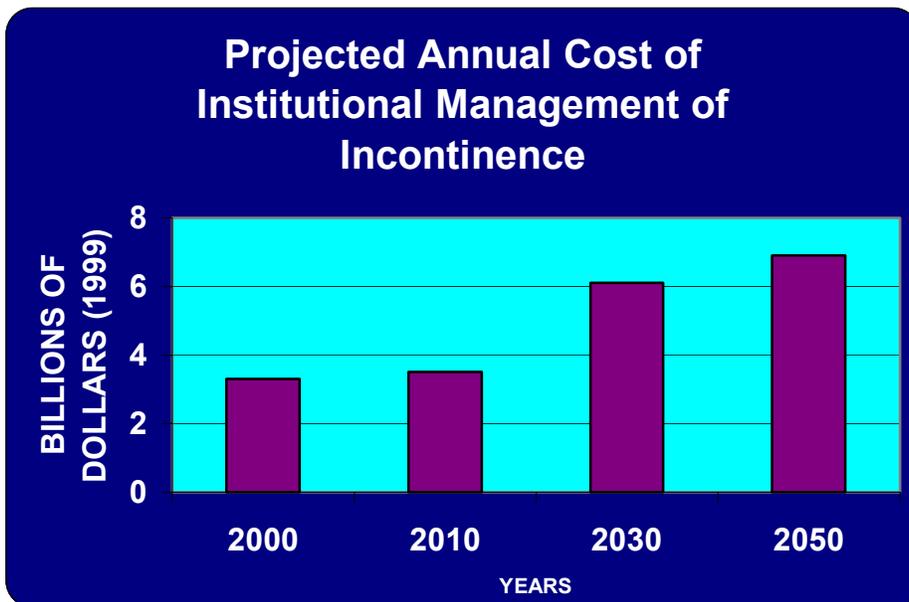


Chart 2
 Copyright Precision Design, Inc. 2003

The costs of care are divided among Labor, Product and Washing textiles. This is illustrated in the graph below prepared based on the US Bureau of the Census data and the Agency for Aging. (4)

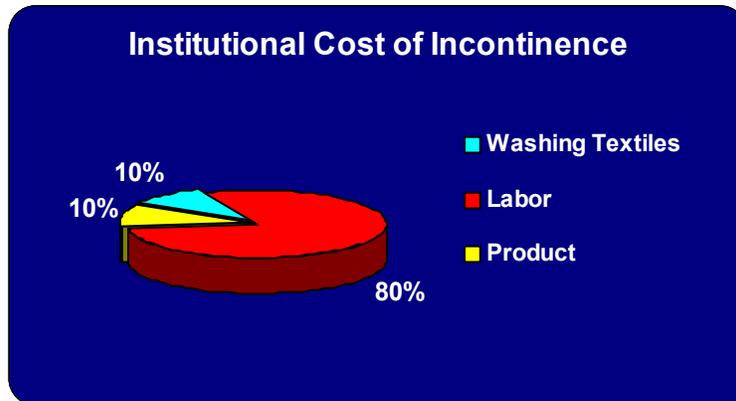


Chart 3
Copyright Precision Design, Inc. 2003

The institutional segment is characterized by hospitals and nursing homes where the typical user is a 75 year old female who has no impact on the purchasing decision. In the U.S. these products enter the market through distributors who represent a variety of me-too products. The VARS technology has a unique opportunity to distinguish itself in this market space by reducing the labor costs associated with the management of incontinence. It is estimated that the institutional care providers spend more than \$6.8-million per day on labor alone with another \$3.8-million per day on adult diapers. A significant study demonstrated that elaborate protocols in institutional settings can reduce the number of toiletings and associated problems such as bed sores however the costs far exceed any savings. (5) This reinforces the fact that this market needs the advantages that only technological innovations, such as VARS, can bring to bear on this costly problem. There are opposing product objectives in this arena. While there is a recognized need for high performance products on the one hand there is also pressure for lower cost products on the other. This puts the VARS technology in an enviable position to become a quality competitor in this market. Chart 4 depicts potential *annualized labor cost savings* to the Institutional Market based on anticipated advantages of the VARS technology based on trials conducted by Precision Design, Inc.(6).

VARS technology will reduce both the cost of labor and 'diapers' associated with management of incontinence in institutional settings by as much as 50%. By 2010 the potential annual savings to the institutional health care industry could be more than \$ 370-million thereby enhancing the likelihood that VARS technology will become the product of choice for institutional settings.



Chart 4
Copyright Precision Design, Inc.

The Retail Market

There are two important aspects of the retail market that should be examined closely. First, the ever increasing portion of the population that is over age 65 and second, the career or active woman in her prime sidelined by incontinence.

We have examined the statistics and projections for the Over 65 aged group. The population of active women is a hidden market. As we have learned from showing the product at one trade show in general people are uncomfortable discussing the topic of urine collection or incontinence.

International Player Sees Growth Ahead

Svensk Cellulosa Aktiebolaget, SCA a Swedish company is a major player in the diaper and personal incontinence market space for both retail, Serenity® and the institutional market with Tena® brands. In the report to investors in 2001 Scott Jungles, of SCA's Global Incontinence Care division said, "Demographics are in our favor. I see huge long term growth opportunities in the incontinence market." Their strategy is to be the leader in North America, they are the leader in Europe, or a strong number two player. (7)

The Personal Market

The best description of the present state of technology for medical needy incontinence is best described by the following quote from a male visitor to an online incontinence newsgroup:

"Okay, not that I need to stir up (pun not intended, but I'll take what I can get) I am 39 years old, and am very active. I also happen to have a bladder problem.

"I read the info on the home page and it sounds like you folks understand the added stress this gives to ones live. With that said, "what will it take to get diaper made (I prefer the brief to those other leaky products) that will work like a pamper?"

"Has anyone tested to see how much volume is released and at what speed it flows for adults. I have 5 kids and put them all trough diapers without nearly the hassles I've had for myself.

"Realizing that changing during the work day is all but impossible, ...is there a way to get a product that will hold more than a cup in the crotch as that's where it all goes when released? I mean there's a puddle in the middle and you have to be aware enough to know you just went so you can position yourself appropriately so you don't leak all over yourself.

"I already bought the larger clothes. I even bought larger underwear to wear over the brief to quiet the noise. But if the products don't work to stop leaking and embarrassment, then why am I paying for them?"

"Please, I beg you, find a solution, I promise I'll even pay more for something that actually works right.

"Here, as an example is what I have to do each morning before work... Put a Longs Overnight diaper on the bed, then using scissors I cut the tapes and elastic from a size 6 baby diaper and slice it down the middle of the plastic covering and place it in the middle of the overnight longs diaper. I put this on making sure that [sic] mr happy is not only pointed south, but in the center of this makeshift diaper so he won't point toward the leg opening.

"Then I strap all these tape strips (it's like tying an octopus to your ass). Now I am ready to get dressed and say a prayer that I won't leak.

"I have talked to others in support groups that agree, [sic] thwe company that come out with a true adult incontinent product for adults that really work, [sic] will be the maker of the only products worth buying.

"For kids they made products that were sex specific. "More in the front for boys", or "More in the middle for girls". For adults there needs to be more in the front and the middle. :) " (8)

The striking thing about this post is that it is from a male and males have more options than females.

The Female Taboo and Opportunity

Suffering in silence. Embarrassment.
Rendered life in tolerable. Depression.
Missed career opportunities.

All are phrases that women afflicted by midlife incontinence use to describe the devastating affect on their lives. It is estimated that as many as 10 million US women between the ages of 40 and 60 -or- from 20% to 50% of all women from age 40 to 60 suffer from some form of incontinence and that they spend \$10-Billion annually searching for help. (9)

While there are several products available for men with incontinence there are few options for women other than a wet diaper. To date, the pharmacological therapies and surgical interventions of the medical model have met with disappointing results

VARS offers these women an alternative that can help them continue to lead an active personal and career life. Its design has the potential to be comfortable and discrete. It allows a career woman to go about her daily routine without embarrassment or interruption. The only restriction would be the wearing of trousers with the present design, which has become an acceptable mode of dress in the workplace.

Illustration 1 shows the adaptability of the VARS unisex design for both female and male users. (10)

VARS

Versatile UNISEX Design

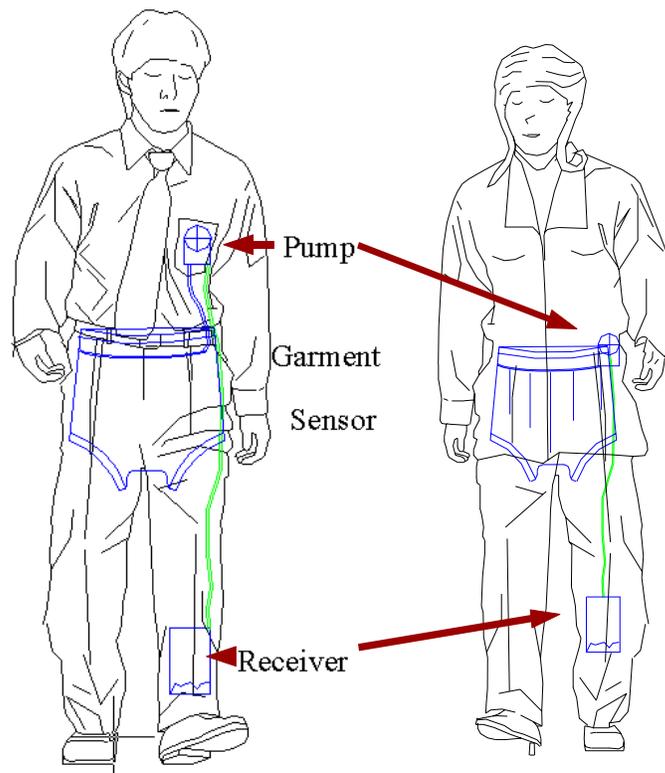


Illustration 1
Copyright Precision Design, Inc. 2003

The Incontinence Industry Gears Up

The potential of this market is easily determined by looking at how the companies that presently serve it and their raw materials providers are responding to the opportunities.

Super Absorbent Products Industry Builds Capacity

Adsorbent material is a segment of the large 'non-wovens' textile industry. A private market intelligence report on the non-wovens industry in North America (9) indicates that half of the world's supply of these materials is manufactured in North American and is one of the few sectors of textiles to show steady growth. It is also a segment with a large export surplus while most others are threatened by low cost imports.

This section of the textiles manufacturing industry serves the infant and adult diaper market so a look at them is very telling. An article in *Technical Textiles International* in the Jan/Feb 2003 issue (12) predicts that the European adult incontinence market will grow 14% per year and fuel the growth of Super Absorbent Products (SAP). The market pressures driving the growth are:

- Continuing increase in the elderly segment of the population
- Trend toward increased use of SAP in each 'unit' of product
- Greater public recognition of adult incontinence

The same market pressures exist in the United States as well.

These growth trends are considered significant enough for major manufacturers of SAP to build additional manufacturing capacity in response, such as

- BASF has a new plant with 100KT capacity announced in Sept. 2002
- DOW adding 35 KT of capacity

Also new product introductions are being made by

- Kolon Chemical
- Lysaa Technologies
- Nippon Shokubai

This confirms that the non-woven portion of the textile industry is thriving, anticipates sufficient growth in the adult incontinence market to invest capital in increased capacity based on the projected needs of the adult incontinence market.

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