



Athena Feminine Technologies, Inc

Athena FT and Incontinence

Athena Feminine Technologies, Inc (Athena FT or the Company) owns a proprietary wireless medical device platform. Medical devices are the fastest growing segment of the Life Science Industry. In the USA, medical devices accounted for approximately \$75 billion dollars in 2003. Athena FT's proprietary platform serves as the basis for the Company's current product, and for the development of additional health products to diagnose and treat medical conditions in the pelvic area.

Athena's first product, the Athena Pelvic Muscle Trainer® (known henceforth as the Athena PMT), has been developed to treat and prevent female incontinence. It also has the capability to treat related pelvic floor problems in women. It is the only wireless electrical stimulation product on the market. This breakthrough product provides effective, non-invasive relief of stress, urge or mixed incontinence, and can be used in the privacy of the home. In the United States, the product's unique incontinence solution has been recognized by two of the most prominent groups involved in consumer and professional education, the National Association for Continence (NAFC) and the National Association of Nurse Practitioners in Women's Health (NPWH). In the United Kingdom, the product's unique solution has received the support of Dr. Chris Steele, the #1 TV doctor.

Women and Incontinence

Approximately 33% of women around the globe will experience incontinence at some point in their lives. For many it begins during pregnancy. In others it develops with age, obesity, or neglect, and is often caused by the weakening of the pelvic floor muscles. Most women suffer silently. Only a small percentage seeks out medical treatment. They do not understand that incontinence is not a normal condition or that there are easy and effective treatments. Many give up activities that are important and enjoyable in order to avoid the embarrassment of wet clothes and odor. Their sexual lives often suffer as well. The inability to deal with incontinence is the #1 reason for women entering nursing homes in the USA.

Current treatment options include drugs, surgery, and exercise/rehabilitation of the pelvic floor muscle through Kegel exercises or electrical stimulation. The Athena PMT® is the only wireless electrical stimulation device for rehabilitation and maintenance of the pelvic floor muscle. It can be used by women in the privacy of their homes and at their convenience. In addition to improving muscle tone which diminishes incontinence, a bonus "side effect" of the PMT is often an improvement of sexual satisfaction. The clinical opportunity is expected to continue growing in proportion to the aging of the population, particularly with the aging of the baby boomers and the trend toward more active senior lifestyles.

The World Health Organization estimates that there are over 182 million women in the world that are incontinent. The current USA incontinence marketplace exceeds \$16.3 billion per annum. In addition, the Athena PMT has a role in preserving pelvic floor health in women who have not yet developed incontinence ("inner fitness"). As the population ages, prevention of incontinence is of vital necessity in health care. Beyond the female incontinence marketplace, there is a significant role for the Athena PMT in the treatment of sexual dysfunction and other vaginal health problems such as prolapse, pelvic and vulvae pain. Under certain circumstances, it may also have the potential to treat male incontinence problems after prostate surgeries.

In the USA the Athena PMT is a prescription-only product, whereas in most other countries throughout the world, it is sold over-the-counter directly to the consumer.



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Athena FT Technology and Products

Athena FT's proprietary wireless technology allows electrical stimulation to move out of rehabilitation clinics and into the home, where patients can use it discreetly, when and where they please. This significantly increases compliance and outcomes. Athena FT's current product, the Athena Pelvic Muscle Trainer, is the first in a series of devices built around the Company's wireless technology platform. Athena FT has a unique upgrade path for future products. Plans for the future include developing the Athena FT's diagnostic potential to measure certain vaginal bio-marker parameters which are important for both patients and clinicians. In addition, the current product and future products focus is on women with incontinence, the *prevention* of pelvic floor weakness, female sexual dysfunction, certain forms of male incontinence and fertility and infertility.

A Clinical and Regulatory Overview

The Athena PMT received a 510(k) (#K033256) clearance from the United States Food and Drug Administration in December of 2003. This was based upon the results of a small patient clinical study of electric muscle stimulation. The product also received ISO 13485 certification and the Medical Device CE mark, in 2007. Finally, because the PMT uses wireless technology, it also requires a medical frequency license, which was granted in 2004. Future products are under consideration and each will require additional medical regulatory filings.

Competition

Potential competitors to the Athena PMT include Kegel exercises, biofeedback therapy, tethered electrical stimulation devices, pessaries, drugs, and surgery. No other electrical stimulation device on the market which offers wireless technology. This important technical achievement allows the Athena PMT to provide the discretion and portability necessary to move treatment into non-clinical settings such as homes, long term care facilities and in the field for business travelers and military women.

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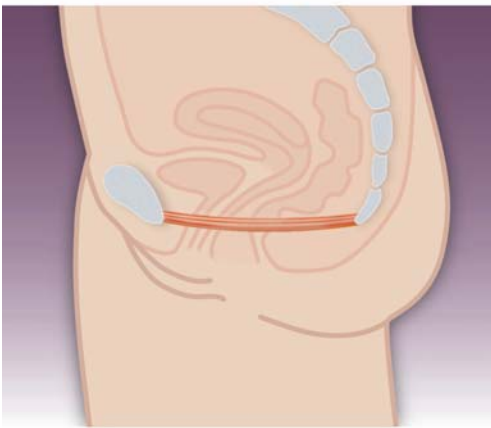
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What is Incontinence?

Incontinence affects most women at some time in their life. It starts gradually and gets steadily worse, yet it can be easily and significantly improved in most cases. To better understand the types and causes of female incontinence, it is important to have a basic knowledge of normal anatomy and function.

The urethra, vagina and rectum all transverse through the pelvic floor muscle. The strength of this muscle plays an important part in regulating the functioning of these areas. The pelvic floor muscles provide most of the strength that regulates the opening and closing of the bladder to urinate.



Strong Pelvic Floor Muscle



Weak Pelvic Floor Muscle



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There are several types of incontinence. The most common include:

Stress incontinence

This occurs when pressure is placed upon the bladder that causes it to leak urine. This condition is often associated with a weakening of the pelvic floor muscle, which acts like a hammock to hold up a woman's (and man's) vital organs. This muscle can be weakened by pregnancy, high-impact exercise, various medical conditions, and aging. When the pelvic floor muscle sags, the internal organs press down upon the bladder, so that a laugh, cough, sneeze, or exercise can lead to the leakage of urine.

Urge incontinence

Involves involuntary leakage of urine accompanied by or immediately preceded by urgency, and is often associated with involuntary contraction of the detrusor muscle, which opens and closes to allow the outward flow of urine. This condition may be seen in overactive bladder.

Mixed Incontinence

Mixed incontinence, the most common form, is a combination of both stress and urge incontinence. The Society for Women's Health Research conducted a study quantifying the significant added medical costs for women treated for SUI in the United States. The findings showed that the incremental, lifetime medical cost of treating a woman with SUI is \$58,000, by comparison with the cost of treating a woman who does not have incontinence. Incontinence is often associated with a weakened pelvic floor muscle. A weak pelvic muscle can lead to:

- Incontinence
- Pelvic Prolapse
- Sexual Dysfunction
- Pelvic Floor Muscle

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Incontinence in Women

Most women do not discuss or understand the subject. They ignore the signs and often think it is normal part of aging. It takes an average of 8 years for a woman to talk with her doctor about any problems they are having with urinary flow control. Because Incontinence is considered an old ladies disease, most women do not consider themselves incontinent.

Incontinence problems affect women of all ages and types:

Athletes:

- 28% to 52% of female athletes suffer from urine leakage during exercise. [3] Bø; “Urinary Incontinence, Pelvic Floor Dysfunction, Exercise and Sport” *Journal of Sports Medicine* 34. 2004 American Foundation for Urologic Diseases AFUD

Mothers:

- In a study by Mason L et al. (*Midwifery*. 1999;15:120-128), the authors reported that stress incontinence was seen in 20% to 67% of women during pregnancy.
- In another study by Dolan, et al., 36% of women suffered from incontinence during pregnancy, and 13% of these women continued to experience incontinence 3 months after childbirth. [4] Dolan, “A Study of Quality of Life in Primigravidae with Urinary Incontinence” *International Gynecology Journal* 15. 2004
- Dr. Amanda Williams of the University of Birmingham, UK / ACOG surveyed 2,100 women shortly after they returned home from delivering infants. She then surveyed 482 of them again 12 months later. She found that urinary incontinence was the most common problem reported, followed by sexual problems:
 - 54% reported stress incontinence (SI)—the inability to hold urine when sneezing, lifting, or experiencing some other type of stress
 - 37% had urge incontinence (UI)—difficulty holding urine when experiencing the urge to urinate
 - 33% reported that they leaked urine on a continual basis
 - 54% of women reported at least 1 issue, for example decreased libido or dissatisfaction with sex
 - 30% reported vaginal pain during sex

Older Women:

An aging population means increasing incontinence. This is becoming a large healthcare problem that will devour many resources, as the statistics indicate:

- 38% of women over 60 years of age are affected
- Incontinence is the number one reason that women enter nursing homes. (HFCA)
- 70% of all hip fractures in women occur as they run to the bathroom, trying to avoid an urge incontinent episode
- 77M baby boomers reaching the critical age

The Cost of Incontinence:

- Incontinence is expensive to manage
- \$8 billion is spent on Incontinence and Pelvic Health products in the USA (NIH figure)
- Additional \$8 billion is spent on surgeries
- Affects Quality of Life
- Affects health, leading to infections and other health problems
- Leads to isolation and inactivity
- Lowers self-esteem and can lead to depression
- Affects sexual functioning

The Environmental Effects of Incontinence:

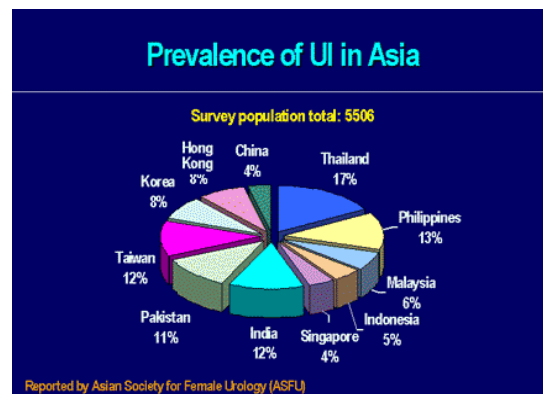
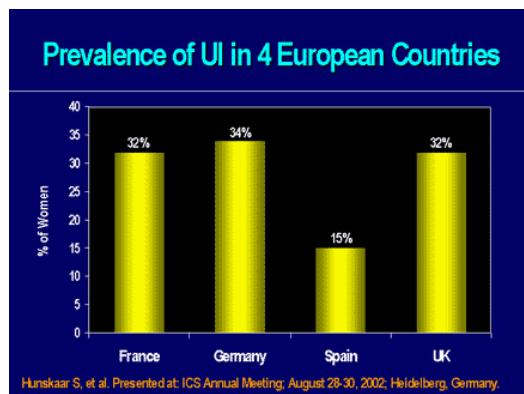
- Adult diapers constitute 2% of municipal landfills
- Adult diapers will surpass infant diapers by 2015
- Adult Disposable Product market is growing at a 6% rate each year

Incontinence – A Global Problem

In the USA, Kaiser Permanente estimates that 1 in 3 women suffer with incontinence and that incontinence has grown into a \$16.3 billion dollar industry. This cost is now greater than the combined cancer care costs for women.

Earlier this year the Chinese Government also issued a press release indicating that 1 in 3 Chinese women suffer from incontinence. This confirms the World Health Organization's estimate (1998) of 200 million incontinent people worldwide of which 182 million are women. As these populations age, this under-served market is experiencing dynamic growth in both patient populations and treatment costs. In addition, there is an emerging potential market for government sales, as female military personnel often develop stress incontinence due to the physical demands placed on them.

As shown in the illustrations below, urinary incontinence is prevalent in all countries. Urinary incontinence is very truly a global problem



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Press Releases: National

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Kaiser Permanente Study Shows One-Third of Women Have Overactive Bladder, Incontinence or Other Pelvic Floor Disorders

Researchers Determine Age Has No Significant Bearing on these Disorders and Urge Physicians to Question Patients about Symptoms

Oakland, Calif. — A new study by Kaiser Permanente found that one-third of women suffer from one or more pelvic floor disorders, which include symptoms such as the frequent urge to urinate, dropped pelvic organs, and incontinence. The study, which consists of the broadest age range of participants to date, of which 80 percent of the 4,000 women studied had given birth. Of those 4,000 women, 25 percent suffered from anal incontinence, 15 percent from stress urinary incontinence, 13 percent from overactive bladder and 6 percent experienced pelvic organ prolapse, the dropping of pelvic organs.

"These conditions really affect women's quality of life. Many women think this is just something they have to deal with as they age and that there isn't anything they can do about it, but that's not true," said lead author Jean M. Lawrence, ScD, MPH, MSSA, a research scientist at Kaiser Permanente's Department of Research and Evaluation in Southern California, where the study was conducted.

Published in the March issue of *Obstetrics & Gynecology*, the study surveyed women ages 25 to 84 in English and Spanish, making it the most extensive research on the subject to date across such a wide age range. Funded by the [National Institutes of Health](#), the findings expand on research published two years ago by the same scientific team from Kaiser Permanente Southern California and the University of California, San Diego Medical Center that found that vaginal births double the rate of pelvic floor disorders compared to Cesarean deliveries and women who have never given birth.

"One of the myths surrounding pelvic floor disorder is that it affects only older women, but the truth is these conditions are extremely prevalent and extremely debilitating. But because the subject matter isn't cocktail conversation, women feel isolated and don't seek support and treatment," said study co-author Karl Luber, M.D., a uro-gynecologist in the Department of Obstetrics and Gynecology at Kaiser Permanente San Diego Medical Center.



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One in 3 women unable to control urine

By Shan Juan (China Daily)

Updated: 2008-01-17 07:23

Nearly one in three Chinese women over 35 suffer from the uncontrolled loss of urine, or urinary incontinence (UI), medical experts have said.

Sufferers may lose several drops of urine while laughing, coughing or running, while others may experience more acute symptoms like feeling a sudden urge to pee – before discharging a large amount of urine, Ma Le, head of the female urinary incontinence department with the Beijing Obstetrics and Gynecology Hospital, said at a medical seminar Wednesday.

"Such symptoms seriously affect people's quality of life," Ma said. "In severe cases, patients develop skin infections after suffering from long-standing UI symptoms."

A large number of women, for fear of the risk of public embarrassment caused by UI, prevent themselves from enjoying many activities with their families and friends, Ma said.

"Some even develop depression," Ma said.

Yang Changjian, executive director of the Chinese Medical Doctors Association, said the affliction is often neglected by patients and medical staff.

Embarrassed by the symptoms, many patients do not seek medical help and simply wait for the symptoms to disappear, which is totally wrong, Yang said.

Just 1 percent of sufferers seek medical help, Ma said.

"Most hospitals do not even have departments for treating UI," Ma said.

"It is a disease common to women due to their physiology and the result of giving birth," Ma said.

"But with medical interventions like surgery, it is curable, Ma said, calling for all patients to seek medical help.

Raising public awareness of the affliction might be the first crucial step, Yang said, citing results from a recent online survey by media site Sohu.com.

Of the 3,000 people polled, 48 percent said they had not considered UI a medical problem and 51 percent said they felt embarrassed by the condition.



The Athena PMT – An Ideal Incontinence Treatment

Women are seeking dynamic, integrated, and preventative approaches to medicine and health. Due to consumer interest, physicians are now seeking less invasive therapies to treat incontinence and pelvic floor disorders.

The Athena Pelvic Muscle Trainer® is an ideal adjunct therapy that is affordable, can be safely used at home, and can be used in conjunction with other noninvasive treatments. It can safely be used over the long term by women to maintain their pelvic floor strength as well as to reeducate the muscles in the privacy of their homes and at a time that fits their schedule. And, the Athena can also be used to determine if a patient is a suitable candidate for other invasive treatments or surgery. Insurance companies are recognizing the importance of first-line, minimally invasive treatments and many are reimbursing the cost of the Athena PMT.



Athena
Pelvic Muscle Trainer®

Designed for Maximum Comfort

The Athena PMT has been carefully designed for maximum comfort, convenience, and ease-of-use.

To begin a session, the woman removes the PMT Trainer from the cradle on the side of the wireless controller and inserts the PMT Trainer vaginally. The woman then uses the wireless hand-held controller to increase the stimulation strength incrementally until the muscles contract, performing Kegels exercises.

During a training session a woman can increase or decrease the strength of the stimulation or turn the unit off. After a 15 minute session the Athena automatically shuts itself off and notes the ending stimulation level. The PMT Trainer is then removed, rinsed with warm water and soap, and returned to its cradle on the side of the Wireless Controller.

When used for the next session the PMT Trainer starts at a low stimulation level then automatically steps itself to the previously recorded level within a minute. During the session (about 15 minutes), the trainer follows a pattern of stimulation and rest in 2.5 second increments. These stimulation patterns (Kegels) are well documented in medical literature and are used for a wide variety of muscle training applications. The device's circuitry is designed to preclude excessive stimulation.

All aspects of the Athena PMT conform to FDA and CE standards and are certified as meeting the regulatory requirements in the USA, the EU, and Australia. The body of the unit is plastic which is qualified for medical use. The battery inside the stimulator conforms to FDA and CE standards and is encapsulated in a hermetically sealed compartment. The battery has enough power to complete an extended program of stimulation without being recharged or replaced.

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Physician Acceptance

The wide acceptance of pelvic floor electrical stimulation (PFES) as a treatment within the medical community is evidenced by the following position statements:

The American College of Obstetricians and Gynecologists (ACOG)

"...their opinion is that PFES may be efficacious for both stress and urge incontinence in women in whom traditional treatment approaches have failed.....ACOG supports the availability of PFES devices for patients because they are convenient, have no side effects..."

American Physical Therapy Association (APTA)

APTA cites several studies which demonstrate that electrical stimulation can significantly reduce UI, and they strongly support its use, particularly in patients who are not capable of voluntary muscle contractions. The APTA feels that PFES is a valuable treatment that improves efficiency of incontinent care along with pelvic floor muscle strengthening and behavioral techniques.

American Urogynecologic Society (AUGS)

AUGS supports the use of PFES therapy as a unique, low risk therapy which strengthens the body's natural continence mechanisms by stimulating particular pudendal nerve reflexes. They state is PFES is non-surgical, provides a potential cure, and is of relatively low cost. They recommend initial diagnostic screening to ensure appropriate patient selection."

Other Studies

In the United States, incontinence has recently become a leading issue in women's health care. Since the 1990s' there has been a renewed interest in the physical and non-surgical therapies. The first prospective, randomized, double-blinded, controlled trial of Pelvic Floor Electrical Stimulation (PFES) was completed in the USA by Peter Sand in 1995.

The conclusions:

"Transvaginal pelvic floor electrical stimulation was found to be a safe and effective therapy for genuine stress incontinence"

"Pelvic Floor Electrical Stimulation has been used as a first option in treating incontinence in women for many years in Europe. A study "6-year Long Term Results of Pelvic Floor Reeducation Training in Women with Urinary Stress Incontinence" was completed at the Department of Neurology at the University of Innsbruck. It concluded that "PFRT electrotherapy is a powerful alternative to operative treatments in female urinary stress incontinence and is effective on long term basis, if properly indicated and performed."

"... we have to select therapy based on the patient's desires and concerns. There are some patients who are dead-set against drug therapy, there are patients who are against surgery, and there are patients who don't want estrogen treatments, for example. There are patients who, because of other conditions such as hypertension, cannot be treated with these types of agents. So I think we have to use those factors in selecting the therapies and, as more research is presented, we're going to see that we have more options.... for stress urinary incontinence".

Mike Siroky M.D. FACS, Boston University School of Medicine



Why Women Need the Athena PMT

Athena FT's solution provides women with a safe, effective, and easy method to increase and maintain their pelvic floor strength in the privacy of their home. The Athena PMT encourages women to exercise their pelvic floor muscles on a regular basis. Consistency is necessary for significant improvements to occur. A growing number of women are using personal health-care products and personal fitness training to maintain their health, independence and youthfulness. When pelvic floor weakness is diagnosed, a majority of doctors recommend the Kegel exercise as the primary protocol to strengthen weak pelvic muscles. The Kegels are difficult to do and require special training, patience, and practice over an extended period before results can occur. Since only a small percentage of the women are able to do these exercises correctly, the Kegels are not a satisfactory rehabilitation regimen for most women.

The Athena PMT is programmed to *automatically* perform the Kegel exercises *correctly* each time to remediate or to prevent the symptoms, which underlie incontinence and related pelvic problems. It is a wireless device, thus freeing women from feeling "hooked-up" to tethered devices on the market.

The Athena PMT® is a safe, small, easy-to-use, discreet, affordable, and personal solution to female incontinence. In appearance, it is packaged as a personal consumer solution rather than as a complicated medical device. As a solution to an intimate problem, it appeals to both healthy women and women experiencing pelvic muscle dysfunction.

The PMT is designed to be used in the home, while most other e-stim products today are tethered and require weekly visits to rehabilitation clinics. The probe or trainer is inserted vaginally twice a day for 15 minutes. When turned on, the probe emits mild electro-stimulation that contracts the pelvic muscles and then releases them every 2.5 seconds. The device automatically turns off after the session is complete. Once satisfactory results are obtained (typically 8-12 weeks) the trainer can be used on a once or twice weekly basis to maintain pelvic strength.

Indications for Use

This therapy may be appropriate if a woman:

- experiences incontinence due to weak pelvic floor muscles.
- is willing to comply with the therapy program on a consistent basis.
- understands how to use the Athena PMT as described in this instruction booklet.
- is generally in good health.

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