

Restore Continnence™

Evidence-Based Biofeedback and Stimulation




personalmed
advancing pelvic health®



Restore Continence is based on a simple notion, that conservative therapies should be the first option for continence care.

Surgery and pharmaceuticals are not without risk and surveys show that most women with incontinence prefer to at least start with a conservative therapy. Conservative therapies can also be empowering for many women, motivating them to be more actively and positively engaged in all aspects of their health.

Biofeedback and stimulation are the most effective, best documented conservative treatments available for all type of incontinence (stress, urge/OAB, mixed UI or fecal). They have few risks and do not preclude subsequent clinical options. When delivered according to Best Practice, in addition to being clinically effective, biofeedback and stimulation can be significant revenue generators for most practices.



Restore Continence, Restore Confidence

We know that when you restore a woman's continence, you restore her confidence. That's why we developed Restore Continence, a programmatic product set that makes patients active participants in their treatment. Restore Continence is a turnkey system* for clinical biofeedback and stimulation that is consistent with both established Best Practice and current coding:

- ◆ Its software automates Beyond Kegels™ and other clinically proven protocols.
- ◆ It utilizes EMG (electromyography) rather than pressure. Not all incontinence can be effectively treated by simply improving muscle tone. Beyond Kegels uses EMG to also retrain muscle coordination and balance. In addition, the specificity and reproducibility of clinical EMG is such that it can be used for diagnosis as well as treatment, whereas pressure biofeedback is more commonly used in inexpensive patient trainers.
- ◆ It monitors two muscle sites simultaneously (again, only practical with EMG). This is important because many women who try to contract their pelvic muscles instead contract their abdominal muscles (Valsalva), which is clinically counter-productive. (Please see Instructive Clinical Reports.)
- ◆ It automatically generates the clinical reports necessary for patient records and payers.

Restore Continence also incorporates the following key features:

- ◆ Easy to use touch-screen interface.
- ◆ Real-time graphic displays of EMG activity over time and games for pediatrics. In contrast, the LED bargraphs used for patient trainers provide only low-resolution feedback of instantaneous activity.
- ◆ Stimulation that automatically turns off when sensor/electrode contact is compromised.
- ◆ A variety of sensors to accommodate patients of all ages and conditions.

*Its components can also be purchased individually

Restore Continnence

System Components

Touch-Screen
All-in-One PC



Software with Beyond Kegels
and other clinically proven
protocols

RC System Cart



SenseRx™ Internal Sensors



InWave™ Clinical Stimulator



Aware EMG™ Biofeedback





The First Step in Bladder Control is Awareness

Aware EMG™

The Aware EMG is a wearable instrument for accurate, real-time monitoring of two muscle sites. It features a wireless connection to the PC, easy-to-use biofeedback software with clinically sound protocols and clear, informative reports.

Being wireless is an important benefit, since it allows freedom of movement and certain movements are closely associated with urine loss.

Simultaneous monitoring of the activity of the pelvic and accessory (abdominal) muscles makes it easier for patients to learn to isolate muscles and develop better control. Internal electrode assemblies like the SenseRx Vaginal or Anal/Small Vaginal Sensors or the IVS-2 Intravaginal Sensor are highly recommended, since they make the most direct measurements of the pelvic muscles.

Surface electrodes on the right side of the abdomen are used for the second site, in order to monitor inappropriate use of accessory muscles.

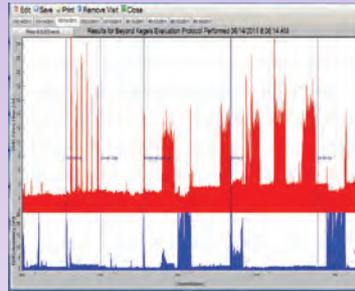
Note: The Aware EMG requires a modern PC.



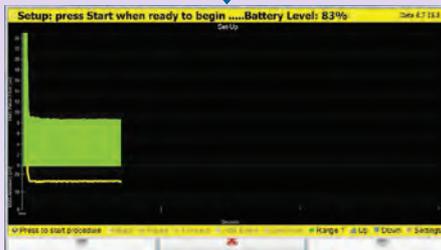
Clinical Pathway

Intake Forms and Database for Patient Records

EMG Evaluation



Biofeedback



Reports

Instructive Clinical Reports

Numerous studies have shown biofeedback to be effective in the treatment of incontinence.^{1, 2, 3, 4} While methodologies can vary, certain elements are common to the most successful biofeedback programs. A long-term study by Dannecker et al⁵ is instructive both for its clinical protocol and outcomes and so is summarized here:

- ◆ Initial examinations included an EMG Study to determine maximal pelvic floor muscle strength (Oxford-grading and EMG-potential).
- ◆ Electric stimulation preceded biofeedback if pelvic floor muscle contractions were considered too weak for active training (Oxford scale < 2).
- ◆ In-office EMG biofeedback was used to teach patients to contract the levator ani “fast and sustained” with close monitoring to ensure that contractions were performed correctly.
- ◆ Patients were individually instructed in lifestyle choices and “supporting coping strategies.”
- ◆ Home training was used to supplement in-office biofeedback. Patients performed 1-2 ten minute sessions at home for 3-6 months.

263 women completed the training. “Self-reported improvement of incontinence symptoms was 95%” and benefits were durable.

Also, the U.S. Dept. of HHS Clinical Practice Guidelines for Urinary Incontinence (1996) reported that “The biofeedback protocol that has been associated with the largest and most consistent symptom reduction is one that reinforces pelvic muscle contraction concurrently with inhibition of abdominal and detrusor contraction.”⁶ This is because many women who try to contract their pelvic muscles will instead contract their abdominal muscles, which is clinically counter-productive.⁷

To account for this, the Aware EMG provides simultaneous monitoring of two muscle sites, the pelvic muscles, typically with an internal sensor,* and abdominal muscles using surface EMG electrodes.

*Sensors are electrode assemblies for vaginal and anal placement

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Non-Pharmacologic Treatment of Overactive Bladder

InWave™ Stimulator

While many treatment options are available for overactive bladder (OAB), the present generation of anticholinergics is known to have a high rate of discontinuance due to adverse events and limited effectiveness.⁸ Consider use of pelvic stimulation instead. Stimulation is a benign therapy with high patient satisfaction.⁹

The InWave is a clinical-grade stimulator that can also be used for patient home training due to its simple operation and built-in safety features that ensure patient protection at all times. Default settings are optimized for treatment of OAB/Urge, but the InWave also incorporates protocols for Stress and Mixed UI. Each protocol has a choice of three work/rest periods. It's easy to select the exact protocol you want.

Patients training with both stimulation and biofeedback can use the same (SenseRx) sensors.

Note: The InWave is a battery-powered device for wearable or hand-held use and does not require a PC.



Introducing



Gemini™ - A New Standard in Patient Trainers



Clinician supervised home training can enhance in-office programs for biofeedback and stimulation.

Gemini is a highly accurate, but very simple to use instrument for home training. Gemini features a large, high-resolution display for biofeedback and standardized protocols for different treatment objectives, specifically:

- ◆ Stimulation for OAB/Urge UI,
- ◆ Stimulation for Stress UI ,
- ◆ Stimulation for Mixed UI and
- ◆ EMG Biofeedback.

Each protocol has a choice of three work/rest periods. Here's how it works: The clinician selects a protocol for an individual patient, which is then "locked in." All a patient has to do to train is to turn the unit on. Gemini then tracks patient compliance.

Note: Gemini is a battery-powered desktop instrument and does not require a PC.

Restore Continence

System Options

- ◆ Dell 18" Tablet
- ◆ 5 hour battery life
- ◆ Theft-proof clamp



Gemini Home Trainer

HP or similar Printer

Extended Warranty

Support & Education

Personal Med offers multiple levels of support:

Support Hot-Line 866-839-9260 or 425-242-6373

Aware EMG Tech Support for software installation and technical issues. Available at no cost through our partnership with SRS Medical:

888-233-1507 support@srsmedical.com

In-Servicing for initial training in system operation and clinical review. Provided by a Personal Med product specialist via Webex:

866-839-9260 support@personalmed.com

Webinar Courses available from Janet A. Hulme, MA, PT, developer of the Beyond Kegels™ program (with CEUs for PT/OT). On-site courses also available. Provided by Phoenix Publishing:

800 549-8371 phoenixi@phoenixpub.com

Practice Development including courses and consulting for coding, clinical issues, business initiatives/ promotion. Provided by Helen Carcio, NP, MS, MEd of the Health & Continence Institute:

413-834-0861 hcario@hc-institute.com

Establish a Pelvic Wellness Center

- ◆ Enhance patient services
- ◆ Create a unique clinical niche
- ◆ Excellent revenue potential (\$200k per 100 patients possible)
- ◆ Minimal start-up costs
- ◆ Offer conservative therapies while growing a surgical base

For a clinically and financially proven template backed by expert training, please contact:

Helen Carcio, Director
413-834-0861

hcario@hc-institute.com

Health & Continence Institute

Coding Basics

Although some payers will cover biofeedback as an initial treatment modality for the treatment of incontinence in cognitively intact patients, others require that patients first fail a documented trial of pelvic muscle exercise (PME) training (defined as no clinically significant improvement in continence after 4 weeks of an ordered plan of PME). All coverage for biofeedback is limited to procedures performed by clinicians in an office or other facility setting. Home use is not covered. Stimulation is generally covered for both in-office and home use.

CPT codes for Physician/NP use include:

Biofeedback Training 90911
Monitored Stimulation 97032
Unattended Stimulation 97014
EMG Study 51784

Please note that a determination of appropriate billing can only be made by CMS/Medicare and the private carriers to whom billing is submitted. Refer to the AMA's *Physicians Current Procedural Terminology* for PT/OT codes and additional guidance.

Remember the Men



Although Incontinence is often considered a women's health issue, it does affect men as well, particularly post-prostatectomy. Restore Continence is equally effective for men, who tend to be strongly motivated in treatment. Personal Med also offers the Regain, a flexible penile clamp for male continence. Regain is an external device that wraps around the penis and provides gentle pressure at the urethra to prevent urine leakage. Its unique design and flexible materials make it more comfortable than other devices

Regain is an OTC product that your patients can purchase for \$29.95 (+TSH) on personalmed4men.com (A prescription version is also available as the C3)



The Quality Standard in Internal Sensors

SenseRx™

Product Nos. 4509C (Vaginal) and 4510C (Anal/Small Vaginal)

SenseRx sensors are the only internal sensors with extensive documentation of clinical efficacy and have been cited in numerous medical texts and peer-reviewed journal articles. With the best “fit & finish” of any internal sensor, they remain the Quality Standard. Internal sensors make the most faithful measurements of EMG, since they most directly contact the pelvic muscles. Their longitudinal (lengthwise, not circular) detection electrodes maintain the proper orientation to muscle fibers for highest accuracy.¹⁰ Because they are self-seating, SenseRx sensors can be patient-inserted and patients can remain fully clothed during treatments. Can be used for both EMG and pelvic stimulation.



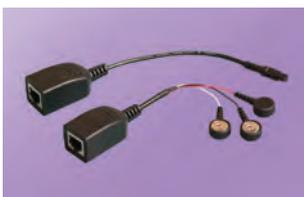
IVS-2 Intravaginal Sensor (EMG only) Product No. 4525

The IVS-2 is the smallest, most comfortable female EMG sensor available and features gold detection electrodes. Gold is a non-polarizing material that provides consistently superior measurements and is also hypoallergenic. The IVS-2 is inserted similarly to a tampon and positions above the urogenital diaphragm. Its small size and unique placement allows it to measure muscle activity even when the patient is moving. This is an important benefit, since certain movements are closely associated with urine loss.



MEP Dual Sensor (EMG only) Product No. 4520

The MEP provides simultaneous EMG measurements of two anal muscle sites via a single connector. It is frequently used in pediatrics because of its small size. The MEP does not have an integral ground electrode and normally relies on use of surface EMG electrodes (for monitoring abdominal muscle activity) to provide a system ground. The 4695G 2ch MEP Adaptor provides separate EMG connections for each MEP muscle site, as well as a system ground.

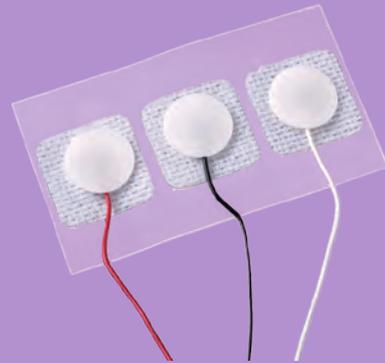


Sensor Adaptors

Personal Med sensors can be used with most clinical EMG biofeedback instruments. Adaptors are available for instruments not manufactured by Personal Med or SRS Med.
Universal Snap Adaptor (works with most surface EMG cables) Product No. 4693
2ch MEP Adaptor (works with most surface EMG cables) Product No. 4695G
Pro Adaptor (connects to 6-pin mini-DIN connectors) Product No. 4707
InWave Adaptor Product No. 4623



Snap Electrodes for Abdominal Placement



Electrodes with Wires for Perineal Placement

Surface EMG Electrodes (50 sets of 3)

Product No. 4630

Personal Med surface EMG electrodes provide excellent signal stability and are optimized for patient comfort and safety. They are soft, flexible, latex-free and their hydrogel adhesive is hypo-allergenic. Voted the electrodes least likely to pull hair.

Electrode Cable - Product No. 4654D

Smart Sensor Electrodes (bag of 100)

Product No. 4636

Single-piece adhesive with three silver electrodes for use with Smart Sensor Preamplified Electrode Assemblies.

EMG Electrodes with Wires (100 sets of 3)

Product No. 4639

Same as the Personal Med surface EMG electrodes, but with the addition of attached wires, which makes it easier to meet infection control standards for perineal placement. The entire electrode assembly is disposable - you never have to clean cables again.

Infection Control Electrode Cable - Product No. 4654

Why Use Internal Sensors?

You'll get better results...

Biofeedback works best when the feedback loop is as direct as possible, but all EMG electrodes detect an aggregation of the motor potentials in their vicinity.



Internal sensors provide the most direct contact with the pelvic muscles, whereas surface electrodes are not only further away, but also atop overlapping muscles and so are subject to more "crosstalk."

...in part because most patients prefer them

Adult patients can insert internal sensors themselves in the privacy of a bathroom and can be fully clothed during biofeedback sessions. This helps them feel more in control and enhances the state of "mindful relaxation" that is optimal for biofeedback. Perineal electrodes change the psychology of the procedure, since each session starts with the clinician placing electrodes around the patient's genitalia, which can feel undignified.

In contrast, surface EMG electrodes to monitor the activity of abdominal muscles are far less intrusive.

A Different Kind of Weight Training

StepFree™ Vaginal Weights

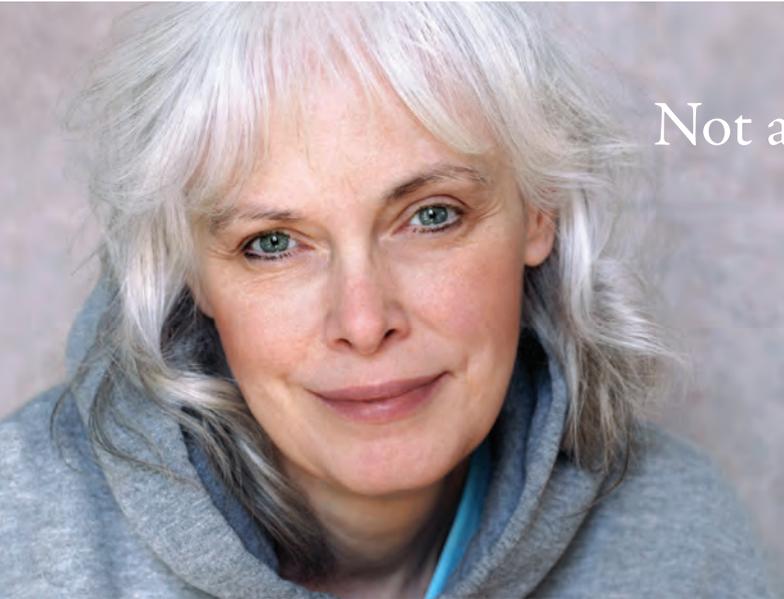


Pelvic muscle exercises, commonly known as Kegels, are a first-line treatment for mild-to-moderate stress urinary incontinence and can be beneficial for postpartum pelvic rehabilitation. Clinical studies have shown that many women need more than verbal instruction to be able to isolate the correct pelvic muscles. The StepFree vaginal weights provide a sensory aid that helps identify those muscles. StepFree also provides a structured, easy-to-follow exercise program with an objective measure of progress (increasing weight). This helps sustain motivation, increasing compliance and improving outcomes.



StepFree is made in the USA in an FDA-registered facility using medical-grade plastic, surgical suture and stainless steel. (Contains no lead.)

StepFree is an OTC product that your patients can purchase for \$59.95 (+TSH) on personalmed.com



Not all pessaries are alike –
Feel the difference

EvaCare® Silicone Pessaries

Pessaries (vaginal inserts) are an effective means of managing SUI and prolapse. A well-placed pessary can achieve clinical results comparable to surgery, with none of the risk.

EvaCare pessaries are made of soft and pliable medical-grade silicone and can be more easily inserted and removed than other brands of pessaries. A variety of types and sizes are available in order to account for different anatomic needs.

For more information, please request the EvaCare catalog: (866) 839-9260 info@personalmed.com



Ring



Oval



Shatz



Gellhorn



Dish



Mar-Land



Hodge



Gerhning



Donut



Cube

Restore Continence™



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