



Pro-Sport™, BEST PRO 1™ and BEST RSI™ Device

Physician and Patient Information Package

Regarding Medicare Reimbursement

This package is presented to physicians and Whole Wellness Club members for their support in prescribing AVAZZIA Biofeedback Microcurrent Electro-Stimulation Devices and then patient self-filing a claim for reimbursement with Medicare without purchasing and processing through a Medicare DME provider. Whole Wellness Club is not a Medicare DME provider.

AVAZZIA BEST™

Microcurrent Biofeedback Electro-Stimulation Technology



BEST-Pro1™



BEST-RSI™

The Pro-Sport, BEST-Pro1 and BEST-RSI devices are FDA cleared Microcurrent Biofeedback Devices

“for symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.”

Medicare reimbursement is available, if the correct procedure is carefully followed

- In-clinic treatments and training
- Device reimbursement

AVAZZIA BEST™ vs. Conventional TENS

AVAZZIA BEST™ devices are FDA cleared as microcurrent biofeedback TENS devices for the symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post surgical and post-traumatic pain.

Technical Comparison

AVAZZIA BEST™	Conventional TENS
<p>21st Century Technology</p> <p>High intensity, very low current, burst pulses</p> <p>Voltage Range: 0-450 volts</p> <p>Amperage Range: Microamps (10⁻⁶ Amps)</p> <p>Signals in the frequency range of 1Hz to 1000 Hz</p> <p>Damped asymmetrical biphasic sinusoidal waveform</p> <p>Signaling always varies based upon changes in impedance of the tissue</p> <p>The AVAZZIA BEST device forms a somatic biofeedback between the device and the tissue</p>	<p>1970's Technology</p> <p>Low intensity, higher current, long duration pulses</p> <p>Voltage Range: 0-40 volts</p> <p>Amperage Range: Milliamps (10⁻³ Amps)</p> <p>Signals in the frequency range of 1Hz to 100 Hz</p> <p>Square waveform, mono-phasic or biphasic</p> <p>Symmetrical or asymmetrical</p> <p>Signaling is typically the same continuous pattern.</p> <p>No biofeedback</p>

Performance Comparison

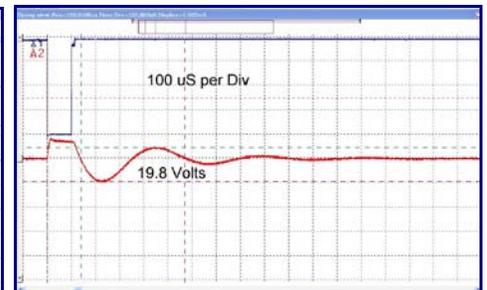
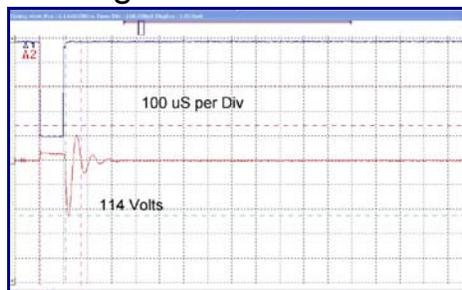
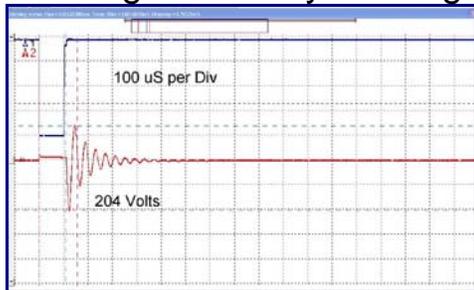
AVAZZIA BEST™	Conventional TENS
<p>Somatic biofeedback prevents neurological habituation and accommodation, for <u>more effective pain management</u></p> <p>Effectiveness lasts several hours after treatment</p>	<p>Develops neurological habituation and accommodation, which <u>severely limits effectiveness</u> of pain management</p> <p>Effectiveness often stops when treatment ends</p>

AVAZZIA BEST™

Microcurrent Biofeedback Electro-Stimulation Technology

Biofeedback is the body's response to the stimulus, and the technology's ability to detect, measure, analyze and respond to the body.

As the BEST™ product is applied, a "high voltage, micro-current" signal is passed through the skin. With each signal, the electrical properties of the tissue changes. The device detects the change and responds, resulting in the very next signal being modified.



In air, there is no conductivity between the electrodes. The output signal waveform appears as shown.

The device immediately detects when the electrodes are placed on reactive tissue as shown.

In **Relax/Assess** mode, the device will 'RING' when it detects the optimum characteristics.

BEST™ Technology

- New concept in electro-stimulation
- Micro-current Electro-Neuro Stimulation
- Automatic Interactive Biofeedback
- Electro-therapy
- Handheld
- Battery-operated
- Measures and sends electric pulses as the unit is moved along the skin



BEST-RSI™, Body-Stim™, and BEST-Pro 1™ micro-current biofeedback devices are FDA cleared for symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.



BEST™ Product Specifications

Biofeedback Electro-Stimulation Technology

BEST™ Devices are hand-held, battery-operated, electro-stimulation medical devices. Each device has 4 modes of operation specifically developed for relaxation and stimulation therapy through the skin.

Size	114mm X 63mm X 51 mm
Weight	Approx. 115 grams (4 oz) Approx. 155 grams (5.5 oz) (with batteries)
Power Source	2 AA size 1.5V DC Batteries
Pulse Duration	10 - 500 μ S
Pulse Frequency	4 - 351 Hz
Output Voltage	20 - 450 V
Output Current	2 - 90 μ A
Timeout	60 minutes
Waveform	Pulsed, damped, bi-phasic sinusoidal

Audible Indicators

- Power on Beep and 3 lights during initialization
- Tick sound every 30 seconds, Double Beep every 2 minutes Ring at dose
- Tick sound with increase/decrease power level
- In Relax/Assess mode, Chirp sound upon detection of body contact and treatment started.
- In Relax/Assess mode a Longer Ring indicates treatment progress achieved.
- Ring at 2 minutes to indicate passing of 2 minutes

BEST™ Devices



Med-Best™

Soothing therapy for minor chronic conditions



Med-Sport™

Sports injury applications



Best-RSI™

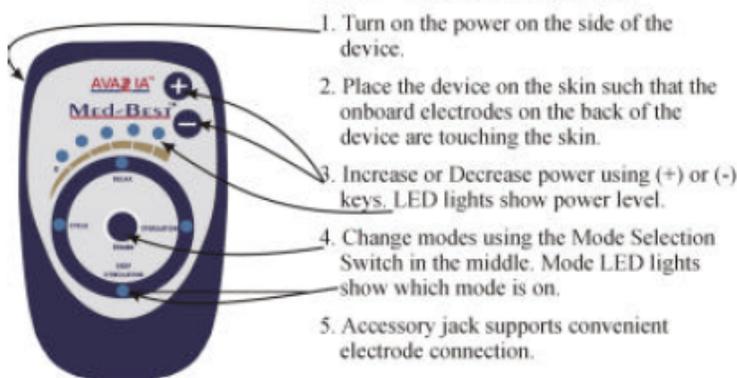
Biofeedback TENS for Chronic Conditions



Best-Pro 1™

Advanced Biofeedback TENS Applications

BEST™ Devices are easy to use.



1. Turn on the power on the side of the device.
2. Place the device on the skin such that the onboard electrodes on the back of the device are touching the skin.
3. Increase or Decrease power using (+) or (-) keys. LED lights show power level.
4. Change modes using the Mode Selection Switch in the middle. Mode LED lights show which mode is on.
5. Accessory jack supports convenient electrode connection.

Accessories



Avazzia self-adhesive electrode pads



Soft Tissue Y-Electrodes



Comb Electrode



Pencil Electrode



0470

BEST™ Devices meet international standards and have earned the CB Scheme Test Certification and CE Certification as TENS devices. Avazzia has earned the prestigious ISO13485 quality management system certification for medical products.

BEST™ Devices Best-PRO 1™ and Best-RSI™ are US FDA cleared as Biofeedback micro-current TENS devices indicated for symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain. US Federal law restricts these devices to sale by or on the order of a physician.

AVAZZIA

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www.avazzia.com

Office Visit and Reimbursement Process

Step 1: Physician – patient conference for chronic, intractable pain

- Patient appointment and evaluation with physician
- Physician prescribes BEST™ technology to start a trial period
 - BEST™ device must be used by patient on trial basis for a minimum of 1 month (30 days) but not more than 2 months (60 days) to qualify for Medicare reimbursement
 - Physician must document location of pain, duration patient has had the pain, and the presumed etiology of pain
 - Physician must document that pain has been present for at least 3 months and what other treatments have been tried and that these treatments failed
- Physician's office or patient faxes, mails, or personally delivers prescription to Medicare

Step 2: Whole Wellness Club delivers the BEST™ device to patient

Step 3: Trial period

- Physician must monitor patient during trial period to determine effectiveness of BEST™ device in modulating pain
- For purchase of BEST™ device, physician must determine that patient is likely to receive significant therapeutic benefit from continuous use of the device over a long period of time
- Physician records must document re-evaluation of patient at end of trial period

Step 4: Patient returns to physician's office after 30-day trial

- Physician documents the trial evaluation confirming effectiveness
- Physician completes and signs Medicare form CMS-848 (included here)
- Physician's office or patient faxes, mails, or personally delivers the CMS-848 and [1490S](#) forms to Medicare. Click on the hyperlink to retrieve form [1490S](#) from Medicare's website.

In this way, the patient is filing their own claim for reimbursement. The [1490S](#) form is for the purpose of filing your own Medicare claim.

Whole Wellness Club is not a Medicare DME provider.

Your local Medicare center may tell you that you must purchase the device from and file a claim through a Medicare DME provider. This is not true.

Step 5: Medicare reimburses patient

Note: Conductive garment is not covered for use with BEST™ device during the trial period

Conductive Garment

Conductive garments are covered by Medicare if ordered by physician for use in delivering a covered BEST™ (TENS) device and one of the following conditions is met:

1. Patient cannot manage without conductive garment because there is such a large area or multiple sites to be stimulated and stimulation must be delivered so frequently that electrodes are not feasible
2. Patient cannot manage without conductive garment for treatment because areas or sites to be stimulated are inaccessible with use of conventional electrodes
3. Patient has documented medical condition, such as skin problem, that preclude the application of conventional electrodes, adhesive tapes
4. Patient requires electrical stimulation beneath a cast to treat chronic, intractable pain

Patient Letter of Medical Necessity BEST™ Therapy

Patient name (insert patient info or sticker here)

Symptoms: ___ Pain ___ Stiffness ___ weakness ___ instability ___ other

ICD9 codes: _____

Diagnosis _____

Therapy is ordered for this patient for AVAZZIA biofeedback micro-current electro-stimulation.

Therapy goals (check goals that apply)

___ Pain relief

___ Pain management at home

Restorative Potential: ___ 25% ___ 50% ___ 75% ___ 90% ___ 100%

Clinical procedures and modalities:

___ Biofeedback ___ Micro-current stimulation – BEST-PRO 1™ or BEST RSI™ Device

___ Self care training

Individual therapy sessions are 30 to 45 minutes in length. Number of therapy sessions required is expected to be _____

At follow up office visit, it will be determined if additional therapy sessions are needed.

Reevaluation in ___ days ___ weeks

Patient should begin treatment AS SOON AS POSSIBLE.

Physician's Name (print): _____ NPI number: _____

Clinic Name: _____ Phone#: _____

Physician's Signature: _____ Date: _____

Physician's Address: _____

Confidential Information

**"Add clinic name, address
phone number and logo"**

Physician's Statement of Medical Necessity (Prescription)

Please Complete, Sign, Date and Fax to Medicare

Patient's Name: _____ Date of Birth: _____ SS#: _____

Patient's Address: _____

Patient's Phone #: _____

Date of Injury/Onset: _____

Diagnosis / ICD9:

_____ Chronic Pain	338.4	_____ Pain: Joint: Ankle	719.47	_____ Pain: Joint: shoulder (region)	719.41
_____ Pain: Postoperative	338.18	_____ Pain: Joint: Elbow	719.42	_____ Pain: Joint: wrist	719.43
_____ Pain: Postoperative: Acute	338.18	_____ Pain: Joint: Foot	719.47	_____ Pain: face, facial	784.0
_____ Pain: Postoperative: Chronic	338.28	_____ Pain: Joint: Hand	719.44	_____ Pain: face, facial: Atypical	350.2
_____ Pain: Extremity (lower) (upper)	729.5	_____ Pain: Joint: Hip	719.45	_____ Pain: face, facial: Nerve	351.8
_____ Pain: Back (postural)	724.5	_____ Pain: Joint: Knee	719.46	_____ Pain: Finger	729.5
_____ Pain: Back: Low	724.2	_____ Pain: Joint: Multiple Sites	719.49	_____ Pain: Foot	729.5
_____ Pain: Joint	719.40	_____ Pain: Joint: Pelvic Region	719.45	_____ Pain: Hand	729.5

Other ICD-9 Codes: _____

Other Diagnosis : _____

Previous Treatment(s)/Medications: _____

Product Description:

Micro-current Biofeedback TENS ___ BEST-PRO 1™ or ___ BEST RSI™ or ___ Pro-Sport™ Device with one lead wire, 1 set conductive pads

Conductive Garment ___ is ___ is not medical necessity. Check any that apply:

- ___ large area to be treated
- ___ multiple sites to be treated
- ___ areas are inaccessible with the use of conventional electrodes, adhesive tapes, and lead wires.
- ___ medical conditions, such as skin problems, that preclude the application of conventional electrodes
- ___ therapy required beneath a cast

- | | | | |
|--------------------------------|---|--|--|
| <input type="checkbox"/> Left | <input type="checkbox"/> Carpal wrap | <input type="checkbox"/> elbow wrap | <input type="checkbox"/> conductive glove |
| <input type="checkbox"/> Right | <input type="checkbox"/> ankle wrap | <input type="checkbox"/> shoulder wrap | <input type="checkbox"/> conductive sleeve |
| <input type="checkbox"/> Both | <input type="checkbox"/> low back wrap (6 inches tall) | <input type="checkbox"/> arm or leg wrap | <input type="checkbox"/> conductive sock |
| | <input type="checkbox"/> high back wrap (8 inches tall) | <input type="checkbox"/> cervical wrap | <input type="checkbox"/> conductive leg sleeve |

Length of Need:

_____ # of Months (short term) _____ 6-9 months (long term) _____ Purchase

I certify that the above prescribed treatment is medically necessary for the patient's well being. In my opinion, the treatment is effective and is reasonable in the treatment of this patient's condition. I also certify that the information noted above is accurate to the best of my knowledge.

Physician's Signature: _____ Date: _____

Physician's Name (print): _____ NPI number: _____

Clinic Name: _____ Phone#: _____

Physician's Address: _____

DO NOT SUBSTITUTE CONFIDENTIAL INFORMATION

Patient Record of In-Office Therapy

Date of Therapy _____

Patient name (insert patient info or sticker here)

Diagnosis (ICD9) _____

Therapy is ordered for this patient for AVAZZIA biofeedback micro-current electro-stimulation.

Clinical procedures and modalities:

CPT code	Descriptions	Time started	Time ended	Duration (mins)	Therapist Initials
97032	Attended electrical stimulation (15 mins)				
G0283	Electrical stimulation unattended (wks comp 97014) (15 mins)				
97112	Neuromuscular re-education (15 mins)				
90901	Biofeedback (15 mins)				

97535	Self care / home management training to use device _____yes _____no
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Patient Signature _____ Date _____

Therapist Signature: _____ Date: _____

Therapists Name (print): _____ NPI number: _____

Clinic Name: _____ Phone#: _____

Address: _____

CONFIDENTIAL INFORMATION

Therapy Codes for Micro-Current Biofeedback Electro-Stimulation Technology

CPT codes

Code	Description
G0283	Electrical stimulation unattended (wkrs comp 97014) (15 mins)
97032	Attended electrical stimulation (15 mins)
97112	Neuromuscular re-education (15 mins)
90901	Biofeedback (15 mins)
97535	Self care / home management training
97001	Pt evaluation – Complete Specialist examination
97002	Pt re-evaluation – Complete Orthopedic examination
99243	Office consultation detailed

ICD9 codes for Pain

Acute and Chronic Pain

338.0 Central Pain Syndrome
 338.11 Acute Pain due to trauma
 338.12 Acute post-thoracotomy pain
 338.18 Other acute post-operative pain
 338.19 Other acute pain
 338.21 Chronic pain due to trauma
 338.22 Chronic post-thoracotomy pain
 338.28 Other chronic post-operative pain
 338.4 Chronic Pain Syndrome

Joint Pain

719.40 Unspecified, joint pain
 719.41 Shoulder (region) pain
 719.42 Upper arm or elbow pain
 719.43 Forearm or wrist pain
 719.44 Hand pain
 719.45 Hip pain
 719.46 Lower leg or knee pain
 719.47 Ankle and foot pain
 719.48 Other specified site pain
 719.49 Multiple sites
 729.5 Pain in limb, pain in extremity (lower)
 (upper), finger or hand

Neck and Back Pain

723.1 Neck pain
 724.1 Thoracic spine pain
 724.2 Low back pain
 724.5 Backache unspecified - back
 (postural)

Facial Pain

784.0 Face, facial pain
 350.2 Atypical Facial pain
 351.8 Nerve facial pain

NO promises are made and NO liability for any damages due to information related to insurance coverage are made or accepted.

Instructions for Physician's Statement of Medical Necessity Prescription Form

Under "Other Diagnoses"

Be certain to indicate "Chronic Intractable Pain"

Under Previous Treatments/Medications

Be certain to indicate at least 3 attempted modalities. E.G. aspirin, Tylenol, massage, etc

Have your physician fill out this prescription form and file it yourself with Medicare to open a claim file. They may tell you that you must purchase such a device from an authorized Medicare DME provider and have them file the claim. This is not true. Just tell them your doctor prescribed the device and you could not find a Medicare DME provider with the device but purchased it from the Whole Wellness Club. Tell them you want to file the claim yourself using form 1490S or by any other self-filing procedure they advise you to use.

Instructions for CMS 848 Certificate of Medical Necessity

BEST™ device must be used by patient on trial basis for a minimum of 1 month (30 days) but not more than 2 months (60 days) to qualify for Medicare reimbursement

Under Supplier Name and Address, write:

Whole Wellness Club
503 Lincoln Dr
Sun Prairie, WI 53590
Phone: 866-549-0267

Section B

To be qualified for reimbursement from Medicare the true and honest answer to questions 1, 4, and 5 must be "Yes" or circle "Y". Question 3 must indicate "5. None of the above"

**Fill out and include Form 1490S
with your submission to Medicare**
If you need help, call 1-800-MEDICARE (1-800-633-4227)