NovoPulse®

Treatment Guide for Physical Medicine Healthcare Providers

March 2024

Welcome to the NovoPulse®

Welcome to the NovoPulse® product information training. Within this training program you will find helpful informational and instructional guidance in the use of the NovoPulse® product line.

Our mission is to improve the quality of life of the pain sufferer through research and development of non-opioid, non-invasive medical devices to alleviate pain and promote healing. BioMagnetic Sciences, LLC (BMS), the developer of the NovoPulse®, is committed to leading the delivery of advanced technology for pain management and treatment of osteoarthritis.

For questions related to the NovoPulse® please contact BioMagnetic Sciences, LLC at contact@Novo-Pulse.com or 952-893-1700 Thank you!

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Introduction 1.

Why Choose NovoPulse® for your patient's pain management?

We are excited you have chosen NovoPulse® to assist you in caring for your patient's non-opioid pain management needs. It is a Thermally Assisted Deep Transcutaneous Electrical Joint Stimulation Device which delivers a three-dimensional electric field directly into the spinal or articular joints, interacting with the articular cartilage to promote positive cartilage rejuvenation, reduce pain, decrease inflammation, and enhance functional mobility.

NovoPulse for the treatment of symptoms of osteoarthritis is an FDA Listed Class I Physical Therapy Medical Device.

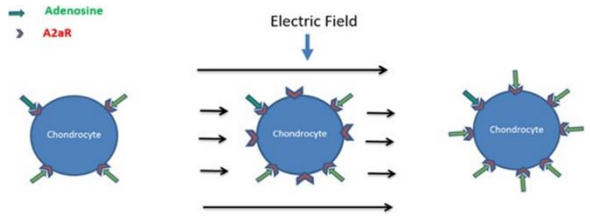
Medical devices are classified by the FDA into three categories: Class I, Class II and Class III. As a Class I medical device, NovoPulse is subject to the FDA Good Manufacturing Process and Quality Systems Requirements, but is exempt from the more burdensome, time consuming and expensive 510(k) notification process and does not require clinical trials or clearance from the FDA.

Osteoarthritis pain affects millions of patients every year and now their pain can be safely managed in-office or at home with the NovoPulse®.

Current Technology Research 2.

What differentiates NovoPulse® from other electrical stimulation devices?
The NovoPulse® was developed based upon the most important scientific finding regarding electric field stimulation to date – which is the discovery of the Adenosine -A2a Receptors anti-inflammatory pathway.

Adenosine -A2a Receptors Anti-inflammatory Pathway Activation through Cellular Interaction
Adenosine is a purine nucleoside generated by inflamed tissues that has been recently recognized as the major anti-inflammatory regulator. Under normal conditions, adenosine is continuously released from cells and maintained at low base concentration. Inflammation causes the level of extracellular Adenosine to rise dramatically (up to 200-fold). Binding of Adenosine to A2a receptors downregulates the activity of the immune system and thus reduces inflammation. The activation of the A2a receptors inhibits early and late events which occurs during an immune/inflammatory response and participates in tissue remodeling and restoration.



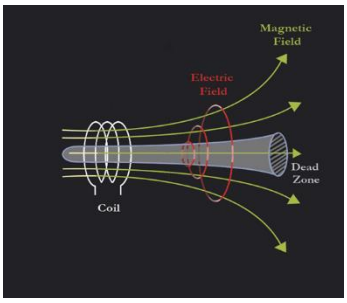
- A2aR = Anti-inflammatory pathway
- A2aR signaling pathway that stimulates anti-inflammatory response and anabolic (restorative) activities of Chondrocytes.
- Accelerates healing of cartilage and subchondral bones.
- Reduces pain by suppressing production of Prostaglandin E2 (pain mediator)

Research demonstrates the Adenosine A2a Receptor anti-inflammatory pathway can be activated by a unique deep electric field. In NovoPulse®, its multicoil system is designed to generate this unique deep electric field and deliver it directly to intervertebral discs, facet, and extremity joints with adequate duration, amplitude, orientation, and distribution. The magnetic field serves as a carrier of the electric field deep into the treatment zone (measured up to 7 cm). The Deep Electric Field Stimulation (DEFS) up-regulates adenosine A2a receptors (A2aAR) on cellular membranes and activates the Adenosine – A2aAR signaling pathway, the single most important regulator of inflammation in humans. This pathway suppresses inflammation and promotes restoration of damaged tissue. It stops cartilage degradation, promotes production of new cartilage and restores the overall architecture of joints. It also suppresses pain by inhibiting production of prostaglandin E2, the major mediator of pain.

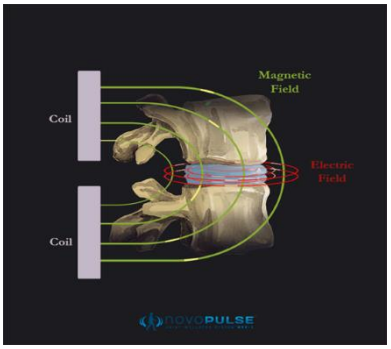
What is the "Unique Deep Electric Field"?
Research has demonstrated, for a cell to interact with an electric field, a minimum pulse width of 5 microseconds is necessary. NovoPulse® uses DC pulses with width of 40-microseconds, up to 250 times per second and amplitude of 5 millivolts per centimeter. The electric field stimulation suppresses inflammation in the joints and promotes regrowth of the damaged cartilage.

Device	DC Pulse Width	DC Pulse Frequency	Amplitude	Dead Zone	Thermal Stimulation
NovoPulse®	40-microseconds	30-250 times per second	5 millivolts per cm at 7cm depth	None	Yes
Other Electric Field Devices	No DC Pulse. Other devices use 10 nanosecond width Sinusoidal Pulses	No DC Pulses.	Less than 1 millivolt (insufficient for cellular response)	Yes	No

The NovoPulse® device generates an electromagnetic field that creates a 360-degree full coverage by electric field (of 5 millivolts per centimeter) inside the body at the target area, measured at a depth of 7cm. By creating the electric field deep inside the body at the location of the joint in the plane of the facet, articular joint, and/or disc cartilage, the electric field is not absorbed by bone (bone has the highest electrical resistivity) and is allowed to interact directly with the cartilage inside the joint or disc. The coverage of the treatment volume is provided by electric field without "dead zones" in which the electric field amplitude is below the therapeutic level.



Example above of typical "Dead Zone" with other types of electric stimulation applications.



Example above of NovoPulse® Deep Electric Field Stimulation measured at 7cm depth of penetration.

This action of DEFS is similar to that of NSAIDs but without the latter's detrimental side effects. And – unlike drugs – this unique electric field stimulation completely and homogenously permeates the whole articular cartilage and the underlying subchondral bone, controlling inflammation, stimulating anabolic activity of chondrocytes, and preventing cartilage degeneration ultimately resulting in chondroprotective activity[i]. The combination with other regenerative medicine injections to the joint are synergistic and complementary of each other because of this anabolic activity and cellular permeation created by deep electric field stimulation.

The NovoPulse® multicoil system is designed to generate this unique deep Electric Field and deliver it directly to intervertebral discs, facet, and extremity joints with adequate duration, amplitude, orientation, and distribution.

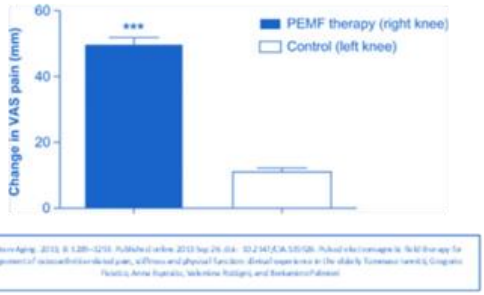
Moreover, research demonstrates restoration of cartilage leads to long-term pain relief that holds for months after treatment and is an exclusive feature of this unique deep electric field stimulation therapy. The best results are achieved when treatment is used consistently over time. Simply put, NovoPulse® is a life-long solution for spine and joint pain.

In addition, regarding thermally assisted electric field stimulation from the Kyoto University Medical School data, heat shock proteins intensify metabolism and accelerate cartilage regrowth by 4-6 times. The NovoPulse® uses the stored energy from the magnetic fields in the off cycle to create a thermal stimulation, which increases the therapeutic effects of the electric field stimulation and enhances the release of heat shock proteins preventing apoptotic death of chondrocytes.

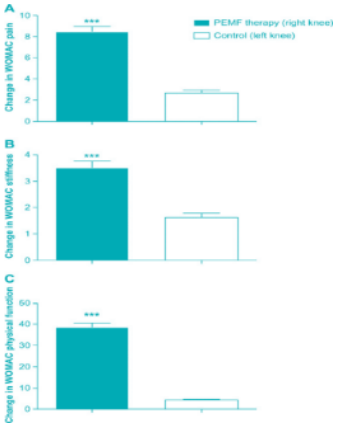
The combination with other regenerative medicine injections to the joint are synergistic and complementary of each other because of this anabolic activity and cellular permeation from the deep electric field stimulation.

Thermal Stimulation of the joint increases blood flow around the joint, promotes diffusion of nutrients in and the waste product out of the joint. The most important aspect of using thermal stimulation is the generation of "heat shock proteins 70" (HSPs). The biological function of HSPs is to preserve cell survival by maintaining the vital functions of proteins. Improved protein function leads to 4 to 7-fold increase in production of the extracellular cartilage matrix, that significantly accelerates its repair and contributes to long-term pain relief in the joint. Chronic pain due to wear and tear or pre-existing late-effect injuries or illnesses is mitigated by Deep Electric Field and Thermal Stimulation which reduces inflammation and pain and promotes healing of damaged tissues.

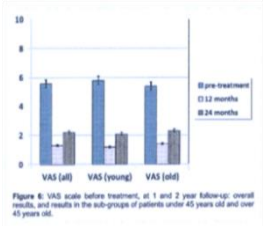
Results from a total of three 30-minute sessions per week for a period of 6 weeks were administered to each patient.

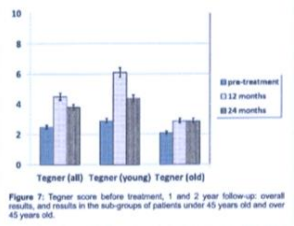


Effectively reduces pain and improves function.



Clin Interv Aging. 2013; 8: 1289–1293. Published online 2013 Sep 26. doi: 10.2147/CIA.S35926. Pulsed electromagnetic field therapy for management of osteoarthritis-related pain, stiffness and physical function: clinical experience in the elderly Tommaso Iannitti, Gregorio Fistetto, Anna Esposito, Valentina Rottigni, and Beniamino Palmieri



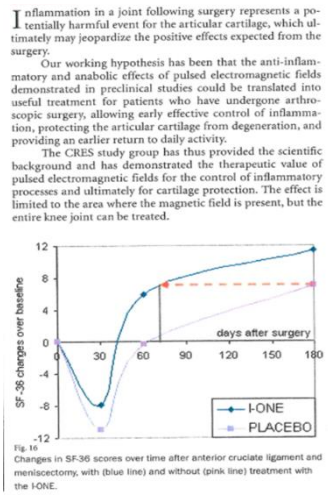


Long term results up to 2 years.

Lad D, Karnatzikos G, Gobbi A (2013) Is there any Role for Pulsed Electromagnetic Fields in the Treatment of Early Osteoarthritis of the Knee? J Osteopor Phys Act 1: 106. doi:10.4172/2329-9509.1000106

Postsurgical recovery and residual pain.

"Inflammation in a joint following surgery represents a potentially harmful event for the articular cartilage, which ultimately may jeopardize the positive effects expected from the surgery…"



Inflammation in a joint following surgery represents a potentially harmful event for the articular cartilage, which ultimately may jeopardize the positive effects expected from the surgery.

Our working hypothesis has been that the anti-inflammatory and anabolic effects of pulsed electromagnetic fields demonstrated in preclinical studies could be translated into useful treatment for patients who have undergone arthroscopic surgery, allowing early effective control of inflammation, protecting the articular cartilage from degeneration, and providing an earlier return to daily activity.

The CRES study group has thus provided the scientific background and has demonstrated the therapeutic value of pulsed electromagnetic fields for the control of inflammatory processes and ultimately for cartilage protection. The effect is limited to the area where the magnetic field is present, but the entire knee joint can be treated.

Fig. 10
Changes in SF-36 scores over time after anterior cruciate ligament and meniscectomy, with (blue line) and without (pink line) treatment with the I-ONE.

J Bone Joint Surg Am. 2007;89(Suppl 3):152-61. Effects of Electrical Physical Stimuli on Articular Cartilage. Doi:10.2106/JBJS.G.00581

Research summary available upon request through the whitepaper: "Novel Treatment of Osteoarthritis: Thermally Assisted Deep Electrical Stimulation Reduces Inflammation and Restores Cartilage."

Product Overview 3.

In NovoPulse® MKX-1 Universal System, a unique multicoil system generates an effective amplitude Electric Field deep to intervertebral discs, facet, and extremity joints with adequate duration, strength, orientation, and distribution. In addition to the Deep Electric Field Stimulation, NovoPulse® provides Thermal Stimulation, which is synergistically combined with Deep Electric Field Stimulation.

Professional and Custom Model
The NovoPulse® MKX-1 Universal System has two available models: Professional RTM Model and the Custom Model. The Professional RTM Model allows the healthcare provider to perform Remote Therapeutic Monitoring (RTM) when it is a necessary part of the patient's treatment plan. The Custom Model is a more affordable option without the RTM capability.

The NovoPulse® MKX-1 Universal System includes the conductive garment applicator, a microprocessor-based controller, a power supply, storage case, and a user application manual. The user manual provides specific instructions on how the device should be oriented for each specific joint. The patient can be in a comfortable position (i.e., sitting, lying, standing) while the therapy is applied to the region for 30 minutes. The system automatically shuts down at the end of the 30-minute session.

When the device is in use, the microprocessor-based controller monitors the performance of the device and shuts down the device in the event of any abnormal conditions. Dosage of treatments per day is recommended by the healthcare provider based on the patient's condition and response to care (please refer to clinical protocols).

NovoPulse® Professional Model Only: Remote Therapeutic Monitoring Application
The NovoPulse® Professional RTM Model includes a carrying case, USB Isolator, Micro USB Cable, and cloud-based interface application. With the Professional Model's Proprietary Cloud-based Remote Therapeutic Monitoring (RTM) Application, data from the device (i.e., date of use, time, error messages) can be downloaded during a Remote Patient Monitoring session and at time of a re-evaluation to effectively track the patient's treatment and adherence.

Indications for Use 4.

A deep transcutaneous electrical joint stimulation device system is prescribed for pain and inflammation of the spine or articular joints of the body which may be acute or chronic pain and involve osteoarthritis. Research indicates that when a unique electric field is delivered deep into the spine and extremity joint, it stimulates the growth of cartilage lining the joint surface in addition to pain reduction.

Patient Selection for NovoPulse® Therapy

Common clinical presentation of osteoarthritis includes:

- Patient age is 45 or over, and
- Patient has activity-related joint pain, and
- Patient has either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes.

Research[ii] indicates that osteoarthritis:

- is diagnosed clinically and usually does not need imaging to confirm the diagnosis, and
- management should be guided by symptoms and physical function, and
- the core treatments for the condition are therapeutic exercise and weight management (if appropriate), along with information and support.

The NovoPulse® OA Pain Assessment Tool (see addendum) provides the healthcare provider and patient a method of determining indication for NovoPulse® therapy and documentation of the patient's specific activity-related pain; which can also be used to monitor the patient's progress.

NovoPulse® Contraindications

Studies conducted to date do not suggest any long-term adverse effects from the use of devices employing pulsed electromagnetic fields (PEMF). However, long-term-effects are unknown. Although no adverse effects have been reported using PEMF, the safety of use during pregnancy and nursing has not been established. This device should not be used by patients with mental or physical conditions which preclude compliance with the device instructions. This device should not be used by individuals who are suffering from epilepsy or other medical complications. Cardiac pacemakers may be adversely affected by exposure to PEMF. This device should not be used by individuals with implanted cardiac pacemakers without consulting their physician. The safety and effectiveness of this device on individuals lacking skeletal maturity have not been established.

NovoPulse® Potential Adverse Reactions

General risks and complications arising from application of NovoPulse® include the following potential risks and safety considerations (see Addendum for Informed Consent example):

- Contact burn may occur if careful consideration and monitoring is not taken in the application of direct contact to the skin and especially in joint areas of the body that do not have much body fat (i.e., knee, foot, ankle, arms).
- Extra caution should be taken if the patient is susceptible to a burn from heat therapy due to:
    - The presence of an underlying disease.
    - If the patient has had a prior surgery to the region heat is applied, or
    - If the patient applies the heat for over 30 minutes at a time.

HCPCS and Procedure Coding 5.

CPT® is a registered trademark of the American Medical Association

NovoPulse® HCPCS Code: E0762[iii]

The Centers for Medicare & Medicaid Services (CMS) formally assigned HCPCS Level II code E0762 "Transcutaneous electrical joint stimulation device system, includes all accessories" to describe NovoPulse®. This code should be used in all billing for rental or sale of the NovoPulse® device.

HCPCS and Procedure Services:

CPT CODE	992XX
DESCRIPTION	Evaluation and Management Service
***Reimbursement Rate Look-up**	https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=2&CT=1&H1=98940&H2=98942&C=40&M=5

Initial and Subsequent Re-evaluations
Evaluation and Management Service (with appropriate CPT E/M Code selection). This code billed is based on either time or medical decision-making criteria during the date of the encounter.

CPT CODE	97XXX
DESCRIPTION	Radiographic Evaluation Service
***Reimbursement Rate Look-up**	https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=2&CT=1&H1=98940&H2=98942&C=40&M=5

Radiographic Evaluation
Radiographic Evaluation Service may be indicated by the healthcare provider to determine a diagnosis of osteoarthritis and the condition severity or presence of other conditions evident from a radiographic evaluation. A written report indicating findings on the same day of E/M is recommended.

HCPCS CODE	E0762
DESCRIPTION	Deep Transcutaneous electrical joint stimulation device system, includes all accessories
***Reimbursement Rate Look-up**	https://med.noridianmedicare.com/web/jddme/fees-news/fee-schedules/dmepos

NovoPulse® Device Assigned HCPCS Code
This code covers the **supply of a deep transcutaneous electrical joint stimulation device** system with all accessories such as electrodes, wires, and electrode fasteners. The healthcare provider uses this device for treating painful spine and joint conditions such as osteoarthritis pain and degenerative joint disease. Use modifiers NU for new durable medical equipment item purchase, RR for rental, and KH for initial claim, purchase or first month rental.

HCPCS CODE	E0731
DESCRIPTION	Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)
***Reimbursement Rate Look-up**	https://med.noridianmedicare.com/web/jddme/fees-news/fee-schedules/dmepos

NovoPulse® Device Conductive Garment
This code covers the **conductive garment** of the NovoPulse® device for delivery of electric field stimulation, with conductive fibers separated from the patient's skin by layers of fabric. The healthcare provider must document the type and use of the conductive garment for medical necessity. This code is **billed on the first visit** when fitted and supplied to the patient.

IN-OFFICE THERAPY

HCPCS CODE	97039
DESCRIPTION	This unlisted modality code may be used to describe Deep Transcutaneous electrical joint stimulation performed in-office
*Reimbursement Rate Look-up	https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=2&CT=1&H1=98940&H2=98942&C=40&M=5

NovoPulse® Deep Transcutaneous electrical joint stimulation is provided to the patient in-office

Since NovoPulse®'s thermally-assisted deep transcutaneous electrical joint stimulation is unique and differentiated from other electrical stimulation devices in design, delivery, and outcome; it is recommended to use the unlisted CPT code 97039 when therapy is provided in-office. When billing, describe the code as "NovoPulse® is a Thermally-assisted Deep Transcutaneous Electrical Joint Stimulation modality (unattended) and applied for 30 minutes to the affected spine or joint region to reduce inflammation and pain".

HOME THERAPY WITH REMOTE MONITORING

NovoPulse® Professional Model

Remote Therapeutic Monitoring may be necessary as an integral part of tracking the patient's treatment plan and management.

CPT CODE	98975
DESCRIPTION	Remote therapeutic monitoring - initial set-up and patient education on use of equipment
*Reimbursement Rate Look-up	https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=0&CT=3&H1=99204&M=5

Remote Therapeutic Monitoring

Using the NovoPulse® Professional Model device, remote therapeutic monitoring can be performed. This code pertains to the **initial set-up and patient education** on use of equipment consisting of the NovoPulse® RTM cloud-based software application. May be performed by physician or other qualified healthcare professional. This code is **billed on the first visit** following set-up and training on the device and NovoPulse® RTM cloud-based software application.

CPT CODE	98977
DESCRIPTION	Remote therapeutic monitoring musculoskeletal system, each 30 days
*Reimbursement Rate Look-up	https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=0&CT=3&H1=99204&M=5

Remote Therapeutic Monitoring (Follow-up at 45 Days)

Remote therapeutic monitoring - RTM includes reviewing and monitoring data from the NovoPulse® RTM cloud-based software application which provides objective data to determine patient's adherence to treatment recommendations as well as assessing the performance of the device. **This code is not reported if monitoring is less than 16 days.** May be performed by physician or other qualified healthcare professional. **This code is reported once per 30 days.**

*Disclaimer: the information provided is general coding information only; it is not advice about how to code, complete or submit any particular claim for payment. CPT® is a registered trademark of the American Medical Association. The information described herein is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information should not replace current Medicare or specific payer policies and/or state or federal laws and regulations. It is always the provider's responsibility to determine medical necessity and to submit appropriate codes, charges, and modifiers for services that are rendered. Although we supply this information to the best of our knowledge, it is always the provider's responsibility to determine and submit appropriate codes, charges, modifiers and bills for the services that were rendered. Payers or their local branches may have their own coding and reimbursement requirements. Before filing any claims, providers should verify these requirements with the payer. The HCPCS code E0762 is only billed following each month of use when billed to Medicare. The conductive garment should not be billed on the same date of encounter as the billing Medicare for the device. Medicare 2024 fee schedule accessed at https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=2&CT=0&H1=15276&H2=15278&M=5

NovoPulse® Clinical Protocols 6.

In-Office Therapy Clinical Protocol

Frequency of Care:
- 3 visits per week

Duration of Care:
- 45-day (6-week) duration of care with re-evaluation of progress.

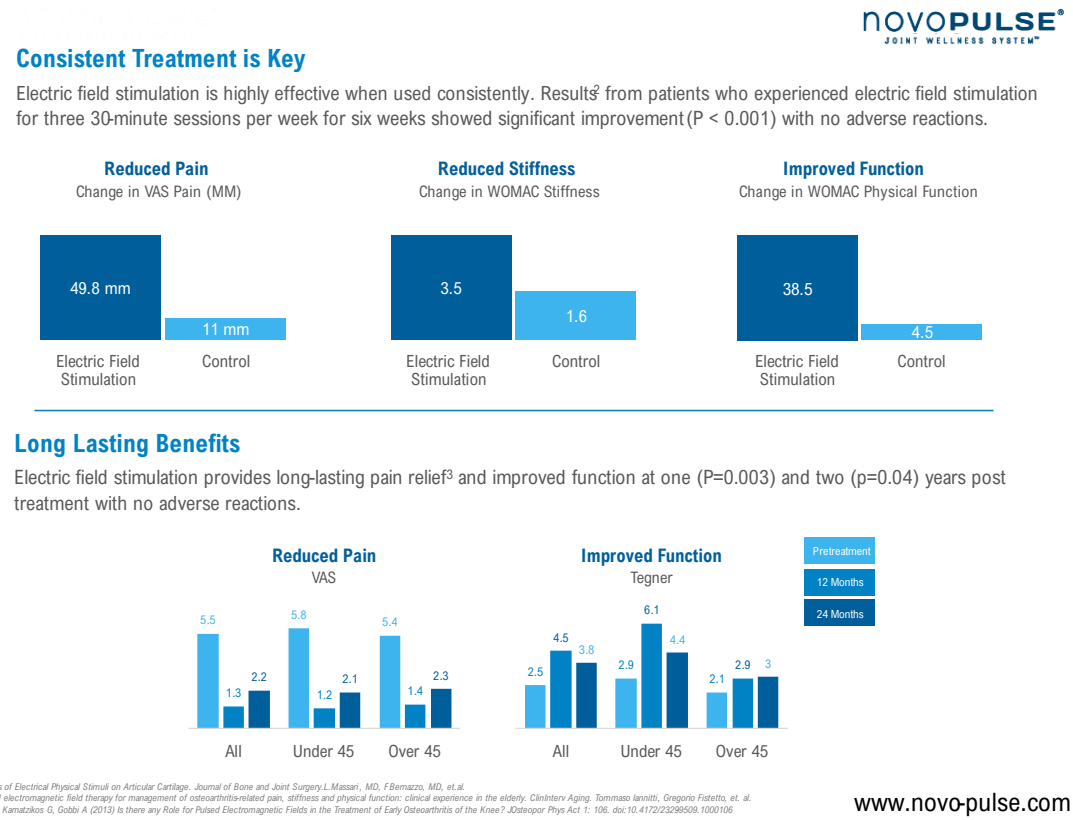
Follow-up:
- Continue as clinically indicated.
- Once the patient has reached maximum therapeutic benefit from the therapy, the patient can be instructed to self-initiate follow-up and return to repeat treatment protocol if needed.

Home Therapy (with or without RTM Clinical Protocol)

Frequency of Care:
- Minimum of 3 visits per week, daily use suggested if clinically indicated based on the patient's response.

Duration of Care:
- 45-day (6-week) duration of care with re-evaluation of progress.

Follow-up:
- Continue as clinically indicated.
- Once the patient has reached maximum therapeutic benefit from the therapy, the patient can be instructed to self-initiate follow-up and return to repeat treatment protocol if needed.



PRACTICE PROFORMA

In-Office Therapy

Based upon the available research on deep electric field stimulation produced with pulse electromagnetic fields, the clinical protocol for treating joint pain (spine or extremity) with the NovoPulse® consists of a **minimum three - 30 minutes sessions per week within a 45-day (6-week) treatment plan duration**. The following sequence of healthcare provider office visits are recommended to manage the treatment plan and maximize the effectiveness of using the NovoPulse® device for the treatment of spine and extremity joint pain:

Initial Visit: Healthcare provider evaluates patient to confirm indications for using the NovoPulse® device.

Services provided:

- 992XX: Evaluation and Management Service with appropriate CPT E/M Code selection.
  - $164.38* (Example Only. Rate and coding determined by healthcare provider)
  - Patient completes selected Outcome Assessment Tool (spine or extremity)

Treatment Visit: Healthcare provider treats patient (recommended at end of the minimum 45-day protocol) to determine status of pain, function, and objective findings and to also perform remote therapeutic monitoring to determine and document therapy adherence and response while using the NovoPulse® device. Healthcare provider and patient determine if further care is warranted.

- 97039: Unlisted Procedure
- $XX (determined by the healthcare provider)
- When billing, describe the code as "NovoPulse® is a Thermally-assisted Deep Transcutaneous Electrical Joint Stimulation modality (unattended) and applied for 30 minutes to the affected spine or joint region to reduce inflammation and pain".

Follow-up Re-Evaluation: Healthcare provider re-evaluates patient (recommended at end of the minimum 45-day protocol) to determine status of pain, function, and objective findings and to also perform remote therapeutic monitoring to determine and document therapy adherence and response while using the NovoPulse® device. Healthcare provider and patient determine if further care is warranted.

Services Provided:

- Evaluation and Management Service (with appropriate CPT E/M Code selection)
  - $164.38* (Example Only. Rate and coding determined by healthcare provider)
  - Patient completes selected Outcome Assessment Tool (spine or extremity)

*The Medicare national average payment rates are provided in this document as a frame of reference for customers. Medicare rates are publicly posted rates and many other payers use the Medicare payment levels to set their own rate. The identification of payment rates is not a guarantee of coverage by Medicare or other payers, as there may be non-coverage policies related to the NovoPulse®. Each Provider is responsible for verifying coverage with the patient's insurance carrier, including the applicability of any non-coverage decision that may exist for the NovoPulse®. Moreover, the identification of codes in this document should not be construed as providing clinical advice, dictating reimbursement policy, or substituting the judgment of a practitioner. It is always the Provider's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered. CPT® is a registered trademark of the American Medical Association.

PRACTICE PROFORMA

NovoPulse® Professional RTM Model (Remote Therapeutic Monitoring)

Based upon the available research on deep electric field stimulation produced with pulse electromagnetic fields, the clinical protocol for treating joint pain (spine or extremity) with the NovoPulse® consists of a **minimum three - 30 minutes sessions per week within a 45-day (6-week) treatment plan duration**. The following sequence of healthcare provider office visits are recommended to manage the treatment plan and maximize the effectiveness of using the NovoPulse® device for the treatment of spine and extremity joint pain:

Initial Visit: Healthcare provider evaluates patient to confirm indications for using the NovoPulse® device.

Services provided:

- 992XX: Evaluation and Management Service with appropriate CPT E/M Code selection.
  - $164.38* (Example Only. Rate and coding determined by healthcare provider)
  - Patient completes selected Outcome Assessment Tool (spine or extremity)
- 98975: Remote therapeutic monitoring – initial set-up and patient education on use of equipment and the cloud-based software application.
  - $19.65* (*Example Only. Rate and coding determined by healthcare provider)

HCPCS Services:

- E0762 Rental to Patient
  - $250/week as prescribed (Example Only. Rate is determined by healthcare provider).
- E0731: Conductive Garment purchased by patient
  - $TBD (Allowed charge varies between states per Medicare DMEPOS Fee Schedule)
- E0762 Sale to Patient:
  - $4950 (Based on MSRP of Professional RTM Model. Sale Price is determined by healthcare provider).

Follow-up Visit: Healthcare provider re-evaluates patient (recommended at end of the minimum 45-day protocol) to determine status of pain, function, and objective findings and to also perform remote therapeutic monitoring to determine and document therapy adherence and response while using the NovoPulse® device. Healthcare provider and patient determine if further care is warranted.

Services Provided:

- Evaluation and Management Service (with appropriate CPT E/M Code selection)
  - $164.38* (Example Only. Rate and coding determined by healthcare provider)
  - Patient completes selected Outcome Assessment Tool (spine or extremity)
- 98977: Remote therapeutic monitoring – scheduled recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days using the NovoPulse® Professional RTM Model cloud-based software application.
  - $46.50* (*Example Only. Rate and coding determined by healthcare provider)

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PRACTICE PROFORMA

NovoPulse® Custom Model (Home use only)

Based upon the available research on deep electric field stimulation produced with pulse electromagnetic fields, the clinical protocol for treating joint pain (spine or extremity) with the NovoPulse® consists of a **minimum three - 30 minutes sessions per week within a 45-day treatment plan duration**. The healthcare provider determines the daily frequency of device use for the patient. The following sequence of healthcare provider office visits are recommended to manage the treatment plan and maximize the effectiveness of using the NovoPulse® device for the treatment of spine and extremity joint pain:

Initial Visit: Healthcare provider evaluates patient to confirm indications for using the NovoPulse® device.

- Services provided:
  - 992XX: Evaluation and Management Service with appropriate CPT E/M Code selection.
    - $164.38* (*estimate – rate and coding determined by healthcare provider)
    - Patient completes selected Outcome Assessment Tool (spine or extremity)

  HCPCS Services:
  - E0762 Rental to Patient
    - $200/week as prescribed (Example Only. Rate is determined by healthcare provider).
  - E0731: Conductive Garment purchased by patient
    - $TBD (Allowed charge varies between states per Medicare DMEPOS Fee Schedule)
  - E0762 Sale to Patient:
    - $3200 (Based on MSRP of Custom Model. Sale Price is determined by healthcare provider).

Follow-up Visit: Healthcare provider re-evaluates patient (recommended at end of the minimum 45-day protocol) to determine status of pain, function, and objective findings and to also perform remote therapeutic monitoring to determine and document therapy adherence and response while using the NovoPulse® device. Healthcare provider and patient determine if further care is warranted.

Services Provided:
- Evaluation and Management Service (with appropriate CPT E/M Code selection)
  - $164.38* (Example Only. Rate and coding determined by healthcare provider)
  - Patient completes selected Outcome Assessment Tool (spine or extremity)

*The Medicare national average payment rates are provided in this document as a frame of reference for customers. Medicare rates are publicly posted rates and many other payers use the Medicare payment levels to set their own rate. The identification of payment rates is not a guarantee of coverage by Medicare or other payers, as there may be non-coverage policies related to the NovoPulse®. Each Provider is responsible for verifying coverage with the patient's insurance carrier, including the applicability of any non-coverage decision that may exist for the NovoPulse®. Moreover, the identification of codes in this document should not be construed as providing clinical advice, dictating reimbursement policy, or substituting the judgment of a practitioner. It is always the Provider's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered. CPT® is a registered trademark of the American Medical Association.

In-Office Documentation 7.

Patient In-Office Therapy Documentation
"Thermally-assisted Deep Electric Field Stimulation was delivered by the NovoPulse®
(E0762) applied unattended for 30 minutes for the purpose of reducing inflammation and providing pain management to the region of the (state joint or spine region)." Diagnosis codes should be documented based on the findings of the initial examination, which establishes indications for NovoPulse® therapy and condition severity.

Remote Therapeutic Monitoring Documentation
"Thermally-assisted Deep Electric Field Stimulation was delivered by the NovoPulse®
(E0762) applied unattended for 30 minutes at home for the purpose of reducing inflammation and providing pain management to the region of the (state joint or spine region). Data has been collected from the NovoPulse® device and is available in the patient's record to confirm proper adherence to the treatment protocol." Diagnosis codes should be documented based on the findings of the initial examination, which establishes indications for NovoPulse® therapy and condition severity.

Documenting Continuing Medical Necessity
Initial evaluation of the patient establishes medical necessity for when the NovoPulse® is first prescribed. Periodic re-evaluations may provide continued justification for medical need depending upon the patient's response to therapy. Ongoing provision of the NovoPulse® should be determined by the status and rate of the patient's progress, pain levels, improvement of activity-related pain levels, and overall condition severity.

The justification for continued medical need includes the timely documentation in the patient's medical record. This information is captured with each periodic re-evaluation through the NovoPulse® Professional RTM Model, which can be further documented in the patient's record.

To access the 3rd Party Payer Explanation of NovoPulse® for billing purposes, see Addendum.

Frequently Asked Questions 8.

1. **What is NovoPulse®?**

NovoPulse® is FDA approved as a Class I device for pain management. It is a Deep Transcutaneous Electrical Joint Stimulation Device which delivers a deep three-dimensional electric field directly into the spinal or articular joints, interacting with the articular cartilage to promote positive cartilage rejuvenation, reduce pain, decrease inflammation, and enhance functional mobility.

2. **What is the primary indication for the use of NovoPulse®?**

Activity-related pain, acute or chronic pain, pain associated with osteoarthritis.

3. **How is the NovoPulse® best used?**

- In-Office: Minimum of three - 30 minutes sessions over 45 days over the region of involvement.
- Home Use: Minimum of three - 30 minutes sessions over 45 days. Recommended use: 30 minutes daily for 45 days over the region of involvement.

4. **Will prior authorization be needed before use of NovoPulse® is reimbursed?**

Possibly. Please check with the patient's health plan for more details regarding their prior authorization process. This product may require the use of a Certificate of Medical Need or a payer specific Prior Authorization form.

5. **When should the patient be scheduled for follow-up with the use of NovoPulse®?**

Schedule patients within 45 days to verify the continuing need of the NovoPulse® for the patient's pain and/or condition, as it pertains to your Plan of Care. The patient's progress should be assessed at 45 days with a face to face or telehealth service re-evaluations to determine the patient's response to care and the need for further treatment.

6. **How do I order this product?**

Contact us at order@Novo-Pulse.com or call 952-893-1700.

7. **How will the patient be instructed on the use of the NovoPulse®?**

The healthcare provider instructs the patient on use. There are also video instructions accessible at www.Novo-Pulse.com

8. **What HCPCS code is used for the NovoPulse® products?**

- E0762: NovoPulse® Device
- E0731: NovoPulse® Conductive Garment

9. **What is the current cost of the NovoPulse®?**

- NovoPulse® Professional RTM Model has an MSRP of $4950.
- NovoPulse® Custom Model has an MSRP of $3200.

10. **What are the maximum units of service allowed for HCPCS E0762?**

One.

11. **Who should we contact if we have questions regarding the use of the NovoPulse®?**

You can reach out to our team at contact@Novo-Pulse.com or call us at 952-893-1700

12. **How should we code our procedures which may be involved in the use of the NovoPulse®?**

Procedure coding should be based upon medical necessity, procedures and supplies provided to the patient. Physicians should report all services performed and are responsible for determining which CPT code most appropriately describes the work performed. See further details in the procedure section of this eBook. CPT® is a registered trademark of the American Medical Association.

13. Are there any contraindications to the use of the NovoPulse®?

Studies conducted to date do not suggest any long-term adverse effects from the use of devices employing pulsed electromagnetic fields (PEMF). However, long-term-effects are unknown. Although no adverse effects have been reported using PEMF, the safety of use during pregnancy and nursing has not been established. This device should not be used by patients with mental or physical conditions which preclude compliance with the device instructions. This device should not be used by individuals who are suffering from epilepsy or other medical complications. Cardiac pacemakers may be adversely affected by exposure to PEMF. This device should not be used by individuals with implanted cardiac pacemakers without consulting their physician. The safety and effectiveness of this device on individuals lacking skeletal maturity have not been established.

14. Can we possibly expect any adverse reactions to use of the NovoPulse®?

General risks and complications arising from application of NovoPulse® include the following potential risks and safety considerations:

- Contact burn may occur if careful consideration and monitoring is not taken in the application direct contact to the skin and especially in joint areas of the body that do not have much body fat (i.e., knee, foot, ankle, arms).
- If the patient is susceptible to a burn from heat therapy due to:
    - The presence of an underlying disease such as diabetes mellitus, high blood pressure, nerve sensitivity issues such as neuropathy,
    - If the patient is older than 65 years of age,
    - If the patient has had a prior surgery to the region heat is applied, or
    - If the patient applies the heat for over 30 minutes at a time.

15. How do I apply the NovoPulse® to my patient effectively?

The NovoPulse® MKX-1 is a universal device for spine and extremity joints. Please refer to the NovoPulse® Instruction Manual for more details:

a. Place the patient in a comfortable position with access to the involved region of treatment.
b. Place the pads (located within the conductive garment) central over the region of pain or spine/joint involvement.
c. Confirm the patient is comfortable.
d. Begin therapy, instructing the patient on how to adjust the thermal stimulation (temperature) of the therapy to a safe level of comfort.
e. Following the completion of the 30-minute session, remove from the patient, and unplug the device.

[i] J Bone Joint Surg Am. 2007;89 (Suppl 3): 152-61 doi: 10.2106/JBJS.G.00581. Effects of Electric Field Stimuli on Articular Cartilage.
[ii] Osteoarthritis in over 16s: diagnosis and management. National Institute for Health and Care Excellence. NICE Guideline published 19 October 2022. https://www.nice.org.uk/guidance/ng226
[iii] Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations. First Biannual (B1), 2022 HCPCS Coding Cycle. Accessed at https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-1-2022-non-drug-and-non-biological-items-and-services.pdf on 10-18-2022.