

Explanation of Pain

Everyone feels pain differently. Overall, pain is an unpleasant sensation that occurs in varying degrees of severity and is a consequence of a number of processes. In order to manage pain, doctors determine its intensity, frequency and the circumstance from which it springs. Throbbing, burning, aching, stinging the terms patients use to describe pain are often different because pain is personal and subjective. Pain is influenced by:

- age
- gender
- race / ethnicity
- psychosocial factors

The International Association for the Study of Pain defines it as an unpleasant experience associated with actual or potential tissue damage to a person's body.

Types of Pain

Pain is typically categorized into two broad areas: acute and chronic.

Acute pain is easier to diagnose and treat than chronic pain. Acute pain, for the most part, results from disease, inflammation, or injury to tissues. It is immediate and usually of a short duration. Typically with acute pain, your heart rate, breathing and sweating increase. Acute pain is a normal response to injury and may be accompanied by anxiety or emotional distress. The cause of acute pain can usually be diagnosed and treated.

Chronic Pain

An article on chronic pain in the *Journal of the American Medical Association* noted that chronic pain is expensive because of the resulting disability and absence from work. In other recent studies, researchers say, "more attention has been paid to the impact of chronic pain on daily living." Additionally, many treatment modalities have been developed over the years, such as pharmacological, physical, psychological, electrotherapeutic, cognitive and surgical (ablation, decompression) approaches to pain management.

According to the National Institute of Health, chronic pain is often defined as any pain lasting more than 12 weeks. Chronic pain can be due to a disease or the treatment of a disease. Surgery can also result in long-term pain secondary to scarring or even permanent nerve damage. There can be several causes of chronic pain and some causes may be unexplainable. People may have sleep disturbances, decreased libido, constipation, lethargy, decreased appetite and personality change as these are all classic symptoms of chronic pain.

Patients with chronic pain often do not appear to be in pain -- but they are! Research suggests that chronic pain sufferers exhibit greater brain activity compared to healthy people when subjected to pain. This may be the reasoning behind why they experience pain differently. Chronic pain sufferers have become accustomed to a life with pain. Instead of seeing typical indications of pain, such as increased vital signs, people with chronic pain can appear to be in no pain at all.

It is important when dealing with chronic pain to understand the different types and mechanisms of pain.

Referred pain is felt some distance from where the pain actually originates. In other words, the site of the pain is not necessarily the source.

Phantom pain occurs when you have had a limb, breast or other body part removed by surgery. People describe the pain as unpleasant sensations coming from the missing body part.

Somatic pain is caused by activation of a pain receptor. Remember, pain nerve endings, called nociceptors, are programmed to respond to various stimuli. The characteristics of somatic pain are very localized aching or throbbing. Examples include joint and bone pain.

Visceral pain is also caused by activation of a pain receptor. The patient often feels achy, vaguely localized pain. It commonly originates in the abdomen or the chest; however it does not feel limited to only one area. A good example of visceral pain is chest pain due to a heart attack. In this case, the pain occurs in the chest, but it can be felt in the neck or down the arm. This type of pain is more difficult to treat.

Neuropathic pain is caused by destruction of a nerve in either the peripheral or central nervous system. People can describe neuropathy as severe, sharp, shooting, or a stabbing pain or a burning, numb, or tingling sensation.

Myofascial pain is muscle pain that occurs in conjunction with other pains. The trigger point is a localized, highly irritable spot in a tight band of skeletal muscle. Palpation of these triggers points will alter the pain and cause it to increase or radiate.

Pain Management

Chronic pain can often interfere with a patient's quality of life, sleep, and productivity. Despite the adverse affects of chronic pain, it is often poorly managed.

Pain often accompanies disease of the bones, muscles, joints, and skin, which affect millions of Americans. Most of these diseases are chronic and may cause lifelong pain. In certain cases, such as with some rheumatic diseases, the sources of pain may include:

- inflammation of the synovial membrane (tissue that lines the joints)
- inflammation of the tendons
- inflammation of the ligaments
- muscle strain
- muscle fatigue

A combination of these factors contributes to the intensity of the pain.

Research on Pain

Pain research is conducted and funded by many of NIH's institutes and centers, including the NIAMS. Although some of this research on pain is not linked to any disease specifically, certain aspects of pain research are applicable to many diseases. Research on pain supported by NIAMS covers a broad spectrum from basic research to clinical studies to behavioral interventions. This research is needed to:

- determine the most effective drug and nondrug therapies and interventions, including complementary / alternative treatments
- remove barriers to effective treatment
- identify assessment tools for patients unable to describe their pain
- identify effective pain management strategies for individuals with disabilities and in underserved populations.

That is why it is essential to support basic studies across the research spectrum and to encourage sharing of knowledge from experts in many disciplines.

Better Understanding of Pain Perception / Pain Tolerance

The levels of pain different people experience and their reactions to it vary widely, perhaps due to:

- psychological state
- age
- gender
- social environment
- cultural background
- genetic or physiological differences

Pain perception needs to be examined at all levels of basic and clinical research, including behavioral research, with the goal of developing interventions to manage or prevent pain.

- **National Institute of Arthritis and Musculoskeletal and Skin Diseases:** NIAMS provides information about rheumatic, bone, muscle, and skin diseases. It distributes patient and professional education materials and refers people to other sources of information.
- **National Institute of Dental and Craniofacial Research:** NIDCR provides information about craniofacial-dental diseases and disorders. It distributes patient and professional education materials and refers people to other sources of information.
- **National Institute of Neurological Disorders and Stroke:** NINDS provides information about neurological disorders. It distributes patient and professional education materials and refers people to other sources of information.
- **American Chronic Pain Association:** This association provides information on positive ways to deal with chronic pain and can provide guidelines on selecting a pain management center.
- **American Pain Society:** This society provides general information to the public and maintains a directory of resources, including referrals to pain centers.
- **National Foundation for the Treatment of Pain:** This organization provides support for patients who are suffering from pain, their families and friends, and the physicians who treat them.

The Science behind Electrotherapy

The Gate Control Theory

The gate control theory hypothesizes that nerves are only able to carry one signal at a time. By over-stimulating those nerves with electrical current the TENS unit is able to confuse the brain and, thereby, block the real pain signals from getting through.

The Endorphin Theory

The second theory is the TENS unit stimulates the production of the body's own natural morphine-like substances known as endorphins. It is believed that electric current stimulates certain nerves, which in turn send messages to the brain causing it to release these natural pain relief chemicals. These endorphins then act in a similar manner to conventional narcotics to provide the body with overall pain relief.

What kinds of pain respond to TENS?

Pain that warns us of external danger and internal illness serves a useful purpose. However, the chronic and acute pain associated with long-term illness, surgical incisions, and unknown diagnoses do not serve a purpose. TENS is an excellent, non-drug alternative for chronic pain. It is also useful in relieving acute pain associated with surgery, traumatic injury, and other conditions.

How can TENS relieve pain?

TENS can relieve pain by blocking the pain message sent by the body's nervous system. This is accomplished by placing electrodes over the painful area and administering a low-volt electrical current. The current overrides the nervous system's message of pain, thereby blocking it.

Does TENS treatment have any risks or side effects?

Unlike surgery or prescription drugs, TENS is virtually risk free from injury, side-effects or addiction. The low volt electrical current delivered by the electrodes only penetrates the skin to the level of the nerve fibers, usually only one to two inches. This poses no danger to most individuals. However, those with cardiac conditions and/or pacemakers, and pregnant women should consult their doctors before using TENS; the use of TENS is not generally advised. Also, using TENS for neck and head pain should be conducted only with the consent of a physician. Use caution when you drive or operate heavy machinery. **Most importantly, always use TENS according to your physician's directions.**

What is the most effective way to use TENS?

To achieve the best results of TENS therapy, it is important to remember that TENS merely activates the body's own pain-fighting mechanism. Placing electrodes directly over or around the painful area delivers pain-blocking current to the nerves leading to that area. Some healthcare professionals have found that placing the electrodes along acupuncture points and meridians is also effective. Also, it is good to vary the placement of the electrodes each treatment to avoid skin irritation.

How long does it take for TENS treatment to produce results?

In most cases, studies show that it takes roughly 30 minutes for TENS treatment to begin to relieve pain. However, for conventional, high-frequency TENS treatment, there is no set treatment limit. Some patients find hours of pain relief from short 30-to-60 minute sessions. Others use their TENS units for several hours a day or all day, depending on the pain generated by daily activities. Always use your TENS unit according to your physician's directions.

When can TENS treatment be administered?

TENS can be administered any time of day or night. It is recommended that TENS not be used while sleeping because movement during sleep may cause electrodes to come off or be pressed into the flesh, causing skin irritation. However, always use your TENS unit according to your physician's directions.

Medical Device Regulations by Region

All medical devices, like medications, are required to comply with the regulations of the country in which it is sold. Countries may borrow or emulate the regulatory requirements of another; therefore, we see regulatory similarities throughout the world. Most regions use a device classification to determine the process by which the device manufacturer must take to legally sell and market a device in a country. A detailed explanation is provided below for the U.S.

United States – The WellnessPro is FDA Cleared as a Class II medical device.

The U.S requires medical device manufacturers implement a quality system under 21 CFR Part 820 and submit a 510(k) Premarket Notification. The U.S. FDA 510(k) Premarket Notification submission requires medical device manufacturers to demonstrate that their device is safe and effective by providing substantial equivalence to an already legally marketed device. The U.S. classification system differs from Europe in that the manufacturer does not use a rules based system, but rather a substantial equivalent device to determine classification. If no equivalent device exists, a classification decision is made by the FDA. Device manufacturers are required to address and submit testing results, clinical data, validation, etc. as part of this 510(k) submission. If the FDA approves the device submission, the device is issued a 510(k) clearance letter and the medical device manufacturer is able to legally market and sell the device in the U.S. The U.S. FDA quality system requirements (21 CFR Part 820) were created many years before ISO 13485. Furthermore, unlike ISO 13485, there is no quality system certification program and no quality system compliance certificate

is issued by the FDA. Instead, the FDA conducts random inspections to determine compliance with the quality system requirements (21 CFR Part 820).

Questionnaire

Please complete this questionnaire and submit to Electromedical Technologies. A Questionnaire needs to be submitted for each applicant and co-applicant listed on the Independent Representative Application and Agreement. Please initial the first page and sign the second page.

Questions may have more than one correct answer. Please mark ALL correct answers.

1. Why is this moment in history so critical for helping people and generating income?
 - Because Healthcare is the fastest growing industry
 - Because nearly 100 million baby boomers are getting older and they are the main economic force in the world
2. Which country has the largest medical device market in the world?
 - USA Canada England
3. What is a WellnessPro device?
 - A MENS device
 - A TENS device
 - A Microcurrent device
 - Royal Raymond Rife device
4. How many wave types does a WellnessPro have?
 - 1 5 1000 10,000
5. Can you select your own frequency with the WellnessPro?
 - No, I can only use preset codes.
 - Yes, in the range from 0.1-10,000 Hz.
6. Who can purchase a WellnessPro in the USA?
 - Licensed health practitioners
 - Distributors of the WellnessPro
 - Anyone without a prescription
 - Anyone with a prescription
7. If you have specific condition, can the WellnessPro help you?
 - Yes, it can cure you.
 - Yes, it can help with reduction of your pain.
 - No, it will not help you.
8. Who can give medical advice related to usage of the WellnessPro?
 - Distributors of the WellnessPro
 - Certified trainers
 - Licensed health practitioners
9. The WellnessPro is regulated by the FDA and cleared in the U.S. as a Class II medical device.
 - True
 - False
10. What regulations is the WellnessPro in compliance?
 - FDA 510(k) Clearance.
 - ISO 13485
 - CE Mark
11. In the US, if I am not a licensed health practitioner and I want to use the WellnessPro on myself in addition to distributing the product, it is necessary to have a doctor's prescription for myself.
 - True, a prescription is necessary
 - False, a prescription is not necessary
12. I have a pacemaker. Can I use the WellnessPro?
 - Yes
 - No, do not use with a pacemaker

Initials: _____

13. I'm pregnant. Can I use the WellnessPro?

- Yes
- No, do not use during pregnancy

14. How long is the warranty period on the WellnessPro?

- 1 year
- 3 years
- 5 years

15. Does the WellnessPro have a money back guarantee period?

- Yes, a 90 day period
- Yes, a 60 day period
- Yes, a 30 day period

16. If I want to advertise on the web or through newspapers and magazines, do I need to have ads cleared by Electromedical Technologies before I place them?

- Yes
- No

17. I can advertise the WellnessPro Pack on the internet for less than \$3,495.00.

- True, I can set any price I want.
- False, I can only advertise at the retail price of \$3,495.00.

18. Can licensed practitioners bill insurances for treatments using the WellnessPro?

- Yes
- No

19. When should I expect my commission check for a sale?

- Immediately after a sale
- 30-45 days after a sale
- 60 days after a sale

20. What is required to become a distributor?

- Purchase any Business Start Kit
- Submit a WellnessPro Questionnaire
- Submit a W9 Tax Form
- Read, understand, and submit a WellnessPro Independent Sales Representative Application and Agreement
- There are not any requirements to become a distributor.

By signing below, I hereby agree to all distributor terms and conditions set by Electromedical Technologies. I understand that it is my responsibility to comply with all federal, state, country, and municipal laws, ordinance rules and regulations regarding medical device distribution.

Printed Name of distributor: _____

Signature: _____ Date: _____

ElectroMedical Technologies reserves the right to cancel any distributorship at any time.