User Manual

Physio Clinique Pro

Neuromuscular Stimulator
V 6.0

I. Introduction

The ***Physio Clinique Pro*** is manufactured/distributed by VALMED SA, Sion, Switzerland.

The ***Physio Clinique Pro*** is manufactured in accordance with the requirements of European Safety Standards EN 60601-1, EN 60601-2-10 and meets requirements of the American Standards for Transcutaneous Stimulators ANSI/AAMI NS4 – 1985. It is approved by the United States Food and Drug Administration (FDA) for prescription sales (K022175)

The Physio Clinique Pro is a Class II Medical Device and conforms to the requirements of European Directive CEE 93/42 and holds certificate number Œ 0535.

Read this *Manual* *before use,* especially sections on Indications and Contraindications and Safety

Manufacturer disclaims any and all liability for damages caused by the improper use of this device.

II. Table of Contents

III. Intended Use and Indications

The ***Physio Clinique Pro*** neuromuscular stimulator (EMS) is intended for use only by prescription and with medical supervision of licensed health practitioners as an adjunct for the treatment of medical diseases and conditions. The ***Physio Clinique Pro*** treatment programs are designed and intended for stimulation of all parts of the body except the head and front part of the neck.

The specific indications include:

- Relaxation of muscle spasms;
- Prevention or retardation of muscle atrophy;
- Muscle re-education;
- Increasing local blood circulation;
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, and;
- Maintaining or increasing range of motion of extremities.

VI. Safety and Precautionary Guidelines

A. MEDICAL CONTRAINDICATIONS

The use of electric neuromuscular devices is **absolutely contraindicated** for all patients with implanted cardiac pacemakers and patients with any type of cancer in active metastatic phase.

B. SPECIAL AND ENVIRONMENTAL WARNING

- Do not use in the presence of functioning high frequency electro surgery devices.
- Do not use in the immediate vicinity (<0.5 m) of an active microwave oven

C. HEALTH PRECAUTIONS

Use caution in the following situations:

- On patients with any type of cancer the electro stimulation can be used only under direct supervision and at a discretion of an attending physician while operating machinery
- Following a recent surgical procedure
- when muscle contraction may disrupt the healing process.
- When there is a tendency to hemorrhage following acute trauma or fracture.
- Over the menstruating uterus.
- Where sensory nerve damage is present and demonstrated by a loss of normal skin sensation.

D. POSSIBLE ADVERSE REACTIONS

Skin irritation and burns beneath the electrodes has been reported from use of some neuromuscular stimulators. Some users may experience skin irritation or hypersensitivity due to the electrical stimulation or the conductive medium.

E. HEALTH WARNINGS

Long term effects of chronic electrical stimulation are unknown

- The safety of use of EMS devices during pregnancy has not been established.
- Adequate precautions should be taken in cases of suspected heart problems.
- Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
- EMS should not be used over the carotid sinus, especially in patients sensitive to carotid sinus reflex.
- EMS should not be used with electrodes positioned over the front of the neck as it may cause severe spasm of laryngeal and pharyngeal muscles strong enough to cause difficulty in breathing and even closing the airway.
- EMS should not be applied trancerebrally.
- EMS should not be used over swollen, infected or inflamed areas or skin eruptions, e.g. phlebitis, acute varicose veins etc.
- Caution should be used when applying EMS transthoracically, as the electrical current may cause heart arrhythmias.

F. ELECTRODE GUIDELINES

The PalsFlex electrodes that are supplied as a standard accessory with your ***Physio Clinique Pro*** mold easily to your body contours and are reusable.

The specific instructions for electrode use are indicated on the factory sealed storage pouch. The recommended sizes are oval 3" by 5" electrodes for large areas (e.g., leg muscles) and round ~3" electrodes for smaller areas such as forearm muscles. One (1) set of each size is supplied with the ***Physio Clinique Pro***.

- Use only skin pads (electrodes) supplied by manufacturer; there is no assurance that other brands have satisfactory performance parameters. Use of smaller electrodes than recommended by manufacturer may result in burns.
- Apply electrodes only to clean, intact, normal skin.
- Do not apply electrodes over open wounds, inflamed, swollen or infected skin area or over any skin eruptions such as varicose veins, phlebitis, etc.
- Do not share electrodes with other users. Multiple users may result in adverse skin reactions.
- Replace self-adhesive electrodes when they do not adhere (stick) firmly to the skin.

V. Introduction to Neuromuscular Stimulation Therapy

A. TERMINOLOGY

Human physical movements are determined by muscle actions on the skeletal system. A muscle is shortened (contracts) when it is "voluntarily" activated by the brain. This shortened muscle exerts force on the attached bone(s), causing movement with joints acting as pivots. All muscle contractions are controlled by brain signals that travel through motor nerves. When an electrical brain signal is sent to a muscle, it activates groups of muscle cells known as "motor units".

A **motor unit** is a single motor nerve and the muscle cells connected to it.

The full contraction of a muscle typically involves multiple motor units acting simultaneously; the force of contraction is proportional to the number of motor units activated. Gradual activation of motor units enables smooth and controlled development of force; this process is termed "**spatial summation**".

Neuromuscular stimulation (EMS) achieves similar muscle movement without use of brain signals. These movements are termed "involuntary".

When a single electrical impulse of adequate intensity is applied externally to a group of neuromuscular junctions **(Motor Points**) in a muscle, the result is a single short contraction (twitch) in the corresponding part of that muscle. When these single twitches are repetitive and the repetition rate exceeds 10 twitches per second, the contractile force of each succeeding twitch adds to the preceding twitch an additional degree of contraction, resulting in a higher overall force and, hence, muscle contraction.

This "effect" is termed "**temporal summation**".

The minimal repetition rate at which twitch contractions "fuse" together is called the "**tetanization frequency**", typically in the range of 25 to 50 impulses per second depending upon muscle. Tetanization frequencies are used to create electrically stimulated contractions known as tetanic muscle contractions.

During natural (voluntary) muscle contractions, the force is partly the result of summation of single repetitive twitches (temporal summation) but also a function of the total number of motor units that have been activated by brain signals. Therefore, a voluntary **muscle contraction force** is a result of both temporal and spatial summations.

During neuromuscular electrical stimulation, the muscle contraction force is highest at the tetanic stimulation frequency due to temporal summation. Contraction force also depends upon the total number of motor units activated, which, in turn, are dependent on placement of electrodes and their distance to the motor points on a muscle.

B. SAFETY

The ***Physio Clinique Pro*** is designed to provide a totally safe treatment without sacrificing effectiveness. In this respect, the ***Physio Clinique Pro*** is non-pareil.

Further, to ensure safety, durability and efficiency, only premium electrical components are used.

The stimulation impulses generated during ***Physio Clinique Pro*** treatment sessions carry such minimal amounts of electrical energy that they are unlikely to produce any adverse effects when the stimulator is used in accordance with this manual. It is important, however, to emphasize that no neuromuscular stimulator, including the ***Physio Clinique Pro*** should be used by a patient with an implanted cardiac pacemaker and that the safety standards for pregnant women has not been established.

The ***Physio Clinique Pro*** is designed so that even improper or accidental application of the device can not produce cardiac rhythm disturbances in patients (who do not have implanted cardiac pacemakers). This is due to the minimal electrical charge of the stimulating impulses, which, under all conditions, do not exceed 24 microcoulombs, zero net current. This charge is below the standard of 25 microcoulombs established in the Association for Advancement of Medical Instrumentation (AAMI) for cardiac rhythm disturbance safety (AAMI/ANSI NS-4-1985).

Many, if not most, individuals harbor apprehension, anxiety or even fear regarding electricity. It is therefore very important that patients understand how completely safe treatments with the ***Physio Clinique Pro*** are.

Educating the patient is therefore a recommended first step!

The effective value of the stimulation voltage patients will experience during treatment with the ***Physio Clinique Pro*** is very low. It is below 5 volts (root mean square) at a maximum setting of the intensity knobs. The ***Physio Clinique Pro*** uses six (6) “C” batteries.

C. PRACTICAL HINTS

During neuromuscular stimulation, the number of motor units in a muscle that are activated depends upon the stimulus impulse energy. This imparted impulse energy, in turn, is a function of:

- The current intensity selected by the practitioner or patient;
- Skin and electrode electrical resistance; less resistance results in more delivered energy, and;
- Electrode placement; the closer electrodes are to motor points, the higher the energy.

As a general rule, the intensity of the stimulation should be at a level where the involuntary muscle contractions are visible and felt by the patient.
The controls on the ***Physio Clinique Pro*** are easily adjusted to achieve this. It is likewise true that the stronger the muscle contractions are, the higher the effectiveness of the therapy. This has to be tempered, however, with a patient’s comfort level. For comfortable and effective stimulation, the delivered energy should be optimized. This can be achieved by a combination of the following steps:

- Ensure that the patient’s skin is clean;
- Apply heat (for example, a thermal wrap) to the skin to increase local blood circulation;
- Moisten skin before placing the electrodes on the skin;
- Reduce electrode resistance by using the largest electrodes possible for a given anatomical area;
- Optimize electrode placement using the placements recommended in this manual, and;
- If possible, have the patient assist by also voluntarily contracting the stimulated muscles;

Dry skin is highly resistant to the conduction of electric current. Wet (or perspiring) skin has significantly lower resistance. It is true that individuals tend to vary in their normal levels of skin moisture. It is best to precede treatments with the application of some form of heat to the areas to be treated. There are a number of means for doing this, form thermal wraps to steam baths or hot whirlpool treatments.

Oily skin also prevents optimal conductivity and should be treated with soap and water prior to start of a treatment session. As a minimum, the skin should be moistened with a sponge or cloth prior to treatment.

Application and Handling of Electrodes

When voluntary muscle movements occur, the complex contraction patterns involving several muscles, bones and joints are represented in the cerebral cortex of the brain rather than the movement of each individual muscle. Thus, the brain typically calls a combination of muscles into action; this should be the objective when using involuntary neuromuscular stimulation (EMS) as well.

There are several different methods for placing electrodes on the body.

The following guidelines are based on using EMS to exercise groups of muscles involuntarily in the same fashion that these muscles contract voluntarily.

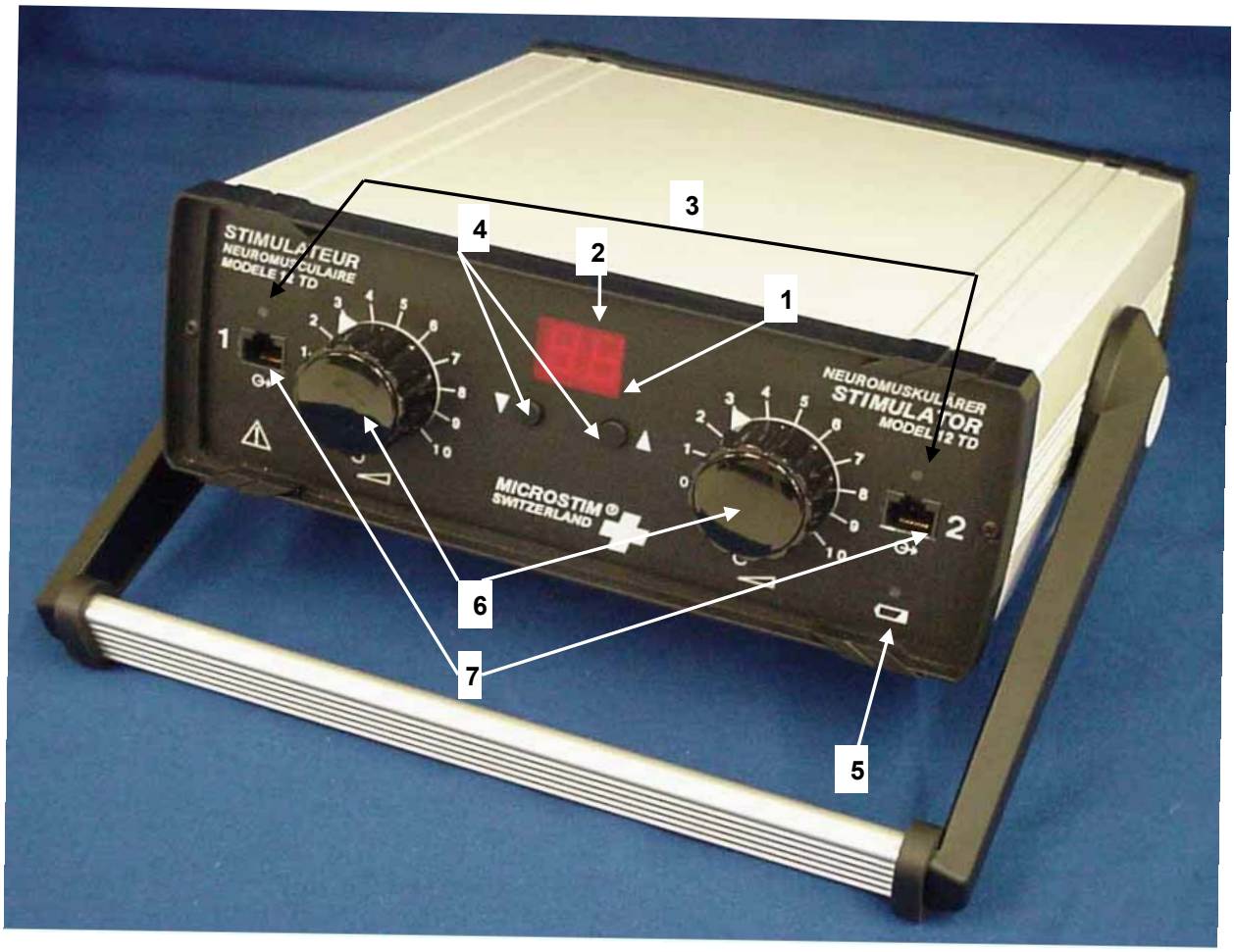
Electrode in pairs layout is the recommended electrode placement. Each pair of electrodes is placed on the same side of the body (e.g., one electrode on the right leg vastus lateralis and the other on the same leg on the vastus medialis), both being a part of the quadriceps muscle group.

Split electrode layout is when one pair of electrodes is split on each side of the body (e.g., one electrode on the right quadriceps and one electrode on the left quadriceps). This layout may result in unevenness of contractions which may be difficult to correct.

Bi-polar electrode layout is ideal for large muscles. An electrode is places at each end of the muscle such that a good, well-controlled contraction is obtained.

For all layouts, the electrode placement should correspond to the location of the motor points of the treated muscle(s). For placement guidance, see **Section XII**.

VI. Physio Clinique Pro Unit Description



The ***Physio Clinique Pro*** controls and features are as follows:

1: ON Status Light (blinking dot)
2: Program and Elapsed Time Display (2 digits)
3: Program Activity/Intensity Lights ((green)
4: Program Control Buttons (▼ and ▲)
5: Low Battery Indicator
6: Intensity Control Knobs (2x)
7: Cable Outlets (2x)

▼▲

Front panel nomenclature will vary depending upon country of sale (Swiss model shown)

VII. Using the Physio Clinique Pro

A. OVERVIEW

Although treatment with the ***Physio Clinique Pro*** adapts to virtually any standard procedure, the following suggestions are made in order to take full advantage of its capabilities. Physical exercise, massage and manipulation all have a place in comprehensive therapies and may be employed prior to, or after electro stimulation treatments. Radiant heat (infrared, etc.) has always been a standard modality in physical therapy and may be added prior (preferably), during or after the treatment. Hydrotherapy, in forms of whirlpool bath, paraffin bath, hot packs, etc., are also useful adjuncts to electrotherapy and may be used in connection with the ***Physio Clinique Pro*** prior to, or after treatment.

Planning the Stimulation Session

The recommended number and frequency of treatment sessions are indicated in **Section IX** for each program.

Before you begin the first treatment, discuss with the patient the method and the sequence of events during the entire treatment. Select electrode placement locations and record them on the treatment chart.

Preparation for a Treatment Session

Place the ***Physio Clinique Pro*** unit close to the patient. Maximum therapeutic results require good muscle contractions. Ensure that the muscle contractions are aided ***isometrically*** by the patient (if the patient is able to do so) as this will optimize the treatment. Also, arms or legs that are being stimulated should be firmly secured against wall or heavy objects to prevent their movement (which may result from muscle contractions).

Separate the two halves of each cable, so that each of the electrodes can reach desired skin contact points. There are 2 electrodes that can be connected to each 2-wire cable, for a total of 4 electrodes. When using non- adhesive (carbonized rubber) electrodes (optional) that are attached using strap fasteners, lay the required number of elastic belts across the treatment area with the hooking ends of Velcro fasteners facing up.

Check intensity control knobs (6) and make sure that all are set to OFF position (maximum counterclockwise) and the green intensity indicator lights (3) next to the output cables of the ***Physio Clinique Pro*** are OFF.

Application and Handling of the Electrodes

When voluntary muscle movement occurs in the body, a complex muscle contraction pattern involving several muscles, bones and joints, rather than the movement of each individual muscle is represented in the cerebral cortex (area of the brain). This means that not only a single muscle, but a defined combination of muscles are called into action to participate in a given movement. Therefore, when using the ***Physio Clinique Pro*** stimulator, it is important to exercise these groups of muscle together if possible.

There are several different methods of electrode placement on the body; however, both electrodes of each stimulator channel must be in contact with the skin at the same time in order to obtain a stimulation effect. Each electrode then works individually and needs not necessarily to be very close to each other. Since all electrodes are specially molded they may overlap each other, if necessary.

Use only the original electrode types supplied with the ***Physio Clinique Pro*** in order to assure effective stimulation. The self-adhesive stimulating electrodes supplied with the ***Physio Clinique Pro***, are suitable for multiple use. In order to avoid cross-contamination of skin of patients by these electrodes, it is essential that the same electrode set be used for one patient only. The set of electrodes used for one patient should be discarded when no longer needed. If non-pre-gelled electrodes are used (e.g. Carbonflex), clean them with water and soap and spray their contact surface after each use with a sterilizing agent.

Place the electrodes on the skin of the patient in places corresponding to motor points of the muscles to be treated and start the treatment as described below. Suggested electrode placement sites are depicted in **Section XII** of this manual. The specific placement of electrodes on the skin depends upon which muscle group or groups are to be stimulated.

Do not place electrodes on patients without visual control. Ensure that an entire surface of the electrodes is in good contact with the skin and then connect the stimulator cables to the electrodes.

Selecting a Stimulation Program

Make sure that the stimulator is OFF with the both control knobs (6) in maximum counterclockwise position and the knob pointers at "0". Only then plug in the patient connecting cables into the ***Physio Clinique Pro*** output sockets.

The program control buttons (4) permit the sequential selection of any of the four treatment programs stored in the memory of the. These pushbuttons are marked (▼) and (▲), respectively. When turned ON, the default Program is Program 1. However, ***after*** the ***Physio Clinique Pro*** is turned ON, the stimulator can be set to the desired program number. This must be done not later than 10 seconds after turning the ***Physio Clinique Pro*** ON. To select Program 2, push the (▲) button once; to select Program 3, push the (▲) button twice; to select Program 4, push the (▲) button three times. If for any reason you have selected a Program number higher than intended, you can adjust to the desired Program by pressing on the (▼) button.

The red digital display (2) just above the program buttons (4) identifies the active program. This is given only during program selection. Program selection is terminated automatically, if no program control buttons are activated within 10 seconds.

The program chosen determines the type of work imposed on the stimulated muscle. Based upon the specific symptoms, select the program that is appropriate. See **Section IX** for ***Physio Clinique Pro*** Indication treatment guidance.

Starting a Stimulation Session

The selected stimulation program starts automatically 10 seconds after program selection using the program control buttons. This start is indicated on the digital display (2) by switching from a one-digit display showing the selected Program to a two digit display indicating the treatment time (in minutes) remaining before program end. In addition, program start is indicated by a single audible "beep".

Adjusting Stimulation Intensity

The output voltage level of the stimulator determines the current intensity and the number of stimulated fibers in the muscle. At a low voltage/ current, there are fewer working fibers, at higher, a larger number of working fibers.

As a rule, the higher the number of working fibers, the more effective the stimulation.

Adjust the output voltage to a level (between 1 and 10) that the patient can maintain without discomfort. This intensity level typically increases as the patient progresses in the treatment regimen.

Intensity adjustments should be done only after electrodes are placed on the patients' skin and connected by cables to the stimulator cable outlets (7). In addition to the automatic intensity control that is imbedded in the programs (e.g. gradual ramps before strong tetanic contractions), the manual intensity control knobs (6) on the front panel override and control the intensity of stimulation. The manual setting of stimulation intensity is done by slowly turning the control knob in a clock-wise direction and observing the reaction of the stimulated muscles. For observation purposes, the brightness of the green-colored indicators (3) located above the intensity control knobs (6) change proportionately to the intensity of stimulation. These indicators flash green light simultaneously with each electrical impulse delivered to the respective outputs.

The stimulation intensity is adequate when there is visible, good quality contraction of the muscle. The numbers on the intensity dial indicate the relative intensity on a scale 1 to 10; the higher the number, the higher the intensity.

Stimulation intensity should be set at the maximum tolerance level of the patient, which varies from person to person. Advance the stimulation intensity controls during the first 5 minutes of each treatment making sure that the contractions are strong but comfortable. Help the patient relax by explaining that a pleasant tingling sensation, accompanied by effortless muscle contractions, will be felt as you slowly advance the intensity controls. This will help achieve maximal level of muscle contractions without exceeding the pain tolerance of the patient.

Sometimes a muscle will need strong stimulation intensity in order to obtain contractions. If a good muscle contraction is neither visible nor felt, despite increasing the intensity of the stimulus, check the contact and the placement of the electrodes on the motor point, re-moisten the electrode contact surface (if necessary) and/or reposition the electrodes. Continue to adjust all the intensity dials in the same manner until visible and perceptible muscle contractions are observed.

There are typically different response in terms of contraction force from different muscles of the body due to differences in size, proximity to skin surface, muscle characteristics and skin resistance.

As a result, the two intensity control dials on the ***Physio Clinique Pro*** may not be on the same numerical setting during treatments.

Skipping/Repeating a Phase of the Stimulation Program

Any part (phase) of the stimulation program can be skipped or repeated during a stimulation session. This is done by pressing once or twice on the program control buttons (4). Pressing the button marked "▲" will skip a part (phase) or parts of the stimulation treatment program. For example, in Program 1, pushing the "▲" button after the start of Phase 1 will skip this phase, and the stimulation sequence will switch to Phase 2. The digital program and elapsed time display (2) will display the new time left until end of stimulation, in this case, 15 minutes. In general, the "▲" pushbutton has the function of shortening the stimulation session by skipping entire stimulation sequences of a program.

To repeat any part (phase) of an already executed stimulation sequence, press the program control (4) button marked "▼". The digital program and elapsed time display (2) will change the display to new, longer time remaining until end of stimulation. In general, the "▼" pushbutton has the function of making a stimulation session longer lasting by repeating the selected stimulation sequences.

Turning the Stimulator ON and OFF

In order to turn the ***Physio Clinique Pro*** **ON** it is necessary to turn **any**, even one, of the intensity control knobs (6) in a clockwise direction, just past the audible click. An audible "BEEP" and the yellow/ orange ON status light (1) indicate that the stimulator is turned ON. **ALWAYS turn the *Physio Clinique Pro* OFF** at the end of each treatment by turning **BOTH** of the intensity control knobs (6) counterclockwise to the OFF position. An audible click will be heard, and all displays on the front panel become inactive. If the ***Physio Clinique Pro*** is left ON, the battery will be prematurely drained.

Ending a Treatment Session

Each treatment program has a pre-programmed time.

When a program is finished, two events happen:

a) Sensation of stimulation stops
b) Both green lights stop blinking

Once the stimulation stops automatically, turn both of the intensity control knobs (indicated as 6 in the drawing on page 10) counterclockwise to the OFF position. Failing to do this will cause premature battery discharge. Remove the electrodes in the reverse order they were placed to avoid tangling, and place them to the front or on the side of the unit.

Possible Errors

The ***Physio Clinique Pro*** is inherently safe and easy to use. Some errors are, nevertheless, possible and are as follows:

- Tingling sensation under electrodes but no visible contractions
  - Probable cause: electrodes are dry or soiled or intensity dials are set too low
  - Remedy: Clean and/or re-moisten electrode surface or adjust intensity dials

- Orange light ON/no stimulation effect
  - Probable cause: Weak or dead battery
  - Remedy: Replace battery

- Increasing intensity level causes unpleasant sensation (pain) under electrodes
  - Probable cause: Incorrect electrode placement
  - Remedy: Reduce intensity to zero and reposition electrodes over/in vicinity of motor points

- Green output lights ON/no contractions and no stimulation sensation
  - Probable cause: Cables not completely plugged into output sockets.
  - Remedy: Push cables fully into sockets; if no effect, replace cable(s).

- No lights when ***Physio Clinique Pro*** is turned on/no stimulation output
  - Probable cause: No battery installed or disconnected battery
  - Remedy: Replace or connect battery

Now, some specific instructions to ensure safe and proper operation of the ***Physio Clinique Pro!***

Inserting or Replacing Batteries

The battery depletion indicator orange light (5) on the front panel warns that the batteries need to be replaced; only several hours of operation remain.

Replace the batteries as soon as possible; when batteries are completely exhausted (or absent), no lights will function. Insert new batteries by opening the battery compartment on the rear panel. The six cells should be inserted observing their polarities as indicated on the drawing on the rear panel. Use brand name alkaline 1.5 V type "C" cell batteries. Recommended types are LR14 or AM2.

Warnings Concerning Battery Handling

Always read and follow the specific instructions provided by battery manufacturers. Note the following:

- Ensure that battery polarity is correct.
- Do not expose batteries to temperatures exceeding manufacturer's specifications.
- Do not store and/or ship this unit with batteries inserted.
- Do not attempt to recharge alkaline or lithium batteries.
- Do not dispose of any battery in fire.
- Note that batteries may present burn or fire hazard if short-circuited.
- Improper battery handling may result in explosion, leakage or flames.

Troubleshooting

If your ***Physio Clinique Pro*** unit is not working, please check the following:

1. Is the battery correctly inserted?
2. Are the cable connectors properly inserted into the ***Physio Clinique Pro*** unit?
3. Are the skin pads (electrodes) connected to the cables?
4. Are the skin pads (electrodes) adhering to the skin? If not, wet the pad surfaces sparingly with water.
5. If there is difficulty in selecting the desired program, is the program select button being pushed ***within 10 seconds*** of turning the control knobs (4) ON?

VIII. Simulation Program Description

The ***Physio Clinique Pro*** has four (4) programs for neuromuscular stimulation treatments.

The following parameters will assist in better understanding of the unique features of the ***Physio Clinique Pro:***

Channels

Two, isolated channels, with independent intensity controls

Output

Variable impulse intensity (each channel), from 0 to 90mA peak ±10% @ 500Ω load
Compensated monophasic rectangular waveform with low voltage of 45Vp ±10% (maximum into open circuit)
Fast rise, asymmetrical biphasic current impulse waveform (during treatment) w/no DC current
Impulse frequency (tetanic) from 50 Hz to 80 Hz depending upon program
Impulse frequency (subtetanic) from 4 Hz to 10 Hz
Impulse duration from 20 to 255 microseconds depending upon program

Controls

One continuously variable intensity knob per channel with ON/OFF safe ON switch.
Two pushbutton switches to select any of the 4 treatment programs from the memory

Displays

2 Output indicator lights; one low battery light; 2-digit display of elapsed time

Timer

Automatic OFF after completed treatment time of 15 to 90 minutes, user selectable.

The timing sequences and frequencies for the ***Physio Clinique Pro*** programs are provided in this table:

		Program 1	***Program 2***	***Program 3***	***Program 4***
Ramp just prior to contraction	sec	-	3	3	3
Tetanic Contraction-Stimulus ON	sec	-	6	12	9
Ramp plus contraction	sec	-	9	15	12
Ramp after contraction	sec	-	-	-	-
Relaxation after contraction Stimulus OFF	sec		21	18	48
Stimulus frequency, maximum with tetanic contractions	Hz Max	120	87	62	89
Max Impulse duration	µs	300	220	255	180
Total Cycle	sec		30	54	60
Contractions/ minute	min				
Program time (total)	min	20	90	15	28

IX. Treating Indications with the Physio Clinique Pro

A. RELAXATION OF MUSCLE SPASM

If a muscle spasm is present in any part of the body, the spasm can be relieved by immediate application of stimulation to the affected muscle(s). A spasm, which is usually painful, is inhibited right away following the treatment and the relief lasts for some time. It is normal to experience a return of pain after some time following each treatment. It may even be reported as an aggravation of pain by some patients. This is only relative and temporary, and the spasm free periods following treatment will become longer and longer until the pain disappears.

To relax the spasms, place at least two electrodes on each muscle in such way that the direction of stimulation (a straight imaginary line between the electrodes) is aligned with the longitudinal axis of the muscle.

Program(s)

Program 1 is best suited; however, Program 4 can be used if preferred by the patient.

Treatment time

20-28 minutes.

Treatment frequency

No more than every 2 hours, for as long as needed

Stimulation intensity

During the first 2 treatments at light intensity, well below maximum. Thereafter, increase the intensity for subsequent treatments in accordance with patient tolerance.

B. PREVENTION OR RETARDATION OF MUSCLE ATROPHY

It has known that during immobilization for medical reasons, all muscles that are temporarily unused are subject to atrophy (wasting). To remedy this, stimulation of muscles is recommended if and when normal physical exercise is impossible.

Program(s)

Program 2 only for at least first 5 treatments; follow with Program 2 in combination with Program 3 for more intense work.

Treatment time

90 minutes (Program 2) for the first 5 treatments then 90 minutes (Program 2) + 15 minutes of Program 3 (105 minutes total treatment time for subsequent sessions).

Treatment frequency

Every 24 hours but not less than every 48 hours, for as long as immobilization lasts.

Stimulation intensity

Initially low, progressively increasing to reach the maximum patient tolerance level.

C. PARTIAL ATROPHY AND/OR SPASM OF PARASPINAL MUSCLES

The ***Physio Clinique Pro*** is especially effective for releasing spasm and accompanying pain in spinal region.
The stimulating electrodes should be placed symmetrically on both sides of the spine (see placement photos) at the level of maximum pain or in positions indicated by the prescribing physician. The following treatment procedure is recommended:

Program(s)

Program 1 only for the first 5 treatments at maximum tolerable intensity in order to relieve muscle spasm, followed by Program 2 for subsequent treatments.

Treatment time

20 + 90 minutes.

Treatment frequency

every 24 hours, for 7 to 10 days

Stimulation intensity

initially low, progressively increasing to reach the maximum patient tolerance level

Normally, spasms, which are usually painful, are inhibited right away following the treatment and the relief lasts for some time. It is normal to experience return of pain after some time following each treatment. It may even be reported as an aggravation of pain by some patients. This is only relative and temporary, and the spasm free periods following treatment will become longer and longer until the pain disappears. Stimulation in such cases has not only spasm relieving action but also it may reeducate paravertebral muscles to provide better support for the spine, thus preventing the recurrence of back problems.

D. INCREASING LOCAL BLOOD CIRCULATION

It is known that local blood flow increases with stimulation. Such increase reaches peak within the first 15 minutes from the onset of stimulation. Therefore for practical reasons, the short lasting stimulation treatments are recommended.

Program

Program 1 is recommended, although blood flow increase happens as a beneficial side effect when stimulating with any stimulation timing program.

Treatment time

20 minutes.

Treatment frequency

every 24 hours, or as needed

Stimulation intensity

initially low, progressively increasing to reach the maximum patient tolerance level.

E. MUSCLE RE-EDUCATION

Electrical muscle stimulation may be applied to patients before, during or after physiotherapy re-education. Electro stimulation may also be applied during and/or after immobilization following orthopedic surgery involving the long bones and joints. After deciding which parts of the body are to be treated, and, upon selection of the appropriate number of electrodes and their location, use the following simplified application method:

Program(s)

If muscle spasm is present, start with Program 1 for 20 minutes followed by Program 2. Otherwise, use only Program 2.

Treatment time

Highly variable, up to a maximum of 120 minutes.

Treatment frequency

Once per day, daily or on alternate days
Number of treatments : Normally 20 treatments, but can be increased to 40 when necessary to reach the treatment goals or recovery of normal or desired functions.

Stimulation intensity

Initially low, progressively increased after two or three treatments, reaching maximum setting, when possible, by the eighth treatment session.

For most effective reeducation of muscles and joints with the ***Physio Clinique Pro***, the following factors are important:

- Try at all times to use the optimal stimulation intensity, i.e., the strongest contractions should be achieved within the limits of patient comfort and tolerance with no pain.

- Stimulation intensity has no absolute value and may vary from day to day and also during a treatment. Thus, when the skin and muscles are warmed (using thermal wraps, for example), or a series of massages (or a steam bath) have been performed before a stimulation treatment, a slightly lower intensity will suffice to give the desired effect.
- It is possible to treat several areas at once on one patient, allowing considerable saving of time.
- It is possible to mount the stimulator electrodes on the skin under a cast and thus prevent muscle atrophy even on a limb which is fully immobilized, as for instance in patients in a pelvipaedic cast.

F. CALF MUSCLE STIMULATION FOR THE PREVENTION OF VENOUS THROMBOSIS BY IMMEDIATE POSTSURGICAL STIMULATION

It has been demonstrated and reported in medical literature that electric muscle stimulation is effective in reducing the evidence of, and preventing, the symptoms of venous thrombosis. After electrode placement on motor points of calf muscles, the following treatment method is recommended:

Program

Program 2

Treatment frequency

As prescribed by physician or up to 3 x per day, for as long as the patient is immobilized

Stimulation intensity

Initially low, progressively increasing up to the maximum patient tolerance level.

G. MAINTAINING OR INCREASING RANGE OF MOTION OF EXTREMITIES

Electrical muscle stimulation may be applied to patients as an adjunct to physiotherapy procedures.

After deciding which extremities are to be treated and upon selection of the appropriate number of electrodes and their location, use the following simplified application method:

Program(s)

If muscle spasm is present, start with Program 1 for 20 minutes and follow with Program 3. Otherwise, use only Program 3.

Treatment time

20 minutes of the Program 1 (optional) plus/or 15 minutes of the Program 3.

Treatment frequency

Once per day, daily or on alternate days

Number of treatments: Normally 20 treatments but can be increased when necessary to reach the treatment goals or recovery of normal or desired function.

Stimulation intensity

Initially low, progressively increased after two or three treatments, reaching maximum setting, when possible, at the eighth treatment session.

For most effective maintenance of range of motion of extremities with the ***Physio Clinique Pro,*** the following factors are important:

- At all times try to use the optimal stimulation intensity; i.e., the strongest contractions within the limits of patient comfort and tolerance, with no pain.
- Stimulation intensity has no absolute value and may vary from day to day and also during a treatment. Thus, when the skin and muscles are warmed (using thermal wraps, for example), or a series of massages (or a steam bath) have been performed before the stimulation treatment, a slightly lower intensity will suffice to give the desired effect.
- It is possible to treat several areas at once on one patient, which permits considerable time savings.

X. Useful Information

A. HANDLING/CLEANING THE *PHYSIO CLINIQUE PRO* UNIT

Use soft brush or soft cloth to clean unit case; do not use liquid cleansers. Use same procedure with electrical leads. The ***Physio Clinique Pro*** is designed to be maintenance free.

B. STORAGE CONDITIONS

The ***Physio Clinique Pro*** may be stored for prolonged periods with no degradation. Remove batteries when the unit is stored.

C. BATTERY DISPOSAL

Always dispose of batteries in accordance with battery manufacturer instructions.

D. REPLACEMENT ELECTRODES

Palsflex® electrodes (part number 896350 for 3"x5" oval electrode and 879300 for ~3" round electrode) are available through Valmed.

E. WARRANTY

The manufacturer warrants to the original buyer that ***Physio Clinique Pro*** is free from defects in material and workmanship for a period of twenty four months from the date of purchase. Valmed SA will replace any defective product free of charge except for shipping charges during the warranty period. To validate the warranty please mail the warranty card to Valmed S.A. To obtain an immediate replacement unit under warranty, please contact Valmed or your local distributor directly. This warranty does not apply to the accessories which include electrodes, body straps, and batteries or to damage related to improper use or abuse. Any product requiring factory service should be returned to the manufacturer, properly packaged to avoid damage during shipping. All description of the problem as well as suspect accessories should be included with the unit.

This manual contains necessary instructions for the correct use of the stimulator. They should be followed in order to obtain the maximum benefits from the use. The warranty card (enclosed) should be returned to the manufacturer within 10 days of purchase. The serial number of the device can be found on the rear panel.

For all other needs of service after sale contact your local representative or Customer Service at

Valmed S.A., Av. de Tourbillon 34,
CH - 1950 Sion (Switzerland).
Phone +41-27-203 65 81 or fax: + 41-27-203 65 87
www.valmed.ch
e-mail: info@valmed.ch

XI. Physio Clinique Pro Technical and Safety Data

A. UNIT TECHNICAL CHARACTERISTICS

Channels

Two isolated channels with independent control of intensity for each channel.

Maximal Output Ratings

Impulse intensity (each channel): 90 mA peak
Impulse value, ±10% on 500Ω.
Effective value of output voltage <5V (rms) ±10%,
Impulse duration: 255 µsec
Impulse frequency: 80 Hz
Electric charge of each impulse < 23 micro coulombs

Controls

Two continuously variable intensity control knobs with safe ON/OFF switch.
Two pushbutton switches to select any of the 4 treatment Programs from the memory and to select treatment time override of automatic timer.

Displays

2 Output indicator lights.(1) Low battery light. 2-digit display of elapsed time

Timer

Automatic OFF after completed treatment time with user selectable override.

Power Supply

Six "C" cells, type 6LR61. Drain:<10mA @standby; <55mA with 2x500 Ω load.
All stimulation and timing parameters are stable throughout battery life, i.e. until the battery discharge is indicated by the warning light (at < 6V).

Standard Accessories

Six 1.5V alkaline cells, 2 each, two-conductor electrode cables, 2 sets, i.e. 4 self-adhesive stimulation electrodes, 1 instruction manual.

Optional

Carbonized rubber and self-adhesive electrodes of different sizes and fasteners.

Weight

2kg net, 3.2kg gross; dimensions of the stimulator (net): 30 x 26 x 10 cm; dimension of complete stimulator with accessories packed in a shipping carton: 40x30x15 cm.

Warranty

Two years free stimulator replacement except electrodes, battery and shipping charges.

B. SAFETY

Specific safety features in the ***Physio Clinique Pro*** include:

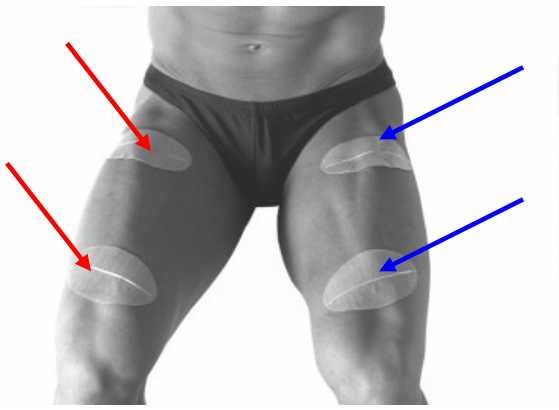
1. Impossible to modify the embedded programs; users can only modify the intensity of stimulation
2. All programs begin with minimal electrical intensity; user must increase the intensity to the desired training level.
3. Maximum possible phase charge is 24.75 microcoulombs.
4. The connector plugs used on ***Physio Clinique Pro*** cables have plastic hood covers that prevent accidental connection to a power source, such as an AC power outlet.
5. Automatic control of stimulation current density prevents excessive current density at the electrode-skin interface and ensures skin safety.

XII. Electrode Placement

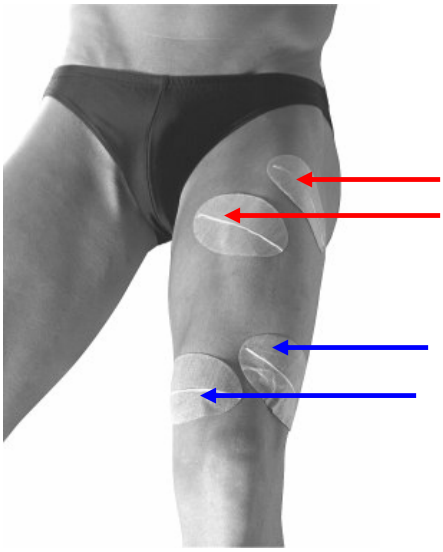
The Physio Clinique Pro should only be used with the electrodes recommended for use by the manufacturer. Use oval 3" by 5" electrodes for large areas (e.g., leg muscles) and round 3" electrodes for smaller areas such as forearm muscles. Use of smaller electrodes than those recommended may result in skin irritation and burns beneath the electrodes.
Leads for Channel 1 are depicted in RED and leads for Channel 2 in BLUE. Where only one set of electrodes is shown, Channel 1 is depicted but Channel 2 may be used instead. Channels may be reversed, if desired, from that indicated in the following photos.

QUADRICEPS

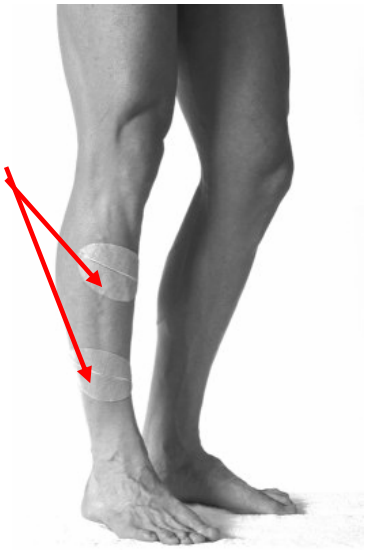
On Both Legs



On One Leg

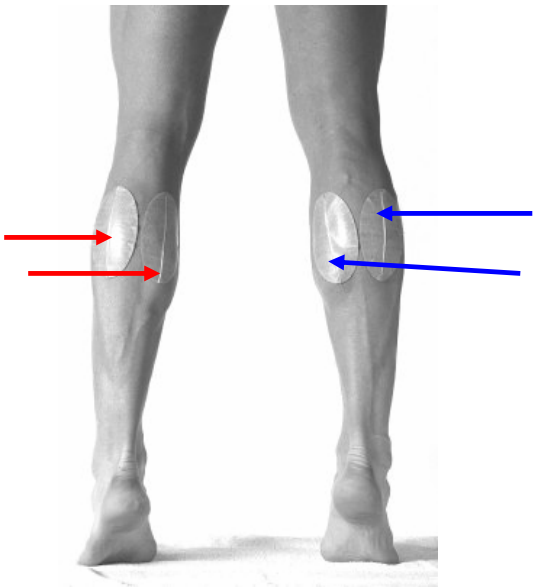


TIBIA

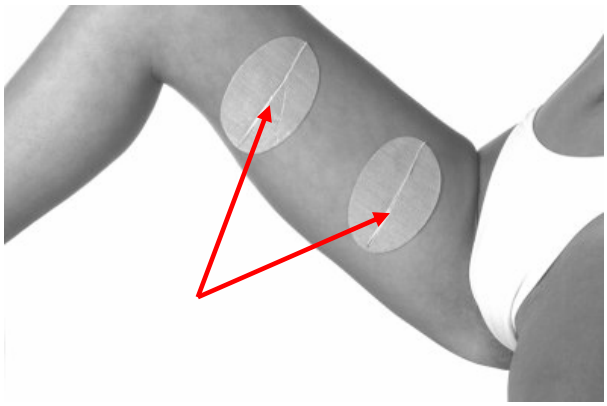


Channel 2 electrodes may be attached to other leg in order to treat both legs

CALVES

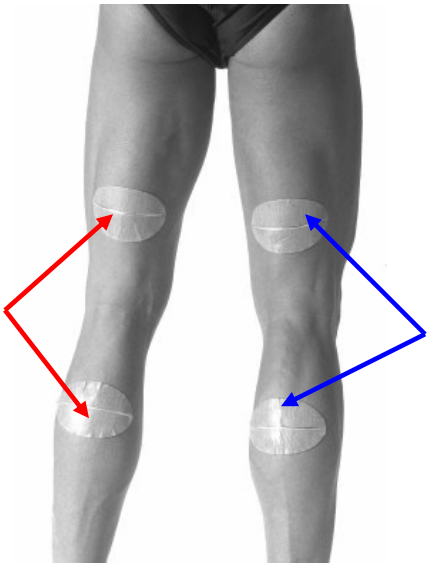


THIGHS

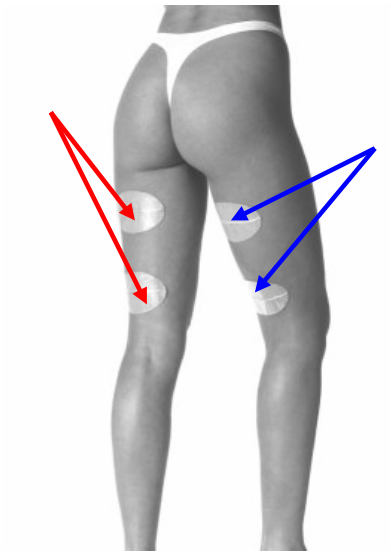


Channel 2 electrodes may be attached to other thigh in order to treat both thighs

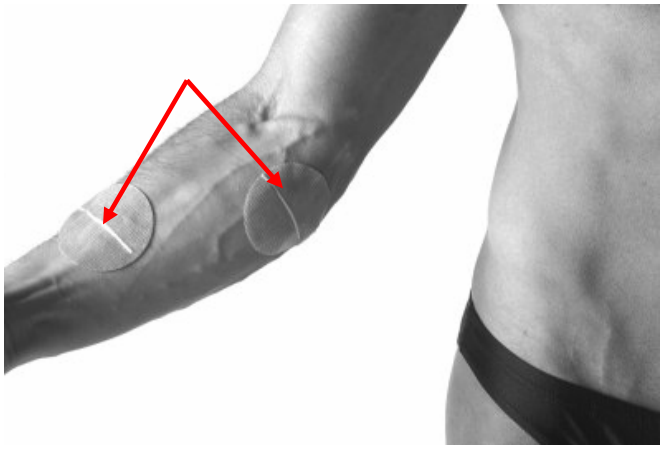
FEMORAL BICEPS AND CALVES



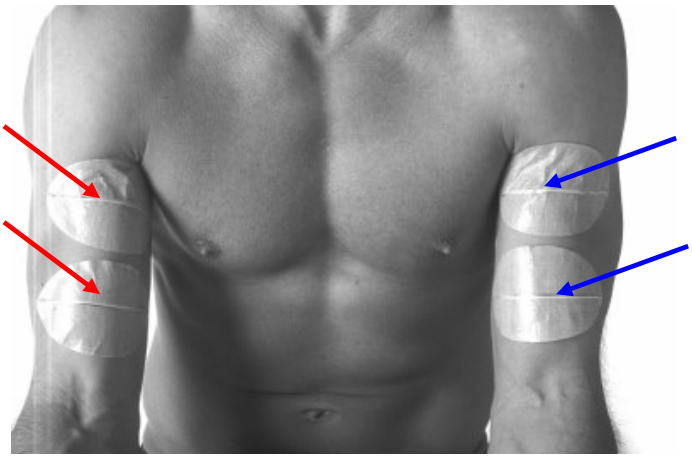
FEMORAL BICEPS



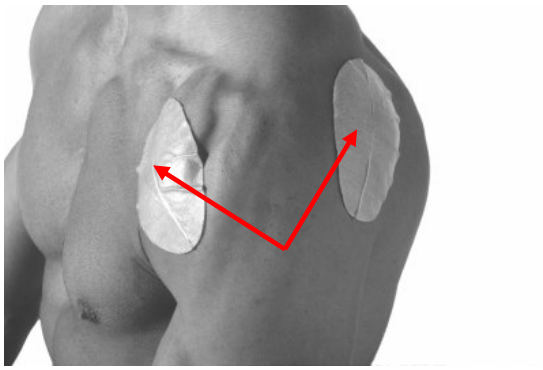
FOREARM



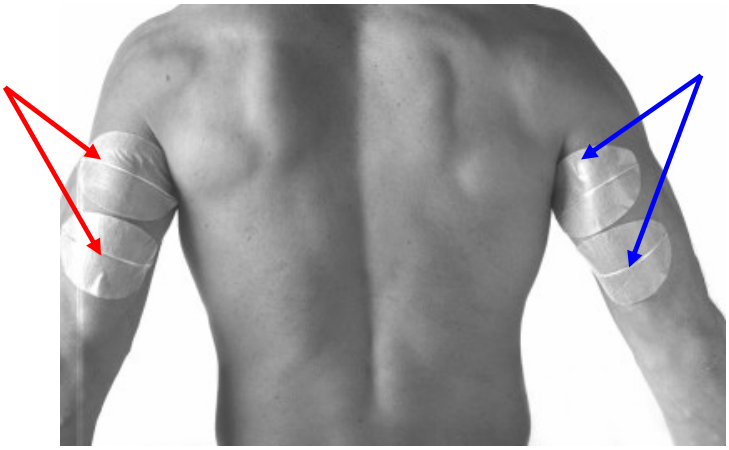
BICEPS



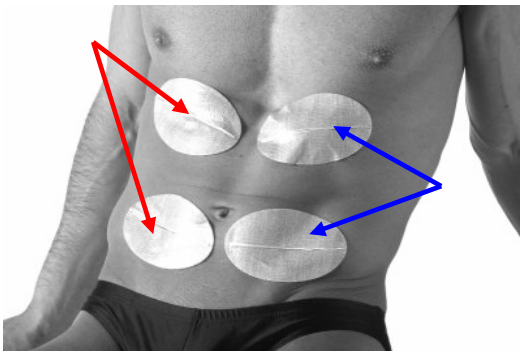
DELTOID



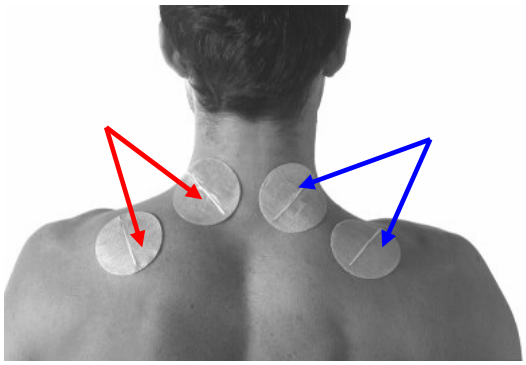
TRICEPS



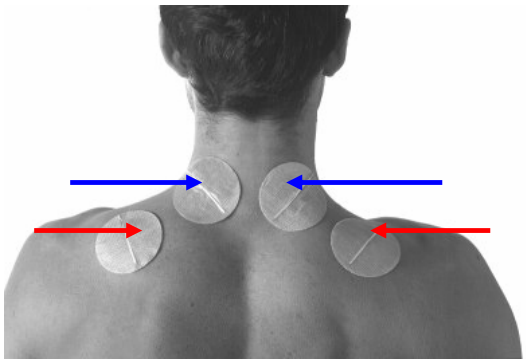
ABDOMINALS



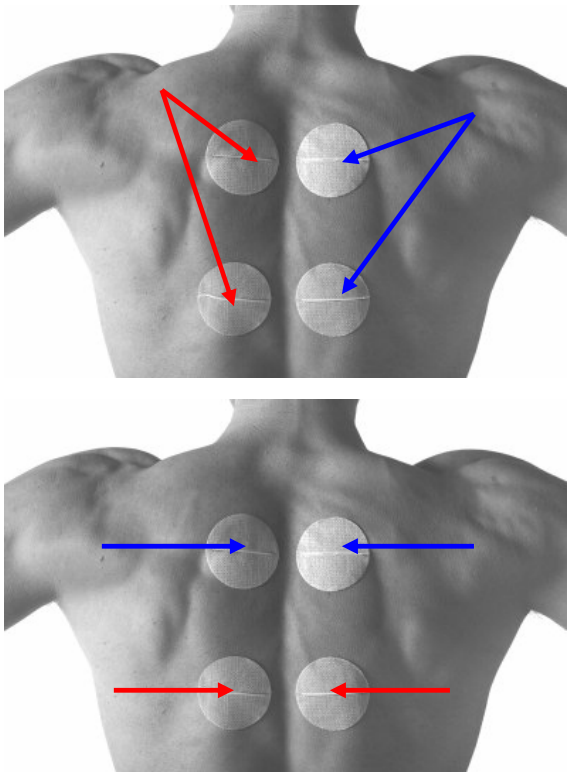
UPPER TRAPEZIUS



or

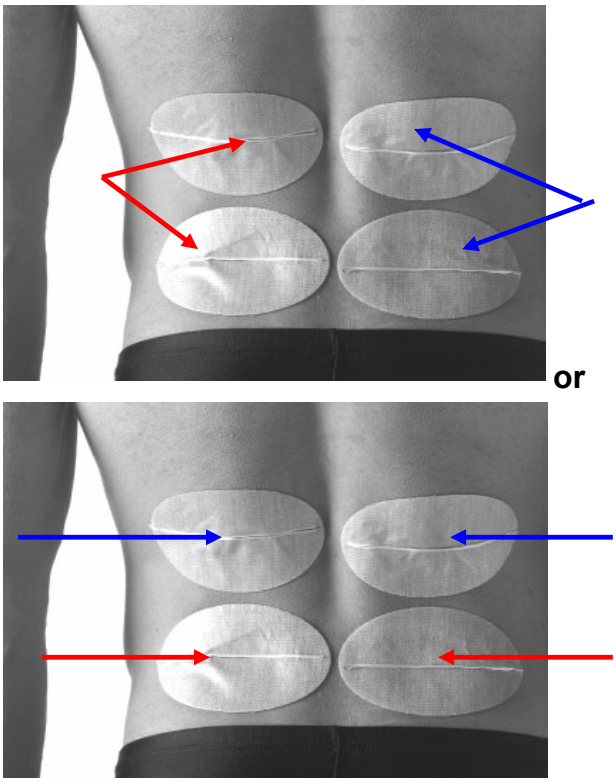


LOWER TRAPEZIUS



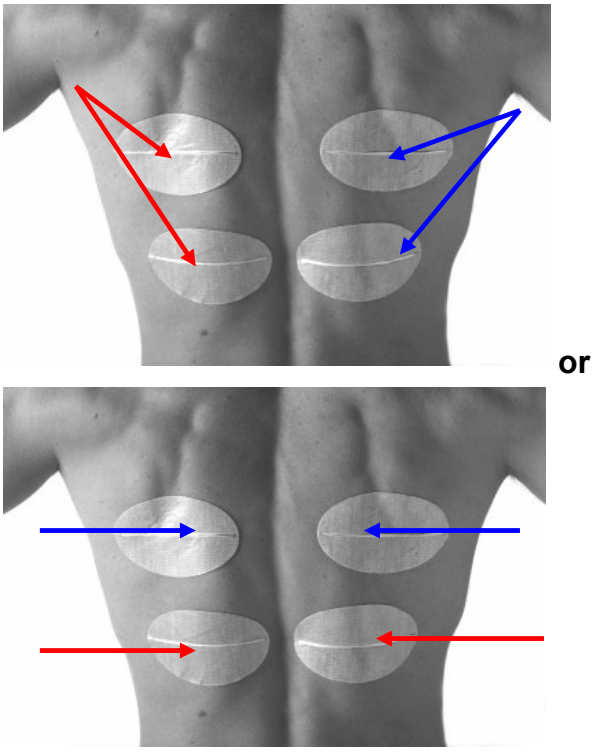
or

LUMBAR VERTEBRAE



or

LARGE DORSAL



or

NECK-BACK