VALMED
SWISS TECHNOLOGY

User Manual

Physio V60

Neuromuscular Stimulator

P4-PH-V60-EN-V10

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INTRODUCTION

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

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

Read this *Manual Before Using the Physio*

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

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INTENDED USE AND INDICATIONS

The ***Physio*** neuromuscular stimulator (EMS) is intended for use by licensed health practitioners; this type of neuromuscular stimulator is limited to prescription sales. The ***Physio*** treatment programs are designed and intended for stimulation of all parts of the body except transthoracically, the head and front part of the neck.

The specific indications include:

- Prevention or Retardation of Muscle Atrophy
- Relaxation of Muscle Spasms
- Partial Atrophy and/or Spasms of Para-spinal Muscles
- Muscle Re-education and Strengthening
- Increasing Local Blood Circulation
- Maintaining or Increasing Range of Motion of Extremities

SAFETY AND PRECAUTIONARY GUIDELINES

A. MEDICAL CONTRAINDICATIONS

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

B. SPECIAL AND ENVIRONMENTAL WARNINGS

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

C. HEALTH PRECAUTIONS

For persons with any type of cancer the electrostimulation 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 haemorrhage 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 persons 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*** 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 large electrodes is supplied with the ***Physio***.

- 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.

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*** is designed to provide a totally safe treatment without sacrificing effectiveness. In this respect, the ***Physio*** is non-pareil. Further, to ensure safety, durability and efficiency, only premium electrical components are used.
The stimulation impulses generated during ***Physio*** 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*** should be used by a person to be treated with an implanted cardiac pacemaker and that the safety standards for pregnant women has not been established.

The ***Physio*** is designed so that even improper or accidental application of the stimulator will not produce cardiac rhythm disturbances (this does not apply to persons who have implanted cardiac pacemakers). This safety factor 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 harbour apprehension, anxiety or even fear regarding electricity. It is therefore very important that person understands how completely safe treatments with the ***Physio*** are.

Educating the person to be treated is therefore a recommended first step!

The effective value of the stimulation voltage a person will experience during treatment with the ***Physio*** is very low, below 5 volts (root mean square) at the maximum setting of the intensity knobs. The ***Physio*** uses one 9 volt battery.

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 person to be treated;
- 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 person to be treated.
The controls on the ***Physio*** 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 person'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 person'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 person to be treated 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 also 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 Program 1 (Facelift) please refer to electrode positions and instructions shown in Section VIII.

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

PHYSIO UNIT DESCRIPTION

The ***Physio*** features include:

1. Sliding Cover
2. Program Select Button
3. Program lights (4 each)
4. Output Intensity Lights (2)
5. Low Battery Indicator
6. Intensity Controls (2 each)
7. Output Sockets (2)

USING THE PHYSIO

A. OVERVIEW

Although treatment with the ***Physio*** adapts to virtually any standard procedure, the following suggestions are made to health professionals in order to take full advantage of its capabilities; obviously, these suggestions also apply to individuals using the Physio. Physical exercise, massage and manipulation all have a place in comprehensive therapies and may be employed prior to, or after electrostimulation 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*** prior to, or after treatment.

B. 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 person to be treated the method and the sequence of events during the entire treatment. Select electrode placement locations and record them on the treatment chart.

The ***Physio*** is powered by a 9V alkaline or lithium type battery. For best results, use only good quality and fresh batteries.

The ***Physio*** must be connected to the skin pads (electrodes) and the electrodes must be positioned on the skin as shown in **"Electrode Placement" Section XI** of this manual entitled "Electrode Placement". The specific placement of electrodes on your skin depends upon which muscle group or groups you intend to stimulate.

To use the ***Physio*** effectively and safely, the following steps **must** be considered:

- Choosing the appropriate training program
- Proper placing of electrodes, and
- Setting the current intensity

C. CHOOSING THE APPROPRIATE PHYSIO TRAINING PROGRAM

The program chosen determines the type of work imposed on the stimulated muscle. Based upon your specific objective or need, select the program that is appropriate. See **Section VIII** for ***Physio*** program guidance.

D. 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*** 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*** in order to assure effective stimulation. The self-adhesive stimulating electrodes supplied with the ***Physio***, are suitable for multiple use.

In order to avoid cross-contamination of skin of persons to be treated by these electrodes, it is essential that the same electrode set be used for one individual only. The set of electrodes used for one person 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 person to be treated 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 XI** of this manual. The specific placement of electrodes on the skin depends upon the specific muscle group or groups that are to be stimulated.

E. SETTING THE CURRENT 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 8) that you can maintain without discomfort. This intensity level typically increases as you progress in your stimulation training using the ***Physio***.

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 person to be treated, 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 person to be treated 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 person to be treated.

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*** may not be on the same numerical setting during treatments.

F. ISOMETRIC POSITION

Always stimulate muscles isometrically; make sure that the arm or leg on which a muscle is being stimulated is firmly secured to prevent the movement of the limb (resulting from muscle contraction).

G. SWITCHING THE UNIT ON

Turn the intensity control knobs until you hear a click.

H. CONNECTIONS

Please refer, as needed, to the control schematic of the ***Physio*** and to

1. Ensure that the intensity control knobs are in the OFF position
2. Connect the skin pads (electrodes) to each output cable
3. Position the skin pads (electrodes) on the motor points of the muscles to be treated

Connect the output cables to the output sockets of the ***Physio*** unit.

I. SELECTING A PROGRAM

Within 5 seconds after switching the unit "ON", select a stimulation program by pushing the program select button until the green indicator light for the desired program flashes. If a selection is not made within 5 seconds, **Program 1** automatically starts by default. There are four Program indicator lights labeled P1, P2, P3 and P4.

J. RUNNING A PROGRAM

1. Do not remove/relocate the electrodes during stimulation; turn unit OFF before removal or relocation of electrodes
2. Each program consists of several stimulation sequences, for example, tetanic contractions followed by periods of rest. The full program should be completed for maximum benefit.

K. ENDING A PROGRAM

- Each program has a preprogrammed duration. Program completion is signaled by three separate events:
  - stimulation signals stop
  - both green lights stop blinking,
  - a continuous "beeping " signal is heard.
- Once the stimulation stops **(or if you wish to end treatment before completion of any program)**, turn both intensity control knobs counterclockwise to the OFF position. Failing to do this will cause battery discharge.
- Remove the skin pads (electrodes) from the skin.
- Disconnect the skin pads (electrodes) from the cables and store them in the hermetically sealed bag.
- To end treatment in any program **before** its preprogrammed duration, turn both intensity control knobs counterclockwise to the OFF position.

L. TROUBLESHOOTING

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

1. Is the battery correctly inserted?
2. Are the cable connectors properly inserted into the ***Physio*** 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 5 seconds*** of turning the intensity control knobs ON?

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

M. INSERTING OR REPLACING BATTERIES

The orange warning light on the ***Physio*** shines when the battery requires replacement. If the battery is not replaced, your ***Physio*** will cease to operate within one (1) hour and no indicator lights will function.

Remove (slide) the battery compartment cover. Remove old battery and insert new 9-volt lithium, alkaline or rechargeable NiMh battery. Ensure proper battery polarity; your ***Physio*** will not operate if polarity is reversed.

N. 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.

STIMULATION PROGRAM PARAMETERS

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

The timing sequences and frequencies for the ***Physio*** 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		18	39	48
Stimulus frequency, maximum with tetanic contractions	Hz Max	120	50	62.5	50
Max Impulse duration	µs	250	180	250	180
Total Cycle	sec		27	54	60
Contractions/ minute	min				
Program time (total)	min	20	90	15	28

PHYSIO TREATMENT PROGRAMS

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 also 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 ATROPHY OF MUSCLES

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*** 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. Electrostimulation 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

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***, 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

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***, 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.

USEFUL INFORMATION

A. HANDLING/CLEANING THE PHYSIO UNIT

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

B. STORAGE CONDITIONS

The ***Physio*** 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

Pals Platinum 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*** 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

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PHYSIO TECHNICAL AND SAFETY DATA

A. UNIT TECHNICAL CHARACTERISTICS

Stimulation Channels

Two, independent, isolated channels. Separate knobs control intensity levels for each channel.

Controls/Indicators

- Two intensity control knobs; audible clicks at the OFF position
- Program selection button
- Two green output intensity lights, four program indicator lights
- Low-battery warning light

Output

- Waveform (open circuit): Low voltage, rectangular, compensated monophasic impulse.
- Peak open circuit voltage during each impulse: 50 Vp ±10%.
- Maximum output RMS voltage at 500 W load ≤ 10 V (volts) ± 10%.
- Frequency range: Maximum 120 Hz, depending on the program and timing sequences.
- Impulse durations during training: from 180µs to 300 µs

Power Supply

One 9 volt lithium, alkaline or NiMh rechargeable battery. Battery power drain is ≤ 1W. Battery power drain during use varies from 0.3W to 0.4W, depending upon stimulation intensity setting. The output and program timing parameters are stable (±2%) throughout the life of the battery.

Standard Accessories

- Four electrode skin pads (nonpolar, self-adhesive, reusable electrodes)
- One alkaline 9 Volt battery
- 2 cables

- Carrying case
- User Manual

Warranty

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

B. SAFETY

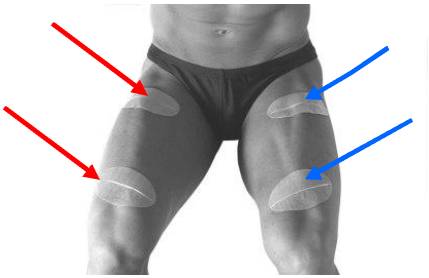
Specific safety features in the ***Physio*** include:

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

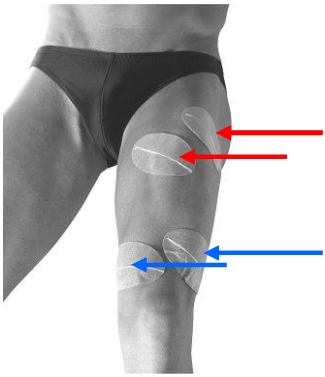
ELECTRODE PLACEMENT

The Physio 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. Do not use smaller electrodes than recommended above; for facelift electrode placement. **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

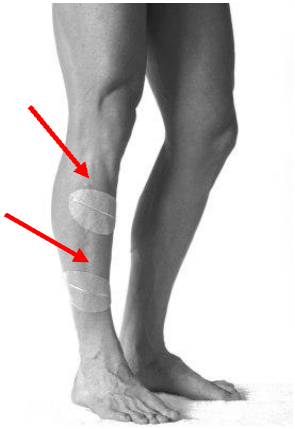


On both legs



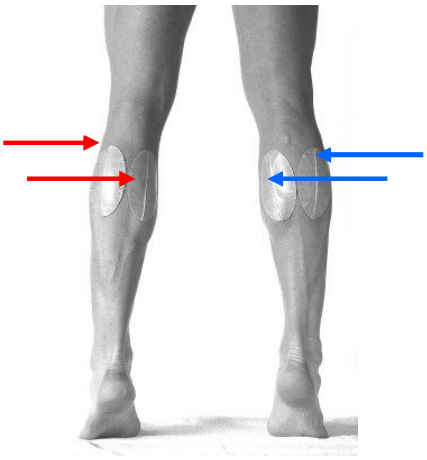
On one leg

TIBIA

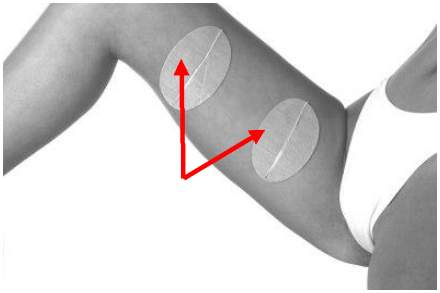


Channel 2 electrodes may be attached to other leg in order to treat both legs

CALVES

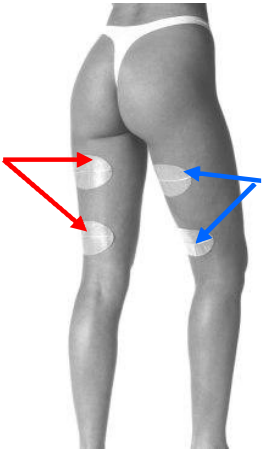


THIGHS

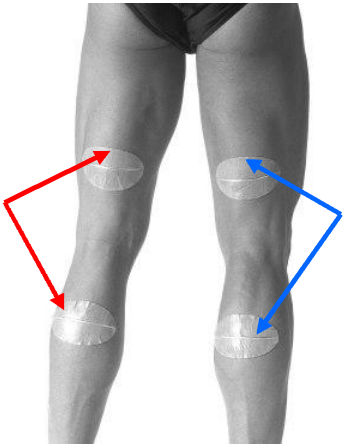


Channel 2 electrodes may be attached to other thighs in order to treat both thighs

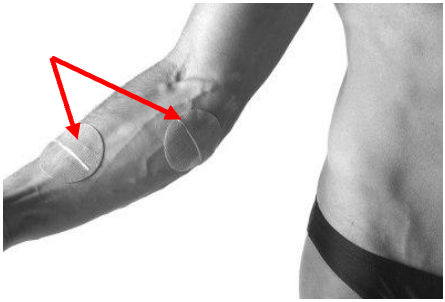
FEMORAL BICEPS



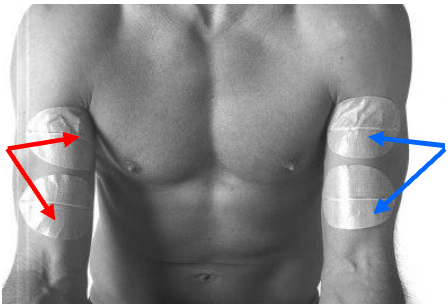
FEMORAL BICEPS AND CALVES



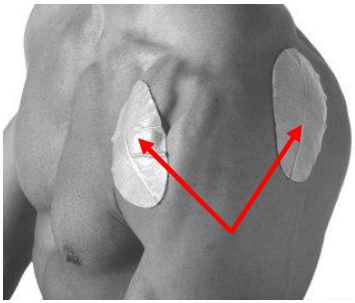
FOREARM



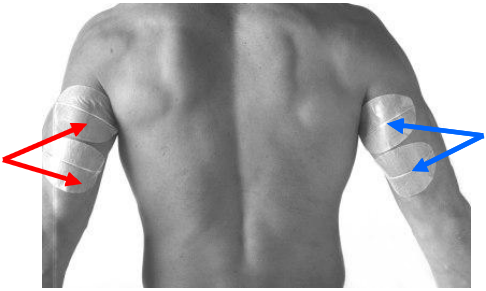
BICEPS



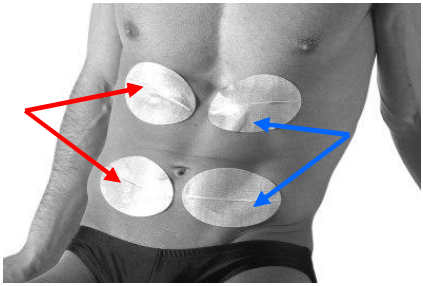
DELTOID



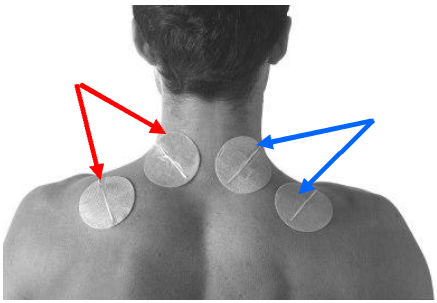
TRICEPS



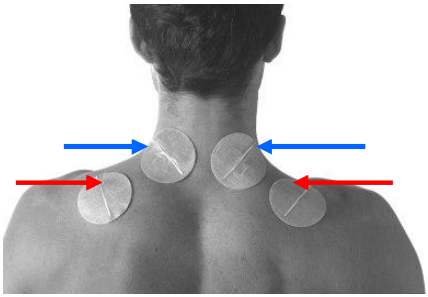
ABDOMINALS



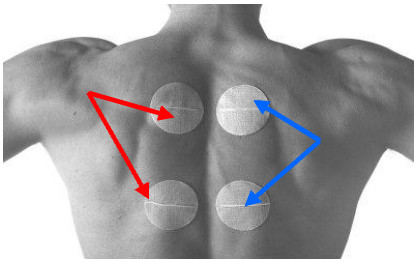
UPPER TRAPEZIUS



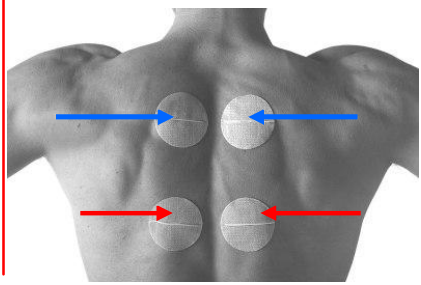
or



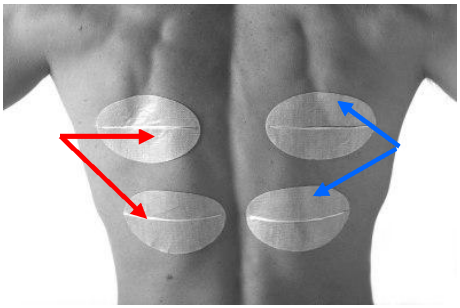
LOWER TRAPEZIUS

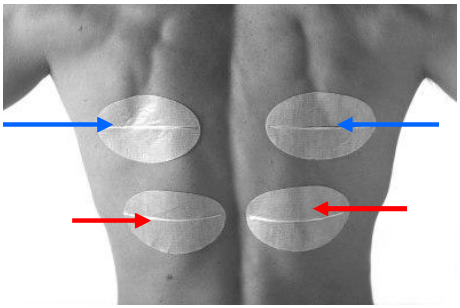


or

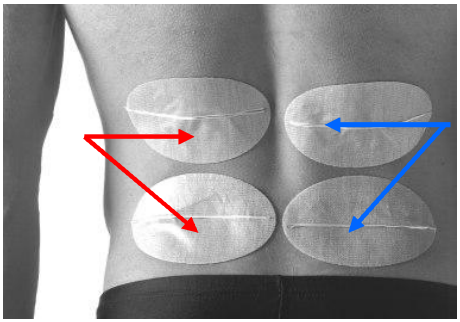


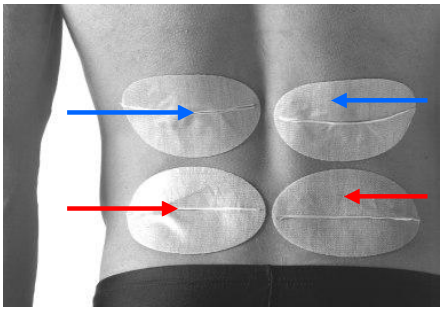
LARGE DORSAL





LUMBAR VERTEBRAE





NECK-BACK