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I - WARNINGS

1 - Counter-indications

- Do not treat persons with implanted electronic equipment, such as pacemakers and intracardiac defibrillators.
- Avoid electrode placement at the front and side areas of the neck.
- Pregnant women should not be treated during the first trimester (12 weeks).
- Do not use thoracic stimulation on patients with cardiac arrhythmia.
- Avoid lower limb stimulation in case of venous thrombosis or severe arterial obstruction (ischemia).
- Avoid abdominal stimulation if you have abdominal or inguinal hernia.

Important!

- Read this manual and the accompanying Practical Guide carefully.

2 - Safety measures



Important points to take into account when using Rehab 400:

- Do not use the stimulator in water or humid environments (saunas, hydrotherapy pools, etc.).
- If pregnant, do not place electrodes directly over the uterus or connect pairs of electrodes across the abdomen. The reason is that, theoretically, the current could affect the foetus's heart (although there are no reports of it being harmful).
- Observe caution if treating patients with sensitivity problems or who are unable to let you know if they feel any discomfort, however slight.
- Observe caution when stimulating in the immediate vicinity of cellular phones that are switched on, since this may affect the output power of the stimulator.
- Do not use the stimulator on a patient

who is connected to a high-frequency surgical instrument as this could cause skin irritation or burns under the electrodes.

- Do not use the stimulator within one metre of short wave or microwave devices as this could alter the currents generated by the stimulator.
- Only use stimulation cables, rechargeable battery units and charger supplied by CefarCompex.
- Always turn off the stimulator or make sure that the intensity for each channel is 0 before disconnecting cables from stimulator or electrodes.
- Never connect the stimulation cables to an external power source due to risk of electric shock.
- Do not use the Rehab 400 stimulator, or charger if any of the elements are damaged (case, cables, etc.) or if the battery compartment is open. There is a risk of electric shock.
- Unplug the charger immediately if your Rehab 400 emits a continuous beeping sound or if you notice any abnormal heat, smell, or smoke from either the charger or the stimulator.
- Never recharge the battery in a confined space (carrying case, etc.) as this could cause a fire or electric shock.
- Keep Rehab 400 and its accessories out of the reach of children.
- Keep the stimulator, battery compartment and charger clean.
- Sudden temperature changes can cause condensation to build up inside the stimulator. To prevent this, allow it to reach ambient temperature before use.
- Do not use your Rehab 400 while driving or operating machinery.
- Observe caution when using electrotherapy at the same time as the patient is connected to monitoring equipment with body worn electrodes. The stimulation might interfere with the signals to the monitoring equipment.



Precautions when using the electrodes:

- Only use electrodes supplied by Cefar-Compex. Other electrodes may have electrical properties that are incompatible with the Rehab 400 stimulator.
- Only place electrodes on healthy skin and never on skin lesions of any kind (wounds, swelling, burns, irritation, eczema, etc.).
- Always turn off the stimulator or make sure that the intensity for each channel is 0 before moving or removing the electrodes.
- Do not place the electrodes in water.
- Do not apply solvents of any kind to the electrodes.
- Do not use electrodes with a surface $< 18 \text{ cm}^2$, as there will be a risk of suffering a burn injury. Caution should always be exercised with current densities $> 2 \text{ mA/cm}^2$
- For optimal results, wash, clean and dry the skin before attaching the electrodes.
- Attach the electrodes so the entire surface is in contact with the skin.
- For hygiene reasons, each patient must have his own set of electrodes. Never use the same electrodes on different patients.
- Some people with very sensitive skin may experience redness under the electrodes after a session. This redness is generally harmless and normally disappears within 10 to 20 minutes. Do not start another stimulation session in the same area, as long as the redness is still visible.
- When the electrodes lose their adhesiveness and do not stick properly to the skin, the stimulation can feel unpleasant. Be sure that the electrodes are in good condition, otherwise they have to be replaced.

II PRESENTATION

1 - Warranty

This warranty is valid only if accompanied by proof of purchase. Your legal rights are not affected by this warranty. Your CefarCompex Rehab 400 stimulator is guaranteed for a period of 2 years from the date of purchase. The warranty covers the stimulator (material and workmanship) but not the battery unit, cables, or charger. All defects arising from substandard material or workmanship are covered. The warranty does not cover damage resulting from impact, accident, improper use, insufficient protection against damp, immersion in water, or repair work conducted by unauthorized personnel.

2 - Maintenance

- Clean with a soft cloth and an alcohol-based, solvent-free cleaning product. Use only a minimum amount of liquid when cleaning the unit.
- Do not disassemble the stimulator or charger as these all contain high-voltage components that could cause electric shock. This may only be done by persons or repair services authorized by CefarCompex.
- Your stimulator does not require calibration. If your stimulator contains parts that seem worn or defective, please contact your nearest CefarCompex customer service centre regarding an upgrade.
- Medical and health professionals are obliged to service the unit in compliance with relevant national laws and regulations. This involves testing performance and safety parameters at regular intervals.

3 - Storage and transportation conditions

The Rehab 400 contains rechargeable batteries and so the storage and transportation conditions must not exceed the following figures:

- Storage and transportation temperature: -20°C to 45°C
- Maximum relative humidity: 75%
- Atmospheric pressure: 700 hPa to 1060 hPa

4 - Usage conditions

Temperature: 0°C to 40°C
Relative humidity: 30% to 75%
Atmospheric pressure: 700 hPa to 1060 hPa.
Do not use in an explosion risk area.

5 - Elimination

Batteries must be disposed in compliance with relevant national regulatory requirements.

Any products bearing the WEEE marking (a crossed-out wheeled bin) must be separated from ordinary household waste and sent to special collection facilities for recycling and recovery.

6 - Standards

CefarCompex Rehab 400 is designed for use by health professionals and as such complies with relevant medical standards and regulatory requirements.

To guarantee your safety, CefarCompex Rehab 400 has been designed, manufactured, and distributed in compliance with the requirements of the European Directive 93/42/EEC on medical devices.

CefarCompex Rehab 400 also complies with the IEC 60601-1 standard on general safety requirements for medical electrical devices, the IEC 60601-1-2 standard on electromagnetic compatibility, and the IEC 60601-2-10 standard on particular safety requirements for nerve and muscle stimulators.

CefarCompex Rehab 400 also complies with Directive 2002/96/EEC on waste electrical and electronic equipment (WEEE).

7 - Standardized symbols



Read the operating instructions before use.



CefarCompex Rehab 400 is a class II device with internal electric power and type BF applied parts.



Waste electrical and electronic equipment (WEEE) marking according to EN 50419 standard.



In compliance with the requirements of the European Directive 93/42 EEC on medical devices.

8 - Technical specifications

A) General information

Battery 941213: Nickel metal hydride (NiMH) rechargeable battery (4.8 V, 2000 mAh).

Battery chargers: Only battery chargers bearing the following information can be used to recharge the batteries supplied with Rehab 400 stimulators.

Europe

683010

Type TR1509-06-E-133A03

Input 90-264 VAC / 47-64 Hz / 0.5 A max.

Output 9 V / 1.4 A / 15 W

UK

683012

Type TR1509-06-U-133A03

Input 90-264 VAC / 47-64 Hz / 0.5 A max.

Output 9 V / 1.4 A / 15 W

B) Neurostimulation

All electrical specifications are given for an impedance of 500-1000 Ohm per channel.

Channels: Four individually adjustable channels that are electrically isolated from each other and earthed.

Impulse shape: Constant rectangular current with pulse compensation to eliminate any direct current component to prevent residual polarization at skin level.

Maximum pulse intensity: 120 mA

Pulse intensity increments: Manual adjustment of stimulation intensity: 0-999 (energy units) - Minimum increment: 0.5 mA

Pulse width: 30 to 400 microseconds
Maximum electrical charge per pulse: 96 microcoulombs (2 x 48 µC, compensated)

Standard pulse ramp-up time: 3 microseconds (20%-80% of maximum current)

Pulse frequency: 1-150 Hz.

C) Information related to electromagnetic compatibility (EMC)

The Rehab 400 is designed to be used in typical domestic or clinical environments and is approved according to the EMC safety standard of EN 60601-1-2.

This device emits very low levels in the radio frequency (RF) interval and is therefore not likely to cause any interference with nearby electronic equipment (radios, computers telephones etc.).

The Rehab 400 is designed to withstand foreseeable disturbances originating from electrostatic discharges, mains supply magnetic fields or radio frequency transmitters.

Despite this, it is not possible to guarantee that the stimulator is not affected by strong RF (radio frequency) fields emitting from for example mobile phones.

More detailed information can be received upon request by contacting CefarComplex.

III USAGE GUIDELINES

1 - Placement of electrodes

For optimal results, use the electrode positions recommended by CefarComplex. For the placement of electrodes, refer to the electrode placement illustration.

It is crucial to choose the right size of the electrodes and correctly position these on the muscle group you want to stimulate to ensure the efficacy of the treatment. To do this, always use the sizes and positions shown in the pictograms unless otherwise required by medical needs. Where necessary, look for the best possible position by slowly moving the electrode over the muscle until you find the point that will produce the best contraction (the motorpoint) or the most comfort for the patient.



CefarComplex disclaims all responsibility for consequences arising from electrodes placed in other positions.

2 - Body position

Refer to the pictures of the electrode placement to determine the stimulation position for your patient depending on the placement of the electrodes and the chosen program.

This position will vary depending on the position of the electrodes, the muscle group you wish to stimulate, and the program you are using.

For programmes that do not involve muscle contractions (Pain relief programmes, for example), make sure that the patient is as comfortable as possible.

3 - Adjusting stimulation energies

The number of fibres recruited in a stimulated muscle depends on the stimulation energies used. It is therefore extremely important to use maximum stimulation energies where possible in order to recruit the maximum number

of fibres. If the stimulation energy is too low, too few fibres will be obliged to work and the improvement in muscle quality will be negligible.

It takes at least 3 sessions to reach this maximum energy level. The first few sessions serve to introduce progressive increments in stimulation energy (and muscle contraction) levels and to help the patient to become used to the method.

After an initial warm-up period, which should produce very clear muscle twitches, increase the stimulation energies gradually, contraction by contraction, for the duration of the session.

4 - Level progression

Generally speaking, it is not advisable to try to reach maximum stimulation levels too quickly. The different levels in each stimulation programme are designed to reeducate the muscle gradually. We recommend you to prioritize the stimulation energies at each level to recruit as many fibres as possible, before moving on to the next level. Also seek to progressively increase energy levels from session to session.

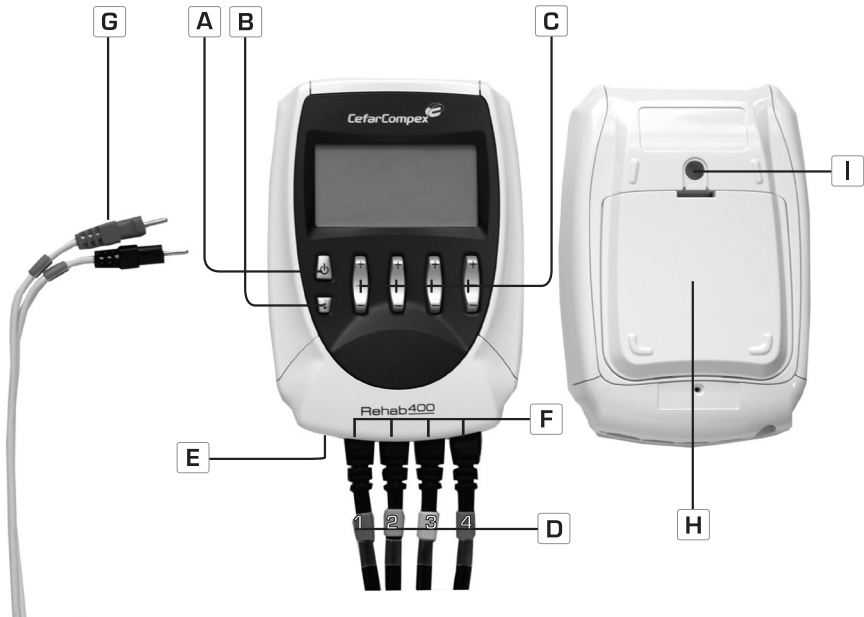
For maintenance purposes, it is a good idea to hold one session per week with the energy level you used in the previous cycle.

IV USING THE STIMULATOR



You are strongly advised to read the counter-indications and safety measures described at the beginning of this manual (chapter 1 "Warnings") prior to using your stimulator.

1 - Description of stimulator



A - On/Off button

B - i button. This is used to:

- Increase stimulation energies in several channels simultaneously.
- Access the Top 5 menu (showing 5 most recently used programs).
- Access the contraction info menu (showing number of contractions and total contraction time).

C - +/- buttons for 4 stimulation channels

D - Sockets for 4 stimulation cables

E - Battery charger socket

F - Stimulation cables Channel 1 = blue
Channel 2 = green Channel 3 = yellow
Channel 4 = red

G - Stimulation cable fitted with pin connector

H - Rechargeable battery compartment

I - Belt clip socket

2 - Connections

A) Connecting the cables

The stimulator cables plug into the 4 sockets on the base of the device. All 4 cables can be connected simultaneously. Both the +/- buttons and the cables are colour-coded to simplify use and facilitate identification of the different channels.



The kit includes four 2,1 mm pin-connector cables.

B) Charging

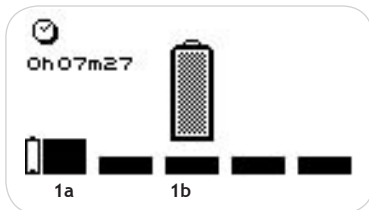
The Rehab 400 is a portable muscle stimulator powered by a rechargeable battery unit.

Recharging

To recharge the Rehab 400, first disconnect the electrode cables from the device, then plug the charger to a wall socket and finally connect the stimulator to the charger.



The charge menu illustrated below appears automatically.



1a: The stimulator has been charged for 7 minutes and 27 seconds (a full charge may take 2-2,5 hours with the rapid charger delivered with your device).

1b: Charging is in progress. When charging is completed, total charge duration flashes and the battery symbol is completely full. The stimulator switches off automatically as soon as you disconnect the charger.

3 - Preliminary settings

A) Language, contrast, volume

When you start the stimulator for the first time, you will need to choose the interface language you wish to use from the options screen. See below for instructions on how to proceed. There are a range of settings that you can adjust to suit your needs (interface language, display contrast, backlighting, volume). To change any of these settings, bring up the options screen by holding the On/Off button on the front of the stimulator for a few seconds.



3b: Use the channel 1 +/- button to choose the language you wish to use.

3c: Use the channel 2 +/- button to adjust the contrast of the screen.

3d: Use the channel 3 +/- button to adjust the volume.

3e: Use the channel 4 +/- button to adjust the backlighting.

On: Backlighting always on

Off: Backlighting always off

Auto: Backlighting activated whenever a button is pressed.

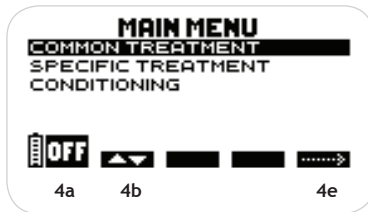
3a: Use the On/Off button to confirm and save your choices. The settings will be applied immediately.

4 - Neurostimulation programmes

To start the stimulator, press the On/Off button. To choose a programme, you must first choose a type of treatment and a programme category.

NOTE: There is a table summarizing the different programmes and their functions at the end of this manual.

A) Choosing a type of treatment



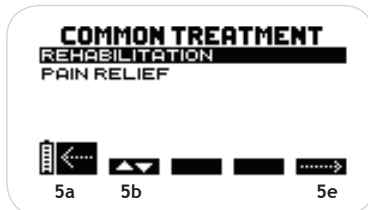
4a: Press the On/Off button to turn off the unit.

4b: Use the channel 1 +/- buttons to choose another type of treatment (for ex Common Treatment or Conditioning).

4e: Press the channel 4 +/- button to confirm your choice and access the programme category selection screen.

Press the **i** button to access the Top 5 menu.

B) Choosing a programme category



5a: Press the On/Off button to return to the previous screen.

5b: Use the channel 1 +/- button to choose a category.

5e: Press the channel 4 +/- button to confirm your choice and access the programme selection screen.

Press the **i** button to access the Top 5 menu.

C) Choosing a programme

NOTE: Consult our Practical Guide for help in choosing a programme. Once you choose a category, the screen will display a list of available programmes.



6a: Press the On/Off button to return to the previous screen.

6b: Use the channel 1 +/- button to choose the programme you want.

6e: Press the channel 4 +/- button to confirm your choice. Certain programmes start right away while others allow you to specify additional options.

TOP 5

To access the Top 5 menu, press the **i** button before selecting a programme. The menu can be accessed from the type of treatment screen (Figure 4), the programme category screen (Figure 5), or the programme list screen (Figure 6).



7a: Press the On/Off button to return to the previous screen.

7b: Use the channel 1 +/- button to choose the programme you want.

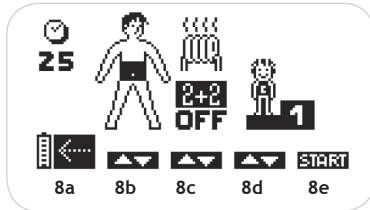
7d: Use the channel 3 +/- button to personalize the programme.

7e: Press the channel 4 +/- button to start the programme.

D) Personalising a programme

Not all programmes have an option screen.

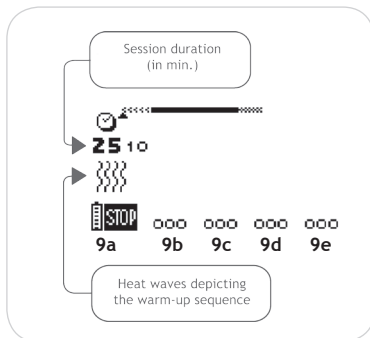
In certain programmes, you will need to choose the muscle group you want to stimulate. The target area is shown in black on the figure above channel 1.



- 8a:** Press the On/Off button to return to the previous screen.
- 8b:** Use the channel 1 +/- button to choose the desired treatment area. You can choose among 7 areas.
- 8c:** Press the channel 2 +/- button to delete the warming-up sequence and to choose if you want to combine with any of the 2+2 programs on channel 3 and 4.
- 8d:** Use the channel 3 +/- button to choose the programme difficulty level.
- 8e:** Use the channel 4 +/- button to confirm your choices and launch the programme.

Adjusting stimulation energies

When you start a programme, you will be prompted to increase the stimulation energies. This is the key to the success of any treatment.



- 9a:** Press the On/Off button to return to the previous screen.

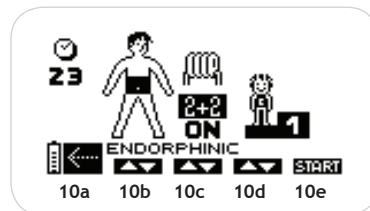
9 b c d e: The unit will beep and the symbols for the 4 channels will alternate between + and 000. The energy level for the 4 channels is at 0. To start the programme, you will need to increase the energy levels in the channels you are going to use. To do this, use the corresponding + buttons.

NOTE: If you want to increase the energy levels in all 4 channels simultaneously, press the i button. Press it twice to increase the levels in the first 3 channels, and 3 times to increase the levels in the first 2 channels. Interdependent channels will be highlighted in white against a black background.

E) Choosing the 2+2 function

You now have the possibility to choose the 2+2 function which means that you can choose one program for the channel 1 and 2, then select one program from the 2+2 program list for channel 3 and 4.

This means that you could treat two different body parts at the same time or combine two different programs on the same body part.



- 10a:** Press the On/Off button to return to the previous screen.
- 10b:** Use the channel 1 +/- button to choose the desired treatment area, You can choose from 7 areas.
- 10c:** Press the channel 2 + to delete the warming up sequence, by pressing the channel 2 - the 2+2 mode is selected and the first program in the list is displayed. Press the channel 2 - again in order to display the next program in the list.
- 10d:** Use the channel 3 +/- button to choose the program difficulty level
- 10e:** Use the channel 4 +/- button to confirm your choices and launch the program.

NOTE: The timer for ch 1+2 will control the total session time. This means that the total time for ch 3+4 could not exceed the session time for ch 1+2.

NOTE: The program for ch 3+4 is always in one phase

NOTE: If a preset program uses more than two channels, it's not available for the 2+2 mode.

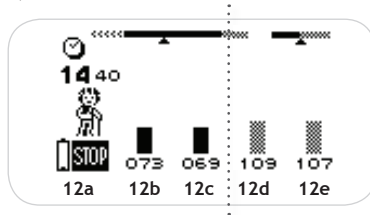


The horizontal bars on top of the display shows the total duration and different phases of the programs. Left bar for P1 and right bar for P2

P1 shows the program chosen for channel 1 and 2

P2 shows the program chosen for channel 3 and 4

F) Stimulation mode



12 b c d e: The different energies reached during the contraction phase are shown by a series of black bar graphs. Active rest phase energies are shown by hatched bar graphs.

NOTE: Active rest phase stimulation energies are automatically set at 50% of contraction intensities but can be modified during the rest phase. Once modified, they will be totally independent of the contraction intensities.

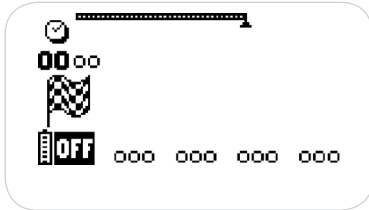
Pause mode

12a: Press the On/Off button to interrupt the programme momentarily. To restart it, simply press the channel 4 +/- button (12e). The session will resume at 80% of the energy levels that were being used prior to the interruption.

NOTE: If your Rehab 400 emits a beeping sound and the + symbols under the active channels begin to flash, the stimulator is suggesting you to increase the level of the stimulation energies. If you are working at the patient's maximum tolerance level, simply ignore this message.

End of programme

Different statistics are displayed depending on the programmes and options used. It should be noted, however, that statistics are not available for all programmes.



At the end of each session, a small flag will be displayed on the screen and a short melody will be played.

NOTE: Press the **i** button to access the contraction info screen.

To turn off the stimulator, press the **ON/OFF** button.

5 - Battery status and recharging

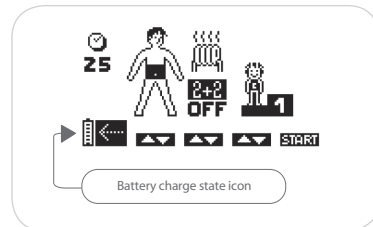
Never recharge the stimulator without first disconnecting the stimulation cables.

Never recharge the battery with a charger other than that supplied by CefarCompex.

The Rehab 400 is powered by a rechargeable battery unit. The battery's duration varies according to the programmes and stimulation energies used. We strongly recommend you to fully charge the battery before using it for the first time as this will extend battery duration and life time. If you do not use your stimulator for long periods of time, remember to recharge the battery regularly.

A) Battery status

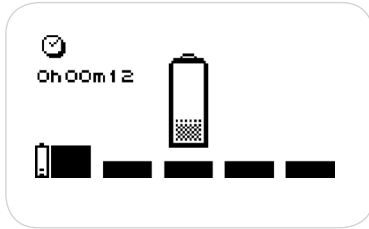
The status of the battery is indicated by a battery icon on the screen. If the battery icon contains just two lines, this means that power is running low. Stop the session and recharge the unit.



If the **START** symbol normally displayed above the channel 4 +/- button is not visible and the battery icon is flashing, this means that the battery is completely discharged. The stimulator can no longer be used. Recharge immediately.

B) Recharging

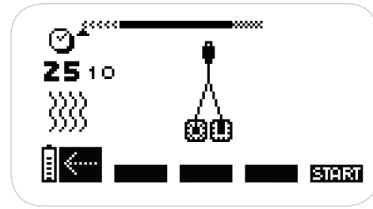
Remove all stimulation cables from the stimulator before recharging it. Connect the charger to the mains and then connect the stimulator to the charger. The charge menu shown below will automatically appear on the screen.



The duration of the recharging operation is displayed on the screen. The charger supplied with the stimulator fully recharges the stimulator within 2-2,5 hours.

The battery icon is animated while the battery is recharging. When fully charged, the icon will be full and the total time taken to recharge the battery will flash on the screen. Simply disconnect the charger and the Rehab 400 will turn off automatically.

6 - Troubleshooting



Electrode error

The Rehab 400 will beep and alternately display a pair of electrodes and an arrow pointing to the channel where the problem was detected. In the example above, the stimulator has detected an error in channel 2.

The electrode error message can mean that:

- there are no electrodes connected to this channel,
- the electrodes are old, worn, and/or the contact is poor: try using new electrodes,
- the electrode cable is faulty: try connecting it to another channel. If the problem persists, replace the cable.

If for any reason your device seems to present a malfunction other than those presented above, please contact Cefar-Complex customer service.

V LIST OF PROGRAMS - Rehab 400

ENG

COMMON TREATMENT	
PROGRAMS	Optional 2+2
REHABILITATION	
DISUSE ATROPHY	x
PREV. OF DISUSE ATROPHY	x
REINFORCEMENT	x
NEURO REHAB Slow start	x
BACK-TRUNK/STABILIZATION	x
ATROPHY (Mod Freq)	x
FORCE (Mod Freq)	x
INCREASE CIRCULATION	x
MUSCLE LESION	x
PAIN RELIEF	
TENS 100Hz	x
TENS 80Hz	x
FREQ MODULATED TENS	x
ENDORPHINIC	x
DECONTRACTION	x
PW MODULATED TENS	x
BURST TENS	x
MIXED TENS	x
SPECIFIC TREATMENT	
PROGRAMS	Optional 2+2
AESTHETIC	
TONING	x
FIRMING	x
SHAPING	x
REFINEMENT	x
ELASTICITY	x

CONDITIONING	
PROGRAMS	Optional 2+2
SPORT	
POTENTIATION	x
ENDURANCE	x
RESISTANCE	x
STRENGTH	x
EXPLOSIVE STRENGTH	x
HYPERTROPHY	x
ACTIVE RECOVERY	x
RECOVERY PLUS	x
FITNESS	
MUSCLE BUILDING	x
MUSCLE DEFINITION	x
POWER	x
MASSAGE	
TONING MASSAGE	x
RELAXING MASSAGE	x
2+2	
PROGRAMS	
FREQ MODULATED TENS	
PW MODULATED TENS	
BURST TENS	
ENDORPHINIC	
REINFORCEMENT (SMALLER MUSCLE GROUPS)	
REINFORCEMENT (LARGER MUSCLE GROUPS)	
DISUSE ATROPHY (SMALLER MUSCLE GROUPS)	
DISUSE ATROPHY (LARGER MUSCLE GROUPS)	