User Manual

PRIMO COMBINATION 860
Model 125

CE
0120

Contents

General information

This manual provides the necessary information for the installation and operation of the Primo Combination 860 unit.

These instructions must be studied before putting the unit into operation.

The information contained in this manual is subject to change without notice.

Record of amendments

ISSUE	COMMENTS	DATE
1	Initial issue	31/03/11
2	Errata corrected	07/04/11
3	Combination therapy instructions corrected.	30/06/11
4	Indications for use added	21/06/12
5	Updated to show latest images	08/10/12
6	Declaration of conformity revised	26/06/14

EC Declaration of Conformity

Product Name	Primo Combination 860
Model Numbers	(125) EMS860

EMS Physio Ltd
Grove Technology Park, Downsview Road
Wantage, Oxfordshire, OX12 9FE, United Kingdom

Declares that the device listed above is in conformity with the essential requirements and provisions of the following EC Council Directives:

Directive	Conformity assessment route
2011/65/EU	Annex II, module A (768/2008/EC) (RoHS)
93/42/EEC	Annex II of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd. Class IIb according to Annex IX of 93/42/EEC

Signature	 M Bowles
Position	Operations Director
Date	26th June 2014
Date first issued	31st March 2011

Warranty

This EMS Physio Ltd., (hereinafter called the Company) product is warranted against defects in materials and workmanship for a period of two years from the date of shipment. The Company will at its option, repair or replace components which prove to be defective during the warranty period, provided that the repairs or replacements are carried out by the Company or its approved agents.

The Company will consider itself responsible for the effects on safety, reliability and performance of the product only if:-

assembly operations, re-adjustments, modifications or repairs are carried out by persons authorised by it,

the product is used in accordance with the instructions for use,

the electrical installation of the relevant room complies with the appropriate national requirements.

Should the product be returned to the Company for repair it must be sent carriage paid.

Consumable items, for example, electrodes, electrode covers and batteries are excluded from the above warranty.

It is intended that the Combination 860 unit is only used by qualified healthcare professionals such as physiotherapists who have received training in electrotherapy.

Introduction

The Primo Combination 860 provides 1 and 3 MHz ultrasound and a complete range of low and medium frequency waveforms for electrotherapy. Both modalities may be used individually or in combination.

Indications for use

Therapeutic ultrasound may be applied to a wide range of conditions with successful outcomes. These include acute and subacute traumatic and inflammatory conditions, chronic rheumatoid and arthritic conditions, scar and excessive fibrous tissue and for pain relief.

Ultrasound may also be used for phonophoresis – the movement of drugs through the skin under the influence of ultrasound. Some drugs are absorbed through the skin very slowly and ultrasound may be used to accelerate the process.

The Primo Combination 860 unit also provides 4 pole and 2 pole interferential therapy as well as a wide range of other electrical stimulation waveforms.

Therapeutic voltage and current waveforms may be applied to a wide range of conditions with successful outcomes. These include acute and subacute traumatic and inflammatory conditions, chronic rheumatoid and arthritic conditions, and for pain relief.

Combination therapy involves the simultaneous application of ultrasound with an electrical stimulation therapy.

By combining ultrasound with interferential therapy, the advantages and effects of each treatment modality can be realised - but lower intensities are used to achieve the effect. The accommodation effects that normally accompany interferential therapy are reduced (or even eliminated). The main advantages of such a combination are in localising lesions (especially chronic), in ensuring accurate localisation of ultrasound treatment to provide increased accuracy / effectiveness in treating deeper lesions, and in treating trigger points.

Galvanic output may also be used for iontophoresis – the movement of drugs through the skin under the influence of a steady electrical voltage. Some drugs are absorbed through the skin very slowly and iontophoresis may be used to accelerate the process.

Precautions

The therapist must be aware of the following precautions and potential hazards.

Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator itself.

Operation in close proximity (less than 1 metre) to shortwave or microwave therapy equipment may produce instability in the stimulator output.

Consideration must be given to the current densities for any electrode used with the Combination 860 unit. Current densities greater than 2 mA rms/cm^2 are not recommended because of the risk of burning. All the standard EMS Physio conductive rubber electrodes may be used up to the maximum output of the unit without exceeding this figure. When using other electrodes, the maximum safe output current should be assessed before use. First estimate the effective contact area of the electrode in square cm, and then apply the following formula: -

rms output current (mA) = Area of electrode (cm^2) x 2

The ratio of the rms to the peak current for the different operating modes is given in the technical specification section of this manual.

The output indication on the LCD shows the peak output voltage or the peak output current in mA depending upon the selected mode of operation.

When using direct current, extreme care must be taken to ensure the patient's safety from electrochemical burning. In particular, care must be taken to avoid uneven pressure on the electrodes causing high local current density.

Electrodes must not be applied where there are cuts or abrasions.

Contraindications - ultrasound

Tumours, as ultrasound affects tissue repair and could therefore encourage growth.

Infections, due to the risk of spreading the infection.

Pregnancy, treatment over the pregnant uterus as ultrasound could affect rapidly dividing cells.

Radiotherapy, sites that have received radiotherapy treatment during the last six months.

Thrombosis and impaired circulation.

Areas of impaired sensation.

Haemorrhage, due to the risk of increased bleeding, including recently controlled bleeding and haematoma.

Haemophilia.

Implanted devices such as cardiac pacemakers should be avoided due to the possibility of affecting their operation. Also some plastics used in replacement surgery may be affected by absorption of ultrasound energy. Metal implants may lead to reflections, and as a precaution low doses of ultrasound should be used near these.

Extreme care should be taken when treating areas near the eye because of the danger of damage to the retina.

Similarly, extreme care should be taken near the ears and reproductive organs.

Similarly, extreme care should be taken near the ears and reproductive organs.

Contraindications - electrotherapy

Acute Sepsis, due to the risk of spreading infection.

Tumours, due to the risk of increased growth or metastatic activity.

Pregnancy, do not treat the lower abdomen, back or pelvis.

Menstruation, do not treat lower back or abdomen due to risk of increased bleeding or pain.

Cardiac conditions, do not treat the chest area or near the cervical ganglion.

Cardiac pacemakers, especially demand type, or any other implanted electronic device, unless specialist medical opinion has first been obtained.

Febrile conditions.

Large open wounds in treatment area.

Dermatological conditions in treatment area.

Thrombosis.

Hypersensitivity or fear of electrical treatments.

Any patient who cannot understand the nature of the treatment, for example, young children, very old or senile patients who cannot report back adequately or understand the potential dangers. This may apply equally to persons who do not speak the same language as the therapist.

Severe hypotension/hypertension, do not treat in the region of the lower cervical spine.

If in doubt the patient's physician should be consulted.

Electrodes should never be placed so that the applied current crosses the chest.

Accessories supplied as standard

Catalogue number	Description
SLA9000	DC power supply 18V 60W
PMA9125	Large dual-frequency transducer
EMS502C	EMS Physio coupling medium (250ml bottle)
PMA3055	Patient lead (4 way – yellow and blue connecting cables included)
NC3053A	4 medium sponge electrode covers (for NC3053B)
NC3053B	4 medium (100 x 70 mm) conductive rubber electrodes
DU2	2 stretch bandages 1200 x 75 mm

Optional accessories

EMS530	Primo shoulder bag
EMS158	Primo trolley
PMA9135	Small dual-frequency transducer
EMS502	EMS Physio coupling medium (8 x 250ml bottles)
EMS502A	EMS Physio coupling medium 1litre bottle
NC3052A	4 small sponge electrode covers (for NC3052B)
NC3052B	4 small (70 x 50 mm) conductive rubber electrodes
NC3054A	4 large sponge electrode covers (for NC3054B)
NC3054B	4 large (130 x 100 mm) conductive rubber electrodes
NC3041	Electrode handle (for circular pad & ball electrodes)
NC3042A	Connecting cable for electrode handle
NC3046	Circular pad electrode 12 mm diameter
NC3048	Circular pad electrode 37 mm diameter
NC311A	Ball electrode for muscle testing
DU1	Stretch bandage 600 x 75 mm
DU4	Stretch bandage 600 x 50 mm

A range of single-patient self-adhesive electrodes is available

Catalogue Number	Description
RB410	33 x 54 mm (pack of 4)
RB430	50 x 50 mm (pack of 4)
RB440	80 x 100 mm (pack of 2)
RB450	25 mm diameter round (pack of 4)

Supplied with each unit is a detachable mains lead suitable for the country to which it is delivered. Replacement or additional mains leads are shown below.

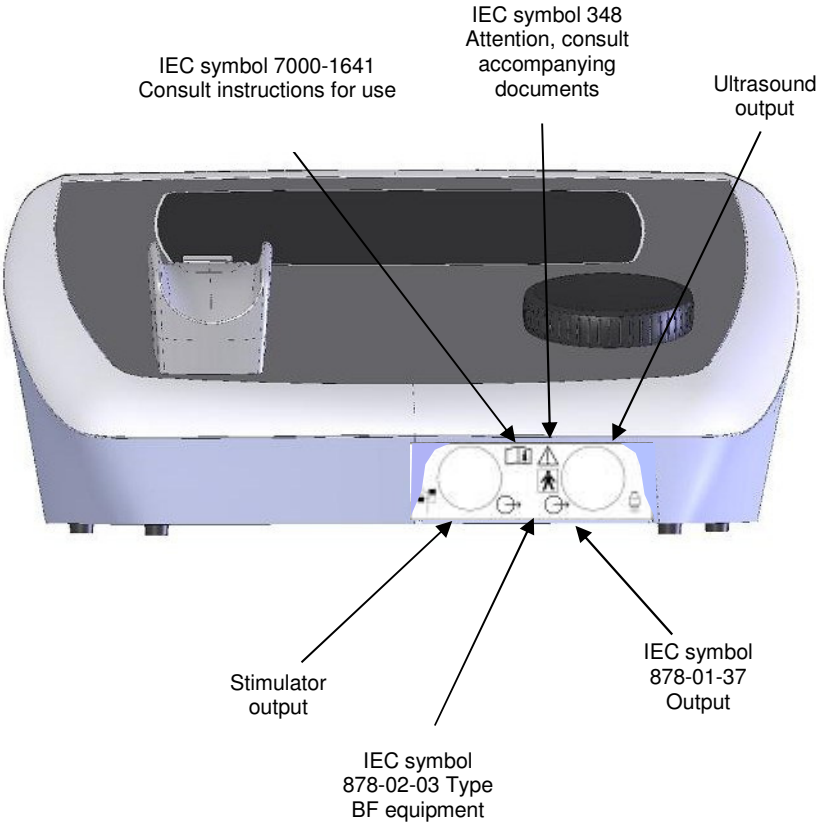
EMS Part Number	Description
6-85	UK mains lead
6-112	European mains lead
6-119	North America mains lead

For other countries contact EMS Physio Ltd. or the agent from whom the unit was purchased.

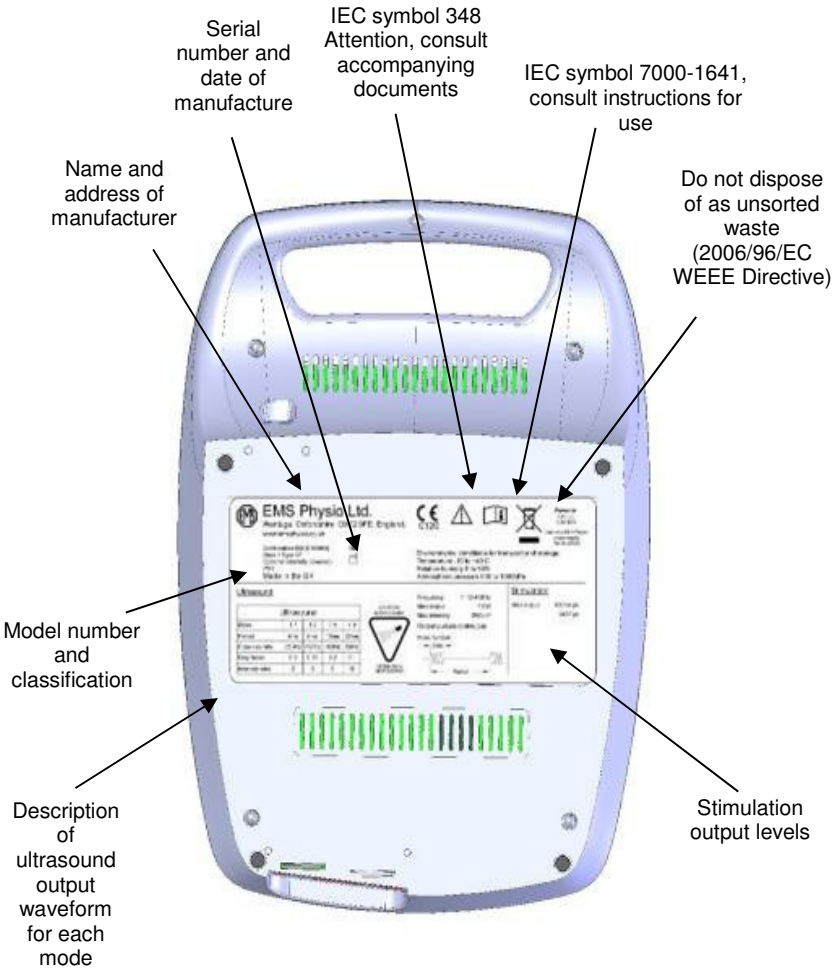
EMS Physio Ltd.
Grove Technology Park
Downsview Road
Wantage
Oxfordshire OX12 9FE
England
T: 01235 772272
F: 01235 763518
E: sales@emsphysio.co.uk
Website: http://www.emsphysio.co.uk

Controls and markings

Primo Combination 860 front panel

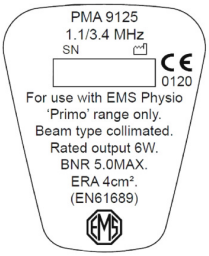


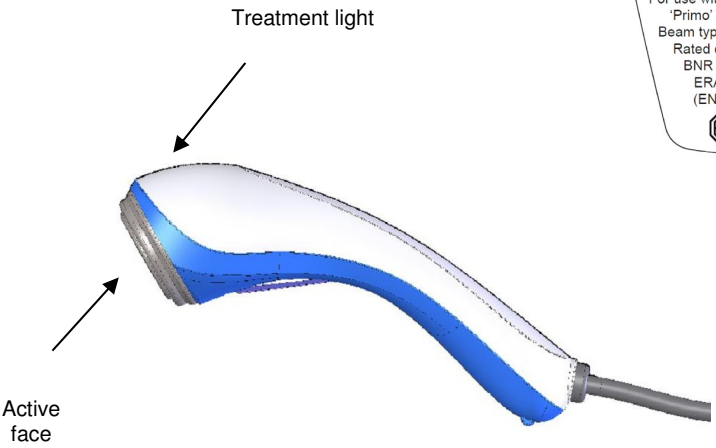
Primo Combination 860 underside



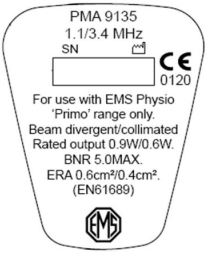
Primo Combination 860 top

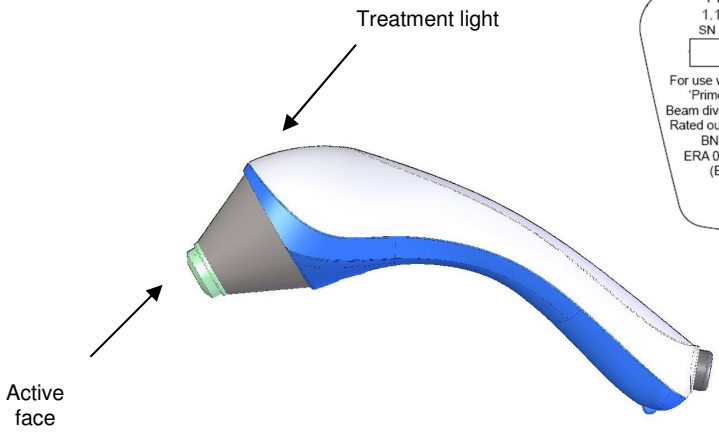
Large transducer





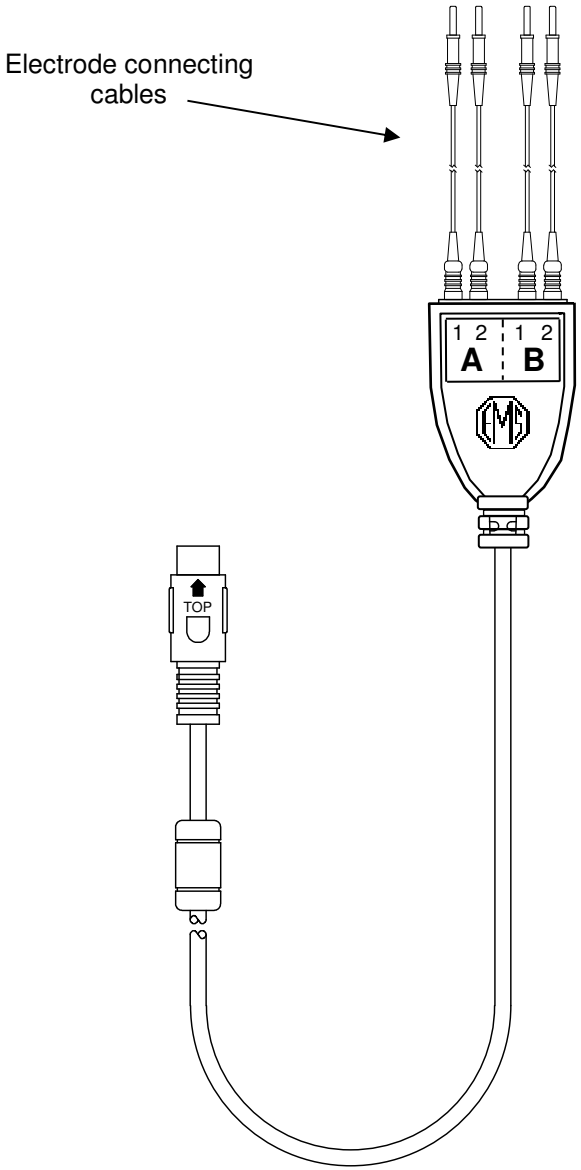
Small transducer





The ultrasound transducers are calibrated independently from the Primo Combination 860 and are fully interchangeable.

Patient lead (PMA3055)



Installation

Upon receipt, check for any visible damage which may have occurred in transit. If any signs of damage are found then retain all packing material and inform, within two working days, the carrier and the Company or its agent from whom the unit was purchased.

The Primo Combination 860 must only be used with an EMS Physio SLA9000 power supply (as supplied with the unit). Units fitted with an internal rechargeable battery may be used powered by the battery only.

The SLA9000 power supply must only be connected to a mains supply with a protective earth conductor. If the integrity of the earth connection is in doubt, do not connect it to the mains supply.

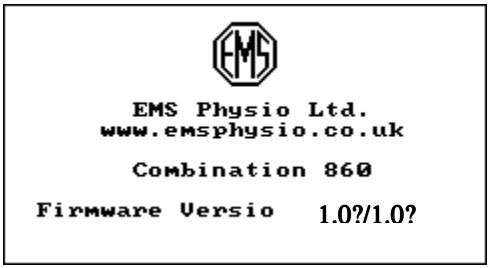
The Primo Combination 860 unit is supplied with a large ultrasound transducer and four medium-sized electrotherapy electrodes with their associated patient lead. An optional small transducer is also available.

Plug the ultrasound transducer into the output socket on the front right of the unit and the patient lead into the one to its left. Each plug has an arrow and the word ‘top’ embossed on it to aid correct orientation.

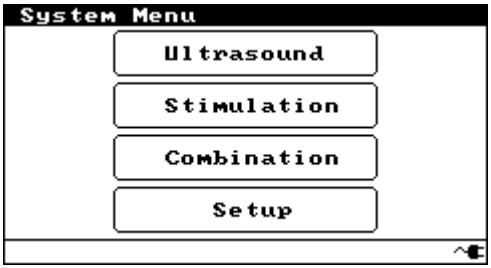
Operating instructions

Power on sequence and general information

When the Primo Combination 860 is turned on, the EMS company logo is displayed on the LCD along with the company web address, the model name and the installed firmware version.



The unit will then give a short beep and display the System Menu screen.



At the bottom of the screen is the status bar.

The status bar shows the current power source and the battery status (if installed).

If the unit is fitted with a rechargeable battery pack, the battery symbol, ▭, will be shown in the status line. The symbol is shaded to show the current charge state of the battery. ▭ indicates a completely discharged battery and ▬ a fully charged battery. The arrow, →, to the left of the battery symbol will be shown if the battery is being charged. To conserve battery life, the unit will automatically turn off the LCD backlight after 1 minute and power itself down completely after 3 minutes if there has been no operator activity and the unit is running off the battery.

Standard user controls

Throughout the operation of the Combination 860 the various modes and parameter settings are all accessed and changed by pressing the relevant display on the LCD touchscreen.

The rotary control is used to increase and decrease the ultrasound intensity when the LCD is showing the ultrasound screen, or it controls the stimulation intensity when a stimulation screen is selected.

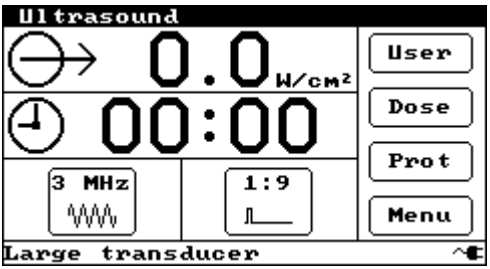
In 4-pole Interferential mode it controls the overall Stimulation intensity, in all other stimulation modes it is possible to independently control the levels of channels A and B by pressing and holding the relevant selection button.

In combination mode three buttons are available (except for 4-pole combination therapy, when there will be two) to select whether the rotary control is assigned to the ultrasound intensity or channel A or B of the stimulator.

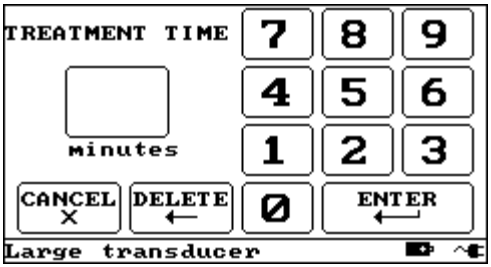
The menu button is used to exit from the current screen or to select the menu option highlighted.

Ultrasound set up

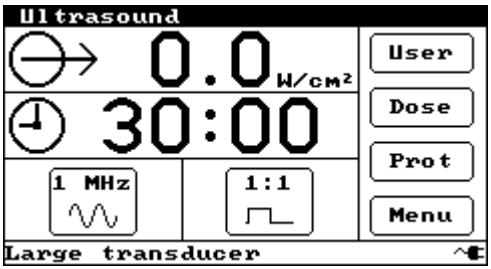
From the System Menu screen, press the button marked ‘Ultrasound’. The Ultrasound set-up screen will appear.



Touch the screen on the digits of the time display to increment some treatment time (maximum 30 minutes). Alternatively, touch the clock symbol to bring up the following screen:-



Type in the desired time and press ENTER to return to the main screen.



Select the desired ultrasound Frequency and Mode (pulsed or continuous) by touching the relevant field on the screen.

Treatment

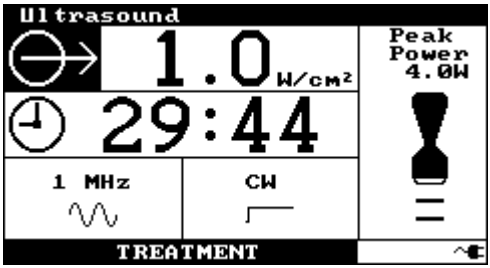
It is recommended that before commencing treatment, the stainless steel front of the transducer is disinfected using a 70% v/v aqueous solution of isopropyl alcohol. Sterile alcohol wipes are suitable for this purpose.

Apply sufficient coupling medium to the area to be treated, EMS Physio Therasonic coupling medium is recommended.

Apply the active face of the transducer to the treatment site via the coupling medium.

Turn the rotary control clockwise to start treatment. The output intensity will increase in 0.1 W/cm^2 steps. The treatment indicator on the transducer will light, the output symbol on the LCD will flash and the treatment time will begin to count down.

If the transducer is not properly connected to the output socket or the treatment time is zero then the unit will give a two tone beep and the output will not be energised.



Move the transducer over the treatment site in small circular paths whilst setting the output intensity to the required level using the rotary control.

Always keep the face of the transducer in contact with the treatment area and always keep the transducer moving to avoid any standing waves.

If the transducer face is lifted from the treatment site or if for any reason there is insufficient contact between the transducer and the treatment site for more than two seconds, the power applied to the transducer will also be reduced to a low level. The treatment light on the transducer will turn off, the treatment time will cease to count down and the status bar will display CONTACT, indicating that the required output cannot be delivered. An audible alarm will sound if this option has been selected in the Setup menu. When good contact is restored, the treatment indicator on the transducer will light, the status bar will display TREATMENT and the timer will continue to count down.

If the output intensity is returned to zero using the rotary control, before the treatment time has elapsed, the display will show the treatment time remaining. When the intensity is increased again the treatment will continue.

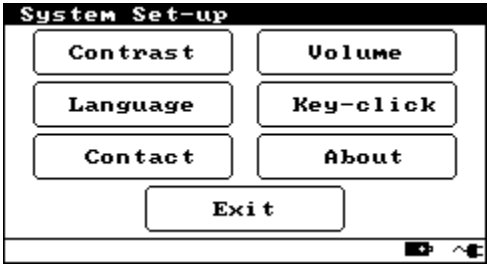
When the treatment time reaches 00:00, treatment is terminated. The intensity and power displays will go to zero, ultrasonic power from the transducer will be turned off, the treatment indicator will turn off and the unit will give a two second beep. Remove the transducer from the treatment site, wipe off any coupling medium and return the transducer to its cradle on the front of the unit.

Remove the remaining coupling medium from the treatment site.

The transducers are also suitable for treatment using a water bath. This is especially useful when treating areas which are not uniform such as feet or hands. When using a water bath it is advisable to use degassed water (water that has been boiled to remove any air and then allowed to cool). After the part of the body has been immersed in the water, remove any air bubbles that may have accumulated on the skin. Set up the treatment parameters and then immerse the transducer in the water before turning the output on. Hold the transducer with its face approximately 1 cm away from the treatment site and using the rotary control set the required intensity remembering to keep the transducer moving in small circular paths to prevent standing waves. At the end of the treatment the intensity and power displays will read zero, and the ultrasound power will turn off. Remove the transducer from the water and dry both it and the area treated.

System set-up menu

Touching the Setup button at the bottom of the System Menu screen takes you to the System Set-up screen.



The Contrast button takes you to a screen where you can adjust the display contrast using up/down buttons.

The Volume button allows for adjustment of the beeper volume (high or low).

Language allows you to change the display language to any that are installed in the unit.

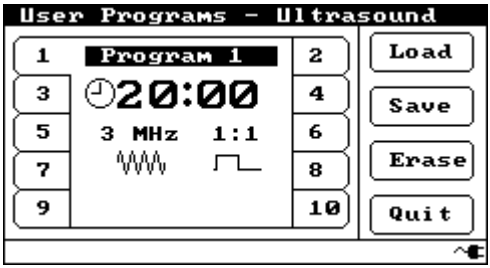
Key-click allows you to turn on or off the beep that happens whenever the screen is touched.

Touching the Contact button gives you a screen with three options for the behaviour of the contact alarm. On is the default mode where poor contact turns out the contact light and stops the timer countdown. Off causes poor contact to turn out the contact light but not stop the timer countdown. Audio gives an additional beeping warning (light goes out, timer stops).

The About button displays the model number and installed firmware version.

Ultrasound user programs

The Combination 860 can store up to 10 user defined set-ups for each modality (ultrasound or stimulation). To access the ultrasound user programs press the User button in the top right corner of the ultrasound set-up screen.



The LCD shows the 10 user programs as file cards with numbered tabs. To select a program card just touch its tab.

To load a program press Load. The settings shown on the file card will be loaded and the user will be returned to the ultrasound set-up screen. If an empty card is selected the unit will give a short beep and no action will be taken.

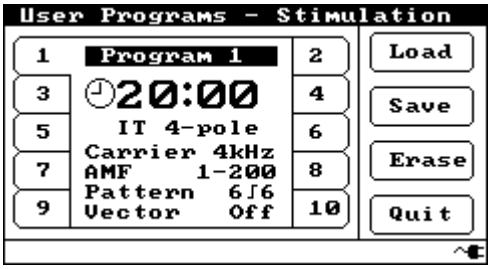
To save the current ultrasound screen set-up as a user program, select the card to which the set-up is to be saved by touching its tab and press Save. The settings will be saved and displayed on the selected card.

To erase a program saved on the current card, press Erase. “Not Used” will be displayed on the selected card to confirm the action.

Select the Quit option to return to the ultrasound page.

Stimulation user programs

Similarly, pressing the User button in any of the stimulation set-up screens will open the stimulation user program screen.



These can be saved, loaded or erased in much the same way as the ultrasound user programs.

Stimulator set-up

From the System Menu screen press the Stimulation button. The following stimulation screen will appear:-

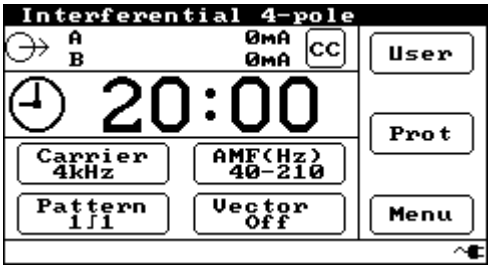
Scrolling down past the TENS setting reveals further stimulation options:-

And more:-

Pressing the menu button now would return the screen to the main system menu.

The following describes the set-up pages for each stimulation type when accessed by pressing the relevant button in the stimulation screen:-

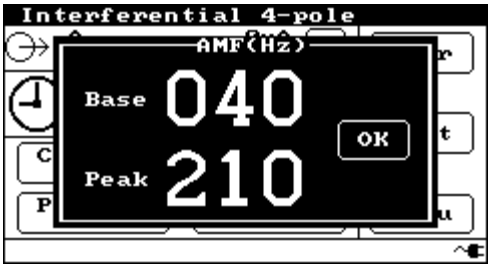
4-pole interferential set-up



Treatment time: Is selected either by touching the digits of the time display or by pressing the clock symbol and entering the desired treatment time. The time can be set in 30s intervals.

Carrier: Pressing this button selects 4, 8 or 2 kHz carrier frequency.

AMF: Pressing this button opens the AMF window.



The amplitude modulation frequency (AMF), or beat frequency, is set as a Base and Peak beat frequency. The beat frequency sweeps between the base and the peak frequency at a rate determined by the setting of the Pattern button. If the base and peak frequencies are set to the same value then a constant beat frequency is produced. The Base and Peak frequencies may be set in 1 Hz increments from 0 to 250 Hz. Press OK when the desired frequencies have been chosen to return to the 4-pole Interferential set-up screen.

Pattern: The pattern determines the rate at which the beat frequency sweeps between the base and peak frequencies. Three patterns are available by pressing the Pattern button.

The 1|1 pattern gives 1 second at the base frequency followed by 1 second at the peak frequency.

The 6|6 pattern gives 5 seconds at the base frequency, sweeps linearly to the peak frequency in 1 seconds, followed by 5 seconds at the peak frequency and finally sweeps back to the base frequency in 1 second.

The 6/\6 pattern sweeps from the base to the peak frequency in 6 seconds and then sweeps back to the base frequency in 6 seconds.

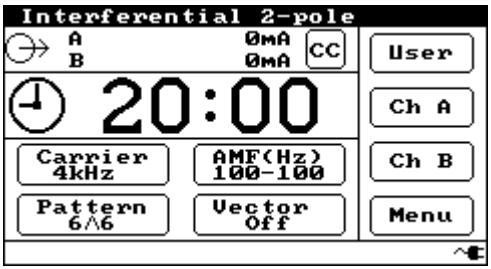
Vector: When the vector option is set to off, output channels A and B deliver the same output level (current or voltage). When the vector option is on, the relative amplitude of the outputs is slowly varied.
Over 5 seconds the output of channel A will increase smoothly from 80% of its nominal amplitude to 100% while the output of channel B falls from 100% to 80%. During the next 5 seconds A will return to 80% and B will rise to 100% and so on. The effect is to move the physical location of the point of maximum stimulation in the tissue and therefore, increase the treatment area.

To change the vector option press the Vector button.

CC/CV: The output from the unit may be set to be constant current (CC) or constant voltage (CV) in nature. In constant current mode the electrode impedance is monitored and if the impedance for either channel is too high then the output is terminated and an alarm sounded. In constant voltage mode, if the electrode impedance rises then the output is automatically reduced. Normally, constant current mode would be used. If the unit is used for combination therapy or with internal electrodes (vaginal or anal) then constant voltage is recommended.

***Protocols**:* The Prot button (4-pole interferential mode only) gives access to a range of pre-set parameter settings aimed at treating various listed conditions – these are explained in more detail later in this manual.

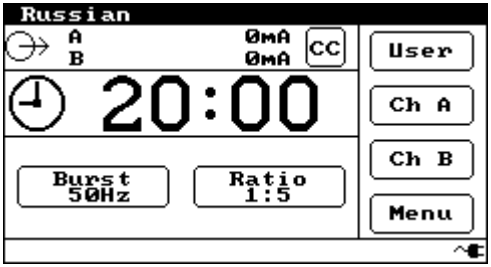
2-pole interferential set-up



2-pole interferential therapy is similar to 4-pole interferential except that the two medium frequencies are added together in the stimulator itself and applied to the treatment site through a single pair of electrodes.

The 2-pole interferential set-up is similar to the 4-pole set-up. The treatment time, carrier frequency, base and peak frequencies, pattern and CC/CV operation are set-up in exactly the same way.

Russian set-up

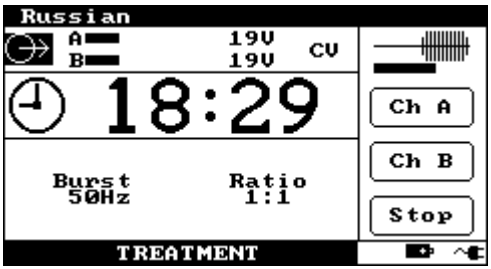


Treatment time: Is selected in the same way as previously.

Burst: The burst frequency may be set from 1 Hz to 100Hz by pressing the Burst button. 0-10 Hz is in 1 Hz steps, 10 – 50 Hz in 5 Hz steps, and 50 – 100 Hz in 10 Hz steps.

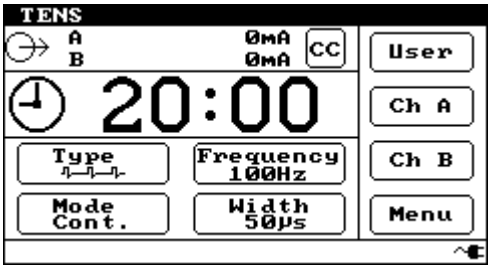
Ratio: The medium frequency bursts used for russian stimulation are surged to produce work and rest periods. The surge time (work) is fixed at 10 seconds. The ratio sets the off or rest time in ratio to the work period. For example, if the ratio is set to 1:4 then the work period is 10 seconds and the rest period is 40 seconds. Press the ratio button to set the ratio to any integer value between 1:1 and 1:5.

When running, the burst status is displayed in the top right corner of the display -



CC/CV: The output may be set to be constant current (CC) or constant voltage (CV) by pressing the CC/CV button. In constant current mode the electrode impedance is monitored and if the impedance for either channel is too high then the output is terminated and an alarm sounded. In constant voltage mode, if the electrode impedance rises then the output current is automatically reduced.

TENS set-up



Treatment time: Is set in the same way as described above.

Three waveform types are available and each type is represented graphically on the LCD.

Type

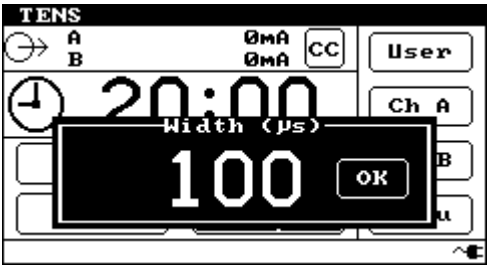
Symmetrical 

Asymmetrical 

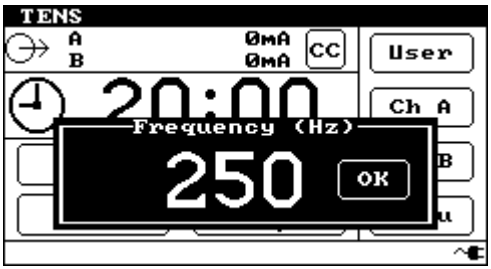
Sequential 

Selection is achieved by pressing the Type button.

Width: pressing this button opens a new window in which the pulse width may be set from 20 to 400 µs in 5 µs increments by pressing the numerical digits and then pressing OK.



Frequency: pressing this button opens a new window.

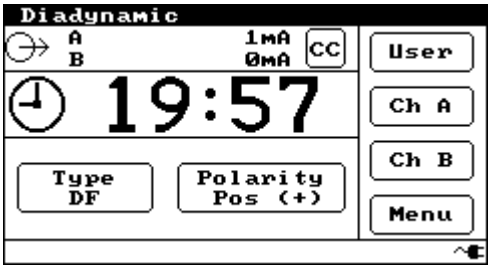


The pulse frequency may be set from 1 to 250 Hz in 1 Hz increments by pressing the numerical digits and then pressing OK.

Mode control: The TENS output may be continuous, burst or surged. Each modulation type is selected by pressing the Mode button.

CC/CV: The output may be set to be constant current (CC) or constant voltage (CV) by pressing the CC/CV button.

Diadynamic set-up



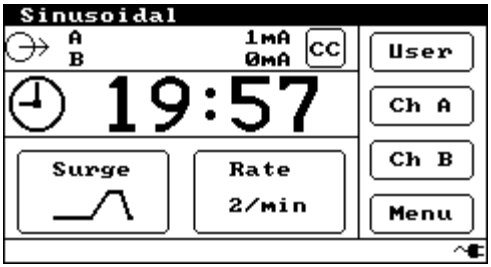
Treatment time: is set as already described.

Type: The diadynamic waveform may be selected by pressing the Type button. The full range of diadynamic waveforms is available: DF - diaphasé fixe, MF - monophasé fixe, CP - modulé en courtes périodes, Cpiso - modulé en courtes périodes isodynamique, RS - rythme syncopé and LP - modulé en longues périodes. Full details of these waveforms are given in the technical specification section of this manual.

Polarity This reverses the polarity of the waveforms (see technical spec.). It is particularly used in combination therapy where the ultrasound head becomes one electrode, and this switch will change the polarity of the stimulator waveform relative to the ultrasound head. If the Autorev option is selected, the polarity of the output will automatically reverse half way through the selected treatment time.

CC/CV: The output may be set to be constant current (CC) or constant voltage (CV) by pressing the CC/CV button.

Sinusoidal set-up

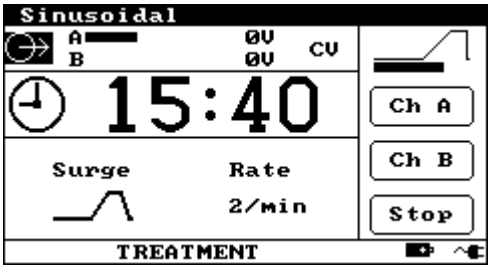


Treatment time: is adjusted as explained above.

Surge: Three surge patterns (envelopes) are available: Rect (rectangular), Tri (triangular) and Trap (trapezoidal). A full description of these surge patterns is available in the technical specification section of this manual. The surge pattern may be changed by pressing the surge button.

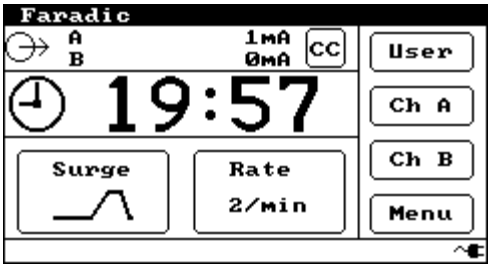
Rate: Surge rates of 2, 5, 10, 20 and 30 per minute are available. The surge rate may be changed by pressing the Rate button.

When running the surge status is shown in the top right corner of the display –



CC/CV: The output may be set to be constant current (CC) or constant voltage (CV) by pressing the CC/CV button.

Faradic set-up

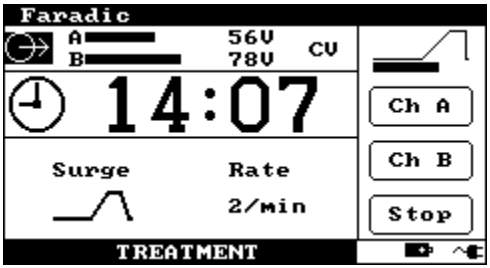


Treatment time: is set as described above.

Surge: Three surge patterns (envelopes) are available: Rect (rectangular), Tri (triangular) and Trap (trapezoidal). A full description of these surge patterns is available in the technical specification section of this manual. The surge pattern may be changed by pressing the Surge button.

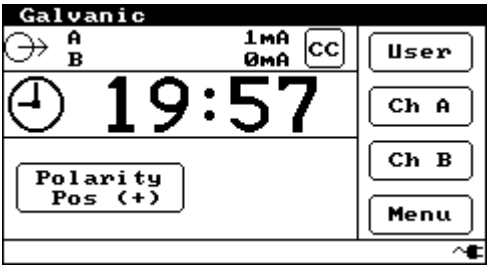
Rate: Surge rates of 2, 5, 10, 20 and 30 per minute are available. The surge rate may be changed by pressing the Rate button.

When running the surge status is shown in the top right corner of the display –



CC/CV: The output may be set to be constant current (CC) or constant voltage (CV) by pressing the CC/CV button.

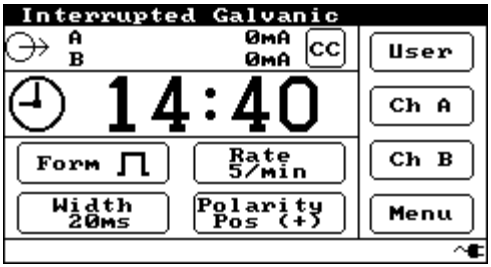
Galvanic set-up



Treatment time: is set as described above.

Polarity: Pressing this button changes the electrical polarity of the galvanic current Pos (+), Neg (-), or Autorev (half way through the selected treatment time)

Interrupted galvanic set-up



Treatment time: is set as described before.

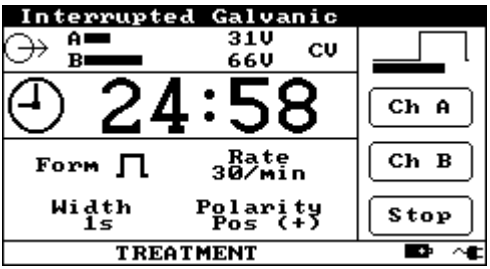
Form: Three different pulse shapes are available: Rectangular), Triangular and Trapezoidal. A full description of these waveforms is available in the technical specification section of this manual.

Width: The pulse width may be set from 1ms to 1s for all waveforms with additional narrower pulses for rectangular only.

Rate: Pulse rates of 2, 5, 10, 20 and 30 per minute are available.

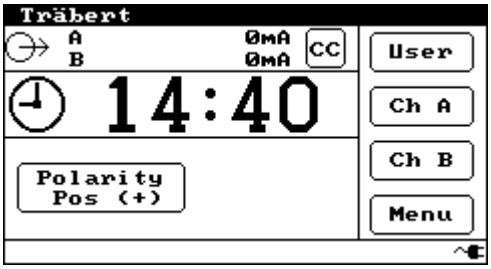
Polarity: Positive going, negative going or auto-reverse polarities are available (auto-reverse occurs half way through the selected treatment time).

When running, the output state is represented by a graphic in the top right corner of the display -



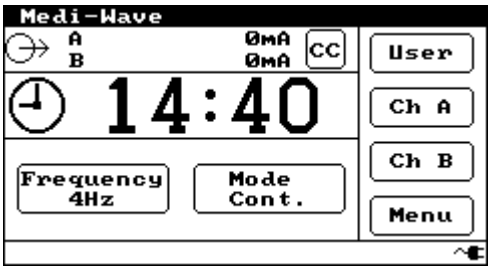
CC/CV: The output may be set to be constant current (CC) or constant voltage (CV).

Träbert set-up

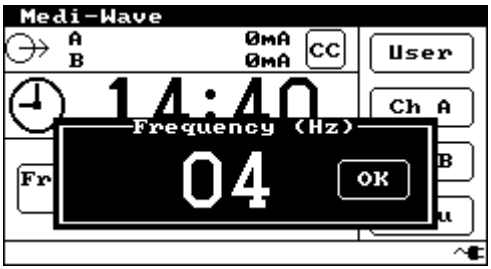


The available options are treatment time, polarity and CC/CV. These are set in exactly the same way as in the other operating modes.

Medi-Wave set-up



Freq: pressing this button opens this window:-

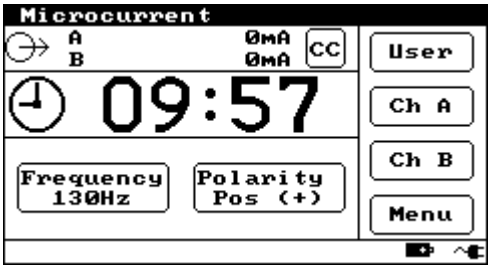


The frequency may be set from 2 to 60 Hz in 1Hz increments.

Mode: Normally Medi-Wave stimulation is used in continuous mode - that is with no modulation (none). In addition, burst and surged modes are also available. In burst mode the burst rate is 2 Hz for pulse frequencies greater than 20 Hz and the pulse frequency divided by 10 for frequencies less than 20 Hz. The duty cycle of the burst is 50%. In surge mode the surge rate is 10 per minute.

CC/CV: The output may be set to be constant current (CC) or constant voltage (CV).

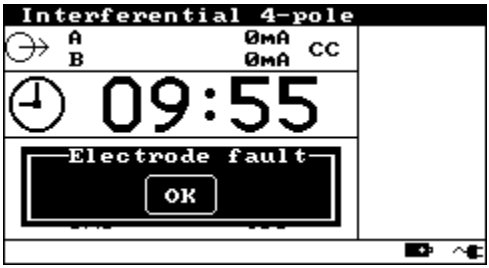
Microcurrent set-up



Freq: The frequency may be set from 1Hz to 1000Hz in ascending jumps by repeated presses of this button.

Polarity: This may be Pos (+), Neg (-), or Autorev (half way through the selected treatment time)

Electrode error detection



When a constant current output is chosen and the unit is operating in 4 or 2 pole interferential, russian, diadynamic, sinusoidal, galvanic or träbert modes, the electrode impedance is monitored to ensure that adequate electrode contact is maintained.

If the unit detects an electrode impedance too high to safely deliver the required current, then the output of the Combination 860 is terminated, an error message is displayed on the bottom line of the LCD and an intermittent alarm is sounded.

To cancel the alarm and clear the error message, press any button or turn the rotary control anticlockwise. The remaining treatment time is maintained. Check the electrodes and leads before continuing treatment. If rubber pad electrodes and sponge covers are being used check that they are held securely with even pressure by the elasticated bandages and that the sponges have not dried out.

Treatment

Connect the patient lead to the output socket of the unit. Attach suitable electrodes to the patient and connect the patient lead to the electrode using the blue and yellow cables provided. The yellow cables are channel A and the blue cables channel B.

For stimulation modes that have a dc component, the number 1 lead is positive and the number 2 lead negative.

Check that all the unit settings are as required for the chosen type of stimulation. Slowly turn the rotary control clockwise whilst pressing and holding the relevant output channel button (right-hand side of screen) to increase the output level*. If the treatment time is zero the unit will give a short alarm to indicate that the output cannot be energised.

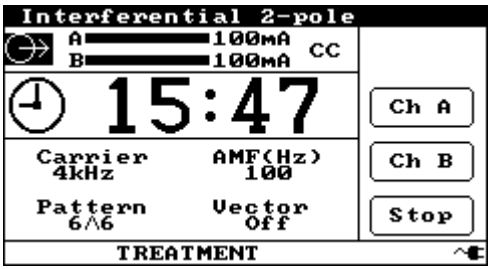
If the treatment time is not zero, the output of the stimulator will be energised, the output symbol will flash and the treatment time will begin to count down. Advance the output control slowly, until the desired effect of the stimulation is produced.

*4-pole interferential does not have independent output channels.

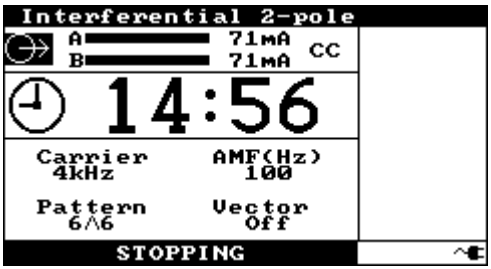
Always advance the output control slowly.

During the last 5 seconds of any treatment, both outputs are smoothly reduced to zero.

During any treatment, a ‘Stop’ button appears in the bottom right-hand corner of the screen –



Pressing this causes both outputs to smoothly reduce to zero over a period of 5 seconds.



In 4-pole and 2-pole interferential modes, the instantaneous frequency (AMF) is displayed.

Note: In soft water areas it may be necessary to add a small amount of bicarbonate of soda to the water used to wet the sponges in order to achieve adequate contact.

When the treatment time reaches zero, a three second alarm is sounded.

From any of the set-up screens, pressing the menu key when the output is off returns to the system menu.

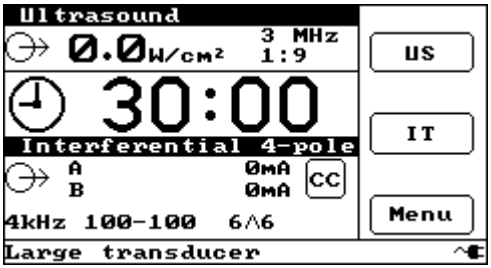
Combination therapy

It is recommended that only the large ultrasound transducer is used for combination therapy in order to maintain sufficient contact area to keep the stimulator current density to a safe level.

The surface of the ultrasound transducer is internally connected to the B1 terminal of the stimulator patient lead and thus becomes that electrode when used in combination mode. As the blue wire coming from the B1 terminal on the patient lead becomes redundant it is advisable to disconnect it during combination therapy. The B2 terminal becomes the electrode paired with the ultrasound head and the yellow wires (A1 and A2) become an independent pair of electrodes on stimulation channel A. If Channel A is not to be used do not turn up its output (an electrode error warning will appear if this is done in CC mode).

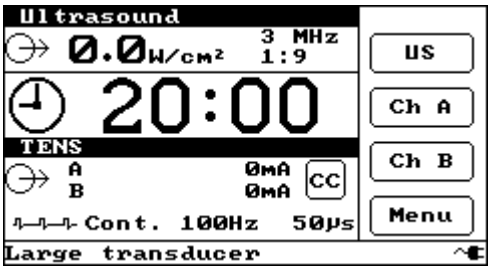
Set up both the ultrasound and the stimulator screens ready for treatment, pressing the menu key after each set-up to return to the system menu.

When both modalities have been programmed press the Combination button. The following combination screen will appear :-



This displays the current ultrasound and stimulation settings in abbreviated form.

If a stimulation setting other than 4-pole interferential was chosen a Combination screen like this will appear:-



Note that two independent buttons for Ch A and Ch B now appear at the right of the screen, reflecting the fact that independent channel level control is available for all stimulation modes except 4-pole interferential.

Also note that the treatment time defaults to the last figure entered if two different times were set for ultrasound and stimulation – this can be altered by highlighting the clock in this page.

Only treatment time and stimulation intensity can be controlled in the combination page.

Apply coupling medium to the treatment site and position the ultrasound transducer on the patient so that the lesion point is between the stimulator electrode(s) and the ultrasound transducer.

Press and hold the stimulator output button (one channel at a time if A and B are available), turn it on (using the control knob) and slowly increase the intensity until the patient just feels the normal 'tingling' sensation associated with the modality.

Turn on the ultrasound output (press and hold the US button whilst turning the control knob clockwise).

The patient may feel a slight increase in sensation.

Increase the ultrasound intensity to the required level.

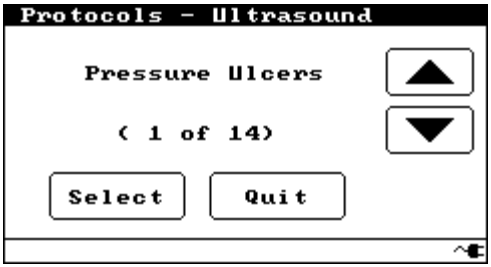
Move the ultrasound transducer towards the lesion area making sure that there is always coupling medium between the face of the transducer and the skin.

When directly over the lesion, the patient will feel increased sensation - this is the centre of the lesion.

Treat with ultrasound and stimulation for the remaining time set.

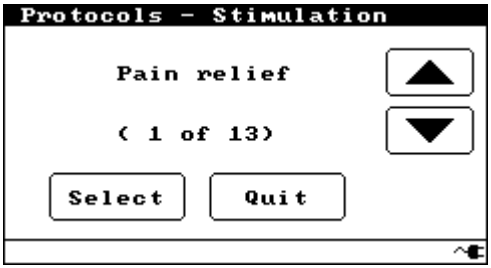
Protocols

Pressing the Prot button in the ultrasound set-up screen will call up a list of pre-sets tailored for treating various conditions.



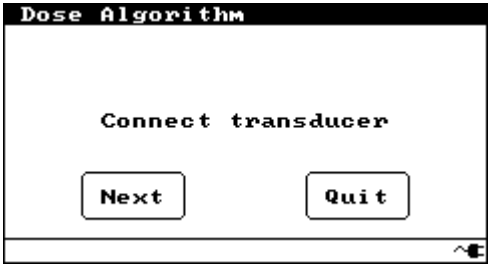
The condition to be treated can be selected using the up/down buttons and then pressing select to call up the ultrasound treatment settings for that particular condition.

There is a similar list of protocols available for stimulation treatment by pressing the Prot button in 4-Pole interferential mode only

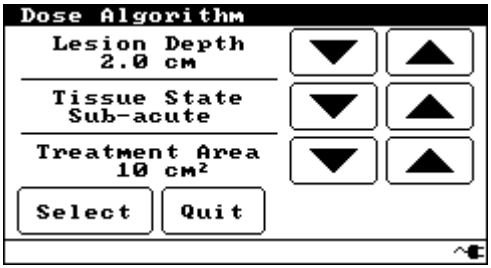


Ultrasound dose algorithm

This is selected by pressing the Dose button in the Ultrasound set-up screen. If a transducer is not connected this screen will appear prompting to connect one.



When a transducer is connected and Next is pressed, this screen will appear



The data concerning the state of the area to be treated is chosen using the Up/Down buttons, then pressing Select will cause the algorithm to calculate the relevant treatment settings.

Electrodes

It is recommended that only electrodes supplied by EMS Physio Ltd. are used with the Combination 860. Three sizes of conductive rubber electrodes are available. These are small (70 x 50 mm), medium (100 x 70 mm) or large (130 x 100 mm). Replacement sponge covers are available for each electrode.

In most applications it is sensible to use as large an electrode as is practical for the area of the body being treated. This will also reduce the possibility of any adverse effects at the site of the electrode due to high current density.

Inspect the area to be treated to ensure there are no open wounds, areas of infection, abrasions etc. Wash the skin in warm soapy water to minimise skin impedance and remove any creams or gels that may have been used.

Explain to the patient what is being done and what is going to happen.

Soak the sponge electrode covers in warm water. In a soft water area it may be necessary to add a small amount of bicarbonate of soda to the water to ensure low contact impedance for the electrodes. Fit the rubber electrodes fully into the sponge covers.

Apply the electrodes to the patient using the elasticated bandages supplied. The bandages must cover the whole of the electrode and maintain an even pressure in order to achieve a uniform current flow. A piece of polythene may be used between the top surface of the sponge cover and the elasticated bandage to prevent the bandage becoming wet.

Connect the electrodes to the stimulator output with the cables provided. For DC applications the yellow lead is positive and the blue negative.

It is important to ensure that the patient feels the expected sensation in the required area during treatment, otherwise the electrodes should be relocated.

The electrodes must never be placed so that the stimulating current crosses the chest or passes near the heart.

Re-useable electrodes should be cleaned and disinfected between patients.

A full range of self-adhesive electrodes is also available (see technical specification section).

Maintenance

The ultrasound transducers, electrodes and covers may be disinfected using a 70% v/v aqueous solution of isopropyl alcohol. They are NOT suitable for steam sterilisation or for disinfectants containing sodium hypochlorite.

N.B. Isopropyl alcohol is flammable and should be kept away from naked flames. Isopropyl alcohol must not be brought into contact with eyes or mouth.

The unit may be cleaned by wiping over with a damp cloth. The use of abrasive materials and cleaning solvents should be avoided.

Regularly (at least monthly) inspect all treatment leads, cables and connectors for signs of damage. The ultrasonic output power should be checked at least annually.

The Combination 860 has the option of an internal NiMh rechargeable battery. Whenever the unit is connected to the power supply the battery is monitored and charged as necessary. This type of battery has a limited life (typically 500 charge / discharge cycles). This battery must only be replaced by authorised service personnel. Do not mutilate, puncture, or dispose of batteries in fire. The batteries can burst or explode, releasing hazardous chemicals. Discard used batteries according to the manufacturer's instructions and in accordance with your local regulations.

There are no user serviceable parts inside the unit and it should not be opened.

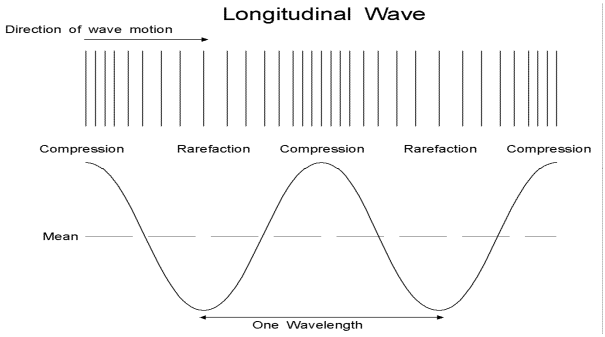
Full servicing instructions are available on request.

Appendix A – Overview of treatment modalities

Ultrasound

Sound is a mechanical vibration. The human ear responds to these vibrations in the range 20 Hz to 20 kHz. Sound above 20 kHz is called ultrasound. Therapeutic ultrasound is sound in the range 500 kHz to 5 MHz.

Sound waves are produced by some disturbance in a material medium causing the particles or molecules of the medium to vibrate. For this reason sound will not pass through a vacuum. If the vibration is continuous and regular a constant tone or frequency is produced. The vibration or sound wave propagates through the medium as particles in the medium pass on their vibration to neighbouring particles and a series of compressions and rarefactions are produced in the direction of travel of the wave. Therefore, sound waves are longitudinal waves.



The diagram shows a sound wave travelling from left to right. The vertical bars represent thin slices of the medium which are displaced to form areas of compression and rarefaction. The sine wave represents their displacement relative to their mean position. The distance over which the vibration repeats itself is called the wavelength. The number of complete vibrations in one second is called the frequency of the sound wave.

The velocity of sound in the medium is given by:

$$\text{Velocity} = \text{frequency} \times \text{wavelength}$$

Sound will travel faster through media where the molecules are closer together and so the velocity is higher in solids than in liquids, and higher in liquids than in gasses. For example, the velocity of sound in stainless steel is approximately 5800 m/s, in water 1500 m/s and in air only 330 m/s.

As the sound wave passes through the medium, causing molecules to vibrate, some of the energy in the wave is converted from kinetic energy to heat. For a collimated sonic beam the intensity, power per unit area decreases exponentially with the distance travelled.

The attenuation of the beam is also dependent upon the frequency of the sound. In solids the attenuation is proportional to frequency whereas in liquids the attenuation is proportional to the square of the frequency. The usual method of specifying the degree of attenuation of ultrasound in different media is by the half depth. The half depth is the distance the ultrasound must travel through the medium for its intensity to be reduced to one half of its original value. Many attempts have been made to measure the attenuation in various types of tissue with varying results. It is perhaps more important to remember which types of tissue have the highest absorption and which the lowest. With the lowest absorption first the order is fat, muscle, skin, tendon, cartilage and bone. For soft tissue the half depth is around 50 mm at 1 MHz and 15 mm at 3 MHz.

It is also important to remember that where there is a change in medium or tissue type there will be both reflection and refraction of the ultrasound beam. In particular, there is almost 100% reflection at the interface of a solid or liquid to air at therapeutic ultrasound frequencies. Any air bubbles in coupling medium will therefore reduce the effective intensity of the ultrasound. Also bone reflects a high percentage of incident ultrasound. It is important, therefore, when applying ultrasound to keep the transducer orthogonal to the surface of the treatment area, to keep the ultrasound transducer moving and to use a good coupling medium to avoid unwanted reflections and locally high intensities.

Electrotherapy

Low-frequency stimulation

Diadynamic currents were introduced by Dr. Pierre Bernard. They are various combinations of half and full wave rectified 50 Hz sinewaves. Their therapeutic benefits include pain relief, reduction of swelling and inflammation, increased local circulation, muscle strengthening and re-education. The Combination 860 produces DF (diphasé fixe), MF (monophasé fixe), CP (courtes périodes), CPiso (courtes périodes isodynamique), LP (longues périodes) and RS (rhythme syncope) waveforms.

Surged 50 Hz sinusoidal currents may be used to produce rhythmical muscle contraction. This can help in the reduction of oedema and produce an increase in circulation in the treated area.

Faradic pulses are of short duration (less than 1 ms) and have a repetition rate of 50 Hz. They are normally surged to produce rhythmical muscle contraction.

Galvanic or direct current is used for pain relief and iontophoresis.

The Combination 860 produces a wide range of interrupted galvanic pulses. Rectangular pulses from 10µs to 1s are available and other shapes from 1 ms to 1s.

Trabert's current, sometimes known as ultra-reiz, has a fixed pulse width of 2 ms and a period of 7 ms, and is used for pain relief.

The Medi-Wave signal is a bipolar exponential decaying wave, which emulates the H waveform found in nerve signals (Hoffman reflex). At low repetition frequencies (2 Hz), Medi-Wave offers profound muscle stimulation and at higher frequencies (60 Hz) deep analgesic pain control.

Medium-frequency stimulation

Interferential therapy employs medium frequency currents used in 2 or 4-pole configurations to produce a low frequency stimulation effect.

Prior to the introduction of interferential therapy in the mid 1950s, low frequency stimulation was used for pain relief, muscle re-education etc. These currents, however, have the disadvantage that normal human skin has a relatively high impedance at such frequencies. In order to overcome the skin impedance a larger voltage has to be used to achieve the desired current, resulting in a more uncomfortable treatment for the patient. In addition, the penetration depth of these currents is poor and in part is limited by the discomfort to the patient.

Interferential therapy overcomes the problem of skin impedance. At 50 Hz (faradic current) the impedance for a 100 cm^2 of skin is approximately 3000 ohms. At 4000 Hz (medium frequency) the skin impedance of the same area is around 50 ohms. This means that a much lower voltage signal can be used to produce the desired current, resulting in less skin sensation and a more comfortable treatment. This medium frequency is, however, well outside of the normal biological frequency range (0.1 to 250 Hz). In order to produce the required stimulation, two medium frequencies are used. A constant frequency of, say, 4000 Hz is applied to one pair of electrodes and a slightly different frequency of say 3900 Hz is applied to the other pair. These two frequencies 'interfere' to produce an amplitude modulated medium frequency (beat frequency) in the tissue. The tissue responds to the cyclic rise and fall in the current intensity. It is the amplitude modulation frequency (AMF) that is within the normal biological frequency range and not the medium frequency (carrier).

Russian stimulation was developed by Dr Y Kotz, and uses 2.5 kHz sinewaves pulse at a low frequency, typically 30 to 80 Hz, to produce comfortable muscle contraction. It is similar to a surged, 2-pole interferential waveform.

Transcutaneous electrical nerve stimulation (TENS) refers to the application of low-intensity, short-duration pulses for the purpose of relieving pain. The Combination 860 provides two channels of asymmetric, symmetric or sequential output with a wide range of pulse widths and repetition rates.

Combination therapy

In general terms, combination therapy involves the simultaneous application of ultrasound with an electrical stimulation therapy.

The main advantages of such a combination are said to be in –

localising lesions (especially chronic) ie. diagnostic use.

ensuring accurate localisation of ultrasound treatment to provide increased accuracy/effectiveness in treating deeper lesions.

treating trigger points.

Possible explanations of effects

It would appear that by applying ultrasound to peripheral nerves their threshold of stimulation is reduced, thus making them more sensitive or excitable. It is likely that this effect is brought about by the alteration of the ion pump activity, predominantly Na^+ and K^+, but also Ca^{++}. By altering the transport of these ions across the cell membrane the resting potential will be altered and, in this case, it would seem that it results in a reduced threshold for depolarisation.

It is reasonable to expect that this effect occurs in other tissue (apart from nerve) although no direct evidence has been noted to date.

When electrotherapy is applied simultaneously with ultrasound through the same tissues a reduced intensity is required in order to achieve the same physiological/therapeutic effects when compared with electrotherapy in isolation. This can easily be demonstrated by turning off the ultrasound component whilst continuing with the electrotherapy. The patient very soon becomes aware of a much reduced sensation/effect which can be restored by restarting the ultrasound.

In addition the simultaneous application of ultrasound with electrotherapy minimises the accommodation phenomenon normally associated with electrical stimulation of the peripheral nerves.

The combination of ultrasound with interferential therapy appears to give rise to less adverse treatment effects than are associated with the combination of ultrasound with diadynamic currents or other electrical stimulations. It has also been suggested that a greater effective treatment depth can be achieved with an ultrasound/interferential combination.

Unlike routine interferential therapy the intensity of the electrical stimulation in combination therapy may need to be REDUCED during treatment, probably due to the continued effect of the ultrasound on the nerve membrane threshold.

In summary, by combining the two treatment modalities none of the individual effects of the treatment are lost, but the benefit is that lower treatment intensities can be used to achieve the same results and there are additional benefits in terms of treatment times.

Appendix B - Technical specification

General

Power input	18V, 3.33A external PSU
Battery pack (optional)	Internal rechargeable (NiMh)
Classification (EN60601-1)	Class 1, Type BF
Fuse	Internal T5A
Size (h x w x d)	108 x 237 x 333 mm
Weight	1.3 kg (excluding battery)
Treatment programs	10 user-defined set-ups. Dose algorithm provided

Ultrasound

Frequency	1.1 MHz ±5% and 3.4 MHz ±5%
Maximum intensity	1.5 W/cm^2 in CW 3.0 W/cm^2 in pulsed modes
Maximum output power	6 W average (PSU operation only)
Output modes	CW and pulsed 1:1, 1:2, 1:4 and 1:9
Pulse duration	2 ms
Treatment timer	0 to 30 minutes (treatment linked)
Contact monitor	Light on transducer

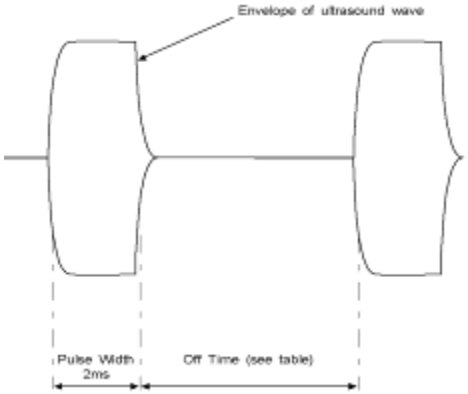
Large ultrasound transducer

ERA	4 cm^2 (IEC 61689) 5 cm^2 (21 CFR 1050.10)
BNR	<5
Beam type	Collimated

Small ultrasound transducer

	1MHz	3MHz
ERA	0.6 cm^2	0.4 cm^2
BNR	<5	<5
Beam Type	Divergent	Collimated

Transducers for use with the Primo Combination 860, Primo Therasonic 360 and 460 are fully interchangeable and suitable for underwater treatment (IPx7 rated).



Pulse Mode	*Frequency*	*Off Time*	*Duty Cycle*	*Temporal peak to average ratio*
1:1	250 Hz	2 ms	50%	2:1
1:2	166 Hz	4 ms	33%	3:1
1:4	100 Hz	8 ms	20%	5:1
1:9	50 Hz	18 ms	10%	10:1

The pulse width is fixed at 2 ms

Interferential 4-pole

Carrier frequency	2 kHz, 4 kHz or 8 kHz
AMF	0 – 250 Hz in 1 Hz increments
Swing pattern	1|1, 6|6 or 6^6
Vector	10s, 20% both channels
Output type	CC 0-100mA peak
	CV 0-70V peak
Output channels	2

Interferential 2-pole

Carrier frequency	2 kHz, 4 kHz or 8 kHz
AMF	0 – 250 Hz in 1 Hz increments
Swing pattern	1|1, 6|6 or 6^6
Output type	CC 0-100mA peak
	CV 0-70V peak
Output channels	2

Russian stimulation

Carrier frequency	2.5 kHz
Modulation frequency	1 – 100 Hz
Surges	1:1 to 1:5
Output type	CC 0-100mA peak CV 0-70V peak
Output channels	2

TENS

Waveform	Asymmetrical, symmetrical or sequential
Pulse width	20 – 400 µs
Repetition rate	1 – 250 Hz
Modulation	None, burst or surged
Output type	CC 0-100mA peak CV 0-60V peak
Output channels	2

Diadynamic currents

Current types	DF, MF, CP, CPiso, RS, LP
Output type	CC 0-70mA peak CV 0-140V peak
Polarity	Positive, negative or auto-reverse
Output channels	2

Sinusoidal

Frequency (AMF)	50 Hz
Surge rate	2 to 30 /minute
Surge pattern	Rectangular, triangular or trapezoidal
Output type	CC 0-70mA peak CV 0-140V peak
Output channels	2

Faradic

Frequency	50 Hz
Surge rate	2 to 30 /minute
Surge pattern	Rectangular, triangular or trapezoidal
Output type	CC 0-70mA peak CV 0-140V peak
Output channels	2

Galvanic

Output type	CC 0-70mA peak CV 0-140V peak
Polarity	Positive, negative or auto-reverse
Output channels	2

Interrupted galvanic

Pulse width	10 µs to 1 s for rectangular 1 ms to 1 s for other shapes
Waveform	Rectangular, triangular or trapezoidal
Pulse rate	1 to 30 /minute
Output type	CC 0-70mA peak CV 0-140V peak
Polarity	Positive, negative or auto-reverse
Output channels	2

Träbert

Waveform	2 ms on, 5ms off rectangular
Output type	CC 0-70mA peak CV 0-140V peak
Polarity	Positive, negative or auto-reverse
Output channels	2

Medi-Wave

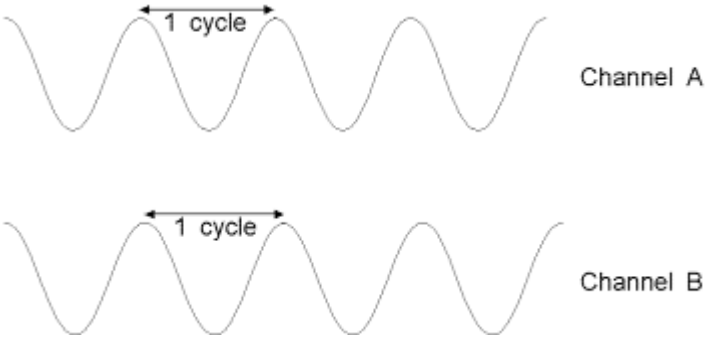
Waveform	6 ms differentiated pulse
Frequency	2 – 60 Hz
Modulation	None, burst, surged
Output type	CC 0-50mA peak CV 0-60V peak
Output channels	2

Microcurrent

Waveform	Square wave (50% duty cycle)
Frequency	1-1000Hz
Output type	CC 0-1mA
Polarity	Positive, negative or auto-reverse
Output channels	2

Output waveforms

Interferential 4-pole



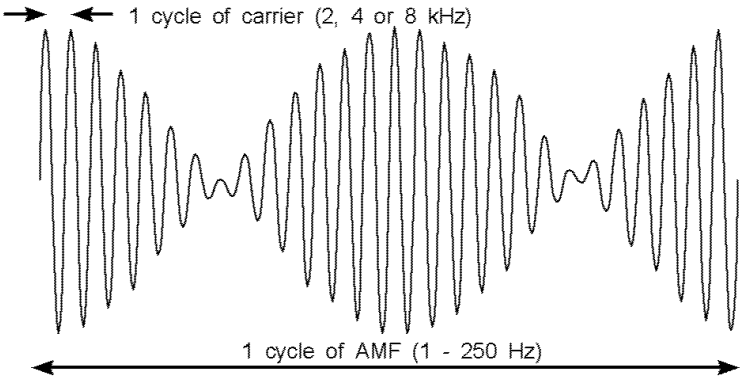
	Channel A		Channel B	
Carrier	Frequency	Period	Frequency	Period
2 kHz	2 kHz	500 µs	1.75-2 kHz	572-500 µs
4 kHz	4 kHz	250 µs	3.75-4 kHz	267-250 µs
8 kHz	8 kHz	125 µs	7.75-8 kHz	129-125 µs

In constant current mode the maximum output current per channel is 100 mA peak (70 mA rms). The maximum load impedance in ohms at any given output current is given by:

Maximum impedance = 70000/(peak output current in mA)

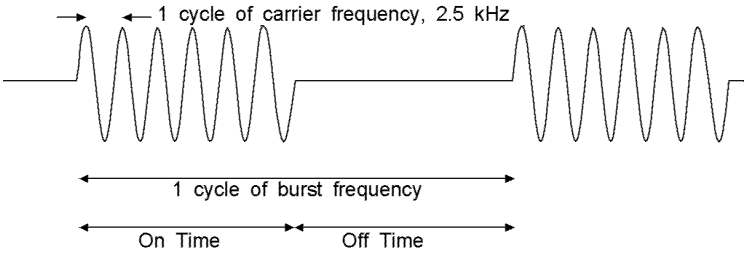
In constant voltage mode, the maximum output voltage is 70Vpeak or (load impedance x 0.1) V peak whichever is the smaller.

Interferential 2-pole



The maximum output voltage and current are the same as for 4-pole interferential operation. Two channels of output are available with independent intensity control.

Russian stimulation

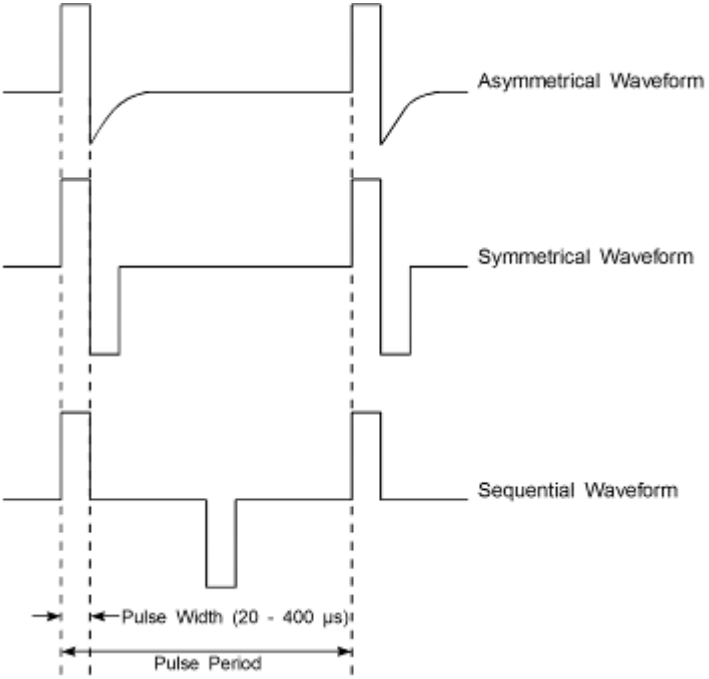


The burst frequency may be set to be from 1 Hz to 100 Hz. The on and off times are always equal and are from 0.5s (1 Hz burst) to 5 ms (100 Hz burst).

The maximum output voltage and current are the same as for 4-pole interferential operation. Two channels of output are available with independent intensity control.

TENS

Three TENS waveforms are available



pulse period = 1/(repetition rate)

TENS Burst mode

For repetition rates greater than 20 Hz, the TENS output is on for 0.25 s and off for 0.25 s (2 Hz burst frequency). For repetition rates less than 20 Hz the on and off times are 5 pulse periods.

TENS Surge mode

For repetition rates greater than 5 Hz the TENS output is zero for 2 s (rest), then increases to the set level during the next 1 s (rise), remains at the set level for 0.5 s (hold) and returns to zero during the next 0.5 s (fall) giving a surge rate of 15 / minute. Below 5 Hz, the rest, rise, hold and fall times are 10, 5, 3 and 2 pulse periods respectively. Two channels of output are available with independent intensity control.

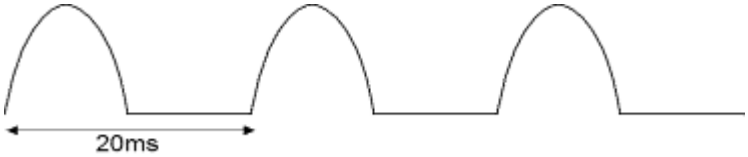
Diadynamic
In diadynamic mode the unit produces six different waveforms.
The maximum peak output current is limited to 70 mA.

DF - diaphasé fixe
The DF waveform is a continuous full wave rectified 50 Hz sinewave.

rms current = peak current x 0.707

The maximum rms current is 50 mA.

MF - monophasé fixe
The MF waveform is a continuous half wave rectified 50 Hz sinewave.



rms current = peak current x 0.5

The maximum rms current is 37.5 mA.

CP - modulé en courtes périodes
The CP waveform is a combination of the MF and DF waveforms. The unit provides 1 s of MF (half wave signal) followed by 1 s of DF (full wave signal), the sequence being repeated continuously.

CPiso - modulé en courtes périodes isodynamique
This is the same as the CP waveform except that the amplitude of the MF signal is 12.5% less than the amplitude of the DF signal.

LP - modulé en longues périodes
The LP waveform provides an MF signal for 5 seconds. Then over the next 2.5 seconds the other phase of the 50Hz rectified signal is smoothly increased in amplitude to give a DF signal for a further 5 seconds. Finally the signal returns to MF by smoothly reducing one phase of the rectified signal over the next 2.5 seconds. The complete sequence takes 15 seconds. Part of the LP waveform showing how the alternate phase increases in amplitude is shown above.

RS – rythme syncopé
The RS waveform is 1 second of MF followed by 1 second of zero output, this sequence being repeated continually.

Two channels of output are available with independent intensity control.

Polarity
The above waveforms exhibit Pos (+) polarity as they all travel above the ground (zero volts) level (equivalent to the flat part of the waveforms). The polarity switch enables the user to reverse this
Neg (-) so that the above waveforms would be rendered 'upside-down' (both channels are inverted). This feature is particularly useful in combination mode, when the ultrasound head becomes one electrode, and we can select the polarity of the waveform relative to the head. A third option is Auto-reverse, in which the polarity automatically reverses half way through the selected treatment time.

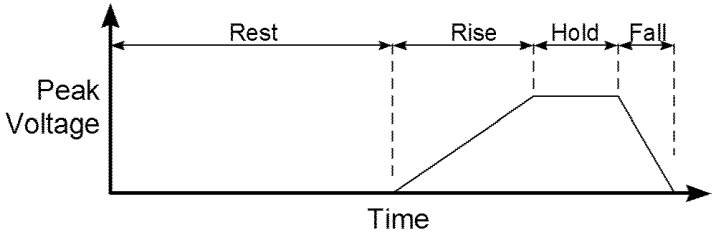
Sinusoidal

In sinusoidal mode, the output is an amplitude-modulated medium frequency (4 kHz) with 50 Hz sinusoidal beat frequency. The amplitude is determined by the output level setting and the surge type and rate. The maximum output is 140 V or 70 mA peak.

For a sine wave the peak output or amplitude is equal to the rms output multiplied by √2, or, conversely

rms output = peak output x 0.707

Three standard surge patterns are provided. The rest, rise, hold and fall times for each pattern as a percentage of the complete surge cycle are shown below.



Pattern	Rest	Rise	Hold	Fall
Rectangular	50	5	40	5
Triangular	50	33	16	1
Trapezoidal	50	25	13	12

Two channels of output are available with independent intensity control.

Faradic

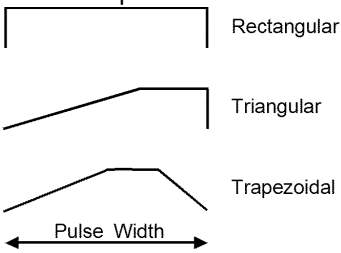
The output in faradic mode is a series of 0.5ms pulses at a repetition rate of 50 Hz with zero dc content. The pulse train is surged in the same way as the sinusoidal output. Two channels of output are available with independent intensity control.

Galvanic

Galvanic mode produces a direct current from 0 to 70 mA in either a positive, negative or auto-reverse (half way through the treatment time) electrical polarity. Two channels of output are available with independent intensity control.

Interrupted galvanic

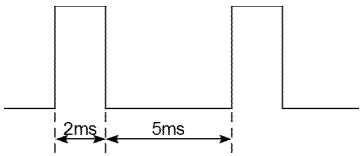
Interrupted galvanic mode produces three standard pulse shapes.



Rectangular pulses are available from 10 µs to 1 s pulse width and triangular and trapezoidal pulses from 1 ms to 1s. The pulse repetition rate is from 2 to 30 pulses per minute. Two channels of output are available with independent intensity control, and their polarity may be selected as Pos (+), Neg (-), or autorev (half way through the treatment time).

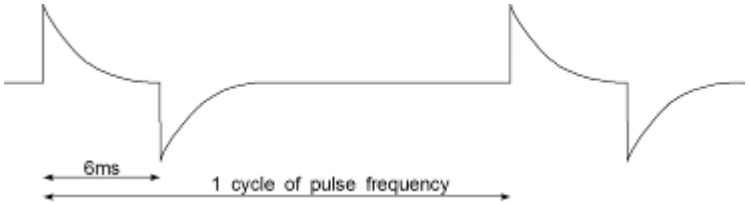
Träbert

This mode produces a continuous train of 2ms pulses with a 5 ms interval between each pulse. The pulse repetition rate is therefore approximately 143 Hz. Two channels of output are available with independent intensity control. Pos (+), Neg (-), or autorev polarities are selectable.



Medi-Wave

The Medi-Wave output is a train of differentiated pulses with a pulse width of 6 ms. In burst mode the burst rate is 2 Hz for pulse frequencies greater than 20 Hz and the pulse frequency divided by 10 for frequencies less than 20 Hz. The duty cycle of the burst is 50%. In surge mode the surge rate is 10 per



minute. Two channels of output are available with independent intensity control.

Microcurrent

The Microcurrent output is a unipolar square wave with a frequency variable between 0 and 1000 Hz. It is a small constant current, variable between 0 and 1mA, and its polarity may be selected as
Pos (+), Neg (-), or autorev (half way through the treatment time)

Environmental conditions for transport and storage

Temperature	-10 to +35 C
Relative Humidity	5 to 95%
Atmospheric Pressure	500 to 1060 hPa

Output display
The Primo Combination 860 display shows the temporal-peak spatial-average ultrasound intensity and optionally the temporal-average power or the temporal-peak power as selected

All information on model, serial number, and month/year of manufacture is located on the rear panel.

The Primo Combination 860 has been designed to meet the requirements of BS EN 60601-1:2006 "Medical Electrical Equipment, Part 1:General requirements for safety", BS EN 601-2-5:2001 "Medical Electrical Equipment, Part 2.5: Particular requirements for the safety of ultrasonic physiotherapy equipment", BS EN 60601-2-10:1998 “Medical Electrical Equipment, Part 2-10: Particular requirements for the safety of nerve and muscle stimulators”, and BS EN 60601-1-6:2007 “Medical Electrical Equipment, Part 1-6; General requirements for safety – Usability.

Appendix C - EMC tables

1	**Guidance and manufacturers declaration – electromagnetic emissions**		
2	The Primo Combination 860 is intended for use in the electromagnetic environment specified below. The customer or the user of the Primo 860 should ensure that it is used in such an environment.		
3	**Emissions Test**	**Compliance**	**Electromagnetic environment - guidance**
4	RF emissions CISPR 11	Group 1	The 860 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
6	RF emissions CISPR 11	Class A	
7	Harmonic emissions IEC 6100-3-2	not applicable	The 860 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
8	Voltage fluctuations Flicker emissions IEC 61000-3-3	not applicable	

Guidance and manufacturers declaration – electromagnetic immunity

The Primo Combination 860 is intended for use in the electromagnetic environment specified below. The customer or the user of the Primo 860 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% *U*T (>95% dip in *U*T) For 0,5 cycle 40% *U*T (60% dip in *U*T) For 5 cycles 70% *U*T (30% dip in *U*T) For 25 cycles <5% *U*T (>95% dip in *U*T) For 5 sec	<5% *U*T (>95% dip in *U*T) For 0,5 cycle 40% *U*T (60% dip in *U*T) For 5 cycles 70% *U*T (30% dip in *U*T) For 25 cycles <5% *U*T (>95% dip in *U*T) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 860 requires continued operation during power mains interruptions, it is recommended that the 860 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE *U*T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturers declaration – electromagnetic immunity.

The primo Combination 860 is intended for use in the electromagnetic environment specified below. The customer or user of the Primo Combination 860 should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Primo Combination 860, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC61000-4-6	3Vrms 150kHz to 80MHz	3V	$d=3.5\sqrt{P}/V_1$
Radiated RF IEC61000-4-3	3V/m	3V/m	$d=3.5\sqrt{P}/E_1$ 80MHz to 800MHz
	80MHz to 2.5GHz		$d=7\sqrt{P}/E_1$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter according to the manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80MHz and 800MHz the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Primo Combination 860 is used exceeds the applicable RF compliance level above, the Primo Combination 860 should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as re-orienting or relocating the Primo Combination 860.

[b] Over the frequency range 10kHz to 80Mhz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Solo 860

The Primo Combination 860 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Primo 860 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Primo 860 as recommended below, according to the maximum output power of the communications equipment.

	150kHz to 80MHz $d=3.5\sqrt{P}/V_1$	**80MHz to 800MHz** $d=3.5\sqrt{P}/E_1$	**800MHz to 2.5GHz** $d=7\sqrt{P}/E_1$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix D - Essential performance

The performance characteristics essential to the correct operation of the Primo Combination 860 are:

Power input	100-240V ac
Treatment time	0 – 30 minutes
Ultrasound	
Frequency	1.1 MHz ±5% and 3.4 MHz ±5%
Maximum intensity	1.5 W/cm^2 (±20%) in CW 3.0 W/cm^2 (±20%) pulsed modes
Maximum output power	6 W (±20%) average
Output modes	CW and pulsed 1:1, 1:2, 1:4 and 1:9
Pulse duration	2 ms (±10%)
Large transducer	ERA 4cm^2 (±20%) (IEC61689), collimated BNR<5
Small transducer	ERA 0.6cm^2 (±20%) (IEC61689), divergent at 1MHz ERA 0.4cm^2 (±20%) (IEC61689), collimated at 3MHz BNR<5
Interferential 4-pole	
Carrier frequency	2 kHz, 4 kHz or 8 kHz) (± 5%)
AMF	0 – 250 Hz in 1 Hz increments) (±2%)
Swing pattern	1|1, 6|6 or 6^6
Output type	CC 0-100mA peak (±10%) into 500 Ω CV 0-70V peak (±10%) into 2 k Ω
Interferential 2-pole	
Carrier frequency	2 kHz, 4 kHz or 8 kHz (± 5%)
AMF	0 – 250 Hz in 1 Hz increments (±2%)
Swing pattern	1|1, 6|6 or 6^6
Output type	CC 0-100mA peak (±10%) into 500 Ω CV 0-70V peak (±10%) into 2 k Ω
Russian Stimulation	
Carrier frequency	2.5 kHz (± 5%)
Modulation frequency	1 – 100 Hz (± 5%)
Surges	1:1 to 1:5
Output type	CC 0-100mA peak (±10%) into 500 Ω CV 0-70V peak (±10%) into 2 k Ω

TENS

Waveform	Asymmetrical, symmetrical or sequential
Pulse width	20 – 400 µs in 5 µs increments (±10%)
Repetition rate	1 – 250 Hz in 1 Hz increments (±10%)
Output type	CC 0-100mA peak (±10%) into 500 Ω
	CV 0-60V peak (±10%) into 2 k Ω

Diadynamic Currents

Current types	DF, MF, CP, CPiso, RS, LP
Output type	CC 0-70mA peak (±10%) into 500 Ω
	CV 0-140V peak (±10%) into 2 k Ω

Sinusoidal

Frequency (AMF)	50 Hz (±5%)
Surge rate	2 to 30 /minute (±10%)
Surge pattern	Rectangular, triangular or trapezoidal
Output type	CC 0-50mA peak (±10%) into 500 Ω
	CV 0-100V peak (±10%) into 2 k Ω

Faradic

Frequency	50 Hz (±5%)
Surge rate	2 to 30 /minute (±10%)
Surge pattern	Rectangular, triangular or trapezoidal
Output type	CC 0-50mA peak (±10%) into 500 Ω
	CV 0-100V peak (±10%) into 2 k Ω

Galvanic

Output type	CC 0-70mA peak (±10%) into 500 Ω
	CV 0-140V peak (±10%) into 2 k Ω

Interrupted galvanic

Pulse width	10 µs to 1 s (± 5%) for rectangular in 1, 2, 5 sequence
	1 ms to 1 s (± 5%) for other shapes
Waveform	Rectangular, triangular or trapezoidal
Pulse rate	1 to 30 /minute (±10%)
Output type	CC 0-70mA peak (10%) into 500 Ω
	CV 0-140V peak (±10%) into 2 k Ω

Träbert

Waveform	2 ms on (± 5%), 5ms off (± 5%)	
rectangular		
Output type	CC	0-70mA peak (±10%) into 500 Ω
	CV	0-140V peak (±10%) into 2 k Ω

Medi-Wave

Waveform	6 ms (± 5%) differentiated pulse	
Frequency	2 – 60 Hz (± 5%)	
Output type	CC	0-50mA peak (±10%) into 500 Ω
	CV	0-60V peak (±10%) into 2 k Ω

Microcurrent

Waveform	Square wave (50% duty cycle)
Frequency	1-1000Hz
Output type	CC 0-1mA(±20%)
Polarity	Positive, negative or auto-reverse

EMS Physio Ltd.

Grove Technology Park
Downsview Road
Wantage
Oxfordshire OX12 9FE
UK

T: 01235 772272
F: 01235 763518
E: sales@emsphysio.co.uk
Website: http://www.emsphysio.co.uk