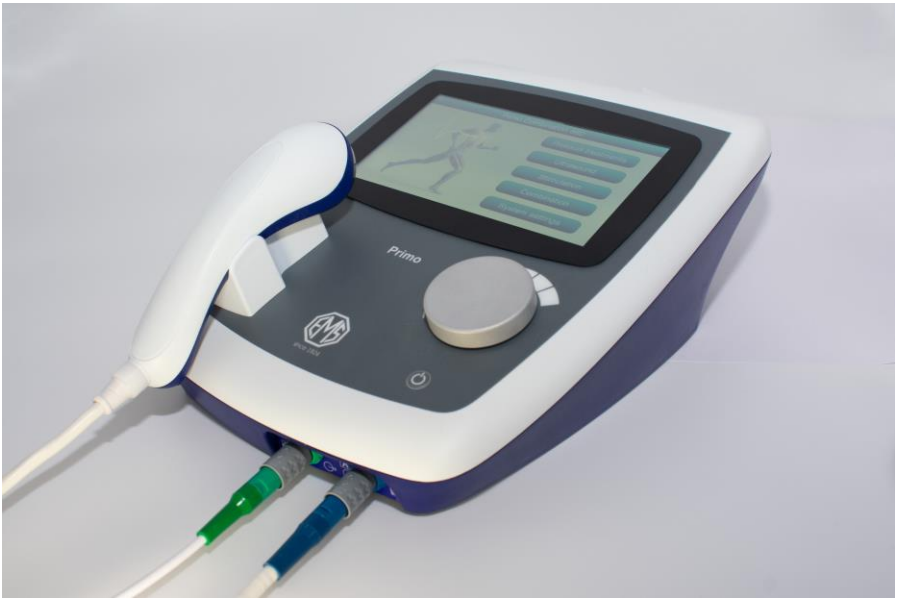
User Manual



EMS860

PRIMO COMBINATION
Model 125

CE
1639

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
7	Technical revisions	15/06/15
8	Updated for colour TFT GUI	08/02/17
9	Minor edits	05/07/17
10	Small transducer constraint in Combi.	15/11/18
11	Corrections	14/12/18
12	Updated for new NB number	27/03/20
13	Updated for independent channel stim.	30/09/21

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 two independent electrical stimulation channels each with a complete range of low and medium frequency waveforms for electrotherapy. Both modalities may be used individually or in combination. The unit may be powered from a (specific) desktop mains to DC PSU or from a suitable external DC power bank.

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 such as chronic rheumatoid and arthritic conditions, for pain relief and for tissue repair during the inflammatory and proliferation stages of tissue repair.

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. Voltage and current waveforms may be used to provide Neuro Muscular Electrical Stimulation (NMES) and relief from musculoskeletal pain. NMES may be used for muscle strengthening and rehabilitation in otherwise healthy subjects recovering from surgery, for muscle strengthening for critically or chronically ill patients or to (re)train weak or ineffective muscles.

Pain relief may be appropriate post-surgery during rehabilitation, or for relief from chronic conditions such as osteoarthritis.

The various output waveforms available from the units are suitable for either NMES and/or pain relief as shown in the chart in Appendix D on page 74.

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.

Precautions

Therapy shall be performed by qualified personnel trained and/or experienced in the use of this device as outlined in an appropriate training program.

Electromagnetic interference: This device may cause electromagnetic interference to electronic devices

The emissions characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

This device is suitable for use in hospital environments except for near active HF surgical equipment or in the RF shielded room of magnetic resonance imaging equipment where the intensity of EM disturbances is high.

WARNING: use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Cross contamination: Patients with skin infection in the treatment area should have precautions taken in order to avoid cross-contamination.

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 display screen 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.

The temperature of the ultrasound transducer treatment head may reach 42° C when operating under maximum operating conditions*.

Maintenance: For continuous and safe operation, regular maintenance and inspection by EMS authorised technicians is required. For the maintenance procedures and schedule, refer to the Maintenance section of this manual.

Coupling media: Water-based ultrasound gel should be used as coupling media between the ultrasound transducers and patient skin.

Cleaning: Proper cleaning of the transducers, electrodes and main unit is required. For cleaning instructions, refer to the Maintenance chapter of this manual

Modification of the EMS860 is not permitted and may result in a hazardous situation.

*If the transducer temperature exceeds 42° C then a detector in the transducer sounds and displays an alarm message on the display screen and ultrasound power is reduced to a low level until the transducer has cooled down sufficiently.

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 previous 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. 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.

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, across the heart or near the cervical ganglion – may cause cardiac fibrillation.

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 goes across or through the head, eye, front of the neck (especially the carotid sinus), upper back or chest.

Electrodes must never cover the mouth.

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

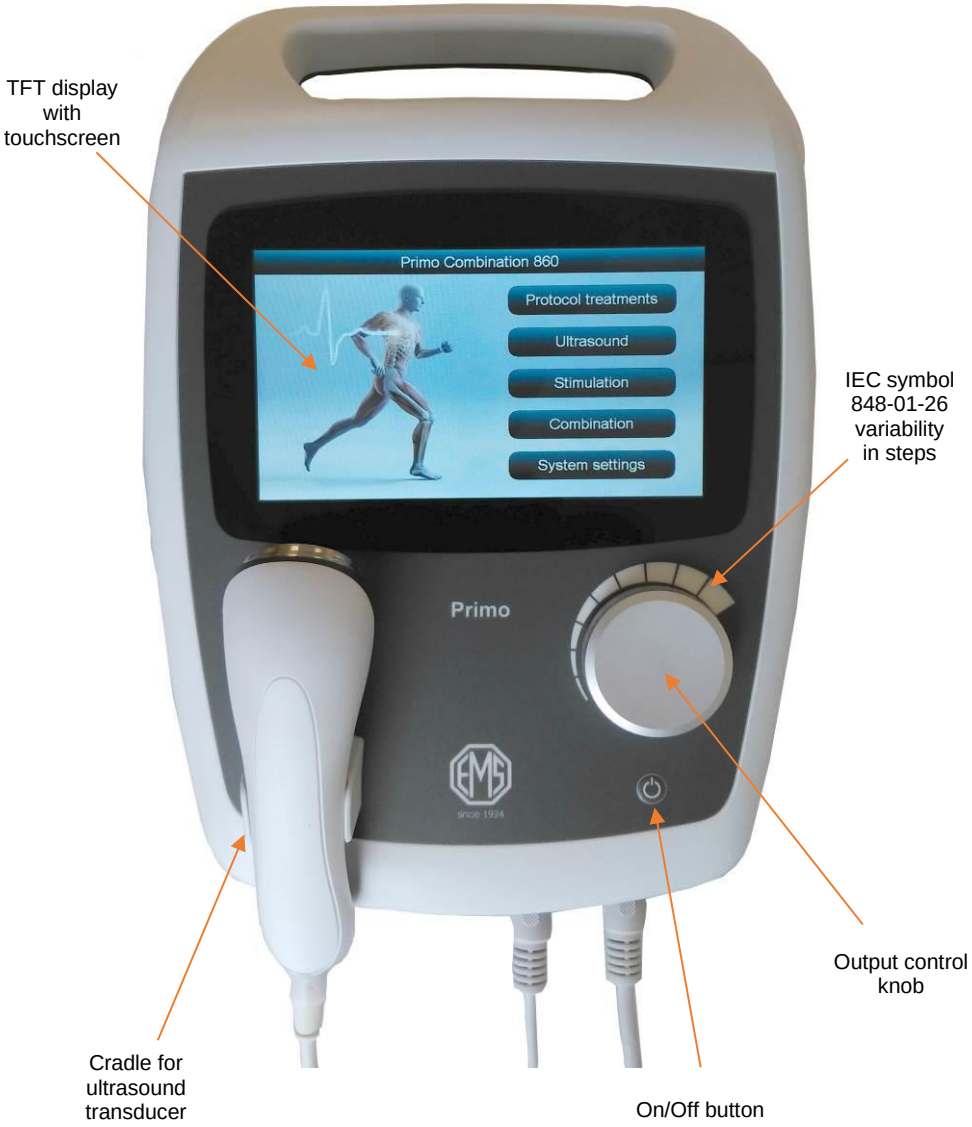
For other countries contact EMS Physio Ltd. (contact details on page 53) or the agent from whom the unit was purchased.

WARNING: Use of accessories such as transducers, electrodes or mains cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

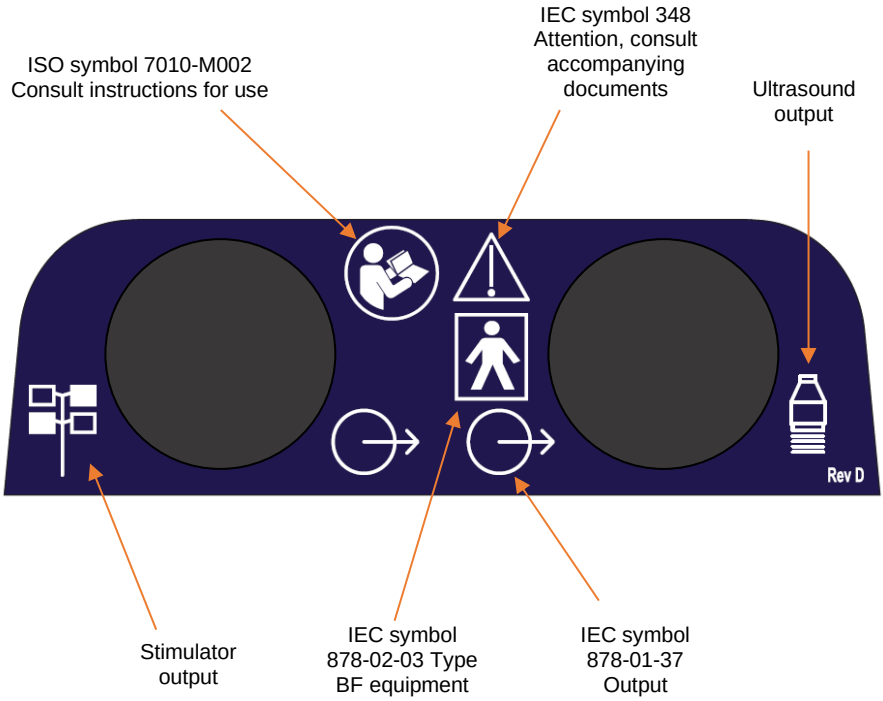
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Combination 860 including cables specified by the manufacturer, otherwise degradation of the performance of this equipment could result.

Controls and Markings

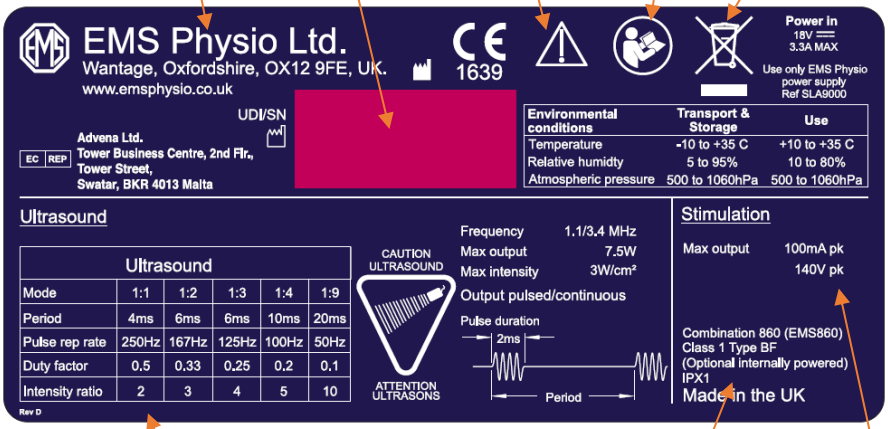
Primo Combination 860 Top



Primo Combination 860 Front Label



Primo Combination 860 Underside Label



Serial number and date of manufacture

IEC symbol 348 Attention, consult accompanying documents

ISO symbol 7010-M002, consult instructions for use

Name and address of manufacturer

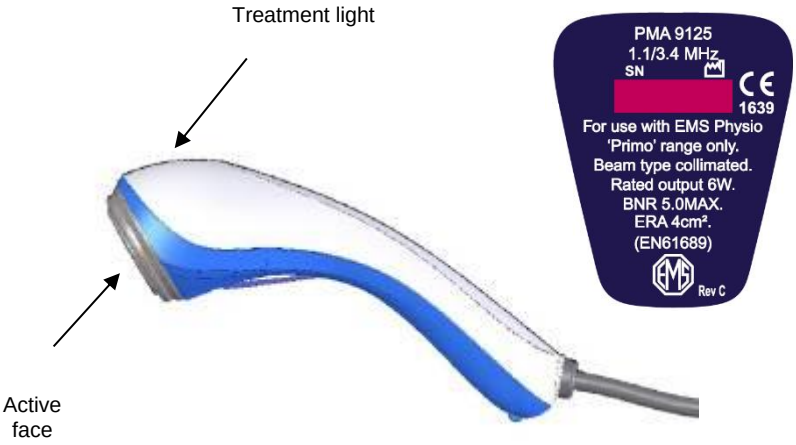
Do not dispose of as unsorted waste (2006/96/EC WEEE Directive)

Description of ultrasound output waveform for each mode

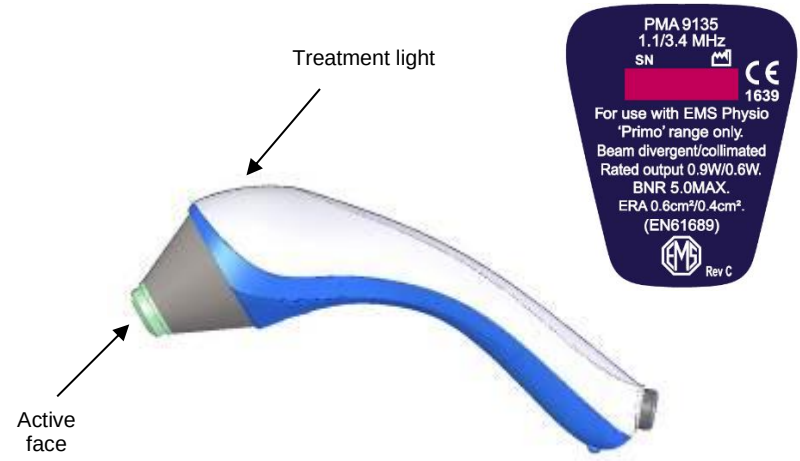
Model number and classification

Stimulation output levels

Large Transducer



Small Transducer



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

Patient Lead (PMA3055)

Electrode connecting cables

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 operates at 18Vdc and if mains driven must only be used with an EMS Physio SLA9000 power supply (as supplied with the unit) which is connected to a mains supply of 100-240V ac. A power cord appropriately rated/approved for the country of use must be used.

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 (risk of electric shock with type B applied parts). The unit must not be positioned in such a way that the mains plug cannot easily be unplugged as the mains plug is the main disconnect device.

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 and connect the electrodes to the yellow and blue cables.

Be careful not to subject the ultrasound transducers to rough handling such as dropping onto a hard surface as this may impair performance.

Operation of the unit in close proximity (less than 1 metre) to shortwave therapy equipment or radio-frequency mobile communication equipment could result in the stimulation output being affected.

Permissible Environmental Conditions Of Use:

Temperature +10 to +35°C
Relative humidity 10 to 80%
Atmospheric pressure 500 to 1060hPa

Permissible Environmental Conditions For Transport And Storage:

Temperature -10 to +35°C
Relative humidity 5 to 95%
Atmospheric pressure 500 to 1060hPa

Expected Service Life:

7 years

Essential Performance

BS EN 60601-1 defines Essential Performance as:
“Performance necessary to achieve freedom from unacceptable risk”

Functions of the Combination 860, the absence or degradation of which could result in a hazardous situation are:

Maximum ultrasound intensity 3W/cm^2
Maximum stimulation output 100mA CC or 140V CV
Maximum treatment time 30 minutes

Loss or degradation of these functions due to EM disturbances (eg. electrostatic discharges or mains voltage dips) may cause temporary loss of output but this is not considered to be hazardous.

Operating instructions

Power On Sequence and General Information

After the Primo Combination 860 is turned on a splash screen appears showing the EMS company logo along with the model name, its serial number and the installed software version.

After a few seconds the unit will give a short beep and display the ‘Home’ screen.

Standard User Controls

Throughout the operation of the Combination 860 the various modes and parameter settings are all accessed and changed by touching the relevant buttons displayed on the touchscreen.

The rotary control is used to increase and decrease the ultrasound intensity when the display is showing the ultrasound screen, or it controls the stimulation intensity when a stimulation screen is selected. In ultrasound only mode turning this control down is a safe way to stop a treatment.

In Interferential 4-pole 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 touching the appropriate selection button.

In Combination mode three output control select buttons are available (except for 4-pole combination therapy, when there will only be two – see pages 50-51 for more a more detailed explanation).

On most display screens touching the back arrow icon in the top left corner will return the user to the last screen displayed, and touching the house icon in the top right corner will return the display to the main 'Home' screen.

Protocol treatments

Touching the 'Protocol' treatments button in the 'Home' screen or the 'Protocols' button in the ultrasound or Interferential 4-pole 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 touching the highlighted button to call up the treatment settings for that particular condition. A choice of ultrasound or stimulation treatments is given

by the two buttons above the list – some conditions allow for treatment with either ultrasound or stimulation but others can only be treated by one or the other.

System Settings Menu

Touching the 'System' settings button at the bottom of the 'Home' screen takes you to the system settings screen.

The **'Display'** button takes you to a screen where you can adjust the display brightness using up/down buttons.

The **'Sound'** button takes you to a screen where you can adjust the pitch and volume of the audio.

'Language' allows you to change the display language to any that are installed in the unit (English, French, German, Spanish, Italian and Vietnamese as standard).

The **'About'** button displays info such as serial number and software version.

'**Help'** brings up an embedded text version of this user manual.

'Clinic' allows you to enter a name label for the machine which will be displayed at the top of all screens.

Touching the **'Contact alarm'** button gives you a screen with three options for the behaviour of the contact alarm. 'On' is the default mode where poor contact makes the contact light flash and stops the timer countdown. 'Off' causes poor contact to flash the contact light but not stop the timer countdown. Audio gives an additional beeping warning (transducer LED flashes, timer stops).

'Maintenance' is designed for service engineers and requires a pass code to enter.

Ultrasound Set Up

From the ‘Home’ screen, touch 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 touch ‘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.

Ultrasound 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, 'TREATMENT' 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 be reduced to a low level. The treatment light on the transducer will start flashing, 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 'System settings > Contact alarm'. When good contact is restored, the treatment indicator on the transducer will relight, 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.

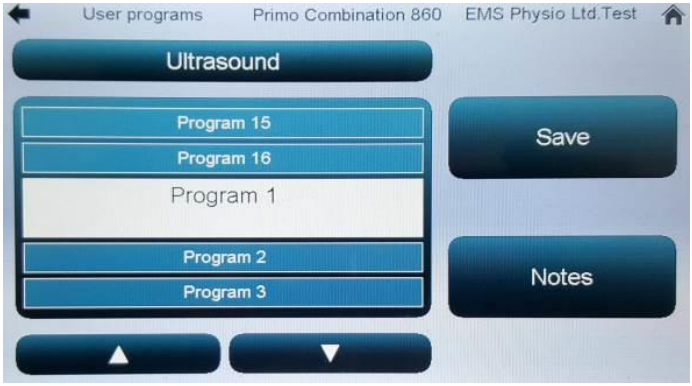
When the treatment time reaches 00:00, treatment is terminated. The intensity and power displays will go to zero, ultrasonic power from the transducer will be turned off, the treatment indicator will turn off and the unit will give a two second beep. Remove the transducer from the treatment site, wipe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

Ultrasound User Programs

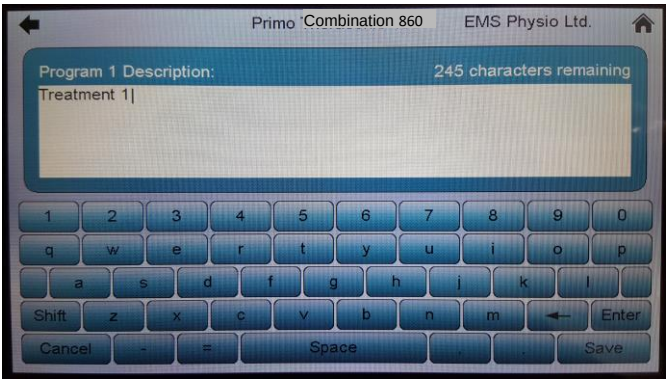
The Combination 860 can store up to 16 user defined set-ups for each modality (ultrasound or stimulation) and another 16 combination set-ups. To access the ultrasound user programs touch the 'User programs' button in the top right corner of the ultrasound set-up screen.



A screen will appear with a scrollable list of program slots – the active one is highlighted in the middle. Touching 'Save' will store the settings last open in the set up screen to this slot – if the slot is not empty a pop-up window will appear asking you to confirm or cancel the save process (to prevent unintentional over-writing of a previously saved program).

To recall a program simply touch its program slot button and a set up screen will open showing the previously stored parameters.

The 'Notes' button in any user program set-up screen opens a qwerty style keypad that allows you to save memo information about the program – the first 16 characters recorded will be displayed as the title of that user program.



Ultrasound Dose Algorithm

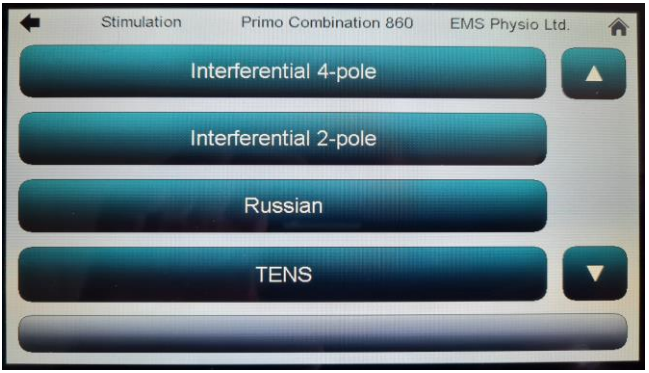
This is selected by touching the Dose algorithm button in the Ultrasound set-up screen. This screen will appear.

If a transducer is not connected 'Intensity' and 'Duration' will not be calculated and the select function will be disabled.

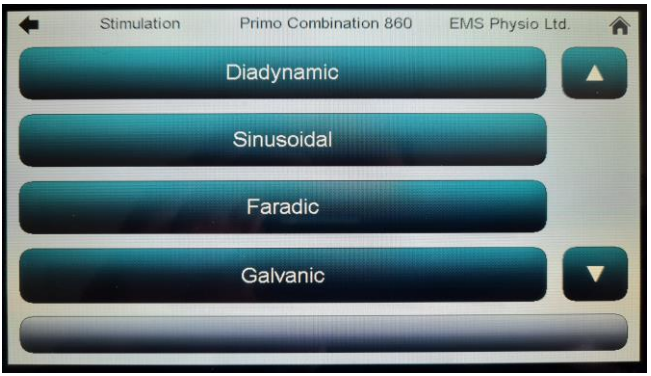
The data concerning the state of the area to be treated is chosen by stepping through the various button options. Once the relevant parameters have been entered touching Select will open a user screen loaded with the calculated treatment settings. Treatment is initiated by turning up the output intensity using the rotary dial, but it will be limited to the maximum value previously calculated.

Stimulator Set-up

From the ‘Home’ screen touch the ‘Stimulation’ button. The following stimulation screen will appear:-



Scrolling down using the arrow button reveals further stimulation options:-



And more:-

The first time the stimulator mode is selected from the list after turning on the unit, or if Interferential 4-pole was previously in use, the selected mode from the list will be applied to both channels A and B. The stimulator set-up screen will be displayed, and for any mode other than Interferential 4-pole the parameters for Channel A will be visible (Ch A is selected at the bottom left of the screen). To observe and separately edit the parameters (or mode) for Channel B, touch the 'B' button at the bottom left.

The following pages describe the set-up pages for each stimulation type when accessed by touching the relevant button in one of the above stimulation screens:-

The following common adjustments are present on the set-up screen for all stimulation types:

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

User Programs: The 'User programs' button allows the current stimulator setup to be stored in the user library – touching it will take you to the User programs screen where touching 'Save' will record the present settings.

Constant Current/Constant Voltage*:* The output from the unit may be set to be constant current or constant voltage in nature by touching the button on the middle right of each screen.

Stimulation User Programs

Touching the User programs button in any of the stimulation set-up screens will open the stimulation user program screen.

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

The settings of both stimulation channels A and B are saved in each user program.

Independent Channel Operation

For all stimulation types except IFT4, two independent channels are available that may be set to the same or different waveforms. The required waveform for each channel is chosen by first selecting Channel A or B at the bottom left of the Setup screen and then touching the 'Waveform' button to select a new waveform from the stimulation type list which appears. The 'Copy setup' button can be used to quickly transfer any edited settings from Ch.A to Ch.B (or Ch.B to Ch.A). When 'Copy setup' is pressed, an interim screen will first appear to Confirm or Cancel the copy process (to prevent accidental over-writing).

Treatment for the selected channel can be initiated from the Setup screen by turning up the encoder – this might be useful for 'auditioning' the treatment settings to check that they are comfortable for the patient, for instance. Alternatively, a treatment proper could be initiated by first turning up the output of Channel A and then selecting the 'B' button at the bottom to move to Channel B, which can then be turned up (the buttons on the bottom row of the display are still active when a treatment is running but all other parameter buttons will be locked out and will have no effect when touched).

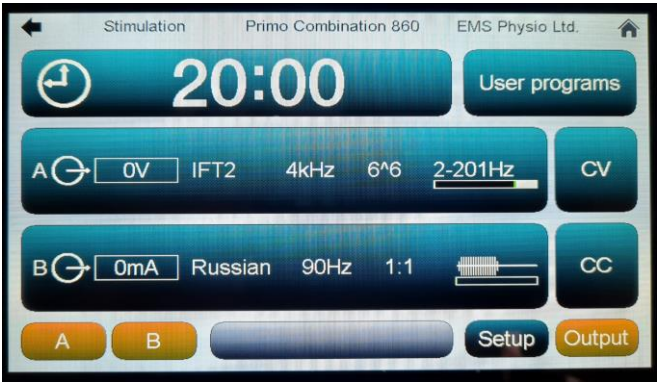
Output Screen

For the status of both channels to be viewed when running simultaneously it is best to move to the Output screen which is achieved by touching the 'Output' button at the bottom right of the display. It is possible to move from the Setup screens to the Output screen while a treatment is running by touching the Output button at the bottom right of the display, but going back from the Output screen to a Setup screen is disallowed (greyed-out) unless the output is first reduced to zero using the encoder (there would be little point in returning to a Setup screen unless editing of a parameter was required, and this can only be done if the treatment is halted anyway).

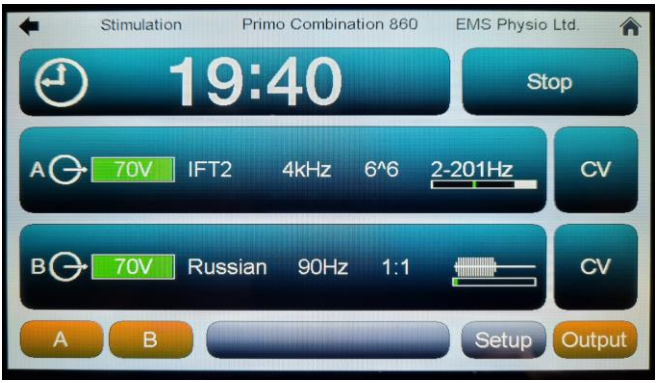
In the Output screen only the output levels of each (or both) channels can be controlled while the treatment is running. The 'A' and 'B' buttons at the bottom left of the display select which channel(s) the rotary control acts on - these latch on and off (highlighted yellow when active) and can be selected individually or both together (which gives simultaneous control of the output of both channels).

The buttons marked CC and CV (constant current or constant voltage) in this screen also give control over selection of either of these modes for each channel independently but are only active when the treatment is halted.

Here is the appearance of the Output screen when Channel A has previously been set to Interferential 2-pole (IFT2) in the Setup screen and Channel B has been set to Russian stimulation (see next page) –



With Channels A and B selected at the bottom left of the display turning up the rotary control will start both channels running together.



Touching either the ‘A’ or ‘B’ button again would de-select it and allow individual control of the still-selected channel.

The status bars to the right of each channel strip give a moving indication of any frequency sweep or Burst/Surge function in real time.

As also in the Setup screen, pressing the ‘Stop’ button will cause the treatment to stop with the output gradually fading to zero over five seconds.

Interferential 4-pole set-up

Interferential 4-pole therapy (IFT4) always uses both output channels A and B. Operating the rotary dial will increment both A and B outputs together.

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

AMF (Amplitude Modulation Frequency): Touching 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. Touch 'OK' when the desired frequencies have been chosen to return to the Interferential 4-pole 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 touching 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.

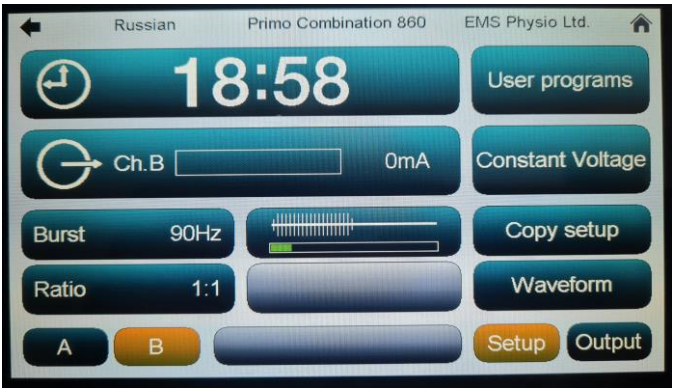
Over 5 seconds the output of channel A will increase smoothly from 80% of its nominal amplitude to 100% while the output of channel B falls from 100% to 80%. During the next 5 seconds A will return to 80% and B will rise to 100% and so on. The effect is to move the physical location of the point of maximum stimulation in the tissue and therefore, increase the treatment area. To change the vector option touch the Vector button.

Interferential 2-pole Set-up

Interferential 2-pole therapy (IFT2) is similar to Interferential 4-pole except that the two medium frequencies are added together in the stimulator itself to produce a beat frequency (equal to the difference in frequencies as defined by the AMF settings) – this is then applied to the treatment site through a single pair of electrodes.

The Interferential 2-pole set up is similar to that of the 4-pole. The treatment time, carrier frequency, base and peak frequencies, pattern and constant current/voltage operation are adjusted in exactly the same way. ‘Vector’ is not available in 2-pole.

Russian Set-up



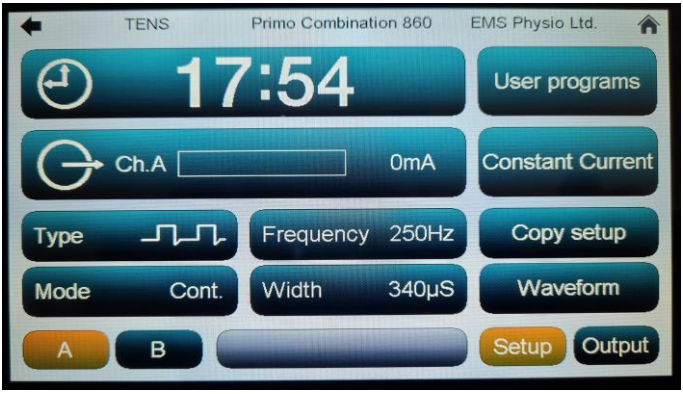
Russian stimulation therapy consists of a 2.5kHz medium frequency which is modulated on and off in bursts that can be set anywhere between 1 and 100Hz. An overall surge envelope can also be applied with variable work and rest periods.

The burst frequency can be set from 1 Hz to 100Hz by touching 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.

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. Touch the 'Ratio' button to set the ratio to any integer value between 1:1 and 1:5.

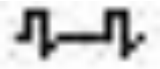
The surge status is displayed in the lower middle window button of the display in the 'Setup' screen and to the right of its channel strip in the 'Output' screen.

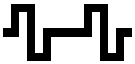
TENS Set-up



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

Type

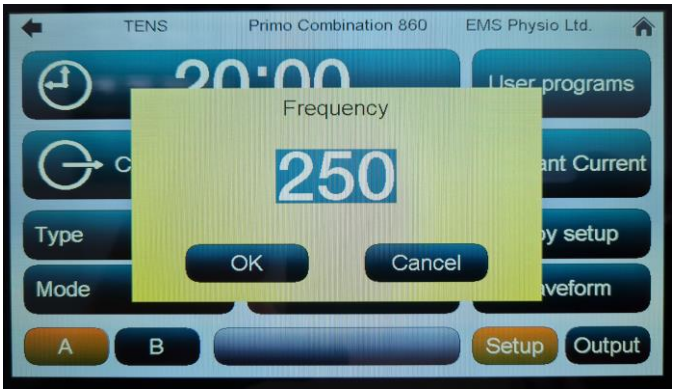
Asymmetrical 

Symmetrical 

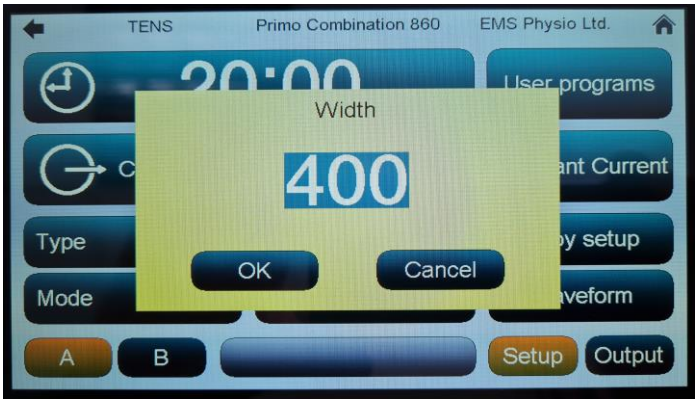
Sequential 

Selection is achieved by touching the ‘Type’ button.

'Frequency': Touching this button opens a new window. The pulse frequency may be set from 40 to 250 Hz in 1 Hz increments by touching the numerical digits and then touching OK.

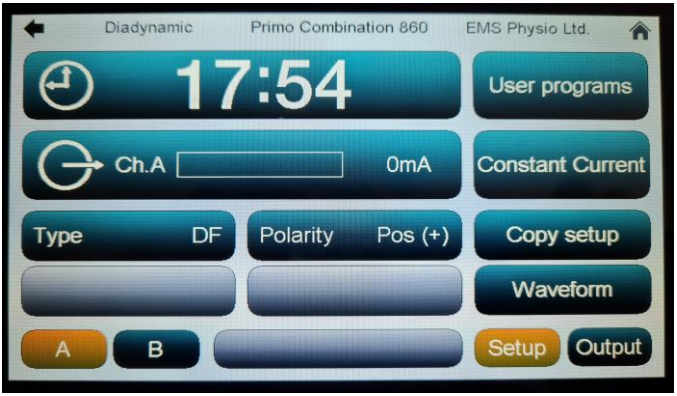


'Width': Touching this button opens a new window in which the pulse width may be set from 40 to 400 µs in 5 µs increments by touching the numerical digits and then touching 'OK'.



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

Diadynamic Set-up



'Type': The diadynamic waveform may be selected by touching 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 useful 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.

Sinusoidal Set-up

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

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

When running the surge status is shown in the lower middle window button of the 'Setup' screen and towards the right of the channel strip in the 'Output' screen when selected.

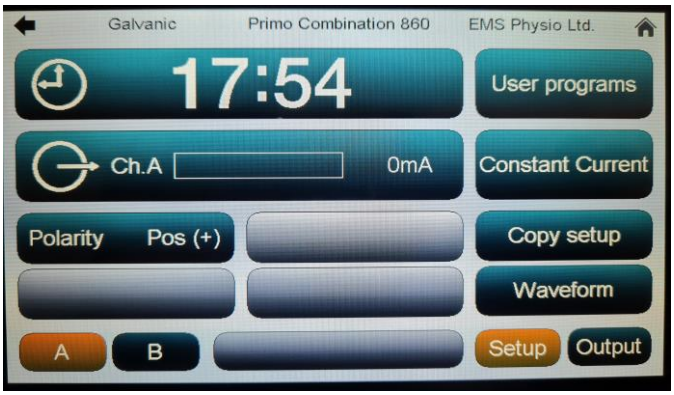
Faradic Set-up

'Surge': Three surge patterns (envelopes) are available: *rectangular, triangular and trapezoidal* – a graphic showing the shape of the selected one is shown on the surge button. A full description of these surge patterns is available in the technical specification section of this manual. The surge pattern may be changed by touching the 'Surge' button.

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

When running, the surge status is shown in the lower middle window button of the 'Setup' screen and to the right of the channel strip when the 'Output' screen is selected.

Galvanic Set-up



'Polarity': Touching this button changes the electrical polarity of the galvanic current to Pos (+), Neg (-), or Autorev (halfway through the selected treatment time).

Interrupted Galvanic Set-up

'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.

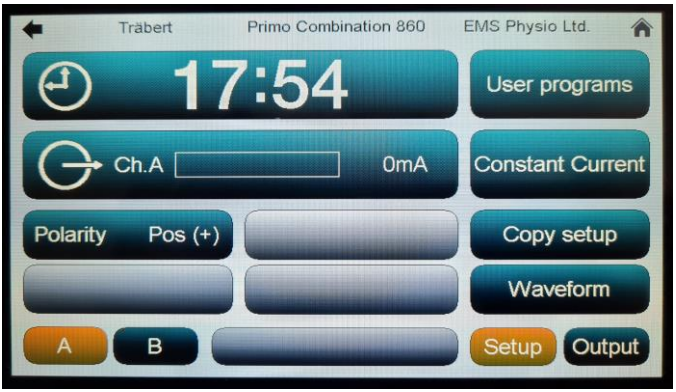
'Width': The pulse width may be set from 1ms to 1s for all waveforms with additional narrower pulses for rectangular only.

'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 lower centre of the 'Setup' screen or to the right of the channel strip in the 'Output' screen if selected.

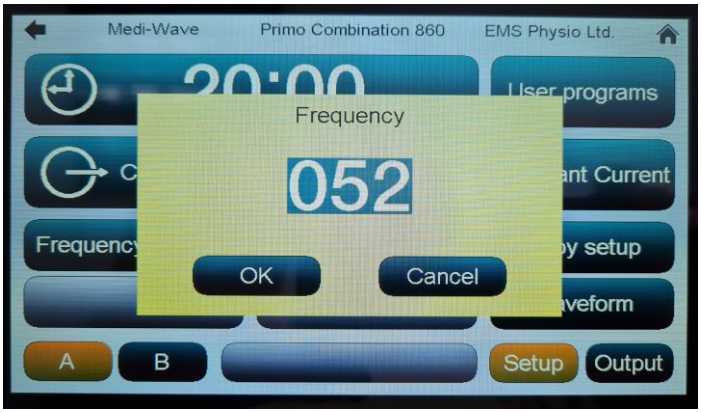
Träbert Set-up



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

Medi-Wave Set-up

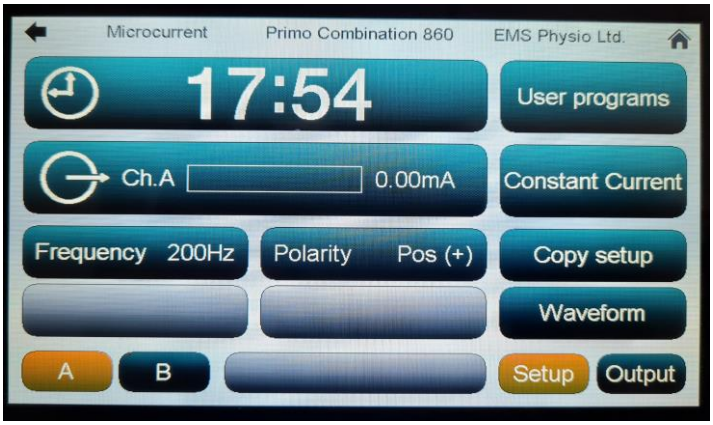
'Frequency': Touching this button opens this window:-



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 (Cont.). 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.

Microcurrent Set-up



'Frequency': The frequency may be set from 1Hz to 1000Hz in a pop-up window.

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

Only constant current output mode is available for Microcurrent.

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, including the necessary amount of treatment time being set on the treatment counter.

Either: From the 'Setup' screen, with channel A or B selected as required, gradually turn up the rotary control until the prescribed output level as displayed on the output level bar is achieved (or a comfortable level for the patient), then select the other channel if also required (from its button at the bottom of the screen) and turn it up using the rotary control until the correct level is achieved. The 'Output' screen can now be selected from its button at the bottom right and the treatment continued with both output levels being visible and independent control of them available using the channel A and B selection buttons at the bottom left.

Or: If the channel parameters have already been set in the 'Setup' screens and 'auditioning' them with the patient is not required then it is possible to go straight to the 'Output' screen by touching its button at the bottom right and then start the treatment from there. It is possible to select both output channels together to control them both at the same time if desired. In Interferential 4-pole mode both channels are selected automatically.

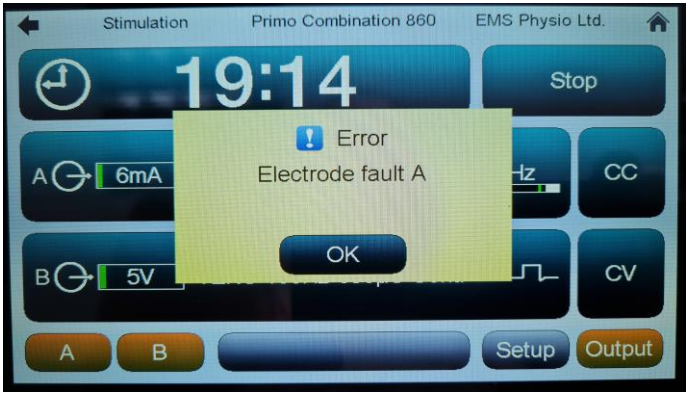
Always advance the output control slowly.

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

During any treatment, the 'User programs' button at the top right of the screen is replaced by a 'Stop' button. Touching this will cause the treatment to stop by being smoothly reduced to zero over a 5 second period. This is also a safe way to stop a treatment.

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

Electrode Fault 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 is terminated, an error message window is displayed and an intermittent alarm is sounded. The output channel in which the contact error has occurred is also displayed in the message window.

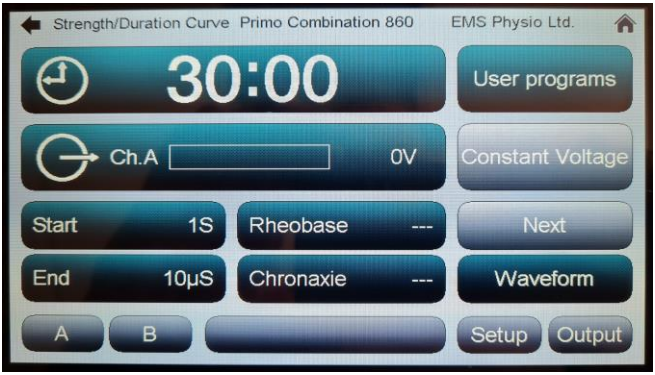
Touch ‘OK’ to cancel the alarm and clear the error message. The remaining treatment time is maintained. Check the electrodes and leads before continuing treatment. If rubber pad electrodes and sponge covers are being used check that they are held securely with even touch by the elasticated bandages and that the sponges have not dried out.

The electrode fault message can also be triggered by trying to turn the output level up too quickly.

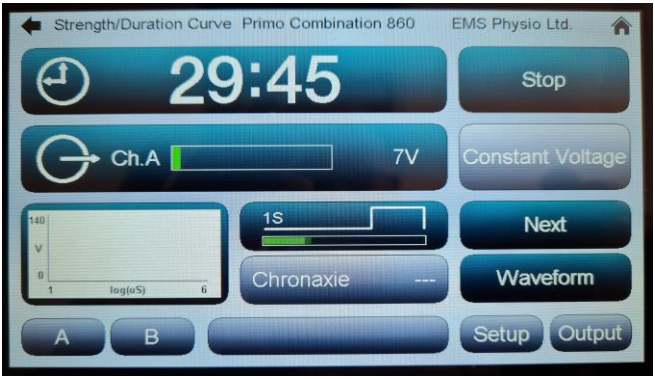
Note: In soft water areas it may be necessary to add a small amount of bicarbonate of soda to the water used to wet the sponges in order to achieve adequate contact.

S/D Curve

This mode generates rectangular interrupted galvanic pulses for plotting strength/duration curves. Output is from channel A at constant voltage only. Pressing the S/D Curve button in the Stimulator mode list produces this screen –

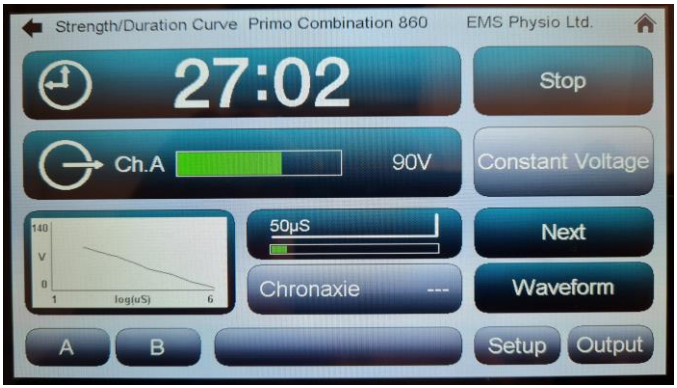


The start pulse width may be adjusted from 100ms to 1s by repeatedly pressing the Start button and the end pulse width from 10µs to 1ms by repeatedly pressing the 'End' button. This defines the range of measurements and thus the start and end points of the S/D graph. Sufficient time must be entered to complete the S/D test – 10minutes should be more than adequate. With the correct electrodes (ball muscle testing electrode and large dispersive pad electrode) in place over the muscle to be tested touch 'OK' then slowly increase the output until a muscle contraction is detected. The screen will be showing a flashing Treatment sign and the axes of the S/D graph will be displayed.

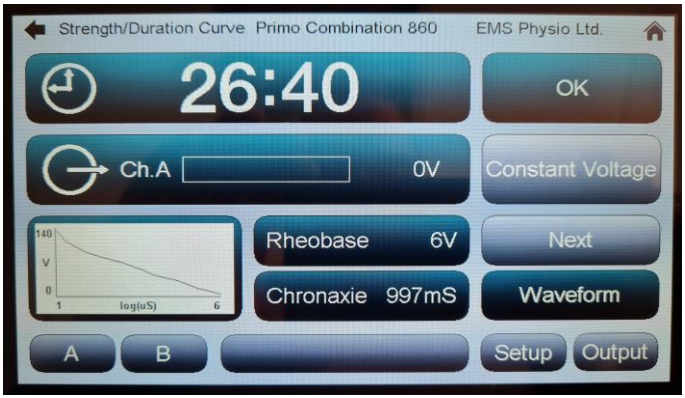


The graphic at the bottom of the screen displays the pulse width and the progress bar shows when the pulse occurs. Pulse repetition rate is fixed at 20/min. Once muscle contraction has just been detected press 'Next'.

The first point of the S/D curve will be plotted and the pulse width will decrement to the next width setting. It will now be necessary to increase the output intensity until muscle contraction occurs again – at this point press 'Next' and the next point in the S/D curve will be plotted.



Repeat this process until the 'End' pulse width is reached. The S/D curve is now plotted. Waiting for or pressing 'Stop' or manually reducing the output to zero will cause the Rheobase and Chronaxie to be calculated and displayed.



Pressing 'OK' will return to the S/D curve set-up screen to allow another test to be run.

Note: As the S/D curve set-up is not appropriate to use in Combination therapy, the Combination button will be found to be greyed-out and inoperable if S/D curve was previously selected. Choose a different stimulation setting if Combination treatment is required.

Combination Therapy

Only the large ultrasound transducer may be 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 (or an interactive pair if 4-pole interferential is selected). 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 constant current (CC) mode).

Set up both the 'Ultrasound' and the 'Stimulator' screens ready for treatment, touching the back or home buttons after each set-up to return to the Home screen.

If ultrasound and 4-pole interferential have been set up touching the Combination button will cause this combination screen to appear:-

This displays the current ultrasound and stimulation settings in condensed form. A treatment can be initiated by selecting the A and B stimulation buttons at the bottom of the screen or the Ultrasound button and then turning up the rotary control. More details of this procedure are described on the next page.

If stimulation settings other than Interferential 4-pole were chosen for each channel a Combination screen like this will appear:-

Note that the ‘A’ and ‘B’ stimulation output select buttons are now selectable independently.

Note also 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 touching the clock icon in this screen.

Only treatment time, ultrasound or stimulation intensity and choice of constant current (CC) or constant voltage (CV) can be controlled in the combination screen.

Treatment: 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.

Touch the ‘stimulator’ output button(s), 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 (touch the ‘Ultrasound’ button before turning the control knob clockwise). The patient may feel a slight increase in sensation.

Increase the ultrasound intensity to the required level and 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.

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 ‘Optional Accessories’).

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, particularly for cracks in the transducer casing which may allow ingress of moisture. The ultrasonic output power should be checked at least annually and a service calibration performed if found to be out of specification.

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

Full servicing instructions are available on request.

Contact details

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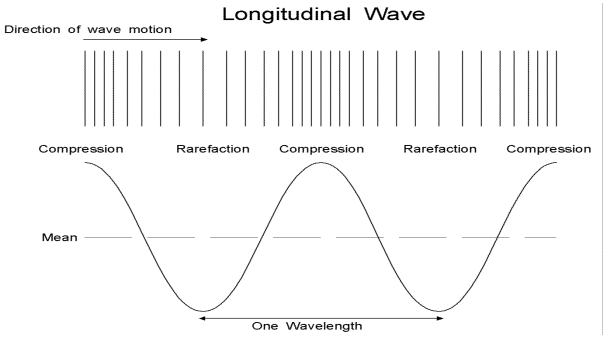
Appendix A – Overview of treatment modalities

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:

Velocity = frequency x 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. Bone also 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, Interferential 2-pole 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 up to 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 (SLA9000)	100-240V ac 1.5A 50-60Hz
(EMS860)	18V, 3.33A (from external PSU SLA9000)
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
Treatment programs	48 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
Output modes	CW and pulsed 1:1, 1:2, 1:3, 1:4 and 1:9
Pulse duration	2 ms
Treatment timer	0 to 30 minutes (treatment linked)
Contact monitor	Light on transducer

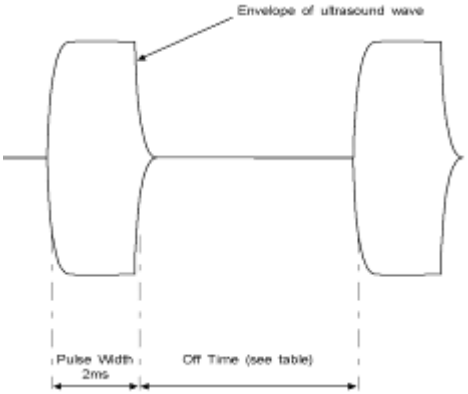
Large Ultrasound Transducer

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
1:3	125 Hz	6 ms	25%	4:1
1:4	100 Hz	8 ms	20%	5:1
1:9	50 Hz	8 ms	10%	10:1

The pulse width is fixed at 2 ms

Stimulation – Constant Current (CC) measured into 500 Ohm, Constant Voltage (CV) into open circuit. Operation outside a safe range is prevented by the electrode fault monitor alarm.

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

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

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

TENS

Waveform	Asymmetrical, symmetrical or sequential
Pulse width	40 – 400 µs
Repetition rate	2 – 250 Hz
Modulation	None, burst or surged
Output type	CC 0-100mA peak CV 0-70V peak

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

Sinusoidal

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

Faradic

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

Galvanic

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

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

Träbert

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

Medi-Wave

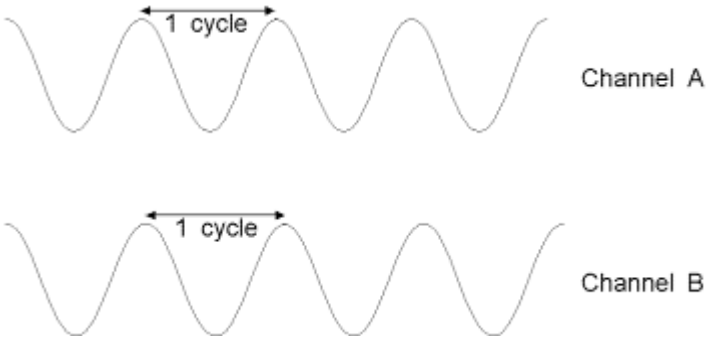
Waveform	6 ms differentiated pulse
Frequency	2 – 60 Hz
Modulation	None, burst, surged
Output type	CC 0-100mA peak CV 0-70V peak

Microcurrent

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

Output waveforms

Interferential 4-pole



Carrier	Channel A Frequency	Period	Channel B 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:

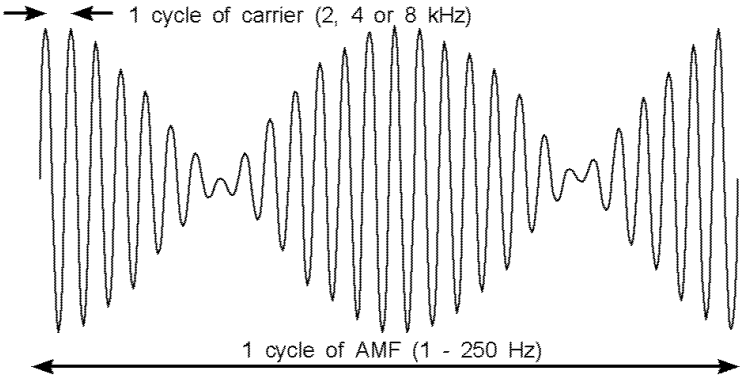
Maximum impedance = 70000/(peak output current in mA)

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

Both output channels of the stimulator (all four electrodes) are required for 4-pole interferential therapy.

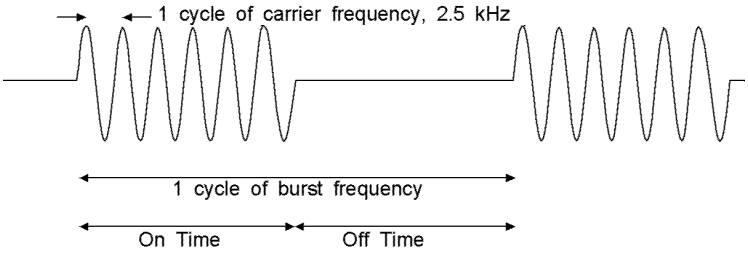
All of the following stimulation waveforms only require one output channel (one pair of electrodes) so it will be possible to run two independent channels of stimulation each with different waveforms and parameters at the same time.

Interferential 2-pole



The maximum output voltage and current are the same as for Interferential 4-pole operation.

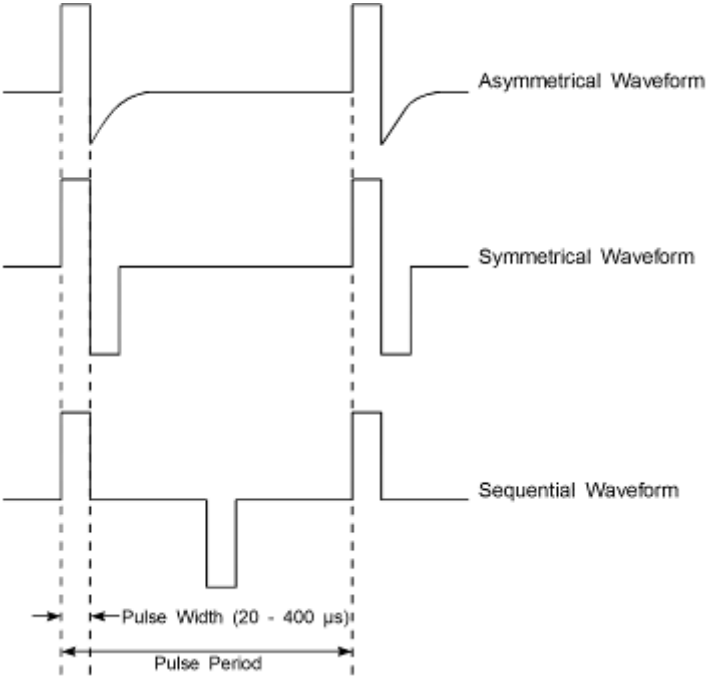
Russian stimulation



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 Interferential 4-pole operation.

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.

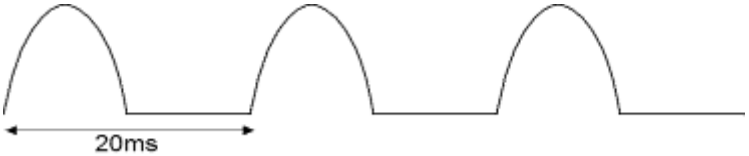
Diadynamic
In diadynamic mode the unit produces six different waveforms.
The maximum peak output current is limited to 70 mA.

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.

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 button enables the user to reverse this Neg (-) so that the above waveforms would be rendered 'upside-down'. 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.

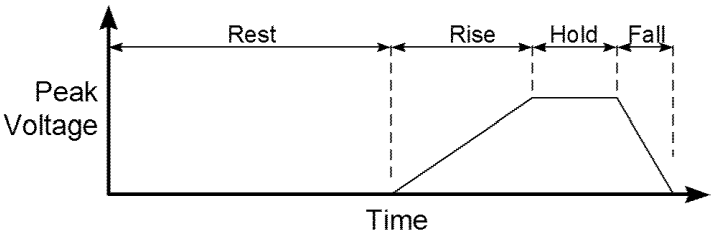
Sinusoidal

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 100 V or 50 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

Faradic

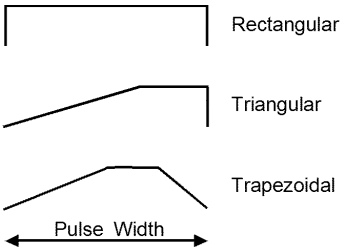
The output in faradic mode is a series of 0.5ms pulses at a repetition rate of 50 Hz with zero dc content. The pulse train is surged in the same way as the sinusoidal output.

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.

Interrupted galvanic

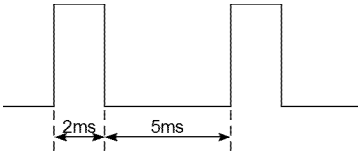
Interrupted galvanic mode produces three standard pulse shapes.



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. Polarity may be selected as Pos (+), Neg (-), or autorev (half way through the treatment time).

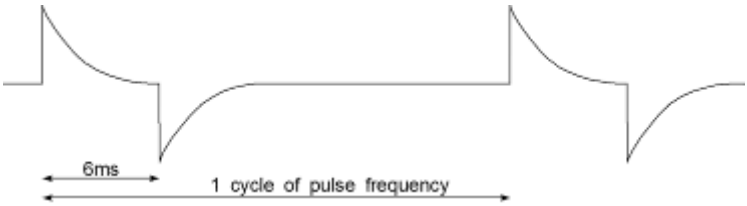
Träbert

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. 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.



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)

S/D curve

The S/D curve mode generates rectangular interrupted galvanic pulses for plotting strength/duration curves. Only channel A is energised in this mode and the peak output voltage is 140V.

Output display

The Primo Combination 860 display shows the temporal-peak spatial-average ultrasound intensity, the temporal-average power and the temporal-peak power.

It also shows the peak output voltage or current of the stimulator.

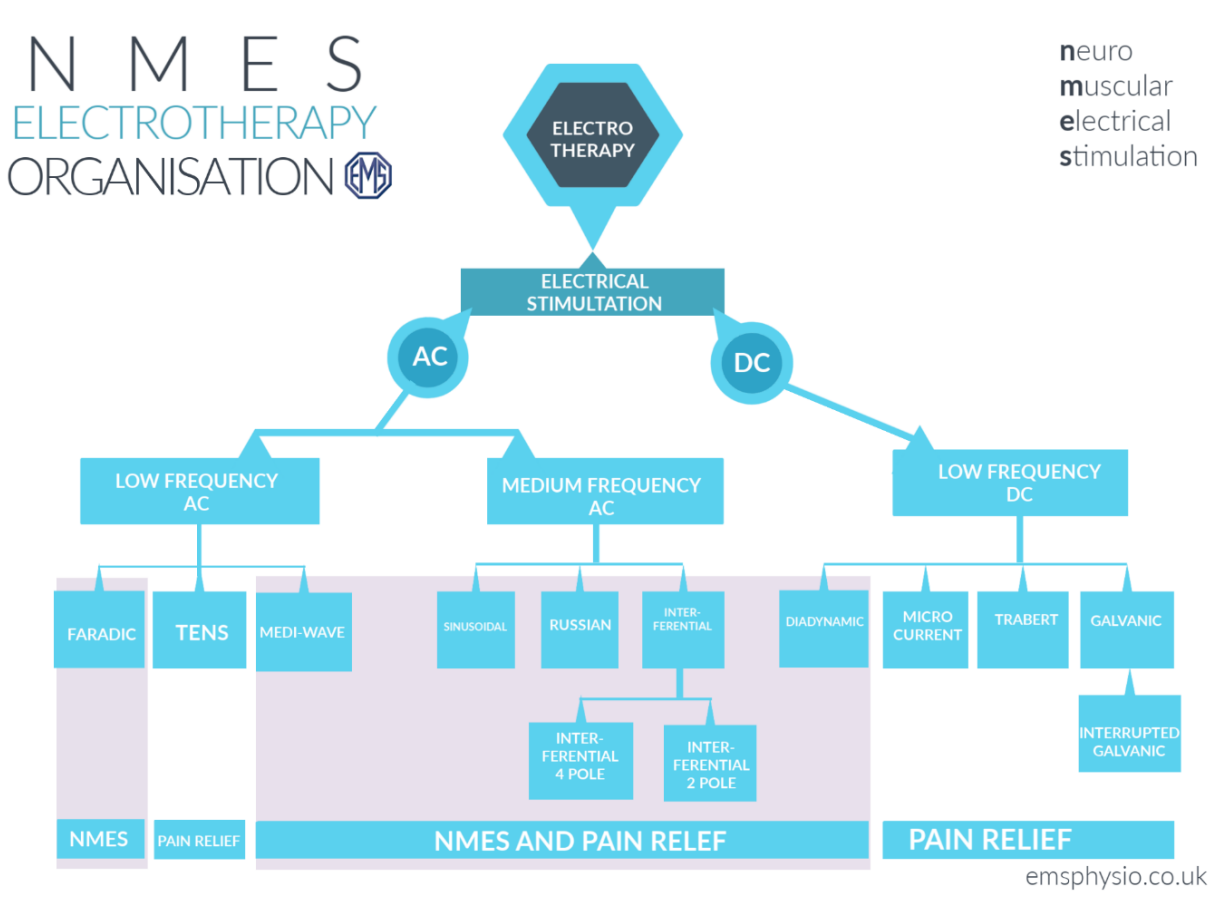
All information on model, serial number, and month/year of manufacture is located on the rear panel.

The Primo Combination 860 has been designed to meet the requirements of BS EN 60601-1:2006+A12:2014 "Medical Electrical Equipment, Part 1:General requirements for safety", BS EN 60601-1-2:2015 “Medical Electrical Equipment, Part 1-2: General requirements for safety – Electromagnetic disturbances”, BS EN 60601-2-5:2015 "Medical Electrical Equipment, Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment", BS EN 60601-2-10:2015 “Medical Electrical Equipment, Part 2-10: Particular requirements for the safety of nerve and muscle stimulators”, and BS EN 60601-1-6:2010+A1:2015 “Medical Electrical Equipment, Part 1-6; General requirements for safety – Usability.

Appendix C - EMC test levels.

Test standard	Description	Class/Group/Immunity test level
CISPR11:2009+A1:2010	Radiated emissions	Class A Group 1
CISPR11:2009+A1:2010	Conducted emissions	Class A Group 1
IEC/EN 61000-4-2	Immunity from electrostatic discharge	±15kV air, ±8kV contact
IEC/EN 61000-4-3	Radiated RF immunity	3V/m
IEC/EN 61000-4-3	Radiated immunity from intentional transmitters	28V/m maximum
IEC/EN 61000-4-4	Immunity from electrical fast transients and bursts	±2kV AC supply line, ±1kV signal lines
IEC/EN 61000-4-5	Surge immunity on AC supply	±2kV common mode, ±1kV differential mode
IEC/EN 61000-4-6	Conducted RF immunity	3V rms 150kHz > 80MHz, 6V rms ISM and amateur bands
IEC/EN 61000-4-11	Immunity to voltage dips, short interruptions and voltage variations	10ms > 5s dip/interruption time

Appendix D – Electrotherapy chart



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