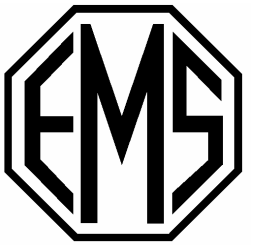

EMS Physio Ltd.
Grove Technology Park
Downsview Road
Wantage
Oxfordshire OX12 9FE
England

User Manual
COMBINATION 855
Model 118

CE
0120

General Information

This manual provides the necessary information for the installation and operation of the Combination 855 Unit.

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

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

The Combination 855 unit is a dual frequency ultrasound therapy unit and a multiple waveform electrotherapy unit in one box. Both modalities may be used individually or in combination.

Therapeutic ultrasound has been 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.

The 855 also provides a complete range of low and medium frequency waveforms for electrotherapy and electro-diagnostics.

It is intended that the Combination 855 unit is only used by qualified healthcare professionals such as physiotherapists who have received training in electrotherapy.

Record of Amendments

ISSUE	COMMENTS	DATE
1	Initial Issue	25/01/2008
2	EMC Tables added	31/01/2008
3	Updated	08/08/2008
4	Protocols and Dose Algorithm added	27/04/2010
5	Revised	28/02/2010

EC Declaration of Conformity

EMS Physio Ltd
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Declares that the following medical device is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC and is subject to the procedure set out in Annex 2 of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd.

Product Name	Combination 855
Model Number	118
Signature	
Position	Technical Director
Date first issued	18/02/08

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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,

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

only if 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.

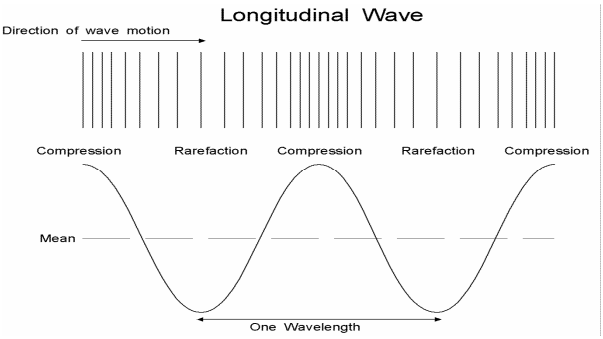
Introduction

The Combination 855 provides 1 and 3 MHz ultrasound and a complete range of low and medium frequency waveforms for electrotherapy and electro-diagnostics.

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 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 sinewave 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, therefore, 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 855 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 855 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 855 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. In Europe diadynamic currents are frequently used but, in the UK, ultrasound is most often combined with two-pole interferential therapy.

By combining ultrasound with an electrotherapy the advantages and effects of each treatment modality can be realised, but lower intensities are needed to achieve the same effect. Also, the accommodation effects that normally accompany electrotherapy are reduced (or even eliminated).

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

in localising lesions (especially chronic) ie. diagnostic use.

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

in treating trigger points.

Possible Explanations

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 diagnosis and treatment times.

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 855 Unit. Current densities greater than 2 mA rms/cm^2 are not recommended because of the risk of burning. All the standard EMS 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

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.

Technical Specification

General

Power Input	18V, 3.33A external PSU
Battery (optional)	Internal Rechargeable (NiMh)
Classification (EN60601-1)	Class 1, Type BF
Fuse	Internal T5A
Size (height x width x depth)	100 x 240 x 210 mm
Weight	2.2 kg (excluding battery)
Treatment Programs	10 user-defined set-ups.

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

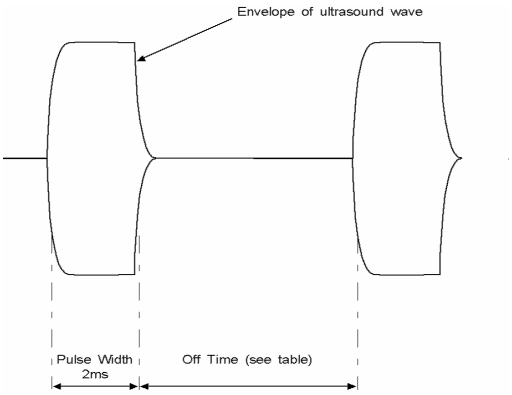
Large Ultrasound Transducer

ERA	4 cm^2
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 Combination 855, Therasonic 355 and 455 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 0-140V peak (1 channel)
	0-70V peak (2 channels)
Output Channels	1 or 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 0-140V peak (1 channel) 0-70V peak (2 channels)
Output Channels	1 or 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
Polarity	Positive or Negative.
Output type	CC 0-70mA peak CV 0-140V peak
Output Channels	1

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	1

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	1	

Galvanic

Output Type	CC	0-70mA peak
	CV	0-140V peak
Output Channels	1	

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
Output Channels	1	

Träbert

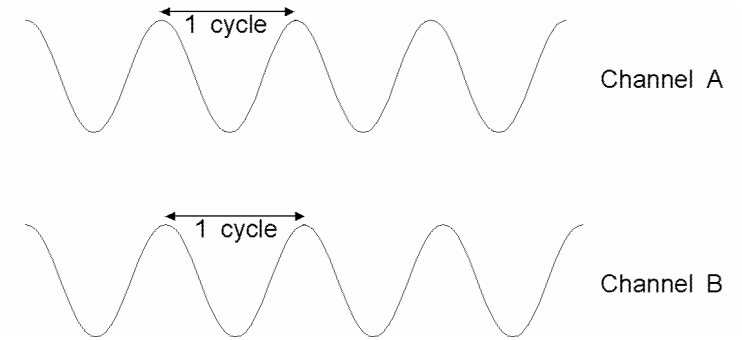
Waveform	2 ms on, 5ms off rectangular	
Output Type	CC	0-70mA peak
	CV	0-140V peak
Output Channels	1	

Medi-Wave

Waveform	6 ms differentiated pulse	
Frequency	2 – 60 Hz	
Modulation	None, Burst, Surged	
Output Type	CC	0-70mA peak
	CV	0-140V peak (1 channel) 0-70V peak (2 channels)
Output Channels	1 or 2	

Output Waveforms

Interferential 4-pole



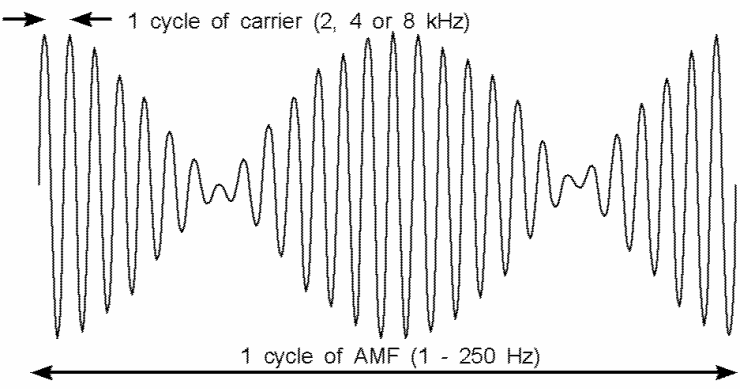
	Channel A		Channel B	
Carrier	Frequency	Period	Frequency	Period
2 kHz	2 kHz	500 µs	1.75-2 kHz	572-500 µs
4 kHz	4 kHz	250 µs	3.75-4 kHz	267-250 µs
8 kHz	8 kHz	125 µs	7.75-8 kHz	129-125 µs

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)

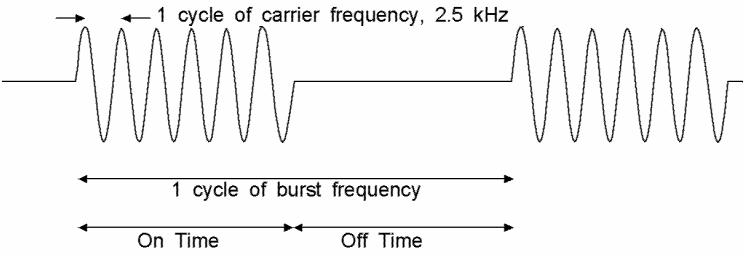
In constant voltage mode, the maximum output voltage is 70Vpeak or (load impedance x 0.1) Vpeak whichever is the smaller.

Interferential 2-pole



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

Russian Stimulation

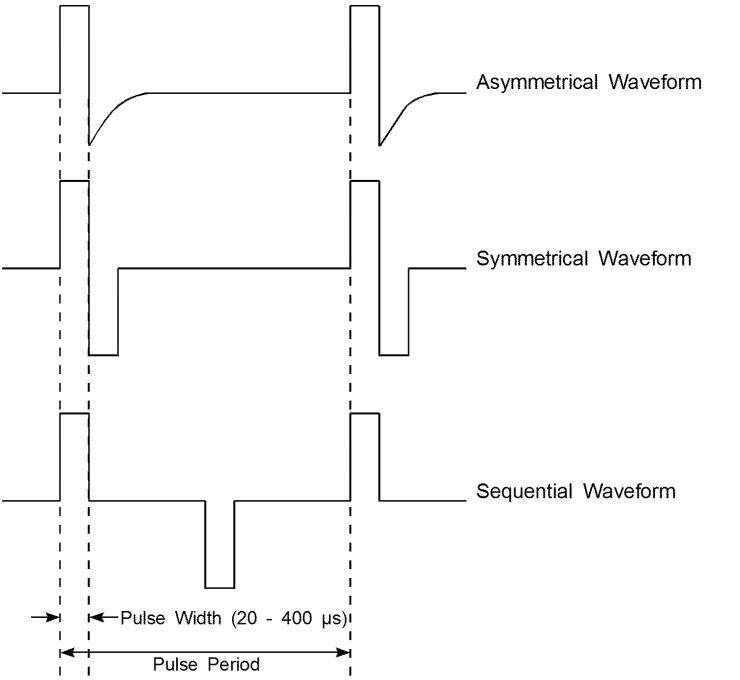


The burst frequency may be set to be from 1 Hz to 100 Hz. The on and off times are always equal and are from 0.5s (1 Hz burst) to 5 ms (100 Hz burst).

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

TENS

Three TENS waveforms are available



pulse period = 1/(repetition rate)

TENS Burst mode

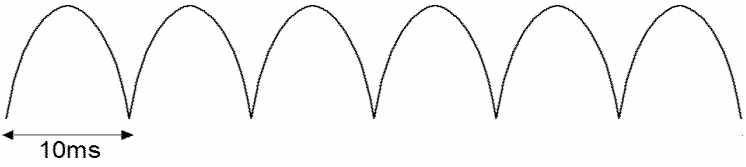
For repetition rates greater than 20 Hz, the TENS output is on for 0.25 s and off for 0.25 s (2 Hz burst frequency). For repetition rates less than 20 Hz the on and off times are 5 pulse periods.

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.

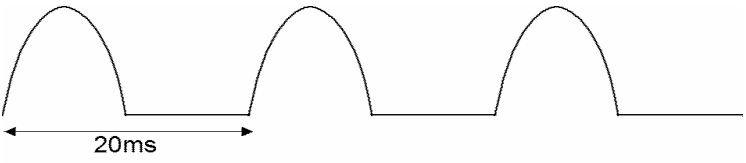
DF - diaphasé fixe
The DF waveform is a continuous full wave rectified 50 Hz sinewave.



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 below.

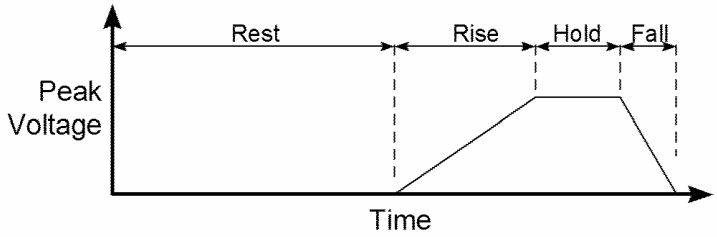
RS – rythme syncopé
The RS waveform is 1 second of MF followed by 1 second of zero output, this sequence being repeated continually.

Polarity
The above waveforms exhibit +ve polarity as they all travel above the ground (zero volt) level (equivalent to the flat part of the waveforms). The polarity switch enables the user to reverse this (-ve) 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.

Sinusoidal
In sinusoidal mode the output is an amplitude-modulated medium frequency (4kHz) 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 sinewave the peak output or amplitude is equal to the rms output multiplied by √2, or, conversely

$$\text{rms output} = \text{peak output} \times 0.707$$



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

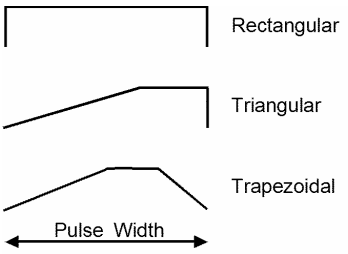
Faradic

The output in faradic mode is a series of 0.5ms pulses at a repetition rate of 50 Hz with a 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.

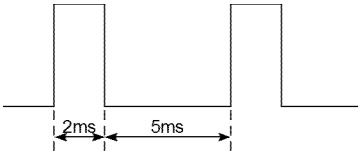
Interrupted Galvanic



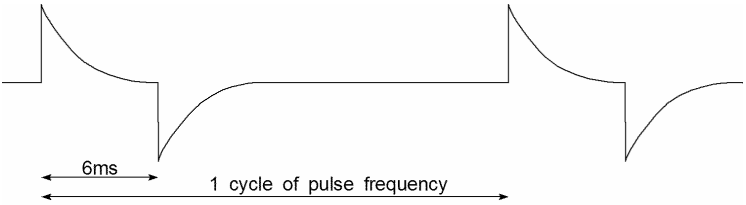
Interrupted Galvanic mode produces three standard pulse shapes. All interrupted galvanic pulses are positive going and monophasic and have therefore, a net dc component.

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 1 to 30 pulses per minute.

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.



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.

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 Combination 855 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 Combination 855 has been designed to meet the requirements of BS EN 60601-1:1990 (BS5724:Part 1:1989) "Medical Electrical Equipment, Part 1:General requirements for Safety", BS EN 601-2-5:2000 "Medical Electrical Equipment, Part 2.5 Particular requirements for the safety of ultrasonic physiotherapy equipment", and BS EN 60601-2-10:1998 “Medical Electrical Equipment, Part 2-10 Particular requirements for the safety of nerve and muscle stimulators.

Accessories

Catalogue Number	Description
SLA9000	DC Power Supply 18V 60W
SLA9120	Large Dual-frequency Transducer
SLA9130	Small Dual-frequency Transducer
SLA9150	Large Angled Dual-frequency Transducer
EMS502	EMS Coupling Medium (12 x 170ml bottles)
EMS502A	EMS Coupling Medium 1litre bottle
EMS502B	Dispenser Pump for 1 litre bottles
SLA3055	Patient Lead (4 way)
NC3052A	4 small sponge electrode covers (for NC3052B)
NC3052B	4 small (70 x 50 mm) conductive rubber electrodes
NC3053A	4 medium sponge electrode covers (for NC3053B)
NC3053B	4 medium (100 x 70 mm) conductive rubber electrodes
NC3054A	4 large sponge electrode covers (for NC3054B)

NC3054B	4 large (130 x 100 mm) conductive rubber electrodes
NC3057	1 pair of blue electrode connection cables
NC3058	1 pair of yellow electrode connection cables
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
DU2	Stretch Bandage 1200 x 75 mm
DU4	Stretch Bandage 600 x 50 mm
EMS525	SoLo Shoulder Bag
EMS157	SoLo Treatment Trolley

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

Catalogue Number	Description
RB410	33 x 54 mm (pack of 4)
RB420	50 x 89 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)
RB460	50 x 130 mm (pack of 2)
RB470	40 x 60 mm oval (pack of 4)
RB480	50 x 100 mm oval (pack of 4)
RB490	80 x 130 mm oval (pack of 2)

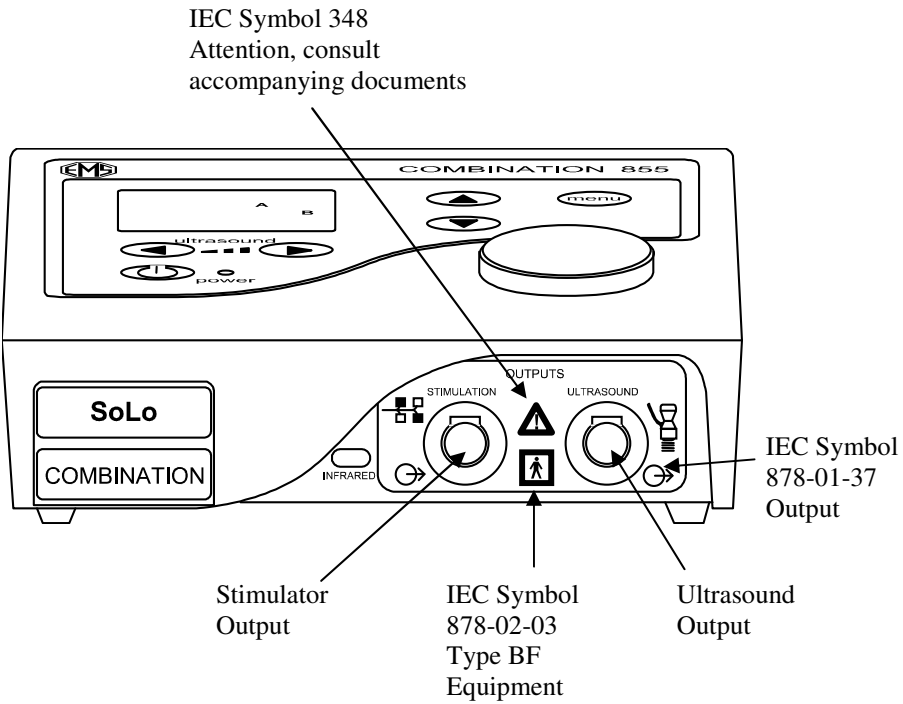
Supplied with each unit is a detachable mains lead suitable for the country to which it is delivered. Replacement or additional mains leads are shown below.

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.

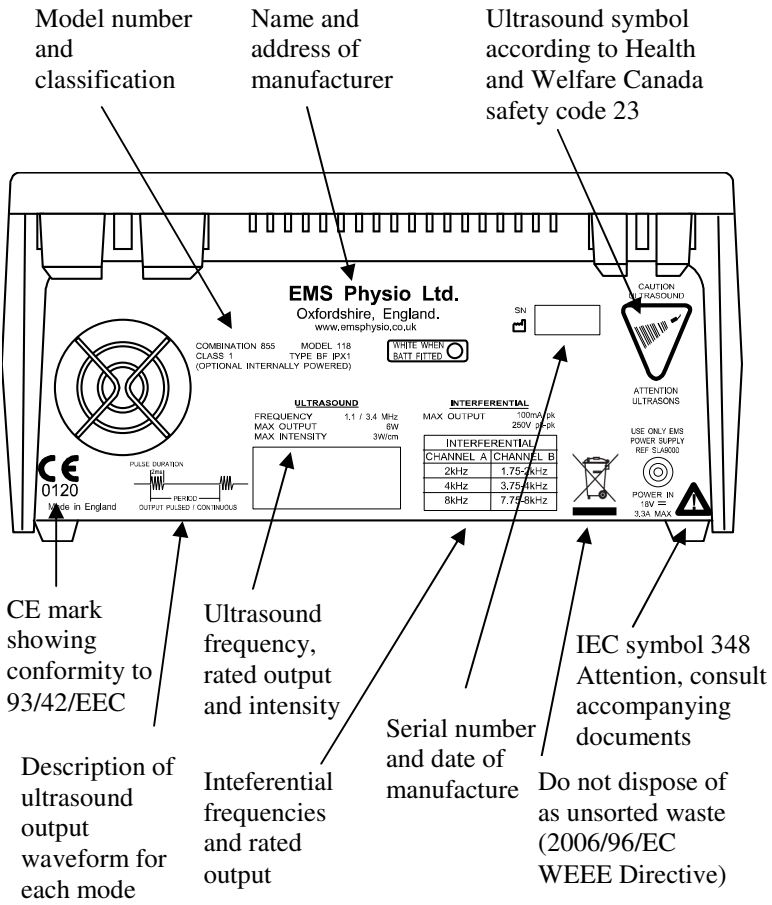
Controls and Markings

Combination 855 front Panel



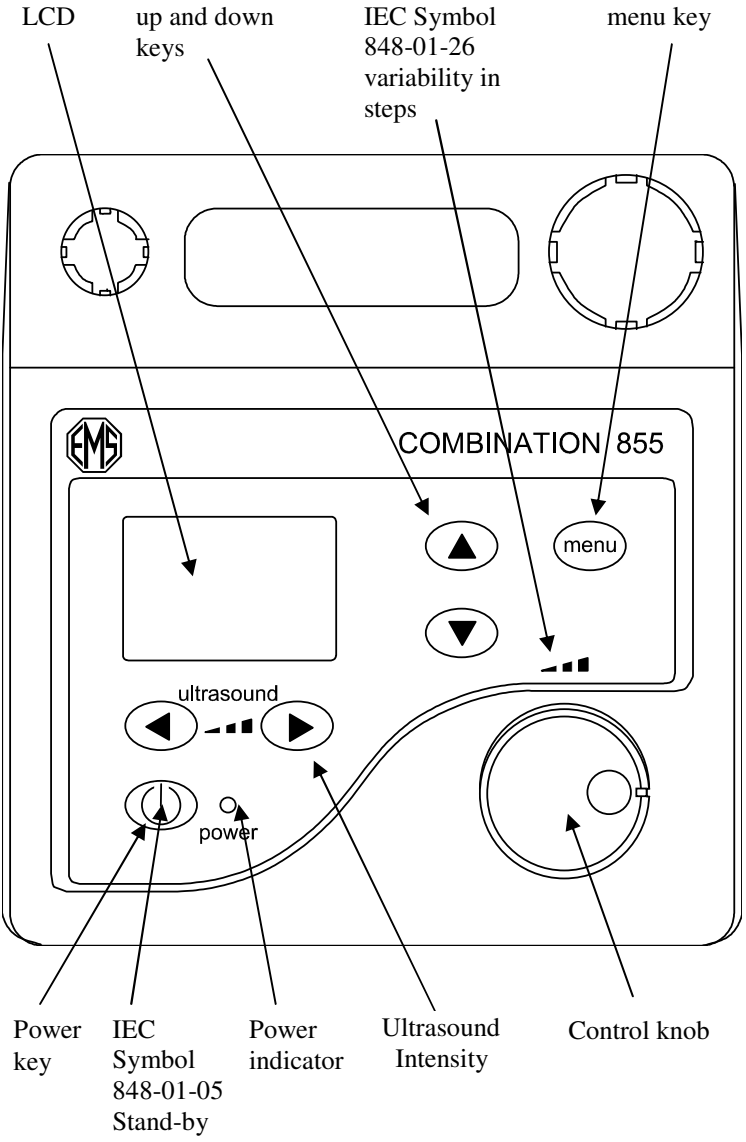
The **infrared** window is for the IrDA interface used for service and calibration purposes.

Combination 855 Rear Panel

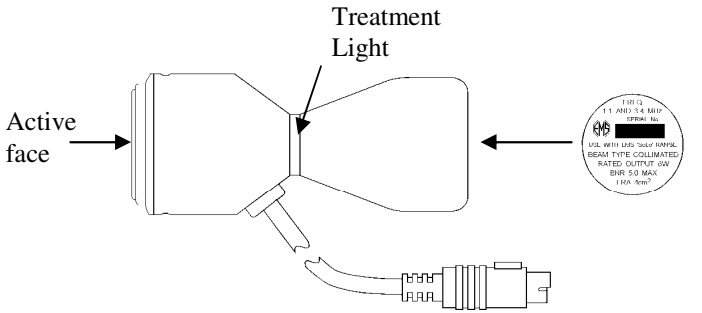


Power connection is via the socket on the right of the rear panel.

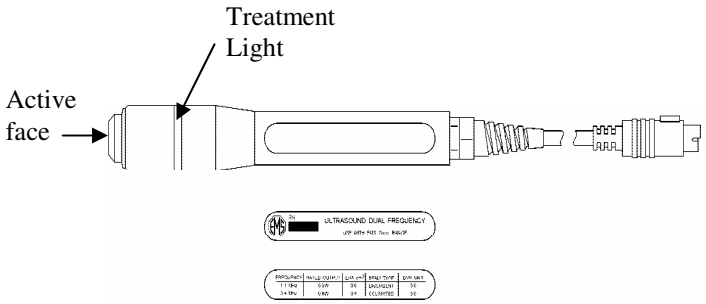
Combination 855 top



Large Transducer

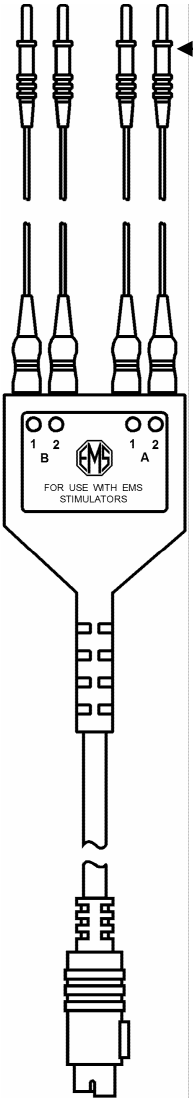


Small Transducer



The ultrasound transducers are calibrated independently from the Combination 855 and are fully interchangeable.

Patient Lead (SLA3055)



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 the carrier and the Company or its agent from whom the unit was purchased.

The Combination 855 must only be used with an EMS SLA9000 power supply (as supplied with the unit). Units fitted with an internal rechargeable battery may be used powered by the battery only.

The Combination 855 unit is supplied with a large (4 cm^2) 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 a raised square section on the top to ensure that it cannot be inserted incorrectly. Push the transducer into the holder adjacent to the handle at the rear of the unit.

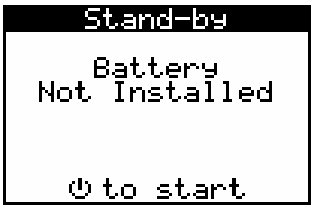
Operation of the unit in close proximity (less than 1 metre) to shortwave therapy equipment or radio-frequency mobile communication equipment could result in the ultrasound output of the Combination 855 being affected.

Operating Instructions

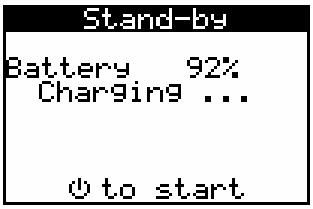
Operation from external PSU

Plug the PSU into the socket on the rear of the unit and to a suitable power outlet. The unit will turn on in stand-by mode indicated on the LCD and the power indicator on the top panel will flash every 2 seconds.

PSU only units will indicate that there is no battery fitted.
PSU / battery units will show the estimated battery capacity and whether the battery is being charged.



PSU only unit



PSU / battery unit

If the unit is left in stand-by mode for longer than 5 minutes then the LCD will be turned off to save power, but the power indicator will continue to flash. If there is a battery installed, the unit will continue to monitor and if necessary charge the battery. The LCD can be restored by pressing any key or moving the rotary control.

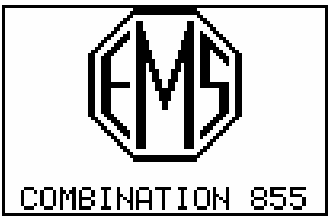
To turn on the unit press the power key.

Battery Operation

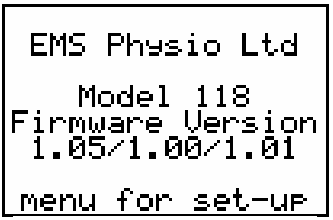
For battery operation (PSU/ battery units only) press the power key and hold it down until the EMS logo appears on the LCD. The power key should then be released.

Power on sequence and general information

When the Combination 855 is turned on, the EMS company logo is displayed on the LCD followed by the model. The unit will then give a short beep and display the information screen showing the model number and software version.

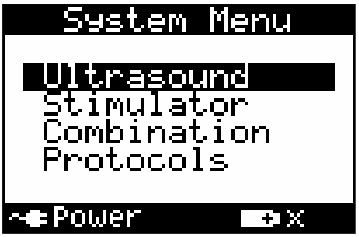


Logo and model



Information screen

After approximately 3 seconds the unit will give another short beep and display the main system menu screen -



At the bottom of the screen is the status bar.

The left side of the status bar shows the current power source.

Mains power

Battery power

The right side shows the battery status. If the unit has a battery installed then the status bar shows an estimate of the remaining battery capacity.


Battery not installed

Battery capacity 99%

Battery capacity 93% and charging

Standard key functions

Throughout the operation of the Combination 855 the up and down keys are used to select the parameter highlighted.

The rotary control is used to increase and decrease the highlighted parameter, **except for Ultrasound power which has its own dedicated up and down keys** (this is to enable simultaneous control of both Ultrasound power and Stimulation intensity when in Combination mode). Pressing the Ultrasound keys together returns ultrasound power to zero.

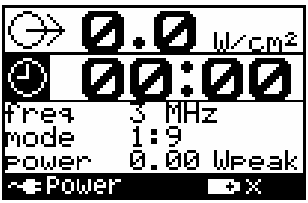
The menu key is used to exit from the current screen or to select the menu option highlighted.

Ultrasound

From the system menu screen, scroll to highlight Ultrasound and press the menu key. The Ultrasound set-up screen will appear.

Ultrasound set-up

.



Ultrasound set-up screen

Treatment Time: When the ultrasound set-up screen is first displayed the clock symbol is highlighted. With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.

Frequency When the freq label is highlighted turning the rotary control clockwise selects 3 MHz operation and anticlockwise selects 1MHz operation.

Mode: The Combination 855 unit provides both continuous wave and pulsed ultrasound. When the mode label is highlighted, turning the rotary control clockwise increases the pulse ratio and anticlockwise decreases the pulse ratio.

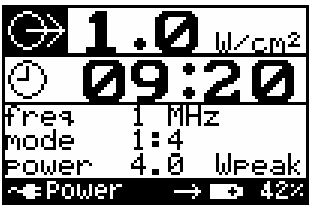
Power: The displayed output power may be the temporal-peak power or the temporal-average power. In continuous mode these are the same but for pulsed modes the temporal-average power is the temporal peak power multiplied by the duty cycle of the pulse. When the power label is highlighted turning the rotary control clockwise selects temporal-average power and anticlockwise selects temporal-peak power.

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 Therasonic coupling medium is recommended.

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



Press the Ultrasound Up key to start treatment. The output intensity will increase in 0.1 W/cm^2 steps. Holding the Up key pressed down will automatically cycle the power upwards. 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. Move the transducer over the treatment site in small circular paths whilst setting the output intensity to the required level using the Ultrasound Up/Down keys.

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

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 output intensity display will flash, indicating that the required output cannot be delivered. When good contact is restored,

the treatment indicator on the transducer will light, the output display will cease to flash and the timer will continue to count down.
If the output intensity is returned to zero using the keys before the treatment time has elapsed, the display will show the treatment time remaining. When the intensity is increased again the treatment will continue.

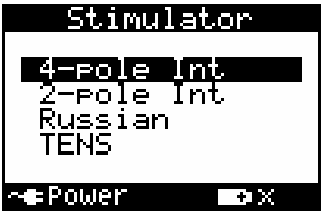
When the treatment time reaches 00:00, treatment is terminated. The intensity and power displays will go to zero, ultrasonic power from the transducer will be turned off, the treatment indicator will turn off and the unit will give a one second beep. Remove the transducer from the treatment site, wipe off any coupling medium and return the transducer to the holder at the rear 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 Ultrasound keys set the required intensity remembering to keep the transducer moving in small circular paths to prevent standing waves. At the end of the treatment turn off the output control, remove the transducer from the water and dry both it and the area treated.

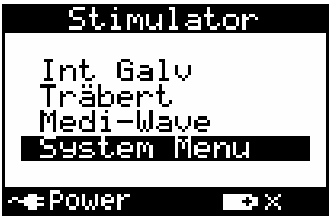
Stimulator

From the system menu screen scroll to highlight the Stimulator option. Pressing the menu button will cause the following Stimulator screen to appear:-



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

And more:-

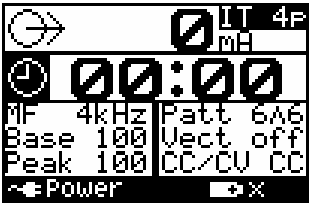


Pressing the menu button now would return the screen to the main system menu.

The following describes the set-up pages for each stimulation type when accessed by highlighting it in the Stimulator menu and pressing the menu key.

4-pole Interferential Set-up

When the 4-pole interferential set-up screen is first displayed the clock symbol is highlighted. At the top right of the screen the current mode is shown (IT 4p – interferential therapy 4-pole).



Treatment Time: With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.

MF (Medium Frequency Carrier): With the MF label highlighted, turn the rotary control clockwise to increase the carrier frequency and anticlockwise to decrease the carrier frequency.

Base and Peak frequencies: 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 set Pattern (Patt). If the base and peak frequencies are set to the same value then a constant beat frequency is produced.

To set the AMF or beat frequency, first highlight Base using the up and down keys. The base frequency may be set in 1 Hz increments using the rotary control from 1 to the current setting of the peak frequency. Press the down key to highlight the Peak. Set the peak frequency using the rotary control. The peak frequency may be set in 1 Hz increments from the base frequency to 250 Hz.

Patt (Pattern): The pattern determines the rate at which the beat frequency sweeps between the base and peak frequencies. Three patterns are available. 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 the sweeps back to the base frequency in 6 seconds. To change the pattern use the rotary control when Patt label is highlighted.

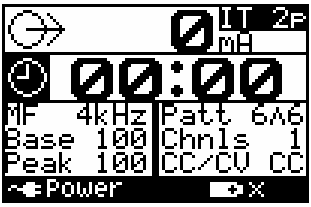
Vector: When the vector option is set to off, output channels A and B deliver the same output level (current or voltage). When the vector option is on, the relative amplitude of the outputs is slowly varied. Over 5 seconds the output of channel A will increase smoothly from 80% of its nominal amplitude 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 highlight the vector label using the up and down keys. Turning the rotary control clockwise sets the vector option to on and anticlockwise off.

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.

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.



At the top right of the screen the current mode is shown (IT 2p – interferential therapy 2-pole).

The 2-pole interferential set-up is similar to the 4-pole set-up. The treatment time, MF (carrier frequency), base and peak frequencies, pattern and CC/CV operation are set-up in exactly the same way. There is no vector option in the 2-pole interferential mode.

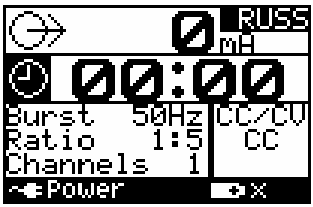
Chnls (Channels): In addition to the normal 2-pole interferential operation, the Combination 855 can provide two separate channels of 2-pole interferential stimulation at the same time. The number of channels can be selected when the chnls label is highlighted. Turning the rotary control clockwise selects 2 channel operation and anticlockwise selects single channel operation.

Note that in 2-channel operation, **all** settings for the two channels are the same, including the output level.

Russian Set-up

When the russian stimulation set-up screen is first displayed the clock symbol is highlighted. At the top right of the screen the current mode is shown (RUSS – Russian stimulation).

Treatment Time: With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.



Burst: The burst frequency may be set from 1 Hz to 100Hz. With the burst label highlighted, rotating the rotary control clockwise increases the burst frequency and anticlockwise decreases the burst frequency.

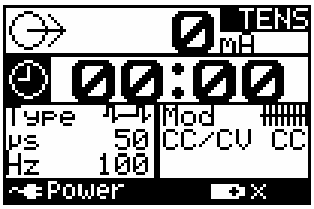
Ratio: The medium frequency bursts used for Russian stimulation are surged to produce work and rest periods. The surge time (work) is fixed at 10 seconds. The ratio sets the off or rest time in ratio to the work period. For example, if the ratio is set to 1:4 then the work period is 10 seconds and the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

Channels: 1 or 2 output channels are available. When the channels label is highlighted, turning the rotary control clockwise selects 2 channel operation and anticlockwise selects single channel operation. Note that in 2-channel operation, **all** settings for the two channels are the same, including the output level.

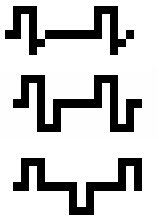
CC/CV: The output may be set to be constant current (CC) or constant voltage (CV). In constant current mode the electrode impedance is monitored and if the impedance for either channel is too high then the output is terminated and an alarm sounded. In constant voltage mode, if the electrode impedance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

TENS Set-up

When the TENS set-up screen is first displayed the clock symbol is highlighted. At the top right of the screen the current mode is shown (TENS).



Treatment Time: With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.
Type: Three waveform types are available and each type is represented graphically on the LCD.



Symmetrical

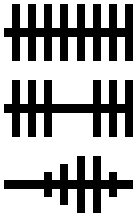
Asymmetrical

Sequential

µs: The pulse width may be set from 20 to 400 µs in 5 µs increments.

Hz: The pulse frequency may be set from 1 to 250 Hz in 1 Hz increments.

Mod: The TENS output may be continuous, burst or surged. Each modulation type is represented graphically on the LCD.



Continuous

Burst

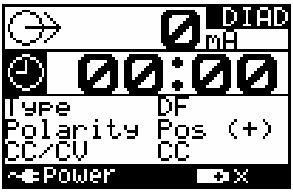
Surged

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

Note that in TENS mode 2 output channels are produced and **all** settings for the two channels are the same, including the output level.

Diadynamic Set-up

When the diadynamic set-up screen is first displayed the clock symbol is highlighted. At the top right of the screen the current mode is shown (DIAD).



Treatment Time: With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.

Type: The diadynamic waveform may be selected using the rotary control when the type label is highlighted. 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.

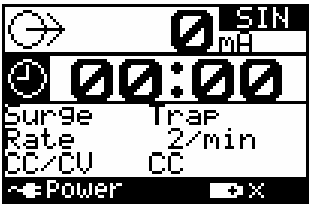
Polarity This reverses the polarity of the waveforms (see technical spec.). It is particularly used in combination therapy where the ultrasound head becomes one electrode, and this switch will change the polarity of the stimulator waveform relative to the ultrasound head.

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

Sinusoidal Set-up

When the sinusoidal set-up screen is first displayed the clock symbol is highlighted. At the top right of the screen the current mode is shown (SIN).

Treatment Time: With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.



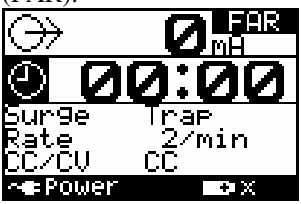
Surge: Three surge patterns (envelopes) are available: Rect (rectangular), Tri (triangular) and Trap (trapezoidal). A full description of these surge patterns is available in the technical specification section of this manual. The surge pattern may be changed using the rotary control when the surge label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

Rate: Surge rates of 2, 5, 10, 20 and 30 per minute are available. The surge rate may be changed using the rotary control when the rate label is highlighted

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

Faradic Set-up

When the faradic set-up screen is first displayed the clock symbol is highlighted. At the top right of the screen the current mode is shown (FAR).



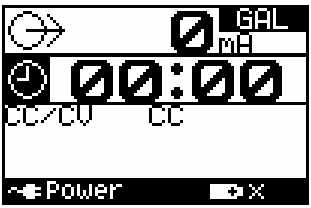
Treatment Time: With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.

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 using the rotary control when the surge label is highlighted

Rate: Surge rates of 2, 5, 10, 20 and 30 per minute are available. The surge rate may be changed using the rotary control when the rate label is highlighted

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

Galvanic Set-up

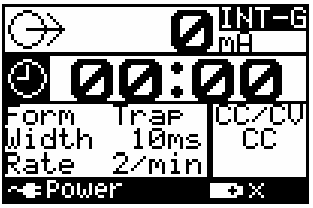


When galvanic is selected from the system menu, the mode is shown at the top right of the screen (GAL). The only available options are treatment time and CC/CV which are set in exactly the same way as the other operating modes.

Interrupted Galvanic Set-up

When the Interrupted Galvanic set-up screen is first displayed the clock symbol is highlighted. At the top right of the screen the current mode is shown (INT-G).

Treatment Time: With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.



Form: Three different pulse shapes are available: Rect (rectangular), Tri (triangular) and Trap (trapezoidal). A full description of these waveforms is available in the technical specification section of this manual. The waveform may be changed using the rotary control when the form label is highlighted

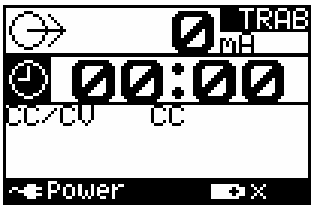
Width: The pulse width may be set from 1ms to 1s for all waveforms with additional narrower pulses for rectangular only.

Rate: Pulse rates of 2, 5, 10, 20 and 30 per minute are available. The pulse rate may be changed using the rotary control when the rate label is highlighted

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

Träbert Set-up

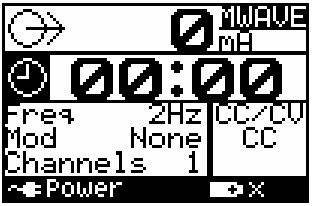
When träbert is selected from the system menu, the mode is shown at the top right of the screen (TRAB). The only available options are treatment time and CC/CV which are set in exactly the same way as the other operating modes.



Medi-Wave Set-up

When the medi-wave set-up screen is first displayed the clock symbol is highlighted. At the top right of the screen the current mode is shown (MWAVE).

Treatment Time: With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.



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

Mod: Normally Medi-Wave stimulation is used in continuous mode - that is with no modulation (none). In addition, burst and surged modes are also available.

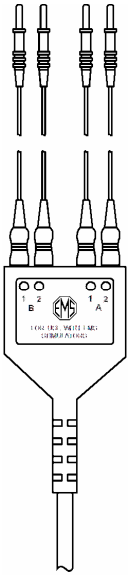
Channels: 1 or 2 output channels are available. When the channels label is highlighted, turning the rotary control clockwise selects 2 channel operation and anticlockwise selects single channel operation. Note that in 2-channel operation, **all** settings for the two channels are the same, including the output level.

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

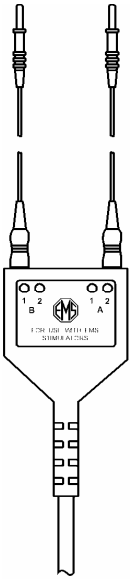
Treatment

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. For 2 channel treatments the yellow cables are channel A and the blue cables channel B. For single channel treatment use the outside yellow and blue cables.

2 channel treatment

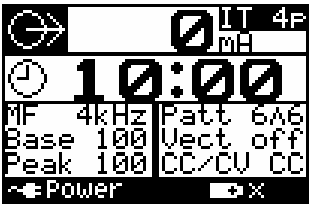


Single channel treatment



For stimulation modes that have a dc component, the yellow lead is positive and the blue lead negative.

Check that all the unit settings are as required for the chosen type of stimulation. Using the up and down keys, highlight the output



symbol on the LCD. Slowly turn the rotary control clockwise 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.

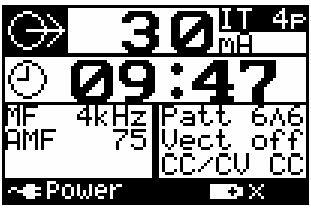
If the treatment time is not zero, the output of the stimulator will be energised, the output symbol will flash and the treatment time will begin to count down. Advance the output control slowly, until the desired effect of the stimulation is produced.

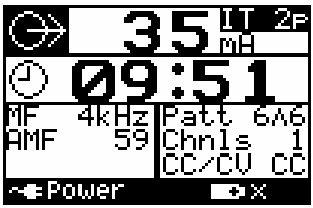
Always advance the output control slowly.

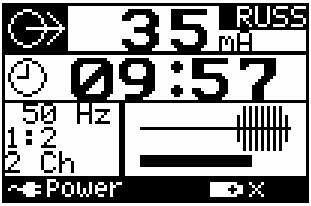
During the last 5 seconds of any treatment, the output is smoothly reduced to zero.

In some operating modes, additional information is displayed when the output of the stimulator is on.

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

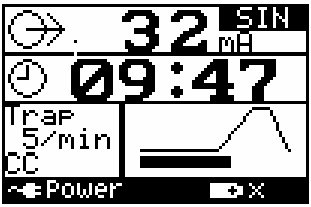


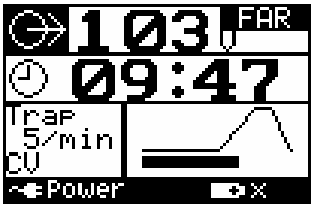


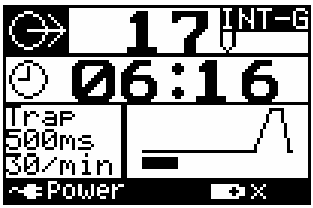


In russian mode, a diagrammatic representation of the output waveform is displayed, with a progress bar beneath it. The set-up information is summarised on the left side of the LCD. The progress bar serves to let the patient and operator know when a surge is expected and in progress.

Similarly, in sinusoidal and faradic modes, a diagram shows the amplitude of the surge envelope and a progress bar shows the current position in the surge cycle.

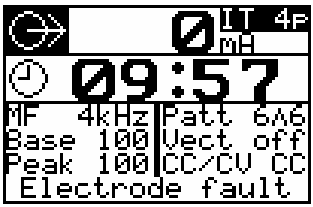






In interrupted galvanic mode, a similar diagram shows the pulse period and the progress bar shows the patient and user when the next pulse is about to arrive.

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 855 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 key on the keypad 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, then check that they are held securely with even pressure by the elasticated bandages and that the sponges have not dried out.



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

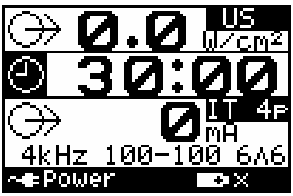
It is recommended that only the large Ultrasound transducer is used for combination therapy in order to maintain sufficient contact area to keep the stimulator current density to a safe level.

The surface of the Ultrasound transducer is internally connected to the B1 terminal of the stimulator patient lead (outside blue wire) 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. If 2-pole interferential is chosen (the most commonly used setting for combination therapy) the A2 terminal (outside yellow wire) becomes the other electrode and the B2 and A1 wires become redundant and should be disconnected. If 4-pole interferential is chosen for combination therapy the B2 terminal (inside blue wire) 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.

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 highlight Combination using the up/down keys and press the menu key again.

The following combination page will appear:-



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

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.

Highlight the stimulator output, 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 (using the ultrasound buttons).

The patient may feel a slight increase to the 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.

Electrodes

It is recommended that only electrodes supplied by EMS Physio Ltd. are used with the Combination 855. 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.

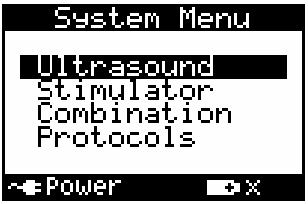
The electrodes must never be placed so that the stimulating current crosses the chest or passes near the heart.

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

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

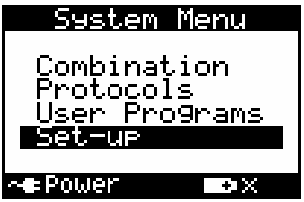
System menu

Pressing the menu key from any set-up screen takes the user to the system menu (except during treatment).



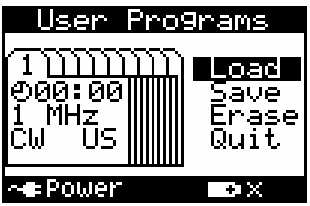
Highlight the required option using the up and down keys and then press menu.

Scrolling down below the Protocols tab reveals the user programs and Set-Up tabs.



User programs

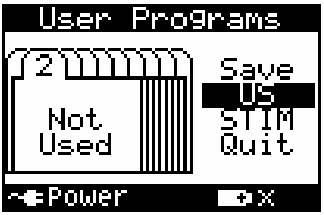
The Combination 855 unit can store up to 10 user defined set-ups. To access the user programs select the option from the system menu.



The LCD shows the 10 user programs as file cards with the first program at the front. To move through the program cards use the rotary control.

On entry to the user program display the Load option is highlighted.

To load the displayed program press the menu key. The settings shown on the file card will be loaded and the user will be returned to the relevant 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 or Stimulator set-up as a user program, select the card to which the set-up is to be saved using the rotary control. Highlight the Save option using the up and down keys and press the menu key. The options will be displayed to save either the current Ultrasound set-up or that of the Stimulator. Select US or STIM, press menu and the set-up will be saved and displayed on the selected card.

To erase a program saved on the current card, highlight the Erase option using the up and down keys. Pressing the menu key will erase the program. “Not Used” will be displayed on the selected card to confirm the action.

Select the Quit option to return to the system menu

Set-up

The set-up option is accessed from the system menu by scrolling down below the User Programs tab, highlighting Set-Up and pressing the menu key. This option allows user preferences to be set for LCD contrast, sounder volume, key-click, language and contact monitor.

Contrast: When the contrast label is highlighted turning the rotary control clockwise makes the LCD darker and anticlockwise makes it lighter.

Volume: There are two volume levels for the sounder. When volume is highlighted, turning the rotary control clockwise sets high and anticlockwise sets low.

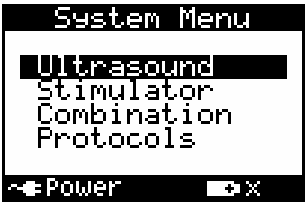
Key-click: When key-click is highlighted turning the rotary control clockwise sets the key-click on and a short beep is produced each time a key is pressed. Turning the rotary control anticlockwise turns the key-click off.

Language: When language is highlighted, the rotary control changes the current display language.

Contact: The ultrasound contact monitor can be set to produce an audible alarm when there is insufficient contact for the correct ultrasound power to be delivered. In this option turning the rotary control clockwise sets the contact monitor to audible and turning it anticlockwise sets the monitor to standard (no audible alarm).

To exit set-up press the menu key.

Protocols and Ultrasound Dose Algorithm Software (Optional Accessory)



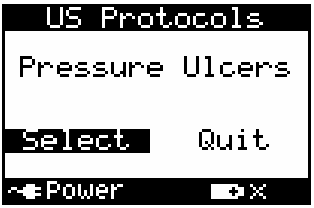
The Protocols are accessed from the main System Menu screen by scrolling down using the UP/DOWN keys and then pressing menu.

Highlighting and then selecting Protocols by pressing the menu key will bring up this selection screen* -

This gives you the choice of Ultrasound Protocols, Interferential Protocols, the Ultrasound Dose Algorithm, or return to the System Menu screen. These are selected by highlighting with the UP/DOWN keys and then pressing menu.

* If the unit does not have the optional Protocols and Dose Algorithm installed, selecting the Protocols tab in the System Menu screen will produce this message –

Ultrasound Protocols

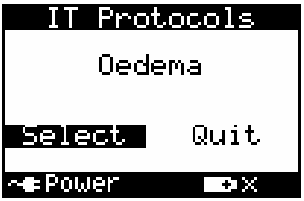


Highlighting Ultrasound Protocols in the selection menu window and pressing the menu button will bring up the ultrasound protocol selection screen. The various different treatment protocols can be selected by turning the rotary dial (use the UP/DOWN keys to access the Quit option). Pressing the menu key will load the treatment settings for the selected protocol. Note that the maximum available intensity will be preset for each protocol to the recommended level for that treatment.

Before commencing treatment (by incrementing the output intensity) it is possible to edit the settings if required (except for output intensity). It is also possible to store an edited version of a protocol as a user program, by pressing the menu key, selecting User Programs and then selecting the program number and the Save option. Upon re-loading these settings from a user program, it will be found that the maximum intensity is no longer preset.

Interferential Protocols

Highlighting Interferential Protocols in the selection menu screen and pressing menu will bring up the Interferential Protocol selection screen.

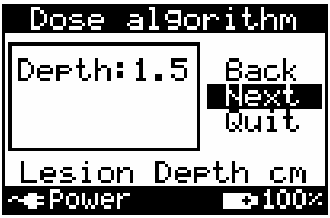


The various different treatment protocols can be selected by turning the rotary dial (use the UP/DOWN keys to access the Quit option). Pressing the menu key will load the treatment settings for the selected protocol.

Before commencing treatment (by incrementing the output intensity) it is possible to edit the settings if required. It is also possible to store an edited version of a protocol as a user program, by pressing the menu key, selecting User Programs, then selecting the program number and then the Save option.

Dose Algorithm (for Ultrasound only)

From the Protocols selection screen, scrolling to Dose Algorithm and pressing the menu button produces this screen:-

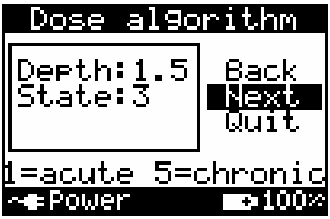


The lesion depth in cm can be changed using the rotary control.

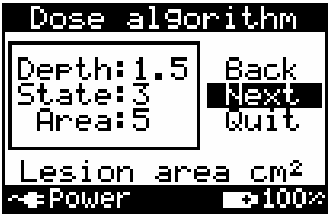
If an Ultrasound transducer is not connected this prompt screen will appear:-

Plugging in an Ultrasound head at this point will cause a return to the Lesion Depth display.

Set the required lesion depth and press the menu button. This next screen will appear:-



Select the relevant state using the rotary control and press the menu button. This final screen will appear:-



After adjusting the treatment area using the rotary control press the menu button and the algorithm will calculate and display the treatment settings for that particular set of input parameters. The maximum available intensity will also be automatically set to the value calculated by the dose algorithm.

Again, it is possible to edit and/or store these settings as described above in the protocols section. Increment the output intensity to begin treatment.

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 855 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.

EMC Tables

1	**Guidance and manufacturers declaration – electromagnetic emissions**		
2	The Solo Combination 855 is intended for use in the electromagnetic environment specified below. The customer or the user of the 855 should assure that it is used in such an environment.		
3	**Emissions Test**	**Compliance**	**Electromagnetic environment - guidance**
4	RF emissions CISPR 11	Group 1	The 855 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	The 855 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.
7	Harmonic emissions IEC 6100-3-2	not applicable	
8	Voltage fluctuations Flicker emissions IEC 61000-3-3	not applicable	

Guidance and manufacturers declaration – electromagnetic immunity			
The Solo Combination 855 is intended for use in the electromagnetic environment specified below. The customer or the user of the 855 should assure 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% *UT* (>95% dip in *UT*) For 0,5 cycle 40% *UT* (60% dip in *UT*) For 5 cycles 70% *UT* (30% dip in *UT*) For 25 cycles <5% *UT* (>95% dip in *UT*) For 5 sec	<5% *UT* (>95% dip in *UT*) For 0,5 cycle 40% *UT* (60% dip in *UT*) For 5 cycles 70% *UT* (30% dip in *UT*) For 25 cycles <5% *UT* (>95% dip in *UT*) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 855 requires continued operation during power mains interruptions, it is recommended that the 855 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 *UT* is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturers declaration – Electromagnetic immunity.

The Solo Combination 855 is intended for use in the electromagnetic environment specified below. The customer or user of the Solo Combination 855 should assure 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 Solo Combination 855, 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 Solo Combination 855 is used exceeds the applicable RF compliance level above, the Solo Combination 855 should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as re-orienting or relocating the Solo Combination 855.

[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 855

The Solo 855 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the 855 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Solo 855 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.

Essential Performance

Power Input	100-240V ac
Treatment Timer	0 to 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 ohms CV 0-70V peak (±10%) into 2 kohms
Output Channels	2
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 ohms CV 0-140V peak (1 channel) (±10%) into 2 kohms CV 0-70V peak (2 channels) (±10%) into 2 kohms
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 ohms CV 0-140V peak (1 channel) (±10%) into 2 kohms CV 0-70V peak (2 channels) (±10%) into 2 kohms

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 ohms CV 0-60V peak (±10%) into 2 kohms

Diadynamic Currents

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

Sinusoidal

Frequency (AMF)	50 Hz (±5%)
Surge Rate	2 to 30 /minute (±10%)
Surge Pattern	Rectangular, Triangular or Trapezoidal
Output Type	CC 0-70mA peak (±10%) into 500 ohms CV 0-140V peak (±10%) into 2 kohms

Faradic

Frequency	50 Hz (±5%)
Surge Rate	2 to 30 /minute (±10%)
Surge Pattern	Rectangular, Triangular or Trapezoidal
Output Type	CC 0-70mA peak (±10%) into 500 ohms CV 0-140V peak (±10%) into 2 kohms

Galvanic

Output Type	CC 0-70mA peak (±10%) into 500 ohms CV 0-140V peak (±10%) into 2 kohms

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 ohms CV 0-140V peak (±10%) into 2 kohms

Träbert

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

Medi-Wave

Waveform	6 ms (± 5%) differentiated pulse
Frequency	2 – 60 Hz (± 5%)
Output Type	CC 0-70mA peak (±10%) into 500 ohms CV 0-140V peak (±10%) into 2 kohms (1 channel) CV 0-70V peak (±10%) into 2 kohms (2 channels)