

EMS Physio Ltd

Wantage Oxfordshire OX12 9FE England

User Manual
MULTIDYNE 965

CE
0120

General Information

This manual provides the necessary information for the installation and operation of the Multidyne 965 unit.

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

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

No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent of EMS Physio Ltd.

The Multidyne 965 provides a complete range of low and medium frequency waveforms for electrotherapy and electro-diagnostics.

It is intended that the Multidyne 965 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	12/02/2004
2	Revised	14/02/2005
3	EMC Tables added	31/01/2008


EC Declaration of Conformity

EMS Physio Ltd.
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United Kingdom

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 Multidyne 965

Model Numbers 113

Signature 

Position Technical Director

Date first issued 12th February 2004

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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 Multidyne 965 provides a complete range of low and medium frequency waveforms for electrotherapy and electro-diagnostics.

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 Multidyne 965 produces DF (diphassé fixe), MF (monophasé fixe), CP (courtes périodes), CPiso (courtes périodes isodynamique), LP (longues périodes) and RS (rythme 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 Multidyne 965 produces a wide range of interrupted galvanic pulses. Rectangular pulses from 10 μ s 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 cm² 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 Multidyne 965 provides two channels of asymmetric, symmetric or sequential output with a wide range of pulse widths and repetition rates.

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 Multidyne 965 Unit. Current densities greater than 2 mA rms/cm² 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 (cm²) 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

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	100-240 Vac 50/60 Hz
Battery (optional)	Internal Rechargeable (NiMh)
Classification (EN60601-1)	Class 1, Type BF
Mains Fuses	2 x T630 mA (5 x 20 mm)
Size (height x width x depth)	100 x 240 x 210 mm
Weight	1.5 kg (excluding battery)
Treatment Time	0 – 30 minutes
Treatment Programs	10 user-defined set-ups

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 μ s
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, Negative and Auto-reverse
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 μ s 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	

Environmental Conditions for Transport and Storage

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

The Multidyne 965 is designed to operate from any 50/60 Hz single phase supply between 100 and 240 Vac capable of supplying 50 VA. Connection is via an IEC socket at the rear of the unit.

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

Each Multidyne 965 is supplied with a detachable mains cable, spare fuses, patient lead, 4 medium (100 x 70 mm) conductive rubber electrodes, 4 medium sponge covers, electrode connecting cables, 2 stretch bandages and this manual.

The Multidyne 965 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 60601-2-10:2001 " Medical electrical equipment. Particular requirements for the safety of nerve and muscle stimulators".

Supplied with each unit is a detachable mains lead complete 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 Electro-Medical Supplies or the agent from whom the unit was purchased.

Accessories

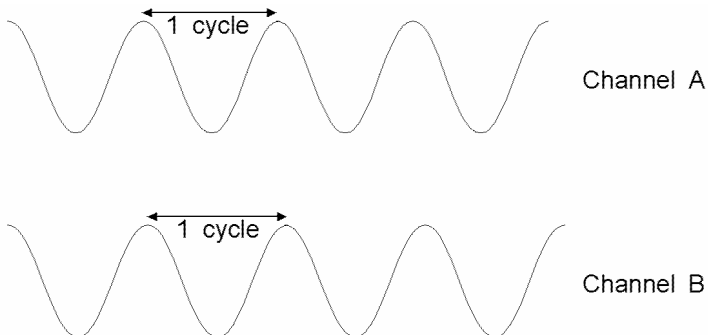
Catalogue Number	Description
SLA3055	Patient Lead (4 way)
NC3052A	4 small sponge electrode covers (for NC3052B)
NC3052B	4 small (70 x 50 mm) conductive rubber electrodes
NC3053A	4 medium sponge electrode covers (for NC3053B)
NC3053B	4 medium (100 x 70 mm) conductive rubber electrodes
NC3054A	4 large 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 electrode 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)

Output Waveforms

Interferential 4-pole



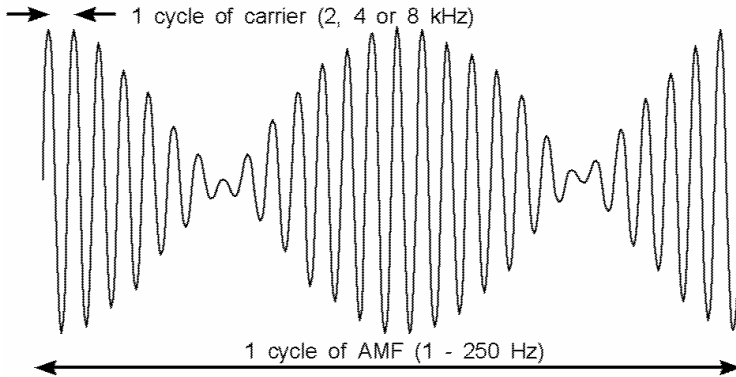
	Channel A		Channel B	
Carrier	Frequency	Period	Frequency	Period
2 kHz	2 kHz	500 μ s	1.75-2 kHz	572-500 μ s
4 kHz	4 kHz	250 μ s	3.75-4 kHz	267-250 μ s
8 kHz	8 kHz	125 μ s	7.75-8 kHz	129-125 μ s

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:

$$\text{Maximum impedance} = 70000 / (\text{peak output current in mA})$$

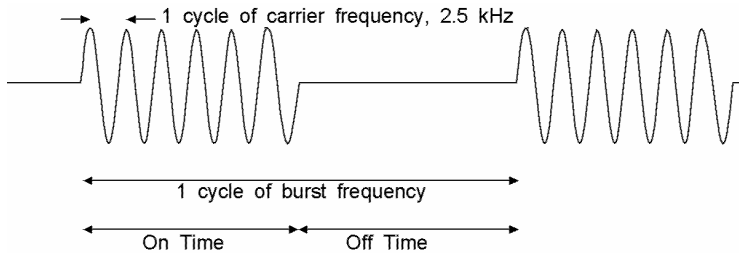
In constant voltage mode, the maximum output voltage is 70V_{peak} or (load impedance x 0.1) V_{peak} whichever is the smaller.

Interferential 2-pole



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

Russian Stimulation

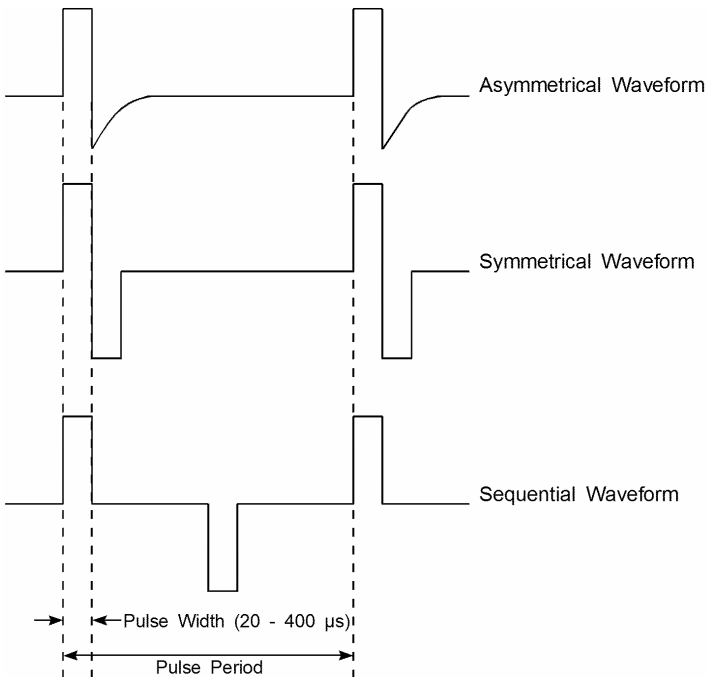


The burst frequency may be set to be from 1 Hz to 100 Hz. The on and off times are always equal and are from 0.5s (1 Hz burst) to 5 ms (100 Hz burst).

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

TENS

Three TENS waveforms are available



$$\text{pulse period} = 1/(\text{repetition rate})$$

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

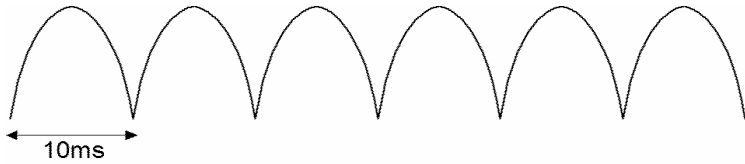
For repetition rates greater than 5 Hz the TENS output is zero for 2 s (rest), increases to the set level during the next 1 s (rise), remains at the set level for 0.5 s (hold) and returns to zero during the next 0.5 s (fall) giving a surge rate of 15 / minute. Below 5 Hz, the rest, rise, hold and fall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

Diadynamic

In diadynamic mode the unit produces six different waveforms are available. 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.

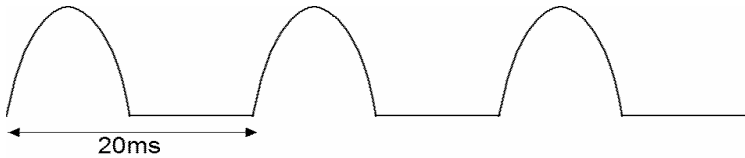


$$\text{rms current} = \text{peak current} \times 0.707$$

The maximum rms current is 50 mA.

MF - monophasé fixe

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



$$\text{rms current} = \text{peak current} \times 0.5$$

The maximum rms current of 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 continually.

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.

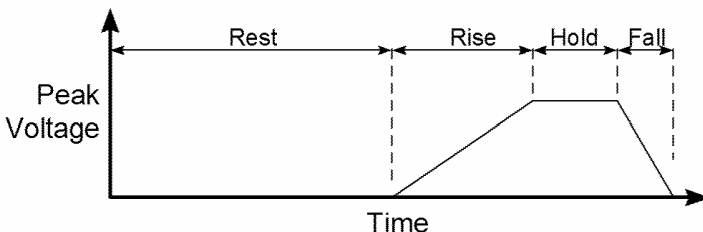
Sinusoidal

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 $\sqrt{2}$, or

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

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

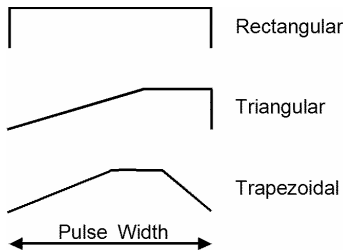
The output in faradic mode is a series of 0.5ms pulses at a repetition rate of 50 Hz with a zero dc content. The pulse train is surged in the same way as the sinusoidal output.

Galvanic

Galvanic mode produces a direct current from 0 to 70 mA.

Interrupted Galvanic

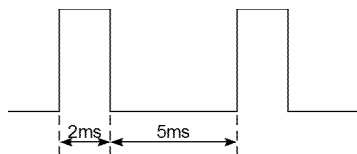
Interrupted Galvanic mode produces three standard pulse shapes. All interrupted galvanic pulses are positive going and monophasic and have therefore, a net dc component.



Rectangular pulses are available from 10 μ s to 1 s and triangular and trapezoidal pulses from 1 ms to 1s. The pulse repetition rate is from 1 to 30 pulses per minute.

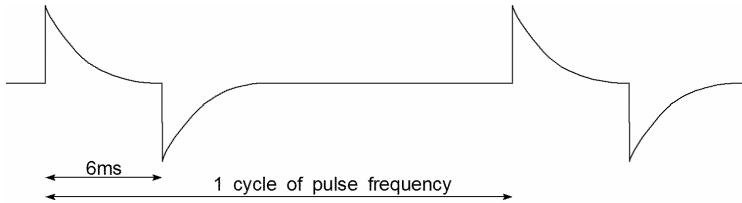
Träbert

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

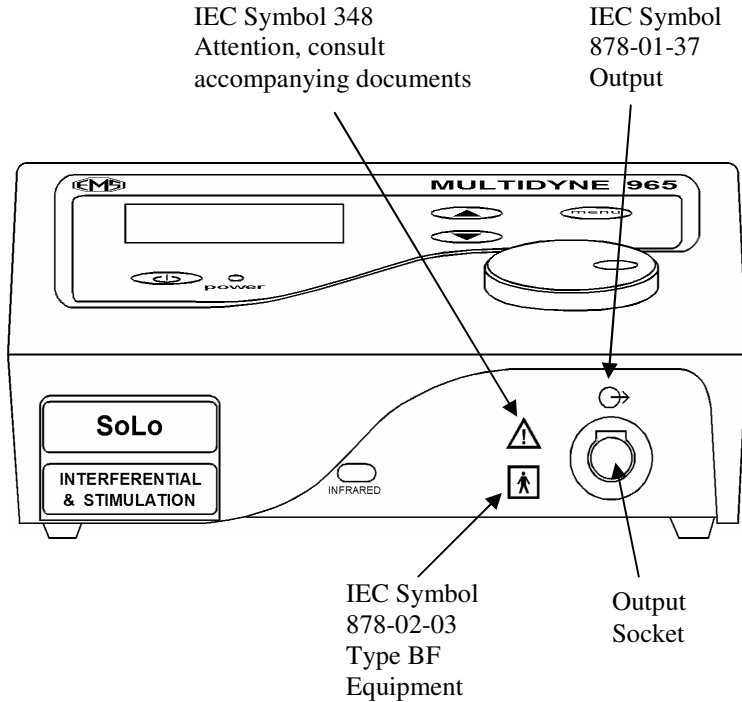
The Medi-Wave output is a train of differentiated pulses with a pulse width of 6 ms.



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.

Controls and Markings

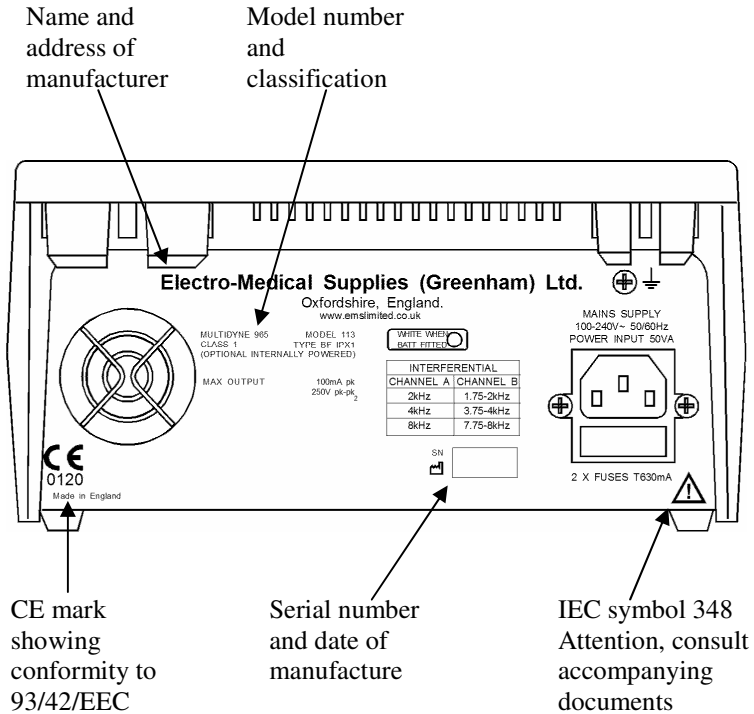
Multidyne 965 front panel



The **Output socket** is for the connection of the patient lead (see page 26).

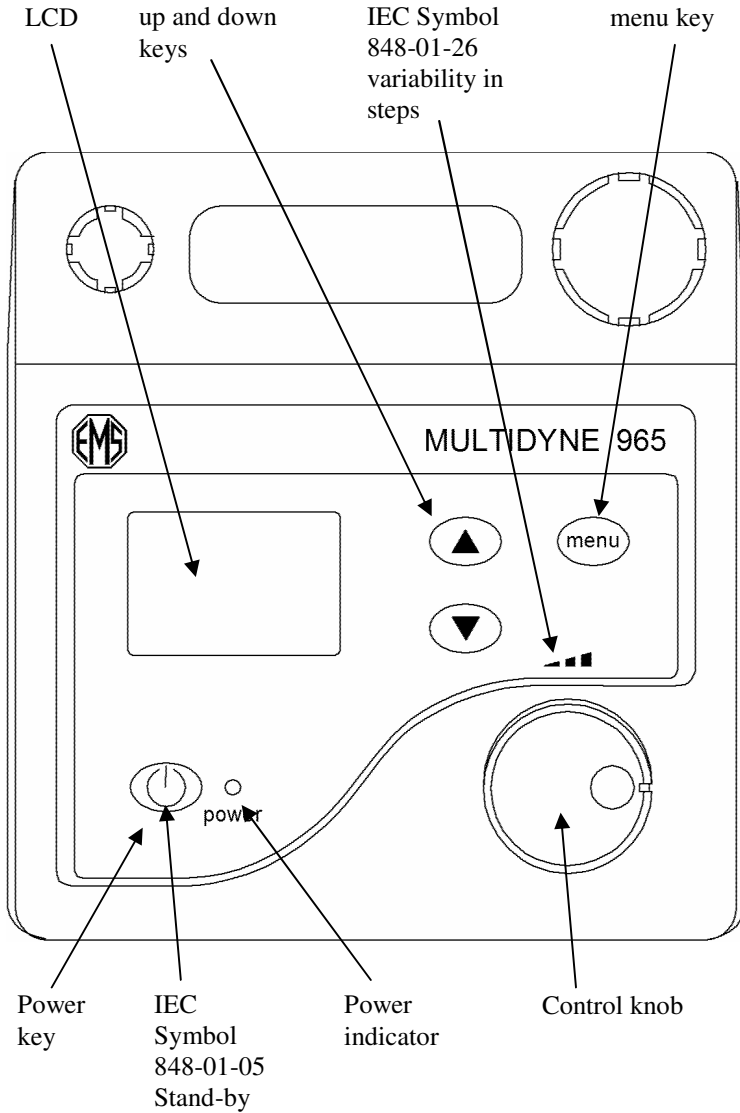
The **infrared** window is for the IrDA interface used for service and calibration purposes.

Multidyne 965 rear panel

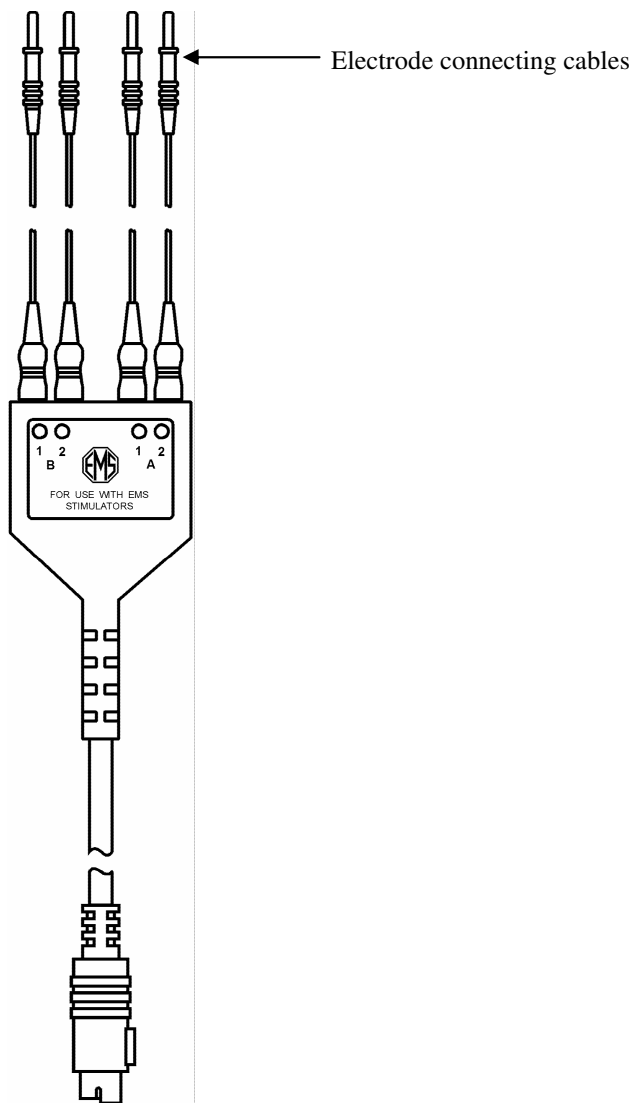


Mains connection is via the IEC socket on the right of the rear panel. Details of the required mains supply are above the connector.

Multidyne 965 Top



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.

If not already fitted, connect a suitable plug to the mains cable. The plug must have provision for an EARTH (GROUND) connection. The mains cable has the following colour code: BROWN is LIVE (LINE), BLUE is NEUTRAL and GREEN/YELLOW is EARTH.

The Multidyne 965 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 the unit to the mains supply. Units fitted with an internal rechargeable battery may be used powered by the battery only.

Plug the patient lead into the output socket on the front of the unit. The connector on the output lead has a raised square section on the top to ensure that it cannot be inserted incorrectly.

Operation of the unit in close proximity (less than 1 metre) to shortwave therapy equipment or radio-frequency mobile communication equipment may produce instability in the output of the Multidyne 965.

Operating Instructions

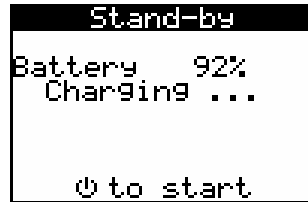
Mains Operation

Connect the mains cable to the IEC 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.

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



Mains only unit



Mains / 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

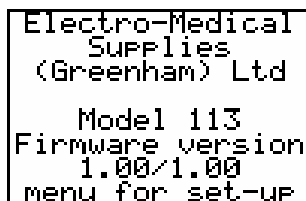
For battery operation (mains / battery units only) press the power key and hold it down until the EMS logo appears on the LCD. The power key should then be released.

Power on sequence and general information

When the Multidyne 965 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 firmware version.

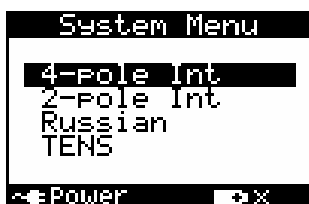


Logo and model



Information screen

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



System Menu

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

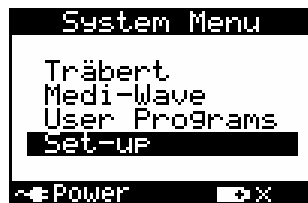
Throughout the operation of the Multidyne 965, the up and down keys are used to select the parameter highlighted.

The rotary control is used to increase and decrease the highlighted parameter.

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

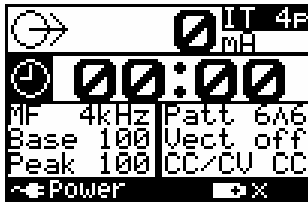
System Menu

The stimulation type can be selected from the system menu. Use the up and down cursor keys to highlight the required stimulation and then press the menu key. Also available from the system menu are the User Programs and Set-up options.



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 111 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.

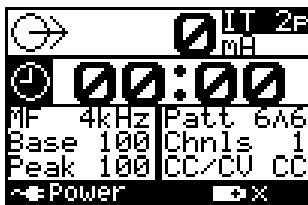
To set the change the vector option highlight the vector label using the up and down keys. Turning the rotary control clockwise sets the vector option to on and anticlockwise off.

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).



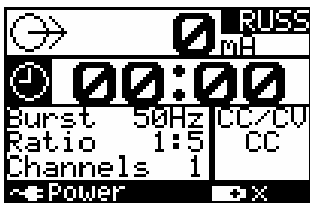
The 2-pole interferential set-up is similar to the 4-pole set-up. The treatment time, MF (carrier frequency), base and peak frequencies, pattern and CC/CV operation are set-up in exactly the same way. There is no vector option in the 2-pole interferential mode.

Chnls (Channels): In addition to the normal 2-pole interferential operation, the Multidyne 965 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.

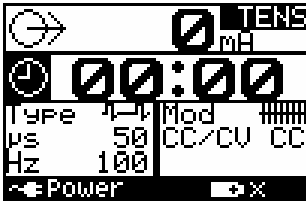
Ratio: The medium frequency bursts used for Russian stimulation are surged to produce work and rest periods. The surge time (work) is fixed at 10 seconds. The ratio sets the off or rest time in ratio to the work period. For example, if the ratio is set to 1:4 then the work period is 10 seconds and the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



Asymmetrical



Symmetrical



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



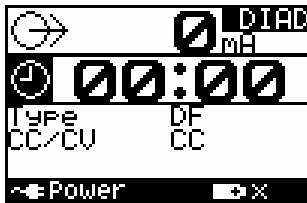
Surged

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).



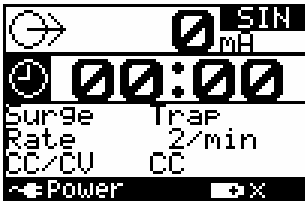
Treatment Time: With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.

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, Cpisto - 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.

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.

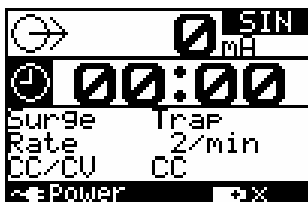
Surge: Three surge patterns (envelopes) are available: Rect (rectangular), Tri (triangular) and Trap (trapezoidal). A full description of these surge patterns is available in the technical specification section of this manual. The surge pattern may be changed using the rotary control when the surge label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



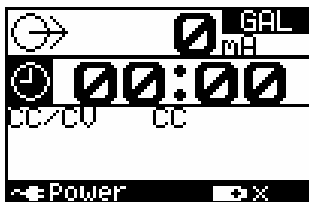
Treatment Time: With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The time can be set in 30s intervals.

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).

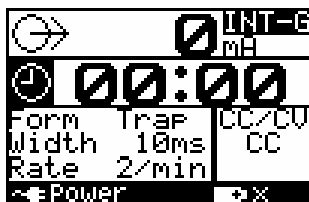
Galvanic Set-up



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 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.

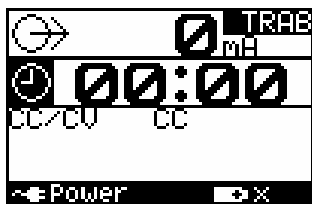
Form: Three different pulse shapes are available: Rect (rectangular), Tri (triangular) and Trap (trapezoidal). A full description of these waveforms is available in the technical specification section of this manual. The waveform may be changed using the rotary control when the form label is highlighted

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).

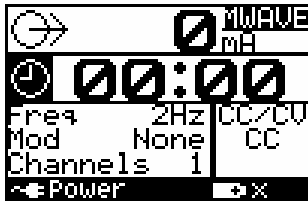
Träbert Set-up



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.

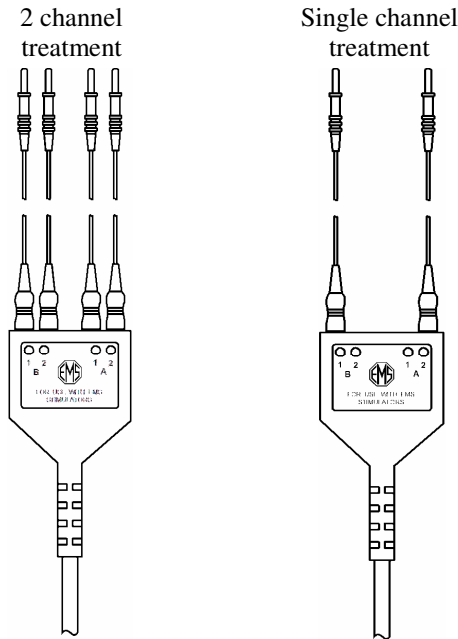
Mod: Normally Medi-Wave stimulation is used in continuous mode - that is with no modulation (none). In addition, burst and surged modes are also available.

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

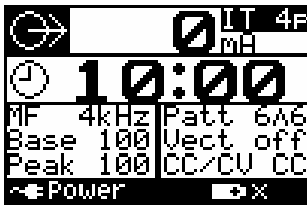
Connect the patient lead to the output socket of the unit. Attach suitable electrodes to the patient and connect the patient lead to the electrode using the blue and yellow cables provided. For 2 channel treatments the yellow cables are channel A and the blue cables channel B. For single channel treatment use the outside yellow and blue cables.



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.

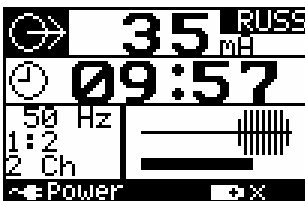
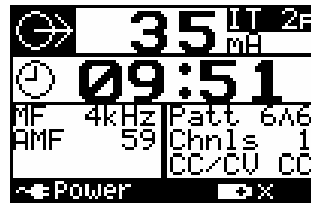
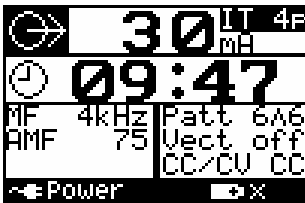
If the treatment time is not zero, the output of the stimulator will be energised, the output symbol will flash and the treatment time will begin to count down. Advance the output control slowly, until the desired effect of the stimulation is produced.

Always advance the output control slowly.

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

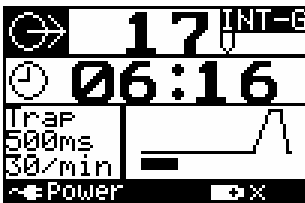
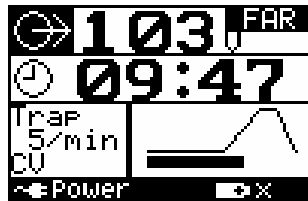
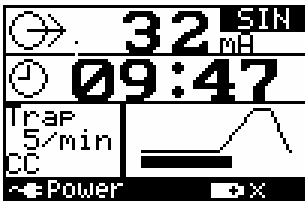
In some operating modes, additional information is displayed when the output of the stimulator is on.

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



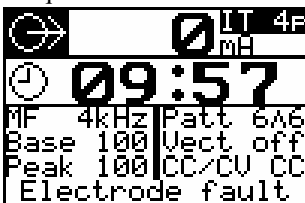
In russian mode, a diagrammatic representation of the output waveform is displayed, with a progress bar beneath it. The set-up information is summarised on the left side of the LCD. The progress bar serves to let the patient and operator know when a surge is expected and in progress.

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 tråbert 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 Multidyne 965 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.

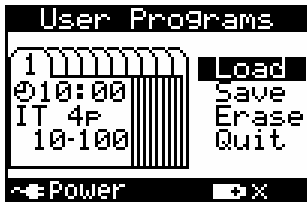
When the treatment time reaches zero, a three second alarm is sounded.

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

User programs

The Multidyne 965 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 appropriate 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 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 settings 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. This option allows user preferences to be set for LCD contrast, sounder volume, key-click and language.



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.

To exit set-up press the menu key.

Electrodes

It is recommended that only electrodes supplied by EMS Physio Ltd. are used with the Multidyne 965. Three sizes of conductive rubber electrodes are available. These are small (70 x 50 mm), medium (100 x 70 mm) or large (130 x 100 mm). Replacement sponge covers are available for each electrode.

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

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

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

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

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

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

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

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

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

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

Maintenance

The conductive rubber electrodes and covers may be disinfected using a 70% v/v solution of isopropyl alcohol.

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 probe leads, cables and connectors for signs of damage.

The unit calibration should be checked at least annually.

The mains fuses are located on the rear panel in a compartment below the mains inlet. The compartment cannot be opened unless the mains lead is removed from the IEC socket. Information on fuse type and rating is given on the rear panel of the unit and in the Technical Specification section of this manual.

If the mains fuses continue to blow then EMS qualified Service personnel must be called in.

The Multidyne 965 has the option of an internal NiMh rechargeable battery. Whenever the unit is connected to the mains 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 Interferential/Multidyne 955/965 is intended for use in the electromagnetic environment specified below. The customer or the user of the 955/965 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 955/965 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 955/965 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 Interferential 955/965 is intended for use in the electromagnetic environment specified below. The customer or the user of the 955/965 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% <i>UT</i> (>95% dip in <i>UT</i>) For 0,5 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) For 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) For 25 cycles <5% <i>UT</i> (>95% dip in <i>UT</i>) For 5 sec	<5% <i>UT</i> (>95% dip in <i>UT</i>) For 0,5 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) For 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) For 25 cycles <5% <i>UT</i> (>95% dip in <i>UT</i>) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 955/965 requires continued operation during power mains interruptions, it is recommended that the 955/965 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 <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturers declaration – Electromagnetic immunity.

The Solo Interferential/Multidyne 955/965 is intended for use in the electromagnetic environment specified below. The customer or user of the Solo Interferential/Multidyne 955/965 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic Environment Guidance
Conducted RF IEC61000-4-6	3Vrms 150kHz to 80MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Solo Interferential/Multidyne 955/965, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=3.5\sqrt{P/V_1}$
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	$d=3.5\sqrt{P/E_1}$ 80MHz to 800MHz $d=7\sqrt{P/E_1}$ 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 Interferential/Multidyne 955/965 is used exceeds the applicable RF compliance level above, the Solo Interferential/Multidyne 955/965 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 Interferential/Multidyne 955/965.

^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 955/965			
The Solo 955/965 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the 955/965 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Solo 955/965 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
<p>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.</p> <p>NOTE 1 At 80MHz and 800MHz the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			