

User Manual



EMS960/970

PRIMO INTERFERENTIAL & MULTIDYNE Model 122/123

C€ 0120



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General information

This manual provides the necessary information for the installation and operation of the Interferential 960 and Multidyne 970 Units.

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 Interferential 960 is an interferential electrotherapy unit.

The Multidyne 970 unit is a multiple waveform electrotherapy unit.

The 970 provides a complete range of low and medium frequency waveforms for electrotherapy and electro-diagnostics.

It is intended that the Multidyne 970 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	09/09/11
2	Updated to show latest images	24/10/12
3	Declaration of conformity revised	26/06/14
4	Updated for colour TFT GUI	11/05/17
5/6	Minor edits	15/11/18
7	Corrections	14/12/18



EC Declaration of Conformity

Product Name Primo Interferential 960/Multidyne 970

Model Number 122/123

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

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

Directive Conformity assessment route

2011/65/EU Annex II, module A (768/2008/EC) (RoHS)

93/42/EEC Annex II of Directive 93/42/EEC under the

supervision of Notified Body Number 0120, SGS

United Kingdom Ltd.

Class IIb according to rule 9 of Annex IX of 93/42/EEC

Signature M Bowles

Position Operations Director

Date 26th June 2014

Date first issued 9th September 2011



Warranty

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

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

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

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 Interferential 960 provides Interferential 4-pole and 2-pole and Medi-Wave electrotherapy only.

The Multidyne 970 provides a complete range of low and medium frequency waveforms (including Interferential) for electrotherapy and electro-diagnostics.

Indications for use

Voltage and current waveforms may be used to provide muscle stimulation and relief from musculoskeletal pain.

Muscle stimulation may be used for muscle strengthening and rehabilitation in otherwise healthy subjects recovering from surgery, for muscle strengthening for critically or chronically ill patients or to (re)train weak or ineffective muscles.

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

Precautions

See also appendix B "Technical Specification".

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 970 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.

Modification of the EMS960/970 is not permitted and may result in a hazardous situation

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

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

Febrile conditions

Large open wounds in treatment area

Dermatological conditions in treatment area

Thrombosis

Hypersensitivity or fear of electrical treatments

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

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

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

Electrodes should never be placed so that the applied current goes across or through the head, eye, front of the neck (especially the carotid sinuus), upper back or chest. Electrodes must never cover the mouth.

Accessories supplied as standard

Catalogue Number	Description
SLA9000	DC Power supply 18V 60W
PMA3055	Patient lead (4 way – yellow and blue connecting cables included)
NC3053A	4 medium sponge electrode covers (for
NC3053B	NC3053B) 4 medium (100 x 70 mm) conductive rubber
	electrodes
DU2	2 Stretch bandages 1200 x 75 mm

Optional accessories

EMS530	Primo shoulder bag	
EMS158	Primo trolley	
NC3052A	4 small sponge electrode covers (for NC3052B)	
NC3052B	4 small (70 x 50 mm) conductive rubber	
	electrodes	
NC3054A	4 large sponge electrode covers (for NC3054B)	
NC3054B	4 large (130 x 100 mm) conductive rubber	
	electrodes	
NC3041	Electrode handle (for circular pad & ball	
	electrodes)	
NC3042A	Connecting cable for electrode handle	
NC3046	Circular pad electrode 12 mm diameter	
NC3048	Circular pad electrode 37 mm diameter	
NC311A	Ball electrode for muscle testing	
DU1	Stretch bandage 600 x 75 mm	
DU4	Stretch bandage 600 x 50 mm	



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

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

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

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

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

EMS Physio Ltd.

Grove Technology Park Downsview Road Wantage Oxfordshire OX12 9FE England

T: 01235 772272 F: 01235 763518

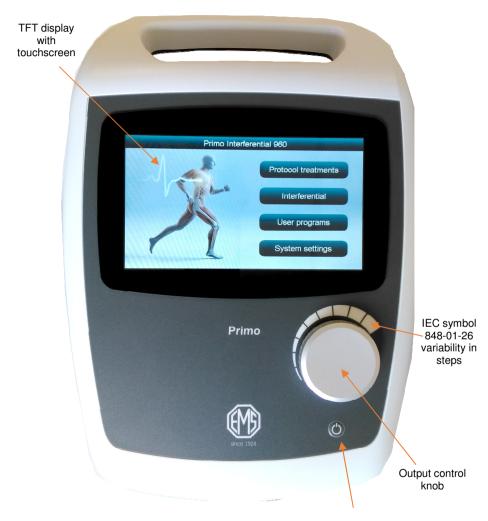
E: sales@emsphysio.co.uk

Website: http://www.emsphysio.co.uk



Controls and markings

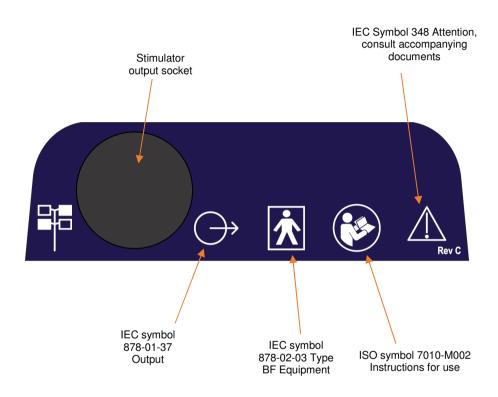
Interferential/Multidyne 960/970 top





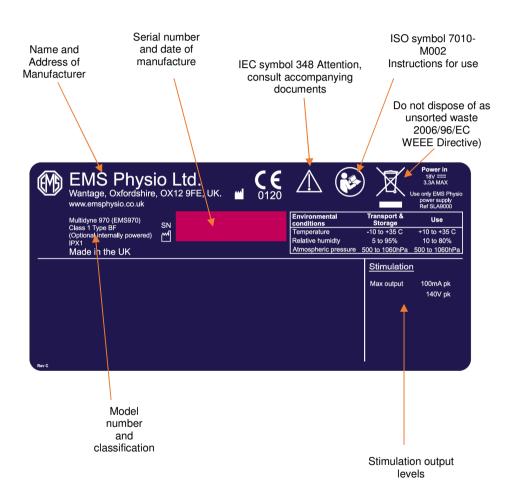


Interferential 960/Multidyne 970 front label



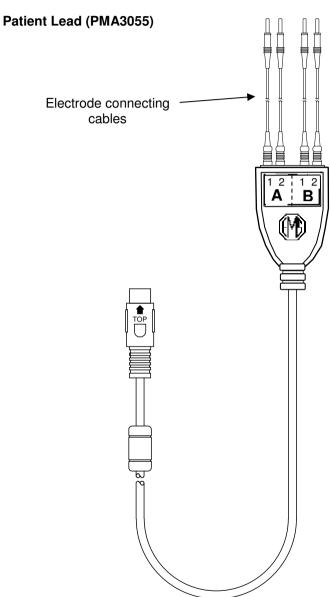


Multidyne 960 underside label (Model 970 is identical)









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 Interferential 960/Multidyne 970 must only be used with an EMS SLA9000 power supply (as supplied with the unit). A power cord appropriately rated/approved for the country of use must be used.

The SLA9000 power supply must only be connected to a mains supply with a protective earth conductor. If the integrity of the earth connection is in doubt, do not connect it to the mains supply (risk of electric shock with type B applied parts). The unit must not be positioned in such a way that the mains plug cannot easily be unplugged – the mains plug is the main disconnect device.

The Interferential 960/Multidyne 970 unit is supplied with four mediumsized electrotherapy electrodes with their associated patient lead. Plug the patient lead into the socket on the front of the unit and connect the electrodes to the yellow and blue cables.

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 output of the Interferential 960/Multidyne 970 being affected.

Permissible environmental conditions of use:

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

Permissible environmental conditions of transport and storage:

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

Operating instructions

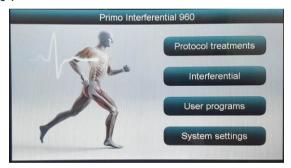
Power on sequence and general information

When the Interferential 960/Multidyne 970 is turned on, the EMS company logo is displayed on a splash screen along with the model name and the software version.



After a few seconds the unit will give a short beep and display the Home screen -

Interferential 960 :-



Multidyne 970:-



Standard user controls

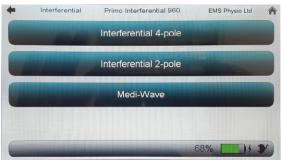
Throughout the operation of the Interferential 960/ Multidyne 970 the various modes and parameter settings are all accessed and changed by touching the relevant buttons displayed on the touchscreen.

The rotary control is used to increase and decrease the stimulation intensity when the TFT is showing a set-up screen. It can also be used to safely stop a treatment by turning it all the way anticlockwise.

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

Stimulator set-up

Touching the 'Interferential' button on the 960 Home screen will open this screen –



At the bottom of most screens is the status bar.

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

If the unit is fitted with a rechargeable battery pack, the battery symbol will be shown in the status line. The symbol is shaded green to show the current charge state of the battery. If the battery is charging the green shading will pulse. To conserve battery life, the unit will automatically turn down the TFT backlight after 1 minute and power itself down completely after 3 minutes if there has been no operator activity and the unit is running off the battery.

Touching the 'Stimulation' button on the 970 Home screen will open this screen –



Scrolling up or down using the \blacktriangle or \blacktriangledown buttons will reveal more stimulation options, such as – (Multidyne 970 only)



or -



System settings

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



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

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

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

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

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

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

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



User programs

The Interferential 960/Multidyne 970 can store up to 16 user defined setups. Touch the User Programs button in the Home screen or in any stimulation set up screen.



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

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

The 'Notes' button in any user program set-up screen opens a qwerty style keypad that allows you to save memo information about the program – the first 30 characters recorded will be displayed as the title of that user program.



Protocol Treatments

Touching the 'Protocol treatments' button will open a screen with a scrollable list of clinical conditions and front/back human body image. Touching different parts of the body will select a list of conditions specific to that body area.



Touching the highlighted condition in the list will open a user screen with the treatment parameters set for treating that condition.

Most parameters in a protocol treatment screen will be 'greyed-out' and not adjustable by the user – the only exception to this is the constant current or constant voltage selection button.

Standard user controls

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

The rotary control is used to increase and decrease stimulation intensity when a stimulation screen is selected.

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

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

The following describes the set-up pages for each stimulation type when accessed by pressing the relevant button in the Interferential/Stimulation screen(s):-

Interferential 4-pole set-up (960 and 970)



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

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

AMF (Amplitude Modulation Frequency): Touching this button opens the AMF window.



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

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

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

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

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

Vector: When the vector option is set to off, output channels A and B deliver the same output level (current or voltage). When the vector option is on, the relative amplitude of the outputs is slowly varied.

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

To change the vector option touch the Vector button.

Constant Current/Constant Voltage: The output from the unit may be set to be constant current or constant voltage 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, an 'Electrode fault' message appears and an alarm is sounded. In constant voltage mode, if the electrode impedance rises then the output is automatically reduced, so the alarm mechanism is not necessary. 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.

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

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

Interferential 2-pole set-up (960 and 970)



Interferential 2-pole therapy is similar to Interferential 4-pole 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. Two separate outputs A and B are available with independent level controls.

The Interferential 2-pole set up is similar to that of the 4-pole. The treatment time, carrier frequency, base and peak frequencies, pattern and constant current/voltage operation are adjusted in exactly the same way.

'Vector' is not available in 2-pole.



Russian set-up (970 only)



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

Treatment time is selected in the same way as previously.

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

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

The surge status is displayed in the lower middle window button of the display.

Constant current or constant voltage output mode may be selected by the dedicated button and behave as explained before.

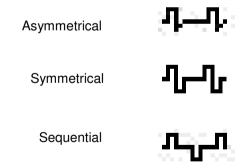
TENS set-up (970 only)



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

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

Type



Selection is achieved by touching the Type button.



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



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



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



Diadynamic set-up (970 only)



Treatment time: is set as already described.

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

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



Sinusoidal set-up (970 only)



Treatment time: is adjusted as explained above.

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

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

When running the surge status is shown in the lower middle window button of the display.



Faradic set-up (970 only)



Treatment time: is set as described above.

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

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

When running the surge status is shown in the lower middle window button of the display.



Galvanic set-up (970 only)



Treatment time: is set as described above.

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



Interrupted galvanic set-up (970 only)



Treatment time: is set as described before.

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

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

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

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

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



Träbert set-up (970 only)



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

Medi-Wave set-up (960 and 970)



Frequency: Touching this button opens this window:-



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

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

Constant Current/Constant Voltage: The output may be set to be constant current or constant voltage by touching the top-right button.

Microcurrent set-up (970 only)



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

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

Only Constant Current output mode is available in Microcurrent.



S/D curve (970 only)

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



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



The graphic at the bottom of the screen displays the pulse width and the progress bar shows when the pulse occurs. Pulse repetition rate is fixed at 20/min. Once muscle contraction has just been detected press Next. The first point of the S/D curve will be plotted and the pulse width will decrement to the next width setting. It will now be necessary to increase the output intensity until muscle contraction occurs again — at this point press Next and the next point in the S/D curve will be plotted.

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



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



Electrode fault detection



When a constant current output is chosen and the unit is operating in, 4 or 2 pole interferential, Russian, diadynamic, sinusoidal, galvanic or träbert modes, the electrode impedance is monitored to ensure that adequate electrode contact is maintained. If the unit detects an electrode impedance too high to safely deliver the required current, then the output of the Interferential 960/Multidyne 970 is terminated, an error message is displayed on the bottom line of the LCD and an intermittent alarm is sounded. Touch 'OK' to cancel the alarm and clear the error message. The remaining treatment time is maintained. Check the electrodes and leads before continuing treatment. If rubber pad electrodes and sponge covers are being used check that they are held securely with even pressure by the elasticated bandages and that the sponges have not dried out.

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



Treatment

Connect the patient lead to the output socket of the unit. Attach suitable electrodes to the patient and connect the patient lead to the electrode using the blue and yellow cables provided. The yellow cables are channel A and the blue cables channel B. For stimulation modes that have a dc component, the number 1 lead is positive and the number 2 lead negative.

Check that all the unit settings are as required for the chosen type of stimulation. Select an output channel button* (right-hand side of the screen) and 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.

*It is possible to select both output channels together to control them both at the same time if desired. In Interferential 4-pole mode both channels are selected automatically.

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, both outputs are smoothly reduced to zero.

During any treatment, a 'Stop' button appears in the middle right of the screen –



Touching 'Stop' causes both outputs to smoothly reduce to zero over a period of 5 seconds – this is also a safe way to stop a treatment.

When running in 4-pole and Interferential 2-pole modes a graphic with a moving cursor at the bottom of the AMF button shows the position in the frequency sweep.

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

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.

Protocols (Interferential 4-pole mode only)

Pressing the Protocols button in the Interferential 4-pole mode set-up screen will call up the same list of pre-sets tailored for treating various conditions as can also be accessed from the 'Protocol treatments' button on the main Home screen.

The condition to be treated can be selected using the up/down buttons and touching the highlighted condition in the list will open a user screen with the treatment parameters set for treating that condition.

Most parameters in a protocol treatment screen will be 'greyed-out' and not adjustable by the user – the only exception to this is the constant current or constant voltage selection button.



Electrodes

It is recommended that only electrodes supplied by EMS Physio Ltd. are used with the Interferential 960/Multidyne 970. 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 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 Interferential 960/Multidyne 970 has the option of an internal NiMh rechargeable battery. Whenever the unit is connected to the power supply the battery is monitored and charged as necessary. This type of battery has a limited life (typically 500 charge / discharge cycles). This battery must only be replaced by authorised service personnel. Do not mutilate, puncture, or dispose of batteries in fire. The batteries can burst or explode, releasing hazardous chemicals. Discard used batteries according to the manufacturer's instructions and in accordance with your local regulations.

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

Full servicing instructions are available on request.



Appendix A – overview of treatment modality

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 reeducation. The Multidyne 970 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 Multidyne 970 produces a wide range of interrupted galvanic pulses. Rectangular pulses from $10\mu s$ 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, Interferential 2-pole waveform.

<u>Transcutaneous electrical nerve stimulation (TENS)</u> refers to the application of low-intensity, short-duration pulses for the purpose of relieving pain. The Multidyne 970 provides two channels of asymmetric, symmetric or sequential output with a wide range of pulse widths and repetition rates.



Appendix B – technical specifications

General

Power input (SLA9000) 100-240V ac 1.5A 50-60Hz

(EMS960/970) 18V, 3.33A (from external PSU SLA9000)

Battery pack (optional) Internal rechargeable (NiMh)

Classification (EN60601-1) Class 1, Type BF
Fuse Internal T3.15A
Size (height x width x depth) 108 x 237 x 333 mm
Weight 1.3 kg (excluding battery)

Treatment programs 10 user-defined set-ups.

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

Interferential 4-pole (960 & 970)

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 (960 & 970)

Carrier frequency 2 kHz, 4 kHz or 8 kHz

AMF 0 – 250 Hz in 1 Hz increments

Swing pattern 1|1, 6|6 or 6^6

Output type CC 0-100mA peak CV 0-70V peak

Output channels 2

Russian stimulation (970 only)

Carrier frequency 2.5 kHz
Modulation frequency 1 – 100 Hz
Surges 1:1 to 1:5

Output type CC 0-100mA peak CV 0-70V peak

Output channels 2

TENS (970 only)

Waveform Asymmetrical, symmetrical or

sequential

Pulse width $40-400~\mu s$ Repetition rate 40-250~Hz

Modulation None, burst or surged Output type CC 0-100mA peak CV 0-70V peak

0.

Output channels 2

Diadynamic currents (970 only)

Current types DF, MF, CP, CPiso, RS, LP
Output type CC 0-70mA peak
CV 0-140V peak

Polarity Positive, negative or

auto-reverse

Output channels 2

Sinusoidal (970 only)

Frequency (AMF) 50 Hz

Surge rate 2 to 30 /minute

Surge pattern Rectangular, triangular or

trapezoidal

Output type CC 0-50mA peak

CV 0-140V peak

Output channels 2

Faradic (970 only)

Frequency 50 Hz

Surge rate 2 to 30 /minute

Surge pattern Rectangular, triangular or

trapezoidal

Output type CC 0-50mA peak CV 0-140V peak

Output channels 2



Galvanic (970 only)

Output type CC 0-70mA peak

CV 0-140V peak

Polarity Positive, negative or

auto-reverse

Output channels 2

Interrupted galvanic (970 only)

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 Positive, negative or

Polarity Positive, negative of

auto-reverse

Output channels 2

Träbert (970 only)

Waveform 2 ms on, 5ms off rectangular

Output type CC 0-70mA peak CV 0-140V peak

Polarity Positive, negative or

auto-reverse

Output channels 2

Medi-Wave (960 & 970)

Waveform 6 ms differentiated pulse

Frequency 2 – 60 Hz

Modulation None, burst, surged CC 0-100mA peak CV 0-70V peak

Output channels 2

Microcurrent (970 only)

Waveform Square wave (50% duty cycle)

Frequency 1-1000Hz Output type CC 0-1mA

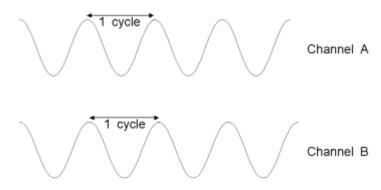
Polarity Positive, negative or

auto-reverse

Output channels 2

Output waveforms

Interferential 4-pole



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

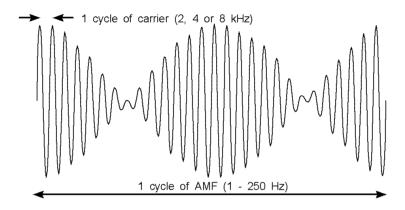
In constant current mode the maximum output current per channel is 100 mA peak (70 mA rms). The maximum load impedance in ohms at any given output current is given by:

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

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

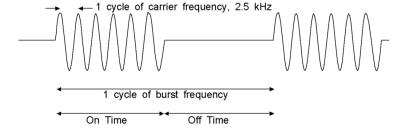


Interferential 2-pole



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

Russian stimulation

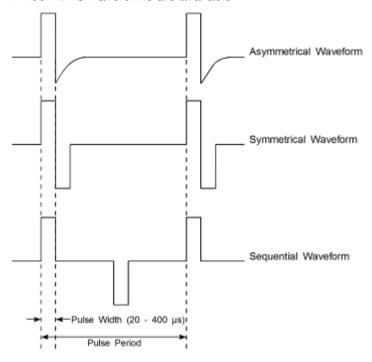


The burst frequency may be set to be from 1 Hz to 100 Hz. The on and off times are always equal and are from 0.5s (1 Hz burst) to 5 ms (100 Hz burst).

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

TENS

Three TENS waveforms are available



pulse period = 1/(repetition rate)

TENS burst mode

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

TENS surge Mode

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

Diadynamic

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

DF - diaphasé fixe

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

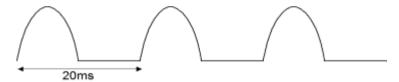


rms current = peak current x = 0.707

The maximum rms current is 50 mA.

MF - monophasé fixe

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



rms current = peak current x 0.5

The maximum rms current is 37.5 mA.

CP - modulé en courtes périodes

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

CPiso - modulé en courtes périodes isodynamique

This is the same as the CP waveform except that the amplitude of the MF signal is 12.5% less than the amplitude of the DF signal.

LP - modulé en longues périodes

The LP waveform provides an MF signal for 5 seconds. Then over the next 2.5 seconds the other phase of the 50Hz rectified signal is smoothly increased in amplitude to give a DF signal for a further 5 seconds. Finally the signal returns to MF by smoothly reducing one phase of the rectified



signal over the next 2.5 seconds. The complete sequence takes 15 seconds.

Part of the LP waveform showing how the alternate phase increases in amplitude is shown above.

RS – rythme syncopé

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

Two channels of output are available with independent intensity control

Polarity

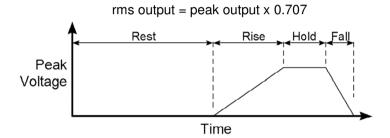
The above waveforms exhibit Pos (+) polarity as they all travel above the ground (zero volts) level (equivalent to the flat part of the waveforms). The polarity switch enables the user to reverse this

Neg (-) so that the above waveforms would be rendered 'upside-down' (both channels are inverted). A third option is Auto-reverse, in which the polarity automatically reverses half way through the selected treatment time.

Sinusoidal

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

For a sine wave the peak output or amplitude is equal to the rms output multiplied by $\sqrt{2}$, or, conversely



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

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

Two channels of output are available with independent intensity control.

Faradic

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

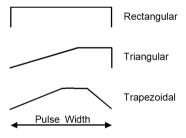
The pulse train is surged in the same way as the sinusoidal output. Two channels of output are available with independent intensity control

Galvanic

Galvanic mode produces a direct current of up to 70mA or 140V in either a positive, negative or auto-reverse (half way through the treatment time) electrical polarity. Two channels of output are available with independent intensity control.

Interrupted galvanic

Interrupted galvanic mode produces three standard pulse shapes.



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



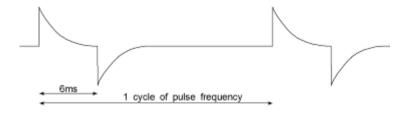
Träbert

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



Medi-Wave

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



Microcurrent

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

S/D curve

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

Output display

The Interferential 960/Multidyne 970 display shows the peak current or peak voltage of each output channel depending on whether constant current (CC) or constant voltage (CV) has been selected for the treatment.

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

The Interferential 960/Multidyne 970 has been designed to meet the requirements of BS EN 60601-1:2006 "Medical Electrical Equipment, Part 1:General requirements for Safety", BS EN 60601-2-10:2015 "Medical Electrical Equipment, Part 2-10: Particular requirements for the safety of nerve and muscle stimulators", and BS EN 60601-1-6:2010+A1:2015 "Medical Electrical Equipment, Part 1-6; General requirements for Safety – Usability.



Appendix C - EMC tables

Guidance and manufacturers declaration – electromagnetic emissions

The Primo Interferential 960/Multidyne 970 is intended for use in the
electromagnetic environment specified below. The customer or the user of the
960/970 should assure that it is used in such an environment.

Flectromagnetic environment

3	Emissions test	Compliance	guidance The 960/970 uses RF energy only for its
4	RF emissions CISPR 11	Group 1	internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
6	RF emissions CISPR 11	Class A	
7	Harmonic emissions IEC 6100-3-2	not applicable	The 960/970 is suitable for use in all establishments other than domestic and those directly connected to the public
8	Voltage fluctuations Flicker emissions IEC 61000-3-3	not applicable	low-voltage power supply network that supplies buildings used for domestic purposes.



Guidance and manufacturers declaration - electromagnetic immunity

The Primo Interferential 960/Multidyne 970 is intended for use in the electromagnetic environment specified below. The customer or the user of the 960/970 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the
IEC 61000-4-2		±8 kV air	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 61000-4-1	<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) 1 For 25 cycles <5% UT (>95% dip in UT) For 5 sec	<5% <i>U</i> T (>95% dip in <i>U</i> T) For 0,5 cycle 40% <i>U</i> T (60% dip in <i>U</i> T) For 5 cycles 70% <i>U</i> T (30% dip in <i>U</i> T) For 25 cycles <5% <i>U</i> T (>95% dip in <i>U</i> T) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 960/970 requires continued operation during power mains interruptions, it is recommended that the 960/970 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 Primo Interferential 960/Multidyne 970 is intended for use in the electromagnetic environment specified below. The customer or user of the Primo Interferential 960/Multidyne 970 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 Primo Interferential 960/ Multidyne 970, 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√P/V₁
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√P/E₁ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter according to the manufacturer and d is the recommended separation distance in metres (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range ^b .
			Interference may occur in the vicinity of equipment marked with the following symbol:

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

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



^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Primo Interferential 960/Multidyne 970 is used exceeds the applicable RF compliance level above, the Primo Interferential 960/Multidyne 970 should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as re-orienting or relocating the Primo Interferential 960/Multidyne 970.

^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 Primo Interferential 960/Multidyne 970

The Primo Interferential 960/Multidyne 970 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the 960/970 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 960/970 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.







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