PlasmaKinetic™ SuperPulse Generator

USER MANUAL

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OVERVIEW OF THE GYRUS ACMI SUPERPULSE GENERATOR

This user manual will familiarize you with the controls and output functions available from your Gyrus ACMI SuprePulse Generator and instruct you on its proper use.

Patents This product may be covered by one or more of the following US patents:
5,944,715; 6,004,319; 6,013,076; 6,015,406; 6,045,549; 6,056,746; 6,074,386, 6,090,106, 6,093,186; 6,152,143; 6,131,579; 6,179,803; 6,210,355; 6,210,405; 6,228,081; 6,234,178; 6,261,286; 6,293,942; 6,303,134; 6,364,877; 6,416,491; 6,416,509; 6,482,202; 6,517,535; 6,371,926; 6,682,501, 6,893,435,6,984,231, 7,214,224, 7,211,081, 7,195,627.
Associated Patents are in place in other countries

OVERVIEW OF THE GYRUS ACMI SUPERPULSE GENERATOR

The Gyrus ACMI SuperPulse Generator forms a versatile platform for Urology and General surgical use.

Ensure that the contents of this User Manual are read and understood before proceeding to use the Gyrus ACMI SuperPulse Generator.

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Gyrus Medical Ltd, Gyrus Medical Inc and are referred to as Gyrus ACMI in this user manual.

This user's manual will familiarize you with the controls and output functions available from your SuperPulse Generator and instruct you on its proper use.

1A. Overview of the SuperPulse Generator

Bipolar electrosurgery is a familiar tool widely employed in surgery. Based on similar principles, the Gyrus ACMI PlasmaKinetic™ (PK) technology combined with Gyrus ACMI PK instruments provides more effective coagulation and cutting of tissues than when similar instruments are used with other electrosurgical generators.

A key feature of the Gyrus ACMI SuperPulse Generator is the capability of the generator to identify the type of Gyrus ACMI PK instrument connected to it. The identification of the instrument causes the generator to operate in the PlasmaKinetic™ (PK) mode that selects a default output designed to produce the desired electrosurgical effect for that particular instrument. This feature provides additional convenience for the user of the device. The user can change this default to obtain a wider range of PlasmaKinetic™ outputs from the device.

1B. Comparison with Conventional Electrosurgery

Conventional bipolar electrosurgery outputs are rarely optimized to the performance characteristics of specific instruments. This can reduce the speed of clinical effect, increase the thermal margin around the application site and result in tissue sticking to the instrument. The following describes the features of the PlasmaKinetic™ Generator when used with Gyrus ACMI PK instruments that distinguishes it from conventional bipolar generators.

- **Vapor Pulse Coagulation (VPC)**

  VPC produces controlled coagulation of vascular pedicles using vapor-focused pulses of energy. VPC has been specifically tailored for delivery through Gyrus ACMI PK Instruments. Once tissue to be coagulated is grasped in a PK Instrument, the tissue is uniquely coagulated using the pulses of PlasmaKinetic™ energy compared to the continuous output employed in conventional bipolar generators. This feature provides controlled and repeatable outcomes under a variety of surgical situations.

- **PlasmaKinetic™ Tissue Cutting (PK)**

  In the PK output mode, the RF energy is used to create an electrical arc into the tissue located between the electrodes of the Gyrus ACMI PK instrument. This provides the tissue the tissue cutting through the vaporization and a level of hemostasis dependent on the selected PK output level. This mode utilizes the conductive properties of the tissue itself and any fluid released from the tissue during application of the RF energy.

1C. Indications for Use

The SuperPulse Generator is a general surgical electrosurgical device intended for use with bipolar instruments used in open, endoscopic and laparoscopic surgical procedures involving the coagulation and cutting of soft tissue. The device is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

1D. Contraindications for Use

The use of this device is contraindicated in patients with the following conditions:

Circumcision procedures
Electrosurgery should not be used for circumcision.

Patients with Pacemakers
Use with caution in the presence of internal or external pacemakers. Interference from an electrosurgical current can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. For further information, consult the pacemaker manufacturer or hospital Cardiology Department.

1E. System Description

The SuperPulse Generator (figure 1.1) is designed for use in surgery for the coagulation and cutting of soft tissue.

A typical system setup would comprise of the following items:

- Generator
- Footswitch (744010) or two 744010 Footswitches connected via connector cable 710003
- Re-usable Connector Cable
- Gyrus ACMI PK surgical instruments and other bipolar surgical instruments.

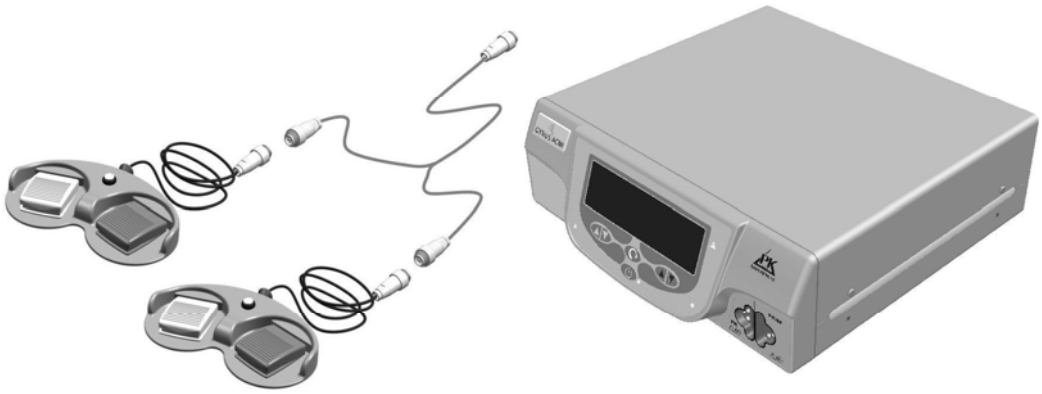


Fig 1.1

1F. Instrument Description

The instruments below are designed and rated to be used with the Generator. For convenience and to improve safety during use, all the dedicated instruments have an internal classification code, which is interrogated by the Generator when the instrument is attached. Default settings and power set adjustment limits are then set appropriately for that particular instrument.

Instruments are supplied sterile and are single use only.

Instrument types:

	Model No	Description	Connector Cable
PlasmaKinetic™ Molly® Forceps	3300PK	33 cm 3 mm Forceps	3 Pin
	3301PK	33 cm 3 mm Forceps w/Trocar	3 Pin
	3330PK	33 cm 5 mm Forceps	3 Pin
	3345PK	45 cm 5mm Forceps	3 Pin
PlasmaKinetic™ Cutting Forceps	3000PK	33 cm 10mm Cutting Forceps	3 Pin
	3001PK	33 cm 10mm Cutting Forceps w/cord	3 Pin
	3005PK	33 cm Cutting Forceps	3 Pin
	3006PK	33 cm Cutting Forceps w/cord	3 Pin
	3045PK	45 cm Cutting Forceps	3 Pin
PlasmaKinetic™ LP Scissors	3804PK	33 cm LP Scissors	3 Pin
	3844PK	45 cm LP Scissors	3 Pin
PlasmaKinetic™ Needle Electrode	3400PK	33 cm Needle Electrode	3 Pin
Lyons® Dissecting Forceps	3700PK	33 cm Dissecting Forceps	3 Pin
	3740PK	45 cm Dissecting Forceps	3 Pin
PlasmaKinetic™ Forceps Macro-Jaw	3600PK	33 cm Macro-Jaw Forceps	3 Pin
	3640PK	45 cm Micro-Jaw Forceps	3 Pin
PlasmaKinetic™ Forceps Micro-Jaw	3601PK	33 cm Macro-Jaw Forceps	3 Pin
	3641PK	45 cm Micro-Jaw Forceps	3 Pin
PlasmaKinetic® L-Hook	3527PK	33 cm L-Hook	3 Pin
PK SEAL® Open Forcep, Curved	3103PK	25 cm (9¾") Seal Open Forcep, Curved	3 Pin
PK SEAL® Open Forcep, Straight	3104PK	25 cm (9¾") Seal Open Forcep, Straight	3 Pin
PK SEAL® Open Forcep, Angle	3105PK	25 cm (9¾") Seal Open Forcep, Angle	3 Pin
PlasmaSpatula®	3220PK	24cm Plasma Spatula	5 Pin
PlasmaSpatula®	3200PK	33cm Plasma Spatula	5 Pin
PlasmaSpatula®	3240PK	45cm Plasma Spatula	5 Pin

1G. Connector Cable Description

The connector cable is designed and rated for 20 uses with the Generator and Instruments.

The Connector Cable is supplied non sterile and should be sterilized before use in accordance with its instructions.

Cable types:

	Model No	Description
PlasmaKinetic™ Single Function	3900	3 Pin
PlasmaKinetic™ Dual Function	3905	5 Pin

1H. Dual Footswitch Connector Cable

This optional re-usable cable allows the connection of two Footswitches to the Generator.

Description	Model No
Dual Footswitch Connector Cable	710003

The safe and effective use of electrosurgery depends to a large degree upon factors and variables solely under the control of the operator. There is no substitute for good surgical technique and properly trained operating room staff. It is important that the operating instructions supplied with this or any electrosurgical equipment be read, understood, and followed.

Electrosurgery has been employed safely in numerous procedures. Before starting any surgical procedure, the physician should be familiar with the medical literature, complications and hazards of electrosurgery in that procedure.

2A. General

WARNING Hazardous Electrical Output: This equipment is for use only by qualified personnel.

WARNING Do not use a monopolar generator/accessories simultaneously with the SP generator. Activation of a monopolar generator/accessories may cause interference with the SP generator resulting in user message changes on the display. Before proceeding with surgery, confirm proper power settings are displayed on the generator. Ensure the appropriate output setting is enabled for the desired surgical outcome.

WARNING Direct contact between activated monopolar accessories and SP generator connected accessories could damage the SP generator. If such damage is suspected, the SP generator should be returned to Gyrus ACMI for inspection.

WARNING Use with caution in the presence of internal or external pacemakers. Interference from an electrosurgical current can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. For further information, consult the pacemaker manufacturer or hospital Cardiology Department.

WARNING Do not use electrosurgical equipment unless properly trained in its use in the specific procedure intended.

WARNING Electrodes and probes used with monitoring, stimulation, and imaging devices (or similar equipment) can provide a path for high frequency current even if they are isolated. To reduce the risk of an inadvertent burn at the electrode site, place the electrode and / or probe as far away as possible from the electrosurgical site.

CAUTION If two accessories are connected to the SP generator, ensure the appropriate accessory is selected prior to activation. Activation of the unintended accessory could cause unintentional tissue effect.

CAUTION Do not activate electrodes while in contact with other instruments as unintended tissue effect may occur.

CAUTION Do not activate the generator in an open circuit condition. To reduce the risk of unintended effects, activate the generator only when the active accessory is near or touching the target tissue.

CAUTION Use the lowest appropriate power setting to achieve the desired effect.

CAUTION This equipment is capable of producing a physiological effect.

CAUTION Read the instructions, cautions, and warnings provided with Gyrus ACMI PlasmaKinetic™ System accessories before use. This device is an integral system; only use Gyrus ACMI approved accessories with the Gyrus ACMI Superpulse Generator.

CAUTION If possible, avoid the use of needle style instruments for any physiological monitoring equipment that may be connected to the patient during electrosurgery.

CAUTION Where practical, only use monitoring equipment that incorporates high frequency current limiting devices during electrosurgical procedures.

CAUTION The connector cable should be positioned so that it avoids contact with the patient and any other leads.

CAUTION Studies have shown that electrosurgical smoke generated during electrosurgical procedures can be potentially harmful to surgical personnel.

CAUTION Examine all accessories and connections to the electrosurgical generator before use. Improper connection may result in arcs and sparks, accessory malfunction, or unintended surgical effects.

CAUTION Do not insert fingers or objects other than the correct cables into the socket. Only activate the footswitch with an instrument attached.

WARNING The PK or SP system has not been cleared for tubal sterilization. Do not use this system for these procedures.

2B. Servicing/Equipment Disposal

CAUTION Electrical Shock Hazard: Do not tamper with the generator housing or attempt to remove the control panel. Refer to authorized personnel for service.

NOTE
1. There are no user serviceable parts within the product.
2. For maintenance of the generator, refer to the recommended periodic equipment safety checks in Section 13.

CAUTION The generator contains electronic printed circuit assemblies. At the end of the useful life of the equipment, it should be disposed of in accordance with any applicable policies relating to obsolete electronic equipment.

CAUTION Dispose of any system accessories according to normal institution practice relating to disposal of biologically contaminated items.

2C. Fire/Explosion

DANGER Explosion Hazard: Do not use in the presence of flammable anesthetics.

WARNING Explosion Hazard: The following substances will contribute to increased fire and explosion hazards in the operating room:

- Flammable substances (such as alcohol based skin prepping agents and tinctures)
- Flammable agents used for cleaning or disinfecting, or as solvents of adhesives should be allowed to evaporate before the application of electrosurgery. There is a risk of pooling of flammable solutions under the patient or in body cavities during endoscopic surgery. Any fluid pooled in these areas should be mopped up before electrosurgery is used.
- Endogenous gases.

- Flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen enriched atmospheres.
- Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of electrosurgical equipment.

The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times.

WARNING Fire/Explosion Hazard: Verify that all oxygen circuit connections are leak free before and during use of electrosurgery. When using electrosurgery in the same room with any of the above substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is being performed.

2D. Before Surgery

Active Accessories

WARNING Electric Shock Hazard: Do not connect wet accessories to the generator.

WARNING Electric Shock Hazard: Ensure that all accessories are correctly connected and that no metal is exposed.

WARNING Do not attempt to re-use instruments labeled for Single Use Only. Heat or chemical Sterilization may render the instrument mechanically or electrically unsafe

CAUTION Read the instructions, warnings and cautions provided with the instrument accessories before using.

CAUTION Accessories labeled as re-usable must only be processed according to the recommended procedure and, where appropriate, recycled the specified number of times.

CAUTION Use default power levels to test an accessory.

CAUTION Always inspect the system accessories for damage prior to use. In particular, check the cables of any re-usable accessory for possible insulation damage.

CAUTION Use only Gyrus ACMI approved accessories supplied for use with this product. Product damage or accessory failure may otherwise result during use.

SuperPulse Generator

WARNING Electric Shock Hazard; Connect the generator power cord to a properly grounded receptacle. Do not use power plug adapters.

WARNING Fire Hazard; Do not use extension cords.

CAUTION Provide as much distance as possible between the generator and other electronic equipment (such as monitors) as an activated generator may cause interference with them.

CAUTION Non-function of the generator may cause interruption of surgery. Ensure that all installation procedures are followed and that all connectors are correctly inserted before use. A backup generator should be available for use.

CAUTION Do not stack equipment on top of the generator or place the generator on top of electrical equipment.

CAUTION Do not set the activation tone down to an inaudible level. The activation tone alerts surgical personnel when an accessory is active.

2E. During Surgery

Contact With Metal Objects

WARNING Use extreme caution when using electrosurgery in close proximity to or in direct contact with any metal objects. Do not activate in contact with another metal object. Localized heating of the instrument and the adjacent metal object may result in product damage or inadvertent injury.

WARNING While using electrosurgery during a surgical procedure, the patient should not be allowed to come into direct contact with grounded metal objects (e.g., surgical table frame, instrument table, etc.). If this is not possible, use extreme caution to maximize patient safety. The use of antistatic sheeting is recommended for this purpose

SuperPulse Generator Power Settings

WARNING Do not simultaneously activate the SuperPulse Generator whilst activating with any other electrosurgical equipment (on the same patient). Failure to observe this may result in the attached instrument being unrecognized by the system.

CAUTION Upon reconnection of an instrument to the SuperPulse Generator, or after navigation using the Mode / Menu button, the power settings for cutting and coagulation may be changed from previously selected values.

WARNING Confirm proper power settings are displayed on the generator before proceeding with surgery. Ensure the appropriate output setting is enabled for the desired surgical outcome before activating the instrument and ensure that activation is for the minimum time to achieve the desired surgical effect.

CAUTION Failure of the HF SURGICAL EQUIPMENT could result in an unintended increase or decrease in output power.

CAUTION Use caution when overriding the default power settings.

CAUTION Should a power supply interruption occur, the generator will revert to its Standby state. The user should press the standby/on button to restart the generator and then press the Mode / Menu button on the front panel to accept the default instrument settings.

Instrument Accessories

WARNING When not in use, place instruments in a clean, dry, non-conductive, and highly visible area not in contact with the patient. Inadvertent activation while in contact with the patient may result in burns.

WARNING Do not wrap accessory cords around metal objects. This may induce currents that could lead to injury to the patient or surgical personnel.

WARNING Fire Hazard: Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical accessories, which are activated or hot from use, can cause a fire.

Endoscopic Procedures

WARNING As visualization may be impaired during endoscopy for a number of reasons, be particularly alert to these potential hazards:

- Ensure the tip of the instrument is visible before activation.
- The instrument tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of activated electrodes outside of the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrical currents carried through conductive objects. Electrical current may be generated in conductive objects by direct contact with the active instrument, or by the active or return instrument being in close proximity to the conductive object while activated.
- Carefully insert and withdraw instruments from trocars to avoid the possibility of damage to the devices and/or injury to the patient.

2F. After Surgery

WARNING Electric Shock Hazard. Always unplug the generator before cleaning.

CAUTION Do not reuse or resterilize accessories labeled “disposable” or “single use only.”

2G EMC Classification

The SuperPulse System has been manufactured and tested to the following requirements: Group 2 Class A as per IEC60601-1-2 (2001)

EMC PRECAUTIONS

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in this document.

EMC WARNINGS

- The generator should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary both the generator and other equipment should be observed to verify normal operation in the configuration in which it will be used.
- The EMC classification of the SuperPulse system (class A) is suitable for use on dedicated supply systems not connected to the public mains network, such as hospitals.

  NOTE: Although class A limits have been derived for industrial and commercial establishments, administrations may allow, with whatever additional measures necessary, the installation and use of class A ISM equipment in a domestic establishment or establishment connected directly to domestic electricity power supplies.

- Portable and mobile RF communications equipment can affect medical electrical equipment.
- The use of accessories and cables other than those for which the system was designed can significantly degrade emissions and immunity performance.

- Keep the accessory cables away from cables from other electrical equipment. Electrical currents may be induced in the other equipment causing unintended effects.

- Do not use a monopolar generator/accessories simultaneously with the SuperPulse generator. Activation of a monopolar generator/accessories may cause interference with the SuperPulse generator resulting in user message changes on the display. Before proceeding with surgery, confirm proper power settings are displayed on the generator. Ensure the appropriate output setting is enabled for the desired surgical outcome.

- Provide as much separation as possible between the generator and other electronic equipment (such as monitors). When activating the generator, unintended electromagnetic coupling may cause interference with the other equipment.

- Should any unintentional effects appear upon other equipment when using the generator, repositioning the generator, the connecting leads or other equipment may alleviate the problem. It may also help to use different mains supply sockets for any affected equipment

The electrosurgical generator described in this manual, in conjunction with the Gyrus ACMI PK Instruments, is designed to provide advanced electrosurgical effects during endoscopic surgery.

3A. Responsibility of the Manufacturer

The manufacturer is responsible for safety, reliability and performance of the equipment only if:

- Installation procedures in this manual are followed.
- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by the manufacturer and the electrical installation of the relevant operating room complies with local codes and regulatory requirements.
- The equipment is used in accordance with this User Manual and the Instructions For Use that accompany all system accessories.

3B. Generator Power Requirements

Please refer to section 10-1 for full voltage details.

Check the Generator Power Connection

The power connector meets all requirements for safe grounding. Its purpose should not be defeated by using extension cords or any form of adaptor. When disconnecting from the mains socket or from the generator, cords should always be grasped by the plug. Do not pull on the cord itself.

3C. Grounding of the Generator

To ensure user safety, the generator must be properly grounded through the inlet plug and power cord. Use only hospital grade power cords.

IMPORTANT Ensure that the electrical installation of the relevant room complies with local codes and regulatory requirements.

3D. Routine Maintenance of the Superpulse Generator

It is recommended that the generator be inspected by qualified service personnel in accordance with Section 13, Periodic Equipment Safety Checks.

3E. Medical Electrical Systems

When the Superpulse generator forms part of a medical electrical system (as defined in EN 60601-1 2.201) or is used with an endoscope that is compliant with EN 60601 2-18 the following applies:

- The Superpulse generator is to be placed outside the patient environment.
- The Superpulse generator footswitch accessory is to be placed outside the sterile field.
- The instruments intended for use with the Superpulse generator are suitable for use inside the patient environment.

WARNING Multiple portable socket outlets shall not be placed on the floor.

WARNING Additional multiple portable socket outlets or extension cords shall NOT be connected to the system.

4A. Gyrus ACMI SuperPulse Generator Indicators and Displays

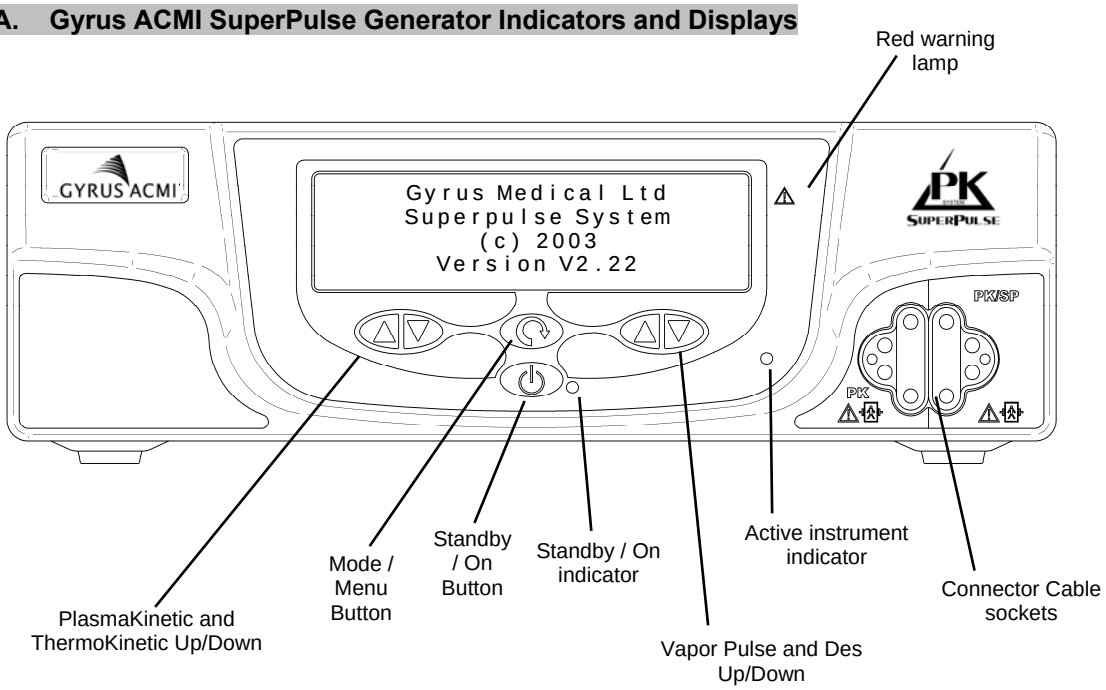


Fig 4.1

Keypad : Standby/On, Up, Down Arrows and Mode / Menu Button

Standby / On

The Standby/On button switches the Generator back and forth between the Standby and Idle / Ready states. The green indicator will change from flashing to continuous when the equipment state changes from Standby to Idle / Ready by pressing the button. To place the generator into Standby press the standby button. When prompted press again to confirm entry to Standby is required.
Following an error condition the generator may be reset by pressing the Standby/On button twice.

Up/Down Arrows

Depressing the up or down arrow when parameter change is permitted increases or decreases the parameter step-wise. Holding the button down will increase or decrease the value in preset steps

Mode / Menu

This button provides access into the waveform selection and setup menus.

Repeated short presses will give access to the frequently used functions, listed below: -

- Cut waveform selection (PK)
- Coagulation waveform selection (VP/DES)
- Volume

A long press will give access to the setup menu, giving access to the following functions below with repeated short presses: -

- Display intensity
- Key click on/off
- Select language
- Enter PIN Code

NOTE If there is no user activity for a short period, the generator will exit the menu and return to the previous state.

When a PK connector cable is attached, the symbol below appears on the display.

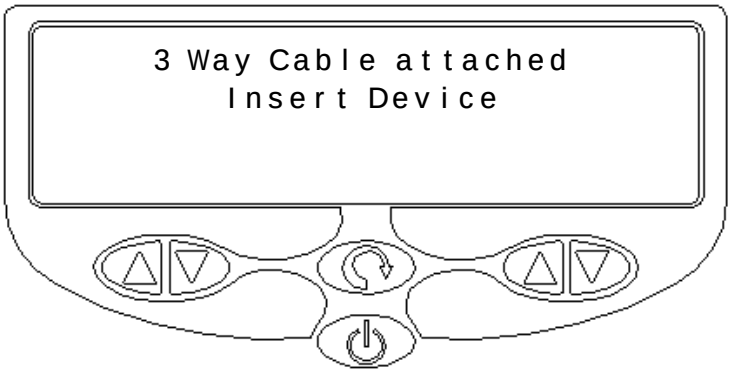


Fig 4.2 Screen for one 3-Way PK cable installed on the selected socket.

Output Displays for PK Instruments

The display is split into two halves; the upper portion of the display is used to indicate the type of instrument active, that is the instrument that will provide an output when the Cut or Coag pedal is pressed. The lower half of the display indicates the output waveform type and power selected.

The left lower portion displays Plasmakinetic™ (PK) mode selection PK1, PK2, PK3, and ThermoKinetic mode selection T1 or T2, with the default power setting from 10 to 200 dependent on the type of Gyrus ACMI PK Instrument attached.

The right portion displays Vapor Pulse Coagulation (VPC) mode selection VP1, VP2, VP3 and standard desiccate (DES), with the default power setting from 10 to 120 dependent on the type of Gyrus ACMI PK instrument attached. The VPC mode is only available with Gyrus ACMI PK instruments.

The appropriate display will flash and an audible alarm will sound when an output is activated.

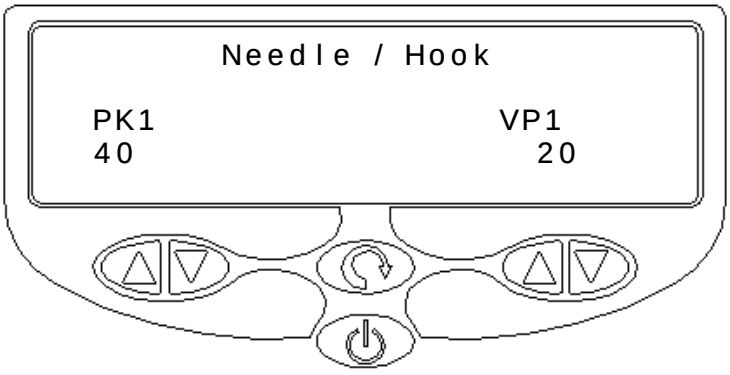


Fig 4.3 Screen for Needle or Hook selected

NOTE The PK output is not available for some PK instruments. The lower left hand portion of the display remains blank in this case.

4B. Output Mode Selection and Power Controls

When using a Gyrus ACMI PK instrument, the generator default power, and waveforms for that instrument will be selected.

Power Up/Down - These buttons adjust the power setting; the yellow arrow buttons for the PlasmaKinetic™ (PK) and ThermoKinetic (T) outputs, and the blue arrow buttons for the Vapor Pulse Coagulation (VPC) and Desiccate (DES) output. Press the appropriate button once for a power increment or decrement. Holding down the button accelerates the rate of change of setting.

NOTE Power can only be adjusted once an instrument is properly connected to the generator.

PlasmaKinetic™	PK3	High impedance tissue (fatty, vascular tissue)	
Cut	PK2	Medium impedance tissue	
	PK1	Low impedance tissue (thin tissue)	↑ Voltage increasing
ThermoKinetic	T2	High impedance tissue (fatty, vascular tissue)	
Cut	T1	Low impedance tissue (thin tissue)	↑ Voltage increasing
Coagulation	DES	General Purpose, Non tissue-specific desiccation	
	VP3	High impedance tissue (fatty, vascular tissue)	
	VP2	Medium impedance tissue	
	VP1	Low impedance tissue (thin tissue)	↑ Voltage increasing

NOTE Output mode selection can only be performed with an instrument and connector cable attached to the generator. The range of modes available will depend on the type of Gyrus ACMI PK instrument being used.

NOTE If the Mode / Menu button on the front panel is quickly pressed and released the generator enters a configuration state, pressing and holding the Mode / Menu button at any time exits this state.

Mode Selection using Gyrus ACMI PK Instruments - There are three PlasmaKinetic™ Modes shown as PK1, PK2 and PK3 that produce a tissue effect increasing from PK1 to PK3 (PK3 delivers power more effectively to higher impedance tissue than PK1). Two ThermoKinetic outputs are also available, shown as T1 and T2, which continuously switch between a PlasmaKinetic™ and Desiccate output during activation. A ThermoKinetic output will provide a greater degree of hemostasis during tissue cutting compared to a PK setting.

Three VPC mode levels and the desiccate (DES) are available.

VP1 is optimal for low impedance tissue, VP2 for intermediate impedance tissue and VP3 for higher impedance tissue or larger diameter instruments. The frequency of pulses in VPC mode will also vary depending on the type of instrument attached: generally, the larger the tissue contact area, the slower the pulses. DES provides a conventional continuous bipolar output.

The modes associated with the blue and yellow pedals can be individually assigned. To change to desired mode press the Mode / Menu button until it is seen on the display (yellow pedal mode appear on the LHS and blue pedal mode on the RHS).

Using the UP/DOWN buttons as indicated on the screen, will cycle through the available modes for the respective pedal (see Fig 4.4 Screen for coag waveform selection below).

When the desired mode is displayed, a further press on the Mode / Menu button will complete the selection

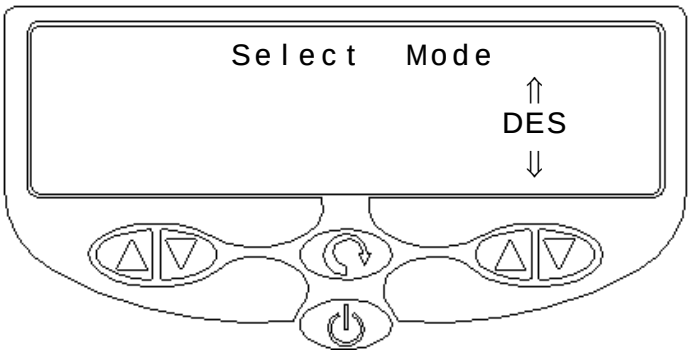


Fig 4.4 Screen for coag waveform selection

Socket Selection

The generator permits two instruments to be fitted simultaneously, via the two 5-way connectors.

Only one socket can deliver RF at any one time. When the generator is switched on from the standby state, it initially operates an automatic socket selection mechanism, and assists primary connection by activating whichever socket first has an instrument attached. The instrument connected to the active socket is indicated on the display. Thereafter socket selection can only be altered manually, by pressing the black mode footswitch, ensuring that the surgeon always has control over which instrument is activated.

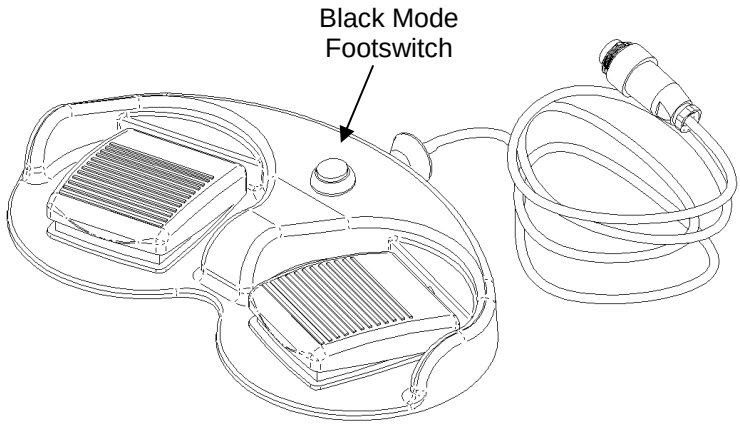


Fig 4.5 Footswitch

Footswitch - Blue Pedal
The blue footswitch pedal is used to administer desiccate and VP output waveforms. The output will be present while the footswitch is held down.

Footswitch – Yellow Pedal
The yellow footswitch pedal is used to administer PK (cut) and ThermoKinetic waveforms. The output will be present while the footswitch is held down.

Footswitch – Black Mode Footswitch
The black mode footswitch enables a rapid change between PK instruments.

Generator Switch On/Off

The mains power On/Off rocker switch is located on the top left of the rear panel (viewed from front). The Generator is switched on by pressing the side marked l. The generator will display the Serial number of the generator, then the internal tests are performed then the green LED below the Mode / Menu button will come on continuously, then flash after a short time. The generator is then Ready state dependent on whether an instrument has been fitted.

The generator display will dim after a period of 30 minutes of not being used and will automatically enter Standby state if it is not used for a period of four hours.

It is advisable to switch off the Generator whenever it is not in use for any extended period, by using the rear panel switch. The side marked “0” should be pressed to do this.

To enable use of the generator the Standby / On button must be pressed and the generator will then enter the Idle state if no instrument is fitted, or the Ready state if an instrument is fitted.

If an instrument is present at switch on then the user has to accept the default powers, by pressing the Mode / Menu button when prompted.

4C. SuperPulse Generator Indicators, Set-up and Malfunction Displays

Impedance Indicator

Impedance is measured by the generator to provide assistance in determining the tissue effect endpoint, in addition to the visual and tactile feedback available to the user. The impedance of the tissue rises during the desiccation/coagulation process. Indication of this is provided via audible and visual signals to be used as a guide to determining when treatment is complete.

The impedance indication is available as a bargraph with audible indication, or the indications can be removed if desired.

The impedance display is in the form of a bar graph.

For the bargraph display thirteen diamonds are displayed initially with the number reducing as the impedance rises.

The audible tone that accompanies the visual display starts at a high pitch and falls as the impedance increases.

Activation Status

Activate - When the generator is activated, the power display of the selected output flashes and an audible tone sounds. If neither occurs, then there is a malfunction.

Activate Tones and Impedance Indicator Volume Adjustment

Volume Adjustment - The activation tone volume can be adjusted between minimum and maximum using the up control of the desiccate (blue) power control. Depress and release the Mode / Menu button until the symbol **"SELECT VOLUME"** appears (Fig 4.6 Screen for Alarm volume selection). Press and release the Mode / Menu button once more to accept the setting.

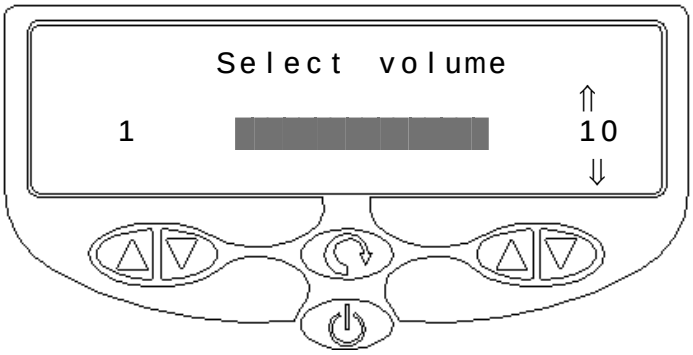


Fig 4.6 Screen for Alarm volume selection

System Failure Displays

Non-critical (Soft) Faults

Shorting

For jawed or grasping Gyrus ACMI PK instruments, if an instrument short occurs an oscillating audible alert is sounded and the display shows the symbol "Regrasp". The surgeon should release the instrument jaw and reposition the tissue.

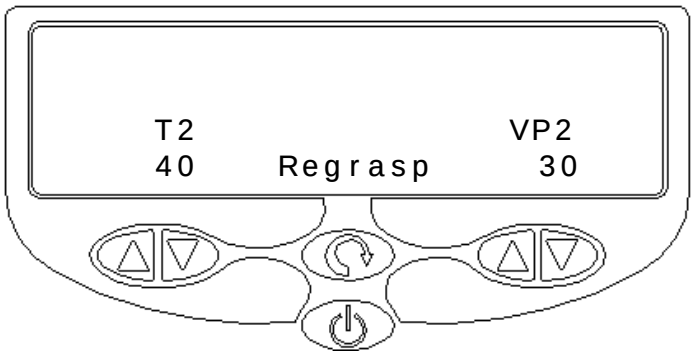


Fig 4.7 Screen for the selected PK electrode shorted

For non-grasping Gyrus ACMI PK instruments, if a Generator "Power Limit" message persists it is indicative of two or more poles of the electrode tip being bridged by a short. This could be caused by contact with other metallic instruments present in the surgical field, or possibly even a build-up of eschar between poles at the electrode tip. If the condition does not resolve itself, the generator after a few seconds, interrupts RF activation with the

"OUTPUT SHORTED, RE-APPLY PEDAL" symbol (Fig 4.10 Screen for shorting of a non-grasping electrode), until the pedal is released and pressed again. Power levels will remain the same as those previously in use. This method of resolution is appropriate where the cause of the short is accidental, transitory and understood.

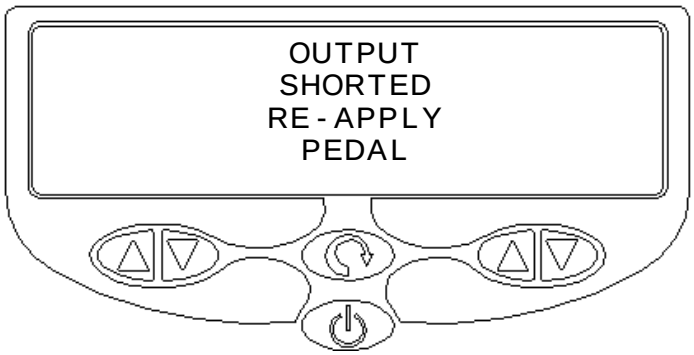


Fig 4.8 Screen for shorting of a non-grasping electrode

Storage at low temperatures – The generator will detect where the enclosure temperature is below the specified minimum allowable for use, and will display a 'WARMING UP" message until an acceptable temperature is reached internally, whereupon normal operation will resume. This condition is possible where the generator has been brought directly into the operating room from a cold storage environment.

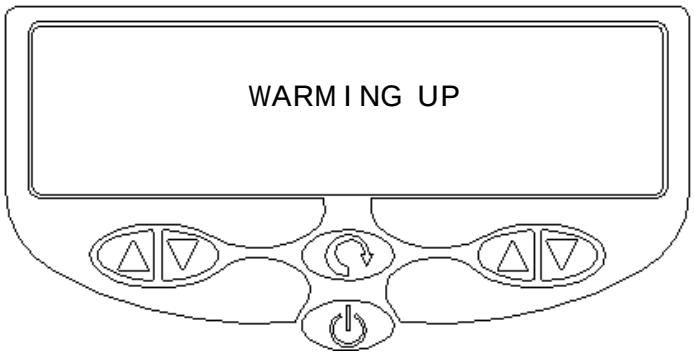


Fig 4.9 Screen for an excessively cold condition

Foot pedals stuck on – The generator will detect where one or more the foot pedals appears to be stuck on, and will wait until the condition disappears before resuming normal behaviour. This condition can be inadvertently caused by the inverting the footswitch or standing on a pedal as the generator is switched on.

Non-critical (Recoverable) Faults

Fault - If a fault is detected during set-up or during use a fault code message is displayed as indicated by the “Fault Code XXX REF XX” symbol on the front panel display (Fig 4.10 Screen for recoverable fault display). Refer to Section 9, Operating Room Troubleshooting.

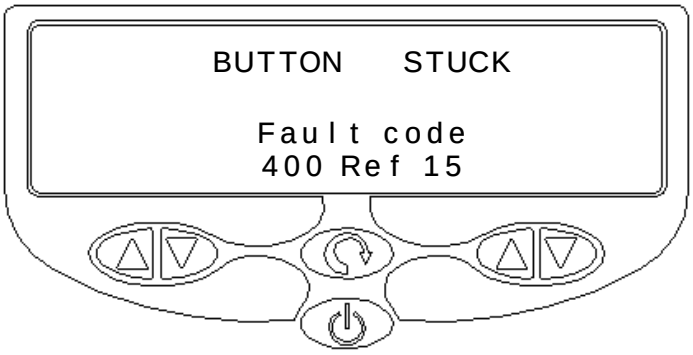


Fig 4.10 Screen for recoverable fault display

Critical (Non-recoverable) Errors

Red Warning Symbol - Except during the self-test routine and a non-critical failure, illumination of the red warning symbol on the front panel when accompanied by the “Error Code XXX REF XX” symbol (Fig 4.11 Screen for critical error display) on the front panel display indicates a critical failure. In the case of a critical failure, **DO NOT ATTEMPT TO USE THE UNIT**. Please refer to Section 11 for information.

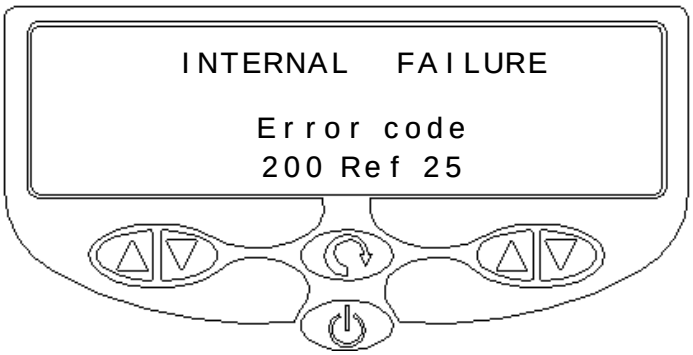


Fig 4.11 Screen for critical error display

SuperPulse Generator Connectors and Sockets

The PK Single Function connector cable is connected to the generator through either of the two PK connector cable sockets on the front panel of the generator (Fig 4.1).

The electrical power cord; footswitch cable and protective earth cable are connected to the generator through fittings on the rear panel (Fig 4.17).

A five-way cable may be available to enable use of tri-polar instruments.

4D. CHANGING THE DISPLAY LANGUAGE

From the Superpulse generator Idle state (with the VFD screen showing the “Connect PK Cable” or “X Way Cable Attached Insert Device” message) press and hold for 3 seconds the Mode / Menu button on the Superpulse front panel.

The Superpulse generator VFD screen will show the “Display Intensity” message, press and release the Mode / Menu button twice so the following screen is displayed.

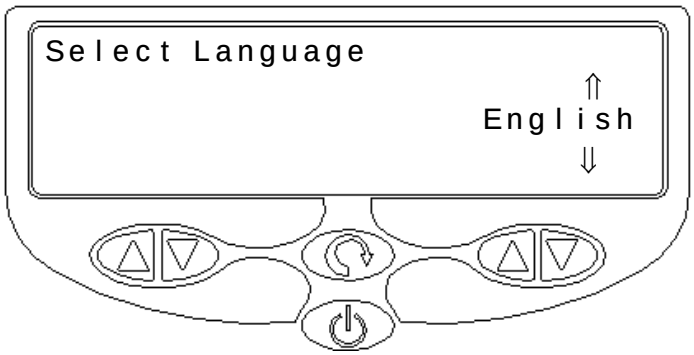


Fig 4.12

Use the right hand arrow buttons to change the language as required. Press and hold the Mode / Menu button down to return to the previous state.

Once the language has been changed from the factory default of English, the Superpulse will continue to use the selected language for all instructions, performance information and error messages on the generator VFD display.

4E ENABLING ADDITIONAL INSTRUMENTS VIA A PIN CODE

As additional instruments are released for use with the Superpulse generator these can be added to the Superpulse generator software and enabled for use. This is done by entering a PIN code into the Superpulse generator using the front panel buttons. The PIN must be entered twice in succession to enable these instruments.

Once the PIN has been entered, the Superpulse generator can then use these additional instruments.

Your local sales representative can provide you with this information as it becomes necessary or alternatively contact Customer Services as detailed at the front of this manual.

The enabling of these instruments is a one off action that must be performed in order to use these additional instruments. The Superpulse generator will remember that PIN and continue to allow the use of these instruments even after it has been switched off.

This facility can be setup in one of two ways:-

Note: If the PIN number entry screen cannot be accessed, contact your local sales representative, or alternatively contact Customer Services as detailed at the front of this manual.

a) Without instrument available at the time of PIN entry

This option can be done at any time prior to surgery.

From the Superpulse generator Idle state (with the VFD screen showing the "Connect PK Cable" or "Insert Device" message) press and hold for 3 seconds the Mode / Menu button on the Superpulse generator front panel.

The Superpulse generator VFD screen will show the "Display Intensity" screen, press and release the Mode / Menu button three times so the Superpulse generator displays the following screen.

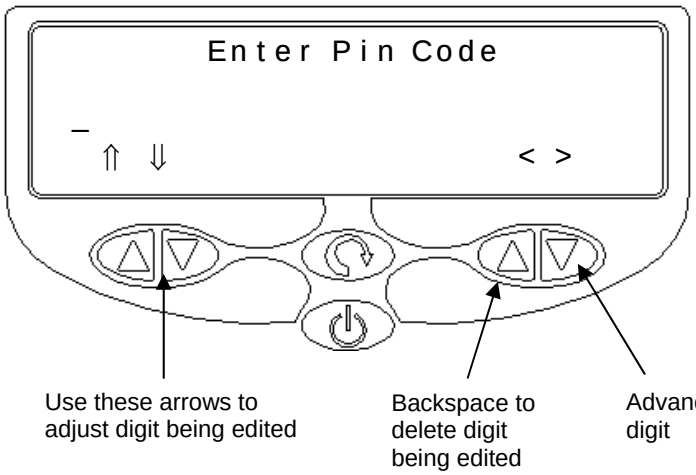


Fig 4.13

Once the PIN code has been entered and is displayed correctly then press the Mode / Menu button, the display will change to that shown in Fig 4.14 below.

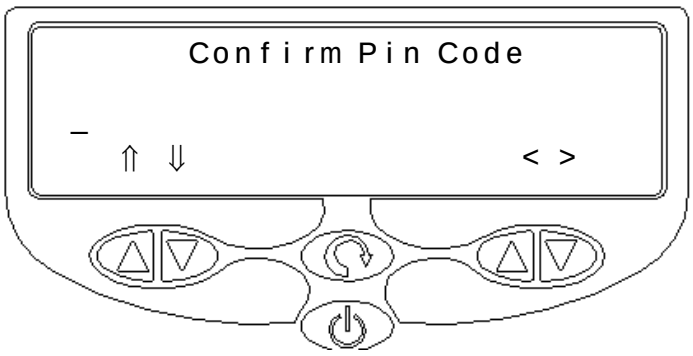


Fig 4.14

Re-enter the PIN code using the same procedure, once this is correctly displayed press the Mode / Menu button, the Superpulse generator will bleep to acknowledge the PIN entry.

If the code is entered incorrectly then the following display will be shown

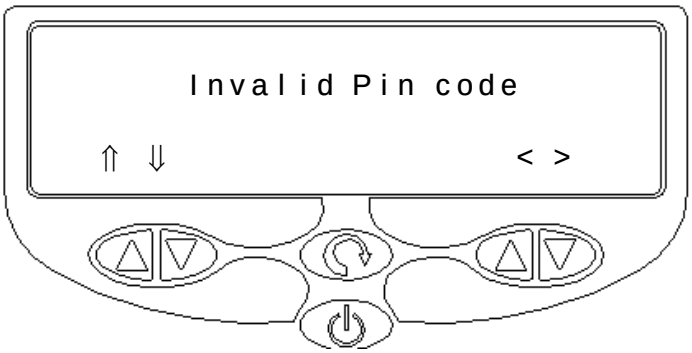


Fig 4.15

The PIN entry sequence must then be repeated, press any arrow button to restart the PIN entry sequence.

Note: If the PIN Entry screen is left displayed for two minutes at any time without any buttons being pressed the Superpulse will return to its default screen “Connect PK Cable” or “Insert Device” and the PIN entry process will have failed and will need to be repeated.

b) With Instrument available at time of PIN entry.

This allows the instrument to be enabled at the start of the surgery if it has not been done previously. Insert the instrument, if the following display is shown on the VFD,

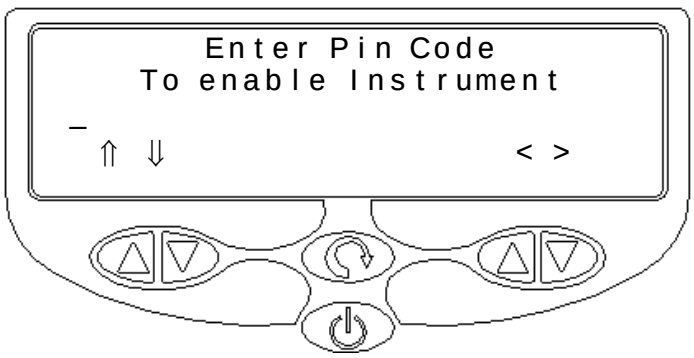
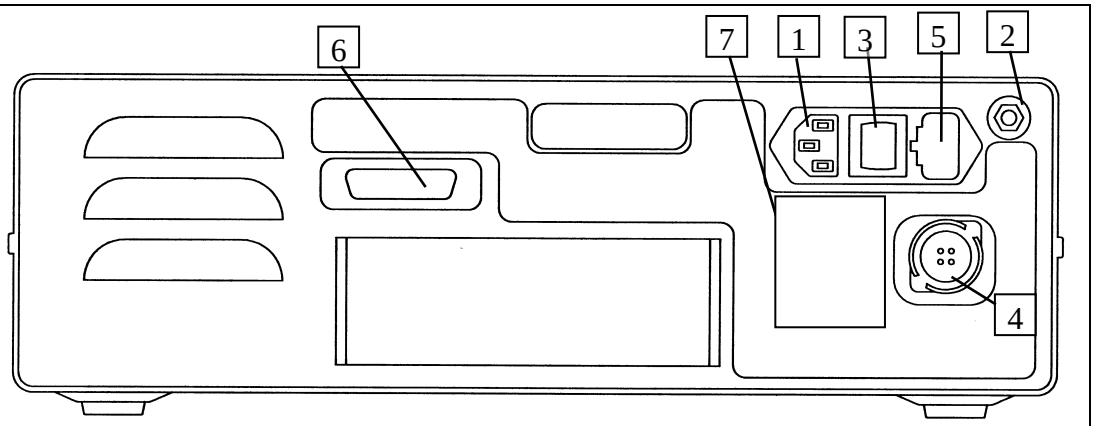


Fig 4.16

then the PIN code must be entered as detailed previously in section 4F, however no timeout will occur when the instrument is connected.



1. **AC Power Connector**
   Connector for the AC line power cable.
2. **Equipotential Connector**
   The connection for the Potential Equalization Conductor terminates at this point.
3. **Power Switch**
   Switch to turn the Generator on/off.
4. **Footswitch Connector**
   The Footswitch is used to initiate the RF On & Mode.
5. **Fuse Compartment**
   Location of line fuses.

   ⚠ **WARNING:** Replace only with T-series 10A, 250V fuse certified to IEC 127 (5 x 20 mm fuse).

6. **RS232 Connector**
   Used by qualified Gyrus ACMI technical personnel only. Do not connect any device to this port.
7. **Fuse Label**
   Provides information on correct fuse to use for fuse replacement.

Fig 4.17

This section describes how to set up the SuperPulse Generator before surgery. Prior to using the system, you should ensure that the following associated equipment has been prepared for use:

- An appropriate sterilized reusable Connector Cable.
- An appropriate Gyrus ACMI PK instrument(s) for the procedure to be performed.

5A. Power up the Generator

Install the Generator

- Place the generator on a table, cart, racking system or other stable platform that can be positioned as close as possible to the operative site during use.
- Ensure that the generator is standing on a flat, firm surface and that it is not at risk of being accidentally dislodged during the course of operating theatre activity.
- Provide at least four inches of space from the rear of the generator. Never cover the generator or stack other equipment on top of it. It is normal for the generator to become warm during use so ensure adequate ventilation.

Connect the Generator

Plug the supplied AC power cord into the receptacle on the rear of the generator and then connect the other end of the cord directly to an AC power point. Avoid the use of extension cords or multiple plug adaptors. Wherever possible, avoid trailing leads and neatly store excess power cord.

Connect the Footswitch

Connect the footswitch to the receptacle at the rear of the generator by orienting the lug on the plug with the groove in the receptacle and pushing the plug into place. Secure the plug by screwing down the locking ring in a clockwise direction.

Switch the Generator On

With the rear panel switch on,.

Press the Standby / On button and verify the completion of the system initialization. The system is now ready for use with any connected instrument.

5B. Select and Connect the Connector Cable

Depending on which instruments are to be used select either a 5 or 3-way PK connector cable.

Introduce the sterile connector cable to the sterile instrument table or trolley according to the sterile handling practices at your facility.

The cable and connectors should be inspected for any processing damage.

IMPORTANT If any of the connector pins are bent or if the cable shows any signs of crush damage, cracking or distortion, it must be discarded. The generator end of the connector cable should then be passed to a non-sterile operative for connection to the generator. Ensure that sufficient length of cable is retained for connection to the instrument, that sufficient slack is provided so that operation is not impeded, and that sufficient slack is also allowed for attachment to the surgical drapes.

5C. Attach Gyrus ACMI PK Instrument to PK Connector Cables

Connect the Gyrus ACMI PK instrument to the PK Connector Cable by aligning the two connector halves and pushing together. Once connection is made the generator display will change to the default settings appropriate to the instrument being used.

This section describes how to use the SuperPulse Generator during surgery.

6A. Recommendations During Surgery

- Refer to the Cautions and Warnings at the front of this manual.
- Unless circumstances dictate otherwise, use Gyrus ACMI PK instrument default settings to enhance patient and user safety.
- Remove any gross tissue build-up from the tips of the instruments to maximize surgical effect.
- Activate only for sufficient time to achieve the desired surgical effect; and use the Impedance and Cut bar graph Indicator systems to aid, but not replace, surgeon judgment.
- Ensure that the correct footswitch is used for the desired output mode.
- Tissues dry out during surgery and regular irrigation of tissues with saline will ensure repeatable surgical effects.
- It should be noted that the SuperPulse Generator incorporates a PK mode output power boost feature on some instruments. When connected to a PK Plasma-V Resectoscope Instrument, this boost is designed to allow rapid formation of the plasma corona around the tip of the instrument. It functions by automatically increasing the selected power output setting of the SuperPulse Generator by 25% during the first 400 milliseconds of cut activation, up to a maximum output of 200W. Similarly when connected to a PlasmaSEAL instrument, the boost functions automatically by increasing the power output to 200W for the first 200 milliseconds of cut activation, thereafter returning to the selected power output setting.

6B. PK Default Settings

The power settings and output mode used for the intended procedures vary considerably both with the surgeon's technique and the configuration of the instrument being used. Some experience may be required before optimal power settings to suit the particular surgical technique are determined. Until the surgeon becomes familiar with the characteristics of the system, caution should be used when adjusting PK default settings, which have been allocated to provide safe and effective performance.

The Generator incorporates a Vapor Pulse Coagulation (VPC) mode, which is the default applied to many of the Gyrus ACMI PK instruments. This mode is designed to reduce both thermal margins and tissue sticking, providing controlled and repeatable outcomes under a variety of surgical situations. The energy absorption is measured during each pulse to provide the Impedance Indicator feedback as a guide to when tissue treatment is completed.

6C. Activation: Output Selection and Audible Tones

In common with conventional electrosurgical generators, output activation is achieved using the blue and yellow pedals of the footswitch.

BLUE PEDAL: Vapor Pulse Coagulation (VP1, VP2, VP3) and Desiccate. (DES). Activation accompanied by flashing of the desiccate power display and an audible tone. In VP1, VP2 VP3 modes used in conjunction with Gyrus ACMI PK instruments, the audible tone acts as the Impedance Indicator feedback. On instruments capable of VP activation modes, the DES mode also has the same audible Impedance Indicator feature.

YELLOW PEDAL: PlasmaKinetic™ (PK1, PK2, PK3) and ThermoKinetic (T1, T2) depending on output mode selection. Activation is accompanied by flashing of the PK or T power display and audible tone.
The Gyrus ACMI PlasmaSEAL instrument provides special audible and visual indications of cut activation time: the tone changes during continuous activation. Similarly a bar graph displays a number of ">>>>>>>>>" during the activation.

IMPORTANT Familiarize yourself with the audible output tones to verify output selection as it is often difficult to visualize the footswitch pedals during surgery. It is important to recognize the tones relating to the various output modes.

Electrical Short Indication

In PK mode, an audible and visual alert warns of an instrument short. For non-grasping instruments, the cause of the short is likely to be contact with other metallic instruments in the surgical field. For jawed or grasping instruments, the surgeon should release the instrument jaw and reposition the tissue.

IMPORTANT Shorting can be caused by the instrument jaws being locked too tightly. If this occurs, release tissue then re-grasp.

6D. Changing Output Mode and Power Setting during Surgery

With an instrument and connector cord properly attached, power adjustment can be made at any time other than while activating or while the generator displays a malfunction. The permissible range of power adjustment will be limited by the identification code of the instrument.

When using a Gyrus ACMI PK instrument, adjustment of output modes: VP1, VP2, VP3 and PK1, PK2, PK3, T1 and T2, can be changed at any time other than while activating or while the generator displays a malfunction. The permissible range of mode adjustment will be limited by the identification code.

6E. Changing Instruments During Surgery

Once a Gyrus ACMI PK instrument is disconnected, the generator will automatically revert to the display showing the **"X Way Cable Attached Insert Device"** where X is "3" or "5" depending upon cable type connected. Inserting a new PK instrument type will reset the generator to the default settings for that specific instrument. Unless the instrument has the same identification code, any adjustments to the generator settings made when using the previous instrument will be overridden.

If the SuperPulse Generator is switched on with a PK instrument attached the generator will display the default power setting and the user has to accept the setting. The operator can then adjust the power setting to that appropriate for the procedure.

If the PK connector cable and PK instrument are connected together and then inserted into the SuperPulse Generator the default setting for that instrument will be displayed.

Where two instruments are attached, if the currently selected instrument is disconnected from its cable then it remains selected and the display changes to "**X Way Cable Attached Insert Device"** where X is "3" or "5" depending upon cable type connected. If the cable is also removed the display changes to **"Connect PK Cable, MODE to Swap Sockets"**.

The alternate output socket can also be manually selected with the black mode footswitch.

6F. Changing Accessories Between Procedures

Section 8 describes the disconnection of the connector cable and instrument.

Once the connector cable is disconnected, the generator will revert to the display showing **"Connect PK Cable"**.

The generator can be left in this Idle state between procedures.

CAUTION If the generator is maintained in this Idle state between procedures and the same PK instrument type is employed for the next procedure, then any adjustments made to the output settings during the previous procedure will be remembered and will supersede the default settings.

Inserting a new PK instrument type will reset the generator to the default settings for that particular type. Any adjustments to the PK Generator settings made during the previous procedure will be overridden.

Switching the power off will clear all prior PK output adjustments.

During surgery, the following are suggestions that a surgeon may wish to follow:

- The surgeon should use the impedance audible and visual feedback system as a guide to optimize the desired level of tissue desiccation. The relative degree of desiccation is determined by the decrease in alarm pitch and decrease in the number of stars on the display graph. These indicators show tissue desiccation progress– this is dependent on the thickness and type of tissue. The surgeon can choose to continue to apply power but this may increase the potential for tissue sticking.

- The impedance feedback system may indicate a decrease in impedance during activation, with an increasing tone and an increase in the number of stars on the display. This may be due to conductive fluids being released from the tissue or flowing from adjacent areas. Changing the grasp during activation will also change the indication sequence. It is advisable to maintain constant grasp force and wherever possible to lift the tissue away from fluid pools during activation.

- When using the Gyrus ACMI PK instruments that require tissue grasping, to optimize performance in the VP mode, tissue should be grasped firmly with the instrument to maintain constant pressure during activation. If, on application, shorting occurs then the tissue should be regrasped, varying tissue position and/or force as necessary. The surgeon should take care when grasping very thin tissue but if shorting continues the surgeon can leave the jaws slightly open and twist as the power is applied. If tissue adherence to the instrument jaws occurs, regrasp and reapply.

- When using PK forceps type instruments, coagulating effect will occur to the tissue between coagulating surfaces. Continue to activate the PK forceps until it has been determined that the desired tissue effect is achieved. Both coagulating surfaces should be in equal contact with tissue for optimum coagulation. If both jaws come in contact with one another (metal to metal) or have minimal tissue involvement, the desired tissue effect may be substantially reduced.

- When using the Gyrus ACMI PK LP Scissors the optimum coagulation performance is attained when rotating the tips clockwise through 90 degrees as power is applied.

- When using the PK modes with the Gyrus ACMI PK L-Hook, irrigation with saline will enhance the cutting action. If the instrument is failing to achieve adequate cutting, the surgeon can apply power and move the instrument from side to side to maintain the cutting action. Cutting may also be improved by taking smaller bites of tissue and by applying counter traction to the tissue to be cut.

- When using the PK modes with the Gyrus ACMI PK L-Hook, try to avoid excessive build up of coagulum between the hooks. This will diminish coagulation performance and increase smoke production during cutting.

- When using the PK modes with the Gyrus ACMI PK Needle to produce a hemostatic incision, it is advisable to change the default mode to ThermoKinetic mode: the hemostatic effect increasing from T2 to T1.

- When using any of the instruments in the Gyrus ACMI PK range in the VPC mode the default setting should be used. If the power is increased, there will be a potential increase in the thermal spread.

After surgery, the following steps should be performed:

8A. Following Surgery

a) Detach the instruments from the connector cable.

CAUTION Always detach by grasping the two halves of the connector and not the cable(s). Failure to do so may result in cable damage.

b) Dispose of the SINGLE USE instrument(s) according to your facility's policy on the disposal of surgical waste.

c) Disconnect the connector cable from the generator by grasping the plug and pulling gently from its socket on the front of the generator.

d) Return the generator to Standby state by pressing the Standby / On button or switch off at the back panel if desired.

WARNING Do not attempt to re-use Single Use Only instruments. Heat or chemical sterilization may render the instrument mechanically or electrically unsafe.

8B. Cleaning the Footswitch

a) Disconnect the footswitch from the rear panel of the Generator by first unlocking the retaining ring by rotating in a counter-clockwise direction and then withdrawing the plug from its receptacle.

WARNING Do not pull on the footswitch cable prior to unscrewing the connector locking ring. Such action may cause malfunction or intermittent activation during use.

b) Remove all gross matter (blood, mucus, and tissue) by wiping each component with a cloth or gauze pad and a mild cleaning solution or detergent capable of removing organic deposits.

IMPORTANT Do not immerse in reprocessing solutions. Do not use abrasive cleaning agents. Do not use ultrasonic cleaners. Product damage may otherwise result.

c) Remove residual cleansing agents with a water dampened cloth.

WARNING The Footswitch is not designed to be sterilized. Sterilization could lead to product damage or malfunction during use.

8C. Cleaning the Generator

Use a mild antibacterial detergent on a damp cloth to clean the generator. Do not allow fluids to enter the generator connectors. Do not use caustic, corrosive, or abrasive cleaning materials. The generator cannot be sterilized.

8D. Cleaning and Sterilizing the PK Connector Cable

Prepare the PK connector cable for steam sterilization according to the following cleaning procedure:

a) Remove all gross matter (blood, mucus, tissue etc.) by wiping the PK Connector Cable with a cloth or gauze pad and a mild cleaning solution or detergent capable of removing organic deposits.

IMPORTANT To avoid damage to the cable and connectors do not immerse in reprocessing solutions or use abrasive cleaning agents.

b) Rinse thoroughly in running water.

c) Remove residual cleaning agents with a water damp cloth.

d) Dry the device thoroughly before sterilizing.

Sterilize the connector cable according to the sterilization procedure described in the Connector Cable Instructions For Use.

IMPORTANT The connector cable supplied as part of the Gyrus ACMI PlasmaKinetic™ SuperPulse System is intended for 20 re-use cycles only.

WARNING Do not attempt to re-use PlasmaKinetic™ Instruments. Heat or chemical sterilization may render the instrument mechanically or electrically unsafe.

WARNING Exceeding the recommended number of uses may result in electrical or mechanical failure during use or difficulty when attaching or detaching the instrument to or from the PK connector cable.

Problem	Suggestions/Solutions
No output power	• Check cables and instrument connections. • Request assistance from Gyrus ACMI Service Support.
Generator resets during activation	• Check grounding of generator. • Check insulation of connector cable. • Check integrity of instrument. • Ensure no contact was made with other equipment during activation.
Red warning symbol illuminates	• Refer to fault code in section 11 and request assistance as necessary.
Unable to activate the generator	• Check footswitch for damage • Ensure approved footswitch is attached.
Alarm tone too loud or too quiet	• Re-adjust volume by means of the Menu / Mode button. Generator will remember the last volume setting employed.
No display on the generator	• Check the inlet fuse, replace with the correct type if necessary; request assistance from qualified service engineer if fault persists.
Generator displays **"Attach PK Cable"** after cable inserted	• Verify that the cable connector is fully inserted. • Check for damage to cable flex. • Remove connector and inspect pins for damage. • Ensure only Gyrus ACMI approved accessories are being used.
Generator flashes **"Insert Device"** or **"Invalid Accessory"** after instrument attached	• Ensure the connector cable contacts are clean and dry and have not been damaged during reprocessing. • Check instrument integrity. • Ensure only Gyrus ACMI approved Instruments and accessories are being used. • Move cables away from any possible source of interference e.g. other active electrosurgical systems.
Generator overheats	• Allow generator to cool down before re-use. • Check that sufficient ventilation is provided around generator. • Ensure ambient temperature is within operating limits (refer to Section 10).
Generator displays **"Press mode to use"** when attempting to activate.	• The generator has detected external interference and requires user confirmation of the instrument type. Press either the black mode footswitch or the Mode / Menu button to confirm. Note: any confirmation will only be required once per instrument connection.
Generator flashes **"SP ELECTRODE IN LHS"** after instrument attached	• Ensure that any SP supported instrument is **only** connected to the Right Hand Side, SP/PK socket. • Check for damage to cable flex and instrument. • Move cables away from any possible source of interference e.g. other active electrosurgical systems.
Generator displays an error message during activation	• Check the tip contact with another metal object. • Remove the instrument from the operative site and inspect it for damage.
No Visual or Audio feedback of impedance	• Option not selected.
Generator does not respond to instrument when attached.	• To ensure your Superpulse generator is compatible with the latest range of Gyrus ACMI instruments please ensure that the Superpulse software is updated with the latest available revision - contact your local Gyrus ACMI sales representative / technical service to arrange.

Environmental Conditions

Transport and Storage	Ambient Temperature	0 to 50°C
	Relative Humidity	10% to 90% non-condensing
	Atmospheric pressure	500 to 1060mBar
Operation	Ambient Temperature	10 to 40°C
	Relative Humidity	10% to 90% non-condensing
	Atmospheric pressure	500 to 1060mBar
Generator Power Source	Operating Range	Nominal 100-120 / 220-240 Volts RMS 50/60 Hz, 1000VA
	Regulation voltage	90-132 / 198-264 Volts RMS
	Inlet Fuses	Time lag 10A (T10A) 250V
Generator Weight	8 kg (18 pounds)(approx.)	
Generator Overall Dimensions	410 x 410 x 135 mm (16.14" x 16.14" x 5.3") (approx with rubber feet) (DxWxH)	

Generator Earth Leakage Currents

< 300 µA at 250Vrms
< 100 µA at 132Vrms

Alarm Volume — Adjustable between 40dB (minimum) and 65dB (maximum) at 1m. This is an activation signal only.

Classification — Class 1 (IEC 60601-1)

Electromagnetic Compatibility — Complies with IEC 60601-1-2

Defibrillator Proof — Type BF equipment with isolated (F) applied part. Each of the instrument terminals can withstand the effects of a defibrillator discharge.

Liquid Spillage as per IEC 60601-2-2

The generator enclosure will prevent reasonable amounts of liquid from interfering with the generator's safe and satisfactory operation.

Intermittent operation — Under maximum power setting and rated load conditions the generator will provide full power output with the minimum constraint of 10 seconds on, 30 seconds off, duty cycle for 1 hour.

Output Waveform and Characteristics

Waveform — The RF output is a variable amplitude sinusoid waveform varying between approximately 320kHz and 450kHz, corresponding to minimum and maximum load impedance respectively.

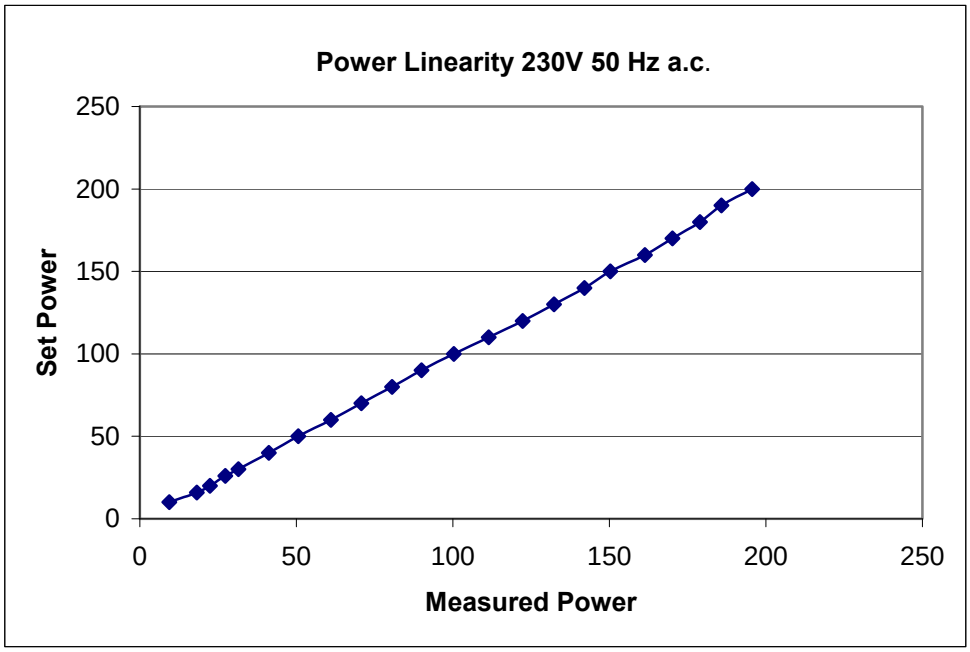
Crest Factor — A constant crest factor of 1.4 nominal for all vaporize outputs; 1.4 to 6.3 for desiccate waveforms.

Power	Maximum power	200 watts into 400 Ohms, PK modes
		128 watts into 70 Ohms, DES modes
		90 watts into 80 Ohms, VP modes

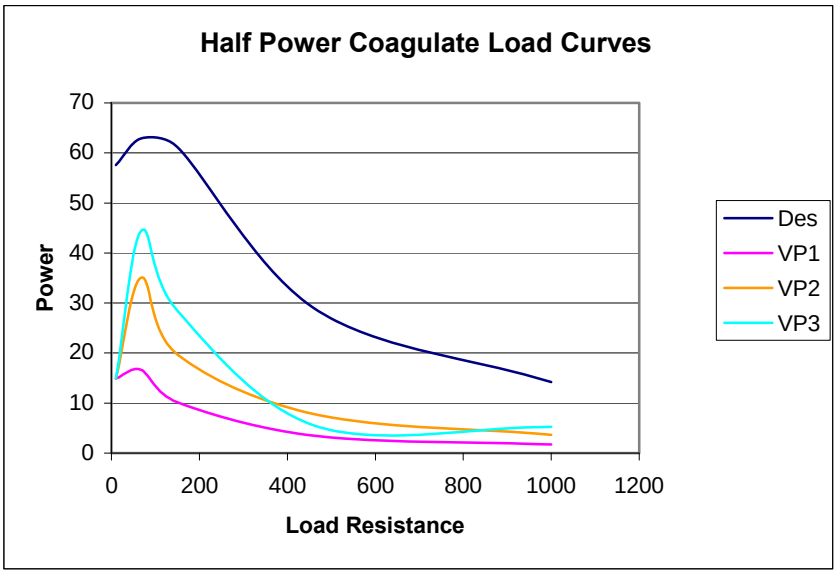
Max Voltage	PK1	360 Volts Peak
	PK2	434 Volts Peak
	PK3	480 Volts Peak
	T1	434 Volts Peak
	T2	480 Volts Peak
	DES	170 Volts Peak
	VP1	103 Volts Peak
	VP2	141 Volts Peak
	VP3	170 Volts Peak
	MR2	480 Volts Peak

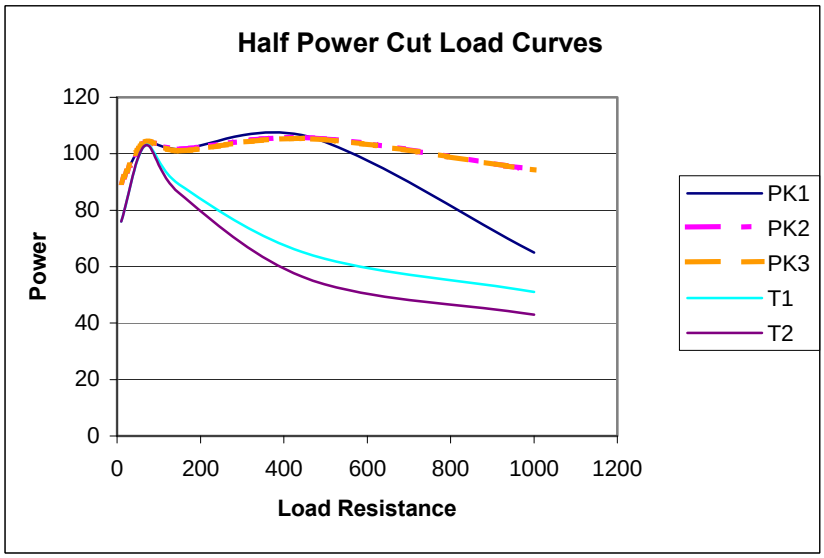
CAUTION The following load curves apply to the fundamental power delivery capability of the generator alone. They do not imply a given power output for any given instrument and connector cable configuration when used with the generator. Each accessory will self-impose an upper set power limit for the generator.

CAUTION Some electrode settings will not allow full power to be administered.

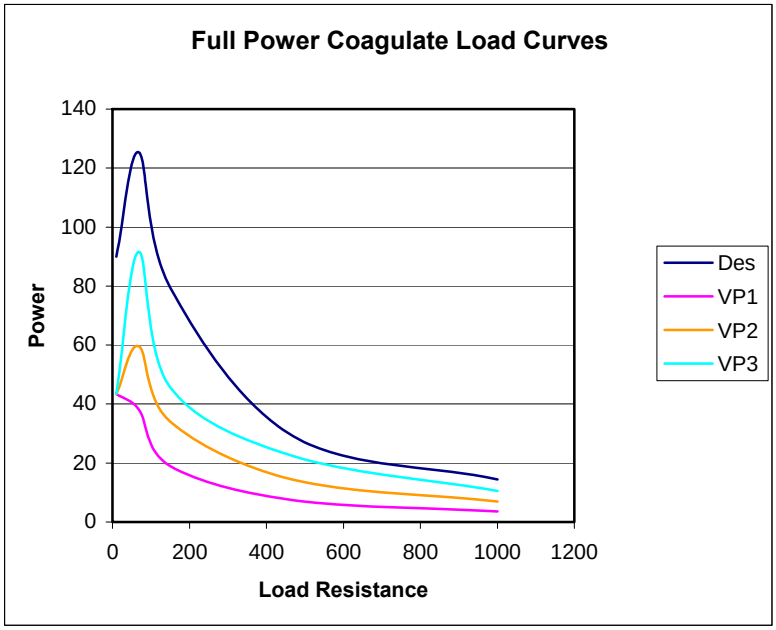


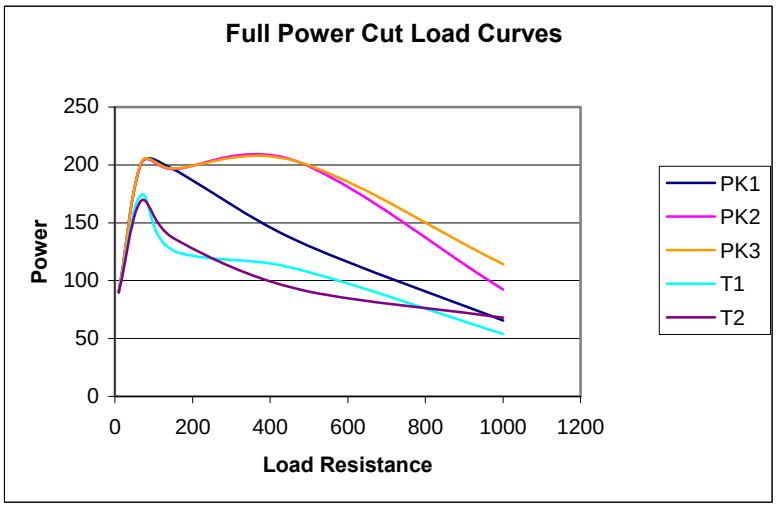
Linearity (PK3 into 150)

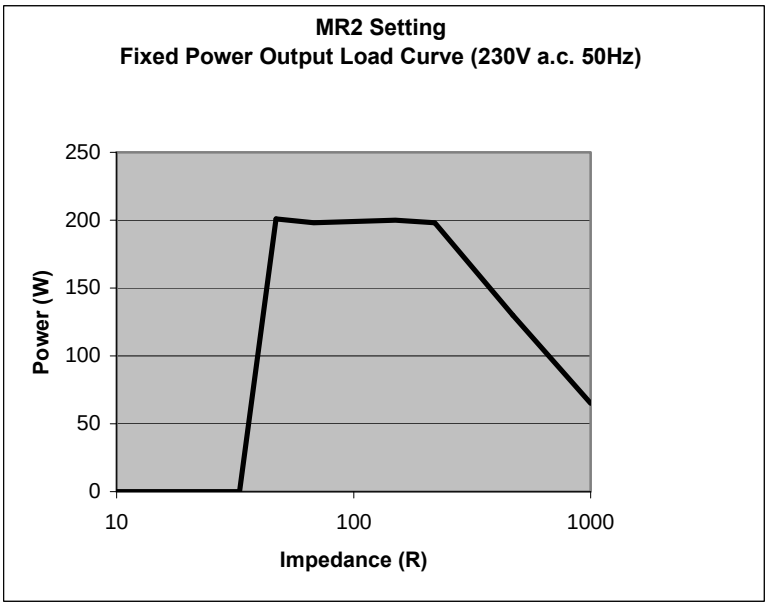




Half Power Load Curves







Full Power Curves

In addition to the primary outputs above other waveforms are available as described below:

Blended Waveforms, T1 & T2:

T1 – A blended output with 50% at PK2, 50% at DES, oscillates at 30 Hz or 500 Hz depending on instrument type.

T2 - A blended output with 50% at PK3, 50% at DES, oscillates at 30 Hz or 500 Hz depending on instrument type.

Vapor Pulse Waveforms, VP3, VP2 & VP1:

Pulsed coagulation outputs with a limited maximum output voltages. During the off periods, no RF output occurs. Repetition rates for each VP waveform will be constant but may vary with different instrument types.

Voltage limits:

VP3 - 120Vrms
VP2 - 100Vrms
VP1 - 73Vrms

The output power is defined as follows:

$$AveragePower = \frac{PeakPower \times OnTime}{CycleTime}$$

Where the Peak power is constant, the cycle time (the time for a complete on/off period) is preset and the On/Off ratio is varied dependent on set power.

Fault and Error Symbol Interpretation

Most technical problems are indicated by either a fault or an error symbol that appears in the Generator display window.

Fault Symbols

Three levels of failure reporting exist within the generator.

A “Soft” [S] Fault describes events bringing the attention of the user to an attempt to use the Generator outside the specification. This will be annunciated by a warning beep.

A “Recoverable” [R] Fault describes a condition that is a transient, non-hazardous event, recoverable using a Generator reset function. To reset the Generator after a fault occurs, first depress and release the Mode / Menu button. The fault symbol on the display should flash. Depress and release the Mode / Menu button once more to complete the reset.

The symbol on the display will be of the form:

“FAULT CODE
X00 REF XX”

IMPORTANT *Remember to take note of the fault symbol for reporting to a service engineer before completing the reset.*

A Fatal [F] Error describes a fault that is not recoverable.

An error symbol is displayed as for the recoverable faults, except that it indicates that a service is required.

WARNING *An error symbol indicates an equipment malfunction that may be hazardous. Disconnect all accessories and switch the Generator off. Switch the Generator back on and if the self-test is completed satisfactorily as evidenced by the “Attach PK Cable” symbol on the display, the failure occurred in the accessories which should be discarded and replaced. If the self-test fails, then all functions will be inhibited and no attempt should be made to use the generator. Contact the appropriate address located on the front of the manual for assistance.*

In the following list, where indicated as recoverable, this would be displayed as a fault symbol as described above.

ERROR CODE	REF	TEXT STRING	TYPE	DESCRIPTION
100	10	SYSTEM RESET	[R]	Software execution failure (watchdog reset)
100	11	INTERNAL FAILURE	[F]	ROM checksum failure
100	12	SETTINGS CORRUPT	[R]	Non volatile memory corrupt or not initialised
100	13	INTERNAL FAILURE	[F]	Program failure (unexpected value or state)
100	14	OUTPUT POWER FAIL	[R]	Power generation fault on start up (PK)
100	15	INTERNAL FAILURE	[F]	Power generation shutdown fault
100	16	OUTPUT POWER FAIL	[R]	Power generation fault on start up (SP)
100	17	SYSTEM RESET	[R]	Software execution failure
100	18	INTERNAL ERROR	[F]	Background loop timing
100	19	INTERNAL ERROR	[F]	Continuous test timing

200	10	INTERNAL FAILURE	[F]	PWM signal: shorted high
200	11	INTERNAL FAILURE	[F]	PWM signal: shorted low
200	12	INTERNAL FAILURE	[F]	SYNC signal: shorted high
200	13	INTERNAL FAILURE	[F]	SYNC signal: shorted low
200	14	INTERNAL FAILURE	[F]	ENERGY signal: stuck high
200	15	INTERNAL FAILURE	[F]	IOUT signal: stuck high (comparator in)
200	16-17	Not used	---	**----**
200	18	INTERNAL FAILURE	[F]	CUT/COAG signal: stuck high
200	19	INTERNAL FAILURE	[F]	CUT/COAG signal: stuck low
200	20	INTERNAL FAILURE	[F]	CLAMP signal error (DAC output)
200	21	INTERNAL FAILURE	[F]	BOOST signal error (DAC output)
200	22	INTERNAL FAILURE	[F]	PEAKSET signal error (DAC output)
200	23	INTERNAL FAILURE	[F]	PEAK signal error: stuck high (comparator in)
200	24	INTERNAL FAILURE	[F]	RF_DET signal error: stuck low
200	25	INTERNAL FAILURE	[F]	OVERDOSE signal error: permanently ON
200	26	INTERNAL FAILURE	[F]	ENERGY signal error: stuck low
200	27	Not used	---	**----**
200	28	INTERNAL FAILURE	[S]	Temperature monitor inoperative
200	29	------	----	Reserved for audio fault detection
200	30	Not used	----	**-----**
200	31	INTERNAL FAILURE	[F]	CURRLIM signal error (DAC output)
200	32	INTERNAL FAILURE	[F]	VOLTLIM signal error (comparator input)
200	33	INTERNAL FAILURE	[F]	BUSVOLTS signal error (analogue input)
200	34	INTERNAL FAILURE	[F]	Incorrect PK RF board installed
200	35	INTERNAL FAILURE	[F]	RF relay 1 (socket) not operating
200	36	INTERNAL FAILURE	[F]	RF relay 2 (poles) not operating
200	37	INTERNAL FAILURE	[F]	SP board RF_ACTIVE stuck on
200	38	INTERNAL FAILURE	[F]	SP board Output relay non-functional
200	39	INTERNAL FAILURE	[F]	SP board BUS relay non-functional
200	40-2	Not used	---	-----
200	43	INTERNAL FAILURE	[F]	CPU POST failure
200	44	RAM	[R]	RAM test failure [POST check]
200	45	INTERNAL FAILURE	[F]	Crystal failure [POST check]
200	47	INTERNAL FAILURE	[F]	Analogue reference failure [POST check]
200	48	INTERNAL FAILURE	[F]	CLAMP_SET failure [POST check]
200	49	INTERNAL FAILURE	[F]	BOOST_SET failure [POST check]
200	50	INTERNAL FAILURE	[F]	CURRLIM_SET failure [POST check]
200	51	INTERNAL FAILURE	[F]	PEAK_SET failure [POST check]
200	52	INTERNAL FAILURE	[F]	COAG_CUT failure [POST check]
200	53	INTERNAL FAILURE	[F]	PK_CUT_COAG failure [POST check]
200	54	INTERNAL FAILURE	[F]	PK_SKT_SET failure [POST check]
200	55	INTERNAL FAILURE	[F]	SUPERPULSE_RELAY failure [POST check]
200	56	INTERNAL FAILURE	[F]	NO_RF failure [POST check]

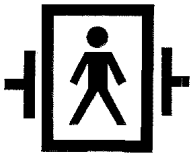
200	65	INTERNAL FAILURE	[R]	RFBUS_VOLTS failure [POST check]
200	66	INTERNAL FAILURE	[R]	POST AUDIO Setup [POST check]
200	67	INTERNAL FAILURE	[F]	PSU_STATUS failure [POST check]
200	68	INTERNAL FAILURE	[F]	Mains input failure [POST check]
200	69	INTERNAL FAILURE	[F]	OVERDOSE failure [POST check]
200	70	INTERNAL FAILURE	[F]	PWM low failure [POST check]
200	71	INTERNAL FAILURE	[F]	ID CAL circuit failure [POST check]
200	72	INTERNAL FAILURE	[F]	BUSLIM failure [POST check]
200	73	INTERNAL FAILURE	[F]	CURRLIM failure [POST check]
200	74	INTERNAL FAILURE	[F]	VOLTLIM failure [POST check]
200	75	INTERNAL FAILURE	[F]	SPRF_ACTIVE failure [POST check]
200	76	INTERNAL FAILURE	[F]	VCC_ANA_DIV_2 failure [POST check]
200	77	INTERNAL FAILURE	[F]	12V failure [POST check]
200	78	INTERNAL FAILURE	[F]	0V failure [POST check]
200	80	INTERNAL FAILURE	[F]	RF_VOLTAGE [POST check]
200	81	INTERNAL FAILURE	[F]	RF_CURRENT failure [POST check]
200	82	INTERNAL FAILURE	[F]	ANALOGUE_REF failure
200	83	INTERNAL FAILURE	[F]	VCC_ANA_DIV_2 failure
200	84	INTERNAL FAILURE	[F]	12V failure
200	85	INTERNAL FAILURE	[F]	0V failure
200	86	INTERNAL FAILURE	[F]	RF_DET stuck high failure
200	87	INTERNAL FAILURE	[F]	PSU_STATUS failure
200	88	INTERNAL FAILURE	[F]	Mains input failure
200	89	INTERNAL FAILURE	[F]	BUSLIM failure
200	90	INTERNAL FAILURE	[F]	CURRLIM_SET failure
200	91	INTERNAL FAILURE	[F]	SP_PSU_OR_PK_RELAY failure
200	92	INTERNAL FAILURE	[F]	Electrode ID Failure
300	10	THERMAL SHUTDOWN	[R]	Internal overheating
300	11	INTERNAL FAILURE	[F]	Excess RF input voltage error (RFBUS > set)
300	12-13	Not used	---	**-----**
300	14	OUTPUT SHORTED	[R]	Accessory error : excessive RF output current
300	15	INTERNAL ERROR	[F]	Impedance V,I feedback circuit error
300	16	INTERNAL ERROR	[R]	SP board not supplying RF energy
300	17-19	Reserved		
300	20	INVALID ELECTRODE	[SOFT]	Unsupported electrode type
300	21	SP OUTPUT ERROR	[R]	Persistent over voltage or current error
400	10	FOOTPEDAL STUCK	[S]	Footswitch BLUE pedal stuck
400	11	FOOTPEDAL STUCK	[S]	Footswitch YELLOW pedal stuck
400	12	FOOTPEDAL STUCK	[S]	Footswitch MODE pedal stuck
400	14	INTERNAL FAILURE	[F]	Electrode identification circuit fault
400	15	BUTTON STUCK	[R]	Front panel : CUT (left) UP button stuck
400	16	BUTTON STUCK	[R]	Front panel : CUT (left) DOWN button stuck
400	17	BUTTON STUCK	[R]	Front panel : blue UP button stuck
400	18	BUTTON STUCK	[R]	Front panel : blue DOWN button stuck

400	19	BUTTON STUCK	[R]	Front panel : MODE / MENU button stuck
400	20	BUTTON STUCK	[R]	Front panel : STANDBY button stuck
400	21	FOOTPEDAL STUCK	[R]	Footswitch pedal state indeterminate
400	30	Not used	---	----
500	10	SERIAL COMMS	[R]	Serial port error

**To report an accessory failure, contact the appropriate address located on the front of the manual for assistance.

Red Warning Symbol
Attention, consult accompanying documents

This equipment intentionally emits RF energy during activation



This equipment provides a degree of protection against electric shock to TYPE B as defined in IEC60601-1. This equipment has an F type applied part capable of withstanding the effects of defibrillator discharge

This symbol indicates the conductor that may be used to provide potential equalization between the equipment and the installation busbar.

This symbol indicates the receptacle to which the generator footswitch should be attached.

Waste electrical and electronic equipment (WEEE)

Storage Conditions

Represents the quantity of devices inside the package.
-Numeral corresponds to the number of devices inside the package and must be present inside the diamond icon.

QTY — Represents the quantity of salable units inside the package.

Manufactured for: — When a product is manufactured for Gyrus ACMI.

Rx only — CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a Physician or Dentist.

The manufacturer recommends that the Generator and Footswitch should be regularly inspected to ensure continued safety of operation throughout its service life. The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge and practical experience to perform such tests.

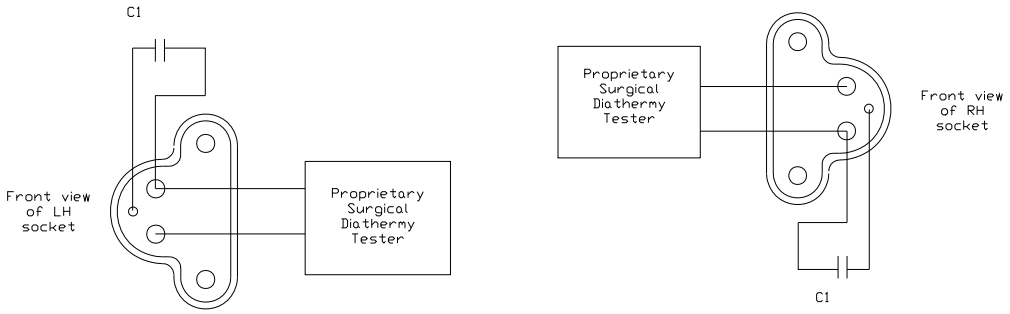
NOTE: *There are no user serviceable items within the generator.*

- Inspect the Generator and the Footswitch for obvious signs of mechanical damage or wear. Ensure that the Generator case shows no sign of tampering. There are no user serviceable items within the Generator or Footswitch.
- Check that the Generator back panel label is present and decipherable and that the front panel markings and symbols are still legible.
- Retract the fuse drawer of the mains inlet connector and verify that both fuses are intact and match the rated current and breaking characteristics as per the back panel label.
- Verify that the resistance between the earth terminal of the mains inlet connector and the Generator enclosure is within the limits defined in EN 60601-1 or the corresponding national standard as applicable.
- Switch on the Generator, ensuring that the initial internal self-test is completed normally, as reported on the front panel display. Check that the audio alarm, front panel warning indicator and vacuum fluorescent display are functioning normally via the user verification sequence which follows initialization. Check Desiccation detector operation.
- Check that the enclosure earth leakage current is within the limits for Class I equipment as prescribed within EN 60601-1 or the corresponding national standard as appropriate.
- Measure the patient earth leakage currents and ensure it is within the limits of BF type equipment as defined within EN 60601-1 or a corresponding national standard.
- If there is any doubt about the PK RF output power of the generator, it must be returned to the supplier for testing. A power output assessment may be performed on the bipolar output by using the connections described below. The output may be compared to the load curves specified in the previous sections. The output should be within ±20% of the relevant curve. The diathermy tester must be rated to read Watts at the appropriate frequency and have non-reactive loads. All connections should be insulated wherever possible to prevent electric shock risk and short-circuiting. The generator sockets receive two and four millimeter diameter plugs.

  To measure Desiccate outputs up to 150 Watts C1 shall be 4.7 nF +/- 1%.

  To measure PK outputs up to 200W C1 shall be 68nF +/-10%.

  Due to the pulsing nature of the SuperPulse and TS outputs, accurate measurements are difficult to carry out without specialized equipment.



- Details of these tests should be recorded in an equipment log with the date of test for future reference. Contact the service repair center selected by the manufacturer, should a unit fault be suspected.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The SuperPulse Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the SuperPulse Generator should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The SuperPulse Generator 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.
RF Emissions CISPR 11	Class A	The SuperPulse Generator 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.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The SuperPulse Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the SuperPulse Generator 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 IEC 61000-4-4	±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 IEC 61000-4-5	±1 kV Differential Mode ±2 kV Common Mode	±1 kV Differential Mode ±2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5 % U_T (>95 % Dip in U_T) for 0.5 Cycle 40 % U_T (60 % Dip in U_T) for 5 Cycle 70 % U_T (30 % Dip in U_T) for 25 Cycle <5 % U_T (>95 % Dip in U_T) for 5 sec	<5 % U_T (>95 % Dip in U_T) for 0, 5 Cycle 40 % U_T (60 % Dip in U_T) for 5 Cycle 70 % U_T (30 % Dip in U_T) for 25 Cycle <5 % U_T (>95 % Dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SuperPulse Generator requires continued operation during power mains interruptions, it is recommended that the SuperPulse Generator 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 fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The SuperPulse Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the SuperPulse Generator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 Vrms 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SuperPulse Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = [1.17]\sqrt{P}$ $d = [1.17]\sqrt{P}$ 80 MHz to 800 MHz $d = [2.33]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter 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 80 MHz and 800 MHz, 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 elctromagnetic site survey should be considered. If the measured field strength in the location in which the SuperPulse Generator is used exceeds the applicable RF compliance level above, the SuperPulse Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SuperPulse Generator. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the SuperPulse Generator

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

Rated Maximum Output Power of Transmitter **W**	**Separation Distance According to Frequency of Transmitter** **m**		
	150 kHz to 80 MHz $d = [3.5/V_1]\sqrt{P}$	**80 MHz to 800 MHz** $d = [3.5/E_1]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [7/E_1]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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

NOTE 1: At 80 MHz and 800 MHz, 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.

The manufacturer warrants the products listed below to be free from defects in material and workmanship under normal use and service for the period(s) set forth below. The manufacturer's obligation under this warranty is limited to the repair or replacement, at its sole option, of any product, or part thereof, which has been returned to it or its Distributor within the applicable time period shown below after delivery of the product to the original purchaser, and which examination discloses, to the manufacturer's satisfaction, that the product is defective. This warranty does not apply to any product, or part thereof, which has been repaired or altered outside the manufacturer's factory in a way so as, in the manufacturer's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect or accident.

The warranty periods for the components of the PlasmaKinetic™ SuperPulse Generator are as follows:

Component	**Warranty Period**
Generator and footswitch	One year from shipment date

This warranty is in lieu of all other warranties, expressed or implied, including, without limitation, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of the manufacturer. The manufacturer neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of the manufacturer's products. Notwithstanding any other provision herein or in any other document or communication. The manufacturer's liability with respect to this agreement and products sold hereunder shall be limited to the aggregate purchase price for the goods sold by the manufacturer to the customer. There are no warranties which extend beyond the terms hereof. The manufacturer disclaims any liability hereunder or elsewhere in connection with the sale of this product, for indirect or consequential damages.

The manufacturer reserves the right to make changes in equipment built and/or sold by it at any time without incurring any obligation to make the same or similar changes on equipment previously built and/or sold by them.

The products listed above are manufactured in the United Kingdom:

Manufactured For:

Gyrus ACMI, Inc.
136 Turnpike Road
Southborough
MA 01772-2104
USA

Customer Service USA:

Customer Service: 1-888-524-7266
Technical Service: 1-800-621-3739
www.gyrusacmi.com

EC REP

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CE 0344

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Rx only - CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician

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NOTE **THE UL APPROVAL APPLIES TO GYRUS ACMI PRODUCTS ONLY**

MEDICAL ELECTRICAL EQUIPMENT
CLASSIFIED BY UNDERWRITERS LABORATORIES INC.
WITH RESPECT TO ELECTRIC SHOCK, FIRE, MECHANICAL
HAZARDS AND OTHER SPECIFIED HAZARDS ONLY IN
ACCORDANCE WITH UL60601-1 AND CAN/CSA C22.2 NUMBER 601.1

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CAUTION	USE ONLY THE POWER CORD PROVIDED BY YOUR PRODUCT SUPPLIER. DO NOT USE ANY OTHER POWER SUPPLY CORD.	**MISE EN GARDE**	UTILISER UNIQUEMENT LE CORDON D'ALIMENTATION FOURNI PAR VOTRE FOURNISSEUR. NE PAS UTILISER D'AUTRE TYPE DE CORDON D'ALIMENTATION.
CAUTION	THE POWER SUPPLY CORD PROVIDED IS INTENDED FOR NORTH AMERICAN 110V USE. THIS POWER CORD IS UL LISTED. TYPE SJT, RATED 120V AT 10A MINIMUM. FOR OPERATION AT OTHER MAINS SUPPLY VOLTAGES CONSULT YOUR LOCAL PRODUCT REPRESENTATIVE FOR ADVICE OR THE PROVISION OF A REPLACEMENT POWER CORD.	**MISE EN GARDE**	LE CORDON D'ALIMENTATION EST CONCU POUR UNE UTILISATION EN AMERIQUE DU NORD SOUS UNE TENSION DE 110V. CE CORDON D'ALIMENTATION EST DE TYPE UL, SJT. ALIMENTATION 120V ET 10A MINIMUM. CONTACTER VOTRE REPRESENTANT LOCAL POUR UNE UTILISATION A UN AUTRE VOLAGE.
WARNING	RISK OF FIRE REPLACE FUSE AS MARKED	**ATTENTION**	RISQUE D'INCENDIE REMPLACER LE FUSIBLE COMME INDIQUE