GYNECARE VERSAPOINT®
Hysteroscopic Bipolar Electrosurgical System

User Manual
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GYNECARE VERSAPOIN USER MANUAL
INTRODUCTION

This user's manual will familiarize you with the controls and output functions available from your GYNECARE VERSAPOINT Hysteroscopic generator and instruct you on the proper use of the equipment.

OVERVIEW OF ENDOSCOPIC SURGERY

An endoscope is an instrument routinely employed to visualize and access the interior of various body cavities for the purposes of both diagnostic and surgical procedures. When the endoscope is inserted through a natural body opening, such as the cervical canal or urethra, the instrument commonly includes one or more integral working channels, as well as conduits for the passage of gas or liquid required to distend the body cavity. Commonly referred to as underwater surgery, liquid distention is usually the preferred method in hysteroscopic, urological and arthroscopic endoscopy. The overall diameter of the endoscope dictates the ease with which dilation of the cervical canal or urethra can be performed under local anesthesia in an outpatient or office setting. Outpatient or day case surgery provides for cost effective healthcare management; a factor which has driven a progressive reduction in the diameter of operating endoscopes, particularly hysteroscopes. The reduction in overall diameter has constrained the size of the working channel. Consequently, this has limited the scope of tissue effect modalities compatible with the new generation endoscopes. Other than the use of mechanical devices such as biopsy forceps and miniature scissors, it is the delivery of laser energy through fine optical fibers which has to date provided the most effective modality. Clearly, one of the main drawbacks of lasers is their expense, installation and maintenance; the GYNECARE VERSAPOINT Hysteroscopic system has been developed as an alternative endoscopic energy source and delivery system to support the expansion of outpatient services.

Electrosurgery is a familiar tool widely employed in surgical practice for the last 50 years. GYNECARE VERSAPOINT brings about a level of tissue performance that combines the most desirable elements from the two conventional output modalities of bipolar and monopolar electrosurgery in specific system configurations for advanced endoscopic surgery. The GYNECARE VERSAPOINT device provides a form of electrosurgery specifically developed for underwater endoscopic applications. It appears and performs like a monopolar device, provides laser-like tissue vaporization, yet retains all the inherent safety features of bipolar electrosurgery.

COMPARISON WITH CONVENTIONAL ELECTROSURGERY

Conventional bipolar electrosurgery requires both “poles” of the electrode contact tissue to complete the electrical circuit and produce a tissue effect. Typically, these electrodes do not operate effectively while immersed in a conductive irrigating solution such as normal saline. The GYNECARE VERSAPOINT system utilizes the fact that the irrigating solution is conductive to stagger the electrode arrangement at the tip so that the “return” electrode is remote from tissue and mounted on the shaft of the instrument. To some extent, this is similar to a monopolar arrangement, in that the return electrode is remote from the tissue contact, or active, electrode. In this instance, however, the proximity of the return electrode to the working tip and the fact that no tissue, other than that contacting the active electrode is involved in the electrical circuit, preserves the recognized safety features of bipolar electrosurgery. Similarly, this arrangement may avoid a lot of the problems commonly encountered
when using bipolar electrosurgery: orientation of the electrode to tissue, visualization of the working tip, tissue sticking and limited power delivery.

One of the additional features of being able to both deliver higher powers through the electrode and the ability to make the active electrode much smaller than the return electrode, allows the system to produce laser-like tissue vaporization by creating a vapor pocket around the active electrode. This effect can be achieved with monopolar electrosurgery but at very high power levels and only in the presence of a non-electrolyte irrigating solution, both aspects of which have recognized complications and safety concerns. In order for the GYNECARE VERSAPOINT system to produce this effect, the generator has integral controls and features to both initiate and sustain the vapor pocket around the active electrode.

Depending on the electrode configuration, the electrode itself also has specific features required to sustain the vapor pocket.

**SYSTEM DESCRIPTION**

The GYNECARE VERSAPOINT Electrosurgical system is designed for hysteroscopic surgical procedures. A typical GYNECARE VERSAPOINT system (Figure 1.1) would comprise the following items:

- GYNECARE VERSAPOINT electrosurgical generator
- GYNECARE VERSAPOINT dual pedal footswitch
- Re-usable 3m connector cable
- A range of sterile, single use electrodes

The electrodes, such as the 5Fr type shown in Figure 1.1, are approximately 360mm long and intended for insertion down the working channel of standard, commercially available hysteroscopes. Different active tip styles are available to provide apposite tissue effect according to preference and nature of the gynecological operation. Other electrode forms are available for use with custom Gynecare endoscopes. The electrodes are designed to provide both ablation and coagulation of tissue, only when activated within a saline environment, by pressing the yellow and blue pedals, respectively, of the footswitch. These terms are more correctly referred to as vaporization or “VaporCut” (VC), and “Desiccate” (DES) when applied to the GYNECARE VERSAPOINT system.
FIGURE 1.1 GYNECARE VERSAPOINT HYSTEROSCOPIC SYSTEM COMPONENTS

1. GYNECARE VERSAPOINT Generator
2. AC Power Input
3. Footswitch Cable
   (Approx. 3m long)
4. Footswitch
5. Blue Pedal
6. Yellow Pedal
7. Connector Cable
   (Approx. 3m long)
8. 5Fr Electrode
   (Approx. 360mm long)
9. Character User Display
10. User Buttons
11. Fault Indicator
12. Connector Cable Socket
13. On/Off Switch

Since the electrodes can only operate within a saline medium, the working tip geometry determines the amount of output power needed from the GYNECARE VERSAPOINT generator to reach the vaporization threshold. To simplify set-up and ensure that a power level commensurate with the electrode type is employed, the GYNECARE VERSAPOINT generator will automatically detect which electrode is in use and configure itself for recommended initial output power levels as defaults and also limit the maximum power available. Power level adjustment for both vaporization and desiccation modalities is performed by the front panel buttons with the selected levels shown on the user display.
A sterile electrode is supplied and is discarded after use. It plugs into one end of the GYNECARE VERSAPOINT connector cable which will already have been attached to the GYNECARE VERSAPOINT generator via the front panel socket. The reusable Connector Cable is designed for steam sterilization and may be resterilized and used a maximum of 20 times. Activation by means of the footswitch, which is attached via the back panel, is prohibited until both the electrode and connector cable have been properly coupled to the GYNECARE VERSAPOINT generator. An audible alarm will sound whenever electrosurgical energy is being output. Diagnostic circuits within the GYNECARE VERSAPOINT generator continuously monitor system performance such that any detected faults are indicated as symbols on the user display in conjunction with illumination of the front panel warning symbol.

**INDICATIONS FOR USE**

The GYNECARE VERSAPOINT Hysteroscopic System is an electrosurgical system used in conjunction with continuous flow hysteroscopes for correction of the following pathologies:

- Myomas
- Polyps
- Intrauterine adhesions
- Uterine Septa

**CONTRAINDICATIONS FOR USE**

The GYNECARE VERSAPOINT electrosurgical system is NOT intended for use in tubal sterilization procedures.

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

- Acute cervicitis
- Pregnancy
- Cervical or uterine malignancy
- Active pelvic inflammatory disease
- Unaddressed adnexal pathology

Use with extreme caution and very close fluid monitoring in the face of severe cardiopulmonary disease.

**Patients with Pacemakers**

Use electrosurgical generators with caution in the presence of internal or external pacemakers. Interference from the 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.
Section 2

PATIENT AND OPERATING ROOM SAFETY

For the purposes of safety procedures and despite the absence of a conventional return pad, the GYNECARE VERSAPOINT system should still be treated as a high power electrosurgical device.

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, and 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 hysteroscopic electrosurgery in that procedure.

GENERAL

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

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 GYNECARE VERSAPOINT accessories before use. This device is an integral system; only use GYNECARE VERSAPOINT approved accessories with the GYNECARE VERSAPOINT generator.

CAUTION
If possible, avoid the use of needle style electrodes 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 accessory 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. These studies recommend using surgical masks or other means of protection.1,2,3

CAUTION
Failure of the HF surgical equipment could result in an unintended increase of output power.

WARNING
When endoscopes are used with energized endoscopically used accessories, the patient leakage may be additive.

Ensure Proper Connections

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

Only For Use In Surgical Procedures With Normal Saline

CAUTION
Tissue effects are achieved by a halo of electrical current surrounding the Electrode tip. Physical contact between the Electrode and tissue should be minimal, since damage to the Electrode tip may result. Similarly, the tip should always be kept in contact with the conductive irrigant solution to ensure proper performance and avoid excessive heating of the Electrode.

CAUTION
Unless specified in the instructions for use accompanying an approved GYNECARE VERSAPOINT accessory, the GYNECARE VERSAPOINT system should only be activated with the working tip of the electrode accessory completely immersed in 0.9% w/v; 150mmol/l sodium chloride solution. For convenience, this will be referred to within the remainder of this manual as normal saline.

CAUTION
As with the use of other hysteroscopic accessories, consideration as to whether or not to monitor the procedure laparoscopically should be based upon the specific procedure, individual patient characteristics, and physician preference. For additional guidance on the use of Laparoscopic monitoring for specific procedures, physicians are advised to reference A.C.O.G. recommendations.

WARNING
Only use normal saline for irrigation during hysteroscopic procedures. Performance will be suppressed by use of other irrigating solutions such as Glycine, Sorbitol, Dextrose, Mannitol or other solutions containing non-physiological concentrations of electrolyte.

WARNING
Fluid monitoring is required even when normal saline is used as a hysteroscopic distension medium.
Servicing

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
For maintenance of the electrosurgical generator unit refer to the recommended periodic equipment safety checks at Section 12.

Servicing/Equipment Disposal

CAUTION
The GYNECARE VERSAPOINT system 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 national or institution related policy relating to obsolete electronic equipment.

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

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)
- Naturally occurring flammable gases which may accumulate in body cavities such as the bowel
- Oxygen enriched atmospheres
- Oxidizing agents such as nitrous oxide (N₂O) atmospheres

The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.

Fire Hazard with Oxygen Circuit Connections

WARNING
Fire/Explosion Hazard: Verify that all oxygen circuit connections are leak free before and during use of electrosurgery. Verify that endotracheal tubes are leak free and that the cuff is properly sealed to prevent oxygen leaks.

BEFORE SURGERY

Active Accessories

WARNING
Electric Shock Hazard: Do not connect wet accessories to the generator.
CAUTION
Read the instructions, warnings and cautions provided with the active accessories before using.

WARNING
Accessories labeled “SINGLE USE” are single use only. Do not reuse or resterilize.

CAUTION
Accessories labeled reusable must only be processed according to the recommended procedure and recycled the specific number of uses.

CAUTION
Use default power levels to test an accessory.

CAUTION
Use only GYNECARE VERSAPOINT approved accessories supplied for use with this product. Otherwise, product damage or accessory failure may result during use.

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

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

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 the accompanying documents.

WARNING
Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING
The use of accessories and cables other than those for which the GYNECARE VERSAPOINT system was designed can significantly degrade emissions and immunity performance.

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

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

Should any unintentional effects appear upon other equipment when using the system, repositioning the GYNECARE VERSAPOINT 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.

WARNING
Do not use monopolar generator/accessories simultaneously with the GYNECARE VERSAPOINT generator. Activation of a monopolar generator/accessories may cause interference with the GYNECARE VERSAPOINT generator resulting in user message changes on 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.
Generator

CAUTION

Nonfunction of the generator may cause interruption of surgery; ensure installation procedures are followed and that all connectors are correctly inserted before use.

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. The working channel and operating sheaths of most hysteroscopes are metal. Do not activate the electrode while any portion of the electrode tip is within the working channel or in contact with another metal object; localized heating of the electrode and the adjacent metal object or working channel may result in damage to the hysteroscope, and/or electrode tip.

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 during certain procedures (e.g., those in which noninsulated head frames are used), use extreme caution to maximize patient safety.

Generator Power Settings

WARNING

Confirm proper electrosurgical generator power settings before proceeding with surgery. Use the lowest appropriate power setting to achieve the desired effect. Always check that the automatic default settings shown on the display match those indicated on the active electrode packaging.

CAUTION

Use caution when overriding the default power settings.

CAUTION

Should a power supply interruption occur, the generator power settings will revert to the minimum values when power is re-established should the accessory combination still be connected.

Active Accessories

WARNING

Do not embed the Electrode tip in tissue as excessive heating and damage to the tip may result.

WARNING

Do not use the Electrode tip to probe or manipulate tissues. Mechanical contact between Electrode tips and tissues or other instruments may result in damage to the instrument.

WARNING

Bubbles are produced during tissue vaporization which may interrupt surgery by temporarily interfering with vision and may also result in over heating and cause damage to the Electrode tip; a continuous flow hysteroscope system is recommended to prevent accumulation and remove bubbles from the operative field.

WARNING

When not in use place active electrodes in a clean, dry, nonconductive, and highly visible area not in contact with the patient. Inadvertent activation while in contact with the patient may result in burns.
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.

Laparoscopy, Endoscopy and Related Procedures

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

- The accessory tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of the activated electrodes outside 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 electrode, or by the active or return electrode being in close proximity to the conductive object.
- Carefully insert and withdraw active electrodes from working channels to avoid the possibility of damage to the devices and/or injury to the patient.
- Only operate the device in the endometrial cavity with continuous flow irrigation to ensure good visualization as well as cooling the accessory tip between activations.
- Only use normal saline irrigation solution. The performance of the system will be adversely affected by use of any other solution.
- Do not activate when not in contact with tissue, or excessive heating of the irrigation medium may result.
- Tissue drilling is a common surgical technique and while the GYNECARE VERSAPOINT electrodes may be used for this purpose, do not insert the electrode beyond the junction of the return electrode and insulator as this may result in overheating and electrode failure. Care should also be taken to avoid perforation of the uterus when employing this technique.

CAUTION
Normal use of the system restrains tissue contact to only the active tip of the electrode. No user or patient hazard will arise should the electrical return electrode portion of the electrode make simultaneous tissue contact other than where explicit warnings are given.

ADVERSE EFFECTS
Contact of heated Electrode tip with tissues not intended for electrosurgical treatment may result in tissue injury.

If excessive heating or physical forces cause damage to the Electrode tip, foreign body fragments may result, requiring extended surgery for removal.

Section 3

INSTALLATION

The electrosurgical generator described in this manual, in conjunction with the available accessories, is designed to be used as a system to provide advanced electrosurgical effects during hysteroscopic surgery including the debulking of intracavitary tissue by vaporization under normal saline irrigation.

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 these instructions for use.

GENERATOR POWER REQUIREMENTS
The generator is designed to operate at 90-132VAC, 198-264VAC at 50/60Hz. This allows the generator output to remain constant in case of power fluctuations.

Check the Generator Power Connection
Your generator supplier will provide a hospital grade power plug.

The power connector meets all requirements for safe grounding. Its purpose should not be defeated by using extension cords or three-prong to two-prong adapters. Cords should always be grasped by the plug. Do not pull on the cord itself.

GROUNDING OF THE GENERATOR
To ensure user safety the generator must be properly grounded through the inlet plug and power cord.

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

EMC CONSIDERATIONS
The GYNECARE VERSAPOINT generator should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, both the GYNECARE VERSAPOINT 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 GYNECARE VERSAPOINT 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.

### Guidance and Manufacturer’s Declaration - Electromagnetic Emissions

The GYNECARE VERSAPOINT Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the GYNECARE VERSAPOINT Generator should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>The GYNECARE VERSAPOINT 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.</td>
</tr>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Class A</td>
<td>The GYNECARE VERSAPOINT 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.</td>
</tr>
<tr>
<td>Harmonic Emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations / Flicker Emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
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### Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

The GYNECARE VERSAPOINT Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the GYNECARE VERSAPOINT Generator should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV Contact ±8 kV Air</td>
<td>±6 kV Contact ±8 kV Air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical Fast Transient / Burst IEC 61000-4-4</td>
<td>±2 kV for Power Supply Lines ±1 kV for Input / Output Lines</td>
<td>±2 kV for Power Supply Lines ±1 kV for Input / Output Lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV Differential Mode ±2 kV Common Mode</td>
<td>±1 kV Differential Mode ±2 kV Common Mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11</td>
<td>&lt;5 % ( U_L \rangle (95 % \text{ Dip in } U_L) \text{ for } 0.5 \text{ Cycle} 40 % \ U_L, (60 % \text{ Dip in } U_L) \text{ for } 5 \text{ Cycle} 70 % \ U_L, (30 % \text{ Dip in } U_L) \text{ for } 25 \text{ Cycle} &lt;5 % \ U_L, (95 % \text{ Dip in } U_L) \text{ for } 5 \text{ sec} &lt;5 % \ U_L, (95 % \text{ Dip in } U_L) \text{ for } 0.5 \text{ Cycle} 40 % \ U_L, (60 % \text{ Dip in } U_L) \text{ for } 5 \text{ Cycle} 70 % \ U_L, (30 % \text{ Dip in } U_L) \text{ for } 25 \text{ Cycle} &lt;5 % \ U_L, (95 % \text{ Dip in } U_L) \text{ for } 5 \text{ sec}</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the GYNECARE VERSAPOINT Generator requires continued operation during power mains interruptions, it is recommended that the GYNECARE VERSAPOINT Generator be powered from an uninterruptible power supply or a battery.</td>
<td></td>
</tr>
<tr>
<td>Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

NOTE: UT is the a.c. mains voltage prior to application of the test level.
### Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

The GYNECARE VERSAPOINT Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the GYNECARE VERSAPOINT Generator should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the GYNECARE VERSAPOINT Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 Vrms 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>Recommended Separation Distance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = \left[1.17\right]_{\text{MHz}}$ 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = \left[2.33\right]_{\text{MHz}}$ 800 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

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, should be less than the compliance level in each frequency range. 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. |

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

* Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Routine Maintenance of the Generator

It is recommended that the generator be inspected by qualified service personnel in accordance with Section 12, Periodic Equipment Safety Checks.

---

**Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the GYNECARE VERSAPOINT Generator**

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

<table>
<thead>
<tr>
<th>Rated Maximum Output Power of Transmitter W</th>
<th>Separation Distance According to Frequency of Transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>d = [3.5V1]√P</td>
</tr>
<tr>
<td>80 MHz to 800 MHz</td>
<td>d = [3.5E1]√P</td>
</tr>
<tr>
<td>800 MHz to 2.5 GHz</td>
<td>d = [7/E1]√P</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.69</td>
</tr>
<tr>
<td>100</td>
<td>11.67</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating 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.
Section 4

GENERAL INFORMATION

GENERATOR INDICATORS AND DISPLAYS

On—Press this button to switch on the generator. When the generator is on, the green light within the on button is illuminated. When the generator is off, it is not available for use.

Off—Press this button to switch off the generator. It is in the user’s interests to switch off the generator whenever it is not in use to avoid any possibility of inadvertent activation.

GENERATOR OUTPUT MODE, POWER CONTROLS AND DISPLAY

Power Up/Down—These buttons adjust the default power setting determined by electrode configuration; the yellow arrow buttons for the VaporCut and Blend outputs and the blue arrow keys for the Desiccate output. Power setting may be set from minimum to maximum using the up arrow buttons, and set from maximum to minimum using the down arrow buttons. Press the appropriate button once for a power increment or decrement. Holding down the button accelerates the incrementation or decrementation.

NOTE

Power can only be adjusted with the generator in the Ready mode once an electrode is properly connected to the generator. The active electrode will determine its own default output power and power set range limits as indicated on the electrode packaging.

Power Setting Displays—The display is divided into two sections indicated by the underlying yellow and blue bars. Above the yellow bar (left-hand side of the display) the nominal output power in Watts is displayed for the selected output mode. Above the blue bar (right-hand side of the display), the nominal output power in Watts is displayed for the desiccate output. When an output is activated, the power display for the selected output flashes and an audible tone sounds.

Mode Selection—There are three VaporCut modalities shown as VC1, VC2 and VC3 on the left hand side of the power setting display. These produce a tissue effect decreasing from VC1 to VC3. Two blended outputs are also available, shown as ‘BL1’ and ‘BL2,’ on the left hand side (YEL) which continuously switch between a VaporCut and Desiccate output during activation. In both cases, the output will alternate many times a second. The principal difference between the two blend modes is the repetition rates employed. A blended output will provide a degree of hemostasis during tissue vaporization. Depressing the mode button once will enable selection of these options using the power up button of the Desiccate (BLUE) output. Once the display shows the desired yellow (YEL) output mode then holding the mode button down for approximately one second will return the generator to the Ready condition upon release of the mode button.
Indicates that the output waveform modality for yellow pedal activation can be selected.

**NOTE**
Output modality selection can only be performed with an electrode and connector cable attached to the generator.

**NOTE**
VC1 mode selection is inhibited by connection of certain electrode configurations to the generator.

**NOTE**
If the mode key is quickly pressed and released the next user set-up option appears.

**GENERATOR INDICATORS SET-UP AND MALFUNCTION DISPLAYS**

**Electrode prompt**

- **Power up**—When the generator is first switched on prior to electrode connection, a user verification sequence will be initiated. Once this is satisfactorily completed the display will prompt the user to first connect the connector cable and then connect an electrode by flashing the symbols "CONNECT CABLE" and "INSERT ELECTRODE" respectively, on the display. This represents the idle mode of the generator. Until an electrode and connector cable are detected by the generator, all controls are inhibited. Once an electrode is properly connected, the generator enters the **Ready** mode which enables the controls.

**Set-up and Defaults**

- **Electrode output default settings**—Each electrode configuration has an internal classification code which is interrogated by the generator. Depending on this code, optimal output mode and power settings are automatically set. These can be adjusted, but certain output modes may be inhibited and power adjustment limits imposed to ensure the safe operation of a particular electrode type.

- **Activation Selection**—From the **Ready** state, depress and release the mode button twice to enable activation selection. If your generator version supports both a footswitch and handswitching accessories that may become available in the future, the activation source can be toggled between FOOTSWITCH and HANDSWITCH. Otherwise the menu will confirm that footswitch operation is enabled by showing FOOTSWITCH on the display. Holding down the mode button for one second and then releasing it will return to the **Ready** state.
Indicates that the footswitch is the activation source for the system.

Activation Status

Activate—Using a footswitch, 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 Tone Volume Adjustment

Activate tone volume—The activation tone volume can be adjusted between minimum and maximum using the up control of the desiccate (blue) power control once the mode selection button has been depressed and released three times. The tone can be verified by depressing the down button of the desiccate (blue) power control during selection. Press and release the mode button once more to return the generator to Ready mode.

Indicates that the audio alarm output level may be selected. ‘MIN’ is the lowest volume available, ‘MAX’ is the loudest.

Error Code Display

Non-critical failure—If a fault is detected during set-up or during use an error code message is displayed. Refer to Section 8, Operating Room Troubleshooting.

Critical Failure

Red Warning light—Except during the self-test routine, when the red warning light on the front panel is illuminated this indicates a critical failure. DO NOT ATTEMPT TO USE THE UNIT. Refer immediately to an approved service agent or return to the manufacturer if the generator is still under warranty.
GENERATOR CONNECTORS AND RECEPTACLES

1. FRONT VIEW
2. DISPLAY WINDOW
3. MEMBRANE PANEL
4. CONNECTOR CABLE SOCKET
5. MAINS ON/OFF SWITCH
6. BACK VIEW
7. HEATSINK
8. SERIAL NUMBER LABEL
9. EARTH STUD
10. MAINS POWER INPUT SOCKET
11. FOOTSWITCH SOCKET
Section 5

**BEFORE SURGERY**

This section describes how to set up the GYNECARE VERSAPOINT system before surgery. You need to perform the following:

- Verify the Connector Cable (see Instructions for Use).
- Package the connector cable for steam sterilization.
- Sterilize the connector cable according to the connector cable Instructions For Use.
- Switch on the generator.
- Select the appropriate electrode(s) for the procedure.

**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.

- Provide at least four inches of space from the rear of the generator. Never cover the generator or stack other equipment on it other than in an approved system cart. It is normal for the generator to become warm during use so ensure adequate ventilation.

**NOTE**

*Your local sales representative will be able to advise you on system cart selection.*

**Connect the Generator**

- Connect the generator directly to an AC power point. Avoid the use of extension cords or multiple plug points. Wherever possible, avoid trailing leads and neatly store excess flex.

**Connect the Footswitch**

- Connect the supplied footswitch to the receptacle at the rear of the generator.

**Switch the Generator On**

- Verify completion of the system initialization sequence by “CONNECT CABLE” flashing on the display prompt, indicating the generator is in idle mode.
SELECT THE APPROPRIATE ELECTRODE(S) FOR THE PROCEDURE

Electrode Default Settings

- For your convenience and to improve safety during use, all electrodes have an internal classification code interrogated by the generator. Default settings and power set adjustment limits are then set appropriately for that particular electrode.

NOTE
Specific information regarding the electrode classification codes and default settings are provided on the labeling of each electrode accessory.

HYSTEROSCOPE AND ANCILLARY EQUIPMENT COMPATIBILITY

To enhance the performance and ease of use of your GYNECARE VERSAPOINT system the following equipment specification should be reviewed with your sales representative:

GYNECARE VERSAPOINT electrodes are designed to fit through endoscopes as indicated in the specific electrode package inserts. An irrigation fluid management system should also be in place.

STEAM STERILIZE THE CONNECTOR CABLE

Sterilize the connector cable according to the connector cable Instructions For Use.

BEFORE SURGERY
Section 6

DURING SURGERY

This section describes how to use the GYNECARE VERSAPoint system during surgery.

ACTIVE ELECTRODE ACCESSORIES

Only Use Approved Electrodes and Connector Cable

Electrode and connector cable accessories other than those specifically designed for use with the GYNECARE VERSAPoint generator must not be used. The GYNECARE VERSAPoint hysteroscopic surgical unit has been designed as a system, with accessory features specifically designed to maximize safety and effectiveness. Unless the generator is able to interrogate the correct identification code contained within the electrode to establish the optimum default settings, all output functions will be disabled.

RECOMMENDATIONS DURING SURGERY

- Refer to the cautions and warnings at the front of this manual.
- Unless circumstances dictate otherwise, use the electrode specific default power and mode settings to enhance patient and user safety.
- Remove any tissue build-up from electrodes to maximize surgical effect.
- Avoid any unnecessary and prolonged activation of the generator to prevent overheating.
- When debulking or vaporizing tissue use a progressive surface shaving technique, rather than burying the electrode in tissue, in order to reduce debris and control the effect to the area of treatment.
- If more than one type of electrode is used during a procedure, unless the second electrode has the same classification code as the first, the generator will revert to the default settings defined by the classification code of the second electrode.

WARNING

Bubbles are produced during tissue vaporization which may interrupt surgery by temporarily interfering with vision and may also result in overheating and cause damage to the electrode tip.

WARNING

When not in use, remove the electrode from the hysteroscope and place outside the operative field away from metallic objects otherwise inadvertent activation may cause injury or equipment damage.

Use of Default Power Settings

The power settings used for the intended hysteroscopic procedures vary considerably both with the surgeon’s technique and the size and/or configuration of the active electrode. Active electrodes are often unique to this type of procedure and may require some experience before optimum power settings are determined. The GYNECARE VERSAPoint system automatically provides the surgeon with appropriate power settings within a given power band for a particular electrode configuration as a default setting.
The GYNECARE VERSAPOINT system has an output power capability more equivalent to a monopolar generator than a conventional bipolar generator. Until the surgeon becomes familiar with the characteristics of the system, caution should be used in increasing power output levels above the default settings.

**CAUTION**

While in a bipolar output format, the GYNECARE VERSAPOINT performs more equivalently to a high power monopolar output. Use caution when adjusting default power settings.

**Use of Default Mode Settings**

Similar to power settings, the mode selection for hysteroscopic surgical procedures will vary considerably with the surgeon’s technique and the size and configuration of the active electrode. Active electrodes are often unique to this type of procedure and may require some experience before the effects of the different mode settings become apparent.

**VC Modes:**

The three VC mode levels adjust the tissue effect of the output:

VC1 > VC2 > VC3, the more aggressive tissue vaporization produced by a VC1 selection. More aggressive tissue vaporization will produce more vapor bubble formation.

**GYNECARE VERSAPOINT ELECTRODES DEFAULT SETTINGS**

See individual electrode labeling

**CAUTION**

The formation of vapor bubbles may obscure hysteroscopic visualization during activation particularly when operating in a very confined space. Use caution when adjusting the VC mode in these circumstances.

**Blend Modes:**

Two blended outputs (BL) are available for use with all electrode configurations. These are indicated as ‘BL1’ and ‘BL2’ on the power setting display. In both options, the output is automatically switched between VaporCut and Desiccate to produce more hemostasis than pure VC outputs, while still providing tissue vaporization. Blend 1 (BL1) switches between VC1 and DES thirty times per second while BL2 alternates between VC2 and DES five hundred times per second. The speed of tissue debulking is reduced compared to the VC modalities and, as with the DES output, the hemostasis effect will depend upon the active electrode contact area.

**Desiccate Mode:**

The DES output is available with all electrode configurations, the hemostatic effect will be dependent on the active electrode contact area and power setting. The output is specifically controlled to prevent vaporization from occurring and to provide a soft coagulation effect. The depth of effect for a given electrode configuration and power setting will be dependent on the application time.
SET UP THE GENERATOR FOR SURGERY

What do I need to set up the GY NECARE VERSAPOINT system?
As a minimum, you need the following items of the GY NECARE VERSAPOINT system before you can set up for surgery:

- Installed generator
- Sterile connector cable
- Selection of at least two electrodes compatible with your continuous flow hysteroscopic system
- GY NECARE VERSAPOINT footswitch

Connect the generator cable
Sterilize the connector cable according to the connector cable Instructions for Use.

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

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

IMPORTANT
If any of the connector pins are bent or the cable flex shows any signs of crush damage, cracking or distortion, it must be discarded.

The generator connector end of the 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 electrode, that sufficient slack is provided so operation is not impeded, and that sufficient slack is also allowed for tethering to the surgical drapes.

NOTE
Once the connector cable is properly connected to the generator the “CONNECT CABLE” symbol on the display will change to the “INSERT ELECTRODE” symbol.

Connect the Electrode
The electrodes are supplied sterile, for single-use only, in a peel pouch tray.

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

Connect the electrode to the generator connector cable. Ensure the connections are correctly oriented before pushing firmly home. Once connection is made, the “INSERT ELECTRODE” symbol flashing on the generator display will change to the default settings appropriate to the electrode classification code. If this does not occur, refer to Section 8, Operating Room Troubleshooting.

IMPORTANT
Visually inspect the connector cable to ensure that it is clean, dry and for any evidence of damage before inserting the electrode.
Introducing the Hysteroscopic Electrode variants through the Working Channel

With the hysteroscope having been inserted into the body cavity, pass the electrode through the working channel ensuring that the working channel tap is in the fully open position prior to introduction.

Once the electrode is inserted, tether excess cable flex to the sterile drapes to prevent dragging during manipulation.

**WARNING**

Avoid the use of excessive force when inserting electrodes through the working channel of hysteroscopes. Angled working channels often include changes in internal diameter which may obstruct free passage. If the free passage of the electrode is obstructed, remove and try again rather than trying to force the electrode tip past the obstruction. Using force to overcome obstruction will result in damage to the electrode tip and risk malfunction or breakage during use.

For other electrode forms see relevant electrode package inserts.

**Activation: Output Selection**

In common with conventional electrosurgical generators, output selection can be made using the blue and yellow pedals of the footswitch.

BLUE PEDAL: Desiccate only. Activation accompanied by flashing of the desiccate power display and an audible tone.

YELLOW PEDAL: VaporCut 1, 2, 3, BL1 or BL2 Blend modes, depending on output mode selection. Activation is accompanied by flashing of the VC/Blend power display and a higher pitched audible tone than the desiccate activate tone.

**IMPORTANT**

Familiarize yourself with the two audible output tones to verify output selection as it is often difficult to visualize the activation pedals (footswitch) during hysteroscopic surgery.

**Changing Output Mode and Power Setting during Surgery**

In Ready mode, power adjustment can be made at any time other than while activated or while the generator displays a malfunction. The permissible range of power adjustment will be limited by the electrode classification code.
Adjustment to output modes: VC1, VC2, VC3, BL1 and BL2 can be made at any time other than while activated or while the generator displays a malfunction. VC1 selection may be inhibited by the electrode classification code.

**Changing Electrodes During Surgery**

An electrode can be removed from the connector cable simply by pulling the electrode connector and connector cable receptacle housing apart.

Once the electrode is disconnected, the generator will automatically enter the idle mode with the display showing the “INSERT ELECTRODE” symbol.

Inserting a new electrode configuration will reset the generator to the default settings for that specific electrode. Unless the electrode has the same identification code, any adjustments to the generator settings made when using the previous electrode will be overridden.

**Changing Accessories Between Procedures**

Section 7 describes the dismantling of the connector cable and electrode assembly.

Once the electrode and connector cable are disconnected, the generator will automatically enter the idle mode with the display showing the “CONNECT CABLE” symbol.

The generator can be left in the idle mode between procedures.

**CAUTION**

If the generator is maintained in the idle mode between procedures and the same electrode configuration 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 electrode configuration will reset the generator to the default settings for that particular electrode classification. Any adjustments to the generator settings made during the previous procedure will be overridden, unless a new electrode with the same electrode configuration is inserted.

Switching the power off will clear all output adjustments and, on subsequent use, the output will assume the default settings for the selected electrode.
Section 7

**AFTER SURGERY**

After surgery, you need to perform the following:

- Withdraw the electrode from the hysteroscope.
- Disassemble the electrode and connector cable.
- Dispose of the SINGLE USE electrode(s).
- Prepare the connector cable for steam sterilization.

**IMPORTANT**

Disconnecting the electrode and connector cable will automatically place the generator into the “CONNECT CABLE” idle mode. The generator can be left in this mode between cases but at the end of the operating session it must be switched off from the power supply.

**Accessory Cleaning Procedure**

Remove all gross matter (blood, mucus, tissue) by wiping each component with a cloth or gauze pad and a mild cleaning solution or blood dissolving detergent. Refer to cleaning product manufacturer for further information.

**IMPORTANT**

The accessories are delicate surgical instruments. Do not immerse in reprocessing solutions. Do not use abrasive cleaning agents. Do not use ultrasonic cleaners. Product damage may otherwise result.

Allow accessory devices to drain thoroughly.

Remove residual cleansing agents with a water dampened cloth.

Dry the accessory devices thoroughly before sterilizing.

**Clean the Connector Cable**

Sterilize the connector cable according to the connector cable Instructions For Use.

**IMPORTANT**

These instructions are intended for electrosurgical accessories supplied as part of the GYNECARE VERSAPOINT system only. You should refer to any specific reprocessing instructions included in the labeling for each accessory.

**IMPORTANT**

The connector cable supplied as part of the GYNECARE VERSAPOINT system is intended for 20 reuse cycles only.

**WARNING**

Do not attempt to reuse any accessories labeled as SINGLE USE.
WARNING
Exceeding the recommended number of uses may result in electrical or mechanical failure during use or difficulty when assembling or disassembling the electrode with the connector cable.

Accessory Sterilization Procedure
Note: The cable is designed for 20 uses only. Each cable should NOT be processed through the steam autoclave more than 20 times. Failure to observe these sterilization instructions in any way could result in improper functioning of the device resulting in serious patient or user injury.

Steam sterilize the accessory devices following procedures approved by your institution. The sterilization cycle conditions will depend on factors specific to your equipment. The Association for the Advancement of Medical Instrumentation (AAMI) Good Hospital Practice for Steam Sterilization and Sterility Assurance identifies the most common steam sterilization parameters as the following:

- Wrapped prevacuum cycle: 132 to 135°C (270 to 275°F) for 3 to 4 minutes.
- Drying times may vary with the type of wrapping material. Please refer to the sterilizer manufacturer for recommended drying times.
- After any sterilization or cleaning process, check the accessory devices for any obvious damage.

Clean 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 generators cannot be sterilized.
## OPERATING ROOM TROUBLESHOOTING

### Problem  |  Suggestions/Solutions
---|---
No output power  |  Check cables.  
  |  Check electrode connection.  
  |  Request assistance from service engineer.

Generator resets during activation (Fault 100.10)  |  Check grounding of generator.  
  |  Check insulation of connector cable.  
  |  Check integrity of electrode.  
  |  Ensure no contact was made with other equipment during activation.

Red light illuminates  |  Refer to fault codes in Section 10 and request assistance as necessary.

Unable to activate the generator  |  If your generator version supports both footswitch and possible future handswitchable accessories check that the correct activation source is selected.  
  |  Check footswitch for damage.  
  |  Ensure approved footswitch is attached.

Alarm tone too loud or too quiet  |  Readjust volume by means of the mode switch.  
  |  Generator will remember the last volume setting employed.

No display on the generator  |  Check inlet fuses, replace with the correct type, if necessary.  
  |  Request assistance from qualified service engineer if fault persists.

Generator flashes “Connect 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 GYNECARE VERSAPOINT approved accessories are being used.

Generator flashes “Insert Electrode” after electrode inserted  |  Ensure the connector contacts are clean and dry and have not been damaged during reprocessing.  
  |  Check electrode integrity.  
  |  Ensure only GYNECARE VERSAPOINT approved accessories are being used.

Generator overheats (Fault 300.10)  |  Allow generator to cool down before re-use.  
  |  Check sufficient ventilation provided around generator.  
  |  Ensure ambient temperature is within operating limits.

GYNECARE VERSAPOINT USER MANUAL
Section 9

PERFORMANCE SPECIFICATIONS

Specifications are subject to change without notice.

In this section, “typical” refers to a specification that is within ±20% of a stated value at room temperature (25°C/77°F).

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: 500 to 1060mBar

Generator power source
Nominal Voltage (at 50/60 Hz): 100-120VAC, 220-240VAC
Operating Range (at 50/60 Hz): nominal 90–132VAC, 198–264VAC
Inlet Fuses: Time lag 5A (T5A)

Generator weight
5.6kg/12lbs 6ozs

Generator overall dimensions
90 x 410 x 368 mm / 3 1/2” x 16 1/8” x 14 1/2” (H x W x D)

Generator leakage currents
Within limits of Type BF equipment as per IEC 60601.

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

Classification
Electrical: Class 1 ordinary equipment as per IEC 60601-1.
EMC: Group 1 Class A as per IEC 60601-1-2.
Defibrillator-Proof
Type BF equipment with isolated (F) applied part.
Each of the electrode terminals of the generator can withstand the effects of defibrillator discharge.

Liquid Spillage as per IEC 60601-2-2
The generator enclosure will prevent reasonable amounts of liquid from interfering with the generators safe and satisfactory operation.

Intermittent Operation
The generator is cooled by natural convection. Under maximum power setting and rated load conditions the generator is suitable for a 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 340kHz and 450kHz, corresponding to minimum and maximum load impedance respectively.

Crest Factor
A constant crest factor of 1.4 nominal for all outputs.

Power
Maximum power 200 watts into 160 ohms.

Max Voltage

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>VC1</td>
<td>340V</td>
<td>RMS</td>
</tr>
<tr>
<td>VC2</td>
<td>307V</td>
<td>RMS</td>
</tr>
<tr>
<td>VC3</td>
<td>254V</td>
<td>RMS</td>
</tr>
<tr>
<td>BL1</td>
<td>340V</td>
<td>RMS</td>
</tr>
<tr>
<td>BL2</td>
<td>307V</td>
<td>RMS</td>
</tr>
<tr>
<td>DES</td>
<td>120V</td>
<td>RMS</td>
</tr>
</tbody>
</table>

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 electrode and connector cable configuration when used with the generator. Each accessory will self-impose an upper set power limit for the generator.
IMPEDEANCE (Ω) VERSUS NOMINAL OUTPUT

HALF POWER (100W) LOAD CURVE

POWER / WATTS
-240 vca
-110 vca
50 100 150 200
PUISSANCE DE SORTIE
SOUS UNE CHARGE DE 150 UHMS
RÉGLAGE DE PUISSANCE

FULL POWER (200W) LOAD CURVE

POWER / WATTS
-240 vca
-110 vca
50 100 150 200
PUISSANCE DE SORTIE
SOUS UNE CHARGE DE 150 UHMS
RÉGLAGE DE PUISSANCE

POWER (WATTS)
LINEARITY OF OUTPUT VERSUS SET POWER

240 Vac
110 Vac

into 150 ohm load
Fault Codes
Any fault code is displayed as: “Fault XXX  Ref XXX”
Faults are transient, non-hazardous events and are recoverable using a generator reset function. Fault conditions can be reset using the mode key. Depressing and releasing the mode key once will initiate user reset, indicated by flashing of the whole fault code on the display. Depress and release the mode key once more to complete reset.

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

Error Codes
Any error code is displayed as: “Error XXX  Ref XXX”

WARNING
An error code indicates a potentially serious malfunction of the generator or an attached accessory. If subsequent checks indicate the problem is not attributable to an accessory no further attempt should be made to use the generator until a service engineer has been consulted.

In the following list, where indicated as recoverable, this would be displayed as a fault message as described above.
<table>
<thead>
<tr>
<th>Error or Fault Code</th>
<th>Ref</th>
<th>Description</th>
<th>KEY: (f) fatal (r) recoverable</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 10</td>
<td></td>
<td>Software failure (recoverable)</td>
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</tr>
<tr>
<td>100 11</td>
<td></td>
<td>ROM checksum failure (fatal)</td>
<td></td>
</tr>
<tr>
<td>100 12</td>
<td></td>
<td>Non volatile memory failure (r)</td>
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</tr>
<tr>
<td>100 13</td>
<td></td>
<td>Memory failure (f)</td>
<td></td>
</tr>
<tr>
<td>100 14</td>
<td></td>
<td>Power generation fault on start up (r)</td>
<td></td>
</tr>
<tr>
<td>100 15</td>
<td></td>
<td>Power generation shutdown fault (f)</td>
<td></td>
</tr>
<tr>
<td>200 10</td>
<td></td>
<td>Unable to drive PWM signal: shorted high (f)</td>
<td></td>
</tr>
<tr>
<td>200 11</td>
<td></td>
<td>Unable to drive PWM signal: shorted low (f)</td>
<td></td>
</tr>
<tr>
<td>200 12</td>
<td></td>
<td>Unable to drive SYNC signal: shorted high (f)</td>
<td></td>
</tr>
<tr>
<td>200 13</td>
<td></td>
<td>Unable to drive SYNC signal: shorted low (f)</td>
<td></td>
</tr>
<tr>
<td>200 14</td>
<td></td>
<td>ENERGY signal: stuck high (f)</td>
<td></td>
</tr>
<tr>
<td>200 15</td>
<td></td>
<td>IOUT signal: stuck high (f)</td>
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</tr>
<tr>
<td>200 16</td>
<td></td>
<td>Unable to drive H/FOOT signal: shorted high (f)</td>
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</tr>
<tr>
<td>200 17</td>
<td></td>
<td>Unable to drive H/FOOT signal: shorted low (f)</td>
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</tr>
<tr>
<td>200 18</td>
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<td>Unable to drive CUT/COAG signal: stuck high (f)</td>
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</tr>
<tr>
<td>200 19</td>
<td></td>
<td>Unable to drive CUT/COAG signal: stuck low (f)</td>
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<tr>
<td>200 20</td>
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<td>CLAMP signal error (f)</td>
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<td>200 21</td>
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<td>BOOST signal error (f)</td>
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</tr>
<tr>
<td>200 22</td>
<td></td>
<td>PEAKSET signal error (f)</td>
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<td>200 23</td>
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<td>PEAK signal error: stuck high (f)</td>
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<td>200 24</td>
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<td>RF_DET signal error: stuck low (f)</td>
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<tr>
<td>200 25</td>
<td></td>
<td>OVERDOSE signal error: stuck high (f)</td>
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</tr>
<tr>
<td>200 26</td>
<td></td>
<td>ENERGY signal error: stuck low (f)</td>
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</tr>
<tr>
<td>200 27</td>
<td></td>
<td>Line voltage relay error (f)</td>
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</tr>
<tr>
<td>200 28</td>
<td></td>
<td>Temperature monitor inoperative (f)</td>
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<tr>
<td>200 29</td>
<td></td>
<td>Audio volume inoperative (r)</td>
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<tr>
<td>200 30</td>
<td></td>
<td>Diagnostic circuit fault (f)</td>
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<td>200 31</td>
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<td>CURR LIM signal error (f)</td>
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<tr>
<td>300 10</td>
<td></td>
<td>Internal overheating (r)</td>
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</tr>
<tr>
<td>300 11</td>
<td></td>
<td>Excess RF input voltage error (f)</td>
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<tr>
<td>300 12</td>
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<td>Out of specification input voltage: low</td>
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</tr>
<tr>
<td>300 13</td>
<td></td>
<td>Out of specification input voltage: high</td>
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</tr>
<tr>
<td>400 10</td>
<td></td>
<td>Footswitch BLUE pedal stuck (r)</td>
<td></td>
</tr>
<tr>
<td>400 11</td>
<td></td>
<td>Footswitch YELLOW pedal stuck (r)</td>
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<tr>
<td>400 12</td>
<td></td>
<td>[RESERVED] Handswitch BLUE button stuck (r)</td>
<td></td>
</tr>
<tr>
<td>400 13</td>
<td></td>
<td>[RESERVED] Handswitch YELLOW button stuck (r)</td>
<td></td>
</tr>
<tr>
<td>400 14</td>
<td></td>
<td>Electrode identification circuit fault (r)</td>
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</tr>
<tr>
<td>400 15</td>
<td></td>
<td>Front panel switch fault: yellow UP button (r)</td>
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<tr>
<td>400 16</td>
<td></td>
<td>Front panel switch fault: yellow DOWN button (r)</td>
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<tr>
<td>400 17</td>
<td></td>
<td>Front panel switch fault: blue UP button (r)</td>
<td></td>
</tr>
<tr>
<td>400 18</td>
<td></td>
<td>Front panel switch fault: blue DOWN button (r)</td>
<td></td>
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<tr>
<td>400 19</td>
<td></td>
<td>Front panel switch fault: MODE button (r)</td>
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<tr>
<td>400 20</td>
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<td>Intermittent activation switch (r)</td>
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<tr>
<td>500 10</td>
<td></td>
<td>Serial port not functional (r)</td>
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</tr>
<tr>
<td>500 11</td>
<td></td>
<td>Serial port timeout (r)</td>
<td></td>
</tr>
<tr>
<td>500 12</td>
<td></td>
<td>Host computer not present (r)</td>
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</tr>
<tr>
<td>500 13</td>
<td></td>
<td>Possible board short (PWM)</td>
<td></td>
</tr>
<tr>
<td>500 14</td>
<td></td>
<td>Possible board short (SYNC)</td>
<td></td>
</tr>
<tr>
<td>500 15</td>
<td></td>
<td>[RESERVED]</td>
<td></td>
</tr>
<tr>
<td>500 16</td>
<td></td>
<td>Possible board short (H/FOOT CUT/COAG)</td>
<td></td>
</tr>
</tbody>
</table>
Section 11

EXPLANATION OF SYMBOLS

Generator back panel

Attention, consult accompanying documents.

Non-ionizing radiation.
This equipment intentionally emits RF energy during activation.

Defibrillator-proof Type BF equipment.
This equipment provides a degree of protection against electric shock to TYPE B as defined in IEC 60601-1. This equipment has an F type applied part capable of withstanding the effects of defibrillator discharge.

This symbol indicates the receptacle to which the generator footswitch should be attached.
This symbol indicates the conductor that may be used to provide potential equalization between the equipment and the installation busbar.

### SYMBOLS USED ON PRODUCT LABELING

- **2**: Do not reuse
- **LOT**: Batch number
- **Use by**: year and month
- **STERILE**: Sterile unless the package is damaged or open. Method of sterilization—Irradiation
- **See Instructions for use**: See Instructions for use
- **Temperature limitations**: Temperature limitations
- **Keep dry**: Keep dry
- **Fragile, handle with care**: Fragile, handle with care
- **Keep away from heat**: Keep away from heat
- **CE Mark and Identification Number of Notified Body. The product meets the Essential Requirements of the Medical Devices Directive 93/42/EEC.**
Section 12

PERIODIC EQUIPMENT SAFETY CHECKS

The manufacturer recommends that the GYNECARE VERSAPOINT electro-surgical generator 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.

- 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 IEC 60601-1 or the corresponding national standard as applicable.

- Switch on the generator ensuring that the initial internal self-test completes 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 that the enclosure earth leakage current is within the limits for Class I equipment as prescribed within IEC 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 IEC 60601-1 or a corresponding national standard.

- Details of these tests should be recorded in an equipment log with the date of test for future reference. Contact the service repair center nominated by the manufacturer should a unit fault be suspected.
Section 13

LIMITED WARRANTY

The manufacturer warrants the products listed below to be free from defects in material and workmanship under normal user 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 GYNECARE VERSAPOINT system are as follows:

<table>
<thead>
<tr>
<th>Component</th>
<th>Warranty Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generator and footswitch</td>
<td>One Year from shipment date</td>
</tr>
<tr>
<td>Reusable Accessories</td>
<td>20 reuse cycles</td>
</tr>
<tr>
<td>Electrodes</td>
<td>Single-use only</td>
</tr>
</tbody>
</table>

This warranty is in lieu of all other warranties, express 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.

Governing Law: This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of New Jersey, USA, without regard to the provisions of those laws dealing with conflict of laws.

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 for Gynecare, Inc.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
MEDICAL ELECTRICAL EQUIPMENT
CLASSIFIED BY UNDERWRITERS LABORATORIES INC.
WITH RESPECT TO ELECTRICAL SHOCK, FIRE, MECHANICAL
HAZARDS AND OTHER SPECIFIED HAZARDS ONLY IN
ACCORDANCE WITH UL60601-1 AND CAN/CSA C22.2 NO. 601.1

CAUTION
USE ONLY THE POWER CORD PROVIDED BY YOUR
PRODUCT SUPPLIER.
DO NOT USE ANY OTHER POWER SUPPLY CORD.

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.

WARNING
RISK OF FIRE
REPLACE FUSE AS MARKED

MISE EN GARDE
UTILISER UNIQUEMENT LE CORDON
D’ALIMENTATION FOURNI PAR VOTRE
FOURNISSEUR. NE PAS UTILISER
D’AUTRE TYPE DE CORDON
D’ALIMENTATION.

MISE EN GARDE
LE CORDON D’ALIMENTATION EST
CONCU POUR UNE UTILISATION EN
AMÉRIQUE DU NORD SOUS UNE
TENSION DE 110V. CE CORDON
D’ALIMENTATION EST DE TYPE UL
SJT, ALIMENTATION 120V ET 10A
MINIMUM. CONTRACTER VOTRE
REPRÉSENTANT LOCAL POUR UNE
UTILISATION À UN AUTRE VOLTAGE.

ATTENTION
RISQUE D’INCENDIE
REPLACER LE FUSIBLE COMME
INDIQUE
TO REPORT ANY DEVICE-RELATED INCIDENTS OR PROBLEMS, PLEASE CONTACT (800) 255-2500 (US DOMESTIC ONLY) OR THE AUTHORIZED EUROPEAN REPRESENTATIVE.

Authorized European Representative: Gyrus Medical Limited
Fortran Road
St. Mellons
Cardiff CF3 OLT
United Kingdom
Tel: +44 (0) 29 20776300
FAX: +44 (0) 29 20776301

U.S. Distribution/ Manufactured for

GYNECARE
A division of ETHICON, Inc.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151 USA

CE 0086
CE mark and identification number of Notified Body. The product meets the Essential Requirements of the Medical Devices Directive 93/42/ECC.