



User Manual
English



**GYRUS P/N:
126063-HC**

**P/N: 103097
Rev: N Revised 11/2014
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User Manual

English

This user's guide will familiarize you with the controls and output functions available from your DePuy Mitek VAPR System and instruct you on the proper use of the equipment. Review this manual thoroughly before installation and use of the VAPR System. Please also read, understand and follow all cautions and warnings in this manual and those included in the Instructions for Use included with the VAPR System accessories. Additional information, training and product servicing are available from DePuy Mitek.

The information contained in this manual is based upon the most current information available at the time of printing. DePuy Mitek reserves the right to update the equipment and its operation without notice.

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This manual covers both the VAPR II and VAPR 3 System. Except where otherwise indicated, the instructions for use apply to both systems.



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INTRODUCTION



BACKGROUND

Arthroscopy relates to the use of an arthroscope to visualize the joint space. A variety of instruments specifically designed for arthroscopic use may be introduced through separate puncture sites, employing the technique of triangulation, in order to perform various surgical procedures within the joint space.

Arthroscopic instruments have been developed to provide specific functions such as tissue removal, cutting, shaping and coagulation. Until recently, these instruments have broadly taken one of three forms; manual instruments, powered instruments, and electro-surgical instruments, each with respective merits and limitations. As a result, it is common practice to employ a combination of instruments during an arthroscopic procedure.

The DePuy Mitek VAPR System represents a new and versatile approach to arthroscopy. Based on an innovative form of bipolar electro-surgery, the VAPR System has been specifically designed to provide a range of arthroscopic surgical modalities including soft tissue ablation (electro-vaporization), contouring, cutting and coagulation and temperature indication.

COMPARISON TO CONVENTIONAL ELECTRO-SURGERY

Conventional electro-surgical systems deliver high frequency electrical current through tissue for the purposes of tissue cutting or hemostasis of blood vessels. Monopolar electro-surgery utilizes an "active" electrode located on the surgical instrument and a separate "return" electrode applied to the patient. Current flow is from the active electrode, through the patient to the return electrode. Bipolar electro-surgery differs in that both the active and return electrodes are located on the surgical instrument, thus minimizing the amount of tissue involved in the electrical circuit.

Problems potentially encountered when using conventional bipolar electro-surgery include limited power delivery and visualization of the working tip, tissue sticking, and dependence upon proper electrode-to-tissue orientation. Additionally, conventional bipolar electrodes do not operate effectively while immersed in conductive irrigating solutions used in arthroscopy, such as normal saline or Ringer's lactate.

In contrast, VAPR bipolar electro-surgery Electrodes are specifically designed to function in conductive irrigating solutions. The VAPR "return" electrode is mounted on the shaft of the instrument and does not have to be oriented to be in contact with tissue during use. This eliminates the need for a separate patient ground electrode. Additionally, since only the tissue that is in contact with the active electrode is involved in the electrical circuit, the recognized safety features of bipolar electro-surgery are preserved.

INTRODUCTION

1-1



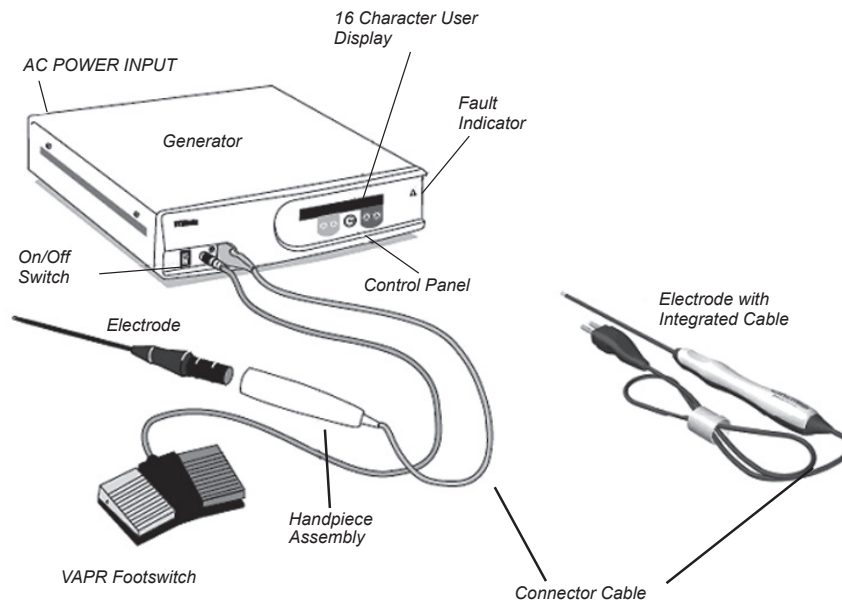
SYSTEM DESCRIPTION

The VAPR System is designed to provide soft tissue ablation (vaporization), contouring, cutting and hemostasis of blood vessels during arthroscopic surgical procedures.

The components of the DePuy Mitek VAPR System (FIGURE 1) are individually described in Section 4 of this manual:

- VAPR Generator
- VAPR Handpiece and Cable
- VAPR Electrodes
- VAPR, VAPR 3 Footswitch
- Power Cord (not provided)

Use only the DePuy Mitek Handpiece and Electrodes with this System.



INTRODUCTION

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VAPR 3 FOOTSWITCH

FIGURE 1



PRINCIPLE OF OPERATION

The VAPR System offers four bipolar modes of operation: Vaporization, Desiccation, Blended Vaporization and desiccation with temperature indication.

- In the Vaporization mode of operation, high frequency power is delivered from the VAPR Generator to the Electrode tip. At specific threshold power levels, a vapor pocket, characterized by an orange glow, is created around the active electrode. Arcs within the vapor pocket produce vaporization of tissue entering the vapor pocket.
- The Vaporization power threshold for a particular VAPR Electrode is automatically set as a default by connecting the Electrode, via the Handpiece, to the Generator. The default setting for each Electrode type is the optimal power required to produce the desired tissue effect. As an inherent safety feature, the VAPR System is designed to minimize the power required to sustain the vapor pocket around the active electrode.
- In the Desiccation mode of operation, the VAPR Generator delivers high frequency power to the active electrode to cause tissue desiccation and coagulation without sparking or cutting. The Desiccation power level is also automatically set as a default for each style of Electrode.
- The Blended Vaporization mode of operation provides tissue vaporization combined with hemostasis. Certain Electrode styles will automatically default to a Blended Vaporization mode.
- In the Desiccation Mode with temperature indication (only available with the VAPR Temperature Control (TC) electrodes), the tip temperature is set as a default, along with a power level. The VAPR System will monitor the actual tip temperature while activating, automatically adjusting the power to maintain the tip temperature at the set temperature.

INTRODUCTION

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NOTE

The Temperature Control system will only automatically adjust the power up to the limit of the current displayed desiccate power level.

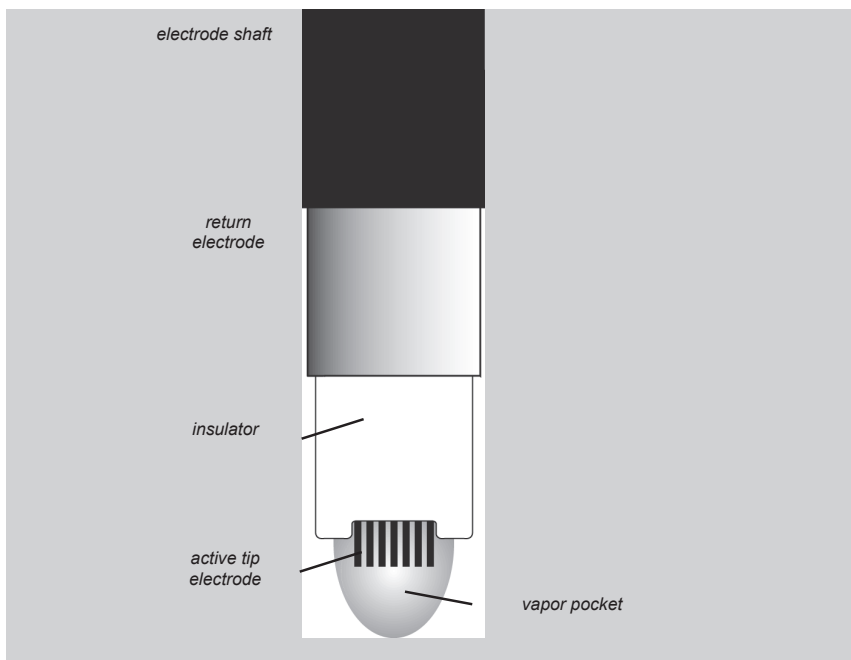


FIGURE 2



INDICATIONS FOR USE, CONTRAINDICATIONS

INDICATIONS FOR USE

The DePuy Mitek VAPR System is intended for resection, ablation and excision of soft tissue, and hemostasis of blood vessels in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist. Arthroscopic surgery could include, for example, the following:

Knee

Meniscectomy
Lateral Release
Chondroplasty
Synovectomy
ACL Debridement
Plica Removal
Meniscal Cystectomy

Shoulder

Labral Tear Resection
Synovectomy
Excision of Scar Tissue
Acromioplasty
Bursectomy
Subacromial Decompression
Chondroplasty

INDICATIONS FOR USE, CONTRAINDICATIONS

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Ankle

Fracture Debridement
Excision of Scar Tissue
Synovectomy
Chondroplasty

Elbow

Synovectomy
Tendon Debridement
Chondroplasty

Wrist

Synovectomy
Cartilage Debridement
Fracture Debridement

CONTRAINDICATIONS

The DePuy Mitek VAPR System is contraindicated in any non-arthroscopic surgical procedure and in procedures where saline or Ringer's lactate is not used as an irrigant. The System is also not appropriate for patients for whom an arthroscopic procedure is contraindicated for any reason. Use of the System is also contraindicated in patients with heart pacemakers or other electronic device implants.



SAFETY

OPERATING PERSONNEL

The surgeon using this device should:

- be trained in arthroscopic surgical procedures
- be aware of the risks associated with those procedures
- have current knowledge of technological advances in surgical products and techniques.

WARNING

Hazardous Electrical Output: This equipment is capable of producing a physiological effect and is for use only by licensed physicians, trained in the use of this device.

WARNING

No modification to the equipment is allowed.

SAFETY

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FIRE/EXPLOSION WARNINGS

- As with all electrosurgical devices, do not use in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide, oxygen or endogenous gases which have accumulated in body cavities. An electrosurgical device has the potential for providing a source for ignition.
- Nonflammable substances should be used for cleaning and disinfecting. Use of flammable substances, such as alcohol-based skin prepping agents and tinctures should also be avoided.
- All oxygen connections must be leak free for the duration of the surgical procedure. Pathways, such as endotracheal tubes, must be leak free and properly sealed to prevent oxygen leaks.
- Electrosurgical accessories which are activated or hot from use can be a potential fire hazard if placed near or in contact with flammable materials. Some materials, such as gauze, cotton or wool, when saturated with flammable liquids, can be ignited by sparks produced during the normal use of electrosurgical devices.

ELECTRICAL SAFETY CONSIDERATIONS

- Examine all accessories and connections to the VAPR Generator before use. Ensure that the accessories function as intended. Improper connection may result in arcing, sparking, or malfunction of the Electrode or Handpiece, any of which can result in an unintended surgical effect, injury, or product damage.
- Unless specified in the instructions for use accompanying an approved VAPR accessory, the VAPR System should only be activated with the working tip of the electrode accessory completely immersed in 0.9% w/v; 150 mmol/l sodium chloride or Ringer's lactate solutions. For convenience, these will be referred to within the remainder of this manual as normal saline or Ringer's, respectively. Performance will be suppressed by use of other irrigating solutions such as Glycine, Sorbitol, Dextrose, Mannitol or other solutions containing a non-physiological concentration of electrolytes.



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 system was designed can significantly degrade emissions and immunity performance.

WARNING

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

WARNING

Do not use a monopolar generator/accessories simultaneously with the VAPR 3 generator. Activation of a monopolar generator/accessories may cause interference with the VAPR 3 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.

ELECTROSURGICAL SMOKE CAUTION

- Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to surgical personnel. Use appropriate surgical masks or other means of protection.
- It is recommended that a suitable extraction method is employed.

PRIOR TO SURGERY

Operator Safety Warnings

- Electric Shock Hazard: Do not connect wet accessories to the handpiece or generator. Ensure that all accessories are securely and properly connected.
- Electric Shock Hazard: Do not remove or tamper with the Generator housing. Contact DePuy Mitek technical service for assistance.
- The power cord must meet all requirements for safe grounding. Do not use extension cords, multiple point plugs or 2 to 3 pronged adapters.
- Do not reuse or resterilize accessories labeled "SINGLE USE," as malfunction, injury or cross-infection may result.
- Non-function of the Workstation may cause interruption of surgery. Ensure that all installation procedures are followed and all connectors are correctly inserted before use. A backup system / method should be made available for use.

Operator Safety Cautions

- Inspect the insulation of all cords for cracks, nicks and breaks. Inspect all connectors for damaged or missing parts.
- Use default power levels to test Electrode performance. Confirm proper default power settings with package insert information before proceeding with surgery.
- Accessories labeled "REUSABLE" must only be processed according to the recommended procedures provided in this manual.
- Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors) because an activated electrosurgical generator may cause interference with them.

SAFETY

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DURING SURGERY

NOTE

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

WARNING

Failure of the HF surgical equipment could result in an unintended increase or decrease in output power, change in output waveform characteristics or absence of electrosurgical output.

Operator Safety Warnings

- Observe extreme caution when using electrosurgery in close proximity to or in direct contact with any metal objects. The majority of arthroscopes and arthroscopic instruments are metal. Do not activate the electrode while any portion of the electrode tip is in contact with another metal object; localized heating of the electrode and the adjacent metal object may result in product damage.
- Do not wrap Handpiece, Footswitch or Generator power cord around metal objects. Wrapping cables around metal objects may induce currents that could lead to shock, fire or injury to patient or surgical personnel.
- During an electrosurgical procedure, the patient should not be allowed to come into direct contact with grounded metal objects such as surgical table frame, instrument table, etc.
- Confirm proper default generator power settings before proceeding with surgery. Always check that the automatic default settings shown on the display match those indicated on the package insert of the Electrode being used.
- Caution should be used when overriding the default power settings. Use the lowest power setting and the minimum tissue contact time necessary to achieve the appropriate surgical effect.
- Visually inspect the Handpiece and Electrode to ensure that they are clean and dry and free of damage prior to inserting the Electrode. Damage to the connectors or the presence of fluid may cause a hazardous electrical short.
- Ensure that the Electrode is fully seated in the handpiece prior to use. Improper connection could result in non-activation of the Electrode and fluid leakage which may produce an electrical short.
- Ensure that electrodes with integrated cables are properly connected to the generator, and that the correct default settings are displayed.
- Introducing the Electrode without an instrument cannula may result in tissue injury and/or product damage.
- Do not insert, withdraw or touch the active tip of the Electrode when power is being applied.
- When not in use, place the active Electrode 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.
- All high frequency electrosurgical devices can potentially cause muscle stimulation during use. System design minimizes this effect, however, muscle stimulation may cause unexpected movement of the patient within the surgical field.
- Skin-to-skin contact (for example between the arms and body of the patient) should be avoided by, for example, insertion of dry gauze.

Operator Safety Cautions

The VAPR 3 system contains an over-current alarm. If this is heard during activation, the electrode and handpiece must be withdrawn and inspected for damage. An accessory that causes repeated over current alarms (when not in contact with a metal surface/object) should be discarded.

SAFETY

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- Maintain the generator volume control to a level that will be audible in a normal operating room environment. The activation tone is heard while the foot pedal is depressed, indicating the electrode is activated.
- If possible, avoid the use of needle style electrodes for any physiological monitoring equipment that may be connected to the patient during electro-surgery.
- Where practical, only use monitoring equipment that incorporates high frequency current limiting devices during electrosurgical procedures.
- The Handpiece, or electrode cable should be positioned so that it avoids contact with the patient and any other leads.
- 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.
- Attempts to bend electrodes can result in electrode fracture or degradation of electrode performance.
- Fluids pooled in the body depressions and cavities should be removed before the use of HF surgical equipment.

Potential Hazards for Arthroscopic Procedures

As visualization may be impaired during arthroscopy, be particularly alert to these potential hazards:

- An activated Electrode tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Maintain the active Electrode in the field of view at all times. Injuries to the patient may result from inadvertent activation or movement of an activated Electrode outside the field of view.
- Use care when inserting and withdrawing the Electrode from a cannula to avoid the possibility of damage to the devices and/or injury to the patient.
- Continuous flow of irrigant is recommended. Fluid flow assists in removing vaporization by-products as well as reducing the temperature of the electrode tip between activations.
- Ensure that the Electrode tip is completely surrounded by irrigant solution during use.
- Outflow is important, especially in small joint spaces.
- Prolonged or unnecessary activation when not in contact with tissue may result in unintentional damage to surrounding tissue.

AFTER SURGERY

WARNING

Electric shock hazard: Turn off the Generator and unplug the power cord from the AC source prior to cleaning Generator.

Equipment Disposal

- The VAPR 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 institutional related policy relating to obsolete electronic equipment.
- Dispose of any system accessories according to normal institution practice relating to potentially contaminated items.

SAFETY

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SYSTEM DESCRIPTION

VAPR GENERATOR

The VAPR Generator (FIGURE 3) is an isolated output radiofrequency generator that provides power for soft tissue vaporization, cutting and coagulation during arthroscopic surgical procedures. Technical specifications are detailed in Appendix A.

OUTPUT MODES

The VAPR Generator allows the user to select one of the following functional modes: a tissue Vaporization mode, or a Blended Vaporization mode that combines Vaporization and Desiccation using generator set-up options, with the selected output mode activated using the Yellow footswitch pedal. The Desiccation (hemostasis) mode is activated using the Blue footswitch pedal. A brief description of each mode is provided below:

SYSTEM DESCRIPTION

4-1

Vaporization (V) Modes

There are three standard V mode levels V1, V2 and V3. The least aggressive tissue vaporization is created in the V1 mode while the most aggressive tissue vaporization is created in the V3 mode.

Desiccate (DES) Mode

The Desiccate mode provides hemostasis of blood vessels without tissue vaporization. Available with all Electrode configurations, the hemostatic effect will be dependent on the active electrode contact area and power setting. The depth of effect for a given Electrode configuration and power setting is dependent upon the application time.

DES with Temp Indication

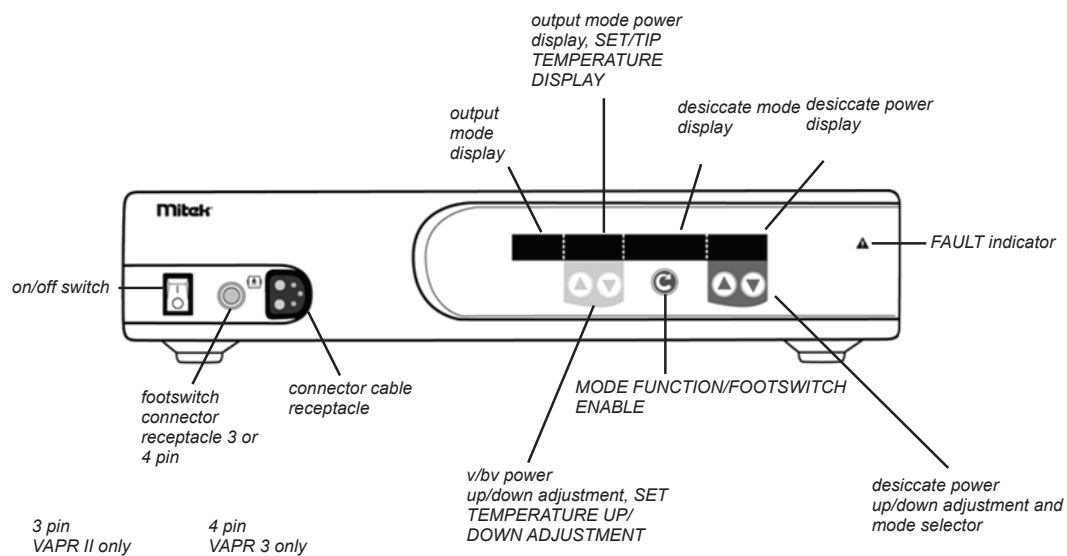
When in desiccation mode, this allows the display of electrode tip temperature, and control against a set temperature.

Blended Vaporization (BV) Modes

There are two Blended Vaporization modes: BV1 and BV2. The Blended Vaporization output modes combine tissue vaporization with hemostasis and are useful when cutting or de-bulking more vascular tissue structures.

- BV1 mode automatically switches between a V2 vaporization mode and desiccate (hemostasis) mode.
- BV2 mode switches between the V3 vaporization mode and desiccate (hemostasis) mode.





SYSTEM DESCRIPTION

4-2

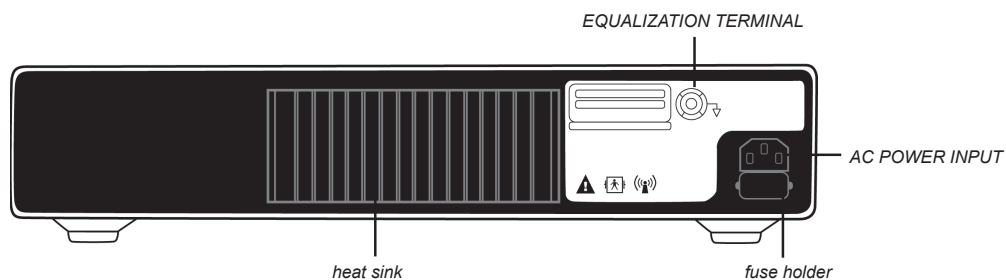
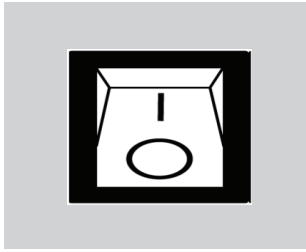


FIGURE 3

GENERATOR CONTROLS AND DISPLAYS



Power Switch

The power switch turns AC power on and off. When the Generator is on, the green light within the power switch is illuminated. It is advisable to switch off the Generator whenever it is not in use to avoid any possibility of inadvertent activation.



Fault Indication Light

This light will illuminate to indicate a Generator critical failure or a VAPR accessory malfunction.

NOTE

The light will illuminate briefly during the self-test routine. This is normal and does not indicate a failure.

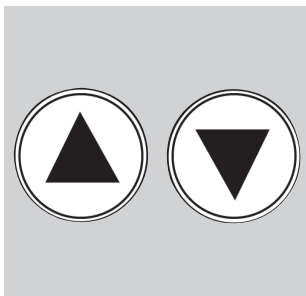


Mode Button

Depressing the mode button once will enable selection of the mode using the Power Up and Down buttons in the Desiccate (blue) section. Once the display shows the desired V or BV output mode, holding the Mode Button down will return the Generator to a Ready condition.

SYSTEM DESCRIPTION

4-3

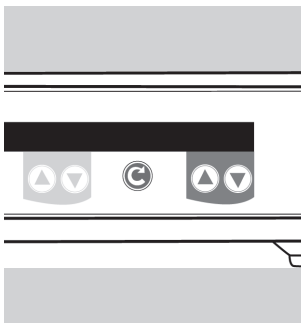


Power Up/Down

The Power Up and Down buttons adjust the default power setting; the Yellow Arrow button controls the Vaporization (V) and Blended Vaporization (BV) outputs in standard electrodes and set tip temperature with TC electrodes and the Blue Arrow buttons control the Desiccate (DES) output. 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 "Ready" mode after an Electrode is properly connected to the Generator. The VAPR Electrode will determine its own default output power and set temperature.



Power/Temperature Setting Display

The display is divided into separate yellow and blue sections. The yellow section (left side) displays the nominal output power in watts for the selected Vaporization or Blended Vaporization modes or set temperature in TC electrodes. The blue section, (right side) displays the nominal output power in watts for the Desiccate output. When an output is activated, the power display for the selected output flashes and an audible tone sounds. For a VAPR TC electrode the actual measured 'TIP' temperature is displayed.



FRONT PANEL DISPLAY SYMBOLS

OUTPUT (YEL)

Indicates that the output mode for yellow pedal activation can be selected.

FOOTSWITCH

VAPR II ONLY

Indicates that the footswitch is the activation source for the system.

ALARM VOLUME

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

CONNECT CABLE

Indicates that the Generator is waiting for the Electrode/Handpiece Cable to be attached to the front panel receptacle.

SYSTEM
DESCRIPTION

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INSERT ELECTRODE

Indicates that the Generator is waiting for an Electrode to be inserted into the Handpiece. Not displayed when using the electrode with integrated cable.

NOTE

Mode selection can only be performed after an Electrode and Handpiece are connected to the Generator. If the Mode button is quickly pressed and released the next user set-up option appears.

OUTPUT SHORTED

VAPR 3 ONLY

May appear if the active tip shorts against nearby metal objects. A warning tone will also be issued. Press the mode button on the front panel or the third footswitch button to resume operation, for TC electrodes only.

For all other electrode types operation will resume automatically when the short is removed (provided foot-pedal remains depressed).

FOOT MENU

OFF

VAPR 3 ONLY

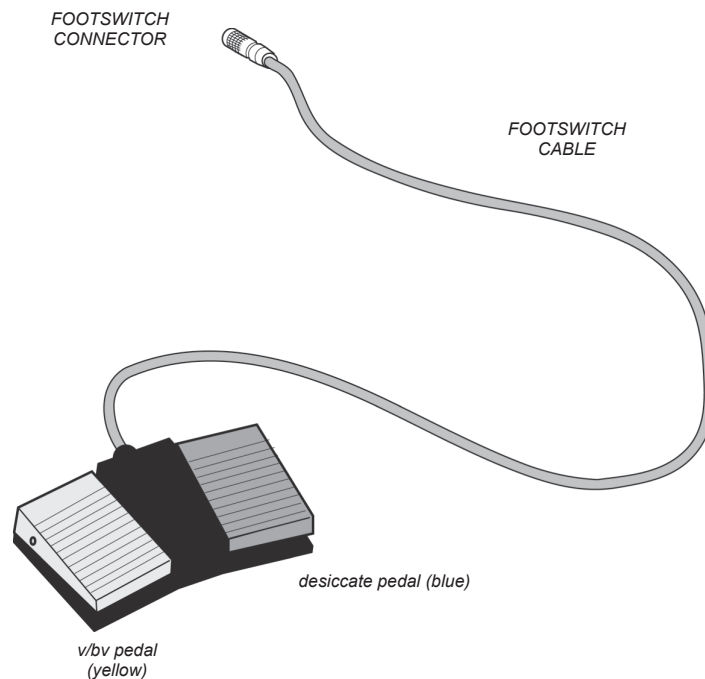
Indicates that the Footswitch menu option is in the default off position.



FOOTSWITCH (VAPR II ONLY)

The 2 pedal Footswitch (FIGURE 4A) connects to the VAPR Generator and has two activation pedals:

- Depressing the yellow pedal activates the selected Vaporization (V) or Blended Vaporization (BV) outputs.
- Depressing the blue pedal activates the Desiccate (DES) output to produce hemostasis or thermal modification of tissue.
- Depressing both footswitches simultaneously can reset the Generator for fault conditions.



SYSTEM DESCRIPTION

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FIGURE 4A

FOOTSWITCH (VAPR 3 ONLY)

The VAPR 3 Footswitch (FIGURE 4b) connects to the VAPR Generator. The yellow and blue pedals are used for output activation with the menu/reset button for fault clearance or remote adjustment of the output settings (if enabled as shown below).

- Depressing the yellow pedal activates the selected Vaporization (V) or Blended Vaporization (BV) outputs.
- Depressing the blue pedal activates the Desiccate (DES) output to produce hemostasis or thermal modification of tissue.
- Depressing the menu/reset button can reset the Generator from a fault condition.

Enabling of Footswitch Setting Feature (software version V1.02 onwards)

- In the “ready” state, press the mode function button (as shown on FIGURE 3) three times, the display will show “FOOT MENU OFF” (the VAPR 3 system is supplied with “OFF” as default).
- Press either of the blue arrow buttons to toggle the state until the display indicates “FOOT MENU ON”.
- Press the mode function button until the generator returns to the “ready” state.
- When enabled as described above the output settings may be controlled as follows:
- Depressing and releasing the menu/reset button when the VAPR Generator is waiting for user interaction (“ready” state) will initiate a setting adjustment procedure.
- After pressing the menu/reset button the first time the VAPR Generator will emit two short beeps and start flashing, the vaporize mode power settings on the left of display as shown in FIGURE 5A.
- While the power setting is flashing, holding down the blue pedal will reduce the value and holding down the yellow pedal will increase it.
- Pressing the menu/reset button once more will advance the setting to the vaporize waveform which will start to flash rapidly on the display. Pressing and releasing the yellow or blue pedals will cycle through the availability modifiers (FIGURE 5B).
- Pressing the menu/reset button again will cause the DES power setting to flash as per FIGURE 5c so that it may be adjusted in the same way as the V/BV power.
- Pressing the menu/reset button once more resumes the “ready” state with a static display.

SYSTEM DESCRIPTION

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FIGURE 4b

NOTE

In some versions of the 3 input footswitch the menu/reset button will be replaced by a gray pedal. For VAPR 3 systems with software V1.01 the footswitch setting feature is always enabled.

| Menu Button | Modify | Yellow Pedal | Blue Pedal |
|---|---|--------------|-------------|
| Press menu button once , hold for 2 beeps (same tone-high), release . | Ablation Power | ↑ | ↓ |
| Press menu button second time , hold for 2 beeps (high-low), release . | Ablation Mode (V3, V2, V1, BV2, BV1) | ↑ | ↓ |
| Press menu button third time , hold for 2 beeps (same tone-low), release . | Desiccation Power | ↑ | ↓ |
| Press menu button fourth time , hold for 2 beeps (low-high), release . | Operative Mode | Ablation | Desiccation |
| To reset to Operative mode from anywhere within the menu process, press and hold menu button for 2 seconds (screen will go blank), release button. | | | |



FIGURE 5A



FIGURE 5B



FIGURE 5c

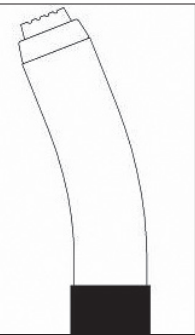
VAPR ELECTRODES

The family of VAPR Electrodes has been designed to facilitate access and control the delivery of energy to the joint space. Each Electrode contains an internal classification code which automatically adjusts the VAPR Generator to the optimal output power setting. The VAPR Electrode has an integrated “return” electrode on its shaft, eliminating the need for a conventional patient ground pad. Angled Electrode styles are also available to facilitate tissue access and positioning during use.

WARNING

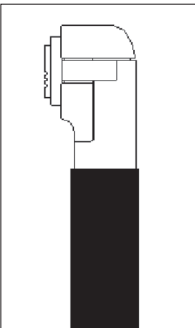
This product is for single-use only. It has not been designed to be re-used/re-sterilized. Reprocessing may lead to changes in material characteristics such as metallic corrosion and dulled edges, ceramic and plastic deformation or splitting which may impact the strength of the device and compromise device performance. Reprocessing of single use devices can also cause cross-contamination leading to patient infection. These risks may potentially affect patient safety.

The working tips of the Electrodes can be divided into the following main functional types according to the geometry of the active electrode and insulation support:



Premiere⁵⁰ Electrode - VAPR3 Default Power 160 W
VAPR S⁵⁰ Electrode - VAPR3 Default Power 60 W

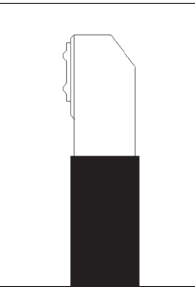
The forward facing active tip is designed to facilitate controlled, precise tissue effects. The RF probe, with angled shaft is intended to be used for removal of soft tissue during Arthroscopic procedures in smaller, more difficult areas of the anatomy to access such as the knee (i.e., posterior horn of meniscus). The integral Suction Port allows bubbles and vaporization products to be removed. The design provides a large area suction path which attracts difficult to access frond tissue to the tip and helps minimize clogging.



LDS, LPS, and VAPR S⁹⁰ Electrodes

The side facing electrode is designed to maximize the tip tissue contact area and provide rapid tissue debulking. The electrode has a large tip-shaft offset which maximizes tactile feedback and facilitates removal of difficult to reach tissue. The integral Suction Port allows bubbles and vaporization products to be removed. The design provides a large area suction path which attracts difficult to access frond tissue to the tip and helps minimize clogging.

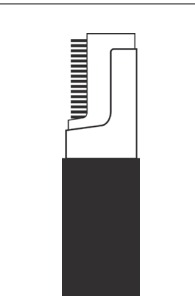
Additionally, the forward facing end of the manifold may be useful in protecting adjacent structures from inadvertent injury during activation.



Premiere⁹⁰ Electrode

The side facing electrode is designed to maximize the tip tissue contact area and provide rapid tissue debulking. The electrode has a large tipshaft offset which maximizes tactile feedback and facilitates removal of difficult to reach tissue. The integral Suction Port allows bubbles and vaporization products to be removed. The design provides a large area suction path which attracts difficult to access frond tissue to the tip and helps minimize clogging.

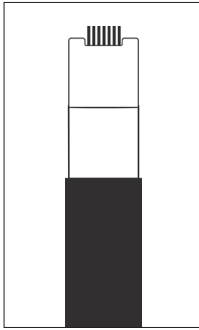
Additionally, the forward facing end of the manifold may be useful in protecting adjacent structures from inadvertent injury during activation.



3.5 Side Effect Electrode

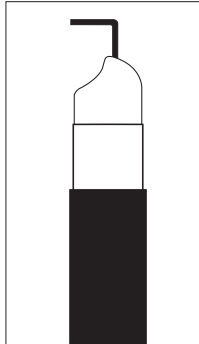
The side-facing electrode is designed to maximize tissue contact area and produce rapid tissue debulking. The active, tissue contact electrode is mounted on the side of the working tip with the return electrode extending over the insulator on the opposite side of the active electrode. This configuration is particularly useful in engaging tissue which is approached at an acute angle. Additionally, the insulator and return electrode assist in protecting adjacent structures from inadvertent injury during activation. The larger contact area of the electrode means that these electrodes also produce effective hemostasis of blood vessels.





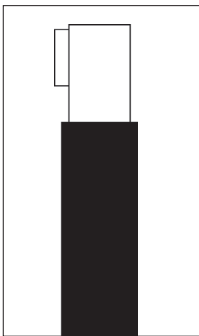
3.5 End Effect Electrode

The forward-facing spring electrode is designed to facilitate controlled, precise tissue effects. Additionally, side extensions of the insulator minimize undesired collateral tissue contact.



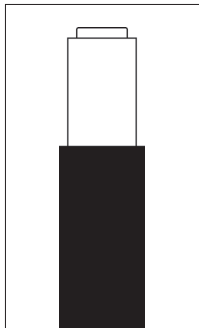
3.5 90° Hook Electrode

The 90° hook electrode is designed to provide tissue cutting. Use of the hook as a probe should be avoided.



2.3 Side Effect Electrode

The side-facing active tip is designed to maximize tissue contact area and produce rapid tissue debulking. The 2.3 configuration is particularly useful in engaging tissue that cannot be approached using the 3.5 electrode.

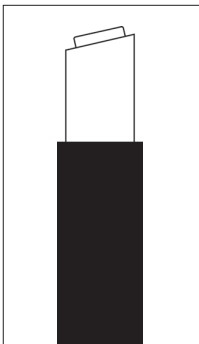


2.3 End Effect Electrode

The forward facing active tip is designed to facilitate controlled, precise tissue effects.

2.3 Temperature Control End Effect Electrode

A soft tissue desiccation device, utilization with a VAPR 3 system allows tip temperature of the electrode to be indicated on the generator display.



2.3 Wedge Electrode

The 45° angled active tip is designed to facilitate controlled, precise tissue effects. Additionally the side extension of the insulator will minimize undesired collateral tissue contact.

SYSTEM DESCRIPTION

4-9

VAPR HANDPIECE AND CABLE

The VAPR Handpiece/Electrode (FIGURE 6) is ergonomically designed to facilitate user comfort and control during use. The reusable Handpiece/Electrode and Cable connects the disposable Electrode with the VAPR Generator.

The Handpiece and Cable are supplied Non-Sterile and must be sterilized prior to each use. Sterilization instructions are provided in Section 6 of this manual.

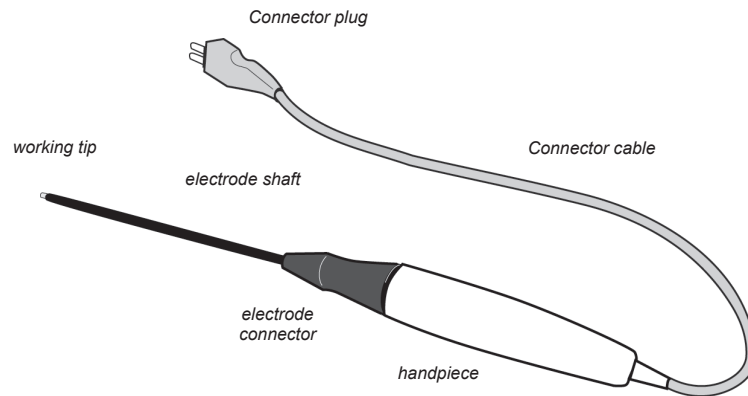


FIGURE 6

SYSTEM DESCRIPTION

4-10

| Part Number | Product Description |
|-------------|--|
| 225002 | VAPR® Handpiece REUSABLE |
| 225023 | VAPR® 3 Footswitch REUSABLE |
| 225303 | VAPR® End Effect Electrode 3.5 mm x 160 mm |
| 225301 | VAPR® Side Effect Electrode 3.5 mm x 160 mm |
| 225305 | VAPR® 90 Degree Hook Electrode 3.5 mm x 160 mm |
| 225304 | VAPR® Angled End Effect Electrode 3.5 mm x 160 mm |
| 225302 | VAPR® Angled Side Effect Electrode 3.5mm x 160 mm |
| 225201 | VAPR® 2.3 Side Effect Electrode 140 mm |
| 225202 | VAPR® 2.3 End Effect Electrode 140 mm |
| 225211 | VAPR® 2.3 Side Effect Electrode (Short) 85 mm |
| 225213 | VAPR® 2.3 Wedge Electrode (Short) 85 mm |
| 225203 | VAPR® 2.3 Wedge Electrode 140 mm |
| 225312 | VAPR® Flexible Side Effect Electrode 3.5 mm x 160 mm |
| 225314 | VAPR® Flexible End Effect Electrode 3.5 mm x 160 mm |
| 227301 | VAPR® Side Effect Electrode 3.5 mm Side Effect with Integrated Handpiece |
| 227305 | VAPR® Hook Electrode 3.5 mm Hook with Integrated Handpiece |
| 227302 | VAPR® Angled Side Effect Electrode with Integrated Handpiece, 3.5 mm x 160 mm |
| 227312 | VAPR® Flexible Side Effect Electrode with Integrated Handpiece, 3.5 mm x 160 mm |
| 227203 | VAPR® 2.3 Wedge Electrode with Integrated Handpiece, 140 mm |
| 227213 | VAPR® 2.3 Wedge Electrode (Short) with Integrated Handpiece, 85 mm |
| 227211 | VAPR® 2.3 Side Effect Electrode (Short) with Integrated Handpiece, 85 mm |

**SYSTEM
DESCRIPTION**

4-11



| | |
|--------|--|
| 227202 | VAPR® 2.3 End Effect Electrode (Short) with Integrated Handpiece, 140 mm |
| 225360 | VAPR® LD Suction Electrode 4.0 mm x 160 mm |
| 225361 | VAPR® LP Suction Electrode 4.0 mm x 160 mm |
| 225370 | VAPR® S90 Electrode 4.0 mm, 90° Suction with Integrated Handpiece |
| 227355 | VAPR® S50 Electrode 50° Suction with Integrated Handpiece |
| 227504 | VAPR® Premiere50 Electrode 50° Suction with Integrated Handpiece |
| 227204 | VAPR® Premiere90 Electrode 90° Suction with Integrated Handpiece |
| 227252 | VAPR® Temperature Control End Effect Electrode with Integrated Handpiece, 2.3 mm x 140 mm |
| 225252 | VAPR® Temperature Control End Effect Electrode 2.3 mm x 140 mm |

**SYSTEM
DESCRIPTION**

4-12

WARNING

Read the instructions, cautions, and warnings provided with all VAPR 3 System accessories before use. This device is an integral system; only use approved accessories with the VAPR 3 Generator. Your sales representative can advise which accessories are available and approved for use with the VAPR 3 System.



INSTRUCTIONS FOR USE

NOTE

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

- *Installation procedures in this manual are followed.*
- *Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by the manufacturer and the electrical installation of the relevant operating room complies with the local codes and regulatory requirements governing such facilities.*
- *The equipment is used in accordance with these instructions.*

The DePuy Mitek VAPR System unit has been designed as a system, with accessory features specifically designed to maximize safety and effectiveness. Use only the DePuy Mitek Handpiece and Electrodes with this System.

INSTRUCTIONS FOR USE

5-1

SYSTEM INSTALLATION

1. 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.
2. 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 other than in a standard cart system. Ensure adequate ventilation, as it is normal for the Generator to become warm during use.

WARNING

- *Ensure that the generator is positioned so that the ability to disconnect or isolate from the mains supply is not restricted.*
- *To avoid the risk of electric shock this equipment must only be connected to a supply main with protective earth.*

CAUTION

EMC CONSIDERATIONS

- *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 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 VAPR 3 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.

3. Insert the power cord into the Power Cord Receptacle on the back of the Generator. A standard hospital grade power cord is necessary for proper connection of the Generator to the power source. To ensure user safety, the Generator must be properly grounded through the power cord and power outlet.
4. Connect the power cord from the Generator directly to an AC source. The Generator is designed to operate as shipped with full regulation between 90-132 VAC or 198-264 VAC at 50-60 Hz. This allows the Generator output to remain constant in case of brownouts or power surges.

WARNING

The power cord must meet all requirements for safe grounding. Its purpose should not be defeated by using extension cords, multiple plug points or three pronged to two pronged adapters. Power cords should always be grasped by the plug. Do not pull the cord itself.

5. Connect the Footswitch to the receptacle on the front of the Generator.
6. Press the Generator power switch to the ON position. Verify that the green light in the switch illuminates. When the Generator is first switched on prior to Electrode connection a system self-check sequence will be initiated.
7. Verify that the "CONNECT CABLE" is flashing on the display prompt on the front of the Generator. This completes the Generator installation procedure. Turn the generator power switch OFF when not in use.

INSTRUCTIONS FOR USE

5-2

SYSTEM SETUP AND USE DURING SURGERY

VAPR II ONLY

VAPR II System Component Requirements:

- A properly installed VAPR II Generator with attached 2 pedal Footswitch
- A Sterile VAPR Handpiece and Cable or VAPR Electrode with Integrated Handpiece
- A VAPR Electrode appropriate to the procedure being undertaken

VAPR 3 ONLY

VAPR 3 System Component Requirements:

- A properly installed VAPR 3 Generator with attached VAPR 3 Footswitch
- A Sterile VAPR Handpiece and Cable
- A VAPR Electrode appropriate to the procedure being undertake

NOTE

The VAPR Handpiece and Cable are supplied NON-STERILE. Refer to Section 6 of this manual for sterilization instructions prior to use.

1. Press the Generator power switch to the ON position. Verify that the green light in the switch illuminates and that the system self-check sequence is initiated.
2. Verify that the "CONNECT CABLE" symbol is flashing on the Generator display, indicating that the Generator is in idle mode.
3. Inside the sterile field, pass the plug end of the sterile Handpiece/Electrode Cable out of the sterile field, and connect it to the front of the Generator.
- *4. Verify that the "INSERT ELECTRODE" symbol is flashing on the Generator display, indicating the Handpiece is properly connected to the Generator.



- *5. Connect the VAPR Electrode to the Handpiece as shown in FIGURE 7. Once connected, the "INSERT ELECTRODE" symbol flashing on the Generator display will change to the default settings for that Electrode style.

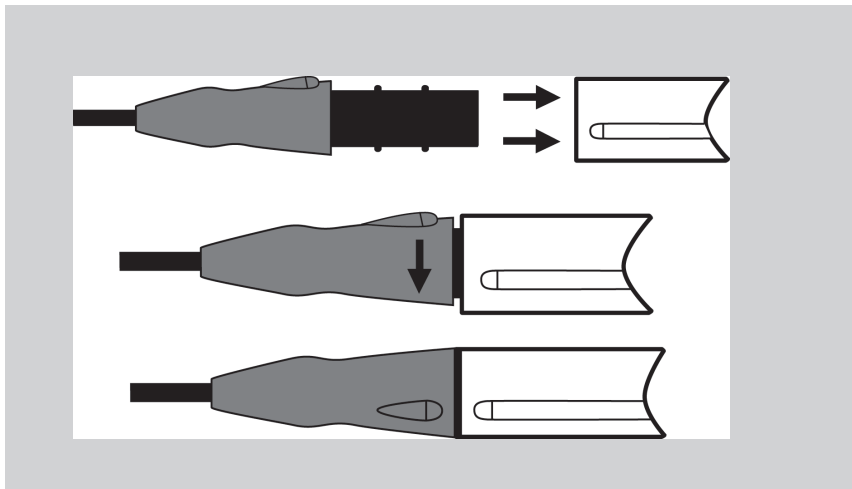


FIGURE 7

NOTE

The Default Power settings used for the intended arthroscopic procedures vary with the size and/or configuration of the active electrode. In the Desiccate mode, increasing or decreasing the Default Power settings will determine the level of performance. In the Vaporization and Blended Vaporization modes, increasing the power setting above the default will have little incremental effect on performance.

6. With the arthroscope inserted into the joint cavity, carefully insert the Electrode through the instrument portal under direct vision. Avoid the use of excessive force. Wherever possible, use an instrument cannula for the access portal. Maintain the active Electrode in the field of view at all times.
7. Press either the yellow or blue pedal of the Footswitch to activate the Electrode:
- YELLOW PEDAL: Activates the Vaporization (V) modes and the Blended Vaporization (BV) modes depending on output mode selection. Activation is accompanied by flashing of the Vaporization or Blended Vaporization power display and a high pitched audible tone.
- BLUE PEDAL: Activates the Desiccate (DES) mode only. Activation is accompanied by flashing of the Desiccate power display and an audible tone.
8. **(VAPR II ONLY)** Power and mode adjustment can only be made when the Generator is not activated. The permissible range of power adjustment is determined by the Electrode style.
- (VAPR 3 ONLY)** Power and mode adjustment can only be made when the Generator is not activated. The permissible range of power adjustment is determined by the Electrode style. Settings may be altered from the front panel button or via the footswitch menu button as described in section 4.

CAUTION

Use caution when adjusting Output Mode settings.

- * Will not be displayed when connecting a VAPR Electrode with Integrated Handpiece.

**INSTRUCTIONS
FOR USE**

5-3

USING VAPR TC ELECTRODES

- When attaching the VAPR TC electrode the generator will automatically configure itself in temperature control mode, the display will indicate the default SET temperature and desiccation power. The vaporization output is inhibited, pressing the yellow pedal will have no effect.
- **(VAPR II ONLY)** The SET temperature may be adjusted from its default using the yellow Up/Down buttons. Similarly the Desiccation power may be adjusted using the blue Up/Down buttons 'on the generator'.
- **(VAPR 3 ONLY)** The SET temperature may be adjusted from its default using the yellow Up/Down buttons. Similarly the Desiccation power may be adjusted using the blue Up/Down buttons 'on the generator'. These settings may also be changed through the menu button adjustment procedure described in section 4.
- Power, SET and mode adjustment can only be made when the generator is not activated.
- During activation, the display will change from the SET temperature to the actual measured TIP temperature.
- The system will only deliver power up to the limit indicated on the display. Occasionally, during high interjoint flow conditions the desired SET temperature cannot be reached. If this occurs, increase the power from its default setting in small increments until correct temperature control is possible.
- For user convenience an over-temperature indicator is operational in temperature control mode, an audible tone will sound if the measured TIP temperature reaches more than 8°C over the SET temperature.

NOTE

Certain conditions may momentarily cause temperature overshoot and trigger the over temperature indicator. Once triggered the tone will sound for a minimum of 1 second. Possible causes are:

1. *Excessive power used with low/no flow environment.*
2. *Insufficient saline around tip.*
3. *Unstable surgical environment, excessive changes in saline flow rate and/or volume.*
4. *Incorrect irrigation solution used.*

ADJUSTING THE TONE VOLUME

The activation tone volume can be adjusted using the following procedure:

- Press and release the Mode button until VOLUME appears on the display.
- Press the Power Up button in the Desiccate (blue) section.
- 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.

NOTE

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

ADJUSTING THE FOOTSWITCH/HANDSWITCH OPTION (VAPR II ONLY)

NOTE

This feature is not available as of the printing of this manual.

To configure the generator for an optional handswitch accessory use the following procedure:

- Press and release the mode button until FOOTSWITCH appears on the display.
- Press the Power Up button in the Desiccate (blue) section until HANDSWITCH appears in the display.



- Press and release the mode button until the display changes to the Ready mode. Handswitching is now active.
- To return to footswitch operation follow the above procedure, instead selecting footswitch.

NOTE

- *The footswitch will become inactive when handswitch is selected.*
- *Switching the generator off will reset the generator to footswitch operation.*

CHANGING ELECTRODES DURING SURGERY

An Electrode can be removed from the Handpiece by unlocking the connector assembly and then pulling the Electrode and Handpiece apart.

Once the Electrode is disconnected, the Generator will automatically enter idle mode with the display showing the "INSERT ELECTRODE" symbol.

Fit a new sterile Electrode as previously described. If the new Electrode has different default settings to the previous Electrode, check that the Generator display matches the Electrode default settings specified on the package insert.

NOTE

When switching to or from a VAPR electrode with Integrated Cable, the generator will display "CONNECT CABLE".

If the new Electrode has identical default settings to the previous Electrode, the Generator will retain the settings previously displayed prior to changing the Electrode.

Switching the Generator power off will clear all output adjustments.

WARNING

Do not insert or withdraw Electrodes while activated. Injury and/or product damage may result.

NOTE

In the event of a power failure, or if the Generator is turned off while an Electrode is connected to the Generator, the Generator will default to its lowest output power level, 5 watts, when power is restored. The power can be increased using the Power Up button.

Recommendations

- Unless circumstances dictate otherwise, use the Electrode default power and mode settings to enhance patient and user safety.
- Remove any tissue buildup from Electrodes to maximize surgical effect.
- Avoid any unnecessary and prolonged Electrode activation to prevent overheating.
- When de-bulking or vaporizing tissue, apply firm pressure using a progressive surface brushing technique. Avoid burying the electrode in the tissue as this could increase debris formation.
- The speed of tissue de-bulking will be determined by the output mode selection, size and style of the Electrode, and application technique.
- When rapidly de-bulking or vaporizing tissue some browning of the tissue can be anticipated. This can either be brushed away with a non-activated electrode or ablated using gentle application pressure during activation.
- If more than one style of Electrode is used during a procedure, the Generator will revert to the default settings defined by each Electrode style.
- Bubbles are produced during tissue vaporization which may interrupt surgery by temporarily interfering with vision. A continuous flow fluid management system is recommended to prevent accumulation and remove bubbles, as well as any particulate products of vaporization, from the operative field.



WARNING

Avoid bubble accumulation in the joint space during use. The accumulation of bubbles around the working tip of the Electrode will diminish performance and may produce overheating sufficient to damage adjacent structures.

USE OF SUCTION ELECTRODES

Suction electrodes are designed to provide improved visibility at the operative site whilst facilitating removal of degradation products. To avoid premature clogging of the suction pathways in these devices.

- Close the pinch clamp before insertion of the device into patient.
- Open the pinch clamp immediately prior to activation (ablation).
- Close the pinch clamp immediately after device activation (ablation).
- The pinch clamp should not be opened for tissue modification or the sealing of blood vessels (blue pedal use) as the suction flow may suck unintended tissue into the device and cause clogging.

In the case of blocked suction electrodes activation of the device in saline at its maximum power for a few seconds may restore the suction pathway.

AFTER SURGERY

After surgery, you need to perform the following:

- Withdraw the Electrode.
- Disassemble the Electrode and Handpiece.
- Dispose of the SINGLE-USE VAPR Electrodes.
- Prepare the Handpiece and Cable for steam autoclave processing.

IMPORTANT

Disconnecting the Electrode/Handpiece will automatically result in the "CONNECT CABLE" idle mode symbol. The Generator can be left in this mode between cases but at the end of the operating session must be switched off from the power supply.

INSTRUCTIONS FOR USE

5-6



CLEANING AND STERILIZATION PROCEDURES

CLEANING THE GENERATOR

WARNING

Electric shock hazard: Turn off the Generator and unplug the power cord from the AC source prior to cleaning Generator.

The VAPR Generator cannot be sterilized. The Generator surfaces can be cleaned with a non-abrasive cleaning agent. Do not allow fluids to enter the Generator connectors.

CLEANING THE FOOTSWITCH

The VAPR Footswitch cannot be sterilized. The Footswitch surfaces can be cleaned with detergents and disinfectant cleaners according to standard hospital practices.

NOTE

The use of strong alkali detergents or cleaners must be avoided as these may damage the device.

CLEANING AND STERILIZING THE VAPR HANDPIECE AND CABLE

1. Remove all gross matter (blood, mucous, tissue) by wiping each component with a cloth or gauze pad and a mild cleaning solution or blood-dissolving detergent.

NOTE

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

2. Rinse thoroughly in running water.
3. Allow the Handpiece to drain thoroughly.
4. Remove residual cleansing agents with a damp cloth.
5. Dry the accessory devices thoroughly before sterilizing.

STEAM STERILIZATION PROCEDURE

- Wrapped Pre-Vacuum Cycle: 134 to 136°C 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 and cleaning process, check the Handpiece for any damage (e.g. crush damage, cracking, or distortion). Discard if damage is observed.

WARNING

The DePuy Mitek Handpiece and Cable is intended for 20 reuse cycles only. 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 Handpiece.



PERIODIC MAINTENANCE INSPECTION

The manufacturer recommends that the VAPR Generator 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.

CAUTION

Do not attempt to remove the cover of the generator or perform servicing on its parts.

- 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 with 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 DePuy Mitek customer service should a unit fault be suspected.

PERIODIC MAINTENANCE INSPECTION

7-1



ERROR AND FAULT SYMBOLS, TROUBLESHOOTING GUIDE

ERROR & FAULT SYMBOL INTERPRETATION

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

- An Error symbol indicates an accessory malfunction or a Generator component failure that requires servicing of the equipment. These symbols include a code number to be used by DePuy Mitek technical service to diagnose why the system failed.
- A Fault symbol indicates a transient non-hazardous event and can be corrected by resetting the system.

ERROR SYMBOLS

An Error symbol is displayed as two alternating messages:

“ERROR XXX REF YYY”

“INTERNAL FAILURE”

WARNING

An error symbol indicates an equipment malfunction which 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 “CONNECT CABLE” symbol in 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 DePuy Mitek customer service for assistance.

FAULT SYMBOLS

A Fault symbol is displayed as two alternating messages:

“FAULT XXX REF YYY”

“TEXTUAL MESSAGE”

where TEXTUAL MESSAGE relates to the type of fault.

NOTE

Remember to take note of the fault code for reporting to customer service before completing the reset.

The generator can be reset after a fault occurs by either:

- 1 Depress and release the MODE button once,

OR

- 2 Depress both footswitches simultaneously and release both footswitches once
(VAPR II ONLY)

OR

- 3 Depress and release the menu/reset button (VAPR 3 ONLY)



If this does not resolve the problem, contact DePuy Mitek customer service.

A list of all Fault symbols and their descriptions is provided below:

There are no user defined alarms used in the VAPR system.

There are no distributed alarms used in the VAPR system.

There is no facility for disabling or silencing alarms used in the VAPR system.

All alarm conditions produced by the VAPR system are LOW PRIORITY technical alarms as per IEC60601-1-8 table 1.

Audio alarms comply with the requirements of IEC 60601-2-2:2009.

Thermistor Electrode Alarm Descriptions

Short start: 500Hz for 75mS followed by 75mS gap repeated five times.

Short end: 500Hz for 130mS followed by 130mS gap repeated three times.

Tip Over temperature: 800Hz for 110mS followed by 500Hz for 110mS repeated while condition occurs.

Non-Thermistor Electrode Alarm Description.

Short 65ms at 800Hz followed by 65ms at 500Hz while condition occurs and pedal pressed.

| Fault Symbol | Ref | Description |
|---------------------|------------|------------------------------------|
| 100 | 10 | Software failure |
| 100 | 11 | ROM checksum failure |
| 100 | 12 | Non volatile memory failure |
| 100 | 13 | Memory failure |
| 100 | 14 | Power generation fault on start up |
| 100 | 15 | Power generation shutdown fault |
| 200 | 10 | PWM signal : shorted high |
| 200 | 11 | PWM signal : shorted low |
| 200 | 12 | MSYNC signal : shorted high |
| 200 | 13 | MSYNC signal : shorted low |
| 200 | 14 | Energy stuck high |
| 200 | 15 | IOUT stuck high |
| 200 | 16 | FOOT signal : shorted high |
| 200 | 17 | FOOT signal : shorted low |
| 200 | 18 | CUT/COAG signal : stuck high |
| 200 | 19 | CUT/COAG signal : stuck low |
| 200 | 20 | CLAMP signal error (DAC output) |
| 200 | 21 | BOOST signal error (DAC output) |
| 200 | 22 | PEAKSET signal error |
| 200 | 23 | PEAK signal error : stuck high |
| 200 | 24 | RF_DET signal error : stuck low |
| 200 | 25 | OVERDOSE signal error : stuck high |
| 200 | 26 | ENERGY signal error : stuck low |
| 200 | 27 | Line voltage relay error |

ERROR AND FAULT SYMBOLS, TROUBLESHOOTING GUIDE

8-2



| | | |
|-----|----|--|
| 200 | 28 | Temperature monitor inoperative |
| 200 | 29 | Audio volume inoperative |
| 200 | 30 | Diagnostic circuit fault |
| 200 | 31 | CURRLIM signal error |
| 200 | 32 | Electrode temperature measurement malfunction |
| 300 | 10 | Internal overheating |
| 300 | 11 | Excess RF input voltage error |
| 300 | 12 | Out of specification input voltage : low |
| 300 | 13 | Out of specification input voltage : high |
| 300 | 14 | Bipolar output short circuit |
| 300 | 16 | Unable to control electrode temperature |
| 300 | 20 | Unsupported electrode attached |
| 400 | 10 | Footswitch BLUE pedal stuck on |
| 400 | 11 | Footswitch YELLOW pedal stuck on |
| 400 | 12 | Reserved for Handswitch BLUE button stuck on |
| 400 | 13 | Reserved for Handswitch YELLOW button stuck on |
| 400 | 14 | Electrode identification circuit fault |
| 400 | 15 | Front panel yellow UP button stuck on |
| 400 | 16 | Front panel yellow DOWN button stuck on |
| 400 | 17 | Front panel blue UP button stuck on |
| 400 | 18 | Front panel blue DOWN button stuck on |
| 400 | 19 | Front panel MODE button stuck on |
| 400 | 20 | Reserved for Intermittent activation switch |
| 400 | 21 | Electrode thermistor open circuit – bands 11/13 |
| 400 | 22 | Electrode thermistor short circuit – bands 11/13 |
| 400 | 23 | Invalid resistor ID – band 12 |
| 500 | 13 | Possible board short (PWM) |
| 500 | 14 | Possible board short (SYNC) |
| 500 | 16 | Possible board short (FOOT CUT/COAG) |

**ERROR AND
FAULT SYMBOLS,
TROUBLESHOOTING
GUIDE**

8-3

The above faults will be detected and reported within 1 second of occurring with the exception of the 400-14 alarm which takes up to 1 minute. This fault code reports a fault in the electrode identification circuit. This is also checked on power-up, at which time a fault would be detected and reported immediately

TROUBLESHOOTING GUIDE

The following troubleshooting guide describes potential problem causes and suggested operator solutions. If the suggested actions do not resolve the problem, please contact technical service.

| Problem | Suggestions/Solutions |
|---|--|
| No output power | Check Handpiece Cable connections. Check Electrode connection. Contact technical service. |
| Generator resets during activation (Fault Symbol 100.10) | Ensure no contact was made with other equipment during activation. Check grounding of Generator. Check Handpiece insulation. Check integrity of Electrode. |
| Fault indicator illuminates | Contact customer service. |
| Unable to activate the Generator | Check footswitch for damage. Ensure correct footswitch is connected. |
| Alarm tone too loud or too quiet | Readjust volume using the mode switch. Generator will remember the last volume setting used. |

| Problem | Suggestions/Solutions |
|--|--|
| No display on the Generator | Request assistance from qualified service engineer if fault persists. Check inlet fuses, replace with correct type. See Service Manual for fuse specifications. Contact customer service if problem persists. |
| Generator displays "CONNECT CABLE" symbol when Handpiece Cable is inserted | Remove connector and inspect pins for damage. Check that connector is fully inserted. Check for damage to Cable. |
| Generator displays "INSERT ELECTRODE" symbol after Electrode is inserted | Ensure the connector contacts are clean and dry and have not been damaged during reprocessing. Check Electrode integrity. Ensure that only DePuy Mitek approved Electrodes are being used |
| Generator overheats (Fault Symbol 300.10) | Ensure ambient temperature is within operating limits. Allow Generator to cool down before re-use. Check sufficient ventilation provided around Generator. |
| Accessory Fault (Fault Symbol 300.14) | Contact may have been made with other equipment during activation such as the scope or other instrumentation. Note, this may also occur when activation occurs in close proximity to such instruments. Remove the electrode from the joint and inspect the accessories for damage. Check the accessories by activating the electrode immersed in irrigating fluid contained in a bowl, or similar, remote from patient contact before proceeding with surgery. If the fault recurs, first replace the electrode and check as above. If the fault remains, replace the handpiece and check as above. If the fault continues, contact DePuy Mitek Customer Service. |

ERROR AND FAULT SYMBOLS, TROUBLESHOOTING GUIDE

8-4



| Problem | Suggestions/Solutions |
|---|---|
| Output Shorted (VAPR 3 ONLY) | <p>When working in a joint cavity the electrode tip may make contact with metallic instrumentation close to the operative site. As a safety measure, the generator will immediately terminate activation and show a warning message with a short alarm tone.</p> <p>In the case of any short, remove the electrode from the joint and inspect the accessories for damage.</p> <p>If the foot pedal remains depressed activation will automatically restart following a short period. For VAPR 3 variants with older V1.01 software and/or the use of TC electrodes, the 'Output Shorted' fault may be cleared by depressing either the footswitch or generator mode buttons to restore the system to its ready condition.</p> <p>Check the accessories by activating the electrode immersed in irrigating fluid contained in a bowl, or similar, remote from patient contact before proceeding with surgery. If the fault recurs, first replace the electrode and check as above. If the fault remains, replace the hand piece and check as above.</p> <p>Do not use any accessory that persistently faults.</p> <p>If the fault continues, contact DePuy Mitek Customer Service, and discontinue use of accessory.</p> |
| Unable to access temperature control mode | The Temperature Control mode is only enabled with purpose built TC electrodes with an internal temperature sensing element. |
| Footswitch inoperative | Check the activation source has not been set to HANDPIECE. (VAPR II ONLY) |
| Generator Displays "UNSUPPORTED TYPE" after an electrode is inserted | Contact customer service to discuss an upgrade to a new generator model. (VAPR 3 ONLY) |

**ERROR AND
FAULT SYMBOLS,
TROUBLESHOOTING
GUIDE**

8-5



TECHNICAL SPECIFICATIONS

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

VAPR ELECTRODE SPECIFICATIONS

| | |
|--|-------------------------------|
| Overall Length: | 5.7 – 8.9 in (14.5 – 22.5 cm) |
| Working Length: | 3.7 – 6.5 in (9.5 – 16.5 cm) |
| Shaft Diameter: | 0.06 – 0.18 in (1.5 – 4.5 mm) |
| Shaft Bend Angle: | 0 – 30° |
| Active Tip Orientation: | 0 – 90° |
| Supplied Sterile and For Single-Use Only | |
| Sterilization Method: | Irradiation |

VAPR HANDPIECE AND CABLE SPECIFICATIONS

| | |
|-----------------------|---------------------|
| Overall Length: | 10.5 ft (3.2 m) |
| Sterilization Method: | Steam (134 – 136°C) |
| Supplied Non-Sterile | |
| 20 x Reusable | |

VAPR GENERATOR SPECIFICATIONS

| | |
|-------------------------|---|
| Dimensions (H x W x D): | 3.5 in x 16 in x 14.5 in (9 cm x 41 cm x 36.8 cm) |
| Weight: | 12 lb. (5.6kg) approximately |

Transport and Storage Conditions

| | |
|----------------------------|----------------------------|
| Ambient Temperature Range: | 32 to 122°F (0 to 50°C) |
| Relative Humidity: | 10% to 90%, non condensing |
| Atmospheric Pressure: | 500 to 1060 millibars |

Operating Conditions

| | |
|----------------------------|----------------------------|
| Ambient Temperature Range: | 60 to 104°F (10 to 40°C) |
| Relative Humidity: | 10% to 90%, non condensing |
| Atmospheric Pressure: | 500 to 1060 millibars |

Power Supply

| | |
|---------------------|--|
| Regulation Voltage: | 90 – 132V RMS, 198 – 264V RMS |
| Operating Range: | nominal 100 – 120/220 – 240V RMS 50/60Hz |
| Inlet Fuses: | Time lag 5A (T5AH 250V) (VAPR II ONLY) |
| Inlet Fuses: | Time lag 6.3A (T6A3H 250V) (VAPR 3 ONLY) |
| Leakage Currents: | Within limits of Class BF equipment as per IEC 60601-1 |
| Alarm Volume: | Adjustable between 40 dB (minimum) and 65dB (maximum) at 1m. This is an activation signal only. |
| Classification: | Electrical: Class 1 ordinary equipment as per IEC60601-1. EMC: Group 1 Class A as per IEC60601-1-2. |



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 Generator's 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.

Temperature Control Mode

| | |
|---------------------|----------------------------|
| Control range | 45 – 95°C |
| Display range | 10 – 99°C |
| Over temp indicator | >8°C above SET temperature |

VAPR FOOTSWITCH SPECIFICATIONS

CAT. NO. 225003 & 225023

| | |
|--------|------|
| Rating | IPX8 |
|--------|------|

OUTPUT WAVEFORM AND CHARACTERISTICS (VAPR II ONLY)

| | |
|----------|--|
| 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 | V1, V2, V3, BV1, BV2 and Desiccate A nominal crest factor of 1.4 for all outputs. |
|--------------|--|

| | |
|-------|--|
| Power | Maximum power 200 watts into 160 ohms. |
|-------|--|

Max Voltage:

| | |
|-------------------|----------|
| V1 | 254V RMS |
| V2 | 307V RMS |
| V3 | 340V RMS |
| BV1 | 307V RMS |
| BV2 | 340V RMS |
| Desiccate | 120V RMS |
| VAPR TC Desiccate | 100V RMS |

NOTE

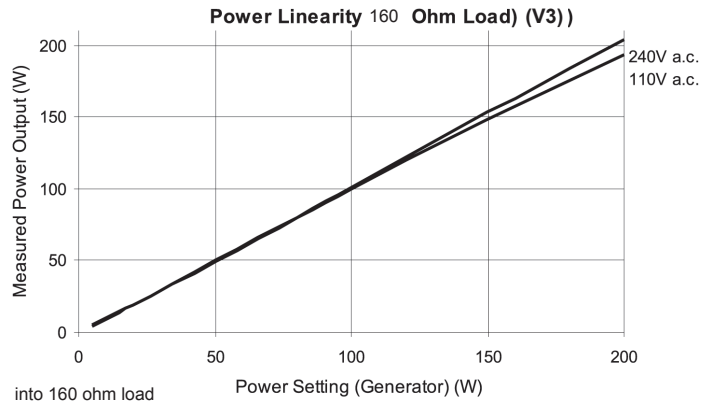
The following load curves apply to the fundamental power delivery capability of the generator alone. They do not imply a given power output for any given electrode and cable configuration when used with the generator. Each accessory will self-impose an upper set power limit for the generator, the value of which will be equal to or below the maximum power delivery capability of the generator.

TECHNICAL SPECIFICATIONS

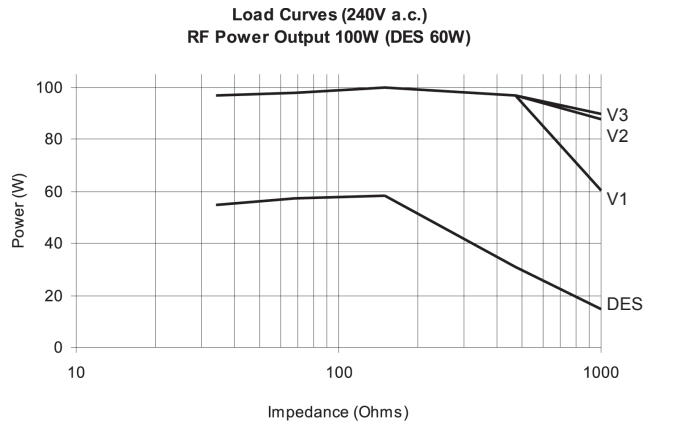
A-2



VAPR II ONLY

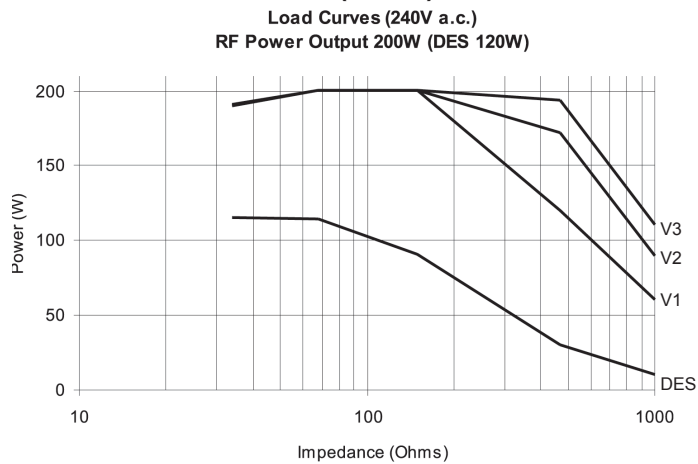


VAPR II ONLY HALF POWER (100W) LOAD CURVE



Desiccate at Half Power 60W

VAPR II ONLY FULL POWER (200W) LOAD CURVE



Note (1): Desiccate Full Power 120W
3A Limit prevents 10R measurement

Note (2): Internal Limiting 10R Output

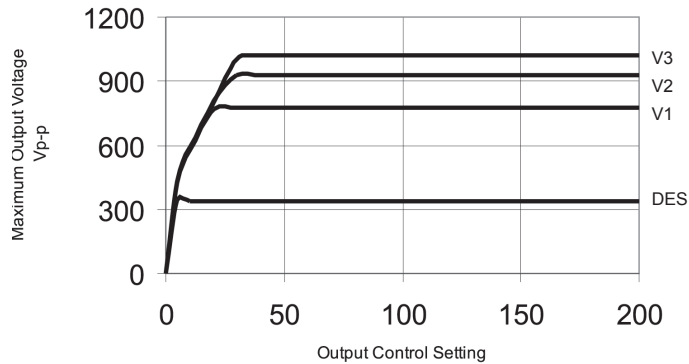
TECHNICAL SPECIFICATIONS

A-3



VAPR II AND VAPR 3

Peak Output Voltage at Open circuit (240Va.c.)
vs. Output Control Setting



OUTPUT WAVEFORM AND CHARACTERISTICS (VAPR 3 ONLY)

TECHNICAL SPECIFICATIONS

A-4

| | |
|-------------------|--|
| 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 | V1, V2, V3, BV1, BV2 and Desiccate A nominal crest factor of 1.4 for all outputs. |
| Power | Maximum power 260 watts into 160 ohms. |
| Max Voltage: | |
| V1 | 254V RMS |
| V2 | 307V RMS |
| V3 | 340V RMS |
| BV1 | 307V RMS |
| BV2 | 340V RMS |
| Desiccate | 120V RMS |
| VAPR TC Desiccate | 100V RMS |

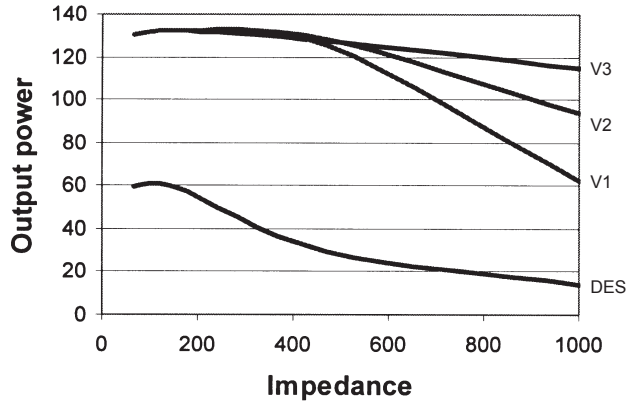
NOTE

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 cable configuration when used with the generator. Each accessory will self-impose an upper set power limit for the generator, the value of which will be equal to or below the maximum power delivery capability of the generator.



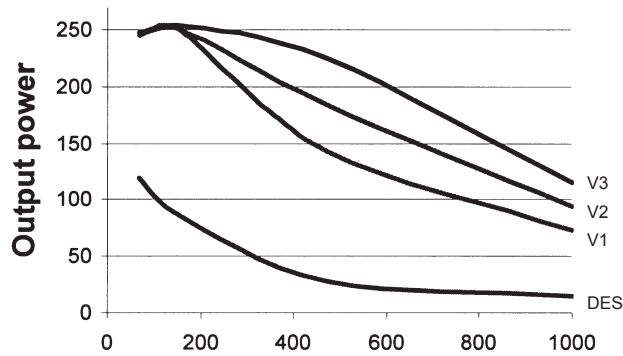
VAPR 3 ONLY
HALF POWER (130W) LOAD CURVE
 LOAD CURVE (240V A.C) RF POWER OUTPUT 130W (DES 60W)

VAPR3 HALF POWER

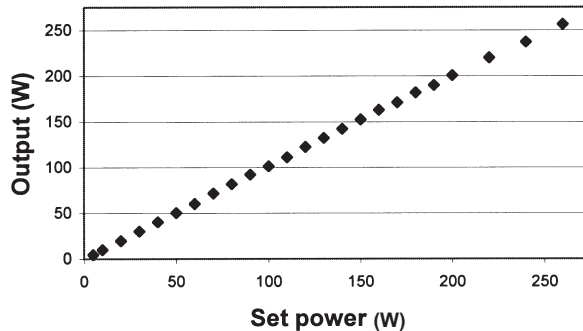


VAPR 3 ONLY
FULL POWER (260W) LOAD CURVE
 LOAD CURVE (240 A.C) RF POWER OUTPUT 260W (DES 120W)

VAPR3 FULL POWER



VAPR 3 ONLY
POWER LINEARITY (160 OHM) v3
VAPR3 LINEARITY



**TECHNICAL
SPECIFICATIONS**

A-5



RF POWER OUTPUT MEASUREMENT

NOTE

This section does not apply to Germany and will not appear in the German version of this manual.

RF power output measurements can be made using an "Output Test Cable" which enables the attachment of an external load and RF Voltmeter to the VAPR generator. The output can be compared to the typical full and half power load curves listed in the following Technical Specifications section.

NOTE

The output specification is $\pm 20\%$ of the typical load curve value.

Note: Output Test Cable #OM101 can be purchased by contacting sales@Esurgical.net or fax to +1 (925) 280-1788 (Fax number does not apply to France).

CAUTION

DePuy Mitek Products Inc. expressly recommends against attempting to make RF output power measurements by any other means than described in this manual.

Technical support in connection with end user corroboration of the published VAPR generator load curves can only be provided by DePuy Mitek on the condition that the user's measurement system corresponds to the test method layout depicted in FIGURE 5.2. This is the scheme adopted by DePuy Mitek for all product manufacture tests and has been found to be in accordance with the power measurement strategy for electrosurgical equipment employed by certified test agencies. Attempting to obtain an output power measurement by direct measure of voltage may give results that are inaccurate and unrepresentative of the system due to inducing earth loop currents or causing imbalance of the floating bipolar output stage.

DePuy Mitek recommends the use of the following equipment, or equivalents with at least commensurate specifications, when measuring RF output power:

EITHER Fluke 8920A True RMS voltmeter

OR Hewlett Packard 3403C True RMS voltmeter

Pearson Model 411 Current monitor (0.1V/A)

Arcol NHS200 series load resistors

When performing such measurements, DePuy Mitek recommends that the resistance loads should be of the noninductive type, minimum rating 200 watts. To verify output power against the published load curves, resistances of 68 ohm, 150 ohm, and 1 kohm will be sufficient. Ensure that the generator has been correctly configured for the desired output modality prior to making measurements.

TECHNICAL SPECIFICATIONS

A-6



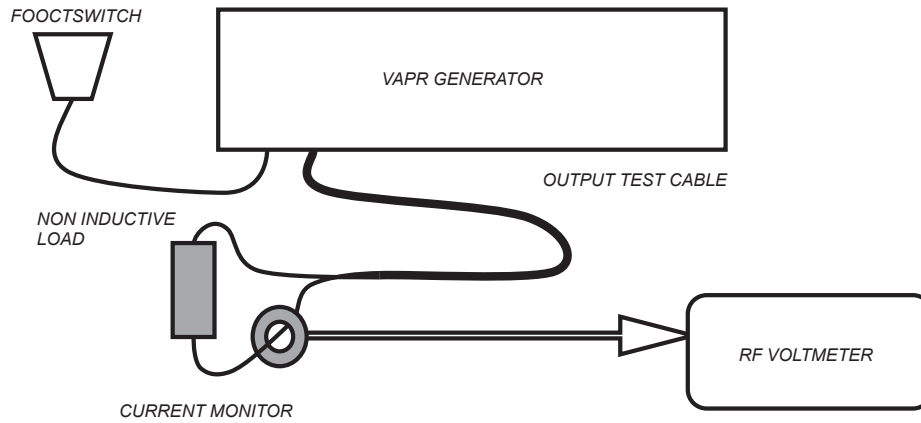


FIGURE 5.2

CAUTION

The practice of using an electrode as the power measurement connection medium is actively discouraged by DePuy Mitek Products Inc. Attempting to fashion a good electrical contact between the two poles of the small geometry electrode tip is fraught with difficulties and can lead to misleading results.

**TECHNICAL
SPECIFICATIONS**

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Equipment fault



Refer to instruction manual/booklet

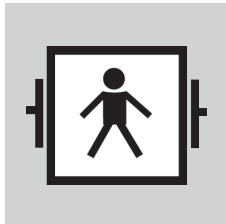


Refer to instruction manual/booklet



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 conductor that may be used to provide potential equalization between the equipment and the installations busbar.



This symbol indicates that the product contains less than the maximum concentration value of all six hazardous substances.

TECHNICAL SPECIFICATIONS


A-8

EMC TABLE

| Guidance and Manufacturer's Declaration - Electromagnetic Emissions | | | |
|---|--|--|--|
| The VAPR GENERATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the VAPR GENERATOR should assure that it is used in such an environment. | | | |
| Emissions Test | Compliance | Electromagnetic Environment - Guidance | |
| RF Emissions CISPR 11 | Group 1 | The VAPR 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 | | |
| Harmonic Emissions IEC 61000-3-2 | Class A | The VAPR 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. | |
| Voltage Fluctuations / Flicker Emissions IEC 61000-3-3 | Complies | | |
| Guidance and Manufacturer's Declaration - Electromagnetic Immunity | | | |
| The VAPR GENERATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the VAPR 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 | ±6 kV Contact | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| | ±8 kV Air | ±8 kV Air | |
| Electrical Fast Transient / Burst IEC 61000-4-4 | ±2 kV for Power Supply Lines | ±2 kV for Power Supply Lines | Mains power quality should be that of a typical commercial or hospital environment. |
| | ±1 kV for Input / Output Lines | ±1 kV for Input / Output Lines | |
| Surge IEC 61000-4-5 | ±1 kV Differential Mode | ±1 kV Differential Mode | Mains power quality should be that of a typical commercial or hospital environment. |
| | ±2 kV Common Mode | ±2 kV Common Mode | |
| Voltage Dips, Short Interruptions and Voltage Variations on Power Supply | <5 % U_T (>95 % Dip in U_T) for 0.5 Cycle | <5 % U_T (>95 % Dip in U_T) for 0.5 Cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of the VAPR GENERATOR requires continued operation during power mains interruptions, it is recommended that the VAPR GENERATOR be powered from an uninterruptible power supply or a battery. |
| Input Lines IEC 61000-4-11 | 40 % U_T (60 % Dip in U_T) for 5 Cycle | 40 % U_T (60 % Dip in U_T) for 5 Cycle | |
| | 70 % U_T (30 % Dip in U_T) for 25 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 5 sec | |
| 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. | | | |

EMC TABLE

B-1

| Guidance and Manufacturer's Declaration - Electromagnetic Immunity | | | |
|---|-----------------------------|------------------|--|
| The VAPR GENERATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the VAPR 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 | 3 Vrms 150 kHz to 80 MHz | 3 V | Portable and mobile RF communications equipment should be used no closer to any part of the VAPR 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 meters (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:  |
| Radiated RF IEC 61000-4-3 | 3 Vrms 80 MHz to 2.5 GHz | 3 V/m | |

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 electromagnetic site survey should be considered. If the measured field strength in the location in which the VAPR GENERATOR is used exceeds the applicable RF compliance level above, the VAPR GENERATOR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VAPR GENERATOR.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

EMC TABLE

B-2

| Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the VAPR GENERATOR | | | |
|--|--|---|--|
| The VAPR GENERATOR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VAPR GENERATOR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VAPR 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 $d = [3.5/V1]\sqrt{P}$ | 80 MHz to 800 MHz $d = [3.5/E1]\sqrt{P}$ | 800 MHz to 2.5 GHz $d = [7/E1]\sqrt{P}$ |
| 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. | | | |

EMC TABLE

B-3

VAPR 3 Only



WARRANTY AND SERVICE

DePuy Mitek products are guaranteed to be free from defects in material and workmanship for the warranty period of a particular product, beginning from date of invoice.

Contact your DePuy Mitek representative for specific product warranty information.

NOTE

This paragraph does not apply to Germany and will not appear in the German version of this manual.

DePuy Mitek offers an expedited service replacement program for its products to minimize downtime in your operating room. For a return authorization number or for additional information on this program, call DePuy Mitek Customer Service at +1 (800) 382-4682 and choose Option 2 in the United States or contact your DePuy Mitek representative.

**WARRANTY AND
SERVICE**



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Raynham, MA 02767, USA
1-800-356-4835

Manufactured for DePuy Mitek by:
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Cardiff, CF30LT, UK



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