



User Manual



User Manual

This user's guide will familiarize you with the controls and output functions available from your DePuy Mitek VAPR® VUE™ RADIOFREQUENCY (RF) System and instruct you on the proper use of the equipment. Review this manual thoroughly before installation and use of the VAPR VUE RF 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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Worldwide Patents pending.

This manual covers the VAPR VUE System only.

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INTRODUCTION



Caution: Federal law restricts this device to sale by or on the order of a physician.

BACKGROUND

Arthroscopy relates to the use of an arthroscope to visualize the joint space, most commonly of the knee, shoulder, ankle, elbow and wrist. 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.

The DePuy Mitek VAPR® VUE™ RF System represents a versatile approach to arthroscopy. Based on an innovative form of bipolar electrosurgery, the VAPR System has been specifically designed to provide a range of arthroscopic surgical modalities including soft tissue ablation (electro-vaporization), contouring, cutting, coagulation, and temperature indication. Complementing the VAPR technology, the VAPR VUE system offers a new approach to tissue management with a CoolPulse™ (CP) RF mode that achieves enhanced ablation.

COMPARISON TO CONVENTIONAL ELECTROSURGERY

Conventional electrosurgical systems deliver high frequency electrical current through tissue for the purposes of tissue cutting or hemostasis of blood vessels. Monopolar electrosurgery utilizes an “active” electrode located on the surgical instrument and a separate “return” electrode applied to the patient. Current flows from the active electrode through the patient to the return electrode. Bipolar electrosurgery 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 electrosurgery 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 electrosurgery 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 electrosurgery are preserved.

SYSTEM DESCRIPTION

The VAPR VUE 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 VUE System (Figure 1) are individually described in Section 4 of this manual:

- VAPR VUE Radiofrequency Generator
- VAPR Handpiece
- VAPR Electrodes
- VAPR Electrodes with integrated handpiece
- VAPR Electrodes with integrated handpiece and hand controls
- VAPR 3 Footswitch
- VAPR VUE Wireless Footswitch
- Power Cord (not provided)

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

INTRODUCTION

1-2

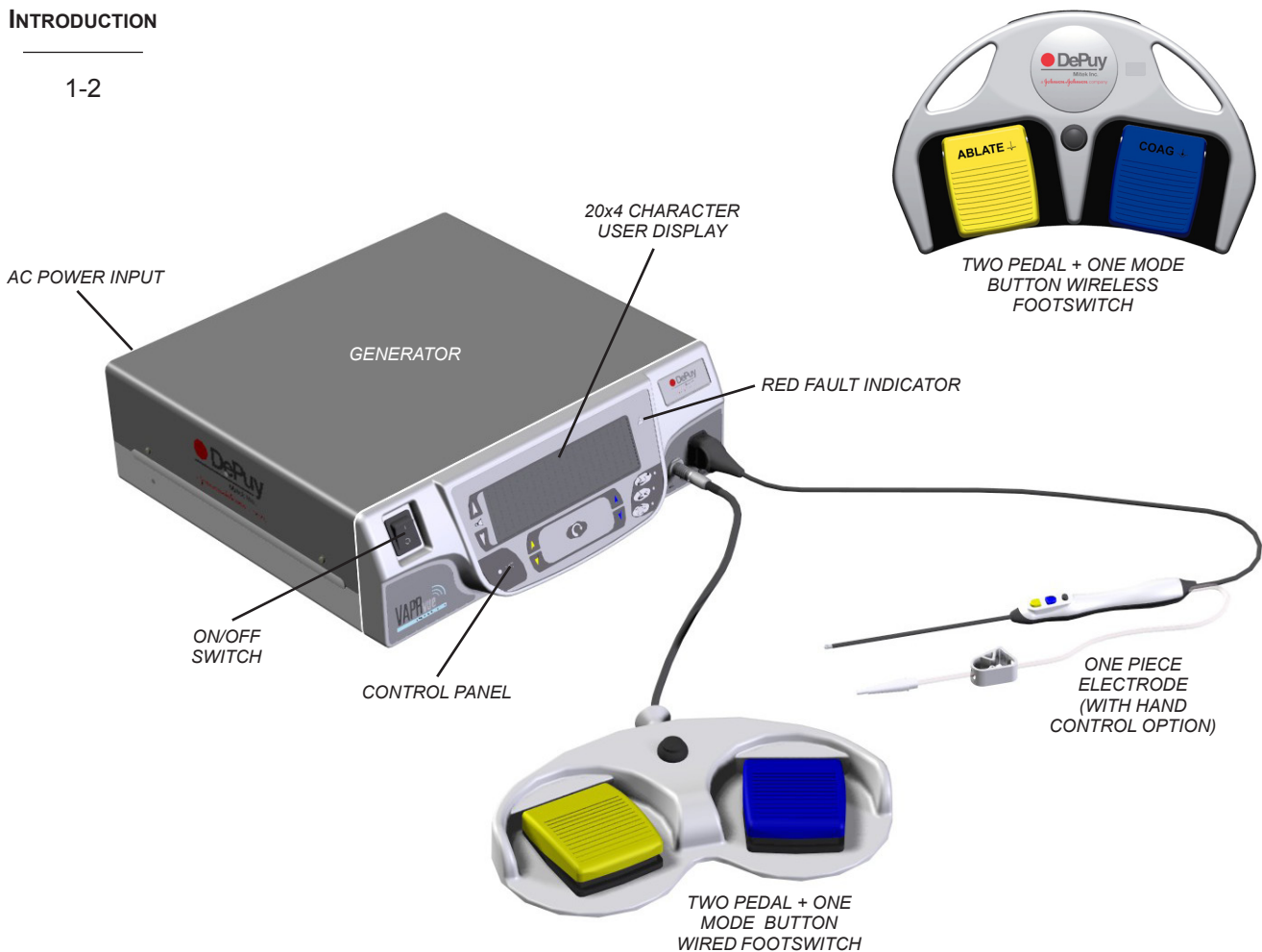


FIGURE 1

PRINCIPLE OF OPERATION

The VAPR VUE System offers five bipolar modes of operation: Ablation (Vaporization), Coagulation, CP (CoolPulse) Ablation, Blended Vaporization, and Coagulation with temperature control.

- In the Ablation mode of operation, high frequency power is delivered from the VAPR VUE 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 lead to vaporization of tissue entering the vapor pocket.
- The Ablation power threshold for a particular VAPR Electrode is automatically set as a default by connecting the Electrode 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 Coagulation mode of operation, the VAPR Generator delivers high frequency power to the active electrode to cause tissue coagulation without sparking or cutting. The Coagulation power level is also automatically set as a default for each style of Electrode.
- In the CP (CoolPulse) Ablation mode of operation, the mode of RF delivery reaches vaporization mode quicker with short-duration high power pulses. Once the vapor pocket is formed around the tip, the RF mode reverts to continuous operation (similar to standard Ablation mode). The CoolPulse mode is able to sustain the vapor pocket better than the standard vaporization mode in difficult conditions such as cold or high-flow saline conditions. The pulses of the CP Ablation mode cause more rapid saline heating at the active electrode with shorter time for heat dissipation.
- The Blended Ablation mode of operation provides tissue vaporization combined with hemostasis. Certain Electrode styles will automatically default to Blended Ablation mode.
- In the Coagulation Mode with temperature control (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 activated, automatically adjusting the power to maintain the tip temperature at the set temperature.

NOTE: The Temperature Control system will only automatically adjust the power up to the limit of the coagulate power level as displayed at time of use.

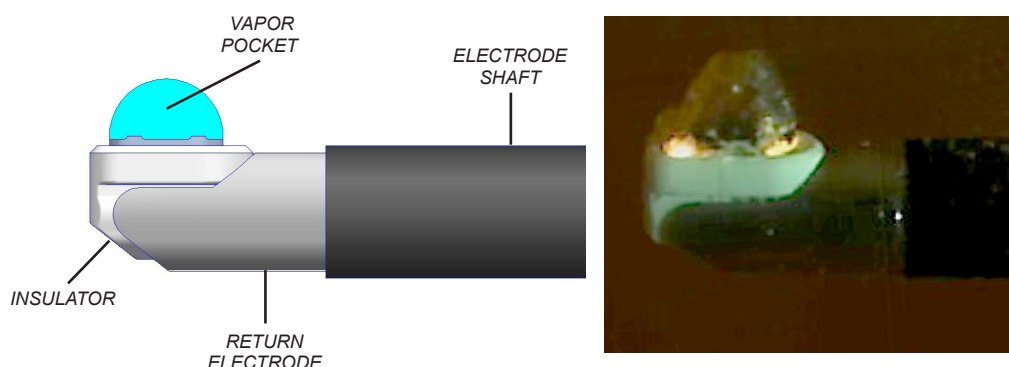


FIGURE 2

INDICATIONS FOR USE, CONTRAINDICATIONS

INDICATIONS FOR USE

The VAPR VUE Radiofrequency (RF) System is intended for resection, ablation, and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, or wrist.

Arthroscopic surgery could include, for example, the following:

Knee

Meniscectomy
Lateral Release
Chondroplasty
Synovectomy
ACL Debridement
Plica Removal
Meniscal Cystectomy

Ankle

Fracture Debridement
Excision of Scar Tissue
Synovectomy
Chondroplasty

Wrist

Synovectomy
Cartilage Debridement
Fracture Debridement

Shoulder

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

Elbow

Synovectomy
Tendon Debridement
Chondroplasty

INDICATIONS FOR USE, CONTRAINDICATIONS

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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.

FIRE/EXPLOSION WARNINGS

- As with all electro-surgical 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 electro-surgical 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.
- Electro-surgical 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 electro-surgical devices.

SAFETY

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ELECTRICAL SAFETY CONSIDERATIONS

- Examine all accessories and connections to the VAPR VUE 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 VUE 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 (ELECTROMAGNETIC COMPATIBILITY) PRECAUTIONS

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

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 or accessories simultaneously with the VAPR VUE generator. Activation of a monopolar generator or accessories may cause interference with the VAPR VUE 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.

SAFETY

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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.

PRIOR TO SURGERY

CAUTION

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

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 plug adapters.
- Do not reuse or resterilize accessories labeled "SINGLE USE," as malfunction, injury or cross-infection may result. These products are for single-use only and have 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.
- When bending the FLEX Electrode, do not exceed a 45° angle relative to the plane of the shaft. Do not change the FLEX Electrode shape more than three times at the same point on the shaft. More than three angle modifications can result in electrode fracture.
- Use of instruments to bend the electrodes can cause damage to the FLEX Electrode. Electrodes should only be bent using fingers.
- Attempts to bend non-FLEX Electrodes can result in electrode fracture.

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.
- Using arthroscopic guidance, ensure that the Electrode tip is completely surrounded by conductive irrigant solution during use.
- 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.
- Avoid touching the ceramic and active tip of the electrode with your fingers or instruments.

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.

CAUTION

Failure of the RF SURGICAL EQUIPMENT could result in an unintended increase of output power.

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 cables around metal objects. Wrapping cables around metal objects may induce currents that could lead to electric shock, fire and/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, 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 handpiece 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.

Operator Safety Cautions

- The VAPR VUE 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 overcurrent alarms (when not in contact with a metal surface/object) should be discarded.
- 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 or hand control button 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 electrosurgery.
- 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.
- A backup means should be available for all RF activation modes (i.e., backup Wireless Footswitch, backup Wired Footswitch, or backup Electrode with hand controls).

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 strongly 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.
- Do not reuse or resterilize accessories labeled "SINGLE USE." These products are for single-use only and have 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.

SAFETY

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SYSTEM DESCRIPTION

VAPR VUE RADIOFREQUENCY GENERATOR

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

OUTPUT MODES

The VAPR VUE Generator allows the user to select one of the following functional modes using generator front panel set-up options: tissue Ablation mode, Coagulation (hemostasis) mode, CP (CoolPulse) Ablation mode, Coagulation mode with temperature control, and Blended Ablation mode that combines Ablation and Coagulation. A brief description of each mode is provided below:

ABLATE Modes

There are three standard V mode ablation 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. Activate using YELLOW foot pedal or hand control button.

Coagulation (COAG) Mode

The Coagulation 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. Activate using BLUE foot pedal or hand control button.

CoolPulse (CP) ABLATE Mode

The CoolPulse Ablation mode provides tissue vaporization with a 'pulse effect'. Available with specific Electrode configurations only, the vaporization effect is dependent upon the application but will typically be more aggressive than the standard V3 mode. Activate using YELLOW foot pedal or hand control button.

COAG with Temperature Control

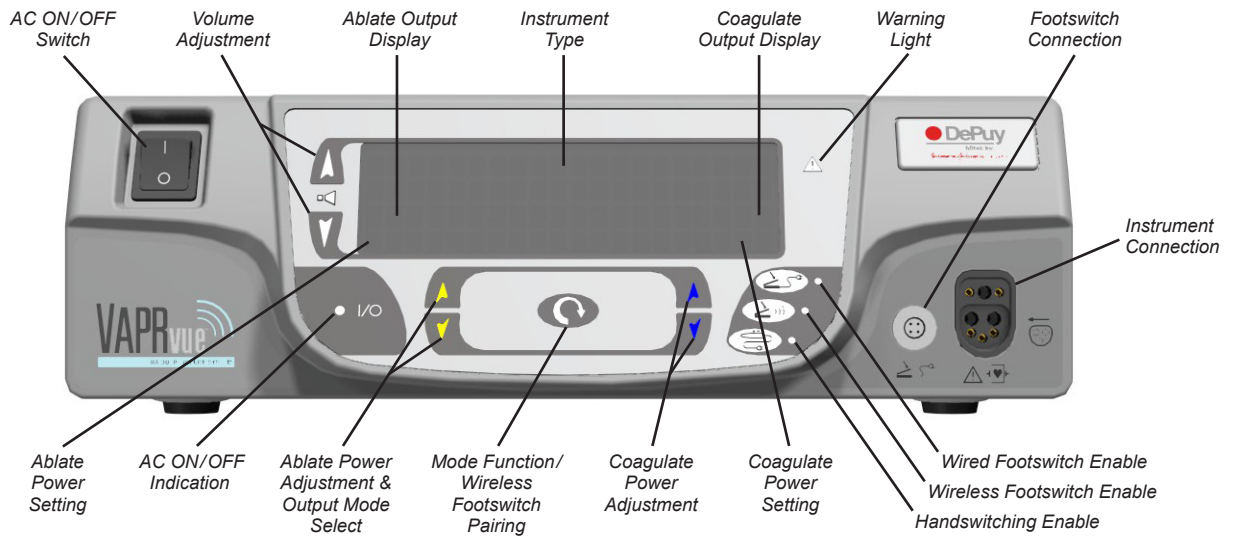
When in coagulation mode, this allows the display of electrode tip temperature, and control against a set temperature. Activate using BLUE foot pedal or hand control button.

Blended ABLATION (BV) Modes

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

- BV1 mode automatically switches between the V2 ablation mode and coagulation (hemostasis) mode.
- BV2 mode switches between the V3 ablation mode and coagulation (hemostasis) mode.

Activate using YELLOW foot pedal or hand control button.



SYSTEM DESCRIPTION

4-2

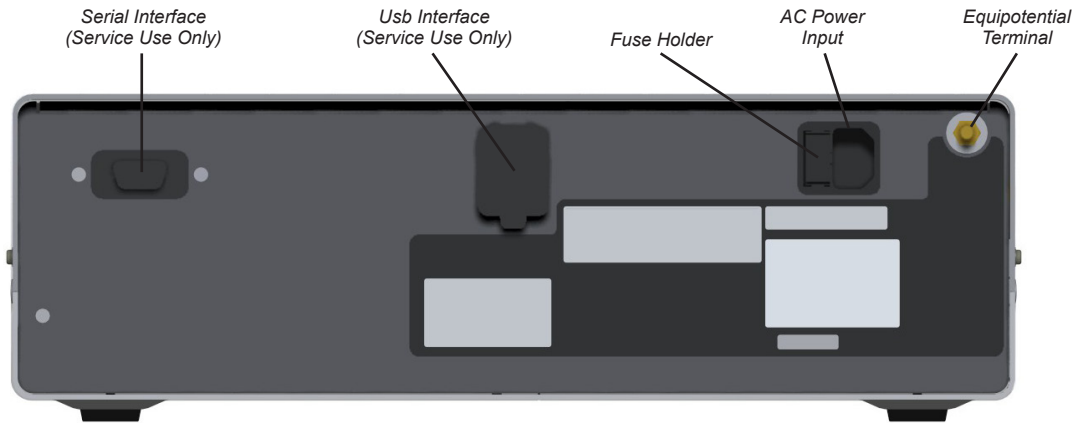


FIGURE 3

GENERATOR CONTROLS AND DISPLAYS



Power Switch

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

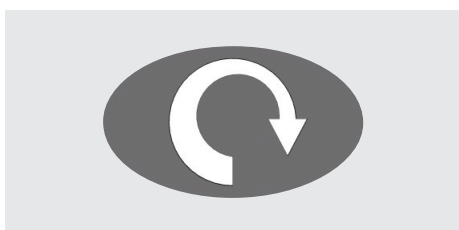


Red Warning Light

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.



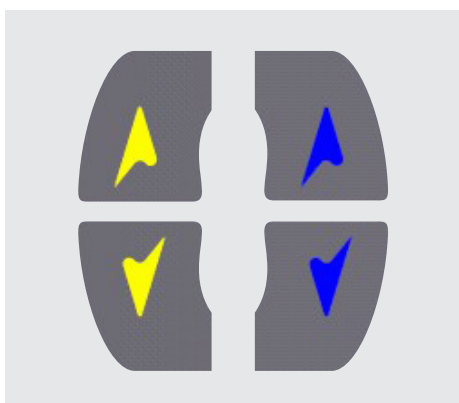
Mode Button

Depressing the mode button once will enable selection of the Output Mode using the Yellow Power Up and Down buttons. Once the display shows the desired V, CP or BV output mode, holding the Mode Button down will return the Generator to a Ready condition.

Depressing the mode button twice will enable selection of User Mode, ADVANCED (output power displayed in Watts) or BASIC (output displayed as relative number from 1 to 10). The equivalent values for ADVANCED and BASIC mode vary by Electrode type. Refer to the Electrode Instructions for Use to confirm the BASIC-ADVANCED Equivalency Table for the specific Electrode type.

NOTE

When an instrument is attached, switching between ADVANCED and BASIC User Mode after adjusting the power output settings will reset the power output values to the default settings for the specific electrode type. The Mode button must be pressed to confirm use.



Power Up/Down

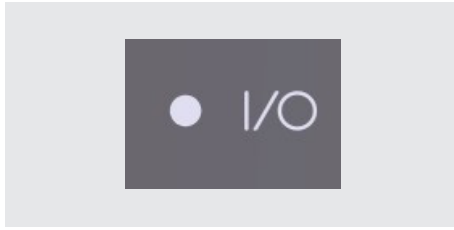
The Power Up and Down buttons are used to override the default power settings. The Yellow Arrow buttons control the Ablation (V), CoolPulse (CP) Ablation and Blended Ablation (BV) outputs in standard electrodes and set tip temperature with TC electrodes. The Blue Arrow buttons control the Coagulate (COAG) output. Press the appropriate button once for a power increment or decrement. Holding down the button accelerates the incrementing or decrementing.

NOTE:

Power can only be adjusted after an Electrode is properly connected to the Generator. Each VAPR Electrode type will determine its own default output power and set temperature.

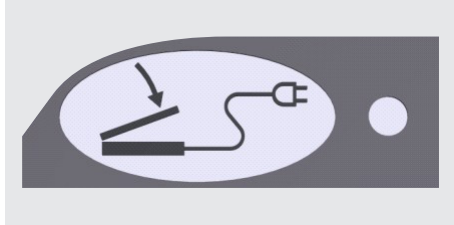
SYSTEM DESCRIPTION

4-4



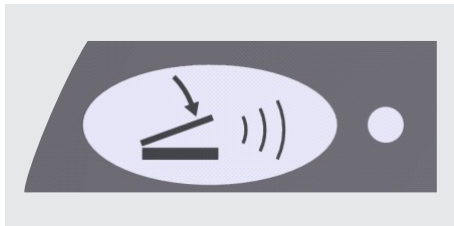
Power Indicator

Illuminates when the unit is switched on.



Wired Footswitch Select

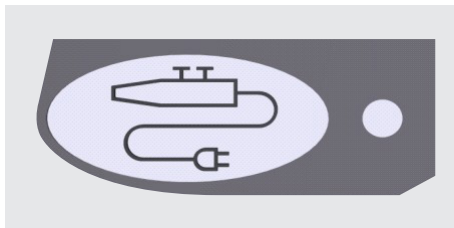
Press to select. Illuminates when the unit is in wired footswitch mode.



Wireless Footswitch Select/Pair

Press to select. Illuminates when the unit is in wireless footswitch mode.

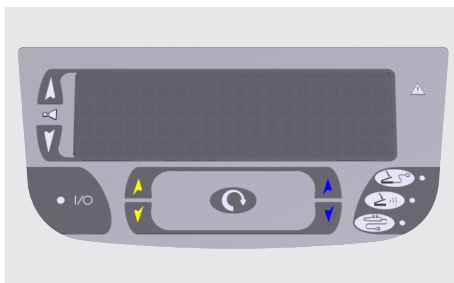
Pressing and holding for 2 seconds will initiate wireless footswitch pairing procedure.



Hand Control Select

(inactive for unsupported instruments)

Press to select. Illuminates when the unit is in hand control mode.



Power/Temperature Setting Display

The left side displays the nominal output power (in Watts or as relative number) for the selected Ablation, CoolPulse Ablation or Blended Ablation modes or set temperature for TC electrodes. The right side displays the nominal output power (in Watts or as relative number) for the Coagulate 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

P	a	i	r	i	n	g		i	n		P	r	o	g	r	e	s	s		
		F	a	i	l		-		R	e	f	e	r		t	o				
				U	s	e	r		M	a	n	u	a	l						
		P	r	e	s	s		M	o	d	e		t	o		U	s	e		

When the generator is powered on, the wireless footswitch module enters a pairing process which may result in mispairing with other foot pedals and generators within close proximity. If this occurs, repairing will be necessary.

NOTE: Letters in grey are flashing.

	A	t	t	a	c	h		I	n	s	t	r	u	m	e	n	t		

Indicates that the Generator is waiting for either the Handpiece or Electrode with integrated handpiece to be attached to the front panel receptacle.

	A	t	t	a	c	h		E	l	e	c	t	r	o	d	e		

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

NOTE

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

SYSTEM DESCRIPTION

4-5

			O	U	T	P	U	T		S	H	O	R	T	E	D			
			R	E	-	A	P	P	L	Y		P	E	D	A	L			

May appear if the active tip shorts against nearby metal objects. A warning tone will also be issued. Operation will resume automatically when the short is removed (provided foot-pedal or hand control button remains depressed). For TC electrodes only, press the mode button on the front panel or footswitch to resume operation.

		S	e	l	e	c	t		L	a	n	g	u	a	g	e		
																	↑	
										F	r	a	n	c	a	i	s	
																	↓	

Indicates the current language and enables (via the blue UP and DOWN buttons on generator) the selection of alternate languages.

The following languages are supported:

- a. English
- b. French
- c. German
- d. Italian
- e. Spanish
- f. Finnish
- g. Dutch
- h. Swedish
- i. Danish
- j. Norwegian
- k. Portuguese

					S	e	l	e	c	t		M	o	d	e					
																		↑		
																	V	1		
																		↓		

Indicates the current output mode and enables (via the **yellow** UP and DOWN buttons on generator) the selection of alternative output modes, where available. Accessible only when an instrument is connected to the generator.

NOTE: Above display is an example only. The "V 1" is one of the output modes.

					S	e	l	e	c	t		U	s	e	r		M	o	d	e		
																					↑	
													A	d	v	a	n	c	e	d		
																					↓	

Indicates the current user mode and enables (via the **blue** UP and DOWN buttons on generator) the selection of user mode, BASIC or ADVANCED. If the user mode is changed (either from BASIC to ADVANCED or from ADVANCED to BASIC), then the following will be displayed:

					E	l	e	c	t	r	o	d	e		R	E	S	E	T			
	t	o			D	E	F	A	U	L	T			v	a	l	u	e	s			
					P	r	e	s	s		M	O	D	E		t	o		u	s	e	

**SYSTEM
DESCRIPTION**

FOOTSWITCHES

Wired Footswitch

The VAPR 3 Footswitch (FIGURE 4) connects to the VAPR VUE Generator. The **yellow** and **blue** pedals are used for output activation. The **black mode** pedal is used for fault clearance or remote adjustment of the ABLATE output setting.

The adjacent light will illuminate on selection.

- Depressing the **yellow** pedal activates the selected Ablation (V), CoolPulse Ablation (CP) or Blended Ablation (BV) outputs.
- Depressing the **blue** pedal activates the Coagulate (DES) output to produce hemostasis or thermal modification of tissue.
- Depressing the **black mode** pedal can reset the Generator from a fault condition.
- Depressing the **black mode** pedal for 2 seconds under normal conditions allows the generator ABLATE power to be adjusted from the VAPR3 footswitch. Each press of the yellow pedal will increment the power level up one level (to the maximum power level for the particular electrode in use). Each press of the blue pedal will decrement the power level down one level.

NOTE

The mode control pedal on the Footswitch can only change ablation power. Coagulation power can be adjusted only using the buttons on the Generator.

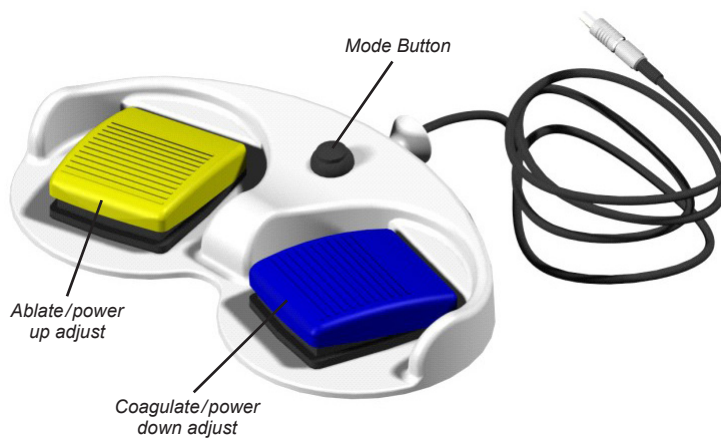
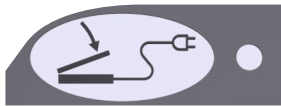


FIGURE 4

Wireless Footswitch



The VAPR VUE Wireless Footswitch (FIGURE 5) interfaces wirelessly to the VAPR VUE Generator. The **yellow** and **blue** pedals are used for output activation. The **black mode** pedal is used for fault clearance or remote adjustment of the ABLATE power settings (if enabled as shown below).



FIGURE 5

SYSTEM DESCRIPTION

4-8

Wireless footswitch pairing process.

To establish a wireless link between the generator and wireless footswitch:

- Prior to the attachment of an Electrode, press and hold the **Wireless Footswitch Select/Pair** button for 2 seconds. Follow the on screen instructions:
- The display will show “Hold Footswitch Face Up”. Hold the Footswitch in a horizontal position with the pedals facing **upward** in close proximity (2 feet or less) in front of the generator for several seconds. Observe the progress bar on the bottom of the display.
- As the progress bar gets close to filling the bottom line of the display, prepare to turn the footswitch upside down.
- The display will change to show “Hold Footswitch Face Down”. Promptly turn and then hold the Footswitch in a horizontal position with the pedals facing **downward** in close proximity (2 feet or less) in front of the generator for several seconds. Observe the progress bar on the bottom of the display.
- Successful pairing is confirmed via audible beep and a displayed message.
- Repeat the pairing process if unsuccessful pairing at the first time.
- **NOTE:** Once a Footswitch is paired to a Generator it will remain so, even after the main power to the Generator is cycled or the wireless Footswitch batteries are changed. If the main power to the generator is cycled, wireless footswitch use must be confirmed by pressing the **black mode** pedal on the footswitch (re-pairing is not necessary).

Front panel display during footswitch pairing process.

		H	o	l	d		F	o	o	t	s	w	i	t	c	h			
							F	a	c	e		U	p						

		H	o	l	d		F	o	o	t	s	w	i	t	c	h			
						F	a	c	e			D	o	w	n				
█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█			

P	a	s	s		-		F	o	o	t	s	w	i	t	c	h		i	s
		n	o	w			r	e	a	d	y		t	o		u	s	e	

If the pairing process is unsuccessful, the following will appear:

P	a	i	r	i	n	g		i	n		P	r	o	g	r	e	s	s
		F	a	i	l		-		R	e	f	e	r		t	o		
				U	s	e	r		M	a	n	u	a	l				

Repeat the pairing process if unsuccessful pairing at the first time.

Once successful pairing has occurred, the following will be displayed upon powering on the Generator:

		P	r	e	s	s		M	O	D	E		p	e	d	a	l		
	t	o		C	o	n	f	i	r	m		S	e	t	t	i	n	g	

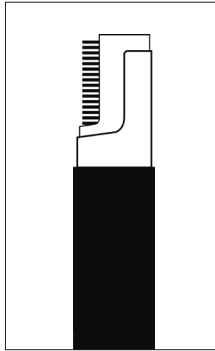
VAPR ELECTRODES

The family of VAPR Electrodes has been designed to facilitate access and control the delivery of energy to the joint space. The Electrodes interface to the Generator via a discrete Handpiece, or they may be equipped as a one-piece Electrode (an integrated handpiece, cable and plug assembly) allowing their direct connection to the Generator. Each Electrode contains an internal classification code which automatically adjusts the VAPR Generator to the optimal output power setting for the specific Electrode. 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. Flexible (FLEX) electrodes are also available. These electrodes can be bent, as specified in product-specific Instructions for Use.

The current product group consists of the following types of electrodes:

Type	Functions
Ablation	Tissue ablation/vaporization and coagulation
Thermal	Tissue coagulation only for collagen shrinkage
Suction	Tissue ablation/vaporization and coagulation with ability to apply suction to remove bubbles and debris.

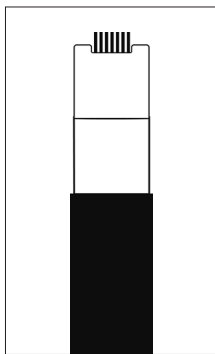
The working tips of the Electrodes can be divided into the following main functional types according to the geometry of the active electrode and insulation support.



Side-facing 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.

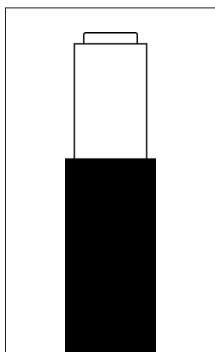
The 2.3 mm configuration is particularly useful in engaging tissue that cannot be approached using the 3.5 mm electrode.



End-facing Electrode

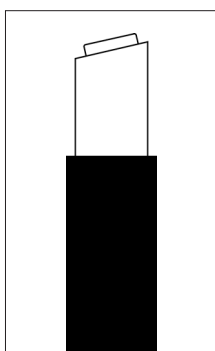
The forward-facing electrode is designed to facilitate controlled, precise tissue effects. Additionally, side extensions of the insulator minimize undesired collateral tissue contact.

The 2.3 mm configuration is particularly useful in engaging tissue that cannot be approached using the 3.5 mm electrode.



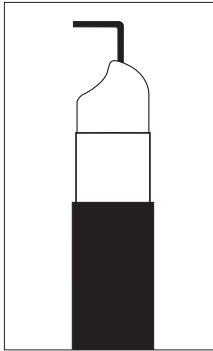
Temperature Control End Effect Electrode

This electrode is a soft tissue coagulation device. Utilization with a VAPR system allows tip temperature of the electrode to be controlled and indicated on the generator display. Intended use is for coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow or wrist.



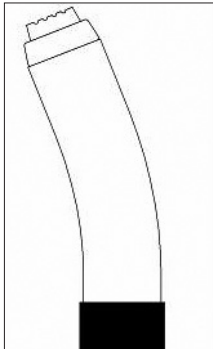
Wedge Electrode

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.



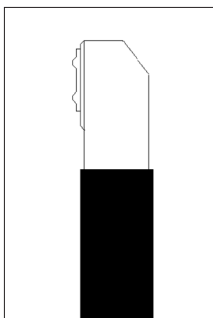
Hook Electrode

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



50 Degree Suction Electrode

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 to access areas of the anatomy such as the knee (e.g., 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.



90 Degree Suction Electrode

The side facing electrode is designed to maximize the tip tissue contact area and provide rapid tissue debulking. The electrode has a large tip-to-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.

WARNING

The VAPR Electrodes are single use, sterile, disposable soft tissue ablation and coagulation devices intended for use with the VAPR System. These products are for single-use only and have 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.

VAPR HANDPIECE

The VAPR Handpiece with Electrode (FIGURE 6) is ergonomically designed to facilitate user comfort and control during use. The Handpiece connects the disposable Electrode with the VAPR VUE Generator. The Handpiece and Cable are supplied non-sterile and must be sterilized prior to each use. Refer to Handpiece Instructions for Use for specific sterilization instruction. It is intended to be re-used up to twenty times.

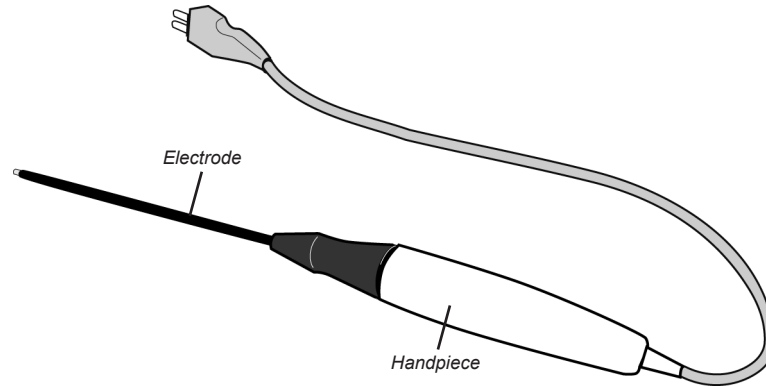


FIGURE 6

VAPR Handpiece with 2-piece Electrode.

SYSTEM DESCRIPTION

4-12

One-piece Electrodes (FIGURE 7) are equipped with an integrated cable and plug, eliminating the need for the Handpiece. These Electrodes are single-use only.

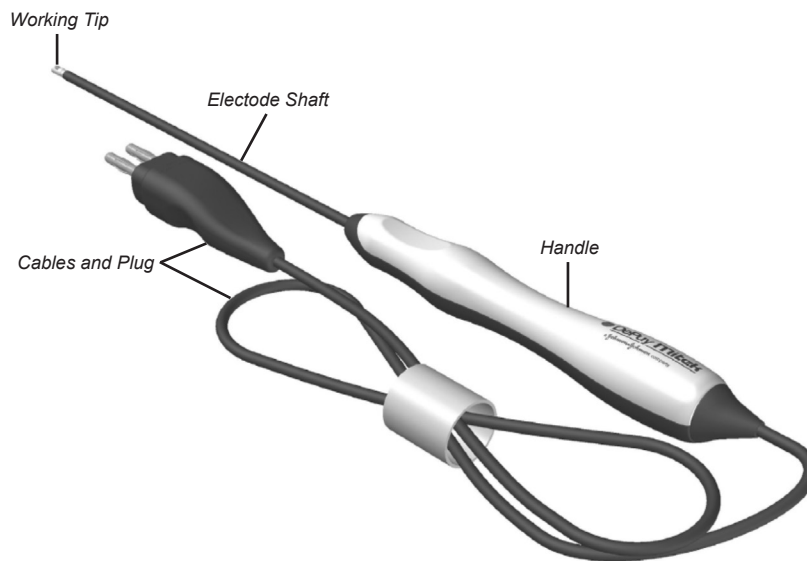


FIGURE 7

VAPR One-piece Electrode.

VAPR Hand Control Electrodes (FIGURE 8) have three integral buttons: ablation (yellow button), coagulation (blue button), and mode (black button) buttons. These Electrodes are single-use only.

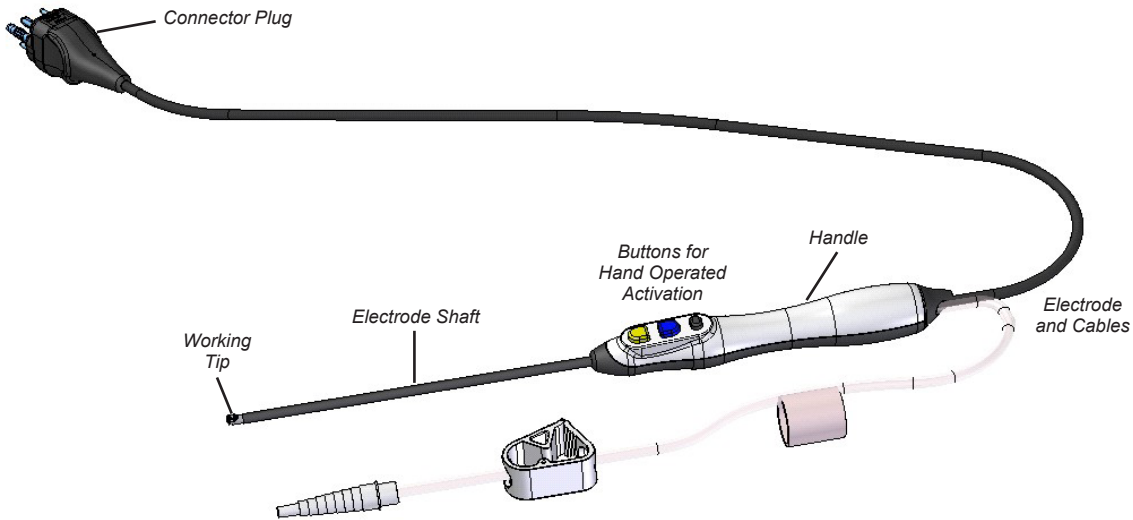


FIGURE 8
VAPR Electrode with integrated handpiece and hand controls

SYSTEM DESCRIPTION

4-13

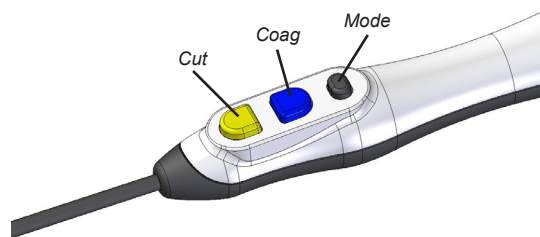


FIGURE 8A.
Details of hand controls

VAPR SUCTION SHEATHS

The VAPR Suction Sheath is used at a set position relative to the electrode to give optimum suction. The suction sheath will need to be connected to OR suction equipment and will aid removal of gas bubbles and debris. They are not intended for use on suction or short electrodes.

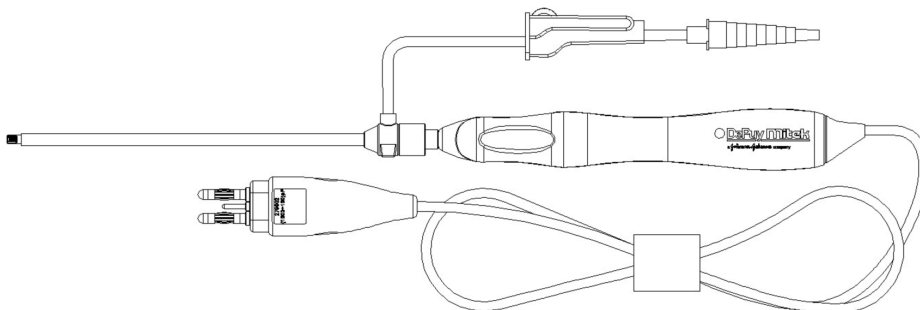


FIGURE 9
VAPR Suction Sheath with non-suction Electrode

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.*

WARNING

The DePuy Mitek VAPR VUE System and accessories have been designed specifically as a system to maximize safety and effectiveness. To avoid incompatibility and unsafe operation, only DePuy Mitek cables and accessories should be used. DePuy Mitek accessories are rated for at least the maximum peak output voltage of the system.

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 VUE 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.

Refer to VAPR VUE Wireless Footswitch User Manual for EMC consideration for the Wireless Footswitch.

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 (10 centimeters) 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.

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 207-253 VAC at 50-60 Hz. This allows the Generator output to remain constant in case of brown-outs 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 Wired Footswitch (if required) to the receptacle on the front of the Generator.
6. Press the Generator power switch to the ON position. When the Generator is first switched on prior to Electrode connection a system self-check sequence will be initiated. Verify that all indicator lights are on and off at least once during this sequence. During the self check sequence the alarm system is verified by checking for three alarm tones of increasing pitch. The first tone is minimum volume, the second maximum volume, the third being the user preset volume. A fourth higher pitch tone may be emitted if an Electrode is connected to the Generator.
7. Verify that "ATTACH INSTRUMENT" 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.

SYSTEM SETUP AND USE DURING SURGERY

Minimum System Component Requirements:

- A properly installed VAPR VUE Generator
- VAPR 3 Footswitch or VAPR VUE Wireless Footswitch (if VAPR Electrode does not incorporate hand controls).
- A Sterile VAPR Handpiece and Electrode, or a VAPR Electrode with integrated hand-piece, or a VAPR Electrode with hand controls appropriate to the procedure being undertaken.

NOTE

The VAPR Handpieces 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 system self-check sequence is initiated.
2. Verify that "ATTACH INSTRUMENT" is flashing on the Generator display, indicating that the Generator is in idle mode.
3. Set up for the desired activation method:
 - a. Wired Footswitch: Attach the wired footswitch connector to the front panel foot switch socket and press the WIRED FOOTSWITCH SELECT button on the front panel.
 - b. Wireless Footswitch: Press the WIRELESS FOOTSWITCH SELECT/PAIR button on the front panel. See "Wireless footswitch pairing process" if pairing is required.

- c. Hand Control: Only available on certain electrodes, if one of these is connected to the generator it will default to this activation method. Alternatively, press the HAND CONTROL SELECT button on the front panel if switching from wired or wireless footswitch back to hand control activation method.
4. The ABLATE and COAG output displays can be shown as maximum power in Watts (ADVANCED) or a relative number from 1 to 10 (BASIC). Refer to Appendix A for equivalencies between ADVANCED and BASIC output displays. Set up for the desired output display style:
 - a. Press MODE button twice. The first press will allow the required Output Mode (CP, V3, V2, V1, BV1, BV2 and COAG as indicated by instrument allowed operating modes) to be selected. The second press of the mode button will allow the ADVANCED or BASIC User Mode to be selected by pressing the BLUE up-down arrows.
 - b. Press MODE button to confirm the selection.
5. Inside the sterile field, pass the plug end of the sterile Handpiece or One-piece electrode out of the sterile field, and connect it to the front of the Generator.
6. (Only when using VAPR Handpiece) Verify that “ATTACH ELECTRODE” is flashing on the Generator display, indicating the Handpiece is properly connected to the Generator.
7. (Only when using VAPR Handpiece) Connect the VAPR Electrode to the Handpiece as shown in FIGURE 10. Once connected, the “ATTACH ELECTRODE” symbol flashing on the Generator display will change to the default settings for that Electrode style.

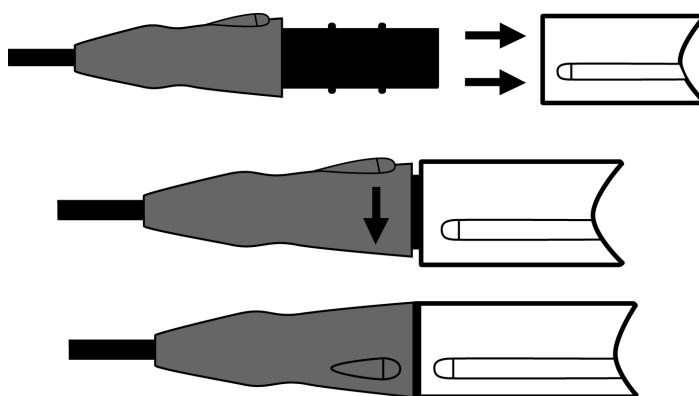


FIGURE 10
Handpiece connection

NOTE

The Default Power settings used for the intended arthroscopic procedures vary with the size and/or configuration of the active electrode. Increasing or decreasing the Default Power settings will determine the level of performance. If the power to the generator is switched ON with an electrode plugged in, the MODE button on the front panel must be pressed to accept the default settings.

If power settings have been overridden to non-default values, the adjusted values will be retained when unplugging and replugging the same electrode, when connecting a new electrode of the same type, or when connecting a different electrode model with the same default values. If the generator is switched off and then on, a newly attached electrode will always revert to its default values. Always confirm proper, desired power settings before proceeding with surgery.

8. 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.

9. Press either the yellow or blue pedal of the Footswitch or yellow or blue button of the hand control, as appropriate, to activate the Electrode:

YELLOW Pedal or Button: Activates the Ablation, CoolPulse Ablation and the Blended Ablation (BV) modes depending on output mode selection. Activation is accompanied by flashing of the Ablation or Blended Ablation power display and a high pitched audible tone.

BLUE Pedal or Button: Activates the Coagulate (COAG) mode only. Activation is accompanied by flashing of the Coagulate power display and an audible tone.

10. 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. All settings may be altered from the front panel buttons. The mode control button on the Footswitch or Hand Control can only change ablation power, as described in section 4. The coagulation power can be adjusted on the Generator, as described in section 4.

USING VAPR THERMAL CONTROL (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 coagulation power. The ablation output is inhibited; pressing the yellow pedal will have no effect.
- The SET temperature may be adjusted from its default using the yellow Up/Down buttons. Similarly the Coagulation power may be adjusted using the blue Up/Down buttons on the generator.
- 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. The desired SET temperature may not be reached such as during high flow conditions in the joint. 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 one 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 by using the dedicated volume UP/DOWN controls on the front panel of the generator (refer to section 4).

NOTE

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

ADJUSTING THE GENERATOR FOR FOOTSWITCH, HAND CONTROL OR WIRELESS FOOTSWITCH OPERATION

To configure the generator for use with Wired Footswitch, Hand Controls or Wireless Footswitch, select the preferred control method by pressing the associated button on the front panel (refer to section 4).

NOTE

- *On selection of the desired control method, other means of control will become inactive.*
- *If a wireless footswitch was the last operational mode selected, turning the AC power to the generator off and then on will revert back to wireless footswitch mode. The mode button on the wireless footswitch must be pressed to acknowledge wireless footswitch operation.*
- *If a wired footswitch was the last operational mode selected, turning the AC power to the generator off and then on will revert back to wired footswitch mode.*
- *If an electrode with hand controls is connected, the generator will default to hand control operation. Wired or wireless footswitch operation, if available, may be selected.*

CHANGING ELECTRODES DURING SURGERY

When using the VAPR Handpiece, 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 "ATTACH ELECTRODE" symbol.

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

When Using VAPR Electrodes with integrated handpiece, insert the plug at the end of the electrode into the connector on the front panel of the generator. Ensure correct orientation of the plug to the connector. At the end of surgery, disconnect the Electrode by pulling on the plug.

NOTE

When switching to or from a VAPR Electrode with integrated handpiece, the generator will display "ATTACH INSTRUMENT".

If the new Electrode has identical default settings to the previous Electrode, the Generator will retain the settings displayed prior to changing the Electrode, even if power settings have been overridden to non-default values.

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 revert to the default settings for the attached Electrode when the mains power is reestablished. The user will be prompted to accept these settings before proceeding. (The display reads "PRESS MODE TO USE").

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 fluid management system is recommended to prevent accumulation and to remove bubbles, as well as any particulate products of vaporization, from the operative field. Use of Electrodes with built-in suction will minimize these effects.

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/SHEATHS

Suction electrodes and sheaths 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/roller clamp before insertion of the device into patient.
- Open the pinch/roller clamp immediately prior to activation (ablation).
- Close the pinch/roller clamp immediately after device activation (ablation).
- The pinch/roller 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.

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 “ATTACH INSTRUMENT” idle mode. 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.

CLEANING AND STERILIZATION PROCEDURES

CLEANING THE GENERATOR

The VAPR VUE 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 3 footswitch and VAPR VUE Wireless Footswitches cannot be sterilized. Refer to the Instructions for Use for the particular footswitch you are using.

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

Refer to the Instructions for Use for the VAPR Handpiece for cleaning and sterilization.

PERIODIC MAINTENANCE INSPECTION

The manufacturer recommends that the VAPR VUE 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.

- 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 Wired Footswitch. There are no user serviceable items within the Wireless Footswitch except the batteries and battery cover gasket.
- 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 main 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 CF 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.
- Inspect the front keypad membrane for any damage.

ERROR AND FAULT SYMBOLS, TROUBLESHOOTING GUIDE

ERROR & FAULT SYMBOL INTERPRETATION AND RECOVERY

Most technical problems are indicated by either an Error or a Fault symbol that appears in the Generator display window. The VAPR VUE system constantly performs self-checking to ensure its correct operation. Fault codes are reported to the user based on time and weighting of those self checks.

- 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 AND FAULT SYMBOLS, TROUBLESHOOTING GUIDE

ERROR SYMBOLS

An Error symbol is displayed as follows:

		I	N	T	E	R	N	A	L		F	A	I	L	U	R	E		
					E	r	r	o	r		c	o	d	e					
					x	x	x		R	e	f		x	x					

FAULT SYMBOLS

A Fault symbol is displayed as follows:

		T	E	X	T	U	A	L		M	E	S	S	A	G	E			
					F	a	u	l	t		c	o	d	e					
					x	x	x		R	e	f		x	x					

where TEXTUAL MESSAGE relates to the type of fault.

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 “ATTACH INSTRUMENT” message on the display, the failure occurred in the accessories which should be discarded and replaced. If the self-test fails, then all functions will be inhibited and no attempt should be made to use the Generator. Contact DePuy Mitek customer service for assistance.

RECOVERY – RESETTING GENERATOR FAULTS AND ERRORS

NOTE

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

Reset the generator by either:

PRESSING MODE BUTTON

Depress and release the MODE button once,

OR

DISCONNECTING THE INSTRUMENT AND CYCLING THE POWER

Press the mains on/off switch twice to cycle the power.

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

ALARMS

Alarms are prioritized in the order listed below.

Fault Type	Description	Alarm Type
[F]	Fatal error. User can reset the generator	Latching
[AF]	Automatic Fatal error. The generator will automatically reset when the condition causing the error is cleared.	Non - Latching
[R]	Recoverable error. User can reset the generator and enter a Ready mode if permitted.	Latching
[SOFT]	Soft error. The unit will automatically recover and continue to operate as normal when the condition causing the error is cleared. For certain faults, the user may be required to confirm the fault before proceeding.	Non - Latching

NOTE:

- A *LATCHING* alarm signal continues to be generated until stopped by a deliberate operator action.
- A *NON-LATCHING* alarm signal automatically stops when the event causing the alarm no longer exists.

Error codes are grouped as shown below:

Error code	Description
100-199	Program crash, memory fault
200-299	Hardware failure (internal)
300-399	Dosage error, over-temperature
400-499	User error or equipment failure
500-599	Reserved for manufacture/engineer diagnostic

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

- There are no user defined alarms used in the VAPR VUE system.
- There are no distributed alarms used in the VAPR VUE system.
- There is no facility for disabling or silencing alarms used in the VAPR VUE system.

Alarm tones for the 4 types of faults are as follows:

Fault Type	Alarm Description
[F]	2kHz tone for 200ms repeated every 500ms indefinitely.
[AF]	2kHz tone for 200ms repeated every 500ms four times.
[R]	2kHz tone for 200ms repeated every 500ms indefinitely.
[SOFT]	2kHz tone for 200ms repeated every 500ms three times.

The list of error codes is presented in the following table:

Error Code	Ref	Vfd Text String	Type	Description
100	10	SYSTEM RESET	[R]	Software execution failure (watchdog reset)
100	11	INTERNAL FAILURE	[F]	ROM checksum failure
100	12	SETTINGS CORRUPT	[R]	Non volatile memory corrupt or not initialised
100	13-16	Reserved	—	—
100	17	SYSTEM RESET	[R]	Software execution failure
100	18	INTERNAL FAILURE	[F]	Continuous test timing
100	19	INTERNAL FAILURE	[F]	Background loop timing
100	20	INTERNAL FAILURE	[F]	Status_event_q overrun
100	21	INTERNAL FAILURE	[F]	User_event_q overrun
100	22	INTERNAL FAILURE	[F]	Vfd_event_q overrun
100	23	INTERNAL FAILURE	[F]	Waveform_generator_event_q overrun
100	24	Reserved	—	—
100	25	INTERNAL FAILURE	[F]	RS232 monitor Rx Queue overflow
100	26	INTERNAL FAILURE	[F]	RS232 monitor Tx Queue overflow
100	27	INTERNAL FAILURE	[F]	ID board communications fault
100	28	INTERNAL FAILURE	[F]	CPU Core failure – indicates a failure with the CPU core or one of its on-chip peripherals.
200	10	INTERNAL FAILURE	[F]	PWM signal : shorted high
200	11	INTERNAL FAILURE	[F]	PWM signal : shorted low
200	12-13	Not used	—	—
200	14	INTERNAL FAILURE	[F]	Energy stuck high
200	15-19	Reserved	—	—
200	20	INTERNAL FAILURE	[F]	CLAMP signal error (DAC output)
200	21	INTERNAL FAILURE	[F]	BOOST signal error (DAC output)
200	22-24	Reserved	—	—
200	25	INTERNAL FAILURE	[F]	OVERDOSE signal error : permanently ON
200	26	INTERNAL FAILURE	[F]	ENERGY signal error : stuck low

**ERROR AND
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Error Code	Ref	Vfd Text String	Type	Description
200	27	Reserved	—	Reserved for audio fault detection
200	28	Warming up	[SOFT]	Generator too cold
200	29	reserved	—	Reserved for audio fault detection
200	30	Reserved	—	—
200	31-32	Reserved	—	—
200	33	INTERNAL FAILURE	[F]	BUSVOLTS signal error (analogue input)
200	34	INTERNAL FAILURE	[F]	Incorrect PK RF board installed
200	35-36	Reserved	—	—
200	37	INTERNAL FAILURE	[F]	SPRF active stuck on
200	38	Reserved	—	—
200	39	CHECK MAINS SUPPLY	[R]	Mains input supply out of limits
200	40	—	—	—
200	41	Not used	—	—
200	42	INTERNAL FAILURE	[F]	CPU POST Thermistor failure
200	43	INTERNAL FAILURE	[F]	CPU POST failure
200	44	RAM	[R]	RAM test failure [POST check]
200	45	INTERNAL FAILURE	[F]	Crystal failure [POST check]
200	46	Reserved	—	—
200	47	INTERNAL FAILURE	[F]	Analogue reference failure [POST check]
200	48	INTERNAL FAILURE	[F]	CLAMP_SET failure [POST check]
200	49	INTERNAL FAILURE	[F]	BOOST_SET failure [POST check]
200	50	INTERNAL FAILURE	[F]	CURRLIM_SET failure [POST check]
200	51	Reserved	—	—
200	52	INTERNAL FAILURE	[F]	COAG_CUT failure [POST check]
200	53-55	Reserved	—	—
200	56	INTERNAL FAILURE	[F]	NO_RF failure [POST check]
200	57-64	Reserved	—	—
200	65	INTERNAL FAILURE	[R]	RFBUS_VOLTS failure [POST check]
200	66	Reserved	—	—
200	67	INTERNAL FAILURE	[F]	PSU_STATUS failure [POST check]
200	68	INTERNAL FAILURE	[R]	Mains input failure [POST check]
200	69	INTERNAL FAILURE	[F]	OVERDOSE failure [POST check]
200	70	INTERNAL FAILURE	[F]	PWM low failure [POST check]
200	71	INTERNAL FAILURE	[F]	ID CAL circuit failure [POST check]
200	72	Reserved	—	Reserved
200	73	INTERNAL FAILURE	[F]	CURRLIM failure [POST check]
200	74	INTERNAL FAILURE	[F]	VOLTLIM failure [POST check]
200	75	INTERNAL FAILURE	[F]	SPRF_ACTIVE failure [POST check]
200	76	INTERNAL FAILURE	[F]	VCC_ANA_DIV_2 failure [POST check]
200	77	INTERNAL FAILURE	[F]	12V failure [POST check]

Error Code	Ref	Vfd Text String	Type	Description
200	78	Reserved	—	n/a
200	79	INTERNAL FAILURE	[F]	PK-RF Thermistor failure [POST check
200	80-81	Reserved	—	n/a
200	82	INTERNAL FAILURE	[F]	ANALOGUE_REF failure
200	83	INTERNAL FAILURE	[F]	VCC_ANA_DIV_2 failure
200	84	INTERNAL FAILURE	[F]	12V failure
200	85-86	Reserved	—	Reserved
200	87	INTERNAL FAILURE	[F]	PSU_STATUS failure
200	88-89	Reserved	—	Reserved
200	90	INTERNAL FAILURE	[F]	CURRLIM_SET failure
200	91-92	Reserved	—	N/a
200	93	INTERNAL FAILURE	[F]	External Watchdog unable to reset CPU
200	94	INTERNAL FAILURE	[F]	Internal Watchdog unable to reset CPU
300	10	THERMAL SHUTDOWN	[R]	Internal overheating
300	11	Reserved	—	Reserved
300	12	INTERNAL FAILURE	[F]	PK-RF board overheating
300	13	EXCESSIVE TIP TEMP	[SOFT]	Tip temperature exceeding 8°C above set temperature during thermal control algorithm.
300	14	<Instrument dependent – see shorted errors in table R10.1.X.20>	[SOFT]	Accessory error : excessive RF output current Output shorted – the error text and user interaction are dependent on the instrument.
300	15-20	Reserved	—	N/a
300	21	<Instrument dependent – see shorted errors in table R10.1.X.20>	[SOFT]	SP Accessory error : excessive RF output current Output shorted – the error text and user interaction are dependent on the instrument.
300	23	INSTRUMENT ERROR	[R]	Instrument thermistor is open circuit
300	24	INSTRUMENT ERROR	[R]	Instrument thermistor is short circuit
400	10	INTERNAL FAILURE	[F]	Coag activation signal stuck
400	11	INTERNAL FAILURE	[F]	Cut activation signal stuck
400	12	INTERNAL FAILURE	[F]	Mode activation signal stuck
400	14	INTERNAL FAILURE	[F]	Electrode identification circuit fault
400	15	BUTTON STUCK	[R]	Front panel : CUT (left) UP button stuck
400	16	BUTTON STUCK	[R]	Front panel : CUT (left) DOWN button stuck
400	17	BUTTON STUCK	[R]	Front panel : blue (Right) UP button stuck
400	18	BUTTON STUCK	[R]	Front panel : blue (Right) DOWN button stuck
400	19	BUTTON STUCK	[R]	Front panel : MODE button stuck
400	20	Reserved	—	—

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Error Code	Ref	Vfd Text String	Type	Description
400	21-24	Reserved	—	—
400	25	Test Time Expired Remove Power Lead	[SOFT]	BioMed Time Credit expired. Notifies the user that the allocated time credit has expired. No RF can be generated until the generator is power-cycled by mains power.
400	26	BUTTON STUCK	[R]	Front panel : Volume UP stuck
400	27	BUTTON STUCK	[R]	Front panel : Volume DOWN stuck
400	28	BUTTON STUCK	[R]	Front panel : Wireless Footswitch activation button stuck
400	29	BUTTON STUCK	[R]	Front panel : Footswitch activation button stuck
400	30	BUTTON STUCK	[R]	Front panel : Handswitch activation button stuck
500	10	Reserved	—	N/a
600	20	FOOTPEDAL STUCK	[AF]	Footswitch cut stuck
600	21	FOOTPEDAL STUCK	[AF]	Footswitch coag stuck
600	22	FOOTPEDAL STUCK	[AF]	Footswitch mode stuck
600	23	HANDSWITCH STUCK	[AF]	Handswitch cut stuck
600	24	HANDSWITCH STUCK	[AF]	Handswitch coag stuck
600	25	HANDSWITCH STUCK	[AF]	Handswitch mode stuck
600	26	FOOTPEDAL STUCK	[AF]	Wireless footpedal cut stuck
600	27	FOOTPEDAL STUCK	[AF]	Wireless footpedal coag stuck
600	28	FOOTPEDAL STUCK	[AF]	Wireless footpedal mode stuck
600	29	“Wireless Footswitch Attention Low Battery”, with “Press Mode to use” / “Refer to User Manual” alternating every 1s	[SOFT]	Wireless footswitch is indicating low battery. This fault is only to be reported if not already acknowledged by the user (since 1 st power-up).
600	30	“Wireless Footswitch Attention Low Reception”, with “Press Mode to use” / “Refer to User Manual” alternating every 1s	[SOFT]	Wireless footswitch is indicating low signal reception. This fault is only to be reported if not already acknowledged by the user (since 1 st power-up).
600	31	“CUT/COAG STUCK”	[SOFT]	Activation input signal stuck. Handswitch or footswitch/wireless footswitch cut or coag button/pedal stuck. Refer to table 9.1 for list of scenarios that will cause this fault.

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 (200-71).

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 integrity of Electrode.
Red warning indicator illuminates	Check error code list for associated fault.
Unable to activate the Generator	Check footswitch for damage. Ensure correct footswitch is connected. Ensure correctly paired wireless footswitch is being used. Check connection of hand control probe. Ensure correct activation device is selected.
Alarm tone too loud or too quiet	Readjust volume. Generator will remember the last volume setting used.
No display on the Generator	Request assistance from qualified service engineer if fault persists. Check inlet fuses, replace with correct type. See Appendix A for fuse specifications. Contact customer service if problem persists.
Generator displays "ATTACH INSTRUMENT" 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 "ATTACH ELECTRODE" symbol after Electrode is inserted	Ensure the connector contacts are clean and dry and have not been damaged. 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 or 300. 21)	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 sterile 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.

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Problem	Suggestions/Solutions
Output Shorted	<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. If the foot pedal remains depressed activation will automatically restart following a short period.</p> <p>For TC electrodes, the 'Output Shorted' fault may be cleared by releasing the BLUE pedal, in this instance activation will not automatically restart if the foot pedal remains depressed. Check the accessories by activating the electrode immersed in sterile 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. Do not use any accessory that persistently faults. If the fault continues, contact DePuy Mitek Customer Service, and discontinue use of accessory.</p>
Unable to access temperature	The Temperature Control mode is only enabled when an appropriate TC electrode is connected.
Wired Footswitch inoperative	Check the activation source has not been set to HAND CONTROL or WIRELESS FOOTSWITCH.
Hand Control inoperative	Check the activation source has not been set to WIRED or WIRELESS FOOTSWITCH.
Wireless Footswitch inoperative	<p>Check the activation source has not been set to HAND CONTROL or WIRED FOOTSWITCH.</p> <p>Verify that the wireless footswitch has been correctly paired with the generator.</p>

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 VUE GENERATOR SPECIFICATIONS

Dimensions (H x W x D):	5 in x 16 in x 16 in (13.5 cm x 41 cm x 41 cm)
Weight:	18 lb. (8kg) approximately

Transport and Storage Conditions

Ambient Temperature Range:	32 to 104°F (0 to 40°C)
Relative Humidity:	10% to 90%, non-condensing
Atmospheric Pressure:	500 to 1060 millibars

Operating Conditions

Ambient Temperature Range:	50 to 104°F (10 to 40°C)
Relative Humidity:	30% to 75%, non-condensing
Atmospheric Pressure:	700 to 1060 millibars

Power Supply

Regulation Voltage:	90-132 Volts RMS, 207-253 Volts RMS
Operating Range:	nominal 100-120/230 V RMS 50/60Hz
Input Rating	1000 VA
Inlet Fuses:	Time lag 10.0A (T10A)
Leakage Currents:	Within limits of Class CF equipment as per IEC

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

NOTE:

The audible signals present during RF activation follow the specific requirements of IEC60601-2-2 and do not represent alarm conditions. All other audible signals are alarm tones and follow IEC60601-1-8 unless otherwise specified. The Red Warning Light on the front panel indicates a Low Priority alarm condition.

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

Liquid Spillage: 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 3 WIRED FOOTSWITCH SPECIFICATIONS

CAT. NO. 225023

Rating	IPX8
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VAPR VUE WIRELESS FOOTSWITCH SPECIFICATIONS

CAT. NO. 227214

Rating	IPX8
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OUTPUT WAVEFORM AND CHARACTERISTICS

Waveform	The RF output is a variable amplitude sinusoid waveform varying between approximately 300kHz and 450kHz, corresponding to minimum and maximum load impedance respectively.
Crest Factor	V1, V2, V3, CP, BV1, BV2 and COAG A nominal crest factor of 1.4 for all outputs. (NOTE: Crest factor for CP is for pulse envelope during ON time).
Power	V output (V1, V2, V3, BV1, BV2) maximum power 260W into 330 Ohms. V output (COAG) maximum power 200W into 28 Ohms. CP output, maximum power 400W into 68 ohms.

Maximum Voltages:

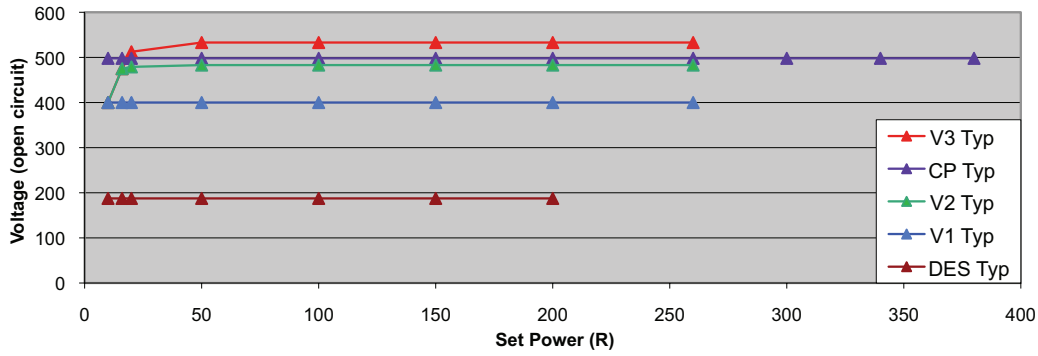
Mode	Maximum (typical into 1K + 20%)	Maximum (typical into open circuit + 20%)
V1	305V RMS 431V PK	340V RMS 480V PK
V2	368V RMS 520V PK	410V RMS 580V PK
V3	408V RMS 577V PK	453V RMS 640V PK
CP	408V RMS 577V PK	423V RMS 598V PK
BV1	As V2	As V2
BV2	As V3	As V3
Coagulate	144V RMS 204V PK	159V RMS 225V PK
VAPR TC Coagulate	124V RMS 175V PK	131V RMS 184V PK

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.

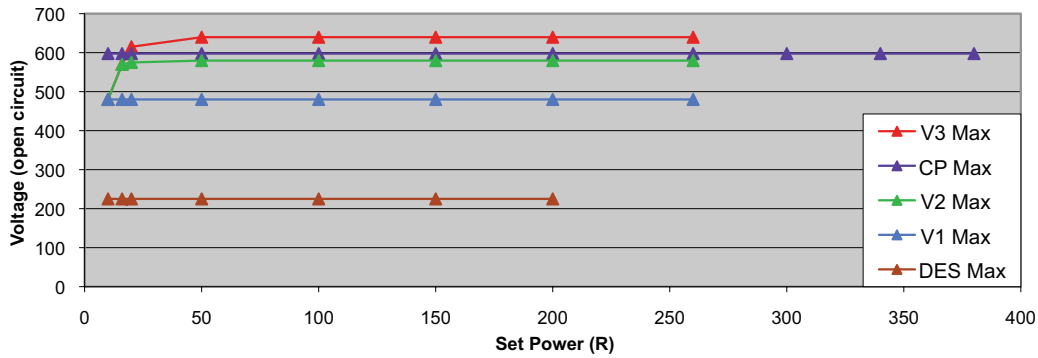
NOTE: In the following curves, "DES" refers to COAG mode. BV1 power output (a composite waveform of V2 and COAG) will be equal or less than V2 output depending on load. BV2 power output (a composite waveform of V3 and COAG) will be equal or less than V3 output depending on load. BV1 and BV2 are blended outputs which are a composite waveform based upon 50% duty cycle for ABLATE and 50% duty cycle for COAG, alternating at 30 Hz.

Typical output peak open circuit voltage

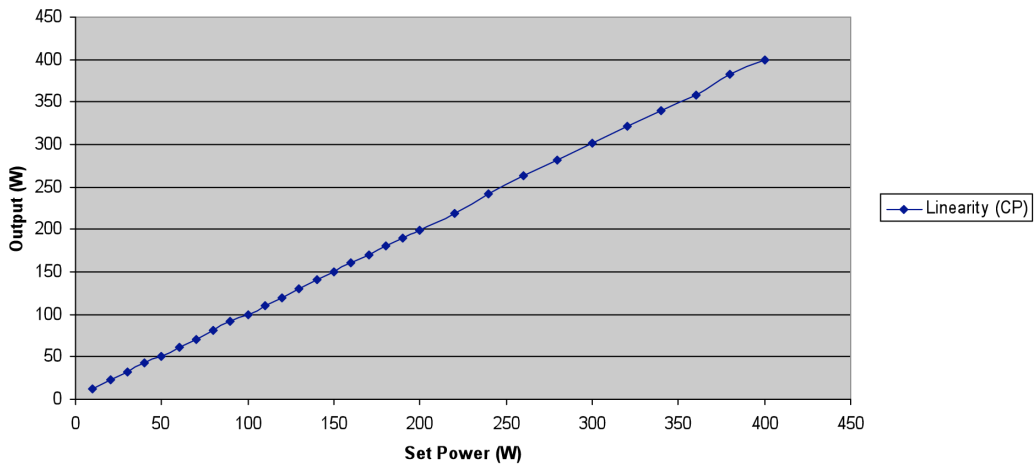


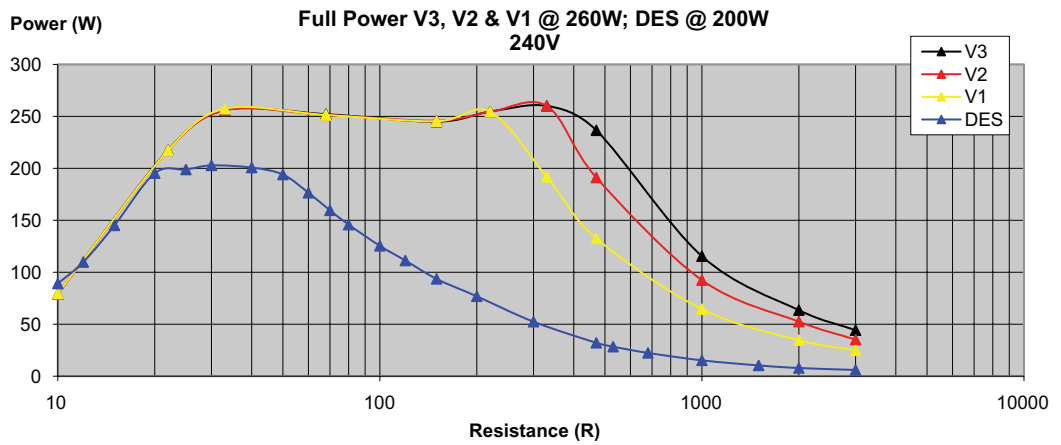
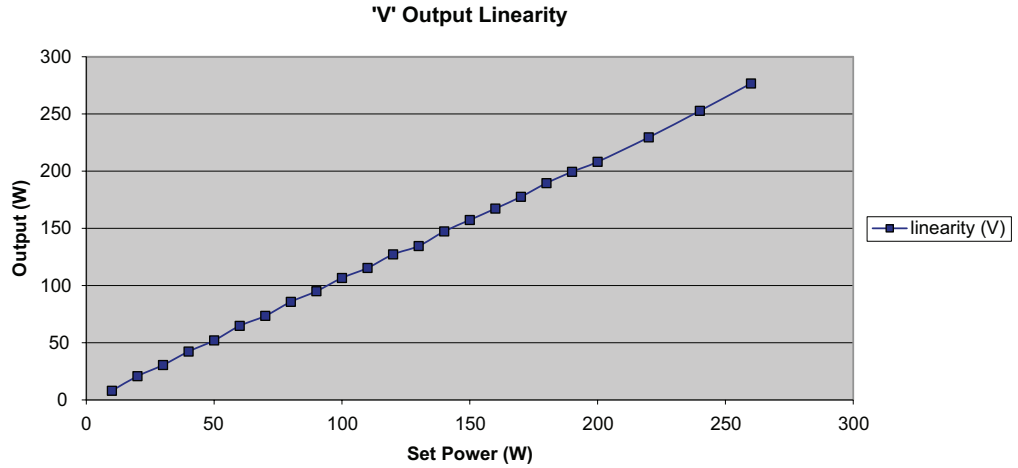
CAUTION: The measurements indicated above are the averaged measurements from a number of generators and are subject to +/- 20% tolerance. Please refer to the graph below and the table on Page A -2 for the maximum voltage values.

Maximum output peak open circuit voltage



'CP' Output Linearity





BASIC-ADVANCED Equivalency Tables

NOTE: The equivalent values for ADVANCED and BASIC mode vary by Electrode type. Refer to the Electrode Instructions for Use to confirm the BASIC-ADVANCED Equivalency Table for the specific Electrode type.

Ablation		
BASIC	ADVANCED	
Value	Lower	Upper
1	10	10
2	20	45
3	50	60
4	80	110
5	120	140
6	160	180
7	200	240
8	260	260

CP Ablation		
BASIC	ADVANCED	
Value	Lower	Upper
1	10	10
2	100	140
3	150	190
4	200	220
5	240	260
6	280	280
7	300	300
8	320	320
9	340	340
10	360	400

Coagulation		
BASIC	ADVANCED	
Value	Lower	Upper
1	10	10
2	20	45
3	50	80
4	90	110
5	120	150
6	160	180
7	190	200

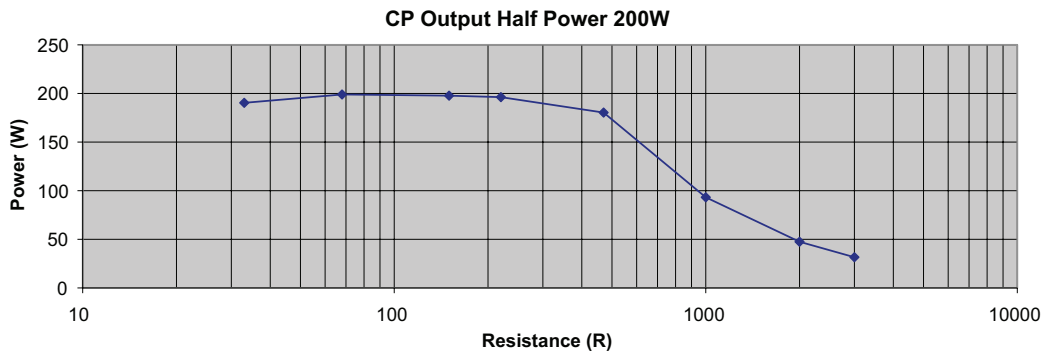
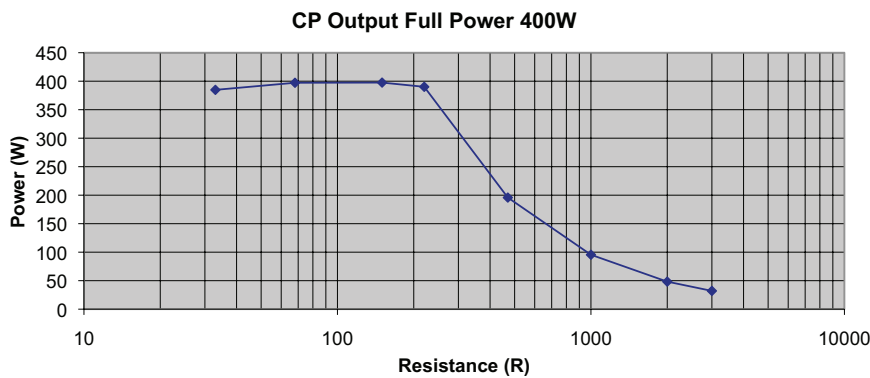
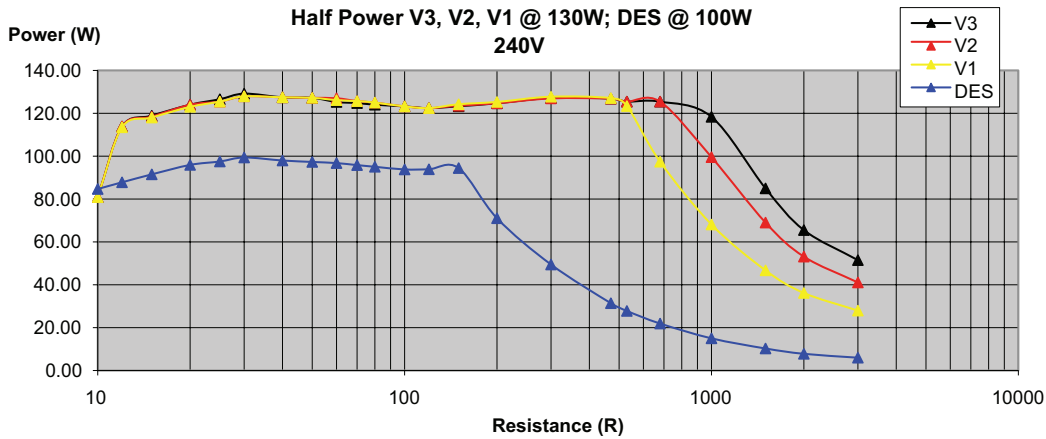
NOTE:

In ADVANCED mode, output power can be adjusted in finer increments than in BASIC mode.

NOTE

When an instrument is attached, switching between ADVANCED and BASIC User Mode after adjusting the power output settings will reset the power output values to the default settings for the specific electrode type. The Mode button must be pressed to confirm use.

The power values for load resistances below 20 Ohms are shown for the Biomed test instrument (Biomedical Engineering and Service use only). For all other instruments the generator will display "OUTPUT SHORTED."

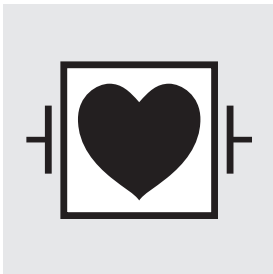




Attention, consult accompanying documents.



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



Defibrillator-proof type CF equipment.

This equipment provides a degree of protection against electric shock to TYPE CF 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 identifies that products contain certain toxic or hazardous substances or elements, and can be used safely during its environmental protection use period. The number in the middle of the logo indicates the environmental protection use period (# of years) for the electronic information product. The logo also signifies that the product should be recycled immediately after its environmental protection use period has expired.

EMC TABLE

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The VAPR VUE GENERATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the VAPR VUE 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 VUE GENERATOR uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The VAPR VUE GENERATOR is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

EMC TABLE

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Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The VAPR VUE GENERATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the VAPR VUE GENERATOR should assure that it is used in such an environment.


Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	±2 kV for Power Supply Lines ±1 kV for Input / Output Lines	±2 kV for Power Supply Lines ±1 kV for Input / Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential Mode ±2 kV Common Mode	±1 kV Differential Mode ±2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5 % <i>UT</i> (>95% Dip in <i>UT</i>) for 0.5 Cycle 40% <i>UT</i> (60% Dip in <i>UT</i>) for 5 Cycle 70% <i>UT</i> (30% Dip in <i>UT</i>) for 25 Cycle <5% <i>UT</i> (>95% Dip in <i>UT</i>) for 5 sec	<5 % <i>UT</i> (>95% Dip in <i>UT</i>) for 0.5 Cycle 40% <i>UT</i> (60% Dip in <i>UT</i>) for 5 Cycle 70% <i>UT</i> (30% Dip in <i>UT</i>) for 25 Cycle <5% <i>UT</i> (>95% Dip in <i>UT</i>) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VAPR VUE GENERATOR requires continued operation during power mains interruptions, it is recommended that the VAPR VUE GENERATOR be powered from an uninterruptible power supply or a battery.
<i>NOTE: UT is the AC mains voltage prior to application of the test level.</i>			

EMC TABLE

B-2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The VAPR VUE GENERATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the VAPR VUE GENERATOR should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
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.
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	

EMC TABLE

B-3

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 VUE GENERATOR is used exceeds the applicable RF compliance level above, the VAPR VUE 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 VUE GENERATOR.

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the VAPR VUE GENERATOR

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

EMC TABLE

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MEDICAL EQUIPMENT

WITH RESPECT TO ELECTRICAL SHOCK,
FIRE AND MECHANICAL HAZARD ONLY
IN ACCORDANCE WITH UL 60601-1,
IEC/EN 60601-1, CAN/CSA C22.2 No 601.1
IEC 60601-2-2

21FA



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.

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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