



VAPR VUE®
Wireless
Footswitches



Manufactured for DePuy Mitek by:
Gyrus Medical P/N: 192055-DC

P/N: 110008

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ENGLISH

VAPR VUE® Wireless Footswitch



INSTRUCTIONS FOR USE

Please read the VAPR VUE® User Manual carefully prior to using the device. The User's Manual is provided with the VAPR VUE Generator. The various components of the VAPR System are designed to be used together as a single unit. Failure to properly follow instructions may lead to electrical or thermal injury and result in improper functioning of device.

IMPORTANT: This package insert is designed to provide instructions for use of the VAPR VUE Wireless Footswitch. It is not a reference to electro-surgical technique.

IMPORTANT: Use only DePuy Mitek VAPR Electrodes and accessories with the DePuy Mitek VAPR VUE System.

INDICATIONS

The VAPR VUE Wireless Footswitch (transmitter) is wirelessly paired with the VAPR VUE Generator (receiver) to activate the electro-surgical system.

WARNINGS

1. **Explosion hazard** – Do not use this equipment in the presence of flammable anesthetics.
2. **Explosion hazard** – Because of battery operation, there is always the chance of spark generation. Do not sterilize this equipment with ethylene oxide or other explosive agents.

3. The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
 - use of the accessory in the PATIENT VICINITY
 - evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 60601-1 harmonized national standard.
4. Periodically, whenever the integrity of the switch is in doubt, test all functions.

PRECAUTIONS

1. For continued safety and performance of the footswitch, it is recommended that the functionality and electrical safety of the footswitch be verified on an annual basis by an authorized DePuy Mitek representative.
2. The footswitch should be inspected every day or before use.
3. The VAPR VUE Wireless Footswitch operates on a frequency range of 2.405-2.480 GHz. It should be tested to assure compatibility with the environment it is working in.
4. Replace the batteries in the transmitter with high quality "AA" size 1.5-volt alkaline batteries (IEC LR6) with a rated capacity of no more than 2000mAh. Do not fit Lithium, Zinc or re-chargeable batteries. Never mix manufacturers when replacing the batteries. Never mix old and new batteries. Care must be taken when replacing the batteries not to damage the O-ring seal on the battery cover.
5. The O-ring seal should be replaced whenever it is damaged or its integrity is in question. DePuy Mitek recommends the seal should be replaced at a minimum every third time batteries are replaced. When replacing the seal lubricate it with petroleum jelly.
6. If the VAPR VUE Wireless Footswitch will not be used for an extended period of time, remove the

batteries to prevent damage due to possible battery leakage.

7. Follow the battery manufacturer's recommendations or your health care facility's policy for the disposal of used batteries.

Report all problems experienced with the footswitch. If the footswitch is not working properly, contact your DePuy Mitek service representative for service. The footswitch should not be used if it is not working properly.

Changes or modifications not expressly approved by DePuy Mitek could void the user's authority to operate the equipment.

IMPORTANT

1. If the receiver (part of the VAPR VUE Generator) does not receive a signal from the transmitter (part of the VAPR VUE Wireless Footswitch) for a period of 525 milliseconds, RF activation will no longer be possible. However, once reception is restored, the VAPR VUE Wireless Footswitch will function normally.
2. The VAPR VUE Wireless Footswitch transmits in all directions. However, every application is different and you may need to adjust the positions of the VAPR VUE Wireless Footswitch or VAPR VUE Generator to obtain optimal performance.
3. Multiple VAPR VUE Wireless Footswitches and VAPR VUE generators may be used in the same vicinity. At any one time, each VAPR VUE Wireless Footswitch can be paired with one and only one VAPR VUE generator.
4. If the footswitch is tipped 60 degrees or more or disturbed in such a way as to activate the internal tip switch, the footswitch will be inoperable until it is stabilized (in 2 seconds).
5. A backup means for activation should be available (i.e., second wireless footswitch, wired footswitch, or electrode with hand controls).
6. The footswitch should be stored with the pedals facing up. The battery life is significantly reduced if the footswitch is stored upside down or sideways.

7. Ensure the pedals and mode button are not depressed when stored. Battery life will be significantly reduced.

INSTRUCTIONS FOR USE

Place the wireless footswitch in a clear, sealable plastic bag prior to use. Refer to the VAPR VUE User Manual on how to pair and operate the VAPR VUE Wireless Footswitch with the VAPR VUE Generator.

Cleaning the VAPR VUE WIRELESS Footswitch

The wireless footswitch is IP68 rated and can be completely immersed briefly. Do not use abrasive cloths, sharp objects, or abrasive cleaners. Dampen a non-abrasive cloth with one of the following products; then wring out until slightly wet and gently rub soiled area until clean.

- Soap and water
- Cidex
- Sodium Hypochlorite 5.25% (Bleach) diluted 10:1

DO NOT AUTOCLAVE OR USE ETHYLENE OXIDE on Wireless Footswitch

General Information

If the foot switch is cold to the touch or below ambient temperature, allow it to reach room temperature before use.

ELECTROMAGNETIC INTERFERENCE

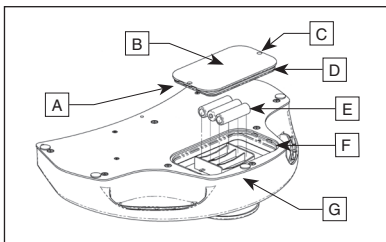
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
 - This device may not cause harmful interference and
 - This device must accept any interference received, including interference that may cause undesired operation.
- This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific

operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This device has been tested and found to comply with the limits for medical devices to the EN 60601-1-2, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health-care and home environments it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of performance of this device.
- This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption or interference may be evidenced by erratic or incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source. The user is encouraged to try to correct the interference by one of the following measures:
 - Turn equipment in the vicinity off and on to isolate the offending equipment.
 - Reorient or relocate the other receiving device.
 - Increase the separation between the interfering equipment and this equipment.
 - If assistance is required, contact your DePuy Mitek Representative.
- The wireless footswitch, in conjunction with the DePuy Mitek VAPR VUE generator, has been tested and found to properly operate in the presence of the following potentially interfering devices:
 - Electrosurgery generators – located on the same cart as the VAPR VUE generator

- Wi-Fi devices – minimum 3 feet away from VAPR VUE generator and wireless footswitch
- Bluetooth device – minimum 3 feet away from VAPR VUE generator and wireless footswitch
- Wireless phones (2.4 GHz) – minimum 3 feet away from VAPR VUE generator and wireless footswitch
- Microwave ovens – minimum 20 feet away from VAPR VUE generator and wireless footswitch
- Other VAPR VUE Wireless footswitches – no minimum distance from VAPR VUE generator and wireless footswitch

Battery Replacement Transmitter



Name	Description
A	2X Locking Tabs
B	Battery Cover
C	Slotted drive ¼ turn fastener
D	O-Ring seal
E	3X "AA" Alkaline batteries
F	Recessed area for cover removal. Gently pry with flat tip device to remove cover
G	3X Battery polarity indicator on bottom face of holder

BATTERY REPLACEMENT

1. Turn the slotted screw (C) ¼ turn counter-clockwise.
2. Remove the battery cover (B) by gently prying with a flat tip device in the recessed area near the screw. Be careful to not damage the O-ring seal (D).
3. Remove and properly dispose of old batteries.
4. Insert 3 fresh “AA” alkaline batteries, observing the polarity markings on the battery holder (G).
5. Observe the O-ring seal for any damage and replace if necessary.
6. Carefully replace the battery cover, ensuring the 2 locking tabs (A) go into their seating position.
7. Press the battery cover down so it is flush with the recessed lip.
8. Turn the slotted screw (C) ¼ turn clockwise.
9. Pairing of the footswitch to the VAPR VUE generator should not be required after changing batteries. If pairing is necessary, follow pairing directions in the VAPR VUE User Manual.

SPECIFICATIONS

- Range: Typically 50 feet
- 2.405 - 2.480 GHz, Channels 1-15
- Latency: Typically 50 milliseconds
- Transmitter battery life: 400 hours @ 50% Duty cycle. Typical Transmitter Stand-by current: 20µA. Typical battery life is 1 year, based on average use.
- Degree of Ingress Protection: IP68 per EN 60529
- Transport & Storage Conditions
 - Ambient Temperature Range:
14 to 104°F (–10 to 40°C)
 - Relative Humidity:
10% to 85%, non-condensing
 - Atmospheric Pressure:
500 to 1060 millibars

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

SAFETY COMPLIANCE

- EN 60601-1 Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance

EMC STANDARDS

- EN 60601-1-2 General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

SIZE

14.0 in (35.6 cm) x 10.0 in (25.4 cm) x 3.0 in (7.6 cm)

WEIGHT

5.5 lbs (2.5 kg) with batteries

QTY

Number of Units

NONSTERILE

Producto no estéril



Refer to instruction manual/booklet



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* For recognized manufacturer, refer to product label.



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