











**PhotonBlade<sup>®</sup> with Adaptive Smoke Evacuation**  
**REF PB2SE**  
**Instructions for Use**



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				<b>STERILE E0</b>		<b>R<sub>x</sub> Only</b>
			Consult Instructions for Use and Symbols Glossary on this website: <a href="http://www.invuity.com/documentlibrary">www.invuity.com/documentlibrary</a>			

## Description

The Invuity PhotonBlade with Adaptive Smoke Evacuation Electrosurgical Device is a single-use, RF device with integrated LED-based illumination, which is powered separately by a replaceable battery. The PhotonBlade with Adaptive Smoke Evacuation consists of a single blade with a rotatable and adjustable length shaft. It is designed to be used with an approved electrosurgical unit (ESU). The PhotonBlade with Adaptive Smoke Evacuation is operated by use of an integrated hand switch or ESU footswitch. The PhotonBlade with Adaptive Smoke Evacuation includes a clip-on suction lumen for the evacuation of smoke.

## Indications for Use

The PhotonBlade with Adaptive Smoke Evacuation is a monopolar RF device coupled with illumination that is indicated for cutting and coagulation of tissue during general surgical procedures and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

## Contraindications

Refer to Instructions for Use provided with the HF Surgical Equipment.

## For Use With



### WARNING

- Use only Invuity-approved components and accessories with and adjacent to the device, unless otherwise specified.
- Always use the device only with a monopolar electrosurgical unit (ESU) that has been tested to and complies with its relevant IEC 60601 series of standards including its collaterals, particulars, national deviations and differences e.g. IEC 60601-1, IEC 60601-2-2, EN 60601-1, EN 60601-2-2, etc.

Description	REF
Battery	CR123A
ElectroSurgical Unit (ESU)	ConMed System 5000, Valleylab FX-C ESU

## Safety Directives

### General Safety



### WARNING

- Healthcare professionals should be thoroughly familiar with the Instructions for Use and the operation of this product prior to use.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this product and the specific technique used for each patient. Invuity, as a manufacturer, does not recommend surgical procedure or technique.
- Always inspect the product and all system components for damage upon initial receipt and before each use. Do not use the product if damage is apparent.
- Always store, transport, and operate the product within the specified environmental condition values.

## Product Safety

### **WARNING**

- Do not activate the ESU or HF functionality unless the battery door is closed.
- Only use the device with HF surgical mode output settings resulting in a peak output voltage not greater than the maximum rated accessory voltage (3000V).
- Both oxygen and nitrous oxide support combustion. Avoid enriched atmospheres, which may result in fires and burns to patients or surgical personnel.
- The following substances contribute to increased fire and explosion hazards in the operating room:
  - Flammable substances (such as alcohol-based skin prepping agents and tinctures)
  - Naturally occurring flammable gases which may accumulate in body cavities such as the bowel
  - The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.
- Verify that all oxygen circuit connections are leak free before and during the use of electrosurgery. Verify that endotracheal tubes are leak free, and the cuff is properly sealed to prevent oxygen leaks.
- Follow all surgical fire cautions and hospital safety procedures. Do not use the device in the presence of flammable gases such as nitrous oxide and oxygen. Do not activate the device until vapors from alcohol-based skin prepping agents have dissipated.
- Proper patient return electrode application is very important. Refer to the ESU and patient return electrode Instructions for Use for guidance regarding the patient return electrode selection, placement and application procedures. Do not rely entirely on the ESU impedance sensing feature as it can be affected by a damaged (shorted) patient return electrode. It is recommended that the operator verify appropriate placement and contact of the patient return electrode. Improper placement or application of patient return electrode may cause patient injury.
- Based on the desired tissue effect, the lowest energy settings should be used. Cut or coagulation settings over 50 watts or any power setting and mode that results in an output voltage of greater than 3000V should not be used. Consult the user manual of the electrosurgical unit (ESU) to determine the voltage output characteristics for different power settings and modes. Refer to Table 1 in Step 5 of the Set Up section for additional information.
- Operate the device using the lowest power settings and the shortest tissue-contact time required for the desired effect, as electrosurgery may cause unintended damage to surrounding tissue.
- During use, do not allow the illumination output surface of the PhotonBlade with Adaptive Smoke Evacuation to be obstructed or rest on tissue. The high intensity illumination has the potential to cause thermal damage or injury if the output surface is obstructed by tissue, gloves, or other material.
- When in use, keep the device in motion to prevent tissue build up on the electrode. However, the blade may be held stationary to spot coagulate. The blade should be carefully cleaned as tissue build-up occurs.
- While activating energy, be aware of critical anatomy that is in contact with the blade, waveguide and telescoping shaft. The waveguide and telescoping shaft should not be touching or retracting tissue while activating energy.
- Only contact the patient with the blade of the device. Do not insert the device into tissue beyond the blade, as unintended injury or damage to the device may occur.
- Do not use in patients that have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g. cardiologist). Possible hazards exist because interference with the action of the electronic implant may occur, the implant or implantable leads may be damaged.

- Do not place active accessories near or in contact with flammable materials, flammable gases, or high levels of oxygen. Electrosurgical accessories that are activated or hot from use can cause a fire.
- Do not contact metal objects or instruments with the PhotonBlade with Adaptive Smoke Evacuation while the cut or coagulation function is activated, including sutures, staples or clips, as this may cause patient or user injury, tissue damage, or damage to the device.
- Do not activate energy unless the active edge of the blade is in direct contact with tissue. Failure to ensure the active edge of the blade is in direct contact with target tissue while activating energy could result in patient injury, including burns.
- Do not touch the blade or telescoping shaft assembly while the cut or coagulation function is activated, as this may result in injury.
- Do not use the PhotonBlade with Adaptive Smoke Evacuation on small appendages, as monopolar electrosurgery may cause thrombosis or unintended tissue injury.
- Do not use electrosurgery in the presence of flammable anesthetics.
- Turn off the Illumination when the device is not in use to prevent the battery life from declining.
- Stop using the device if energy discharge is observed from any other areas besides the active edge of the blade.
- If tissue builds up on the blade of the device, use soft wet gauze or the provided slot in the holster to clean the device electrode during the procedure. Do not use sharp or abrasive objects, such as a scratch pad, on the PhotonBlade with Adaptive Smoke Evacuation, as it may damage the device.
- Do not allow the Adaptive Smoke Evacuation Attachment to interfere with accessibility to the cut and coagulation buttons on the device, as the user may not be able to operate the buttons or may activate the wrong button.
- Should the level of suction applied through the tubing be excessive, immediately engage the pinch clamp to occlude the smoke tubing and stop suction to prevent tissue damage.
- This product contains Lithium-ion material. To reduce the risk of fire or burns, do not disassemble, crush, burn, or puncture the battery.
- Do not service or repair this equipment during a procedure with a patient.

## Caution

- The PhotonBlade with Adaptive Smoke Evacuation should be handled and operated by hospital personnel familiar with and trained in its use. Handle all instruments with care.
- Use of instruments for any purpose or in any manner other than described in this Instructions for Use may cause instrument damage or failure, which could result in patient or user injury.
- Inspect the device packaging before use. Do not use if the packaging is opened or if the device has passed the labeled expiration date.
- Before use, inspect the device and do not use the device if there are breaks, chips, cracks, scratches, tears or missing insulation on the blade or telescoping shaft of the device. See Figure 1.

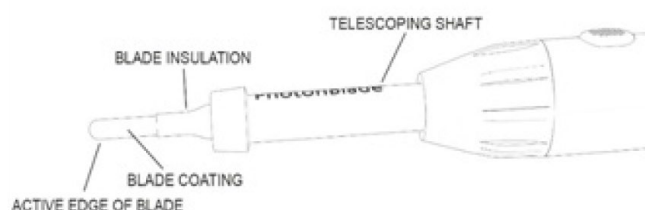


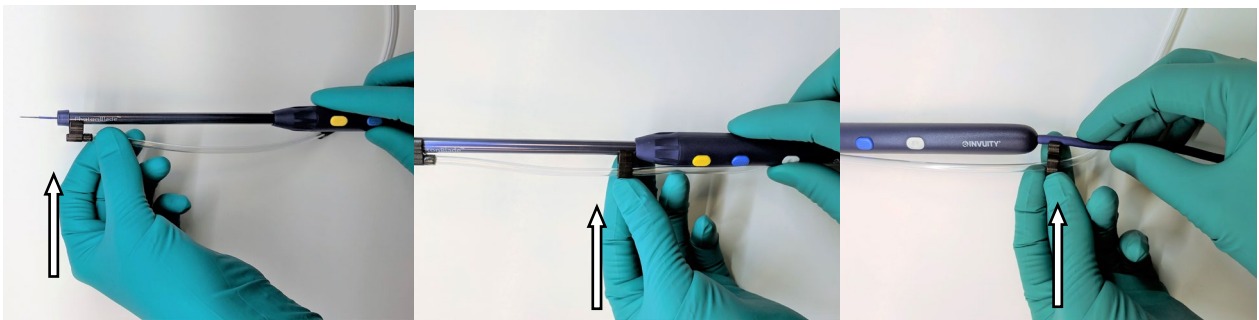
Figure 1

- Only use CR123A 3V batteries for the illumination function.
- Activation of the device when not in contact with tissue, but close to a conductive object, may cause capacitive coupling.
- Confirm proper electrosurgical generator power settings before proceeding with surgery.
- Do not look directly at the LED light source while illumination is active. The light source is extremely intense and may temporarily impair vision.
- Position the cable to the side of the operating table to avoid contact with the patient or a potential tripping hazard.
- Avoid fluid contact with the device hand switch, as this may cause damage to the device.
- When not in use, keep the device in the provided holster, with the holster securely attached to the surgical drape, or a dry, non-conductive area away from the patient to prevent unintended contact with patient or user.
- Do not activate the device near electrocardiograph electrodes, as the electrical current may cause interference.
- Position the patient return electrode cable to avoid contact with the patient or other cables.
- Before installing or removing the patient return electrode, ensure that the handset is not connected to the electrosurgical generator, or the generator is off or in Standby mode, if available.
- Do not resterilize or reuse. The PhotonBlade with Adaptive Smoke Evacuation is provided sterile and intended for single use only.
- After use, dispose of the PhotonBlade with Adaptive Smoke Evacuation and the battery according to hospital procedures and in accordance with local, state and federal laws and regulations.
- To prevent inadequate suction levels, ensure barb connector of Adaptive Smoke Evacuation Attachment is securely connected to the secondary suction hose.
- If the smoke tubing becomes blocked with debris, use the stylet included with the device to clean the tube as needed to maintain adequate suction.
- Ensure that the Instructions for Use provided with the Smoke Evacuation Unit are followed, including all user instructions, warnings, and precautions.
- Inspect the device connector for bent pins and do not use if damaged.

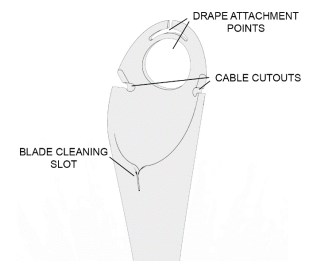
# PhotonBlade with Adaptive Smoke Evacuation: Directions for Use

## Set-Up:

1. Before use, open the battery door to remove the battery protection.
  - The Invuity PhotonBlade is provided with a CR123A 3V battery for the illumination function.
  - The battery is located in the connector.
  - There is a battery protection tab (clear tab protruding from battery compartment door) in place for protection during shipment and storage. (See Battery Replacement section below).
2. If replacement is necessary, only use a CR123A 3V battery for replacement
3. Place the patient return electrode on the patient. Connect the patient return electrode to the ESU.
4. Remove the PhotonBlade with Adaptive Smoke Evacuation from the package and inspect the tip of the device for damage. Do not use if damaged.
5. Inspect the Smoke Evacuation attachment before use. The attachment comes with the 3 distal clips pre-connected to the PhotonBlade. If any of the clips are detached, re-attach as shown below.



6. Attach the provided holster to the surgical drape. Place the cable of the device through the cutout in the side of the holster.



7. Connect the barb connector of the Smoke Evacuation Attachment to the PhotonBlade cable. The connection point should be approximately one hand width from the full length of the Smoke Evacuation tubing.



8. Insert the barb connector of the Smoke Evacuation Attachment into the secondary suction hose with a diameter of ¼” or 9/32”. Attach the secondary suction hose to the smoke evacuation unit.

**NOTE:** The secondary suction hose is not provided with the PhotonBlade with Adaptive Smoke Evacuation Attachment. Use a commercially available secondary suction hose compatible with the smoke evacuation unit.

9. Turn on the ESU. Follow the manufacturer’s manual for setup instructions. Plug the PhotonBlade monopolar connector into the monopolar port of the ESU.



10. Based on the desired tissue effect the lowest energy settings should be used. Cut or coagulation settings over 50 watts or any power setting and mode that results in an output voltage of greater than 3000V should not be used. Consult the user manual of the electro-surgical unit (ESU) to determine the voltage output characteristics for different power settings and modes.

Table 1 lists cut and coagulation power settings and modes used with the PhotonBlade device in combination with the ConMed System 5000 and Valleylab FX-C ESUs to conduct in-vitro testing that confirmed device performance in the specified tissue types.

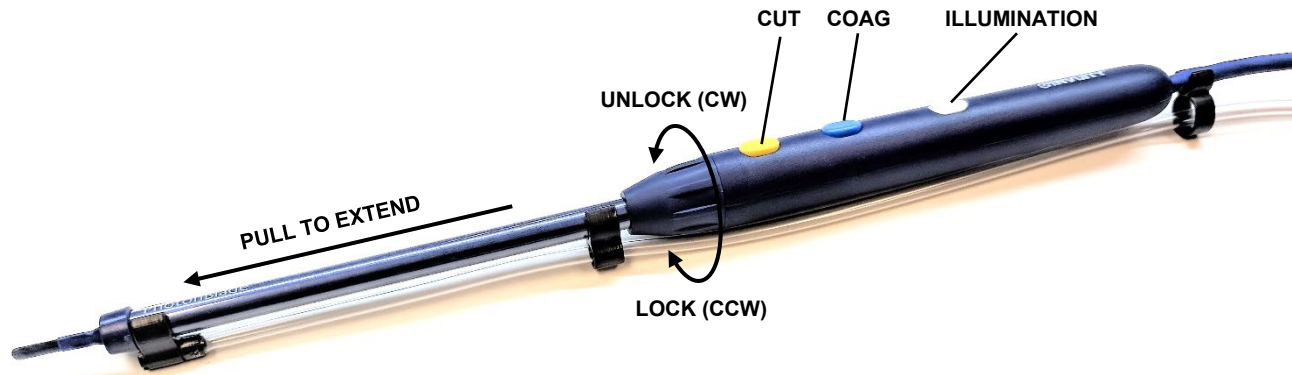
	ConMed System 5000 ESU (muscle)			Valleylab FX-C ESU (muscle, liver, kidney)		
	Power (Watts)	Mode	Approximate Open Circuit Max. Voltage (Volts)	Power (Watts)	Mode	Approximate Open Circuit Max. Voltage (Volts)
Cut	20	Pure	400	20	Low	380
	35	Pure	450	35	Low	560
	50	Pure	500	50	Low	560
Coagulation	20	Pinpoint	700	20	Desiccate	900
	35	Standard	1800	35	Fulgurate	2500
	50	Standard	2500	50	Fulgurate	3000

**Table 1**

Comparable output voltage characteristics to those shown in Table 1 can be obtained with other approved electro-surgical units by using similar power settings and modes. Consult the user manual of the electro-surgical unit to determine the voltage output characteristics for different power settings and modes.



## Using the PhotonBlade with Adaptive Smoke Evacuation:



1. Set the desired length and rotation of the device shaft:
  - a. To extend the shaft, unlock the handle nose cone by rotating it 90° clockwise.
  - b. Pull the shaft distally to the desired length and rotate the shaft to the desired position.
  - c. Lock the nose cone by rotating it 90° counterclockwise. Confirm that shaft is secured in the desired position before proceeding.



2. To collapse the shaft of the device, loosen the nose cone, push on the shaft to the desired length, then tighten the nose cone.
3. Adjust the length and rotation of the PhotonBlade shaft as needed throughout the procedure.
4. The position of the Smoke Evacuation attachment can be adjusted throughout the procedure. To adjust, rotate or slide the attachment along the shaft as needed.
5. To cut, press and hold the yellow button continuously on the handswitch. The Cut button is the most distal on the hand-piece.
6. To coagulate, press and hold the blue button continuously on the handswitch. The Coagulation button is the middle button on the hand-piece.
7. To turn the illumination on, first ensure the device is not contacting tissue, then press the **white** button on the handswitch once. The illumination button is the most proximal on the hand-piece.
8. To turn the illumination off, first ensure the device is not contacting tissue, then press and hold the white button on the hand switch for 2 seconds.



### NOTE:

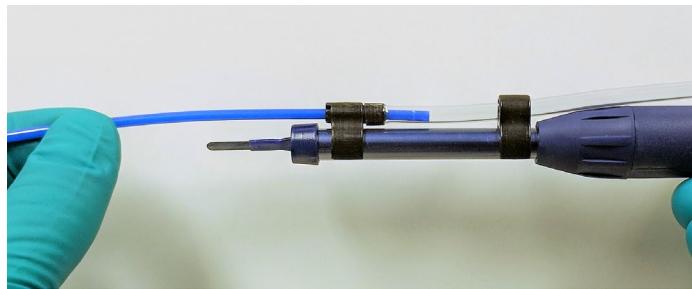
- a. Do not contact tissue when turning the illumination on or off.
  - b. Turn off the illumination when the device is not in use to preserve the battery.
9. Illumination has no effect on the cut and coagulation functions.
  10. To evacuate smoke, activate the smoke evacuation unit per the manufacturer's instructions.
  11. Keep the electrode clean throughout the procedure. Remove tissue build-up with wet gauze pads or by sliding the blade through the provided slot on the holster.



12. Keep the waveguide clean throughout the procedure. Remove fluid or debris with a tapered swab.



13. If needed during the procedure, clear the Smoke Evacuation suction lumen using the stylet.



### Battery Replacement:

1. The PhotonBlade with Adaptive Smoke Evacuation will provide approximately 2 hours of illumination. If the battery needs to be replaced:
  - a. Turn OFF the ESU and unplug the device from the ESU.
  - b. Then, press firmly inward and up on the battery compartment door tab, located on the side of the monopolar connector.
  - c. Replace the battery with a new CR123A 3V battery. The positive end of the battery should be oriented toward the connector pins.
  - d. Dispose of the used battery according to hospital procedures and in accordance with local, state and federal laws and regulations.
  - e. Close the battery door and plug the connector back into the ESU.



**NOTE:** The Cut and Coagulation functions of the device operate independently of the illumination. If the illumination decreases or stops, there is no effect on the Cut and Coagulation functions.

### After Surgery:

1. Turn off the ESU.
2. Disconnect the PhotonBlade connector and the patient return electrode from the ESU.
3. Remove the battery from the battery compartment on the connector.
4. Discard the PhotonBlade with Adaptive Smoke Evacuation and battery according to hospital procedures and in accordance with local, state and federal laws and regulations. Do not re-use the device.

<b>Electromagnetic Compatibility</b>		
<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</b>		
The Invuity PB2SE PhotonBlade with Adaptive Smoke Evacuation is intended for use in the electromagnetic environment specified below. The customer or user of the Invuity PB2SE PhotonBlade with Adaptive Smoke Evacuation should ensure that it is used in such an environment.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment – Guidance</b>
RF Emissions	Group 1	The Invuity PB2SE PhotonBlade with Adaptive Smoke Evacuation by itself 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. When it is connected to HF surgical equipment and when that equipment is activated, it should be considered Group 2. Per CISPR 11 & IEC 60601-1-2: Invuity PhotonBlade with Adaptive Smoke Evacuation was connected to a High Frequency (HF) surgical generator in standby mode and the illuminator function was active.
RF Emissions	Class A	The Invuity PB2SE PhotonBlade with Adaptive Smoke Evacuation is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:  <b>WARNING:</b> This equipment is intended for use in a professional healthcare facility environment. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the HF system or shielding the location.

<b>Recommended electromagnetic immunity separation distances between RF communications equipment and the Invuity PhotonBlade with Adaptive Smoke Evacuation</b>
<b>WARNING:</b> Portable RF equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HF System including cables specified by the manufacturer. Otherwise, degradation of the performance of the equipment could result.

## After Use

### Cleaning and Sterilization

The PhotonBlade with Adaptive Smoke Evacuation is provided sterile and intended for single-use only. See Disposal Section.

Do not reuse, reprocess, or repack a device that is intended for single use only.

- A single use device may not withstand chemical, chemical vapor, or high temperature sterilization reprocessing.
- Design features may make cleaning difficult.
- Reuse may create a contamination risk and compromise structural integrity resulting in operational failure.
- Critical product information may be lost during repackaging.
- Failure to comply may lead to infection or cross infection and result in patient and/or healthcare staff injury.

## References

### Disposal/Recycle

Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulation. Do not reprocess.

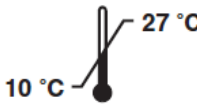
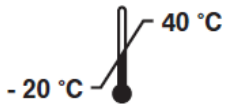
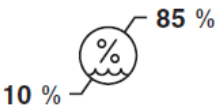
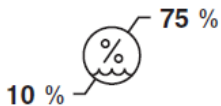
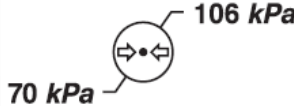
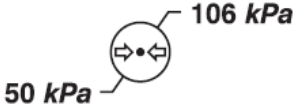
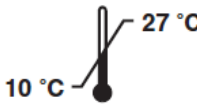
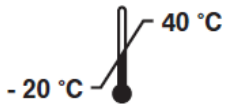
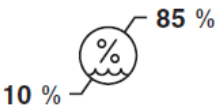
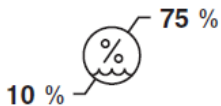
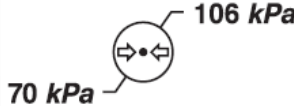
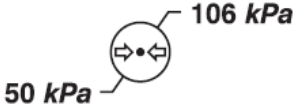
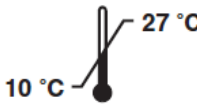
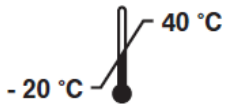
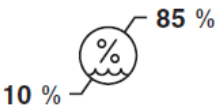
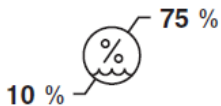
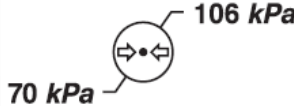
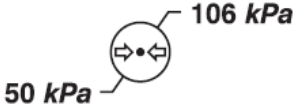
## Troubleshooting

### **WARNING**

Do not disassemble, modify, or repair this product without the authorization of the manufacturer. Contact Invuity for service.

<b>Observation</b>	<b>Corrective Action</b>
Loss of illumination	Check/replace battery
Loss of RF energy	Check PhotonBlade connection to ESU, check electrical connection to ESU

# Specifications

Specifications									
Model:	PhotonBlade with Adaptive Smoke Evacuation (REF: PB2SE)								
Dimensions:	Unextended 20 cm [7.9 inch] length  Extended 27.5 cm [10.8 inch] length  Cord: 305 cm [120 inch] length								
European Conformity:	N/A								
Mass:	0.163 kg [0.357 lb]								
Mode of Operation:	LED: Continuous HF/RF: Non-continuous								
Duty Cycle:	Time ON: 10 seconds Time OFF: 30 seconds								
Applied Part(s):	The electrode at the distal end of the device that comes into physical contact with the patient during normal use as defined by the manufacturer.								
Ingress Protection:	IPX0								
Illumination Power Source:	3VDC CR123A								
Maximum Rated Accessory Voltage	3000V Peak								
Environmental Conditions	<table border="0" style="width: 100%; text-align: center;"> <thead> <tr> <th style="width: 50%;">Operation</th> <th style="width: 50%;">Storage and Transportation</th> </tr> </thead> <tbody> <tr> <td>  <p>10 °C — 27 °C</p> </td> <td>  <p>- 20 °C — 40 °C</p> </td> </tr> <tr> <td>  <p>10 % — 85 %</p> </td> <td>  <p>10 % — 75 %</p> </td> </tr> <tr> <td>  <p>70 kPa — 106 kPa</p> </td> <td>  <p>50 kPa — 106 kPa</p> </td> </tr> </tbody> </table>	Operation	Storage and Transportation	 <p>10 °C — 27 °C</p>	 <p>- 20 °C — 40 °C</p>	 <p>10 % — 85 %</p>	 <p>10 % — 75 %</p>	 <p>70 kPa — 106 kPa</p>	 <p>50 kPa — 106 kPa</p>
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 <p>10 % — 85 %</p>	 <p>10 % — 75 %</p>								
 <p>70 kPa — 106 kPa</p>	 <p>50 kPa — 106 kPa</p>								
Temperature Limitation:									
Relative Humidity Limitation:									
Atmospheric Pressure Limitation:									


## Warranty

INVUITY warrants, for the earlier of (i) the expiration date, if applicable, or (ii) one (1) year from the date of purchase, that this medical device is free from defects in both material and workmanship when used normally for its intended purposes. Suitability of the medical device for any surgical procedure shall be determined by the user alone (in light of relevant instructions for use) and not by INVUITY, and such user shall be responsible for understanding how to use the device for its intended purpose. In the event that purchaser believes that any INVUITY medical device is defective, purchaser will promptly notify INVUITY. Any INVUITY brand named instrument delivered from INVUITY proving to be defective will, as purchaser's sole and exclusive remedy, be replaced at no charge or the amount paid refunded, at INVUITY's discretion, so long as the defect is discovered and reported to INVUITY within the earlier of thirty (30) days of discovery or one (1) year of purchase, and INVUITY determines that the product is defective and is covered by the warranty. Notwithstanding, INVUITY shall not be responsible for normal wear and tear, including minor cosmetic damage compromise or defect caused by re-sterilization. INVUITY does not repair, sharpen, recoat or otherwise refurbish any used product. The foregoing limited warranty and limited obligation of replacement is void and of no effect in the event that there is any modification made to the medical device or the medical device is used for any purpose other than its intended purpose.

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### REVISION HISTORY

Rev	CO #	Description	Approved Date	Effective Date	Originator
A	18-0499	Initial Release	11/13/18	11/14/18	J. Wentz
B	19-0134	Update Indications for Use and Contraindications; Add set up steps for battery protection. Add language per USAR to aligned with IFU	06/12/2019	06/18/2019	J. Wentz
C	19-0439	Added Contraindication Section. Added For Use With section. Reformatted and reworded Warnings section: Divided into General Safety, Product Safety, and Caution sections. Simplified Inspect before use instruction. Replaced abbreviations for CUT and COAG. Added "with Adaptive Smoke Evacuation". Reformatted and condensed Electromagnetic Immunity Section. Added After Use instructions. Added Reference Section. Added Troubleshooting Section. Added Specifications Table.	03/10/2020	03/18/2020	J. Clark



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## **PRINTING INSTRUCTIONS**

Print in-house or at an approved supplier.

Do not print Revision History or Printing Instructions pages (page 14 & 15).

Print double sided, booklet style in black ink on white paper.

Fold in booklet and staple fold.

Fold in quarters (folded size is 4.25 in x 5.5).