

Reporting a Medical Device Failure or Malfunction

The Valleylab Clinical Hotline occasionally receives calls regarding generators or accessories that have not functioned according to expectation. Under the Safe Medical Devices Act, user facilities must report to the device manufacturer all serious or potentially serious device-related injuries or illness of patients or employees. If the incident results in death, it must be reported to the Federal Food and Drug Administration (FDA). (In compliance with the Act, Valleylab reports all serious or potentially serious device-related injuries to the FDA.)

The Act is intended to serve as an early-warning system from which the FDA can obtain important information on device problems. Its provisions apply to all inpatient units, ambulatory surgical care units, perioperative units, diagnostic units, and outpatient treatment centers that are not designated physician offices. When a device-related incident causes injury or death, employees and facilities are to adhere to the Safe Medical Device Act guidelines below.

A customer may question whether a malfunctioning product needs to be reported if no injury occurred or if there is incomplete product information. User facilities are encouraged, but not required to report malfunctions that do not result in death or serious injury. Although these reports are voluntary, the FDA recommends using Form 3500A to report malfunctions to the manufacturer, as this form provides considerable detail regarding the event and the device. Such reports provide important safety information to the manufacturer and FDA¹.

Malfunctions and failures involving Valleylab products can be reported directly to the Valleylab Quality Assurance Department. Effective reporting depends on gathering correct product information. The following list of product information is provided to assist customers in gathering relevant and complete information for prompt and accurate reporting. Reporting a malfunction provides the manufacturer with significant guidance data when testing product functionality. Reporting a

Safe Medical Devices Act

Reporter	Event	To Whom	Form	Time Frame
Facility	Death	FDA and manufacturer	FDA 3500A	Within 10 working days
Facility	Serious injury*	Manufacturer (FDA if mfr is unknown)	FDA 3500A	Within 10 working days
Distributor	Death or serious injury	FDA and manufacturer	FDA 3500A	Within 10 working days
Manufacturer	Death, serious injury, or malfunctions**	FDA	FDA 3500A	Within 30 calendar days of learning of event
Manufacturer	Event that requires immediate action to prevent risk to public	FDA	FDA 3500A	Within 5 working days of learning of event

*Serious injury: Injury or illness that is life threatening, could cause permanent impairment, or necessitates medical or surgical intervention.

**Reportable malfunction: The chance of death or serious injury could result from a recurrence of the malfunction. Refers to use and labeling.



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Clinical Information Hotline News is a free service provided by Valleylab for the advancement of perioperative safety.

Clinical Information Hotline

1-800-255-VLAB (8522) x press 4

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For Hotline News – www.valleylab.com

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malfunction is also a necessary step for product replacement or credit from Valleylab.

Generator Malfunction

When a malfunction or failure is suspected, the generator and accessories in use at the time of the malfunction should be removed from service and saved. In order to complete a comprehensive evaluation of a Valleylab generator, whether by completing Form 3500A or calling Valleylab Quality Assurance Department, it is helpful to have the following information readily available:

Generator Evaluation

- Name and account number of the facility
- Date of occurrence
- Generator information
 - Model (name) of generator
 - Serial number (found on the back of the unit)
 - Description of the malfunction
 - Error code(s) noted

If the unit malfunctioned during use:

- Procedure performed during malfunction
- Electrosurgical accessories used
 - Manufacturer
 - Product number
- Patient return electrode
 - Manufacturer
 - Product number
- Pad site(s)
- Generator settings and modes

If an injury is suspected:

- Type of injury
- Location of injury
- Description of the injury, such as:
 - Shape and size of lesion(s)
 - 1st, 2nd, or 3rd degree lesion(s)
 - Blood loss
- When the injury was discovered
- Treatment of injury or return to surgery

Device Evaluation

To complete a comprehensive evaluation of a Valleylab electrosurgical accessory, the following information is essential:

- Name and account number of the facility
- Date of occurrence
- Accessory product number(s)
- Lot number(s)
- Description of the malfunction

If the accessory malfunctioned during use:

- Generator model (name)
- Generator serial number
- Procedure performed during malfunction
- Generator settings and modes

If an injury is suspected:

- Type of injury
- Location of injury
- Description of the injury, ie:
 - Shape and size of lesion(s)
 - 1st, 2nd, or 3rd degree lesion(s)
 - Blood loss
- When the injury was discovered
- Treatment of injury or return to surgery

Valleylab takes pride in delivering safe and effective products to hospitals and outpatient facilities throughout the world. When product quality is in question, Valleylab appreciates the opportunity to evaluate any malfunctioning devices, and to replace or credit the customer if needed. Product complaints include customer dissatisfaction with product identity, quality, durability, reliability, safety, effectiveness, or performance.

Allied health professionals including physicians, nursing staff, and materials management are an essential link in an effective complaint-reporting system. Reporting may be time consuming, but it is a valuable tool for good patient care. A little time spent gathering pertinent information and making a phone call may eventually save time and money, and, most importantly, can result in better patient care.

If you have questions about any Valleylab products and would like to speak to a Registered Nurse, please call the Valleylab 24-7 Clinical Hotline at 800.255.8522 ext. 2005. We will be glad to assist you with any inquiries or reporting.

If you have a product quality issue to report, please contact Valleylab Quality Assurance at 800.321.0263 ext. 25239 or 25231.

Links to websites:

For complete information on the Safe Medical Devices Act, please visit:

- <http://www.fda.gov/opacom/laws/>

Click: [Safe Medical Devices Act of 1990 \(summary\)](#)
PL 101-629 (Nov. 28, 1990)

For information on mandatory and voluntary reporting forms please visit:

- <http://www.fda.gov/medwatch/how.htm>

For information on Medical Device Reporting for User Facilities, including frequently asked questions on the rules, regulations, and reporting forms visit:

- <http://www.fda.gov/cdrh/mdruf.pdf>