



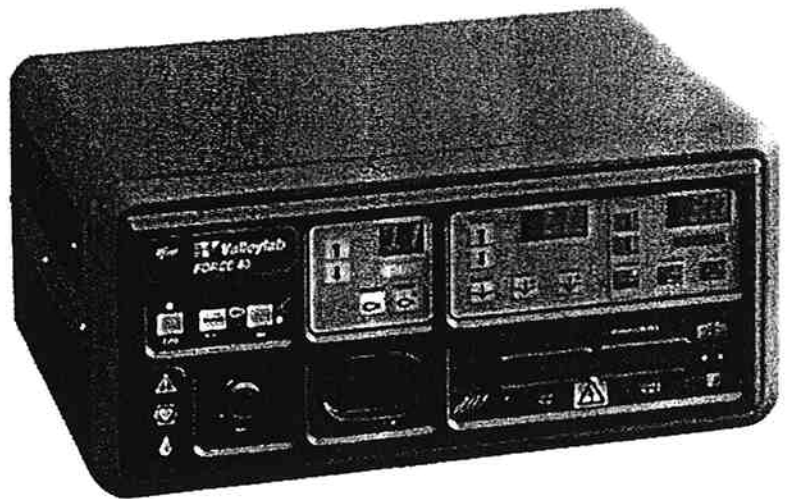
Valleylab®

Force 30

Force 40S

Electrosurgical Generator

Instruction Manual



Force

Instruction Manual

Force 30

Force 40S

Valleylab Inc

Pfizer Hospital Products Group

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Foreword

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed.

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

Valleylab Part No.: 945 110 137

Effective Date: June, 1993

Equipment covered in this manual: Force 30 and Force 40S Electrosurgical Generators
110 - 120 V~ nominal

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The warranty periods for Valleylab's products are as follows:

| | |
|--------------------------------|---|
| Electrosurgical Generators | One Year from date of shipment. |
| Mounting Fixtures (all models) | One Year from date of shipment. |
| Footswitches (all models) | One Year from date of shipment. |
| Patient Return Electrodes | Shelf life only as stated on packaging. |
| Sterile Disposables | Sterility only as stated on packaging. |

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Valleylab Inc, its dealers and representatives, reserve the right to make changes in equipment built and/or sold by them at any time without incurring any obligation to make the same or similar changes on equipment previously built and/or sold by them.

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Attention:
Refer to the
accompanying
documents.



Type CF equipment
Low Leakage
Suitable for cardiac use
Defibrillator proof



Drip Proof



Caution: To reduce
the risk of electric
shock, do not
remove cover.
Refer servicing to
qualified service
personnel.



The generator is high
frequency isolated per
IEC 601-2-2

Section 1 Cautions and Warnings

The safe and effective use of electrosurgery depends to a large degree upon factors solely under the control of the operator. There is no substitute for a properly trained and vigilant operating room staff. It is important that the operating instructions supplied with this or any electrosurgical equipment be read, understood, and followed.

Electrosurgery has been employed safely in numerous procedures. Before starting any surgical procedure, the physician should be familiar with the medical literature, complications, and hazards of electrosurgery in that procedure.

General

Warning: Hazardous Electrical Output: This equipment is for use only by qualified personnel.

Caution: This equipment is capable of producing a physiological effect.

Caution: Read the instructions, cautions, and warnings provided with electrosurgical accessories before using.

Fire/Explosion

Danger: Explosion Hazard: Do not use in the presence of flammable anesthetics.

Warning: Explosion Hazard: The following substances will 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
- oxygen enriched atmospheres
- oxidizing agents (such as nitrous oxide [N₂O] atmospheres)

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

Fire Hazard with Oxygen Circuit Connections

Warning: Fire/Explosion Hazard: Verify that all oxygen circuit connections are leak free before and during the use of electrosurgery. Verify that endotracheal tubes are leak free, and that the cuff is properly sealed to prevent oxygen leaks.

Inadvertent RF Burns

Warning: Electrodes and probes used with monitoring, stimulation, and imaging devices (or similar equipment) can provide a path for high frequency current even if the electrodes or probes are isolated at 50-60 Hz, insulated, and/or battery operated.

To reduce the risk of an inadvertent electrosurgical burn at the electrode or probe site, place the electrode/probe as far away as possible from the electrosurgical site and/or patient return electrode. Protective impedances (resistors or RF inductors) installed in the monitoring leads may reduce the risk of such burns. Consult the hospital biomedical engineer for further information.

Warning: In some circumstances, potential exists for alternate site burns at points of skin contact (e.g., between the arm and the side of the body.) This occurs when electrosurgical current seeks a path to the patient return electrode which includes the skin to skin contact point. Current passing through small skin to skin contact points is concentrated and may cause a burn. This is true for grounded, ground referenced, and isolated generators.

To reduce the potential for alternate site burns, do one or more of the following:

- Avoid skin to skin contact points, such as fingers touching leg, when positioning the patient.
- Place two to three inches of dry gauze to ensure that contact does not occur.
- Position the patient return electrode to provide a direct current route between the surgical site and the return electrode which avoids skin to skin contact areas.
- In addition, place patient return electrodes according to the manufacturer's instructions.

Warning: Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.

Electrosurgical Smoke

Caution: Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to surgical personnel. These studies recommend using surgical masks and adequately ventilating the smoke by using a surgical smoke evacuator or other means.

Servicing

Caution: Electrical Shock Hazard: Do not remove cover. Refer to authorized personnel for service.

Notice: Refer to the Service Manual for maintenance recommendations and, function and output power verification procedures.

Ensure Proper Connections

Caution: Examine all accessories and connections to the electrosurgical generator before using. Ensure that the accessories function as intended. Improper connection may result in arcs and sparks, accessory malfunction, or unintended surgical effects.

Active Accessories

Warning: Do not wrap the accessory cords or patient return electrode cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical personnel.

Contraindications

Patients with Pacemakers

Use electrosurgical generators with caution in the presence of internal or external pacemakers. Interference from the electrosurgical current can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. For further information, consult the pacemaker manufacturer or hospital Cardiology Department.

Circumcisions

Valleylab recommends against the use of monopolar or bipolar electrosurgery for circumcisions.

Contact with grounded metal objects

While using electrosurgery during a surgical procedure, the patient should not be allowed to come into direct contact with grounded metal objects (e.g., surgical table frame, instrument table, etc.). If this is not possible during certain procedures (e.g., those in which noninsulated head frames are used), use extreme caution to maximize patient safety:

- Use the lowest power setting to achieve the desired effect.
- Place the patient return electrode as close to the surgical site as possible.
- Place gauze between the patient and the grounded object if possible.
- Continually monitor the contact point(s).

Before Surgery

Active Accessories

Caution: Read the instructions, warnings, and cautions provided with the active accessories before using. Specific instructions are not included in this manual.

Warning: Electric Shock Hazard: Do not connect wet accessories to the generator.

Warning: Connect accessories to the proper receptacle. Improper connection of accessories may result in inadvertent accessory activation or other potentially hazardous conditions. Follow the directions provided with electro-surgical accessories for instructions on proper connection and use.

Caution: Set power levels to the lowest setting before testing an accessory.

Caution: Inspect reusable accessories and cords for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or operating room personnel.

Caution: Accessories labeled "disposable" are single use only. Do not reuse or re-sterilize.

Patient Return Electrodes

Potential for alternate site burns increases if the return electrode is compromised. Valleylab recommends the use of REM patient return electrodes and Valleylab generators with the REM System.

Warning: The safe use of monopolar electro-surgery requires proper placement of the patient return electrode. To avoid radio frequency burns beneath the patient return electrode, follow all directions on the product package for proper return electrode placement and use.

Warning: Do not cut a patient return electrode to reduce size. Patient burns due to high current density may result.

Warning: Do not apply a patient return electrode for a bipolar only procedure. Unintended surgical effects may occur.

Warning: Using a conventional nonREM Patient Return Electrode will not activate the Valleylab REM Contact Quality Monitoring System.

Generator

Warning: Electric Shock Hazard: Connect the generator electrical cord to a properly grounded receptacle.

Warning: Electric Shock Hazard: Do not use extension cords and/or adapter plugs.

Caution: Provide as much distance as possible between the electro-surgical generator and other electronic equipment (such as monitors) because an activated electro-surgical generator may cause interference with them.

Caution: Do not turn the activation tone down to an inaudible level. The activation tone alerts personnel when the accessory is active.

Caution: Nonfunction of the generator may cause interruption of surgery. A backup generator should be available for use.

Notice: If required by local codes, connect the generator to the hospital equalization connector with an equipotential cable.

During Surgery

Use near metal objects

Warning: Use extreme caution when using electrosurgery in close proximity to or in direct contact with any metal objects. These metal objects include but are not limited to Gomco clamps, Kocher clamps, speculums, and hemostats. Using electrosurgery in these circumstances may result in unintentional and unwanted tissue destruction and burns.

Generator Power Settings

Warning: Confirm proper electrosurgical generator settings before proceeding with surgery. Use the lowest appropriate power setting to achieve the desired effect.

Warning: Never increase the power settings without first checking both the active electrode and patient return electrodes and their connections. Use the active electrode only for the minimum time necessary to achieve the desired surgical effect in order to minimize the possibility of burns. This is especially true in pediatric and neonatal patients and where small appendages are involved.

Caution: The Force 30/40S electrosurgical generators cut effectively at power settings lower than previous models offered by Valleylab. Use caution in selecting initial power settings.

Forceps

Notice: Do not activate the generator until the forceps have made contact with the patient. Product damage may occur.

Suction Coagulators

Warning: To avoid the possibility of a burn to the surgeon, always turn the generator off prior to bending or reshaping the coagulator suction tube.

Warning: Ensure that the outside of the coagulator suction tube remains free of blood and mucus. Failure to clean the coagulator suction tube can allow electrical conductance by means of the contaminants which may result in patient burns.

Warning: Do not immerse the suction coagulator handswitch mechanism in saline solution or other conductive fluids. Unintended activation may result.