

AcuPulse™

Carbon Dioxide Laser **Operator Manual**



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Use of this Manual:

The AcuPulse laser system is designed to meet international safety and performance standards. Personnel operating the system must have a thorough understanding of the proper operation of the system.

This manual has been prepared to aid medical and technical personnel to understand and operate the system. Do not operate the system before reading this manual and gaining a clear understanding of the operation of the system. If any part of this manual is not clear, please contact your Lumenis representative for clarification.

The information provided in this manual is not intended to replace physician training or professional training on the clinical use of the AcuPulse CO₂ laser system. Such training should include a review of published literature, seminars, workshops and appropriate preceptorships. Please contact your Lumenis representative for current information on available training.

This manual should always accompany the system, and its location must be known to all personnel operating the system. Additional copies of this manual are available from your Lumenis distributor.

System and accessory specifications subject to change without notice.

For further information about Lumenis, visit the Lumenis Website: <http://www.Lumenis.com> or send email to information@Lumenis.com



Authorized Representative in the European Community:

Lumenis (Germany) GmbH
Heinrich-Hertz-Str. 3
D-63303 Dreieich-Dreieichenhain
Germany
Tel: +49 (0) 6103-8335-0

Manufactured by Lumenis Ltd.

6 Hakidma Street
P.O.B. 240
Yokneam 2069204, Israel
Tel: +972-4-959-9000

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Chapter 1

Overview

1.1. Introduction

AcuPulse encompasses a family of DC-excited CO₂ laser system models for use in a variety of surgical and aesthetic applications:

1. **AcuPulse 30** – CO₂ laser system (30 Watts) with **Manual** operating mode.
2. **AcuPulse 30ST** – CO₂ laser system (30 Watts) with **Manual** and **SurgiTouch** operating modes.
3. **AcuPulse 40** – CO₂ laser system (40 Watt) with **Manual** operating mode.
4. **AcuPulse 40ST** – CO₂ laser system (40 Watts) with **Manual** and **SurgiTouch** operating modes.
5. **AcuPulse 40AES-F** – CO₂ laser system (40 Watts) with **Manual** and **Aesthetic** operating modes (Fractional Resurfacing).
6. **AcuPulse 40AES-R** – CO₂ laser system (40 Watts) with **Manual** and **Aesthetic** operating modes (Fractional and Conventional Resurfacing).
7. **AcuPulse 40AES-A** – CO₂ laser system (40 Watts) with **Manual**, **SurgiTouch** and **Aesthetic** operating modes (Fractional and Conventional Resurfacing).

The AcuPulse systems deliver maximal power of:

System Power: ➔	30 Watt System	40 Watt System
Continuous Wave Mode	30 Watts	40 Watts
Pulser Mode	25 Watts	35 Watts
SuperPulse Mode	10 Watts	15 watts

1.2. Characteristics of the CO₂ Laser Beam

The CO₂ laser wavelength falls in the mid-infrared region of the electromagnetic spectrum. This wavelength is invisible to the human eye.

Carbon dioxide laser energy is readily absorbed by water in tissue. Since soft tissue is comprised primarily of water, CO₂ laser energy can be used effectively for the excision, incision, ablation, vaporization, and coagulation of soft tissue.

1.3. *Laser Preparation*

The laser is shipped directly from the factory to your site. Your local Lumenis representative initially uncrates, inspects, sets up and installs the laser to ensure that it is ready for use. In addition, Lumenis provides in-service training to ensure that your staff is experienced with the operation and safety considerations of the laser.

Thereafter, you or the staff at your facility will perform the daily maintenance routines associated with the laser and with any delivery systems and/or accessories used during surgery, including inspecting and cleaning the laser and delivery systems; sterilizing and connecting/disconnecting the accessories. These procedures are detailed in this manual.

Most nursing staff prefer to inspect the laser and delivery systems daily, usually prior to scheduled cases and before patients are premedicated. Doing so will ensure adequate time to troubleshoot a problem or seek professional service with the least disruption to patient care. These routine tasks may be performed outside of the sterile field; in this case, ensure enough time to sterilize any components, as necessary, before scheduled cases.

1.4. *Scope of This Manual*

This manual is intended to provide the surgeon and other personnel who operate or maintain the system with information regarding the operating principles, controls, safety precautions, installation and maintenance of the system. While this manual is intended to aid in the use and care of the equipment, it does not serve as a substitute for proper training in the clinical applications of medical laser devices.

This operator's manual incorporates the following chapters:

Chapter 1: Overview	Contains a general introduction to the system.
Chapter 2: Laser Safety	Contains explanations and directions concerning safety measures for operating the system. This chapter also includes regulatory information and requirements.
Chapter 3: System Installation	Lists electrical, space and environmental requirements for installation of the system and basic installation instructions.
Chapter 4: System Description	Contains a detailed overview of the system and its various components, controls, displays and connections. Includes detailed specifications of all facets of the system.

Chapter 5: Operating Instructions	Explains how to operate the system.
Chapter 6: Delivery Systems	Describes the various delivery systems used with the AcuPulse.
Chapter 7: Maintenance	Provides a detailed review of how to maintain the system.
Chapter 8: Troubleshooting	Lists the system's error messages that might occur during operation, their probable causes and what actions to take.
Appendix A: Clinical Guide: Surgical Applications	Offers information about staff training, indications and contraindications for use, recommended setup parameters and suggested professional reference literature.
Appendix B: Clinical Guide: Aesthetic Applications	Offers information about staff training, indications and contraindications for use, recommended setup parameters and suggested professional reference literature.
Appendix C: EMC Guidance	Describes the electromagnetic environment in which the system may be operated.

1.5. *Manual Conventions*

Throughout this manual, notes, cautions and warnings are used to provide critical information needed before the device is used.

Examples:



Note

A **Note** is a statement that alerts the operator to particularly important information.



Caution

A **Caution** is a statement that alerts the operator to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, and damage to the device or other property. The caution statement includes the precaution that should be taken to avoid the hazard.



Warning

A **Warning** is a statement that alerts the operator to the possibility of injury, death, or serious adverse reactions associated with the use or misuse of the device.

1.6. *Physician Responsibility*

Federal (USA) law restricts prescription medical devices to sale by or on the order of a physician, or properly licensed practitioner.

The properly licensed practitioner will be responsible for the use and operation of the device and for all user qualifications. Lumenis makes no representations regarding federal, state or local laws or regulations that might apply to the use and operation of any medical device. The physician is responsible for contacting his or her local licensing agencies to determine any credentials required by law for clinical use and operation of the device.

1.7. *Maintenance*

The AcuPulse is a precision, technical medical device that requires routine service. All service must be performed by a Lumenis technician and all parts must be purchased from Lumenis. Failure to obtain service and parts through Lumenis voids all warranties, express and implied. Please call Lumenis or your local representative for details.

1.8. *Modification of the Device*

Unauthorized modification of the hardware, software or specifications of the AcuPulse voids all warranties, express and implied. Lumenis takes no responsibility for the use or operation of such a device.



Caution

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

1.9. *Resale Inspection*

The AcuPulse is a precision, technical medical device. If any Lumenis device is resold by anyone other than an authorized sales representative, Lumenis offers a resale inspection by a Lumenis technician to assure that the device is working in accordance with manufacturer's specifications. Using the device after it has been resold and before it has been inspected is a misuse of the device, which may result in injuries and voids all warranties, express and implied.

Lumenis also offers service contracts and extended warranties for its devices. For more information about the services or about the costs of inspections or service calls, please call Lumenis or your local representative.

1.10. *Abbreviations and Acronyms*

"	Inches
°C	Degrees Celsius
°F	Degrees Fahrenheit
ANSI	American National Standards Institute
CE	European Directives Compliance Marking
cm	Centimeters
CO ₂	Carbon Dioxide
CW	Continuous Wave
DC	Direct Current
ENT	Ear, Nose and Throat
FDA	Food & Drug Administration (USA)
GUI	Graphic User Interface
GYN	Gynecology
Hz	Hertz
IEC	International Electrotechnical Commission

ISO	International Standards Organization
J/cm²	Joules per square centimeter
kg	Kilogram
lbs	Pounds
LAM	Laser-Assisted Myringotomy
LAN	Local Area Network
LAUP	Laser-Assisted Uvulopalatoplasty
LCD	Liquid Crystal Display
LED	Light Emitting Diode
m	Meters
mJ	MilliJoules
mm	Millimeters
mW	MilliWatts
nm	Nanometers
OD	Optical Density
PS	Power Supply
SP	SuperPulse
UL	Underwriters Laboratories
USB	Universal Serial Bus
VAC	Volts, Alternating Current
W	Watts

Chapter 2

Laser Safety

2.1. *Introduction*

Operators must take precautions to prevent exposure of laser energy to the eyes and skin from either direct or diffusely reflected laser beams, except as a therapeutic application. Additional precautions must be taken to prevent fire, electrical injury, and explosion.

Lumenis does not make recommendations regarding the practice of medicine. Laser treatment parameters are provided as a guide. Individual treatment should be based on clinical training, clinical observation of laser-tissue interaction, and appropriate clinical endpoints.

Patient safety should always be the clinician's first concern. This chapter of the manual includes the minimum information required to operate the system safely. In addition to the guidelines presented here, follow all applicable institutional procedures. Read this chapter completely before attempting a procedure with the AcuPulse laser system.

This chapter includes:

- Basic institutional requirements, including responsibilities of the Laser Safety Officer.
- How and why the laser impacts tissue, and how this is controlled.
- Hazards associated with unsafe laser use.
- Safety features of the AcuPulse.
- Notes, precautions, cautions and warnings associated with the AcuPulse.

2.2. *Training and Institutional Requirements*



Caution

No one should use the AcuPulse, or any other medical laser, without specific training in both medical laser use and laser safety.

Both user and safety training is available from Lumenis. Contact your Lumenis representative to inquire about seminars in your area.

2.2.1. *Laser Safety Guidelines*

American National Standards Institute specification ANSI Z136.3-2005 and Z136.1-2000 include a very thorough discussion of laser safety and guidelines for medical laser use. These standards were developed in the earliest days of lasers and are routinely revised to keep up with growing technology. ANSI Z136.3 is written specifically for the use of lasers in medicine. While non-binding, the guidelines are excellent guides for an office or institution seeking to set up a formal safety program.

Lumenis strongly recommends that the operators read these two ANSI standards before using a laser in clinical practice.

2.2.2. *Laser Safety Officer*

Large institutions are following the prescriptions of ANSI 136.3 by setting up Laser Safety Committees and appointing Laser Safety Officers to manage laser use. Even the smallest office should have one person to act in the capacity of Laser Safety Officer.

ANSI Z136.3 requires the Laser Safety Officer to fulfill the following responsibilities:

1. Classify, or verify classification of, lasers and laser systems.
2. Evaluate hazards of laser treatment areas.
3. Assure that the prescribed control measures are in effect and recommend or approve alternates when the primary ones are not feasible.
4. Approve operational procedures, including any procedural checklists.
5. Recommend or approve protective equipment, and assure that it is periodically inspected to ensure proper working order.
6. Approve wording on signs and equipment labels.
7. Approve installation and equipment prior to use, and modifications to existing equipment and facilities.
8. Assure adequate safety education and training is provided for all personnel.

The Laser Safety Officer may also assume other responsibilities, such as keeping laser use and maintenance logs. The Laser Safety Officer should become familiar with the periodic maintenance requirements in the **Maintenance** chapter of this manual.

2.2.3. Laser Treatment/ Operating Area

According to ANSI Z136.3, the Laser Safety Officer is responsible for the area in which laser treatments are carried out. In meeting this requirement, the Laser Safety Officer should ensure that:

1. The surroundings are safe for both the patient and the operator.
2. The floor is uncluttered and clear access is maintained to the footswitch. Cables are secure and not crimped.
3. The operating area is occupied only by authorized personnel.
4. Appropriate warning signs are posted in the operating area and just outside of it. The AcuPulse is a Class IV laser; the door warning sign for the AcuPulse is shown in Figure 2-1.

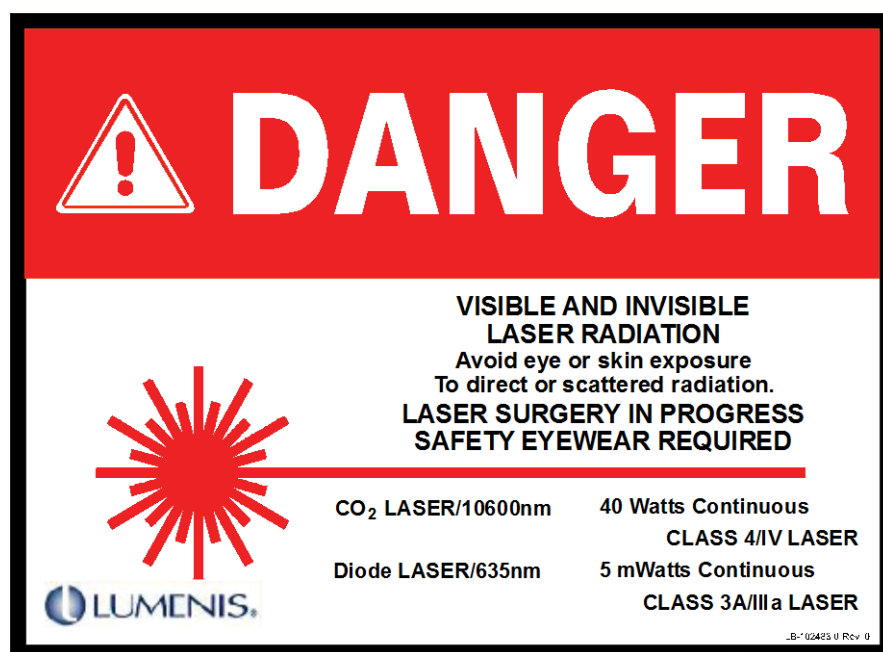


Figure 2-1: Laser Treatment Room Warning Sign

2.3. *Understanding and Controlling Laser Impact on Tissue*



Warning

The AcuPulse system contains a Class IV, CO₂ laser which produces an invisible beam of high energy infrared radiation. Improper use could result in serious personal injury. Observe all safety precautions for Class IV lasers.

Many different types of lasers have been developed for multitudes of different uses. Each type of laser has a certain potential for harm if misused. Even lasers designed for use on living tissue must be used and applied carefully in order to avoid:

- Hazards to the patient or clinical personnel
- Hazards to the physical surroundings

For this reason, it is important to understand the basics of how laser energy affects living tissue and how to control this energy so as to avoid misapplication.

The tissue damage that a misused laser may do depends on the following factors:

- **Class** of the laser
- **Wavelength** of the laser
- **Tissue variability** of the area in contact with a laser beam
- **Spot size** or beam diameter
- **Power**
- **Exposure**, or time duration of beam contact

The following sections describe these factors in more detail.

2.3.1. Laser Classes

Lasers are divided into classes by power according to the degree of safety hazards they present (see Table 2-1).

The AcuPulse is a Class IV laser and is therefore potentially hazardous to both patient and operator.

Table 2-1: Laser Classes

Laser Class	Example	Characteristics
Class I	Grocery store scanner	Class I lasers do not emit levels of optical radiation above the exposure limits for the eye under any circumstances - they are no more harmful than an electric light bulb.
Class II	Laser pointer	Momentary viewing of Class II lasers is not considered dangerous.
Class III	Laser light show	Class III lasers may be hazardous for direct viewing.
Class IV	Most surgical lasers	Class IV includes all lasers that exceed over 0.5 Watt average power over 0.25 seconds or those that exceed 10 J/cm ² . They can cause serious eye and skin injuries and set fire to many materials. Both the direct and reflected beams are hazardous to the eye and skin.

2.3.2. Wavelength and Tissue Variability

Different types of lasers generate different wavelengths of light. When laser energy strikes tissue, the laser wavelength and the target tissue type determine the basic nature of the impact.

Lasers of different wavelengths show different effects on a given type of tissue. Conversely, a laser of a given wavelength affects different types of tissue in different ways. The primary factor is the efficiency with which the tissue absorbs light of the given wavelength.

An example that illustrates this concept is the use of the Argon laser for retinal surgery. The Argon laser is used for retinal surgery because the tissues and fluids in front of the retina do not absorb the Argon laser wavelength, whereas the retina itself does. By comparison, the CO₂ laser wavelength would be totally absorbed by the lens and would damage it before reaching the retina.

The AcuPulse is a CO₂ laser. The CO₂ emits a concentrated beam of light at a wavelength of 10.6 microns, which is in the invisible infrared portion of the electromagnetic spectrum. The effects, and therefore the risks, of the CO₂ laser are primarily thermal.

Light at the CO₂ laser wavelength is efficiently absorbed by water, the primary component of soft tissue. When the laser beam strikes soft tissue, its energy is absorbed by water in the tissue. The water heats up, boils, and vaporizes, taking the surrounding tissue with it. CO₂ laser energy is effectively absorbed by all soft tissue, regardless of the pigmentation.

The effect of the CO₂ laser on tissue is further discussed in the **Clinical Guide** chapters of this manual.

Note that the CO₂ laser beam can also damage bone or teeth, causing pitting, glazing and explosive separation.

2.3.3. *Spot Size, Power and Exposure*

Assuming that the laser wavelength and target tissue are given, the spot size, power, and exposure (including exposure duration) determine the laser's degree of impact.

The operator sets the power in Watts with the laser controls. Note the relationship of spot size and power: at a given power setting, a larger spot size spreads the power out over a larger area. This yields a larger area of impact, but a lesser tissue effect.

The operator controls the exposure with the laser controls. The exposure determines the duration of the applied laser beam. Obviously, the longer the exposure is, the greater the tissue impact will be. The primary exposure control is the footswitch.

The AcuPulse system's modes of operation are based on two distinct types of settings: the laser operation mode and the tissue exposure mode settings. The laser operation modes control the power pattern and the peak power outputs, while the tissue exposure modes control the duration pattern of the laser beam delivered to tissue.

The system offers three laser operation modes and three tissue exposure modes:

<i>Laser Operation Modes</i>	<i>Tissue Exposure Modes</i>
1. Continuous Wave (CW)	1. Continuous
2. SuperPulse	2. Single Pulse
3. Pulser	3. Repeat Pulse

The clinician uses spot size or scan shape & size, power, depth, operation mode and exposure mode to control the interaction of the AcuPulse's laser beam, and its attendant thermal effects, on the patient's tissue. Safe and effective use of the laser in clinical procedures comes with a mix of clinical training, mentoring and experience. A more complete discussion may be found in the **Clinical Guide** chapters of this manual.

2.4. Laser Safety Eyewear

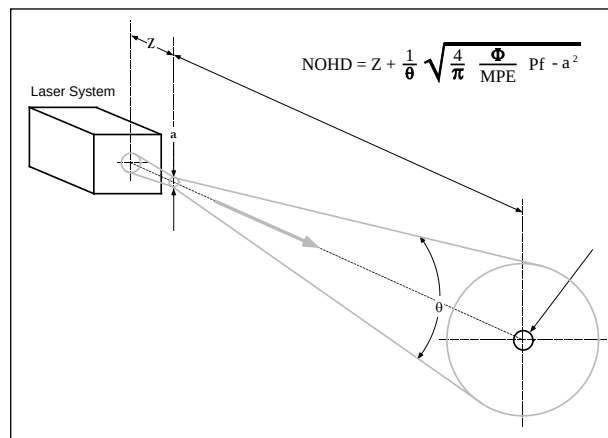
Laser safety eyewear is routinely required with most lasers. When using the laser system, the Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Hazard Zone (NHZ), the Nominal Ocular Hazard Distance (NOHD), and the optical density (OD) for the available laser emission and the configuration of the treatment room (usually within the controlled area). For additional information, refer to ANSI Z136.1-2000, ANSI Z136.3-2005, or European Standard EN 60825.

The following formula was used to calculate the worst case NOHD for the Lumenis AcuPulse laser system used with the articulated arm.

$$\text{NOHD} = Z + \frac{1}{\theta} \sqrt{\frac{4}{\pi} \frac{\Phi}{\text{MPE}} \text{Pf} - a^2}$$

Where:

- Z = the distance of the beam waist from the laser system;
- a = the beam waist diameter (1/e² of axial irradiance for Gaussian beam);
- θ = minimum full angle beam divergence (1/e² of axial irradiance for Gaussian beam);
- e ≈ 2.7182818285, the base of natural logarithms;
- Φ = maximum energy of one laser pulse or maximum CW laser power;
- Pf = the profile correction factor (1 for uniform profile or 2 for Gaussian irradiance);
- MPE = Maximum Permissible Exposure, in energy density units (energy per unit area), or power density units (power per unit area);
- NOHD = the Nominal Ocular Hazard Distance (measured from laser aperture;
= the distance required to reduce the energy density or power density to the MPE.



Using this approach we derive the following values:

$\theta =$	0.00952 rad;
Φ (Maximum Average Power) =	40W;
MPE =	0.1 W/cm ² for CO ₂ laser;
Pf =	2 for Gaussian irradiance;
a =	0.257 cm;
Z =	165 cm;

which results in a worst case NOHD of: **337 meters**.

All personnel within the operating area of the laser must wear eye protection with protection level D LB4, I LB3 for 10600 nm according to EN 207 and with a *minimum* optical density (OD) of **4.0** for 10600 nm according to ANSI Z 136.3.

In addition to providing the required laser safety eyewear, take the following steps to secure the treatment room:

1. To alert personnel before they enter the controlled area, place a warning sign on the outside of the treatment room door when the laser is in use.
2. Close the treatment room door during operation of the laser.
3. External door interlocks that automatically disable the laser when the treatment room door is opened may be installed.



Note

A blocking barrier, screen, or curtain capable of blocking or filtering the laser beam could be placed to create a controlled area inside a large treatment room. The barrier should be made of material that can withstand the power of the treatment beam for the maximum exposure time, relative to the configuration of the controlled area and the treatment parameters for the specific medical application.

2.4.1. Additional Ocular Protection



Warning

- Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.
- Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.
- Use caution when performing procedures around the eyes. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
- Never look directly into any optical lens, scanner, handpiece, probe, laser articulated arm or laser system aperture while the laser is energized. Severe eye or skin damage could occur. Turn off the laser before inspecting any delivery system or laser components.
- Depending on the procedure, the physician must protect the patient's eyes with either laser safety eyewear or one of the following items moistened with a nonflammable solution: thick cloth, eye pads, or gauze 4 x 4's.

2.5. Additional Safety Considerations



Warning

- Scan shape & size or spot size and laser energy are independently controlled. If the user changes to a delivery system with a smaller spot size during a procedure, the user must remember that the energy or power density will increase.
- Incision/excision ideally should be performed with small laser spot sizes and appropriate power/energy densities. At the highest power densities, avoid prolonged exposure to limit depth of incision.
- Plastic instruments such as speculums or eye shields can melt when impacted by the laser beam, possibly resulting in chemical burns or noxious gases. Therefore, use only stainless steel surgical instruments designed specifically for laser use.
- Carbon dioxide light can be reflected off of smooth metallic surfaces, even though they may be blackened.



Caution

- US federal law restricts this device to sale by or on the order of a physician.
- Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.

2.5.1. Skin Hazards

The skin is the second most vulnerable organ of the body. The damage from either direct or reflected laser light is thermal and shows as an erythematous reaction (reddening). The skin may also become dry and itch, or even char.

- **Drapes** – use wet packs or wet drapes and cotton pads thoroughly moistened with sterile saline to protect the patient from adjacent tissue burns.
- **Gloves and Gowns** – the clinician should wear gloves and gowns for added protection from chronic skin exposure.
- **Hair** – wetting the hair during procedures on the face and scalp will not guarantee it will not burn. Surgically drape hair to the maximum extent possible.
- **Accessory Tips** – the tip of the accessory may become hot during lasing and may cause tissue damage to either the clinician or patient on

contact. After lasing has stopped, allow the tip to cool before touching it.

- **Diffuse reflections** – in some cases the patient may be burned by diffuse reflections from instruments and other surfaces. When procedures are performed in the clinic or office, neither doctor nor should patient wear reflective jewelry, such as gold watchbands, rings, or pendants.

2.5.2. *Smoke Evacuation – Laser Plume Pollution Hazards*



Warning

- Laser plume may contain viable tissue particulates.
 - The laser plume obscures the operative field and is noxious to those who come into contact with it. The plume presents a possible biologic and pollution hazard and should be effectively evacuated.
-

Operators are advised to consider the following:

- A commercial smoke evacuator designed for use with surgical lasers may be used; these are usually most effective when the plume is extensive. The vacuum tubing or probe used to evacuate the laser plume should not be used to suction blood or fluids unless it is specifically designed and set up to perform both functions simultaneously.
- Instruments with built-in features to enhance evacuation of the laser plume (such as speculums and laryngoscopes) should be used whenever possible.
- Special in-line vacuum systems designed for evacuation of the laser plume may be installed. Flow capabilities should be adequate to effectively remove the laser plume.
- Repeated suctions of the laser plume into standard hospital wall suction systems without the use of an in-line filter system may eventually clog that system, requiring extensive repair. For minor procedures, wall suction may be used; however, first install an in-line disposable filter.
- The operating surgeon should be wearing a micron-filtered mask during the procedure.

2.5.3. *Airway Precautions*

Use of the laser in the presence of oxygen increases potential fire hazard. When performing a laser procedure, the surgeon and anesthesiologist should carefully consider airway management. Oxygen concentrations should be as low as clinically permissible during airway laser procedures. Anesthetic gases should be least-supportive of combustion.

When choosing endotracheal tubes consider the complications that may result from by-products of tube combustion. Use endotracheal tubes that are least hazardous to the patient. Laser-resistant, cuffed, and flexible stainless steel endotracheal tubes are commercially available. Red rubber or silicone endotracheal tubes with FDA-approved, laser-resistant wrapping can also be used.

The endotracheal tube cuff can be inflated with saline to protect it from inadvertent penetration. The saline can be dyed with methylene blue so that evidence of cuff-penetration by the laser will readily appear on surrounding gauze sponges. The endotracheal tube can be further protected by strategic placement of wet sponges to absorb accidental or stray laser energy. Ensure that the sponges do not dry, as this increases potential fire hazard.

2.5.4. *Protecting Non- Target Tissues*

Non-target tissues may be protected in the following ways:

- Saline soaked gauze sponges, moistened cotton-tipped applicators, or titanium rods may be used as backstops for the laser beam.
- Saline may be used in the abdomen to absorb stray laser energy.
- Specialized instrumentation such as laparoscopes with laser beam backstops and retractors designed to protect nontarget tissues may be used.
- Patients' lips can be protected by moist gauze. When operating in the oral cavity, care should be taken to protect teeth and bone by using wet gauze or other nonflammable, heat-absorbing protective material.
- When anesthesia or pain medication is not used, the comfort and pain tolerance of the patient must be assessed. Unexpected movement by the patient could result in unintended laser exposure to nontarget tissue.



Caution

- To prevent unintended laser discharge, always turn off the laser before connecting a delivery system.
-

**Warning**

- Never discharge the laser without a target to absorb it and without consideration given to what lies behind the target. Place energy-absorbing material behind the target tissue when aiming the laser at an oblique target.
 - Metal instruments used behind the area of treatment, such as tongue depressors or laser backstops, must be anodized or ebonized matte-finished to avoid reflection.
 - Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration, or power application. The lowest energy, repetition rate, exposure duration, and power settings that are effective for the intended application should be used until familiar with the instrument's capabilities. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.
 - Except during actual treatment, the system must always be in **Standby** mode. Maintaining the system in **Standby** mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
 - Only the person directing the laser beam towards the target tissue should have access to the laser footswitch. Use caution pressing the laser footswitch when it is in proximity to footswitches for other equipment. Make sure the footswitch pressed is the correct one to avoid unintended laser exposure.
 - Never place hands or other objects in the path of the laser beam. Severe burns could occur.
 - Dirty optical components degrade laser energy transmission. Cleaning the device optics may eliminate this problem; however, this may also effectively increase the laser energy delivered to the treatment site, causing an unintended tissue effect and possible serious tissue damage. Therefore, it is important that after cleaning the device optics, and prior to surgical use, the surgeon test the system and device to verify the lowest effective settings for the specific procedure. The lowest effective treatment settings should be used until the biological interaction and surgical effect are verified. Settings can then be increased in appropriate increments until the optimum treatment settings are obtained.
 - Backstops exposed to continuous CO₂ laser energy may become excessively hot. Do not allow a hot backstop to touch tissue or any flammable materials. Doing so may cause possible injury or fire.
-

2.6. Fire Hazards

Operating room personnel should be aware of the following safety considerations and potential fire hazards when using a CO₂ laser:

- A CO₂ laser beam can ignite most non-metallic materials.
- Use fire-retardant drapes and gowns.
- A UL or CE approved or equivalent fire extinguisher and water should be readily available.



Warning

- Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, volatile surgical preparation solutions, and similar substances. An explosion or fire could occur.
 - The area around the target site can be protected with wet towels or gauze sponges. If allowed to dry, these protective towels and sponges can increase the potential fire hazard.
 - When procedures are performed in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.
 - Never use oxygen as a purge gas. When used with lasers, combustible gases, such as oxygen, increase the potential fire hazard, and may cause patient injury.
 - Laser treatment of adipose tissue may cause cellular fat to liquefy and accumulate into lipid pools. Pooled lipids are flammable and can be ignited by laser radiation, resulting in fire and potential patient injury.
-

2.7. Electrical Hazards

Because the AcuPulse contains high-voltage components, there is a danger of severe shock if its covers are taken off by other than trained personnel. In addition, the system must be properly grounded during operation. Always use proper cables and do not attempt to use three-prong adapter plugs to defeat the grounding system. The use of extension cables is not recommended.

To guarantee both operator and patient safety, operator service is limited to the items described in the **Maintenance** chapter of this manual. Other service must be performed only by Lumenis trained personnel.



Warning

- Never open the laser console protective covers. Opening the covers will expose personnel to high voltage components, the laser resonator and possible laser radiation. Only Lumenis-certified service technicians are qualified to service the system.
 - To avoid electrical shock, the area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cables are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis' recommendations and institutional standards.
-

2.7.1. Grounding the System

Proper grounding is essential for safe operation. The system is grounded through the grounding conductor in the power cable. To ensure grounding reliability, always plug the power cable into a properly wired hospital grade power receptacle. For potential equalization, use the equipotential terminal on the system's service panel (see Chapter 3).



Warning

Use the system only when it is properly grounded via the ground wire lead in the power cable supplied with the AcuPulse system.

2.8. Operating Safety Cautions & Warnings

2.8.1. Cautions

Fire – keep a bottle of sterile saline and a fire extinguisher in the same room where a laser procedure is being performed.

Training – do not use the AcuPulse in clinical, office or surgical procedures unless you have been trained:

- In general laser safety, including operator and patient protection.
- By a qualified mentor in hands-on situations.
- On the AcuPulse system.

Before Performing Procedures – read this manual before performing any patient procedures. The information in this manual should be used in conjunction with, not as a substitute for, formal training.

Power Settings – Lumenis suggests that you begin new or unfamiliar procedures at the lowest recommended power settings and gradually increase the setting until you see the desired effect.

Accessory Cleaning –

- To avoid losing efficiency of any non-electronic accessory, always rinse thoroughly after cleaning and dry thoroughly before use.
- Disassemble and clean the accessories over a white cloth so that small dropped parts are easier to find.

Handpiece Sterilization –

- After sterilization, handpieces with internal mirrors must be completely dry before use.
- If a liquid or steam sterilant is used, make sure that all parts in the laser beam path are completely dry before use.

Smoke Evacuation – always evacuate smoke. If the smoke evacuator on the system you are using shuts off during the procedure, use another smoke evacuator.

Console Cleaning – when cleaning the console, use a dampened cloth. Avoid saturating the exterior panel areas and electrical input area.

Static-Sensitive Components – electronic components in laser systems may be sensitive to damage. Use proper grounding techniques.

Warranty Void – internal maintenance by unqualified service technicians may cause system damage. This damage is not covered under warranty.

2.8.2. Warnings

CO₂ Laser – the AcuPulse system contains a Class IV, CO₂ laser which produces an invisible beam of high energy infrared radiation. Improper use could result in serious personal injury. Observe all safety precautions for Class IV devices.

To Avoid Injury or Fire – observe all warning and other labels on the equipment. Failure to do so could result in injury or fire.

Inadvertent Lasing – when not actively lasing, set the system to **Standby** mode.

Backstop Lasing – avoid lasing on the backstop.

Accessory Sterilization – sterilize accessories before each use.

Sterility – wear sterile gloves and use aseptic technique when handling the accessories in order to maintain their sterility.

Infection Control – with all accessories, always use good infection control practices, including barrier products and sterile components when appropriate.

Risk of Embolism –

- During intrauterine laser surgery, do not use air for purging the laser accessory or for insufflation. This may cause a life-threatening air embolism.
- Pressurized purge air exits accessory aperture tip during lasing. To reduce the risk of an air embolism, do not bring the aperture into contact with a blood vessel or vascular tissue.

Laser Emission – in **Ready** mode laser light will be emitted through the laser aperture when the footswitch is pressed.

Handling of Compressed Gas Tanks – for safe gas tank handling:

- Gas tank must be secured in position prior to use.
- Review proper procedures for handling compressed gasses before assembling yoke or CGA valve to tank. Check with your Biomedical Engineer if you are unfamiliar with this procedure.

2.9. System Safety Features

The AcuPulse is equipped with various built-in safety features to provide maximum protection for both clinician and patient. Before using the system for the first time, become familiar with these features and how they operate.

2.9.1. Password Protection

Entry to the system's surgical operating program is protected by a password assigned to each user of the system (see Chapter 5). If the password is not keyed in, the operating system is not accessible and laser beam emission will not be available.

2.9.2. Self Testing at Start Up

When the AcuPulse is turned on, the system computer automatically executes system self-testing. Self-testing checks the following:

- Ability of the system to generate lasing power
- Functionality of the computer systems
- Safety monitoring circuits

If the self-test is successfully completed, the system enters **Standby** mode. The test circuits continuously monitor the operation of the system during treatment.

2.9.3. Safety Shutter

The automatic safety shutter blocks the laser beam to prevent accidental lasing.

The automatic shutter is opened when the footswitch is pressed. When the footswitch is released, the shutter closes. Lasing typically stops within 1/10th of a second.

2.9.4. Door Interlock Connector

The door interlock connector plug must be inserted into the proper receptacle on the system's service panel in order for the laser to operate. It can be wired to an external switch to disable the laser if the treatment room doors are opened during treatment.

2.9.5. Safety Interlocks and Failsafes

2.9.5.1. Dual-Footswitch Microswitch

The footswitch incorporates a dual-microswitch safety mechanism, which requires the pedal to be firmly pressed – operating both microswitches – in order to generate laser beam emission. If the footswitch is pressed too lightly, it will not operate.

- 2.9.5.2. Laser Stop Button** This red knob is designed for emergency shutdown. When pressed it immediately disables the laser and switches the system to **Standby** mode.
- To release the emergency shut-off button, turn it clockwise in the direction of the arrows. Once released, the system must be turned off and back on to restart.
- 2.9.5.3. Shutter Position Failsafe** The AcuPulse incorporates optoelectronic detectors which monitor the opening and closing of the automatic shutter. This monitoring helps to ensure that shutter failure is recognized. If the shutter does not close within ½ second after releasing the footswitch, or open when pressing the footswitch, lasing is disabled.
- 2.9.5.4. Power Measurement Failsafe** The AcuPulse compares lasing power as read by the internal power meter to an internal table of anticipated electrical input power. If there is a significant discrepancy, an appropriate error message is displayed.
- 2.9.6. Safety Timer** The safety timer resets the system from **Ready** to **Standby** mode if the system is left idle in **Ready** mode for more than a user-defined time limit, to prevent unintentional activation of the laser with the footswitch.
- 2.9.7. Continuous Internal System Monitoring** The system's computer continually monitors internal system status. The following are among the items monitored:
- 2.9.7.1. System Faults** If a fault is detected an appropriate error message is displayed on the LCD monitor. If the error is non-recoverable lasing is disabled until the fault is corrected. If the error is recoverable, follow instructions on the screen. A complete discussion of system faults may be found in the **Troubleshooting** chapter of this manual.
- 2.9.7.2. Internal Power Monitoring** To prevent accidental delivery of excessive energy to tissue, laser energy is monitored continuously. An appropriate error message is displayed on the LCD monitor if a $\pm 20\%$ deviation in the laser output is detected, the system returns to **Standby** mode and you may try power convergence to the same level or a different one.
- 2.9.7.3. Temperature** If the system begins to overheat, an appropriate error message will be displayed on the LCD monitor (refer to the **Troubleshooting** chapter of this manual).

2.9.8. *Laser Beam Emission Indicators*

The system features two laser emission indicators: a yellow LED located on the top of the control console and a speaker.

The yellow LED has three modes of operation:

- **Off** - When the system is turned on, and in **Standby** mode.
- **Flashing** - In **Ready** mode, alerting the user that laser emission will start upon footswitch activation.
- **Continuous** - During laser emission (footswitch pressed or during power convergence).

The speaker sounds during laser emission.

2.10. *Compliance with International Standards*

Refer to the Lumenis website (www.Lumenis.com) to view a complete list of international regulatory standards that the AcuPulse system is designed to comply with.

In compliance with these standards, the system is equipped with:

- Laser emission indicators
- Beam shutter
- Power display
- Emergency shut-off button
- Door interlock connector
- Proper labeling

In accordance with the regulations, a recommended routine inspection and maintenance schedule is provided in the **Maintenance** chapter of this manual.

2.11. *Warning, Certification and Identification Labels*

Figure 2-2 displays the labels affixed to the system:

1. **Identification and Certification** – The label is located on the system's rear panel and contains the following information:
 - Manufacturer's and/or distributor's details.
 - Assures that the system complies with U.S. Federal Performance Standards.
 - System's model name and part number.
 - Serial number and date of manufacture.
 - The system's electrical requirements.
 - Degree and type of protection against electric shock.
 -  – Follow instructions for use.
 - CE marking.
 - CSA – compliance symbol.
 - WEEE symbol – directs that the electrical/electronic product be disposed of in an environmentally safe way as the directive sets collection, recycling and recovery targets for all types of electrical goods.
 - Location of US patents on file for the AcuPulse system.
2. **Laser Emission Danger** – warns against possible exposure to laser beam radiation and specifies the type and classification of laser beams present. The label is located on the system's rear panel.
3. **Non-Interlocked Warning Label** – warns against and about:
 - Risk of explosion if used in the presence of flammable anesthetics.
 - Possible electrical shock when covers are removed.
 - Proper electrical grounding of the system.
4. **Laser Aperture** – indicates laser beam exit location, located at the articulated arm's endjoint.
5. **Articulated Arm Release** – advisory to release the articulated arm from its storage without damage.
6. **Federal Law Restriction** – USA federal law restricts this device to sale by or on the order of a physician.
7. **EPUP** – **E**nvironmental **P**rotection **U**se **P**eriod: indicates the number of years before any substance is likely to leak out into the environment.



Lumenis Ltd.
Yokneam Industrial Park
Hakidma 6, 2069204,
ISRAEL
Tel: +972 (0) 4959-9000

Lumenis (Germany) GmbH
Heinrich-Hertz-Str 3 D-63303
Dreieich-Dreieichenhain
GERMANY
Tel: +49 (0) 6103 8335 0

EC

REP

AcuPulse

Made in Israel

MODEL - P/N

MANUFACTURED

MONTH YEAR

SYS. S/N

SERIES

This Product Complies with Federal Performance Standards 21 CFR 1040.10 and 1040.11 for Class IV Laser Products

This device complies with Part 18 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

POWER: 100-240V~/50-60HZ/9A








Patents: <http://www.lumenis.com/product-labels>

LB-1024812_B



LASER CLASS 4/IV
CO₂: 10.6µm, 60W Max, CW
Max Pulse Width: 290 µs
Max Pulse Energy: 30mJ

LASER CLASS 3R/IIIa
Diode Laser: 635nm, 5mW Max, CW

**VISIBLE AND INVISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO
DIRECT OR SCATTERED RADIATION**

CLASS 4 LASER PRODUCT per EN 60825-1/2007
CLASS IV LASER PRODUCT per 21 CFR 1040.10 & 1040.11
except for deviations pursuant to Notice 50, Dated June 24, 2007
LB-1043342

DANGER

RISK OF EXPLOSION
IF USED IN THE PRESENCE
OF FLAMMABLE ANESTHETICS.

CAUTION

TO REDUCE RISK OF ELECTRICAL
SHOCK, DO NOT REMOVE COVERS.
REFER SERVICING TO QUALIFIED
SERVICE PERSONNEL.

CAUTION

GROUNDING RELIABILITY CAN ONLY
BE ACHIEVED WHEN THIS MACHINE
IS CONNECTED TO AN EQUIVALENT
RECEPTACLE MARKED "HOSPITAL GRADE"

LB-1024840 Rev_0

LASER APERTURE

PL2877000_B

ATTENTION

RELEASE THE ARTICULATED ARM FROM
ITS COMPARTMENT ONLY BY PULLING
THE TAB ATTACHED TO THE ARM.

PULLING THE ENDJOINT MAY RESULT IN
MISALIGNMENT OF THE OPTICAL SYSTEM.

LB-1024850

CAUTION

In the US, Federal law restricts this device
to sale by or on the order of a physician,
dentist, veterinarian, or any other practitioner
licensed by the law of the state in which he
practices to use or order the use of the device.

AX0000012_B



LB-1012140

Figure 2-2: System Labels

2-22

UM-1091300, Rev. F

Chapter 3

System Installation

3.1. Introduction

When the AcuPulse system is purchased, complete on-site installation, including initial system testing and calibration, is included.

System transportation and installation is carried out by Lumenis authorized personnel, who do the following:

- Unpack the system and position it in its pre-selected location.
- Verify the integrity of the system and its components.
- Plug the system into a designated electrical outlet.
- Test the system for proper calibration and functional operation of all components and software.
- Coordinate the performance of an on-site safety inspection, if required.



Note

In Canada this instrument must be installed and operated according to CAN/CSA-Z386-08: Laser Safety in Health Care Facilities.

3.2. Unpacking the System

The AcuPulse system is shipped in a shockproof container. Contents may vary according to the purchase agreement with Lumenis, but the parts and accessories generally shipped in the container are:

- AcuPulse system console
- Safety eyewear
- Footswitch
- System accessories¹
- Bacteriological filter
- Door interlock connector plug (installed)
- Laser danger sign(s)
- Operator's manual
- Instructional material

¹ According to purchase agreement

To unpack the AcuPulse, carefully remove all components from the shipping container. Set the console down on its base. Save all packaging materials in case repacking and shipping becomes necessary at a later date.

3.3. Facility Requirements

Before unpacking the system, ensure that the site meets the requirements described in the following sections.

3.3.1. Space and Positioning Requirements

Space should be allocated with adequate ventilation and free air flow. The working area for the system should be prepared according to the dimensions shown in Figure 3-1. In order to guarantee proper ventilation, and easy accessibility to the power circuit breaker, always keep the sides of the system at least 0.5 m (20") from the wall or from other obstructions to air flow. After positioning the system, **lock the wheels' brakes** by pressing the pedals on top the four wheels.



Figure 3-1: Physical Dimensions

3.3.2. *Electrical Requirements*

The system is equipped with a universal power supply module. Accordingly, the system will require a separate line supply of:

- 100-240 VAC, 9A, 50/60 Hz, single phase

Input power lines should be free of transients, voltage and current spikes, sags and surges. Consequently, the system power line should not be shared with other heavy variable loads such as elevators, air conditioning systems, large motors, etc.

It is strongly recommended that the system be connected to a separate power line with separate circuit breakers. Lumenis cannot guarantee adequate performance unless the system is connected to a dedicated circuit.

3.3.3. *Environmental Requirements*

Air Quality:

The system should operate in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components and the surfaces of optical components.

Air-borne dust particles should be kept to a minimum. Dust particles absorb light and heat up. Hot particles located on the optical lenses can damage them. Metallic dust is destructive to electrical equipment.

Temperature:

To ensure that the system performs optimally, it is recommended to maintain ambient room temperature between 5°C and 30°C (41°F - 86°F) and relative humidity of 5-85% non-condensing. When the system is used intensively it will emit heat. Therefore, it is recommended that the treatment room be air-conditioned.

3.4. *Installation and Setup*

The system has passed full quality assurance testing before shipment and should be operational upon delivery.



Note

Any damage to the packaging or to the system found prior to opening the packaging, or during unpacking and installation of the system, should be immediately reported to your Lumenis distributor and to the insurance carrier.

On-site system installation and initial setup should be carried out only by Lumenis-authorized personnel.

The assembled AcuPulse laser system is shown in Figure 3-2.

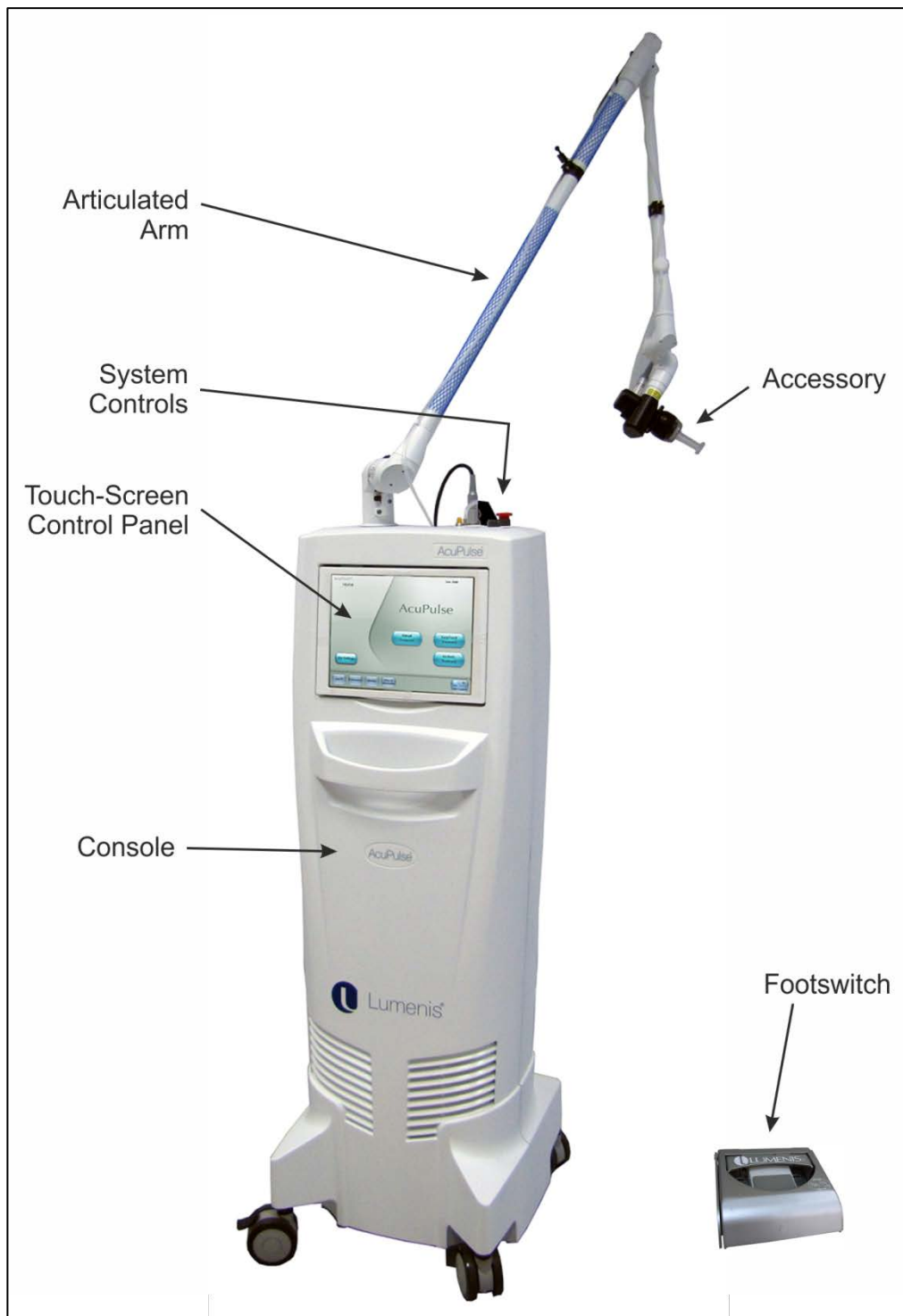


Figure 3-2: Assembled AcuPulse Laser System

3.4.1. Articulated Arm Setup

Refer to Figure 3-3:

1. Release the articulated arm endpoint from its clip in the articulated arm compartment (A).
2. Release the longer arm section from its clip **only** by pulling the tab attached to the arm (B); release the arm from its compartment.



Caution

Pulling the endpoint or the shorter arm section to release the arm from its compartment may result in misalignment of the optical system.

3. Raise the longer arm section until the arm locking pin on the main bearing is engaged (you will hear and feel a 'click').
4. Rotate the articulated arm 180° around the main bearing axis.
5. Disengage the tab and clip to release the short section of the arm from the long section.

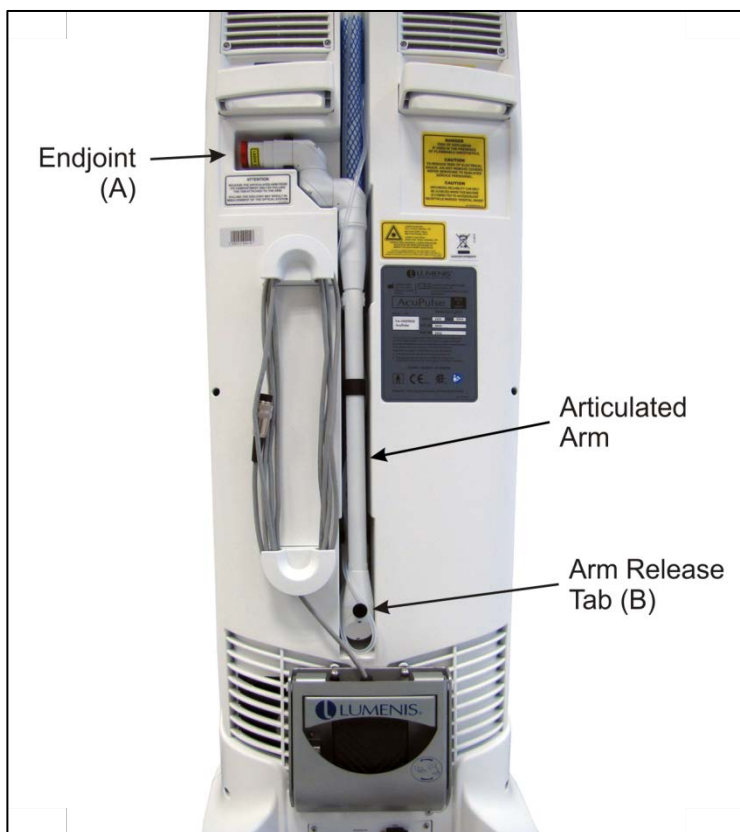


Figure 3-3: Release the Articulated Arm

3.4.2. Bacteriological Filter Installation

A dedicated unidirectional bacteriological filter is supplied with the AcuPulse system to provide clean compressed air at the surgical accessory.

The filter is equipped with a short flexible tube on its outlet for connection to the nipple on the laser surgical accessory in use. The inlet (free end) of the filter should be connected to the delivery nipple of the compressed air supply on the system's control panel. Then the filter should be clipped onto the last arm section, as close as possible to the endpoint. The compressed air flow through the bacteriological filter should be inspected prior to each use and replaced when insufficient flow is detected.

3.4.3. Service Panel Connections

The service panel is located on the lower section of the system's rear panel and incorporates the following (see Figure 3-4):

1. Power cable connection port.
2. Power circuit breaker.
3. Footswitch connection port.
4. External equipotential connection port.
5. Smoke evacuator connection port.
6. Door interlock connection port.
7. USB connection ports.
8. LAN connection port.
9. Remote control connection port (future option).
10. VGA monitor port.

Refer to Chapter 4 for a complete discussion of these elements.

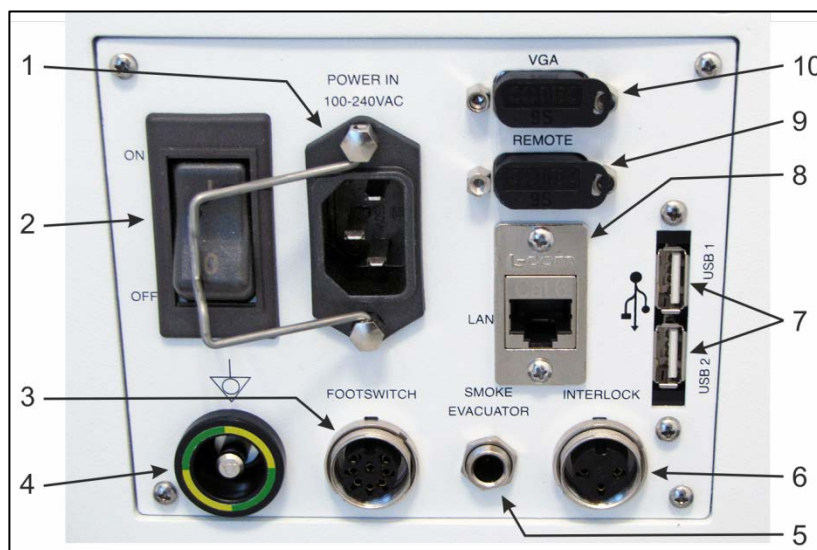


Figure 3-4: Service Panel

3.5. Initial System Testing

Prior to clinical use, test out the AcuPulse system to verify that the system, including its built-in safety features, is operational.

Read the entire operating manual before turning on the system. Of particular importance is Chapter 2 – **Laser Safety**.

Before beginning system test, make sure that the laser operating area is safe and secure. As when performing any laser procedure, flammable materials should be moistened or beyond contact of the laser beam. All personnel should wear protective goggles or glasses.

The required test includes the following procedures, which should be performed in the order indicated:

1. **System Startup** – see Section 3.5.3
2. **Door Interlock Check** – see Section 3.5.4
3. **Footswitch Interlock Check** – see Section 3.5.5

If at any point during the test the system does not perform as described, discontinue use and contact Lumenis Service.

3.5.1. System Controls

Before beginning the initial system test, familiarize yourself with the system controls described below. Use of the controls is described fully in the **Operating Instructions** chapter of this manual.

3.5.2. Main Control Panel

The main control panel is located at the top of the console and incorporates system controls and the touch-screen LCD panel.

Refer to Figure 3-5: For initial system testing it is important to know the locations of the **On/Off** switch, the **Emergency Stop** button and the **Laser Emission** indicator.

3.5.3. System Start Up

1. Turn the system's power circuit breaker – located on the service panel (see Figure 3-4) – to the **On** position.
2. Make sure that the emergency stop button is not engaged (pressed down). If it is, turn it clockwise until it releases and pops up.
3. Press the **On/Off** switch; the system will turn on, the software will initialize and the LCD panel will display a splash screen.
4. The system will perform a series of internal power-up routines. When these have completed satisfactorily, the **Login** screen will appear on the LCD (see Chapter 5).

5. If the system does not perform as described, discontinue use and contact Lumenis Service. If the system performs as described, complete the login and continue on to the footswitch check (see Section 3.5.5).

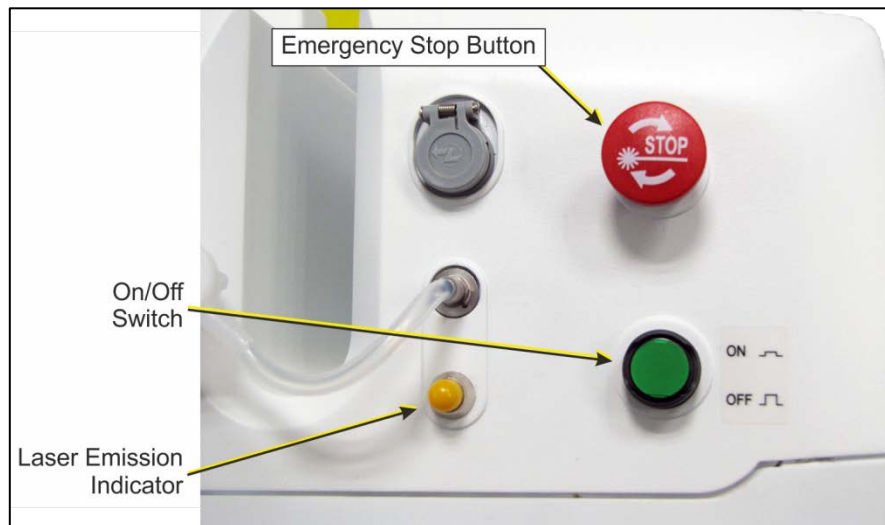


Figure 3-5: Control Panel

3.5.4. Door Interlock Check

Laser beam emission is disabled when the door interlock plug is not connected or is improperly connected to the service panel, even if it is not wired to an actual door interlock. To check this:

1. Set the system to **Ready** mode.
2. Unplug the door interlock plug; the system should display the following error message: **Remote Interlock error. Please verify treatment room door is closed.**
3. If the system does not display the error message and remains in **Ready** mode, discontinue use and contact Lumenis Service.

3.5.5. Footswitch Connection Check

Laser beam emission is disabled when the footswitch is not connected or is improperly connected. To check this:

1. Set the system to **Ready** mode.
2. Unplug the footswitch; the system should display the following error message: **Footswitch is not connected. Please connect.**
3. If the system does not display the error message and remains in **Ready** mode, discontinue use and contact Lumenis Service.

3.5.6. *Laser Stop Button Check*

The Laser Stop button is designed to disable laser emission when pressed. To check this button:

1. While the system is on and the main **Treatment** screen is displayed, press down on the laser stop button; the system should display the following error message: **Laser stop button engaged. Please disengage to proceed.**
2. To resume operation, turn the button clockwise until it pops up; the system will return to **Standby** mode.
3. Touch the **Ready** key to enable lasing.

3.6. *Moving, Transporting and Storage*

3.6.1. *Moving the System within the Facility*

Most users of the AcuPulse laser system have more than one operating location. The system can easily be moved between them by rolling the console on the base-mounted wheels using the top-mounted maneuvering handle. The only disassembly required is disconnection of the footswitch and power cable to ease maneuvering.

Rather than disconnecting them for each move, it may be easier to install a power cable and footswitch in each location, leaving them in place.

3.6.2. *Transporting the System*

Prepare the system for transport as follows:

1. Unplug the system from the wall outlet.
2. Disconnect any accessory connected to the articulated arm.
3. Coil the power cable around the cable hangers on the rear panel.
4. Disconnect the footswitch from the service panel.
5. Fold and store the articulated arm in its storage compartment in the system's rear panel.
6. Consult your Lumenis representative for shipping advice if desired.

Caution

Do not ship the system without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Contact Lumenis if packaging materials or repacking instructions are required.



Warning

The AcuPulse console weighs approximately 50 Kg (110 Lbs). Use proper lifting techniques. Do not hurt yourself!

Chapter 4

System Description

4.1. General Laser Theory

LASER is the acronym for **L**ight **A**mplification by **S**timulated **E**mission of **R**adiation. The laser is a device consisting of an active medium and a pumping source, enclosed in a pump cavity. The pumping source "pumps" the active medium from its ground energy state to excited states. If "population inversion" between two excited states takes place (where the higher energy state is more populated) stimulated emission of radiation (photons) can occur. This emission is resonated (reflected back and forth) within the optical resonator and is amplified. A portion of this amplified electromagnetic radiation is then emitted as a laser beam.

The main properties of the beam are:

- **Monochromaticity** – the radiation is within an extremely narrow wavelength range on the spectrum
- **High degree of collimation** – unidirectional beam with very small divergence
- **Coherence** – all photons are in phase, both in space and time

The high degree of collimation and coherence enable the focusing of the beam to small spot sizes.

The active (lasing) medium of a laser can be either gas, liquid or solid. Most gas lasers consist of atoms, molecules, or mixtures of both. Solid-state lasers consist of atoms or ions "doped" in some solid matrix. Liquid lasers consist of higher molecular weight molecules dissolved in liquids.

Under specific pumping conditions, all these materials can undergo the unnatural phenomenon of "population inversion" that results in stimulated emission of radiation at a wavelength characteristic of the active medium.

4.2. CO₂ Laser Theory

This system incorporates a DC-excited CO₂ laser tube. The gas used is enclosed within a glass laser tube equipped with electrodes. The laser tube is positioned between the two mirrors of the optical cavity. The rear mirror is totally reflective, whereas the front mirror is partially reflective and transmits the CO₂ laser beam into the delivery system.

The direct current power supply (pumping source) provides voltage to the electrodes which produce an electrical discharge perpendicular to the tube. The discharged electrons collide with the CO₂ molecules in the gas mixture, and excite them to a vibrationally excited level (an asymmetric stretching mode).

The stimulated emission takes place between this level and a lower vibrationally excited level (a symmetric stretching mode), resulting in laser emission in the far infrared range at a wavelength of 10.6 microns.

The CO₂ laser wavelength falls in the mid-infrared region of the electromagnetic spectrum. This wavelength is invisible to the human eye.

CO₂ laser energy is readily absorbed by water in tissue. Since soft tissue is comprised primarily of water, CO₂ laser energy can be used effectively for the excision, incision, ablation, vaporization and coagulation of soft tissue.

4.3. *AcuPulse Laser System*

The AcuPulse is an advanced computer-controlled, user friendly CO₂ laser system based on a sealed-off CO₂ laser tube providing up to 30 or 40 Watts (model dependent) on tissue. The system incorporates the CO₂ laser tube within the main cabinet, an articulated arm beam delivery system and attachable laser accessories. The system is activated for laser emission by a footswitch.

4.4. *System Description*

The AcuPulse laser system is composed of the following units:

- **Control Panel** – situated on top of the system's console, incorporating:
 - ✓ System controls
 - ✓ A liquid crystal display (LCD) with touch-screen technology.
- **Electronic and Software Systems** – control, display, and monitor the system; the GUI computer:
 - ✓ Translates GUI commands to signals and controls.
 - ✓ Controls the interface module's operation.
 - ✓ Incorporates the operating system and runs the self-test routine.
 - ✓ Monitors and regulates laser output power.
 - ✓ Automatically tests the system, monitors its performance, and indicates specific malfunctions.
 - ✓ Automatically shuts off the laser during unsafe operating conditions.
 - ✓ Acts on commands from the control panel and updates the display.
- **Interface Module** – that serves as in interface between the system's main computer and modules.
- **Low Voltage Power Supply** – provides modulated power low DC voltage, and DC voltage to the HVPS.
- **High Voltage Power Supply** – converts low DC voltage to high DC voltage for laser generation.

- **DC Excited CO₂ Laser Tube** – creates the laser beam. The laser is a sealed-off, DC excited, free-space CO₂ laser. The system generates a narrow, concentrated beam of invisible infrared light of a 10.6 micron wavelength.
- **Optical Bench Assembly** – the optical bench transmits the laser energy from the output of the laser tube to the treatment site. Inside the console the beam is directed by folding mirrors past an automatic shutter. The beam delivery articulated arm is mounted on top of the console.
- **Power Meter** – the system's internal power meter samples the laser power during the power convergence, after the user selects the desired power and enters **Ready** mode.
- **Purge Air Pump** – the system console contains a built-in air pump which provides purge air flow, through a bacteriological filter, to blow away smoke. The air flow is automatic during lasing, and it continues for a user-defined number of seconds after lasing stops.

Figure 4-1 presents a description of the AcuPulse laser system

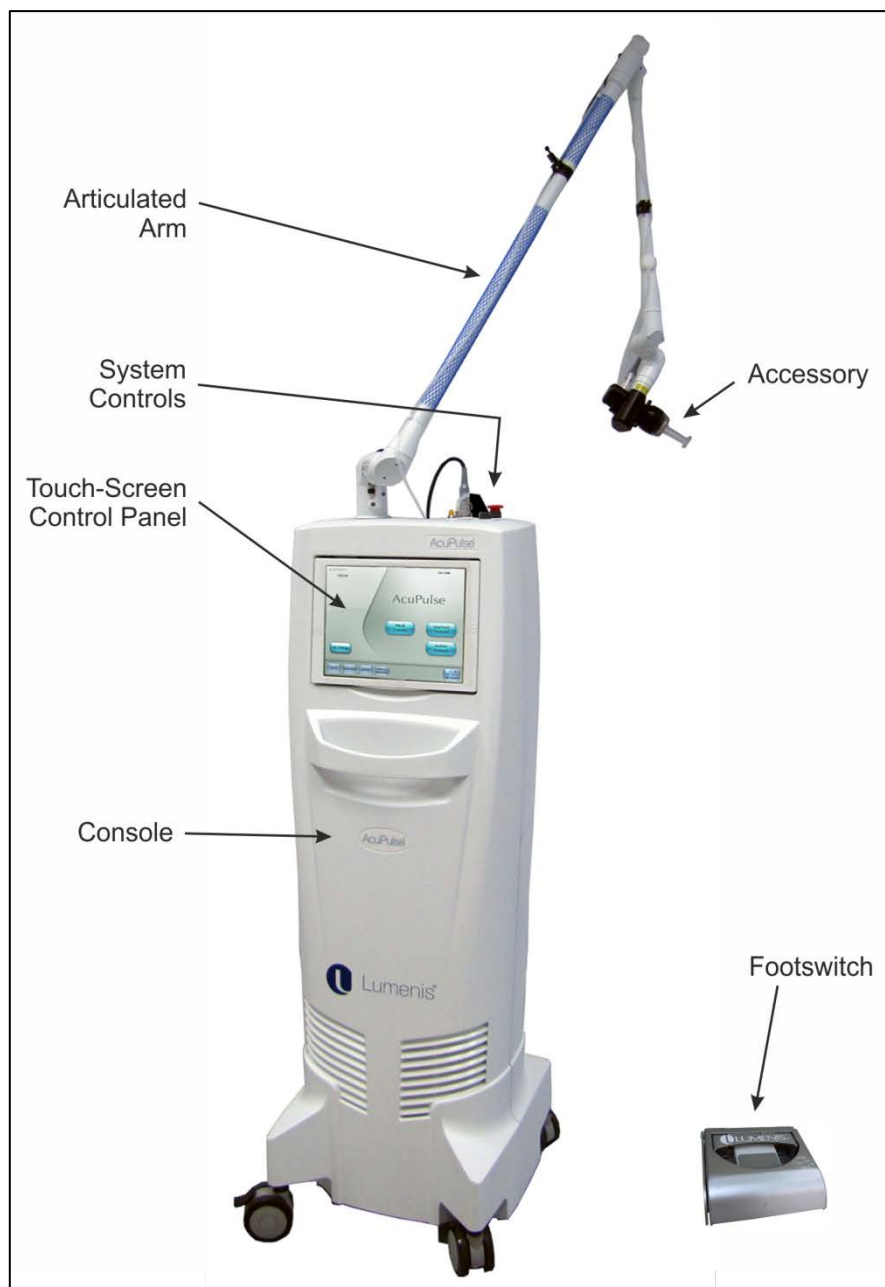


Figure 4-1: AcuPulse System Description

4.4.1. Control Panel

The AcuPulse control panel, located on top of the system console, incorporates the following elements (refer to the numbered items in Figure 4-2):

1. **On/Off Switch** – a push-button switch that initiates the system's functions. A green LED indicator built into the button indicates that the system is on.
2. **Laser Stop Button** – a two-position, normally released, push-type button for emergency shutdown of laser emission. The button actuator is a large, red mushroom-shaped knob that is operated by pressing down. To release the switch to its normal position, rotate the knob (direction is marked on the knob's face).



Caution

The laser stop button should be activated **only** in case of an emergency.



Figure 4-2: Control Panel

3. **Laser Emission Indicator** – the yellow LED has three modes of operation:
 - ✓ **Off** – when the system is turned on, and in **Standby** mode
 - ✓ **Flashing** – in **Ready** mode, alerting the user that laser emission will start upon footswitch activation
 - ✓ **Continuous** – during laser emission (footswitch pressed or during power convergence)

4. **Flashscanner Connection Port** – this is the connection point for the communications cable of the SurgiTouch flashscanner or AcuScan120 microscanner.
5. **Purge Air Tube Connection Barb** – this is the connection point for the purge air tube.
6. **LCD Touch-Screen Panel** – communication with the system is performed by means of the touch-screen panel. All commands are inserted into the system by "pressing" the appropriate "buttons", or keys, on the LCD. Figure 4-3 presents a sample control screen; all aspects of the operating system will be discussed in the **Operating Instructions** chapter of this manual.



Figure 4-3: AcuPulse Treatment Screen (sample)

4.4.2. Optical Bench Assembly

The optical bench assembly is comprised of the sealed-off laser tube and its optical resonator, the CO₂ laser shutter assembly, the power meter, the aiming beam assembly and the CO₂ and aiming beam combiner.

The aiming beam is a low-powered diode laser with an adjustable intensity control. It can also be configured to illuminate constantly or blinking.

The beam combiner combines the CO₂ laser beam and the aiming beam coaxially, and guides them into the articulated arm beam delivery system.

4.4.3. Cooling System

The CO₂ laser tube and the laser power meter are cooled by an internal closed-loop liquid-to-air cooling system. The coolant used is Fluorinert FC-770, an inert liquid that does not conduct electricity.

The coolant is circulated in the system by means of an electric pump, absorbing heat from the CO₂ laser tube and from the power meter. The heat is expelled through a finned tube heat exchanger.

In addition to the coolant circulation system, a forced-air fan circulates air through the system's console.

4.4.4. Service Panel

The service panel is located on the bottom of the system's rear panel. The panel incorporates controls and connection ports for the following (see Figure 4-4):



Figure 4-4: Service Panel

4.4.4.1. Potential Equalization

For potential equalization use the equipotential terminal on the system's service panel (lower-left terminal in Figure 4-4).



Note

Using the equipotential terminal is recommended whenever it is required to make the system equipotential with other systems operating in the same environment.

4.4.4.2. <i>Footswitch Connection</i>	To connect the footswitch, place it on the floor and plug its power cable into the footswitch connection located in the panel. Screw the cable's threaded cap onto the connection terminal securely. A polarizer on the socket prevents incorrect connection of the cable (see item # 3 in Figure 4-4).
4.4.4.3. <i>Door Interlock Connection</i>	The door interlock connection is a safety feature that disables the laser if the treatment room doors are opened or the interlock plug is removed while the laser is in Ready mode (see item # 6 in Figure 4-4). Use of a door interlock connection is optional; however, you must insert the interlock plug into the service panel receptacle whether or not you are using a door interlock connection. The laser remains inoperative until the plug is inserted into the receptacle. When a door interlock connection is in use, the laser is automatically disabled and returns to Standby mode if the treatment door is opened or the interlock plug is removed, and an error message displays on the control panel screen. To resume treatment, close the treatment room door or reinsert the interlock plug, and press Ready to resume normal treatment.
4.4.4.4. <i>Smoke Evacuator Connection</i>	A portable smoke evacuation system may be connected to the system at this port (see item # 5 in Figure 4-4).
4.4.4.5. <i>Power Circuit Breaker</i>	The power circuit breaker should be turned off when the system is left unused for extended periods of time (see item # 2 in Figure 4-4).
4.4.4.6. <i>Power Cable Connection</i>	Connect the power cable to this port (see item # 1 in Figure 4-4). Use only: • The power cable and plug specified for your system • A power cable and plug that are in good condition • A hospital grade plug and a correctly matched power receptacle
4.4.4.7. <i>USB Connections</i>	The USB connection ports are normally utilized by Lumenis-authorized service engineers for servicing the system and for uploading periodical software upgrades (see item # 7 in Figure 4-4).
4.4.4.8. <i>VGA Monitor Connection</i>	An external VGA monitor may be connected to the system (see item # 10 in Figure 4-4).

4.5. *Understanding Laser Delivery*

The AcuPulse delivers three basic modes of laser energy: **CW**, **Pulser** and **SuperPulse**:

- **CW Mode** is optimal for incision or ablation where hemostasis is desirable. CW is a continuous delivery of lasing energy with peak power as set. CW mode delivers a steady beam of laser energy useful for cutting. Because the pulses of energy are continuous, just enough energy is transferred to surrounding tissue to provide hemostasis, while at the same time providing a clean incision with optimal penetration.
- **Pulser Mode** high-frequency delivers pulses in a constant preset pulse frequency. The average power requested and delivered to tissue is controlled by the microprocessor by varying the **On** time.
- **SuperPulse Mode** is optimal for incision or ablation where char-free performance is desirable. This includes many dermal applications. SuperPulse is a continuous series of short duration, high peak power pulses whose average power is the set power. Because of its very high peak power, SuperPulse laser energy brings the water in the cells to the boiling point so rapidly that the target tissue vaporizes and only a negligible amount of heat is transferred (by conduction) to adjacent tissue.

The time between each SuperPulse of high energy is long enough that the surrounding tissue has time to cool before being hit with the next SuperPulse. Because of this, SuperPulse helps reduce charring and minimizes surrounding tissue damage.

Tissue incision capability is generally enhanced with higher peak power of the laser beam. Thermal damage to surrounding tissue is usually reduced with shorter laser activation durations, whereby the adjacent healthy tissue has more time to cool between pulses.

The three laser power modes can also be characterized as:

- **CW** – higher thermal energy is transferred to surrounding tissue.
- **Pulser** – medium thermal energy is transferred to surrounding tissue.
- **SuperPulse** – lower thermal energy is transferred to surrounding tissue.
- Refer to Figure 4-5 through Figure 4-7 for CW, Pulser and SuperPulse power delivery comparisons.

4.5.1. Exposure Types

Both CW and SuperPulse can be set to deliver any of three different exposure types:

- In **Continuous** exposure, lasing lasts as long as the footswitch is pressed.
- In **Single** exposure, one timed exposure is delivered for each press of the footswitch.
- In **Repeat** exposure, the laser beam cycles between On and Off while the footswitch is pressed.

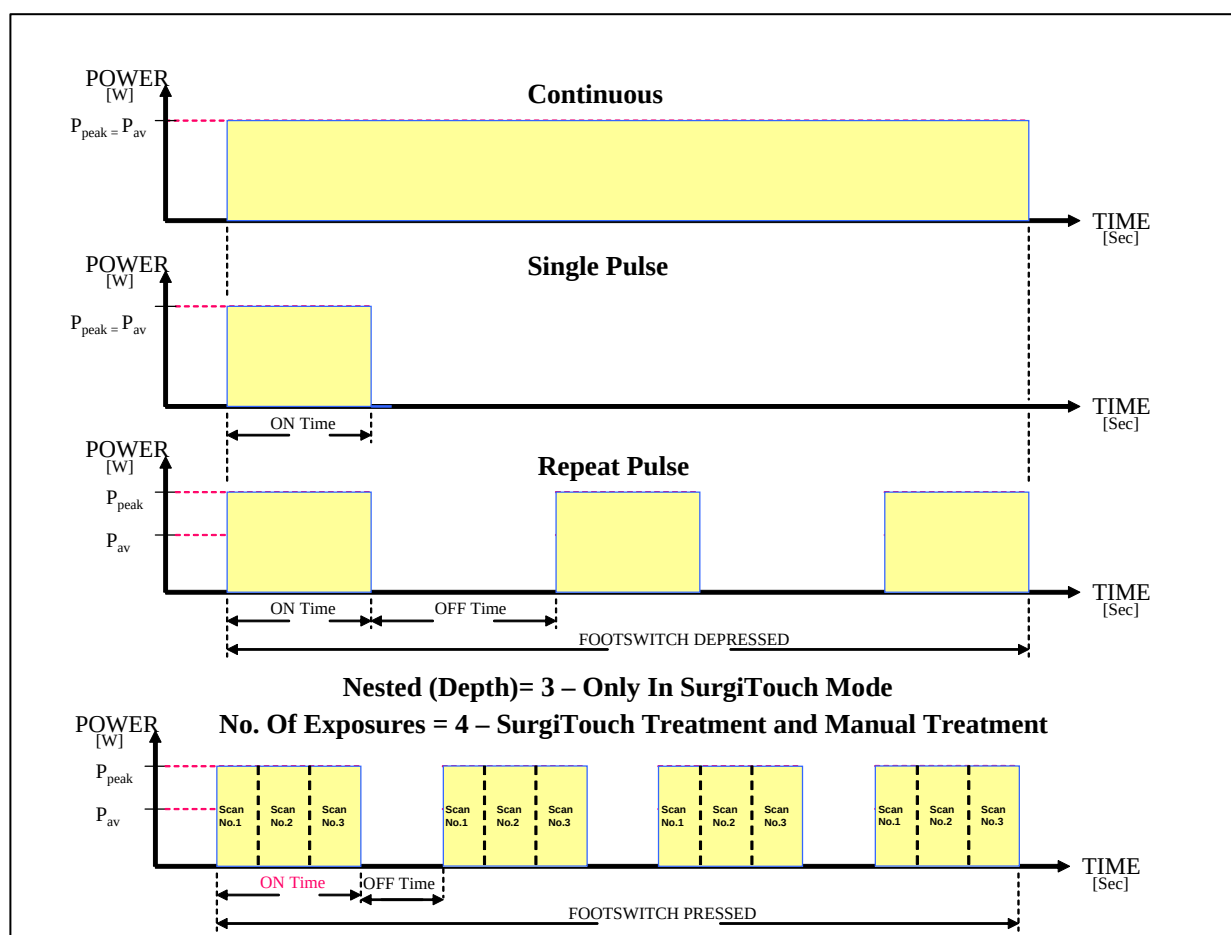


Figure 4-5: CW Exposure Types

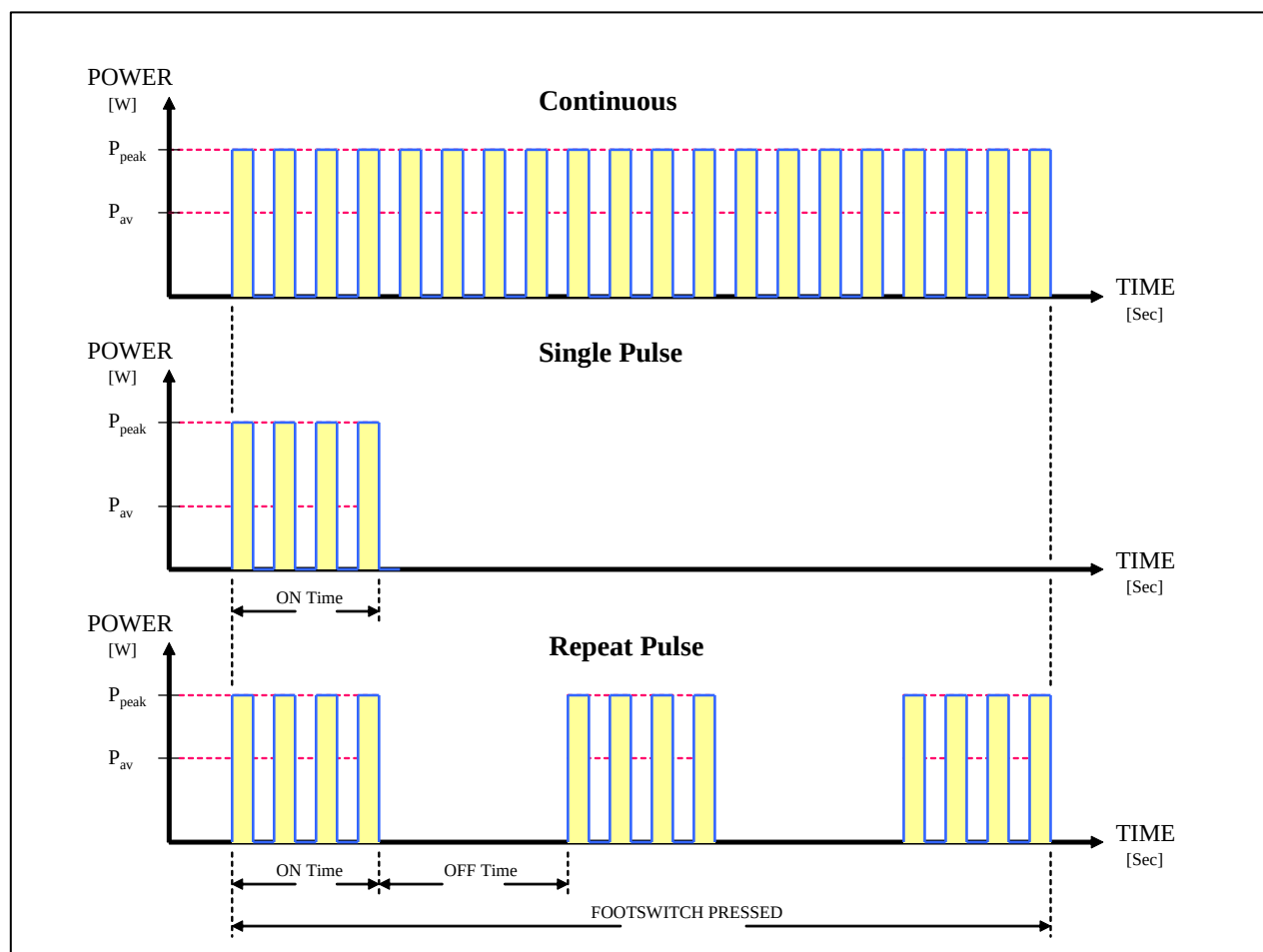


Figure 4-6: Pulser Exposure Types

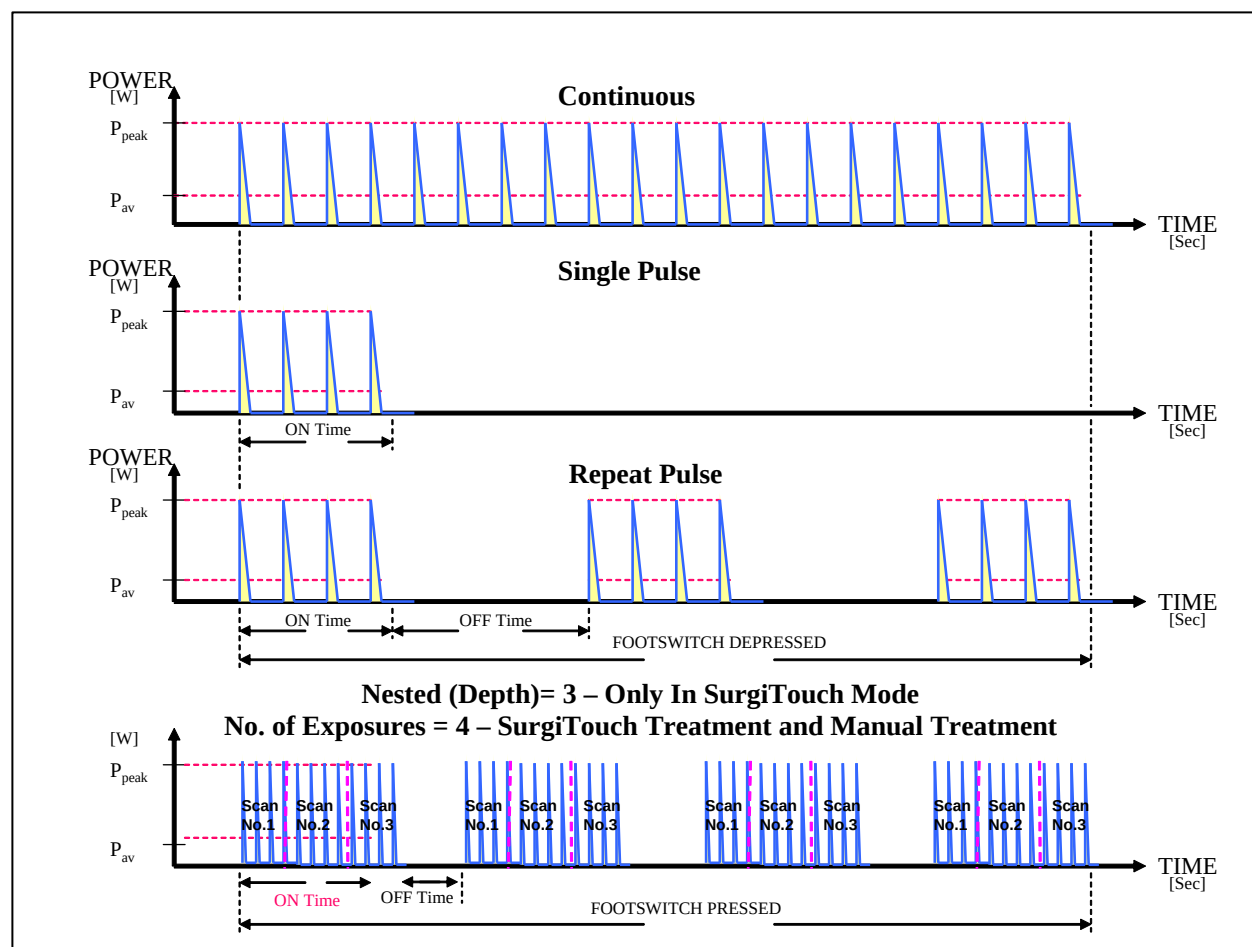


Figure 4-7: SuperPulse Exposure Types

4.6. System Specifications

4.6.1. Outputs

Treatment Laser

- Type: CO₂ laser tube, sealed-off, DC-excited
- Wavelength: 10.6 microns (invisible infrared)
- Mode structure: TEM₀₀ (Gaussian)

Aiming Laser

- Type: Diode
- Wavelength: 635 nm
- Intensity: 6 settings – off to 5mW max.
- Operational modes: Continuous or blinking

Laser Operating Modes

- Continuous Wave (**CW**)
- Pulser
- SuperPulse (**SP**)

Tissue Exposure Modes

- Continuous
- Single Pulse
- Repeat Pulse

Continuous Wave Power

- **30** Watt model: 1.0 – 30.0 Watts
- **40** Watt model: 1.0 – 40.0 Watts

Pulser Average Power

- **30** Watt model: 1.0 – 25.0 Watts
- **40** Watt model: 1.0 – 35.0 Watts

SuperPulse Average Power

- **30** Watt model: 0.5 – 10.0 Watts
- **40** Watt model: 0.5 – 15.0 Watts

ON and OFF Time Intervals – CW Exposure Type *

Tissue Exposure Mode	Power [Watts]	ON-Time [Sec]	OFF-Time [Sec]	Repeated [Counts]
Continuous	1.0 – 4.5 *			
Continuous	5.0 – 40.0			
Single	1.0 – 4.5 *	0.05 – 1.00		
Single	5.0 – 40.0	0.01 – 1.00		
Repeat	1.0 – 4.5 *	0.05 – 1.00	0.01 – 1.00	2 – 10 **
Repeat	5.0 – 40.0	0.01 – 1.00	0.01 – 1.00	2 – 10 **

(*) Available only in **Manual**, **No Scan** and **Blepharoplasty** modes

(**) As long as the footswitch is pressed

ON and OFF Time Intervals – Pulser Exposure Type *

Tissue Exposure Mode	Power [Watts]	ON-Time [Sec]	OFF-Time [Sec]	Repeated [Counts]
Continuous	1.0 – 35.0			
Single	1.0 – 35.0	0.05 – 1.00		
Repeat	1.0 – 35.0	0.05 – 1.00	0.01 – 1.00	2 – 10 **

(*) Available only in **Manual**, **No Scan** and **Blepharoplasty** modes

(**) As long as the footswitch is pressed

ON and OFF Time Intervals – SuperPulse Exposure Type *

Tissue Exposure Mode	Power [Watts]	ON-Time [Sec]	OFF-Time [Sec]	Repeated [Counts]
Continuous	0.5 – 15.0			
Single	0.5 – 15.0	0.05 – 1.00		
Repeat	0.5 – 15.0	0.05 – 1.00	0.01 – 1.00	2 – 10 **

(*) Available only in **Manual**, **No Scan** and **Blepharoplasty** modes

(**) As long as the footswitch is pressed

Spot Size

- From 0.1mm, focused at 50mm working distance, to 6.7mm, fully defocused at 400mm working distance.
- AcuScan120 Microscanner: fixed at 120 microns

Delivery System

- Lightweight, carbon fiber, 7-joint, spring-balanced articulated arm
- Working radius at full arm extension: 120 cm (47")
- Horizontal rotation of articulated arm: 360°

4.6.2. Operation and Control***Control***

- Microprocessor based, touch screen, high resolution, multicolor GUI
- Storing and recall capability

System Turn-on

- Power circuit breaker on service panel
- On/Off switch on control panel
- Proprietary password access for each user

System Turn-off

- On/Off switch on control panel
- Power circuit breaker on service panel

Laser Emission Control

- Footswitch

Laser Emission Indicators

- Yellow lamp
- Audible buzzer

4.6.3. Cooling System

- Closed-loop liquid-to-air cooling system
- Fluorinert FC-770 coolant

4.6.4. Electrical Requirements

- 100-240 VAC, 9A, 50/60 Hz, single phase

4.6.5. *Physical Specifications*

Dimensions and Weight

- Height of console: 118.5 centimeters (46.65 inches)
- Height with articulated arm at full vertical deployment:
245.5 centimeters (96.65 inches)
- Width: 40 centimeters (15.75 inches)
- Depth: 40 centimeters (15.75 inches)
- Weight: ~50 kilograms (~110 pounds)

4.6.6. *Environmental Specifications*

Ambient Temperature

- Operating: 5 to 30°C (41 to 86°F)
- Storage: (-20) to 70°C [(-4) to 158°F]

Relative Humidity

- Shipping & Operating: 5 to 85% relative humidity, non-condensing
- Shipping & Storage: 10 to 90% relative humidity, non-condensing

Atmospheric Pressure

- Operating: 70 – 106 kPa
- Storage: 70 – 106 kPa

4.6.7. *System Classifications*

Type of Protection against Electric Shock

- Class I

Degree of Protection against Electric Shock for Applied Parts

- BF

Suitability for use in Presence of Flammable Mixture

- Not suitable

Protection against Ingress of Water

- IPX0

Mode of Operation

- Can be used continuously

Chapter 5

Operating Instructions

5.1. Introduction

This chapter of the AcuPulse laser system operator's manual describes normal system operation. It includes:

- Pre-operation system preparation
- Operating the system via the graphic user interface

Instructions for system setup are included in Chapter 3 – **Installation**. Maintenance and troubleshooting issues are detailed in Chapters 7 & 8 – **Maintenance** and **Troubleshooting**. Chapter 6 – **Delivery Systems** – lists and describes the use and care of the system's standard and optional accessories.



Note

- Read this manual before performing any patient procedures. The information in this manual should be used in conjunction with – not as a substitute for – formal training.
 - In Canada this instrument must be installed and operated according to CAN/CSA-Z386-08: Laser Safety in Health Care Facilities.
-

5.2. Safety Considerations

Read Chapter 2 – **Laser Safety** – before attempting any procedures. Be aware of the hazards when using lasers and take appropriate protective measures. Some important reminders:

1. Restrict access to the laser operating area. Post the laser warning sign before beginning any procedure.
2. Make sure that the laser operating area is safe and secure. Any flammable materials should be moistened, or should be beyond contact of the laser beam. All personnel and patient should wear protective goggles or glasses.
3. Remember that the footswitch is enabled (allowed to operate the system) when the system is in **Ready** mode. The footswitch is disabled (not allowed to operate the system) when the system is in **Standby** mode. When not actively lasing, set the system to **Standby** mode.
4. When the procedure is complete, turn off the system by following the steps in Section 5.13.

5.3. Starting the System

5.3.1. Before Turning On the System

Before you turn the system on, verify that:

1. The system is plugged into an appropriate power outlet.
2. The power circuit breaker on the service panel is turned to the **On** position.
3. The laser stop button is not engaged. If it is, turn the button clockwise to release it.
4. The footswitch is connected to the electrical connection panel.
5. The purge air tube is connected to its barb.
6. The wheel brakes are locked.
7. A delivery system accessory is connected to the articulated arm's endjoint.
8. The patient and all other personnel in the room are wearing adequate safety eyewear.

5.4. Operating the System

1. Press the green **On/Off** switch on top of the system's console; the system starts its initialization process, during which a splash screen is displayed on the LCD.
2. The **Login** screen will now appear (see Figure 5-1); insert the password by pressing the numbered buttons on the screen's virtual keypad. If you pressed a wrong button by mistake, press the button with the  icon – this will clear the last character entered:
 - User's initial password: **1 2 3 4**
 - Administrator's initial password: **1 8 0 8**



Note

It is strongly recommended that the administrator change the initial passwords as soon as possible.

3. Press the **Login** key in the top-right corner of the screen; a self-test routine starts that checks out the system. If a fault is detected, the system issues an appropriate error message (see Chapter 8). Once the system satisfactorily completes the self-test routine, it is ready for operation and displays the **Home** screen (see Figure 5-2).

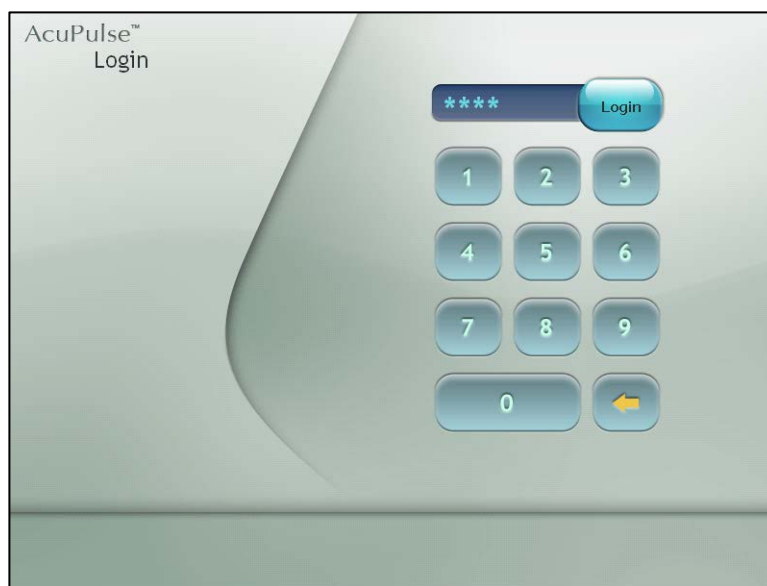


Figure 5-1: Login Screen



Note

To switch from one logged-in user to another or from the logged-in administrator to a user, press the **Logoff** button; the **Login** screen will reappear and an alternate user may log in with his/her proprietary password.

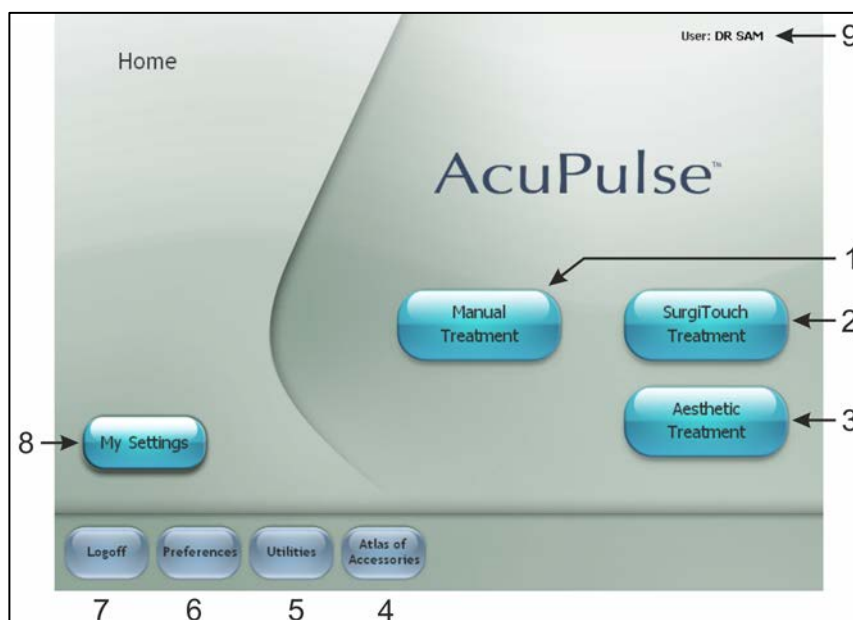


Figure 5-2: Home Screen

Figure 5-2 and the following sections offer explanations and rules of navigation through the operator settings and operation of the AcuPulse laser system.

Pressing each of the following buttons will take you to the appropriate area of the operating system:

1. **Manual Treatment** – sets up the system to treat the patient with manually-input operating parameters and a standard, non-scanning handpiece (see Section 5.5.4).
2. **SurgiTouch Treatment** – sets up the system to treat the patient with surgical accessories (see Section 5.5).
3. **Aesthetic Treatment** – sets up the system to treat the patient with aesthetic accessories (see Section 5.7).
4. **Atlas of Accessories** – displays images and details of all Lumenis laser accessories available for use with the AcuPulse system (see Section 5.9).
5. **Utilities** – navigates to the screen where several of the system's functional utilities may be accessed for reconfiguration (see Section 5.11.).
6. **Preferences** – navigates to the screen where the user may change the functionality of many of the system's operational and performance settings (see Section 5.10).
7. **Logoff** – used for logging out of the system for shutdown, or to change from one user to another, with or without administrator rights.
8. **My Settings** – navigates to the screen where the user may select any of his/her proprietary treatment settings quickly and easily (see Section 5.8.2).
9. **User** – the name of the currently logged-on user is displayed here.

5.5. SurgiTouch Treatment

5.5.1. Select Specialty

Press the **SurgiTouch Treatment** button on the **Home** screen (see Figure 5-2); the **Select Specialty** screen will appear (see Figure 5-3).



Note

- Refer to Chapter 6 – **Delivery Systems** – for a complete discussion concerning the SurgiTouch accessory system.
- For complete operating instructions for the AcuScan120 accessory system, refer the **AcuScan120 Microscanner Operator's Manual** (Lumenis catalog # UM-1044640).

The elements of the **Select Specialty** screen are (refer to the numbered items in Figure 5-3).

1. **Select Specialty** – select the desired surgical specialty from the array of buttons; the active specialty will be high-lighted and the system will take you to the **SurgiTouch Menu** screen (see Section 5.5.2 and Figure 5-4).
2. **Remember my specialty** – the user may choose to have the system always remember his/her specialty, and go straight to that specialty after login. Mark this checkbox by pressing it on the screen.
3. **Home** – press this button to return to the **Home** screen (see Figure 5-2).

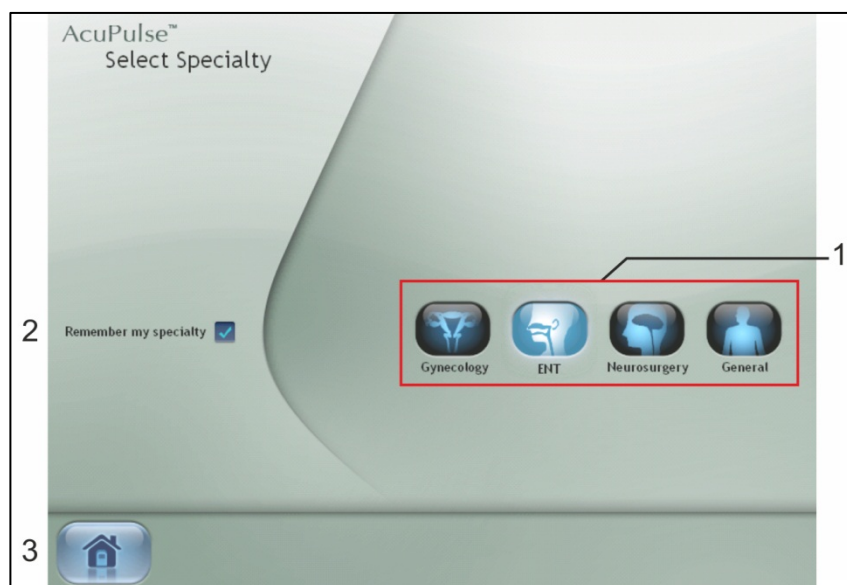


Figure 5-3: Select Specialty Screen

5.5.2. SurgiTouch Menu

The elements of the **SurgiTouch Menu** screen are (refer to the numbered items in Figure 5-4).

1. **Selected Specialty Icon/Button** – this icon indicates which specialty is currently selected. It is also a button that when pressed, navigates the system back to the **Select Specialty** screen (see Figure 5-3).
2. **Application Icons/Buttons** – this bar of icons displays all of the SurgiTouch specific application modes available within the selected specialty. The active application is highlighted, and the lower part of the screen displays the accessories available for that mode. Pressing any of the icons changes the selected application and with it also the available accessories.
3. **Select Accessory** – the AcuPulse system is programmed to offer you the Lumenis surgical CO₂ laser accessories suitable for use with the selected specialty and application. Scroll through this menu by pressing the ▲ or ▼ buttons till you find the desired accessory, and press the name of the accessory to select it.
4. **Accessory Image Information** – this window will display an image of the selected accessory to confirm your selection. Press the image to open a new screen that will display an associated video clip, showing you how to connect and prepare the accessory for operation (see Section 5.9).
5. **Treatment** – press this button after selecting the accessory to advance to the **Treatment** screen (see Figure 5-5).

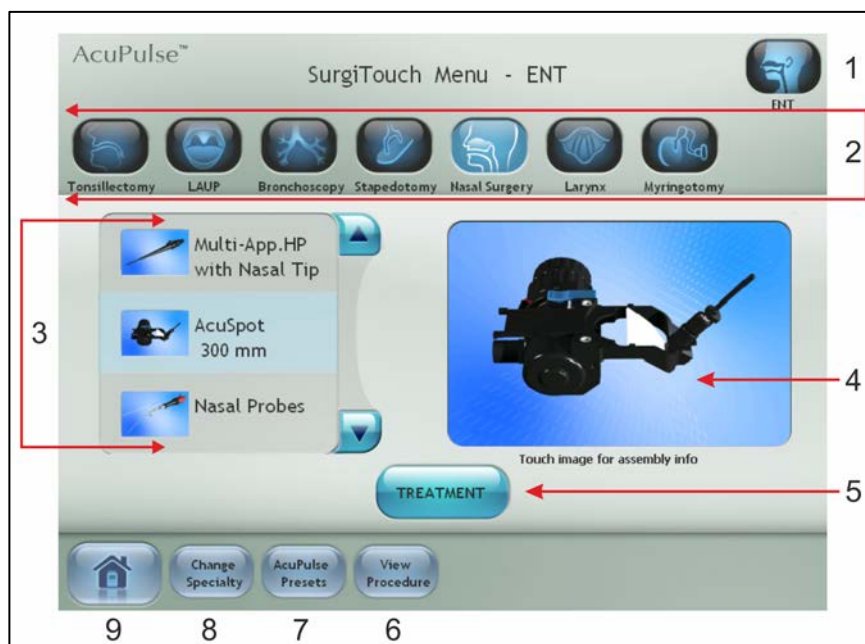


Figure 5-4: SurgiTouch Menu Screen – ENT

6. **View Procedure** – pressing this button transitions to a new screen and launches an associated video clip, exhibiting several Lumenis-recommended methods of performing the selected application with various accessories.
7. **AcuPulse Presets** – navigates to the screen where the user may select Lumenis-recommended operating parameters for treatments associated with the selected accessory (see Section 5.8.3).
8. **Change Specialty** – press this button to return to the **Select Specialty** screen (see Figure 5-3) for the purpose of selecting a different specialty.
9. **Home** – press this button to return to the **Home** screen (see Figure 5-2).

5.5.3. Treatment Screen: Scan Mode

The elements of the **Treatment** screen are (refer to the numbered items in Figure 5-5).

1. **Scan / No Scan** – the system can be operated with no scan patterns even if the SurgiTouch flashscanner is connected to the system. Select the appropriate tab for scanning or non-scanning operations.
2. **Selected Specialty Icon/Button** – this icon indicates which specialty is currently selected. It is also a button that when pressed, navigates the system back to the **Select Specialty** screen (see Figure 5-3).

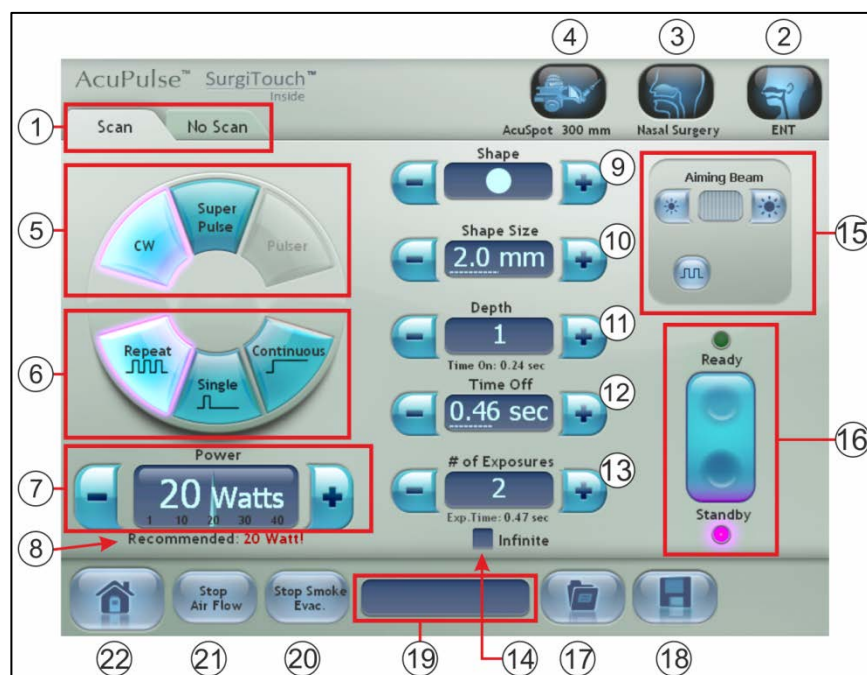


Figure 5-5: SurgiTouch Treatment Screen – Scan Mode

3. **Application Icon/Button** – displays which SurgiTouch application is selected. Pressing this button navigates back to the **SurgiTouch Menu** screen (see Figure 5-4) in order to select a new application.
4. **Selected Accessory Icon/Button** – this icon displays which Lumenis accessory is selected for use in the application. Pressing this button navigates back to the **SurgiTouch Menu** screen are (see Figure 5-4) in order to select a different accessory.
5. **Laser Emission Mode** – select **CW (Continuous Wave)**, **SuperPulse** or **Pulser** as the desired emission mode. The active mode is highlighted with a pink halo.
6. **Timed Exposure Mode** – select the desired type of laser beam exposure: **Repeat**, **Single** or **Continuous**. The active mode is highlighted with a pink halo.
7. **Power Setting** – set the desired laser power, measured in Watts:
 - Press the ► or ◀ buttons to raise or lower the power setting in 1/2-Watt increments between 1.0 – 10 Watts, and single-Watt increments from 10 Watts and higher.
 - Press anywhere on the power bar to immediately set that power setting.

**Note**

- Due to the physical characteristics of the CO₂ laser tube, when the system is set to the lowest power and time settings, the system may deliver less than the requested energy per pulse setting (mJ).
- If this occurs, the following message will appear on the screen:
The delivered energy may be less than expected for this setting.
- Press the **OK** button to accept this limitation, or **Cancel** to return to **Standby** mode; change the settings on the screen:
 - ⇒ In **Scan** mode: increase the scan size or depth settings as necessary.
 - ⇒ In **No Scan** mode: increase the Time-On setting as necessary.

8. **Recommended Power Setting** – after selecting the specialty, application & accessory, and transitioning to the **Treatment** screen, the system will automatically set the laser power parameter to the Lumenis-recommended setting. If you change this setting, a remark will appear under the power bar stating the recommended setting.

9. **Scan Shape Selector** – select the scan shape; scroll through the shapes with the **+** or **—** buttons until the desired shape is displayed. The available shapes are: circle, square, ring, kidney, line and curved line. **Note that** not all shapes are available for all accessories.
10. **Shape Size Selector** – select the size of the scanned shape; scroll through the sizes with the **+** or **—** buttons until the desired size is displayed. **Note that** not all sizes are available for all accessories in all modes.
11. **Depth** – select the depth of the scan; the depth is determined by the number of scans pulsed at the same spot, the higher the number of scans, the deeper the effect will be. Scroll through the number of applied scans per pulse with the **+** or **—** buttons until the desired number is displayed (not available in **Continuous** mode).
12. **Time Off** – select the desired delay time interval between scans in **Repeat** mode; scroll through the available intervals with the **+** or **—** buttons until the desired interval is displayed (not available in **Single** or **Continuous** modes).

**Note**

- The system's operational design is based on a train of consistent pulse cycles, comprised of laser-emission and laser-paused periods.
- The length of the pulse cycle is determined during the system's automatic power convergence.
- The user-selected Off-time (displayed on the screen) determines the number of pulse cycles that will be blocked during the continuity of laser beam emission.

13. **# of Exposures** – this setting governs the number of sequential scans that will be emitted for as long as the footswitch is pressed. When that number of scans has been emitted, the system will stop. To continue scanning, release and re-press the footswitch.
14. **Infinite** – when this checkbox is marked (✓), the system will emit sequential scans for as long as the footswitch is pressed.
15. **Aiming Beam** – determine the intensity of the aiming beam during laser emission:
 - Press the  button to increase the intensity – all the way to full.
 - Press the  button to decrease the intensity – all the way to off.

- Press the  button to toggle between a continuous or blinking aiming beam.
- Press the  button to transition directly to the **Beam Offset** screen.

16. Ready/Standby Buttons and Indicators –

- Press the **Ready** button to set the system to **Ready** mode.
- Press the **Standby** button to reset the system to **Standby** mode



Warning

Laser energy is radiated from the laser accessory when the system is in **Ready** mode and the footswitch is pressed. Observe laser safety rules – wear safety glasses!



17. **My Settings** – pressing this button offers direct access to the **My Settings** screen (see Section 5.8).



18. **Save** – navigates to the **Add Settings** screen (see Figure 5-11) where the user may designate and save protocols of operational settings as user presets (see Section 5.8.1).

19. **Message Area** – short operational messages are displayed here.

20. **Smoke Evac.** – if a medical smoke evacuation system is connected to the AcuPulse laser system (via the service panel), activation of this button will turn on or shut off the smoke evacuator. The smoke evacuator will also automatically turn on during laser beam emission.

21. **Air Flow** – activating or deactivating this button will toggle the purge air compressor on or off. Activation of this button will toggle the air flow to enabled or disabled modes during laser beam emission.

22. **Home** – press this button to return to the **Home** screen (see Figure 5-2).

5.5.4. Treatment Screen: No Scan Mode

To continue operating in the same specialty and application, using the same accessory but without scanning, press the **No Scan** tab on the treatment screen (see Figure 5-6); the **Shape** and **Shape Size** selection fields will become disabled, as will the galvanometric mirrors in the SurgiTouch flashscanner.

Removing the SurgiTouch flashscanner is not necessary – the straight laser beam will pass through the flashscanner without being modified.



Figure 5-6: SurgiTouch Treatment Screen – No Scan Mode

5.6. Manual Treatment

Press the **Manual Treatment** button on the **Home** screen (see Figure 5-2); the **Manual Treatment** screen will appear (see Figure 5-7).

This is a treatment screen where you may set your own proprietary parameter settings, regardless of which Lumenis accessory is connected to the system.

Operating in the **Manual Treatment** screen is without scanning – note that the **Shape** and **Shape Size** selection fields are disabled.

Any protocol of settings entered on this screen can be saved as a user preset in **My Settings** (see Section 5.8).



Figure 5-7: Treatment Screen – Manual Settings

5.7. Aesthetic Treatments

Press the **Aesthetic Treatment** button on the **Home** screen (see Figure 5-2); the **Aesthetics Menu** screen will appear (see Figure 5-8).



Figure 5-8: Aesthetics Menu Screen

1. Select the desired **Application** from the selection of buttons, and then select the desired Lumenis accessory from the selection associated with that application.
2. Press the **Treatment** button to transition to the appropriate Treatment screen.

3. If you have selected the **SilkTouch**, **FeatherTouch**, **FineTouch**, **ToeTouch**, **Paint** or **Bleph** application, the appropriate **Treatment** screen will appear (see Figure 5-9) with the selected application and accessory.

The controls and indicators in these screens operate in the same manner as those described in Section 5.5.3, earlier in this chapter.



Figure 5-9: Aesthetics Treatment Screen

5.7.1. Fractional Applications

Refer to Figure 5-10: the four fractional applications – **Deep (A)**, **Superficial (B)**, **Combo (C)** and **StretchTouch (D)** – are available from the **Aesthetics Menu** screen with (by default) the **AcuScan120** accessory. Selecting any of these modes will bring up the appropriate screen.



Figure 5-10: Aesthetics Treatment Screen: Deep, Superficial, Combo and StretchTouch

Note several major differences in the **Fractional** treatment screens:

- Instead of Power, you will adjust the **Energy** setting, measured in milliJoules (**mJ**), with the ability to raise or lower the energy setting:
 - ⇒ **Deep** fractional treatment energy may be adjusted in 2.5 mJ increments between 7.5 to 30 mJ. The Lumenis-recommended setting is 10 mJ (see Figure 5-10, view **A**).
 - ⇒ **Superficial** fractional treatment energy may be adjusted in 10 mJ increments between 50 mJ and 170 mJ. The Lumenis-recommended setting is 70 mJ (see Figure 5-10, view **B**).

- ⇒ **Combo** mode offers the possibility of applying **Deep** and **Superficial** modes at the same scan. View **C** in Figure 5-10 exhibits the parameter selection areas for both modes, within the same energy ranges as described above.
- ⇒ **StretchTouch** fractional treatment energy may be adjusted in 1 mJ increments between 10 mJ and 25 mJ. The Lumenis-recommended setting is 10 mJ (see Figure 5-10, view **D**).
- Instead of Depth, you will select the **Density** of the dots in the scanned pattern:
 - ⇒ Deep fractional treatment – between **5% – 25%**, in 5% increments.
 - ⇒ Superficial fractional treatment – two settings are available: **40%** and **60%**.
 - ⇒ StretchTouch fractional treatment – three settings are available: **5%**, **10%** and **15%**.

**Note**

For complete operating instructions for the AcuScan120 accessory system, refer the **AcuScan120 Microscanner Operator's Manual** (Lumenis catalog # UM-1044640).

5.8. User Presets

5.8.1. Programming User Presets

The operating system offers every individual user the possibility of creating proprietary presets. A preset is a protocol of operating parameters, created by the clinician, and saved to the system with a name or designation. The preset can then be rapidly recalled for operation without having to enter each operating parameter.

After the user presets are programmed into the system's memory, they can be quickly accessed and set for operation through the **My Settings** screen (see Section 5.8.2).

User presets are programmed as follows:

1. Set up your desired operating parameters in any of the treatment screens (for example Figure 5-5).
2. Press the **Save** button on the Treatment screen; the **Add Settings** screen will appear (see Figure 5-11).
3. Use the virtual keyboard to type in a name for the procedure; the name will appear in the **Save As:** box.
4. Press the **Save** button to save the preset to the system's memory; the screen will transition back to the Treatment screen.
5. Press **Cancel** to exit the **Add Settings** utility without saving the preset.



Figure 5-11: Add Settings Screen

5.8.2. My Settings

After the user presets are programmed into the system's memory (see Section 5.8.1) they can be quickly accessed and set for operation through the **My Settings** screen.

There are two ways to access the **My Settings** screen (see Figure 5-12):



- Press the **My Settings** button on the **Home** screen (see Figure 5-2).
- Press the access button on any of the **Treatment** screens.

1. Use the ▲ or ▼ buttons on the slider to scroll to the desired settings preset. The display presents the name, the assigned Lumenis accessory, specialty and application mode designations.
2. Press the desired preset to select it; it becomes highlighted.
3. Press the **Treatment** button; the system will transition to the **Treatment** screen with all parameters of the preset in place and ready for operation.
4. If you wish to assign a new name to the preset, press the **Rename** button; the virtual keyboard will appear where you can type in the new name and save by pressing the **Save** button.
5. Press the **Delete** button to permanently remove the highlighted user preset from the system's memory.

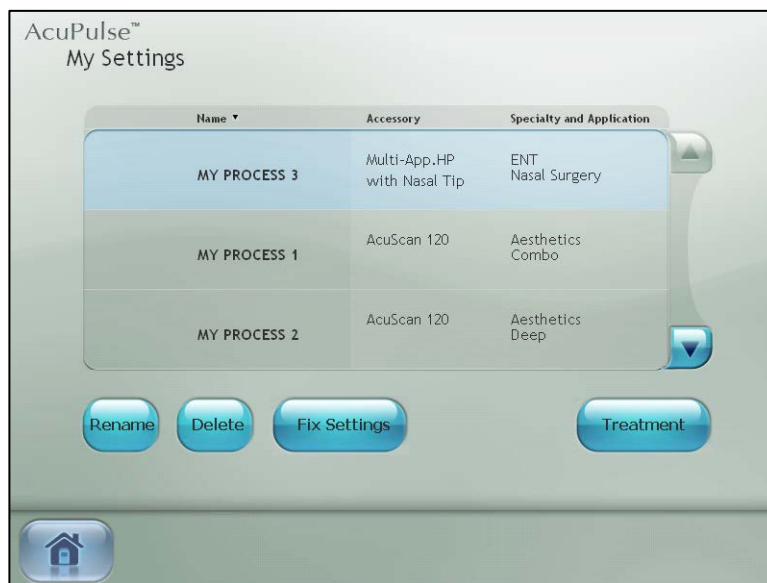


Figure 5-12: My Settings Screen

5.8.3. Fix Settings

Determining treatment parameter settings for a particular combination of clinical indications is a result of clinical experience and expertise.

For the convenience of the user, the AcuPulse system is furnished with a set of Lumenis presets of treatment parameters, called **Fix Settings**. These presets are based on successful results obtained by experienced physicians using CO₂ laser systems.

The Fix Settings screen (see Figure 5-13) is accessible by pressing the **Fix Settings** button on the **My Settings** screen (see Figure 5-12).

Here you may view and select any of the Lumenis-recommended operating parameters for various laser procedures. Scroll through the selection with the ▲ or ▼ buttons on the slider. The display presents the name of the preset, the assigned Lumenis accessory, specialty and application mode designations.

When you locate the desired procedure, press its name to select (highlight) it and press the **Treatment** button; the appropriate **Treatment** screen will appear with all parameters of the preset in place and ready for operation.

To exit this screen without selecting a fixed Lumenis preset, press the **My Settings** button to return to that screen (see Figure 5-12) or press the **Home** button.



Note

Fixed Settings cannot be renamed or deleted from the system's memory.

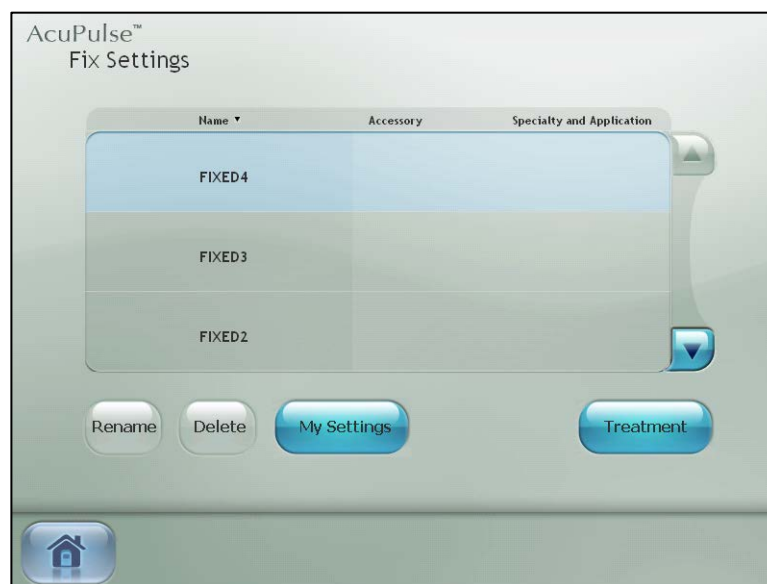


Figure 5-13: SurgiTouch Presets Screen

5.9. *Atlas of Accessories*

The AcuPulse operating system's software incorporates a complete atlas of Lumenis accessories designed for use with the Lumenis family of CO₂ surgical laser systems. The atlas is accessible from the **Home** screen (see Figure 5-2) by pressing the **Atlas of Accessories** button.

In the atlas screen (see Figure 5-14) you may view and perform the following:

1. Select the **Specialty** and **Application** within which you want to view the accessories available for use. Use the drop-down menus to make these selections.
2. Scroll through the selection of accessories with the ▲ or ▼ buttons on the slider until you find the one you are interested in.
3. When you have found the desired accessory, press its name to highlight it and press the **View Details** button; this will bring up an **Accessory Description** screen offering an image and detailed information about the accessory. Press the image to open a new screen that will display an associated video clip, showing you how to connect and prepare the accessory for operation.
4. Pressing the **View Procedure** button transitions to a new screen and launches an associated video clip, exhibiting several Lumenis-recommended methods of performing the selected application with various accessories.
5. Press the **Treatment** button; the appropriate **Treatment** screen will appear with all parameters of the **Specialty** and **Application** in place and ready for operation with the selected accessory.

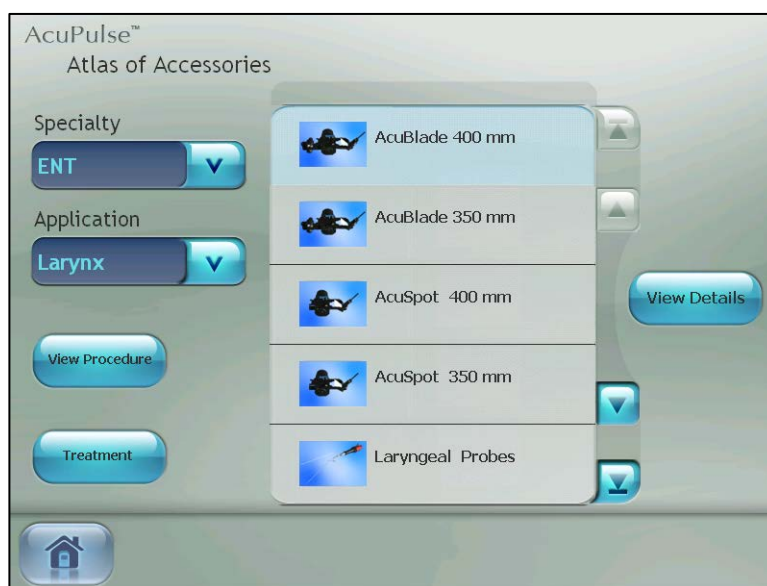


Figure 5-14: Atlas of Accessories Screen

5.10. Preferences

To configure the AcuPulse system's software and hardware preferences, press the **Preferences** button on the **Home** screen (see Figure 5-2); the first of three preferences screens will appear.

5.10.1. General Preferences

This is the default preferences screen that appears, and this is where you can make changes to several general system settings (refer to the numbered items in Figure 5-15):

1. Access buttons to the secondary preferences screens: **Air Flow** (see Section 5.10.2) and **Sound** (see Section 5.10.3).
2. **Language** – open the drop-down menu to select the desired language in which the **Note**, **Caution** and **Warning** pop-up windows will be displayed. The available languages are: English, German, French, Spanish, Italian, Japanese, Chinese and Portuguese.
3. **Show Smoke Evacuation Button** – mark this checkbox to offer the smoke evacuator option button in the **Treatment** screens. If you never plan to use a smoke evacuator, leave this checkbox unmarked.
4. **Automatic Standby** – this is a safety timer that resets the system from **Ready** to **Standby** mode if the system is idle for more than a user-defined time limit, to prevent unintentional activation of the laser with the footswitch. Set the desired time interval with the **+** or **–** buttons.
5. **Brightness** – increase or decrease the LCD screen's brightness setting with the **+** or **–** buttons until you reach your comfort level.

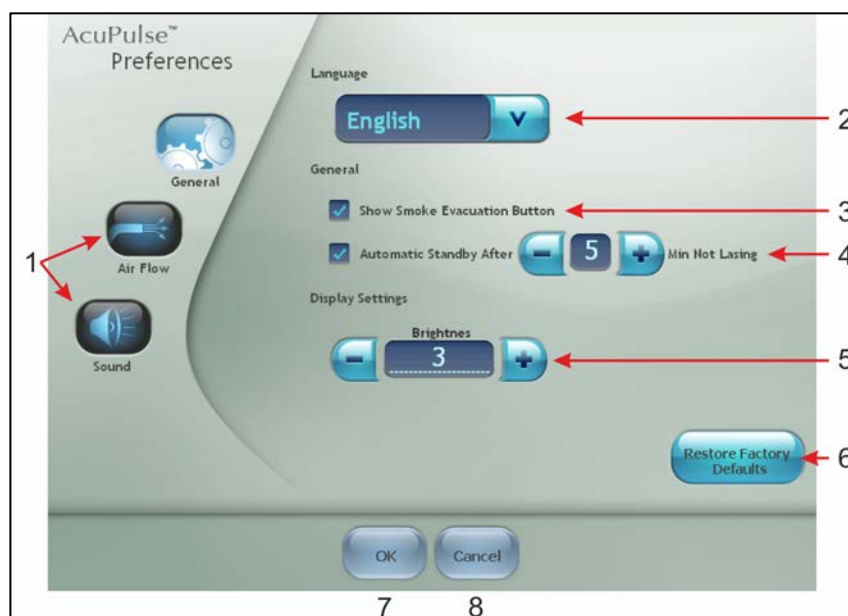


Figure 5-15: General Preferences Screen

6. **Restore Factory Defaults** – press this button to reset all of the system's software and hardware preferences to their original factory settings.
7. **OK** – press this button to save the changes to the preferences and exit the **Preferences** screen back to the **Home** screen.
8. **Cancel** - press this button to exit the **Preferences** screen without changes.

5.10.2. Air Flow Preferences

Press the **Air Flow** button on the **General Preferences** screen to adjust the performance features of the purge air compressor (refer to the numbered items in Figure 5-16):

1. **Show Air Flow Button** – mark this checkbox to offer the air flow option button on the **Treatment** screens. If you never plan to use compressed purge air, leave this checkbox unmarked.

Air Flow While in READY:

2. **Automatic Control** – mark this checkbox to enable the air flow setting to operate automatically during laser procedures.
3. **Air Flow While Lasing** – mark this checkbox if you want the purge air to flow during laser emission.

Air Flow While Not Lasing – mark this checkbox if you want the purge air to flow constantly while the system is in **Ready** mode, even if you are not lasing at the time.

4. **After Lasing** – the purge air can be configured to keep flowing after the footswitch is released and laser emission has ceased for a determined amount of time; increase or decrease the time interval setting with the **+** or **–** buttons until you reach the desired interval.

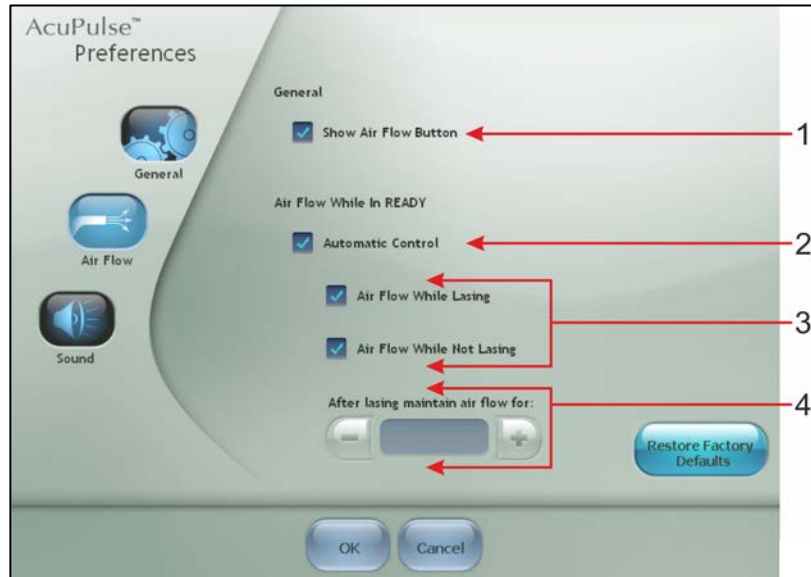


Figure 5-16: Air Flow Preferences Screen

5.10.3. Sound Preferences

Press the **Sound** button on the **General Preferences** screen to adjust the performance features of the system's audible alerts (see Figure 5-17):

1. Four occurrences of system operation may be accompanied by audible sound alerts. Select the occurrences you want sound alerts for, and mark them to activate the alert features by pressing their checkboxes.
2. Increase or decrease the sound alert's volume setting with the **+** or **—** buttons until you reach the desired level.



Figure 5-17: Sound Preferences Screen

5.11. Utilities Menu

The **Utilities Menu** screen (see Figure 5-18) is accessed by pressing the **Utilities** button on the **Home** screens (see Figure 5-2), and offers the following:

- **Software Configuration** – an information block displaying the currently installed versions of the system's various software packages.
- **System Configuration** – information regarding the system's hardware components.
- **Scanner Disconnect** – see Section 5.11.1.
- **New Scanner** – see Section 5.11.2.
- **Service** – available only in **Technician** mode. This area may only be accessed by Lumenis-authorized service personnel.
- **Cnfg. Upgrade** – for upgrading the system's hasp plug. Available in **User** mode and **Technician** mode (see Chapter 7 - **Maintenance**).
- **Data Base Backup** – for periodic backing up of the user-developed database from the system (see Section 5.11.4).

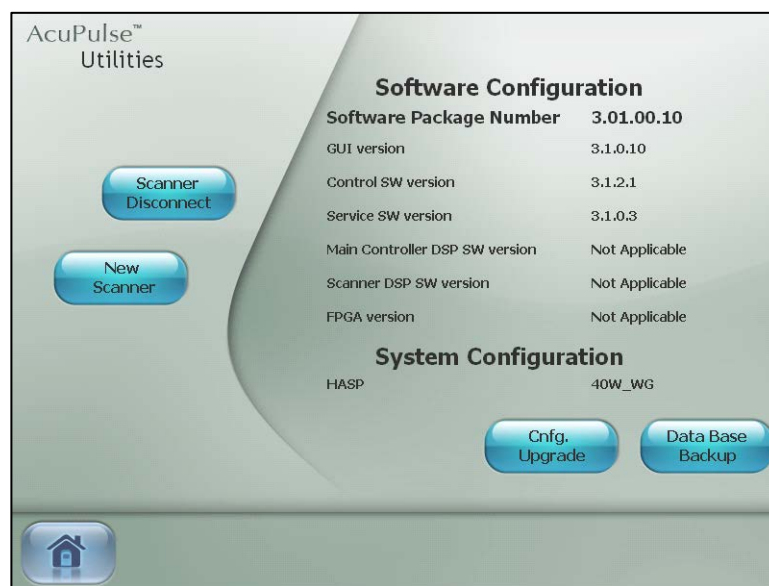


Figure 5-18: Utilities Menu Screen

5.11.1. Disconnecting the Scanner

Before disconnecting the scanning accessory at the endpoint of the articulated arm, the scanner software module needs to be paused in order to prevent possible damage to the system.

Pause the scanner software module by pressing the **Scanner Disconnect** button; a pop-up window will appear stating: **It's safe now to disconnect scanner** (see Figure 5-19).

Disconnect the communication cable from the scanning accessory and disconnect the accessory from the articulated arm.

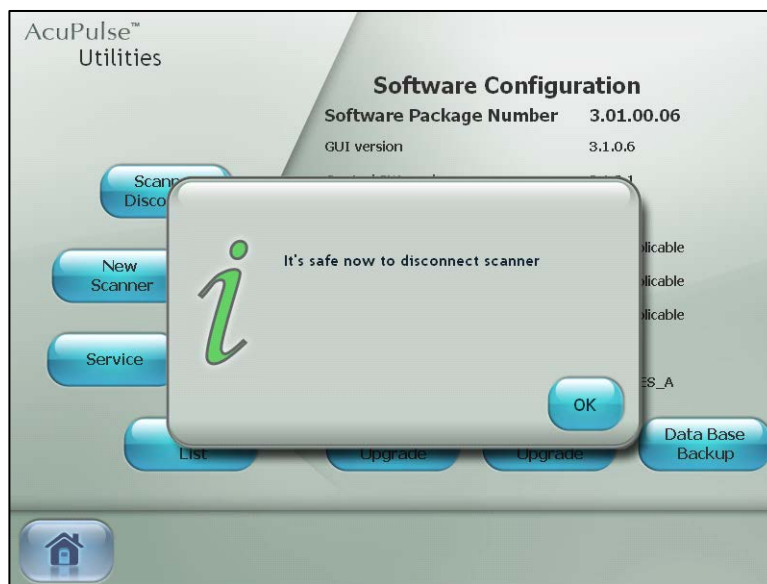


Figure 5-19: Disconnect Scanner Pop-Up Message

5.11.2. Installing a New Scanner

Lumenis offers several types of scanners for the AcuPulse system as optional accessories. When purchased, it arrives with proprietary installation software on a dedicated USB flash drive ("disk-on-key"). To install:

1. Connect the new scanner to the articulated arm's endjoint and connect the communication cable.
2. Connect the USB flash drive to either of the USB connection ports on the system's service panel.
3. Turn on the system and access the **Utilities Menu** screen (see Figure 5-18). Press the **New Scanner** button.
4. When the **Welcome to new scanner Upgrade!** pop-up window is displayed (see Figure 5-20), follow the on-screen instructions to install the new scanner's software.
5. When the installation is complete, remove the USB flash drive and restart the AcuPulse system.

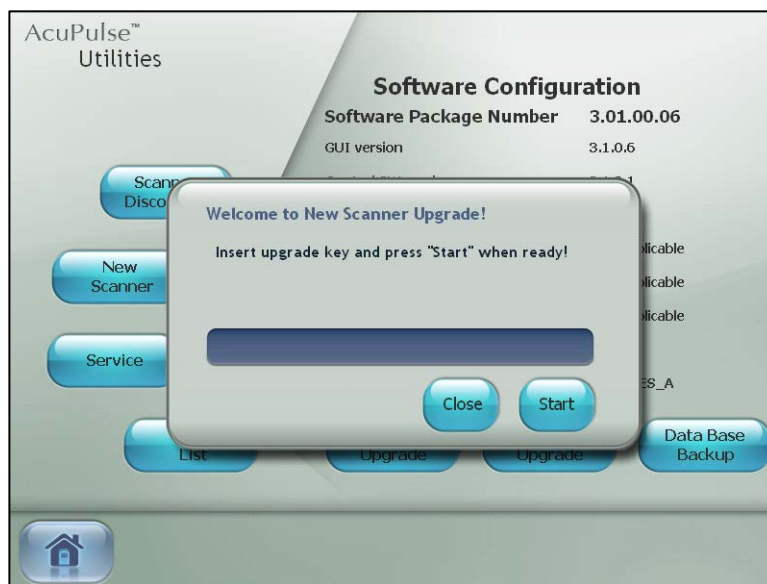


Figure 5-20: New Scanner Upgrade Pop-Up

5.11.3. Users List

The **Users List** screen is only accessible when the administrator is logged into the system. The administrator may add a new user, edit a user's information, and delete a user.

Refer to Figure 5-21:

1. To add a new user, press the **Add User** button; the **Add User** screen will appear (see Section 5.11.3.1).
2. To edit a user's details, scroll with the ▲ or ▼ buttons to find the user's name, press the name to highlight it and press the **Edit User** button; the **Edit User** screen will appear (see Section 5.11.3.2).
3. To delete a user, scroll with the ▲ or ▼ buttons to find the user's name, press the name to highlight it and press the **Delete User** button; the user will be permanently removed from the system's memory.



Figure 5-21: Users List Screen

5.11.3.1. Add User

To add a new user's information:

1. Press the **User Name** field to activate it, and use the virtual keypad to enter the new user's name.
2. Do the same in the **Password** field. Make sure that every individual user has his/her own proprietary password.
3. If the new user is to have administrator rights, mark the **Administrator** checkbox by pressing it.
4. Press the **Save** button to accept the new information, or **Cancel** to reject.



Figure 5-22: Add User Screen



Note

If an attempt is made to enter a new user with the same credentials as an existing one, the system will consider this an error and display the following message: **Failed to add user. Check if name and password are valid.**

5.11.3.2. *Edit User*

To edit an existing user's information:

1. Press the **User Name** field to activate it, press the **←** key to erase the existing name and use the virtual keypad to enter the new or corrected name.
2. Do the same in the **Password** field. Make sure that every individual user has his/her own proprietary password.
3. If the edited user is to have (or lose) administrator rights, mark or un-mark the **Administrator** checkbox by pressing it.
4. Press the **Save** button to accept the new information, or **Cancel** to reject.



Figure 5-23: Edit User Screen

5.11.4. Database Backup

The **Database Backup** utility is designed to safeguard the database of information that is developed and stored in the AcuPulse system's memory, such as names, passwords and ID's of the various users, and all of the proprietary protocols of operating parameters stored in the system (**My Settings**) by the users.

To back up the database:

1. Insert a USB flash drive (disk-on-key) into one of the USB ports in the system's service panel (see Chapter 4).
2. Press the **Data Base backup** button on the **Utilities** screen (see Figure 5-24).
3. Follow the on-screen instructions until the backup procedure is complete.

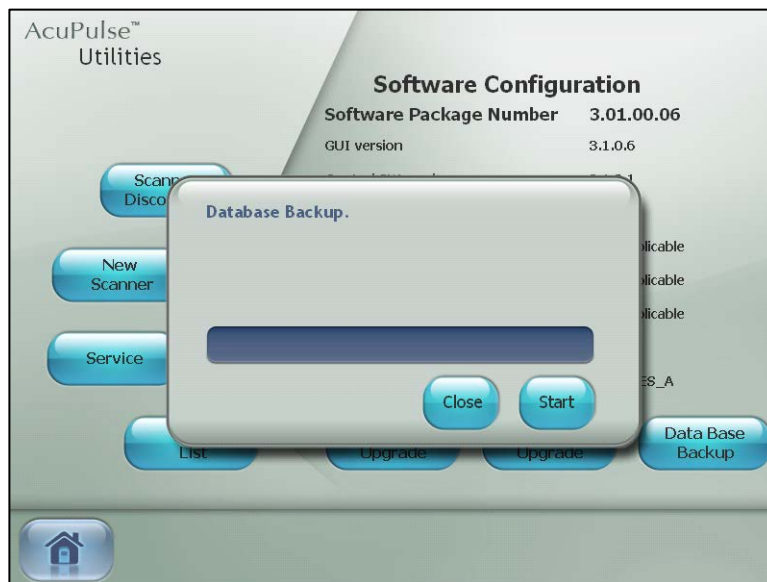


Figure 5-24: Database Backup Screen

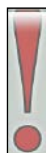
5.12. System Messages

The AcuPulse system employs pop-up windows to deliver important information, error messages or warnings relevant to unintended misuse of the system or a possible internal malfunction.

There are three types of pop-up messages:



Information Dialog – offers important information specific to the given situation.



Error Message – offers details of a system malfunction or a non-functional setup. The problem should be resolved before continuing with the treatment.



Warning Dialog – warns against a serious system malfunction that can create a health hazard to the patient or operator. The system must be shut down and the problem resolved before using the system again.

5.13. System Shut-Down

1. Press the **Home** button on any screen in the operating system to return to the **Home** screen.
2. Press the **Logoff** button to log out of the operating system.
3. Turn the system off by pressing the green **On/Off** switch on top of the system's console.
4. Turn the power circuit breaker switch on the service panel to the **Off** position.
5. Clean/sterilize the surgical accessories (refer to Chapter 6).

Chapter 6

Delivery Systems

6.1. Introduction

This chapter discusses the delivery systems and accessories that are designed to operate with the AcuPulse laser system.

The following sections will describe the accessories and discuss their components, operation, care and maintenance.

6.2. 125mm Incisional Handpiece Set

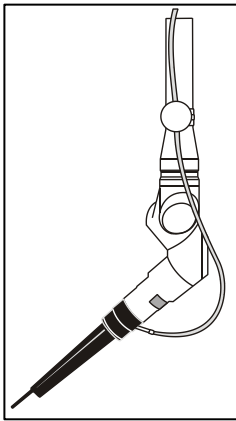


Figure 6-1:
125mm Incisional Handpiece

The 125mm incisional handpiece set is the standard laser accessory delivered with the AcuPulse system.

The CO₂ laser beam focal point is indicated by the straight tip on the handpiece. With the 90° and 120° reflector tips, the focal point is 1cm distal to the reflecting mirror. The spot size for the handpiece is 0.26mm.

The 125mm incisional handpiece set includes:

Description	Qty.	Part #
125mm lens holder, including the lens	1	AA0742900
125mm extender	2	AA2171600
Straight focus-indicating tips	2	PM0163930
90° reflector tip	1	AA0198900
120° reflector tip	1	AA0198800
Endjoint cap, attached to the articulated arm's endjoint to prevent dust from entering the endjoint when an accessory is not attached.		

6.2.1. Handpiece Assembly

To assemble the 125mm incisional handpiece (see Figure 6-1):

1. Screw the lens holder into the articulated arm's endjoint connection.
2. Connect the bacteriological filter's outlet (short flexible tube) to the compressed air nipple on the lens holder.
3. Prior to use, whether or not already installed, the bacteriological filter should be inspected for clarity of color.
4. Screw the extender into the lens holder.
5. Screw the desired tip (straight tip; 90° or 120° reflector tip) into the extender and ensure that all the connections are tightly secured.
6. Check for proper beam alignment before treating a patient (see Section 6.5).

6.3. *FeatherTouch Handpiece Set*

The FeatherTouch handpiece set (Model # 15100, P/N # AA2775200) contains three handpieces used with the SurgiTouch scanner, mostly for aesthetic applications, and is normally provided as standard equipment with any aesthetic configuration of the AcuPulse system.

The FeatherTouch handpiece set contains:

<i>Description</i>	<i>Model #</i>	<i>Part #</i>
125mm handpiece with Smoke Evacuation	15128	AA2814900
200mm SilkTouch Handpiece	15211	AA2778200
260mm SilkTouch Handpiece	15261	AA2782600
Straight Focus-Indicating Tip for 125mm Handpiece		PM5116930
Straight Focus-Indicating Tip for 200mm Handpiece		PM5085230
Straight Focus-Indicating Tip for 260mm Handpiece		PM5052830
Smoke Evacuation Tip for 125mm Handpiece		AA5125900
Smoke Evacuation Tip for 200mm Handpiece		AA2775600
Smoke Evacuation Tip for 260mm Handpiece		AA2775700
Cleaning Brush		MD1651400

6.4. *Scanning Accessories*

Two scanning accessories are available for use with the AcuPulse system: **AcuScan120** and **SurgiTouch**. Each of these accessories consists of flashscanner and user interface software built into the AcuPulse system's operating program, with pre-set recommendations for parameters and delivery devices. The AcuScan120 and SurgiTouch scanners are the same in design and the way they are controlled by the AcuPulse system.

The AcuScan120 Microscanner and its procedures deliver laser energy in a fractional technique via a scanner for rapid coverage of large surface areas. A "fractional" technique is one where the physician can selectively treat less than 100% of the skin's surface (a fraction). Depending on the condition to be treated, the physician may select to use either a superficial or deep treatment modality, within which different treatment densities (how much skin is covered) and energy settings (for different depths, different amounts of heat/ablation, etc.) can be selected. This allows the physician to "optimize" the treatment according to each patient's condition. By minimizing/eliminating the previous compromise between treatment efficacy, down-time, pain management, side-effects, observable results and other factors; the physician can now bridge the gap between the patient's expectations and their results.

The AcuScan120 microscanner's control screens and scanner provide precise control over the laser energy, the beam scan shape, beam scan size and beam scan density.

The SurgiTouch Scanner is designed for a variety of applications, in aesthetics, ENT, gynecology, neurosurgery and general surgery.

The unique scanning mechanism of the SurgiTouch scanner delivers a focused laser beam with constant velocity in a spiral pattern (see Figure 6-2) over a designated scan area. Laser energy is delivered so quickly that it never lingers on any given point in the scan longer than the thermal relaxation time of tissue, resulting in char-free ablation and predictable, repeatable vaporization.

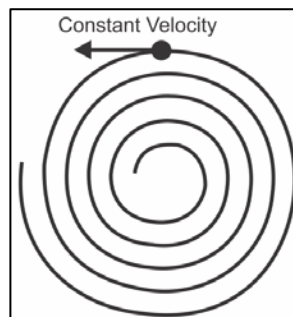


Figure 6-2: SurgiTouch Beam Scanning Pattern

The SurgiTouch Scanner uses multiple devices depending on the surgical or aesthetic application it is used with.

The AcuPulse system's user-friendly graphic display provides step-by-step operating instructions, shows the correct accessories and operating parameters for each procedure, and keeps the user in control of the procedure at all times. The SurgiTouch scanner can be used with the Lumenis delivery devices listed later in this chapter.

6.4.1. *SurgiTouch Scanner Kit Contents*

The SurgiTouch scanner kit (P/N # KT-1000100) contains:

- SurgiTouch scanner (includes scanner & handpiece assemblies).
- Communication cable (P/N # SPHS-1023010).
- AcuPulse system software upgrade on USB flash drive.

6.4.2. *Scanning Accessories Operator Manuals*

Refer to the respective operator's manual of each scanning accessory system for complete pre-operative, operating and post-operative instructions.



Warning

Replace the AcuScan120's lens assembly after 10 treatments or before if the lens assembly is stained or otherwise damaged.

6.4.3. Setting up a Scanning Accessory System

Setting up the scanner requires the connection of the optical head to the articulated arm's endjoint; connecting the communication cable and connecting the accessory to the optical head (see Figure 6-3):

1. Connect the scanner optical head's entry port to the endjoint of the laser system's articulated arm, and fasten it by screwing the end-joint's rotating knob until it stops.



Caution

The scanning accessory's software module must be paused when connecting or disconnecting a scanner accessory. Refer to Chapter 5 – **Utilities Menu** screen.

2. The exit port is a swivel connector that allows free rotation of the handpiece. If free rotation is not required, simply lock the lever on the exit port.
3. Connect the communication cable between the optical head and the system cable connection port on the AcuPulse system's control panel.
4. Route the communication cable along the articulated arm and attach it to the arm's segments with the supplied clips.
5. Connect the desired accessory to the optical head's exit port.

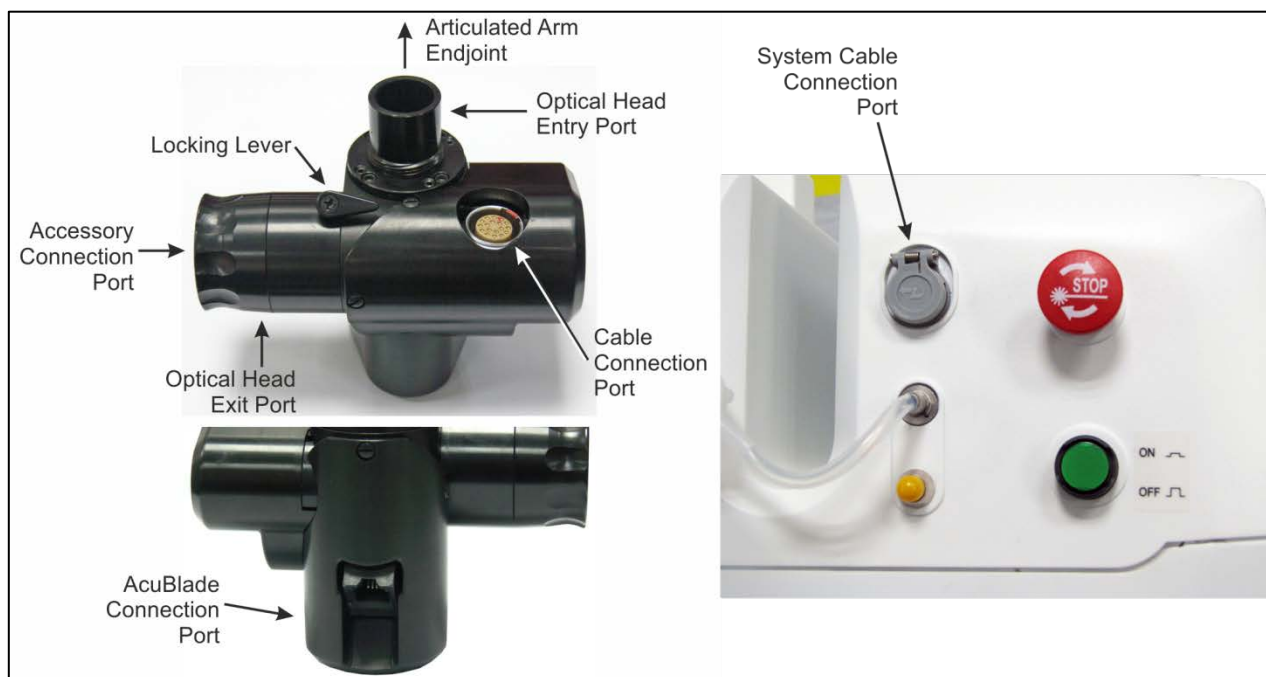


Figure 6-3: Setting Up the Scanning Accessory (for illustration purposes only)

6.4.4. *Cleaning the Optical Heads*

The AcuScan120 and SurgiTouch optical heads are intended to be used as non-sterile devices. The external surfaces may be cleaned with a cloth or cotton swab dipped in hospital grade 70% alcohol.

6.5. **Beam Alignment Check**

Most nursing staff prefer to perform a laser beam alignment check daily, usually prior to scheduled cases and before patients are premedicated. Doing so ensures adequate time to troubleshoot a problem or seek professional service with the least disruption to patient care.



Warning

- Beam alignment checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; call your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.
 - Do not perform the beam alignment check in line with the patient, operating room personnel, or flammable materials. Laser energy can penetrate most non-metallic and non-laser-proof substances and ignite underlying flammable material, resulting in possible injury. If necessary, place energy-absorbing material behind the target area.
-

Perform the beam alignment check as follows:

1. Verify that all persons in the treatment room are wearing appropriate laser safety eyewear.
2. Mark an “X” on a wooden tongue depressor and moisten with water.
3. Turn on the laser.
4. Connect the 125mm incisional handpiece to the articulated arm's endjoint.
5. Access the **Manual Treatment** screen, and set the laser's operating parameters as follows:
 - Laser mode: **CW**
 - Exposure mode: **Single**
 - Power: **2.0 Watts**
 - Time on: **0.10 sec**
6. Press the **Ready** button to set the laser to ready mode.

7. Position the distal end of the accessory's tip on the tongue depressor in a perpendicular orientation. Adjust the aiming beam intensity on the laser until the aiming beam is bright enough to be viewed under normal ambient light.
8. Direct the aiming beam at the center of the "X", and press the laser footswitch. Observe the burned spot on the tongue depressor; it should appear sharp and non-diffused.
9. Verify that the burn spot lies within the area of the aiming beam's red outline (see Figure 6-4).

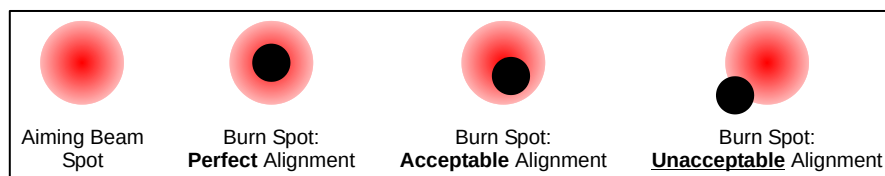


Figure 6-4: Beam Alignment Check Results

10. Press the **Standby** button to set the laser to **Standby** mode until ready for use.
11. If the burn is not within the aiming beam, if the spot placement is unacceptable, or if the aiming beam is not visible:
 - Verify that the accessory is securely attached to the articulated arm.
 - It may be helpful to move the articulated arm or rotate the articulated arm knuckles closest to the accessory. Sometimes changing the orientation of the articulated arm knuckles can affect aiming beam transmission, particularly if the articulated arm is extended or moved during a procedure.
 - If the brightness of the aiming beam fluctuates greatly or if the aiming beam is not visible, the laser articulated arm may be out of alignment; contact your local Lumenis representative.
 - Repeat the beam alignment procedure. If the beam alignment is still unacceptable, contact your local Lumenis representative.

6.6. *Optional Accessories*

The following table offers a list of Lumenis CO₂ laser surgical and aesthetic accessories that may be used with the AcuPulse system. Contact your Lumenis distributor for in-depth information concerning any of these accessories:

- SurgiTouch Scanner
- AcuScan120 Microscanner
- Digital AcuBlade
- Laser Bronchoscope
- Multi-Application / Oral Pharyngeal Handpiece Set
- LAUP (Laser Assisted Uvulopalatoplasty) Handpiece
- FeatherTouch Handpiece Set
- Nasal Probe Set
- Laryngeal Probe Set
- OtoLAM System (with NTSC or PAL video monitors)
- 125mm Incisional Handpiece
- Skin Resurfacing Handpiece Set for SurgiTouch;
Scanner Handpieces: 125mm – spot size ~0.25mm
200mm – spot size ~0.4mm
260mm – spot size ~0.6mm
- AcuSpot 712 Micromanipulator
- AcuSpot 712L Micromanipulator (dedicated to Leica microscopes)
- AcuSpot 712Z Micromanipulator (dedicated to Zeiss microscopes)
- Microslad Models: 715, 716, 717, 718 and 719
- ColpoSlad Models: 725 and 726
- 300mm BeamAlign Coupler
- 200mm BeamAlign Coupler
- BeamAlign Alignment Kit
- Single Puncture Laparoscopic Set
- Second Puncture Laparoscopic Set

6.7. Cleaning, Sterilization and High-level Disinfection



Caution

The instructions given in this section are not applicable to optical or electronic components, such as the SurgiTouch optical head.

6.7.1. General

Proper infection control techniques for a delivery accessory depend on the degree of risk and patient contact involved in the use of that accessory. This section discusses proper techniques for the accessories identified in this chapter as "reusable and sterilizable", primarily external handpiece components.

The system's console should be cleaned with a clean cloth and a mild detergent. The LCD control panel should be cleaned periodically with a dedicated LCD cleaning solution, available from any office supply store.

Other sterilization and disinfection techniques than those detailed may be equally effective. It is the responsibility of the clinical user to validate alternative techniques.

Proper sterilization or disinfection always starts with disassembly, followed by cleaning.

6.7.2. Deciding on Sterilization or High-level Disinfection

All components identified as reusable and sterilizable may have either a sterilization or high-level disinfection process applied. Selecting which is appropriate is based upon the degree of risk involved with its usage in your clinical application.

Refer to the list below to determine the appropriate risk category of each accessory:

Critical items – sterilization is required for instruments or objects that are introduced directly into the bloodstream or into other normally sterile areas of the body.

Semi-critical items – when a noninvasive tool comes into contact with intact mucous membranes, but doesn't penetrate a body surface, a high-level disinfection procedure is recommended as a minimum precaution. Sterilization can also be used, and may be very cost-effective. In most cases, meticulous physical cleaning followed by an appropriate high-level disinfection treatment gives the user a reasonable degree of assurance that the items are free of pathogens.

Non-Critical Items – non-critical items are those that either do not ordinarily touch the patient or touch only intact skin. These items rarely, if ever, transmit disease. Consequently, depending on the particular piece of equipment or item, washing with a detergent may be sufficient.

- SurgiTouch Scanner – **Non-Critical**
- AcuScan120 Microscanner – **Non-Critical**
- Digital AcuBlade – **Non-Critical**
- Laser Bronchoscope – **Critical**
- Multi-Application / Oral Pharyngeal Handpiece Set – **Critical**
- LAUP (Laser Assisted Uvulopalatoplasty) Handpiece – **Critical**
- FeatherTouch Handpiece Set – **Critical**
- Nasal Probe Set – **Critical**
- Laryngeal Probe Set – **Critical**
- OtoLAM System (with NTSC or PAL video monitors) – **Semi-Critical** (only the speculums)
- 125mm Incisional Handpiece – **Critical**
- Skin Resurfacing Handpiece Set for SurgiTouch (Scanner Handpieces 125mm, 200mm, 260mm) – **Critical**
- AcuSpot 712 Micromanipulator – **Non-Critical**
- AcuSpot 712L Micromanipulator (dedicated to Leica microscopes) – **Non-Critical**
- AcuSpot 712Z Micromanipulator (dedicated to Zeiss microscopes) – **Non-Critical**
- Microslad Models: 715, 716, 717, 718 and 719 – **Non-Critical**
- ColpoSlad Models: 725 and 726 – **Non-Critical**
- 300mm BeamAlign Coupler – **Non-Critical**
- 200mm BeamAlign Coupler – **Non-Critical**
- BeamAlign Alignment Kit – **Non-Critical**
- Single Puncture Laparoscopic Set – **Critical**
- Second Puncture Laparoscopic Set – **Critical**

6.7.3. *Repeated
Sterilization or
High-level
Disinfection*

The identified components may be sterilized or disinfected repeatedly until visual inspection detects corrosion, warping, or any corruption of the metal surface.



Caution

Do not reuse if components show signs of corrosion, warping, or corruption of the metal surface.

6.7.4. *Cleaning
Procedure*

After disassembly, use the following cleaning techniques before sterilization or disinfection.

1. Use proper biosafety techniques. Wear waterproof, disposable gloves when handling contaminated parts.
2. Contain soiled components and transport to sterilization work site.
3. Wipe any visible contaminants off the components using a soft gauze pad.
4. Prepare a liquid enzyme-based presoak for medical appliances by dissolving 1 oz. (30 ml) of the solution with 1 gallon (3.8 liters) of cold tap water.
5. Immerse the components in the prepared presoak solution.
6. Soak the components for two minutes.
7. Remove and rinse components thoroughly with cold, running tap water.
8. Prepare a medical instrument detergent cleaner by dissolving ½ oz. (15 ml) of the solution with one gallon (3.8 liters) of cold tap water.
9. Clean the components while immersed by brushing with a soft-bristled brush. Pay close attention to crevices, and hard-to-clean areas.
10. Use a cotton-tipped swab to clean internal channels.
11. Rinse thoroughly with cold tap water.
12. Air-dry or blot dry with a soft cloth.



Note

To help ensure proper sterilization, it is best to clean parts immediately following use.

6.7.5. *Sterilization Techniques*

Steam sterilization using the following procedure is recommended:

1. Place cleaned components in a sterilization container or instrument tray. Components placed on a perforated metal tray must be wrapped in gauze or an instrument wrap.
2. Load and operate the steam sterilizer according to the following guidelines:
 - Sterilizer Type: Gravity Displacement
 - Temperature: 250°F / 121°C
 - Method: Wrapped
 - Sterilization Time: 50 minutes
 - Drying Time: 40 minutes

**Note**

- Sterility Assurance Level (SAL) is 10^6 (6 log reduction).
 - Flash sterilization is not recommended.
-

6.7.6. *High-level Disinfection Techniques*

For high-level disinfection, the following procedure is recommended:

1. Clean components as described in Section 6.7.4.
2. Prepare a liquid enzyme-based presoak for medical appliances according to the manufacturer's instructions.
3. Place cleaned components into a sterile container.
4. Add a high-level disinfection solution to the container, covering the components.
5. Allow components to soak in solution for 45 minutes.
6. Pour off the disinfection solution and cover the components with sterile distilled water.
7. Rinse the items thoroughly with sterile distilled water.
8. Allow components to air-dry.

Chapter 7

Maintenance

7.1. *Introduction*

This chapter contains the maintenance instructions for the AcuPulse laser system. Routine maintenance may be performed by clinic staff unless otherwise specified. Any maintenance procedure not mentioned in this chapter must be performed **only** by Lumenis-authorized technical personnel.



Note

Calibration procedures described in this chapter should be performed only by qualified service personnel. See warning in Section 7.6.

7.2. *Service Information*

In communications with authorized Lumenis representatives regarding the system, always include the model and serial numbers from the identification label located on the system's rear panel (refer to the **Safety** chapter of this manual).

Questions or problems should be referred to your Lumenis representative.



Warning

- Unauthorized servicing or modification of this system, not described in this manual, may expose the operator/patient to potential electrical energy and laser radiation hazards.
 - Improper use or adjustment of this system may invalidate the service warranty agreement.
-

7.3. ***Routine Periodic Maintenance***

Regular cleaning, inspection, testing, and repair are the basis of any effective preventive maintenance program. Such a program helps keep the system in top working order and ensures the reliability of safety interlocks and failsafe mechanisms.

A recommended routine inspection and maintenance schedule is provided in Table 7-1:

Table 7-1: Recommended Routine Inspection and Maintenance Schedule

<i>Inspection / Service</i>	<i>Frequency</i>	<i>Performed By</i>	<i>Remarks</i>
Disinfect / sterilize the non-scanning accessories.	Before each procedure.	Clinic Staff	
Accessories cleaning and maintenance.	After each procedure.	Clinic Staff	
Routine exterior cleaning.	As required by clinic protocol.	Clinic Staff	
Purge air flow check.	Daily	Clinic Staff	If no air flow, replace bacteriological filter.
Inspect accessories, handpieces, cables and all external surfaces for damage.	Weekly	Clinic Staff	If damage is found, call Lumenis Service.
Inspect electrical connections.	Weekly	Clinic Staff	
Check door interlock and laser stop button.	Annually	Clinic Staff	If interlock and button do not perform as required, call Lumenis Service.
Electrical safety checks.	Annually (or as required by institutional procedures).	Lumenis Service	Must be performed only by Lumenis-authorized technical personnel.
Check and perform power meter calibration procedures.	Annually, or as required if system does not perform to specifications, or occurrence of error messages.	Lumenis Service	Must be performed only by Lumenis-authorized technical personnel.
AcuScan120 microscanner lens assembly replacement.	After 10 treatments or before if the lens assembly is stained or otherwise damaged.	Clinic Staff	

7.4. Lumenis Service

Customer-performed maintenance is limited to the procedures contained in Section 7.5. – **Clinic Staff Maintenance**.

The service procedures described in Section 7.6. – **Professional Maintenance** detail the preventive maintenance procedures that must be performed only by Lumenis-authorized technical personnel.

Lumenis Service should also be contacted when service is required for correction of any problem or system fault listed in the troubleshooting tables.

If the AcuPulse must be shipped for service, follow the shipping instructions in Section 7.9.2. Always repackage the system using the original packaging materials.



Caution

Do not ship the system without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Contact Lumenis if packaging materials or repackaging instructions are needed.

7.5. Clinic Staff Maintenance

7.5.1. Visual Inspection

The exterior of the system should be inspected once a week to ensure that there are no loose cable connections and that there is no damage to the system.

7.5.2. Routine Exterior Cleaning

The external surfaces of the system (console, LCD panel and articulated arm) and the footswitch should be cleaned when the system is received, and thereafter as required by clinic protocol.

The outer surfaces of the system may be wiped clean with a soft, lint-free cloth dipped in 70% isopropyl alcohol, or a hospital-grade disinfectant solution.

The LCD panel should be cleaned with a dedicated LCD cleaning liquid, available in most office supply stores.

7.5.3. Safety Interlock Checks

The two safety interlocks to be checked are:

- Door Interlock (see Section 7.5.3.1.)
- Emergency Stop Button (see Section 7.5.3.2.)

7.5.3.1. Door Interlock

Laser beam emission is disabled when the door interlock plug is not connected or is improperly connected to the service panel, even if it is not wired to an actual door interlock. To check this:

1. Set the system to **Standby** mode.
2. Unplug the door interlock plug.
3. Try to select **Ready** mode; the system should display the following error message: **Remote Interlock Fault, Please verify Treatment Room door is closed.**
4. If the system does not display the error message and remains in **Ready** mode, discontinue use and contact Lumenis Service.

7.5.3.2. Laser Stop Button Check

The **Laser Stop Button** is designed to disable the laser when pressed.

To check this interlock:

1. With the system **On**, press down on the laser stop button; the system will reset itself to **Standby** mode.
2. Turn the button clockwise to release it; the system will automatically return to **Standby** mode.
3. Press the **Ready** button on the LCD to enable lasing.

If this is not the situation, discontinue use and contact Lumenis Service.

7.5.4. Purge Air Flow Check

Check the purge air flow as follows:

1. Turn on the system.
2. Set the power to 0.5 Watts.
3. Select CW exposure, continuous wave mode.
4. Remove the air tube from the connection nipple on the system's control panel.
5. Ensure that the system's preferences are set to deliver purge air while the system is in **Ready** mode, without lasing.
6. Set the system to **Ready** mode and check that there is air flow from the nipple.

If there is no air flow, contact Lumenis Service.

7.6. Professional Maintenance

This section covers checks, calibrations and maintenance that require internal access to the AcuPulse console and special skills.



Warning

These procedures demand specific knowledge, training and use of tools not available to repair personnel outside of Lumenis. Since performing these procedures may expose the user to potential electrical and laser energy hazards, Lumenis requires that these procedures only be performed by trained service personnel.

7.6.1. Power Meter Calibration

Power meter check and calibration must be performed by an engineer or technician qualified to work with laser equipment. Questions regarding this procedure should be referred to your local Lumenis representative.

Disclaimer warning:

Calibration is a service procedure to be performed only by Lumenis-certified service engineers. Adjustment by anyone other than a trained Lumenis service engineer voids any existing manufacturer's warranty on the instrument. It is company policy not to distribute service tools outside of the Lumenis Service Organization. Possession of service instructions or tools does not authorize repair or modification of a Lumenis instrument by uncertified personnel.

7.6.1.1. Internal Power Meter Check

The AcuPulse incorporates an internal power meter which is used for display and control of lasing energy. The power meter check compares the internal power meter reading to the reading from an external power meter.



Note

Optical components must be clean before the power meter check is performed.



Warning

- All personnel in the immediate area must wear eye protection rated specifically for the CO₂ laser.
 - An out-of-calibration power meter will cause power delivery to tissue to be different than that displayed.
-

The power meter check procedure is performed as follows:

1. Ensure that all personnel are wearing the appropriate laser safety eyewear.
2. Position a calibrated, external power meter 15 cm (6 inches) from the output end of the laser articulated arm.
3. Turn on the laser as instructed in Chapter 5 – **Operation** – of this manual.
4. Access the **Manual Treatment** screen.
5. Set the laser system to **CW** mode, **Continuous** wave and **5** Watts of delivery power.
6. Target the aiming beam at the external power meter's thermopile disc.
7. Set the laser system to **Ready** mode.
8. Press the footswitch to deliver the laser energy into the external power meter's detector disc. Maintain delivery of the laser energy for 20 seconds.
9. Release the footswitch and record the power meter's reading.
10. Repeat steps 4 through 8 at power settings of **10, 15, 20, 30 & 40** Watts.
11. If the external power meter reading falls above or below $\pm 20\%$ of the requested power on your laser, discontinue this procedure and contact your local Lumenis service representative.

7.7. Software Upgrade

Contact your local Lumenis representative for information concerning available software feature upgrades.

7.8. HASP Upgrade

After performing any feature upgrade to the system, the system's HASP utility needs to be upgraded as well. These upgrades include among others:

- Software package upgrade
- Installing a new scanner

The new HASP utility upgrade will be delivered on a USB flash drive (Disk-on-Key):

1. Connect the USB flash drive to either of the USB connection ports on the system's service panel.
2. Turn on the system and access the HASP utility upgrade by pressing the **Cnfg. Upgrade** button on the **Utilities** screen.
3. When the **Welcome to feature Upgrade!** pop-up window is displayed (see Figure 7-1), follow the on-screen instructions until the upgrade is complete.
4. When the upgrade is complete remove the USB flash drive from the service panel.

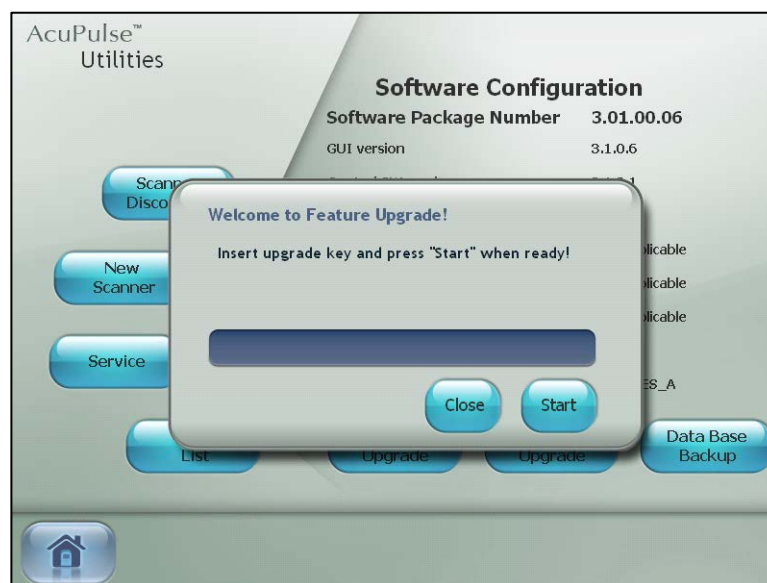


Figure 7-1: System Hasp Plug Upgrade Pop-Up Window

7.9. Moving and Transporting the System

7.9.1. Moving the Assembled System

Most users of the AcuPulse laser system have more than one operating location. The system can easily be moved between them by rolling the console on the base-mounted wheels using the top-mounted maneuvering handle. The only disassembly required is disconnection of the footswitch and power cable to ease maneuvering.

Rather than disconnecting them for each move, it may be easier to install a power cable and footswitch in each location, leaving them in place.

7.9.2. Transporting the System

Prepare the system for transport as follows:

1. Unplug the system from the wall outlet.
2. Disconnect the power cable from the service panel.
3. Disconnect the footswitch from the service panel.
4. Fold and store the articulated arm in its storage compartment in the system's rear panel.
5. Consult your Lumenis representative for shipping advice if desired.



Caution

Do not ship the system without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Contact Lumenis if packaging materials or repacking instructions are required.



Warning

The AcuPulse console weighs ~50 Kg (110 Lbs). Use proper lifting techniques. Do not hurt yourself!

Chapter 8

Troubleshooting

8.1. Introduction

The AcuPulse laser system is equipped with self-testing software that continuously monitors system operation. If a system malfunction is detected, an error message will appear on the display screen. Should a malfunction occur, consult the troubleshooting guides in Section 8.4.

Do not attempt to open or disassemble the system's covers.

Only Lumenis-authorized technical personnel are qualified to service the interior of the system.

8.2. Warranty

The AcuPulse system is warranted for a period of one year.

The surgical and aesthetic accessories are warranted separately, each according to the purchase agreement.



Caution

Improper use or adjustment of this system may invalidate the service warranty agreement. Please contact your authorized Lumenis distributor before attempting to troubleshoot this system in any manner other than those specified in this manual.

8.3. Hazard Precautions

The system generates high electrical voltage and laser radiation within the main cabinet and optical bench. Only Lumenis-authorized technical personnel are qualified to service the interior of the system.

8.4. Troubleshooting Guides

Table 8-1 provides a list of error messages that may appear on the LCD monitor. Some of these situations will automatically reset the system from **Ready** mode to **Standby** mode, and some of them will include possible remedies that may be attended to by clinic staff. In the latter case the operator has the option of correcting the problem setting the system back to **Ready** mode and continuing with normal operation.

Table 8-2 lists some possible system symptoms that indicate malfunctions that do not appear on the display screen. If the corrective action listed in the table does not solve the problem, contact Lumenis-authorized technical personnel.

If any error situation cannot be resolved, or if an error message returns repeatedly, contact Lumenis Service.

The following troubleshooting tables do not attempt to list all possible system failures. Any fault not listed should be referred to authorized technical personnel.

Table 8-1: Error Messages Troubleshooting Guide

Message #	Error Message Text
01	Open shutter error. Please restart system. If error persists, please call service.
02	Closed shutter error. Please restart system. If error persists, please call service.
04	Footswitch error. Please restart system. If error persists, please call service.
06	Footswitch is not connected. Please connect.
07	Footswitch engaged. Please disengage to proceed.
08	Smart Footswitch error – Please replace.
12	Cooling system flow switch error. Please restart system. If error persists, please call service.
13	Cooling system pump current error. Please restart system. If error persists, please call service.
15	Cooling system fan error. Please restart system. If error persists, please call service.
16	Cooling system overheating warning. Please allow 5 minutes for system cool down.
17	Cooling system overheating error. Please allow 20 minutes for system cool down.
18	System fan error. Please restart system. If error persists, please call service.
19	System overheating warning. Please allow 5 minutes for system cool down.
20	System overheating error. Please allow 20 minutes for system cool down.
23	Remote Interlock error. Please verify Treatment Room door is closed.
24	Laser stop button engaged. Please disengage to proceed.
26	HVPS Error. Please restart system. If error persists, please call service.
28	HVPS 110V status error. Please restart system. If error persists, please call service.
34	Invalid parameters error. Please restart system. If error persists, please call service.
35	GUI PC - DSP Communication error. Please restart system. If error persists, please call service.
36	DSP - FPGA Communication error. Please restart system. If error persists, please call service.
37	FPGA Status is 10xx. Please restart system. If error persists, please call service.

Table 8-1: Error Messages Troubleshooting Guide (continued)

Message #	Error Message Text
39	Offset calibration (2.5V) error. Please restart system. If error persists, please call service.
40	Offset calibration (0.5V) error. Please restart system. If error persists, please call service.
41	LVPS 5V error. Please restart system. If error persists, please call service.
42	LVPS $\pm 12V$ error. Please restart system. If error persists, please call service.
43	LVPS -12V error. Please restart system. If error persists, please call service.
44	LVPS +24V error. Please restart system. If error persists, please call service.
45	Power meter disk HW1 error. Please restart system. If error persists, please call service.
46	Power meter disk HW2 error. Please restart system. If error persists, please call service.
47	Power meter reading error. Please restart system. If error persists, please call service.
48	Power meter Low-Med (1W) error. Please restart system. If error persists, please call service.
49	Power meter Med-High (5W) error. Please restart system. If error persists, please call service.
50	Current monitoring error. Please restart system. If error persists, please call service.
51	Self test Interlock error. Please restart system. If error persists, please call service.
53	Current 1, 2 compare error. Please restart system. If error persists, please call service.
54	Temperature monitoring error.
55	On line monitor limit error.
56	Power convergence failure, max reachable power is # xxW
57	Self test power out error. Please restart system. If error persists, please call service.
65	Scanner synchronization error. Please restart system. If error persists, please call service.
66	Scanner communication error. Please restart system. If error persists, please call service.
68	Unsecured scanner disconnection error.
69	Scanner position error. Please restart system. If error persists, please call service.
70	Scanner is disconnected. Please connect.
71	Scanner board present error. Please restart system. If error persists, please call service.
74	Scanner position (X) error. Please restart system. If error persists, please call service. *
75	Scanner position (Y) error. Please restart system. If error persists, please call service. *

(*) Refer to Section 8.5

Table 8-1: Error Messages Troubleshooting Guide (continued)

Message #	Error Message Text
76	Scanner PS $\pm 15V$ error. Please restart system. If error persists, please call service.
78	Scanner ACUBLADE error. Please restart system. If error persists, please call service.
79	Scanner Servo (X/Y) calibration error. Please restart system. If error persists, please call service.
82	Scanner ACUBLADE switch engaged. Please disengage to proceed.
83	SPI Bus error. Please restart system. If error persists, please call service.
84	CAN Bus error. Please restart system. If error persists, please call service.
300	HASP is not connected. Please restart system. If error persists, please call service.
301	HASP is not valid. Please restart system. If error persists, please call service.
302	Data base error. Please restart system. If error persists, please call service.
303	Data base update error. Please restart system. If error persists, please call service.
304	Software error. Please restart system. If error persists, please call service.

Table 8-2: Undisplayed System Malfunctions Troubleshooting Guide

Symptom	Probable Cause	Action
System does not function when plugged in and turned on.	1. No AC power from wall outlet. 2. Tripped power circuit breaker (clinic power supply).	1. Check if AC power is available from wall outlet, and power cable is properly plugged into AC outlet. 2. Reset power circuit breaker.
System will not switch to Ready mode.	1. Footswitch not connected properly. 2. Footswitch malfunction. 3. System malfunction.	1. Check footswitch connection. 2. Contact Lumenis Service. 3. Contact Lumenis Service.
Laser emission does not occur when footswitch is pressed.	1. System is not in Ready mode. 2. Damaged accessory. 3. Footswitch malfunction. 4. System malfunction.	1. Set system to Ready mode. 2. Replace accessory. 3. Contact Lumenis Service. 4. Contact Lumenis Service.
System not responding to touch-screen commands	Control panel's touch-screen is out of calibration.	Contact Lumenis Service.
Laser emission indicator does not flash in Ready mode.	Burnt LED.	Contact Lumenis Service.

Table 8-2: Undisplayed System Malfunctions Troubleshooting Guide (continued)

Symptom	Probable Cause	Action
System changes from Ready to Standby mode without input command.	Inadvertent, light pressure on the footswitch (for more than 3 seconds) may have activated 1 of the 2 internal microswitches, causing the mode change for safety purposes.	Press the Ready key and resume normal operation.

8.5. Scanner Position Error

A scan beam positioning error may occur with the 200mm, 260mm or LAUP laser accessories when connected to the SurgiTouch scanner:

The error may occur on either of the X or Y planes because there are no boundaries to the adjustments that can be made in the Beam Offset correction screen with these accessories (see Section 5.11.1 in Chapter 5).

The error can happen as a result of the following scenario: you have set up the scanner and 260mm handpiece for operation with a small shape size (i.e., 4mm Ø), and you have moved the scan's location off-center using the Beam Offset correction screen to a point near – but not outside – the accessory tube's boundary. Next, you increase the shape to a larger size (i.e., 10mm Ø); a portion of the scan's shape may now fall outside the accessory tube's boundary (see Figure 8-1), causing the error. The system will exhibit error message # **74** or # **75**.

To correct the error: restart the AcuPulse system and select the previously used accessory. Go into the **Beam Offset** screen (via the **Treatment** screen) and press the **Reset Offset** button; this returns the scan shape to the center of the accessory tube's work field.

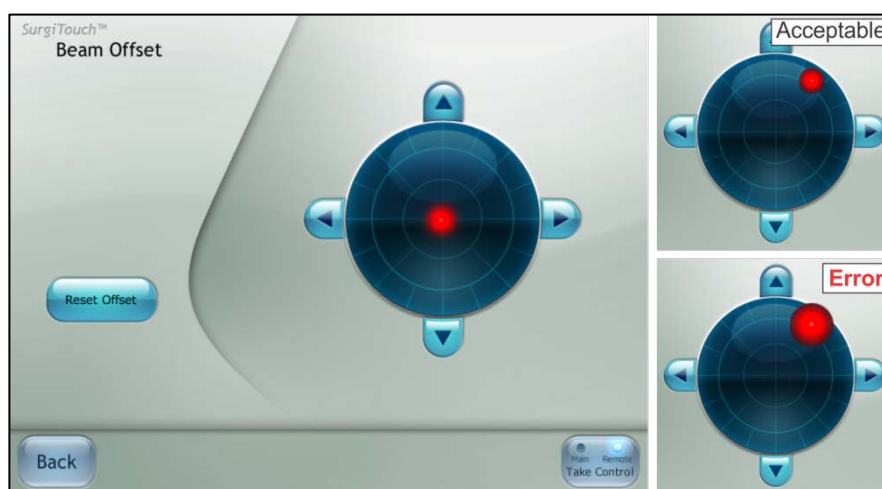


Figure 8-1: Scanner Position Error (for illustration only)

The correct manner to adjust the Beam Offset is as follows:

- 1.** Select the largest scan shape size available.
- 2.** Make your beam offset adjustment.
- 3.** Reduce the scan shape to the desired size.

Appendix A

Clinical Guide: Surgical Applications

A.1. Introduction

This chapter is provided to aid professionals in the use of the AcuPulse laser system for soft tissue applications in surgery. It adds to or reinforces information presented in the operator's manual concerning instructions for use, precautions and warnings necessary to reduce the risk of injury. All operators must read the entire operator's manual before reviewing this section and before operating the system.

A.2. Indications for Use

The intended use of the AcuPulse system is for the vaporization, incision, excision, ablation, or photocoagulation of soft tissue in the surgical specialties of:

- Podiatry
- ENT
- Gynecology
- Laparoscopic Surgery including GYN Laparoscopy.
- Dental and Oral Surgery.
- Neurosurgery
- Orthopedics
- General Surgery and Podiatry.

The carbon dioxide laser wavelength is indicated for use in specific surgical applications, as detailed in this chapter. Read and comprehend all of the following general contraindications, warnings, precautions, and recommendations, as well as indications and safety considerations for appropriate specialties.

The physician is also advised to consult medical publications for clinical parameters, techniques, and other current information on carbon dioxide laser treatment in a particular specialty.



Warning

Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient and the operating room personnel, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.

**Note**

The use of a laser instrument for an application is at the physician's discretion except in cases where the application has been specifically contraindicated.

A.3. Contraindications

- Unless specifically indicated, do not use the CO₂ laser on hard tissues, such as bone or teeth.
- Unless otherwise specifically indicated, do not use the CO₂ laser for cutting or ablating dense, healthy bone or bone marrow (for example, hard palate and mandible).
- Do not use the CO₂ laser on vessels greater than 0.5 mm in diameter, as hemostasis may not be effective
- Do not use the CO₂ laser where a clinical procedure is precluded by anesthesia requirements, site access, or other general operative considerations.

A.4. General Laser Recommendations

- The surgeon must employ appropriate patient selection and pre- and post-operative management.
- Select the appropriate delivery device for the intended application after consulting with surgical experts, reviewing the published literature, and attending procedure-specific training programs.
- Ensuring the immediate availability of other surgical instruments for coagulation (i.e., electrocautery, graspers, sutures, etc.) to control hemostasis is strongly recommended.
- For char-free superficial ablation, pulsed laser modes or a scanner accessory are recommended.
- As with conventional non-laser surgery, there is no guarantee that treatment with the CO₂ laser will entirely eliminate any disease entity. Repeat treatment or alternative therapies subsequently may be required.

A.5. General Safety Considerations**Warning**

- There is a risk of infection and scarring associated with any surgical procedure. Therefore, appropriate pre-and post-surgical care should always be practiced.
 - Purge gases used with CO₂ delivery devices and waveguides may increase the risk of gas embolism where large, open vessels are present. Monitor all patients for gas embolism, which may occur even without the use of the laser.
-

A.6. Podiatry

The AcuPulse laser is indicated for use in podiatry for the following applications:

**A.6.1. Podiatry
Indications**

- Laser ablation, vaporization and/or excision of soft tissue for the reduction, removal, and/or treatment of:
 - ⇒ Verrucae vulgares/plantar (warts), including paronychia, periungual, and subungual warts.
 - ⇒ Fungal nail treatment.
 - ⇒ Porokeratoma ablation.
 - ⇒ Ingrown nail treatment.
 - ⇒ Neuromas/fibromas, including Morton's neuroma.
 - ⇒ Debridement of ulcers.
 - ⇒ Other soft tissue lesions.
- Laser ablation, vaporization, and/or excision for complete and partial (nail) matrixectomy.

**A.6.2. Safety
Considerations and
Complications for
Podiatry**

General podiatry complications include:

- Infection
- Ulceration of tissue.

Laser matrixectomy complications also include:

- Sterile inflammatory condition.

**A.7. Otolaryngology
(ENT)**

The AcuPulse laser is indicated for laser incision, excision, ablation, and/or vaporization of soft tissue in otolaryngology for the treatment of:

A.7.1. ENT Indications

- Choanal atresia.
- Leukoplakia, including oral, larynx, uvula, palatal, and upper lateral pharyngeal tissue.
- Nasal obstruction.
- Adult and juvenile papillomatosis polyps.
- Polypectomy of nose and nasal passages.
- Lymphangioma removal.
- Removal of vocal cord/fold nodules, polyps and cysts.

- Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords.
- Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue.
- Zenker's Diverticulum/ pharyngoesophageal diverticulum [endoscopic laser-assisted esophagodiverticulostomy (ELAED)].
- Stenosis, including subglottic stenosis.
- Tonsillectomy (including tonsillar cryptolysis and neoplasma) and tonsil ablation/tonsillotomy.
- Pulmonary bronchial and tracheal lesion removal.
- Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial).
- Benign and malignant lesions and fibromas (nose and nasal passages).
- Benign and malignant tumors and fibromas (oral).
- Acoustic neuroma in the ear.
- Stapedectomy, Stapedotomy.
- Superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease.
- Telangiectasia/hemangioma of larynx, pharynx, and trachea (includes uvula, palatal, or upper lateral pharyngeal tissue).
- Cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx, and trachea.
- Myringotomy/tympanostomy (tympanic membrane fenestration).
- Uvulopalatoplasty (LAUP, laser UPPP).
- Turbinectomy and turbinate reduction/ablation.
- Septal spur ablation/reduction and septoplasty.
- Partial glossectomy.
- Tumor resection of oral, subfacial and neck tissues.
- Rhinophyma
- Verrucae vulgares (warts).
- Gingivoplasty/gingivectomy.

A.7.2.ENT Contraindications

- LAUP for palatal snoring is contraindicated without demonstrated obstruction by uvulopalatal tissue.
- LAUP for palatal snoring is contraindicated in pediatric patients (less than 16 years) because the upper airway is not fully developed.
- When used as the only form of treatment for palatal snoring, LAUP may not be effective in obese patients, patients with severe tonsillar hyperplasia, patients with macroglossia or patients with disproportionably short necks.

A.7.3.Safety Considerations for General ENT



Warning

- To prevent airway fires and severe injury to the patient, protect endotracheal tubes from exposure to the CO₂ wavelength, or use CO₂ laser-resistant endotracheal tubes.
- To prevent airway fires and severe injury to the patient, do not direct the CO₂ laser at any tracheal tube in any oxygen-enriched environment, or any other environment that supports combustion.
- To prevent airway fires and severe injury to the patient, consideration of the type of anesthesia and ventilation are important.
- To prevent severe injury to the patient, middle ear surgery should be performed with appropriate parameters, considering acoustic and thermal effects.
- Nasal and laryngeal probes (waveguides) produce a divergent beam with a minimum spot size close to the tip of the instrument.
- Avoid placing the tip of the nasal or laryngeal probe (waveguide) in direct contact with tissue to prevent reduction of purge flow and to reduce the risk of systemic gas embolism.
- Patients undergoing oropharyngeal or laryngeal surgery have to be closely watched in the postoperative period for severe edema which may cause life threatening airway obstruction and for uncontrolled bleeding. The length of close observation depends on the specific procedure and is up to the physician's consideration.

A.7.3.1. Safety Considerations for LAUP



Caution

The physician should take appropriate precautions when evaluating and selecting patients presenting with chronic palatal snoring and other significant symptoms of sleep apnea.

A.7.3.2. *Safety
Considerations for
Myringotomy/
Tympanostomy*



Warning

Clinical studies have shown that patency time is directly related to the diameter of the laser fenestration. The average diameter used is 2.0mm; therefore, clinical judgment and caution should be used when exceeding this diameter.

Uncooperative pediatric patients should be appropriately restrained during office OtoLAM myringotomy/tympanostomy procedures.

- It is recommended that a local or topical anesthesia be administered prior to the OtoLAM myringotomy/tympanostomy procedure.
- Following laser-assisted myringotomy/tympanostomy, a pressure-equalizing tube may be used in situations when long-term ventilation has been determined to be necessary.
- Laser assisted myringotomy/tympanostomy should not be performed on patients who do not have an accumulation of middle ear fluid present.

A.7.4. *ENT Complications
and Expected
Sequelae*

General ENT complications include:

- Unintended thermal injury from combustion of anesthesia or other volatile surgical preparation solutions.
- Excessive bleeding.
- Infection
- Edema
- Hearing loss.

Zenker's Diverticulum:

- Transient soft tissue emphysema.
- Mediastinitis

Tonsil Ablation/Tonsillotomy:

- Transient dysphagia.
- Mucosa lesions.

Cordotomy:

- Formation of granuloma.

Turbinate Reduction/Ablation: transient nasal obstruction associated with postoperative edema and limited nasal crusts.

LAUP complications include:

- Excessive bleeding.

- Infection
- Edema
- Rhinophonia
- Nasopharyngeal stenosis.
- Velopharyngeal incompetence.

Myringotomy/tympanostomy complications include:

- Scarring
- Transient otorrea.
- Infection
- Recurrence of otitis media.

**A.8. Gynecology and
GYN Laparoscopy**

The AcuPulse laser is indicated for use in gynecology for the following applications.

**A.8.1. Gynecology and
GYN Laparoscopy
Indications**

- Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of:
 - ⇒ Conization of the cervix, including cervical intraepithelial neoplasia (CIN), and vulvar and vaginal intraepithelial neoplasia (VIN, VAIN).
 - ⇒ Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowenoid papulosa (BP) lesions.
 - ⇒ Leukoplakia (vulvar dystrophies).
 - ⇒ Incision and drainage (I&D) of Bartholin's and nabothian cysts.
 - ⇒ Herpes vaporization.
 - ⇒ Urethral caruncle vaporization.
 - ⇒ Cervical dysplasia.
 - ⇒ Benign and malignant tumors.
 - ⇒ Hemangiomas.
- Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including gynecological laparoscopy, for the treatment of:
 - ⇒ Endometrial lesions, including ablation of endometriosis.
 - ⇒ Excision/lysis of adhesions.
 - ⇒ Salpingostomy
 - ⇒ Oophorectomy

- ⇒ Fimbrioplasty
- ⇒ Metroplasty
- ⇒ Microsurgery (tubal).
- ⇒ Uterine myomas and fibroids.
- ⇒ Ovarian fibromas and follicle cysts.
- ⇒ Uterosacral ligament ablation.
- ⇒ Hysterectomy

A.8.2. *Gynecology and GYN Laparoscopy Contraindications*

- Use of the CO₂ laser is contraindicated for patients who are not candidates for general surgery, where local or spinal epidural anesthesia is inappropriate.
- Use of the CO₂ laser is contraindicated for laparoscopic applications where laparoscopy is contraindicated.

A.8.3. *Safety Considerations for Gynecology and GYN Laparoscopy*



Warning

- When using a laser laparoscope or waveguide accessory, maintain an adequate flow of purge gas through the delivery device. High purge flows require a specialized purge system or recirculating insufflator/ smoke evacuator to prevent over-pressurization and over-distention of the pneumoperitoneum and resultant complications.
- Ensure that the laser laparoscope is properly aligned and a clear, round aim beam is visible at all times.
- Laparoscopic waveguides produce a divergent beam with a minimum spot size close to the tip of the instrument.
- Avoid placing the tip of the waveguide in direct contact with tissue to prevent reduction of purge flow and to reduce the risk of systemic gas embolism.
- In patients of fertility age, whenever surgery on the uterus is planned either by laparoscopy or hysteroscopy, pregnancy has to be excluded.

A.8.4. *Gynecology and GYN Laparoscopy Complications*

Gynecology and laparoscopic surgery complications include:

- Excessive bleeding.
- Infection
- Excessive thermal injury or vaporization of tissue.
- Gas embolism
- Subcutaneous emphysema.

A.9. Neurosurgery Indications

The AcuPulse laser is indicated for laser incision, excision, ablation and/or vaporization of soft tissue in neurosurgery for the treatment of the following indications (note Restriction below*):

- **Cranial**

- ⇒ Posterior fossa tumors.
- ⇒ Peripheral neurectomy.
- ⇒ Benign and malignant tumors and cysts, for example, gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas, and large tumors.
- ⇒ Arteriovenous malformation.
- ⇒ Pituitary gland tumors (transphenoidal approach).

- **Spinal Cord**

- ⇒ Incision/excision and vaporization of benign and malignant tumors and cysts.
- ⇒ Intra- and extradural lesions.
- ⇒ Laminectomy/laminotomy/microdiscectomy.

Restriction

Neurological indications in contact with Central Nervous System are only for USA.

A.9.1. Neurosurgery Contraindications

Do not use the laser on tumors that are inoperable or inaccessible with the laser beam.

A.9.2. Safety Considerations for Neurosurgery



Warning

Using the laser to open the dura causes shrinkage that may make closure difficult or impossible.

A.9.3. Neurosurgery Complications

- Gas embolism
- There are no known complications specific to the use of the CO₂ laser in neurosurgery. However, the physician is advised to consult current literature for any new information on potential neurosurgery complications relating to CO₂ laser treatment.

A.10. Orthopedics

The AcuPulse laser is indicated for incision, excision, and vaporization of soft tissue in orthopedic surgery, including the following applications.

**A.10.1. Orthopedics
Indications**

- Arthroscopy
 - ⇒ Meniscectomy
 - ⇒ Chondromalacia
 - ⇒ Chondroplasty
 - ⇒ Ligament release (lateral and other).
 - ⇒ Excision of plica.
 - ⇒ Partial synovectomy.
- General
 - ⇒ Debridement of traumatic wounds.
 - ⇒ Debridement of decubitus and diabetic ulcers.
 - ⇒ Microsurgery
 - ⇒ Artificial joint revision.
 - ⇒ PMMA removal.

**A.10.2. Safety
Considerations for
Orthopedics****Warning**

- When performing arthroscopic surgery with waveguides where purge gas is required, control the purge gas with a tourniquet to prevent pressurization of an enclosed space (for example, shoulder), which can result in gas embolism or systemic subcutaneous emphysema.
- Residual carbon by-products of tissue vaporization are believed to increase the risk of postoperative synovitis and other complications. Mechanically scrape observed char from lased tissue surfaces following use of the laser.

**A.10.3. Orthopedics
Complications**

Orthopedics complications include:

- Subcutaneous emphysema.
- Synovitis

A.11. General and Thoracic Surgery

The AcuPulse laser is indicated for incision, excision, and vaporization of soft tissue in general and thoracic surgery, including endoscopic and open procedures. Applications include the following.

A.11.1. General and Thoracic Surgery Indications

- Debridement of decubitus ulcers, stasis, diabetic, and other ulcers.
- Mastectomy
- Debridement of burns.
- Rectal and anal hemorrhoidectomy.
- Breast biopsy.
- Reduction mammoplasty.
- Cytoreduction for metastatic disease.
- Laparotomy and laparoscopic applications.
- Mediastinal and thoracic lesions and abnormalities.
- Skin tag vaporization.
- Atheroma
- Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips.
- Pilonidal cyst removal and repair.
- Abscesses
- Other soft tissue applications.

A.11.2. Contraindications for General and Thoracic Surgery

Use of the CO₂ laser is contraindicated for laparoscopic procedures where laparoscopy is contraindicated.

A.11.3. Safety Considerations for General and Thoracic Surgery

Refer to Gynecology in this chapter for safety considerations that are specific to laparoscopic procedures.

A.11.4. General and Thoracic Surgery Complications

General and thoracic surgery complications include:

- Excessive bleeding.
- Infection
- Excessive thermal injury or vaporization of tissue.

A.12. Dental and Oral Surgery

The AcuPulse laser is indicated for incision, excision, and vaporization of soft tissue in dentistry and oral surgery. Applications include the following.

A.12.1. Dental and Oral Surgery Indications

- Gingivectomy/removal of hyperplasias.
- Gingivoplasty
- Incisional and excisional biopsy.
- Treatment of ulcerous lesions, including aphthous ulcers.
- Incision of infection when used with antibiotic therapy.
- Frenectomy (frenum release).
- Excision and ablation of benign and malignant lesions.
- Homeostasis
- Operculectomy
- Crown lengthening.
- Removal of soft tissue, cysts, and tumors.
- Oral cavity tumors and hemangiomas.
- Abscesses
- Extraction site hemostasis.
- Salivary gland pathologies.
- Preprosthetic gum preparation.
- Leukoplakia
- Partial glossectomy.
- Periodontal gum resection.

A.12.2. Contraindications for Dental and Oral Surgery

Use of the CO₂ laser is contraindicated for hard tissue applications.

A.12.3. Safety Considerations for Dental and Oral Surgery**Warning**

While directing the laser beam near the tooth, shield the tooth from laser energy using either nonreflecting metal or an instrument inserted between the tooth and gum, being careful to prevent laser reflection.

A.12.3.1. Complications of Dental and Oral Surgery

Dental and oral surgery complications include:

- Laser damage to teeth through inappropriate use.
- Infection

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Appendix B

Clinical Guide: Aesthetic Applications

B.1. Introduction

This chapter is provided to aid professionals in the use of the AcuPulse laser system for soft tissue treatments in dermatology and plastic surgery applications. It adds to, or reinforces, information presented in the operator's manual concerning instructions for use, precautions and warnings necessary to reduce the risk of injury. All operators must read the entire operator's manual before reviewing this section and before operating the system.

This clinical guide does not cover the use of the different handpieces.

The AcuPulse laser system is intended solely for use by physicians trained in the operation of CO₂ lasers.

Read and comprehend all of the following general contraindications, warnings, precautions, and recommendations, as well as indications and safety considerations for the appropriate specialties.

The physician is also advised to consult medical publications for clinical parameters, techniques, and other current information on carbon dioxide laser treatment in a particular specialty.

B.2. Indications for Use

The intended use of the AcuPulse system is for the vaporization, incision, excision, ablation, or coagulation of soft tissue in the aesthetic surgical specialty. The carbon dioxide wavelength is indicated for use in specific aesthetic applications, as detailed in this chapter.



Warning

Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient, yourself and the operating personnel, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation. Should you have any questions, consult with your local Lumenis representative.

**B.3. General
Contraindications**

- Do not use the CO₂ laser on hard tissues, such as bone or teeth.
- Do not use the CO₂ laser for cutting or ablating dense, healthy bone or bone marrow (for example, hard palate and mandible).
- Do not use the CO₂ laser on vessels greater than 0.5 mm in diameter, as hemostasis may not be effective.
- Do not use the CO₂ laser where a clinical procedure is precluded by anesthesia requirements, site access, or other general operative considerations.
- Do not use the CO₂ laser if the following conditions apply to the patient:
 - ⇒ Any concurrent cancer or history of skin cancer, except treatment of specifically indicated skin cancer lesions (see Dermatology indications for use below).
 - ⇒ Immune-compromised conditions (i.e., uncontrolled diabetes).
 - ⇒ Known anticoagulation treatment or thromboembolic condition.
 - ⇒ Pregnancy or possibility of pregnancy, postpartum or nursing.
 - ⇒ Use of photosensitive medication and/or herbal preparations for which exposure to the 10.6 micron laser wavelength is contraindicated.
 - ⇒ Medical history of Koebnerizing isomorphic diseases (vitiligo, psoriasis).
- Do not use the CO₂ laser if the following conditions apply to the treated area:
 - ⇒ Recent exposure to sun in the 4-6 weeks pre-op plan or artificial tanning in the past 2-3 weeks pre-op plan, remaining suntan, sunburn or artificially toned skin.
 - ⇒ Any concurrent skin condition such as active infections.
 - ⇒ Active Herpes simplex (treatment can be given post preventive treatment).

**B.4. Dermatology and
Plastic Surgery
Contraindications**

Patients should not be considered for laser skin resurfacing procedures if they:

- Have taken Isotretinoin within the past 12 months.
- Have a history of poor wound healing.
- Have a history of keloid formation, unless specifically indicated.
- Demonstrate excessive or unusually prolonged erythema or edema (post- appropriate laser test patching) that may lead to hyper-pigmentation or hypopigmentation.

**B.5. General Laser
Recommendations**

- The physician must select appropriate patients and manage the pre- and post-operative care.
- Select the appropriate delivery device for the intended application after consulting with medical experts, reviewing the published literature, and attending procedure-specific training programs and preceptorships.
- As with conventional non-laser procedures, there is no guarantee that treatment with the CO₂ laser will entirely eliminate any lesion entity. Repeat treatment or alternative therapies subsequently may be required.

**B.6. General Laser
Safety
Considerations****Warning**

- There is a risk of infection and scarring associated with any CO₂ procedure. Therefore, appropriate pre- and post-treatment care should always be practiced.
 - All personnel within the operating area of the laser must wear suitable 10.600nm eye protection with a minimum optical density (OD) of **5.0**.
-

**Caution**

Laser test patching in an small inconspicuous area within the treatment zone is recommended prior to treatment to validate desired parameters and to avoid unexpected results.

B.7. Dermatology/Plastic Surgery (Aesthetic)

B.7.1. Dermatology/ Plastic Surgery Indications

The AcuPulse laser is indicated for use in dermatology and plastic surgery for the following applications.

- Ablation, vaporization, excision, incision, and coagulation of soft tissue in the performance of:
 - ⇒ Laser skin resurfacing for the reduction, removal and /or treatment of:
 - Wrinkles, rhytids, and furrows (including fine lines and texture irregularities).
 - Keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheic wart and verruca seborrheica.
 - Vermillionectomy of the lip.
 - Cutaneous horns.
 - Solar/actinic elastosis.
 - Cheilitis, including actinic cheilitis.
 - Lentigines, including lentigo maligna or Hutchinson's malignant freckle.
 - Uneven pigmentation/dyschromia.
 - Acne scars.
 - Surgical scars.
 - Keloids including acne keloidalis nuchae.
 - Hemangiomas (including buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectatica).
 - Removal of small skin tumors, including periungual (Koenen) and subungual fibromas.
 - Superficial benign pigmented lesions.
 - Adenosebaceous hypertrophy or sebaceous hyperplasia.
 - Rhinophyma reduction.
 - Cutaneous papilloma (skin tags).
 - Milia
 - Debridement of eczematous or infected skin.
 - Basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions.
 - Nevi, including spider, epidermal and protruding.

- Neurofibromas
- Laser de-epithelialization.
- Tricoepitheliomas
- Xanthelasma palpebrarum.
- Syringoma
- Laser dermabrasion.
- Laser burn debridement.
- Laser ablation, vaporization, and/or excision for complete and partial nail matrixectomy.
- Vaporization/coagulation of:
 - ⇒ Benign/malignant vascular/avascular skin lesions.
 - ⇒ Moh's surgery
 - ⇒ Lipectomy
 - ⇒ Verrucae and seborrhoecae vulgares, including paronychial, periungual, and subungual warts.
- Laser incision and/or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.
- Laser incision and/or excision of soft tissue for the creation of recipient sites for hair transplantation.

B.7.2. Dermatology and Plastic Surgery Contraindications

Patients should not be considered for laser skin resurfacing procedures if they:

- Have taken Accutane® (Isotretinoin) within the past 6-12 months.
- Have a history of keloid formation.
- Have a history of poor wound healing.
- Demonstrate excessive or unusually prolonged erythema or edema (post- appropriate laser test patching) that may lead to hyper-pigmentation, or hypopigmentation.

B.7.3. Safety Considerations for Dermatology and Plastic Surgery



Caution

In some treatments (for example tattoo removal), scar tissue formation has been reported which may fade or become permanent. Therefore, use of the CO₂ laser for cosmetic removal of dermal skin lesions should be performed with caution since there is a potential for scar formation.

*B.7.4. Complications,
Expected Side
Effects and
Immediate
Responses*

General dermatology and plastic surgery potential complications include:

- Scarring
- Ulceration
- Persistent edema and/or erythema.
- Infection

General dermatology and plastic surgery expected side effects include:

- Erythema that resolves over time.
- Swelling/edema that resolves over time.

In addition to these general complications and side effects, note the following procedure-specific complications and responses.

Rhinophyma potential complications include:

- Transient pustule formation.
- Alar lift

Laser Matrixectomy potential complications include:

- Sterile inflammatory condition.

Blepharoplasty potential complications include:

- Ectropion
- Asymmetry of eyelids.
- Fold release (Asian eyelids).
- Wound dehiscence
- Postoperative bleeding
- Hematoma
- Keratoconjunctivitis sicca (dry eyes)
- Suture abscesses that resolve without treatment.
- Allergic reaction to surgical suture material.
- Conjunctivitis (usually transient).
- Ptosis (usually transient).

Blepharoplasty expected immediate responses include:

- Minimal bruising and swelling (as compared to cold steel).
- Minimal ecchymosis (as compared to cold steel).

- Reduced intra-operative and/or post-operative pain (as compared to cold steel)
- Slightly reduced healing time (as compared to cold steel)

Laser skin resurfacing potential complications include:

- Hypopigmentation
- Hyperpigmentation that resolves over time.
- Scarring that generally resolves over time with steroid treatment.
- Induration that generally resolves over time with steroid treatment.
- Formation of fibrotic tissue that generally resolves over time with steroid treatment.
- Preauricular flap necrosis
- Postauricular skin slough/loss

Laser skin resurfacing possible short-term reactions include:

- Transient pain that is observed immediately post-operatively and generally resolves quickly.
- Transient burning sensation that is observed immediately post-operatively and generally resolves quickly.
- Itching that generally resolves within the first 2 weeks post-operatively.
- Sensation of tightness that resolves over time.

Laser skin resurfacing possible medium-term reactions include:

- Crusting that is observed immediately post-operatively through 2 weeks postoperatively.
- Formation of milia that resolves over time.
- Contact irritant dermatitis to postoperative topical agents (primarily antibiotics).
- Reactivation of herpes simplex.



Caution

The incidence and duration of post-operative hyperpigmentation may be higher in patients with darker skin types (Fitzpatrick IV-VI,) than in patients with lighter skin types (Fitzpatrick I-III). Selection of treatment parameters should be considered carefully to reduce the post-inflammatory response and care should be employed to perform test patching before the procedure within sufficient period of time as per skin type.

B.8. Patient Care and Treatment Recommendations

The medical management of resurfacing is an evolving field. In addition to studying current literature regarding the latest techniques, physicians are advised to obtain training by attending professional workshops and preceptorships conducted by specialists in resurfacing.

The wavelength of this laser is absorbed by water. Combined to appropriate treatment parameters, the laser beam provides an efficient source of energy for the cutting and ablation of tissue with high water content. This efficiency is coupled with a controlled residual heating that may stimulate the wound healing process.

The effect of heat on the skin is both immediate and prolonged. Immediate effect can be noted by erythema and edema due to the ablation, coagulation and related skin inflammation process and collagen denaturing that may also result in skin shrinkage. The long-term effect leads to fibroblast activation and collagen remodeling. Therefore the accumulated effect of treatment is expected over time and should be explained to the patient.

The AcuPulse enables the use of four resurfacing techniques:

- **Full resurfacing** – the full surface of the treated area, epidermis to dermis, are ablated to the desired depth according to the selected parameters. Full resurfacing can only be achieved when using the Skin Resurfacing Handpiece Set for SurgiTouch (Scanner Handpiece 125mm, 200mm or 260mm).
- **Deep resurfacing in a fractional manner** – 120 micron laser spots ablate a fraction of the epidermis and dermis causing demarcated zones of deep impact with surrounding healthy tissue, the relation of which is dependent on the selected energy and coverage. Deep resurfacing in a fractional manner can only be achieved when using the AcuScan120 microscanner.
- **Superficial resurfacing in a fractional manner** – 1.3mm laser spots ablate a fraction of the epidermis and a minimal amount of dermis causing demarcated zones of superficial impact with surrounding healthy tissue, the relation of which is dependent on the selected energy and coverage. Superficial resurfacing in a fractional manner can only be achieved when using the AcuScan120 microscanner.
- **Combo resurfacing in a fractional manner** – using the same AcuScan120 microscanner, **Superficial** and **Deep** fractional resurfacing are made possible within the same scan combining the above-described features. When using **Combo** mode, as compared to Superficial or Deep alone, consider prolonged treatment downtime.

The **Deep** and **Superficial** resurfacing techniques may be used separately or in conjunction for combined treatment, according to the desired effect.

B.8.1. Pre-Operative Care

Review and align with the patient the expectations for immediate and long-term effect of treatment. Proper patient selection for fractional laser resurfacing is essential.

- Smokers should be instructed to decrease smoking as much and as long as possible before and after procedure to minimize the risk of delayed or impaired wound healing.
- At the discretion of the physician, patients with Types III-VI skin may be prescribed topical tyrosinase inhibitors, or an equivalent depigmenting agent to prepare the skin.
- Patients with unrealistic expectations should be identified during the consultation and discouraged.
- Once the appropriate laser candidate is selected, documentation in the form of written, informed consent is essential as well as photo documentation.

Along with your patient, decide on the prophylactic anti-viral, antibiotic and antifungal drug that will suit the best for the planned treatment.

Ensure that the patient's skin area to be treated is thoroughly clean and dry prior to treatment. If topical anesthesia is used prior to treatment, it is important to ensure thorough removal, cleaning and drying of the treatment area before treatment.

- Follow the guidelines of the manufacturing healthcare professional for application dosage, occlusion and timing.
- Topical anesthetic:
 - ⇒ Must be applied at the medical facility under the supervision of a licensed practitioner.
 - ⇒ Should not be applied to large areas because of the potential risk for systemic absorption.

Prior to laser resurfacing, a test patch should be conducted with treatment settings in a small inconspicuous area, but still in the requested anatomical treatment zone.

- Especially people with darker skin types (Fitzpatrick IV to VI), with sensitive skins or without pre-treatment regimen may develop delayed healing, hyper- or hypopigmentation.
- Selection of treatment parameters should be considered carefully and care should be employed to evaluate test patching following an appropriate period of time.

B.8.2. Post-Operative Care

- Patients should be instructed to abstain from thermal impact or mechanical injury to the treated area following treatment.
- Patients should apply cold gauzes soaked in sterile saline solution immediately after treatment.
- Patients should be instructed that, as part of the wound healing process, skin crusts (eschar) will appear in the treated area and should be left to shed of naturally. Do not debride (wipe off eschar) and do not use a wound dressing as these may prolong healing time. The denatured eschar will serve as a completely bio-compatible wound dressing.
- Patients should maintain an occlusion barrier coating of bland petroleum-based ointment or an equivalent occlusive ointment or dressing, to prevent direct contact between the treated tissue and the air during the healing process.

**Note**

The use of a barrier coating improves patient comfort, prevents inflammation and reduces the sensation of pain and burning by preventing air from contacting the treated region. The occlusive dressing should be maintained or changed as needed until crusting of the serous exudates is diminished.

- The patient should gently wash area with tepid water and mild cleanser 3-4 times a day, starting morning after treatment; immediately re-apply occlusive ointment for a “glossing” effect.
- Avoid environmental irritants during healing process (i.e. dust, dirt, perfume, sun).
- Patients should discontinue use of occlusive ointment and begin the use of a facial moisturizer following wound closure and as per the physician's discretion.
- The patient should resume daily use of sunscreen and topical tretinoin following wound healing. At the discretion of the physician, patients with Types III-VI skin may also resume use of topical tyrosinase inhibitors, or an equivalent depigmenting agent (twice daily).
- Recommend that the patient avoid direct sunlight as part of the early post-op instructions and then uses sun protector with high SPF (50+) for at least 2 months after the treatment.

B.9. Adverse Event Management

**Note**

If there is any adverse effect, treatment should be discontinued until the treatment site has completely healed and the reason for the adverse reaction is understood.

Laser skin resurfacing procedures have a minimal risk of adverse effects.

In the rare cases where adverse effects do occur, the most common are:

- **Pruritus**

- ⇒ Mild-to-moderate pruritus may occur during re-epithelialization and may last for about 10 days.
- ⇒ Recent evidence suggests that this symptom relates to a yeast infection or colonization in healing skin.
- ⇒ Treatments with emollients or topical steroids are the common practice.

- **Acne Flares and Milia**

- ⇒ Swelling of the skin from the procedure, and skin debris – dead skin cells – left behind may block pores. Blockage of the pores can lead to build up of skin oils.
- ⇒ May last for approximately 12 days.
- ⇒ Limitation of the occlusiveness of healing ointments mostly minimizes the risk.

- **Post-Inflammatory Hyperpigmentation**

- ⇒ PIH may become apparent between 2 weeks and 2 months after post-operative erythema has resolved.
- ⇒ As soon as re-epithelialization is complete and erythema resolved, a topical bleaching regimen may be prescribed.
- ⇒ Post-inflammatory hyperpigmentation is usually reversible over time. It can take between 3-6 months and can be easily concealed in the meantime with makeup.

- **Hypopigmentation**

- ⇒ May be clinically apparent 1 to 6 months after treatment. It is more commonly observed on darker skin types and often related to the depth of resurfacing or to the usage of inappropriate laser parameters.
- ⇒ Sun exposure must be avoided (imperative); it may actually worsen the change of pigmentation and its duration.
- ⇒ May last 6-12 months but could also remain permanent.

- **Scarring**

⇒ Most often result from poor technique, poor post-operative care or post-operative infection.

⇒ May be treated with injections of intralesional corticosteroids.

B.10. References

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Appendix C

EMC Guidance and Manufacturer's Declaration

C.1. Electromagnetic Emissions

<i>Guidance and Manufacturer's Declaration - Electromagnetic Emissions</i>		
AcuPulse is intended for use in the electromagnetic environment specified below. The customer or the user of AcuPulse should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment – guidance
RF emissions CISPR 11	Group 1	AcuPulse 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	AcuPulse 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 IEC61000-3-3	Complies	

C.2. Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
AcuPulse is intended for use in the electromagnetic environment specified below. The customer or the user of AcuPulse should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±2,4,6kV contact ±2,4,8kV 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 IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV line to ground ±1kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV Differential mode ±2kV Common mode	±0.5, 1kV Differential mode ±0.5, 1, 2kV 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 IEC61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec.	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of AcuPulse requires continued operation during power mains interruptions, it is recommended that AcuPulse be powered from an uninterrupted power supply or a battery.
Power frequency (50/60Hz) 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.
NOTE: Ut is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (continued)			
AcuPulse is intended for use in the electromagnetic environment specified below. The customer or the user of AcuPulse should ensure that it is used in such an environment.			
			Portable and mobile RF communications equipment should be used no closer to any part of the AcuPulse system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 Vm	$d = 1.17\sqrt{P}$ 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: 
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 AcuPulse is used exceeds the applicable RF compliance level above, the AcuPulse should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AcuPulse. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

C.3. Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the AcuPulse			
The AcuPulse is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AcuPulse can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AcuPulse as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
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.			