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SHARPLAN 1041S

CO_2 SURGICAL LASER SYSTEM

USER'S MANUAL

Notes:

1. *System and accessory specifications subject to change without notice*
2. *Manual Catalog No. PB2395300*
3. *Manual Version No. D*
4. *System Software Versions: Master 1.24D/KBDC 1.25D*
5. *Prepared March 1996*

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ISO-9001

CE

This device complies with the requirements of 89/336/EEC Directive concerning Electromagnetic Compatibility

Use of Manual:

The SHARPLAN 1041S system is designed to meet international safety and performance standards. Personnel operating the unit 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 SHARPLAN representative for clarification.

This manual should always accompany the unit, and its location must be known to all personnel operating the unit. Additional copies of this manual are available at cost price from your SHARPLAN distributor.

TABLE OF CONTENTS

TABLE OF CONTENTS Cont.

TABLE OF CONTENTS (cont.)

TABLE OF CONTENTS (cont.)

TABLE OF CONTENTS (cont.)

TABLE OF CONTENTS (cont.)

TABLE OF CONTENTS (cont.)

TABLE OF CONTENTS (cont.)

TABLE OF CONTENTS (cont.)

TABLE OF CONTENTS (cont.)

TABLE OF CONTENTS (cont.)

LIST OF ILLUSTRATIONS

LIST OF TABLES

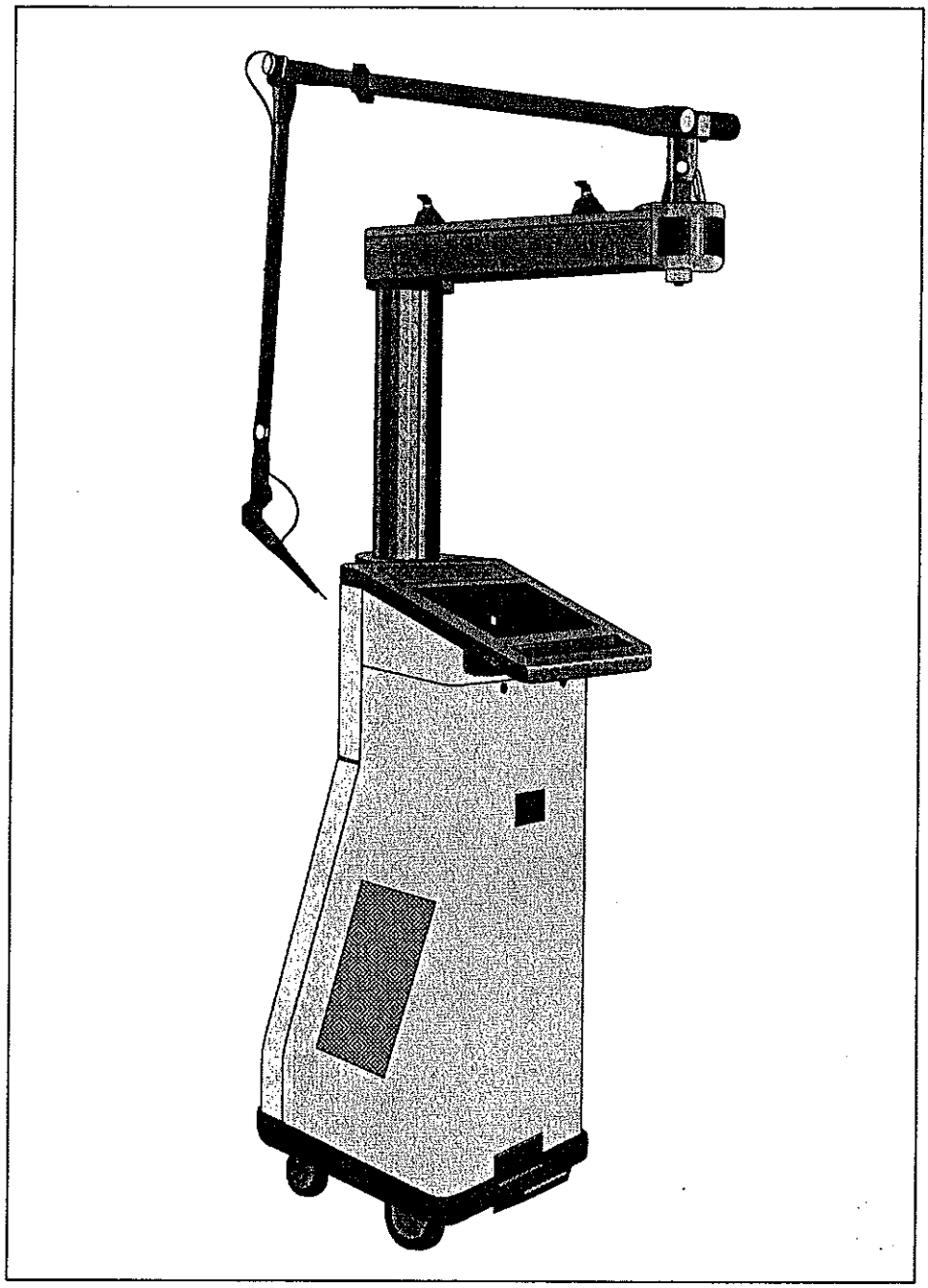


Figure 1. SHARPLAN 1041S Laser Unit

Chapter 1

Operating Safety Precautions and Compliance With International Standards

1.1. General

The SHARPLAN 1041S CO_2 surgical laser system is specially designed to minimize accidental exposure to hazardous radiation.

> **Cautions**
>
> 1. Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure. Therefore, personnel operating the SHARPLAN system must be thoroughly familiar with all its safety requirements and operating procedures.
>
> 2. Improper use or adjustment of this system may invalidate the SHARPLAN service warranty agreement. Please contact your SHARPLAN representative before attempting to use this system in any manner other than as specified in this manual.

The areas of concern for safe CO_2 laser operation are discussed in this chapter.

1.2. Burn Hazard

CO_2 laser radiation is invisible to the human eye and can cause third-degree burns, even when unfocused.

1.3. Reflection and Direct Eye Exposure Hazard

The system output beam contains visible and invisible laser radiation that is hazardous to the eye. **Never stare into the CO_2 laser beam or allow it to be reflected from any reflecting surface – even rough metal can reflect the CO_2 laser beam.** As a precaution against accidental exposure to the output beam or to its reflections, all personnel must wear safety eyewear.

Never stare directly into the He-Ne beam. Also ensure that the He-Ne beam is not directed at anyone's eyes. Although this beam is low powered, direct exposure can be hazardous to eyes.

1.4. Safety Eyewear

All personnel in the vicinity of the laser unit **must** wear safety eyewear, and must ascertain that the eyewear provides adequate protection from the 10.6 micron wavelength radiation. This is generally provided by most quality safety glass spectacles with side guards for protection from lateral exposure. The American Optical spectacle-type safety glasses, or equivalent, provide ample protection.

Safety eyewear is not required when viewing through a microscope, colposcope or an endoscope, as the glass lenses provide sufficient protection.

1.5. Patient Safety

For enhanced patient safety, perform the following safety procedures:

1. Surround the surgical area with wet towels.
2. Make sure that safety eyewear is available to the patient, if conscious.

For facial surgery, completely cover the patient's eyes with moistened eye pads.

1.6. Explosion and Fire Hazard

Do not operate the unit in the presence of flammable anesthetics or volatile substances such as alcohol, gasoline or solvents. Flammable drapes, surgical gowns, gauze and other ignitable materials must be kept out of the beam path. The use of nonflammable materials and instruments is advised. Flame retardant surgical drapes, gowns, etc., are recommended. A readily accessible fire extinguisher in the vicinity of the unit is also recommended.

1.7. High Voltage Hazard

The SHARPLAN 1041S unit generates high voltages within the main cabinet. To avoid injury, do not operate the unit before ensuring that all its panels are properly closed. Do not attempt to remove or disassemble any panels. SHARPLAN-authorized technical personnel **only** may service the unit.

1.8. Using the Proper Power Receptacle And Plug

Use only a power receptacle and plug that are in good condition, and that are specified for your unit.

Use only a hospital grade plug and a correctly matched power receptacle.

The wiring instructions are noted on the hospital grade connection label attached to the power cord (see 1.11).

To remove the power cord from the receptacle, hold it by the plug. Never pull the power cord to remove the plug from the receptacle.

1.9. Grounding the Unit

The unit is grounded through the grounding conductor in the power cord. Good grounding is essential for safe operation. To ensure grounding reliability, always plug the power cord into a properly wired hospital grade power receptacle.

Additional grounding can be provided by using the external ground connection point (see 2.4).

1.10. Fuse Replacement

The operator may replace the fuses on the service panel **only** (see Figure 4-5, item 48). Access to fuses inside the main cabinet is limited to SHARPLAN-authorized technical personnel **only**.

To avoid fire hazard, use **only** the fuses specified for your unit. Replacement fuses must be identical in type, voltage rating and current rating to the original fuses. Fuse type is LITTLEFUSE No.212 slow-blow, or equivalent.

For exact fuse rating, refer to the fuse listing on the service panel.

Note

The fuse originally labeled as 3A may be replaced by a slow-blow fuse rated for 3.15A.

Warning

Before removing a fuse, turn off the keyswitch, remove the power cord from the power receptacle and wait approximately two minutes to allow high voltage discharge.

1.11. Compliance with International Standards

The SHARPLAN 1041S laser unit complies with:

- U.S. Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for Class IV laser products
- European Directive 89/336/EEC Concerning Electromagnetic Compatibility.

The SHARPLAN 1041S laser unit is designed to comply with the IEC 601-1 Standard for Safe Use of Electromedical Equipment, the IEC 825-1 Safety of Laser Products – Equipment Classification Requirements, and the User's Guide for Class IV Laser Products.

In compliance with these standards, the SHARPLAN 1041S unit is equipped with a protective housing for the laser beam, a master keyswitch, an isolation transformer, an emission indicator, a beam shutter, a power display, a remote interlock system connection and proper labeling.

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

1.12. Warning, Certification and Identification Labels

Figure 1-1 shows the location of the important labels affixed to the unit. These include:

1. Laser emission danger label – warning against possible exposure to laser radiation and specifying the types of lasers present. (Location: main cabinet front panel, upper left-hand corner)
2. Non-interlocked danger label – warning against possible radiation exposure when laser enclosure is opened. (Location: periscope inner metal cover, visible upon removal of periscope outer plastic cover)
3. Laser aperture warning label – indicating laser beam exit location. (Location: articulated endjoint)
4. Certification label – assuring that the unit complies with U.S. Federal Performance Standards. (Location: on inside of service panel access door)
5. Identification label – noting unit model number, serial number, electrical requirements and date of manufacture. (Location: on inside of service panel access door)
6. Fuses warning label – warning that replacement fuses must be identical in type and rating to the original fuses, and specifying fuse types. (Location: on inside of service panel access door)
7. Class I, type B label – indicating that the unit meets class I type B requirements, as defined in IEC 601.1 and UL 544 Standards for electrical protection. (Location: inside of service panel access door)
8. Protective earth label – indicating the location of the external ground connection point. (Location: service panel)
9. High voltage danger label – warning against the high voltage within the unit. (Location: service panel)
10. Hospital grade connection label – indicating that only a hospital grade plug should be connected to the power cable, and providing the wiring instructions for the plug. (Location: affixed to power cable)
11. Risk of explosion or fire label – warning against risk of explosion or fire if used in the presence of flammable anesthetics or materials. (Location: main cabinet front panel, below the laser emission danger label.)

12. Electric shock warning label – warns user to properly ground the unit, and against opening the unit's cover.

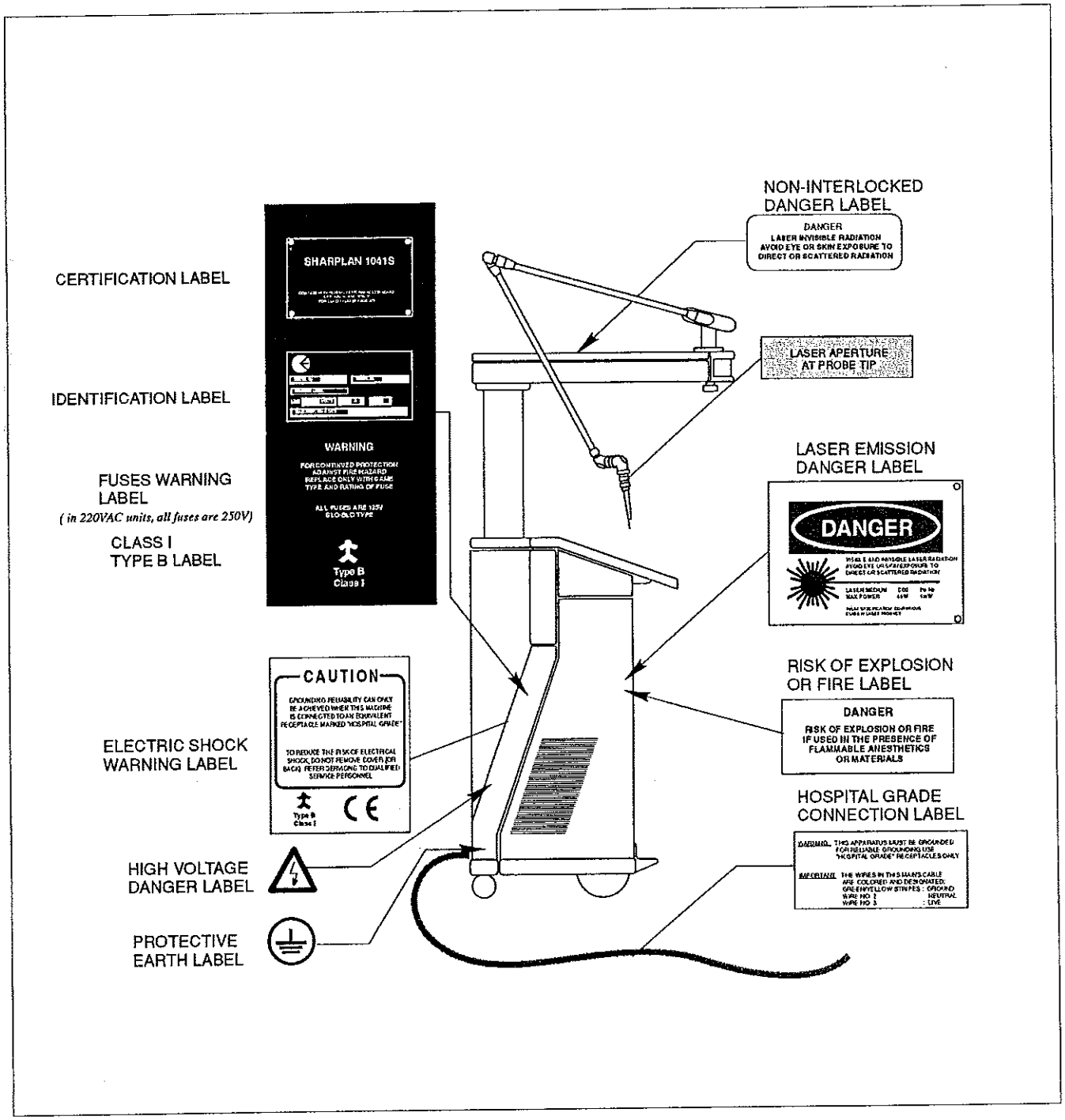


Figure 1-1. Warning, Certification and Identification

Chapter 2

Installation

2.1. *Unpacking and Inspection*

The SHARPLAN 1041S unit has passed full quality assurance testing before shipment. Thus, the unit should be operational upon delivery.

The unit may be unpacked, installed and tested **only** by a SHARPLAN-authorized technician. No attempt should be made by the purchaser to unpack or assemble the unit.

> **Note**
>
> Any damage to the container or to the unit found prior to opening the container or during unpacking, installation or testing of the unit should be immediately reported to your SHARPLAN distributor.

2.2. *Equipment List*

The SHARPLAN 1041S system includes the following:

1. SHARPLAN 1041S laser unit
2. 125mm handpiece set
3. Footswitch (in footswitch compartment)
4. Remote interlock connector assembly (installed)
5. Set of master keys
6. Spare fuses (X5)
7. Disposable bacteriological filter (X5)
8. Adaptor for suction/inert gas hoses (X3)
9. User's Manual.

2.3. *Space Requirements*

The working area for the SHARPLAN 1041S unit should be prepared according to the dimensions shown in Figures 2-1 and 2-2. The length of the unit's power cable is 3.5m. The unit should be positioned at least 50cm (20") from the wall (or other obstructions to air flow) to guarantee adequate ventilation. After the unit is properly positioned, press the brake pedal (see Figure 4-1, item 14) to lock the wheels of the unit.

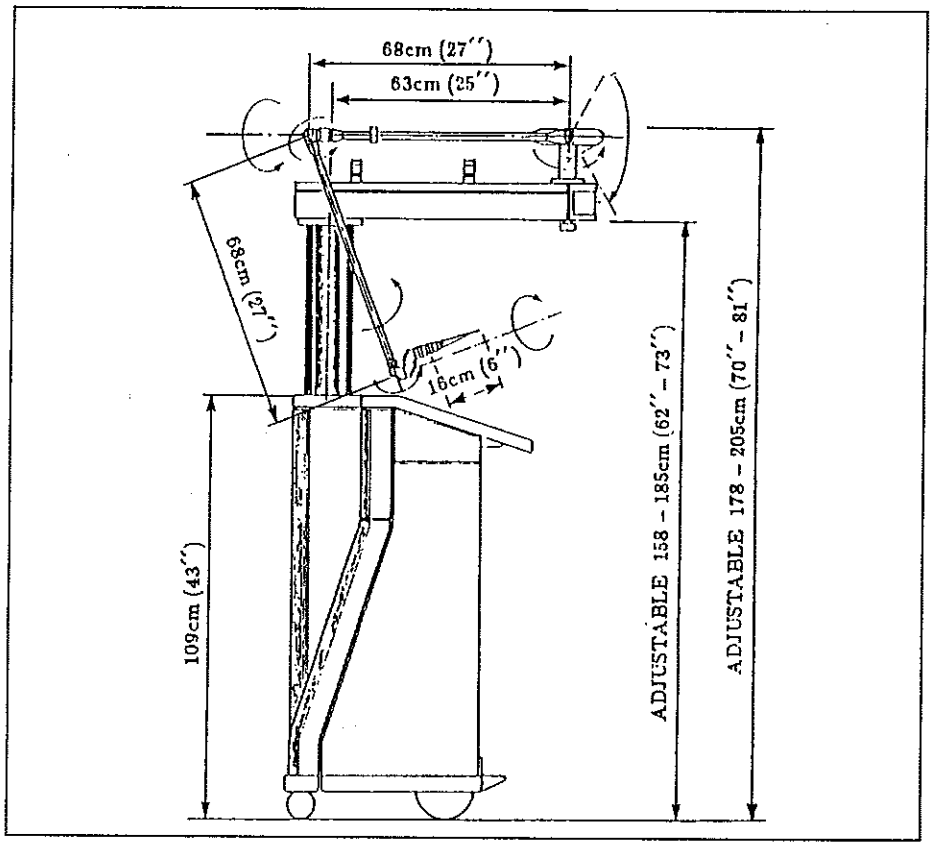


Figure 2-1. Dimensional Drawing – Side View

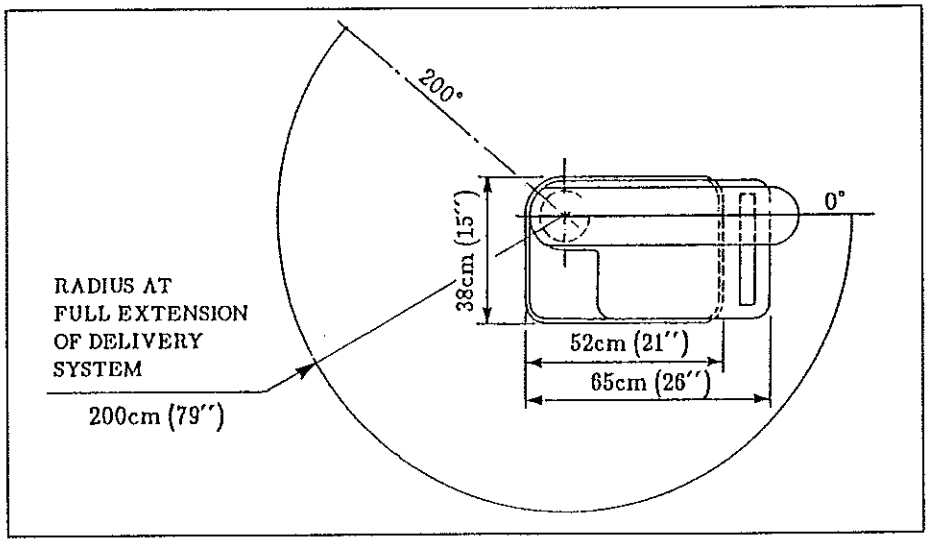


Figure 2-2. Dimensional Drawing – Top View

2.4. *Line Power Considerations*

The unit is delivered factory-set for the proper ac line voltage rating of the country to which it is shipped. The ac line voltage and maximal working current ratings appear on the identification label affixed to the inside of the service panel access door.

The unit is equipped with a power cord with a 3-pin plug for connection to a grounded, hospital grade, single-phase ac power receptacle, suitable to the labeled power rating.

Use the external ground connection point on the service panel (see Figure 4-5, item 49) to provide additional equipotential grounding, by connecting it to a reliable ground, such as a water pipe.

2.5. *Remote Interlock System Connection*

The SHARPLAN 1041S unit has a remote interlock connection point (REMOTE SWITCH CONNECTOR) on the service panel (see Figure 4-5, item 45), to which a "normally open" external switch rated for at least 12Vdc can be connected to create a remote interlock system. This external switch can be mounted (e.g., on an operating theater entrance door) in such a manner that if the external switch contacts open, the laser beam is extinguished and the message display reads **REMOTE INTERLOCK**, followed by **PRESS C TO CONTINUE**, once the contacts are closed.

Unit operation is then reinitiated and the system is placed in the safe STBY mode.

To connect the remote interlock system, perform the following steps, referring to Figure 2-3:

Warning

Turn off the unit, and disconnect the power cable from the power receptacle before connecting or disconnecting the remote interlock system.

1. Disconnect the remote interlock connector from its connection point.
2. Remove screw 8 and disassemble cover 10.
3. Using pliers, remove circlip 7 and remove cover 6.
4. Slide knurled barrel 1 out of the connector, open half-cylinders 3 and 4, and remove plug 2 and rubber cap 5.
5. Slide cover 6, rubber cap 5 and knurled barrel 1 onto the external switch cable insulation.
6. Disconnect the short between the pins of plug 2, solder the external switch leads to the pins, and slide rubber cap 5 onto the pins.
7. Insert the flange of plug 2 (with rubber cap 5 attached to the plug) into the recess on the right of half-cylinder 3. Rotate plug 2 until the recess in the plug catches on the half-cylinder.
8. While pressing half-cylinder 4 to half-cylinder 3, slide knurled barrel 1 and cover 6 onto the assembly.
9. Insert circlip 7 into the recess on the left of the half-cylinders to secure the assembly.
10. Secure the external switch leads to cover 6, using tightening band 9.
11. Reassemble cover 10 onto cover 6, and secure with screw 8.

If an external interlock is not required, do not disconnect the remote interlock connector from its connection point, or the short between the pins of plug 2.

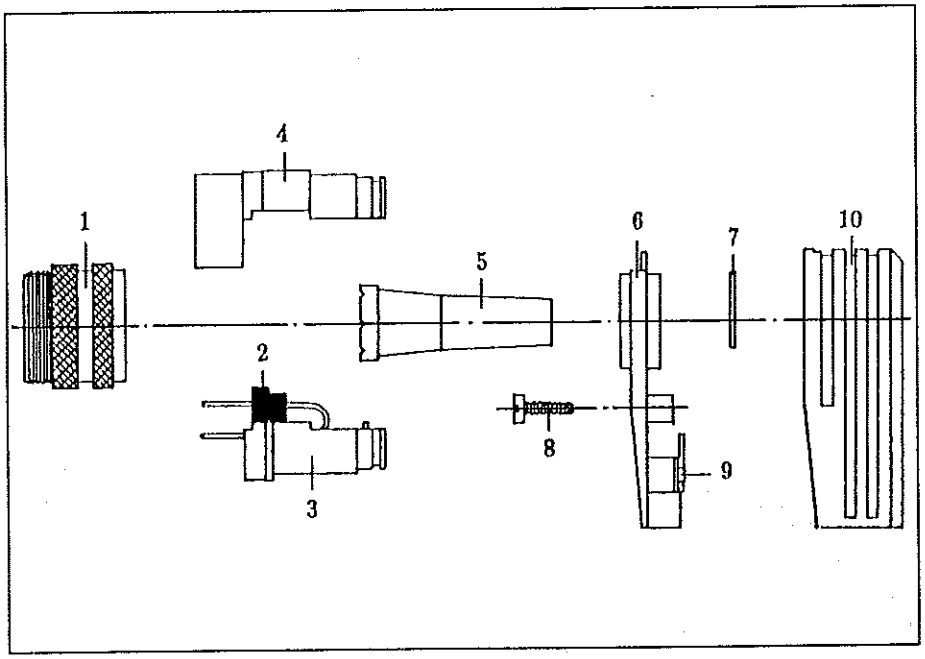


Figure 2-3. Remote Interlock Connector Assembly

2.6. *Footswitch Connection*

The footswitch is stowed in the footswitch compartment, located above the service panel. To connect the footswitch to the unit, position it on the floor and plug its cable into the FOOTSWITCH connection point, located on the service panel (see Figure 4-5, item 44). A polarizer on the socket prevents incorrect connection of the cable.

2.7. *Installation of Bacteriological Filter*

A dedicated unidirectional bacteriological filter (Model 110) is supplied with the SHARPLAN 1041S unit to ensure clean compressed air/inert gas at the surgical accessory.

The filter is equipped with a short flexible tube at its outlet for connection to the nipple on the laser surgical accessory in use. The inlet (free end) of the filter should be inserted into the distal end of the clear silicone tube attached to the articulated arm; then the filter should be clipped onto the last (vertical) arm section, as close as possible to the endjoint. The compressed air/inert gas flows through the bacteriological filter, which should be inspected prior to each use and replaced when insufficient flow is detected.

2.8. *Connection to Regulated External Inert Gas Supply*

The SHARPLAN 1041S laser unit incorporates a built-in air compressor which supplies compressed air for dispersion of fumes and debris at the target site. However, it is possible to use a regulated external inert gas supply, such as dry nitrogen (N_2) or carbon dioxide (CO_2) of hospital grade quality for this purpose.

Note that gas/air flow is active for as long as the the unit is in READY state. If desired, gas/air flow can be activated in READY state, **only** by pressing the footswitch, and will continue for 2 seconds after footswitch release. The selection between the two modes is made by the user upon system turn-on, by choosing/disabling the FlexiLase mode.

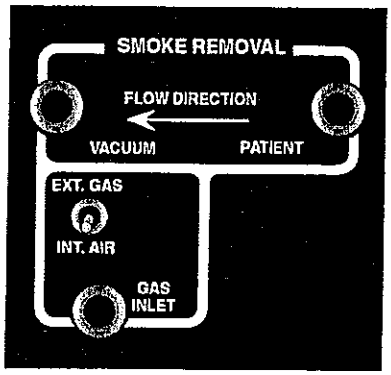


Figure 2-4. Inert Gas Connection Point, Smoke Evacuation Ports and EXT GAS/INT AIR Switch on the Service Panel.

To hook up an external inert gas cylinder, connect the external cylinder to a standard regulator; then connect the regulator outlet to the unit's external cylinder connection point (GAS INLET) located on the service panel (see Figure 2-4), using the suction/inert gas hose adaptor (PM2378630) and a 6mm/1/4" o.d. flexible silicone tube.

After the external gas cylinder is connected to the unit, slowly open the gas cylinder valve. Turn the regulator knob to set the line pressure (shown on the regulator gauge) at the required level, up to 4 atm/60 psi. Set the compressed air/inert gas switch (see Figure 2-4) to EXT. GAS. The system switches over to accept compressed air when the switch is set to INT. AIR.

To adjust the compressed air/inert gas flow rate, refer to 5.5.

Notes

1. A gas cylinder should be replaced when its pressure falls below 10 atm/150 psi.

2. If the compressed air/inert gas switch is set to EXT. GAS (inert gas position), but the gas cylinder is depleted or disconnected, neither inert gas nor compressed air is available at the endpiece (no message is displayed).

Warning

Do not use the compressed air/external gas system in sensitive laparoscopic procedures requiring insufflation of CO_2 gas. This system is not intended for such applications.

2.9. *Connection to Smoke Evacuation System for Endoscopic Procedures*

The SHARPLAN 1041S unit enables synchronization of smoke evacuation with laser emission during laparoscopic, bronchoscopic and rectoscopic procedures, providing a clear, smoke-free field of view and a laser beam path free of obstacles.

Note

The suction is active for as long as the the unit is in READY state. If desired, suction can be activated in READY state, **only** by pressing the footswitch, and will continue for 2 seconds after footswitch release. The selection between the two modes is made by the user upon system turn-on, by choosing/disabling the FlexiLase mode.

For synchronized smoke evacuation in an endoscopic procedure, perform the following steps, referring to Figures 2-4 and 2-5:

1. Connect an external suction pump (such as the O.R. suction pump unit, with a smoke filter, or an independent suction unit) to the VACUUM port on the service panel, using the suction/inert gas hose adaptor (PM2378630) and a disposable 6mm/1/4" o.d. tube.
2. Connect the endoscope to the PATIENT port on the service panel, using the suction/inert gas hose adaptor (PM2378630) and a 6mm/1/4" o.d. tube with a suction canister and a bacteriological filter, both attached to the tube.

Notes

1. Take care to correctly match the connections; mismatched connections will result in inadequate smoke suction.

2. It is recommended to use a suction canister attached between the endoscope smoke evacuation port and the PATIENT port on the service panel to prevent liquids from entering the laser unit.

3. Set the EXT. GAS/INT. AIR switch on the service panel to EXT. GAS.
4. If the system is in the FlexiLase mode, suction can be verified without laser emission by pressing the footswitch while in STBY state.
5. When smoke evacuation is no longer required, turn the switch to INT. AIR.

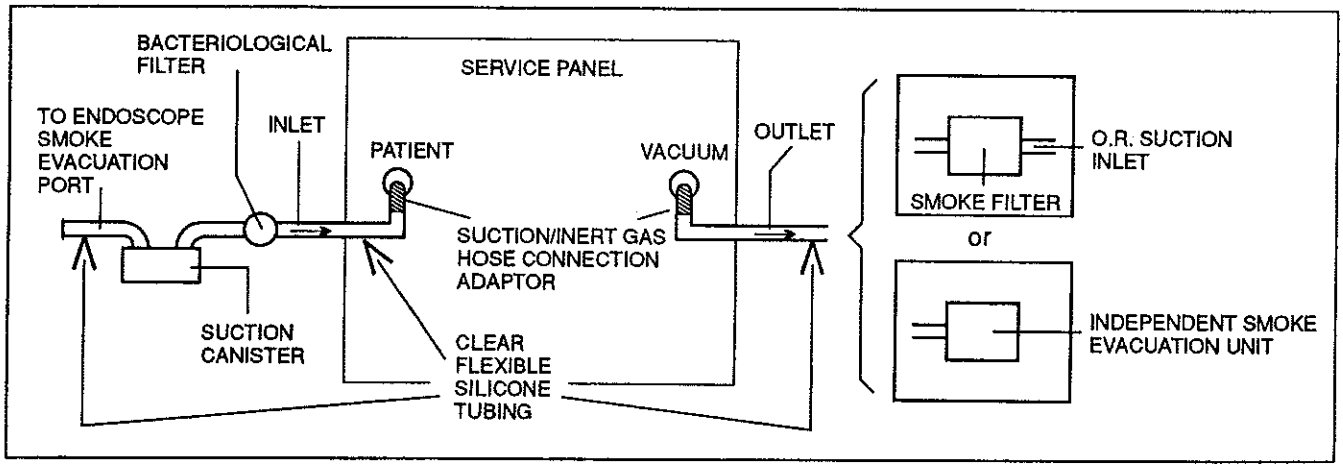


Figure 2-5. Connection to Smoke Evacuation System

Chapter 3

System Description

3.1. *General Laser Theory*

LASER is an acronym for Light Amplification by Stimulated Emission of Radiation. The laser is a device consisting of an active medium, enclosed in an optical cavity, and a pumping source. The pumping source "pumps" the active medium from its ground energy state to its excited energy 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 radiation is bounced back and forth in the optical cavity and is amplified. This amplified electromagnetic radiation is emitted as a laser beam.

The properties of the beam are:

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

The active medium of a laser can be either gas, liquid or solid. Most gas lasers consist of atoms, small 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 liquid.

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

The beam's transversal power distribution or mode structure determines its quality. For medical applications, the best choice is the TEMoo mode, wherein the beam has a Gaussian (bell-like) transversal power distribution, ensuring a minimal spot size, and thus maximal power density on tissue.

3.2. *Intended Use of SHARPLAN CO_2 Lasers and Accessories*

SHARPLAN CO_2 lasers and accesories are intended for those freehand and endoscopic surgical applications for which the FDA has granted clearance for marketing. Any other use of this CO_2 laser is considered investigational. Contact SHARPLAN's Regulator Affairs Department for approval status of specific procedures (1-800-394-2000 for U.S.A.).

SHARPLAN CO_2 lasers are intended for cutting, coagulation, and vaporization of soft tissue in:

- Gynecologic Surgery
- General/Thoracic Surgery
- Neurosurgery
- Dermatologic/Plastic Surgery
- Podiatric Surgery
- Laparoscopy
- ENT, Head and Neck Surgery
- Urologic Surgery (External and Intra-abdominal)
- Arthroscopic Surgery (Knee only)
- Dental/Periodontal Surgery (Soft tissue only)

3.3. *CO_2 Laser Theory*

The SHARPLAN 1041S CO_2 laser unit incorporates a sealed-off CO_2 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 CO_2 laser beam into the unit's articulated arm.

The dc power supply (pumping source) provides voltage to the electrodes which produce an electrical discharge along the tube. The discharged electrons collide with the CO_2 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.

3.4. *General System Description*

The SHARPLAN 1041S unit is an advanced microprocessor-controlled, user friendly CO_2 laser system based on a sealed-off CO_2 laser tube providing up to 40 watts on tissue for a wide range of surgical applications in freehand surgery, microsurgery and endoscopic surgery. The system incorporates the main cabinet, the column, the "periscope" assembly (the term "periscope" is adopted due to similarity in configuration and operation to an actual periscope), an articulated arm beam delivery system and attachable laser accessories. The unit is activated for laser emission by a footswitch. Figure 3-1 shows a side view of the unit.

Being certified in the ISO 9001, SHARPLAN designed and manufactured this product, like all SHARPLAN products, according to the highest quality standards.

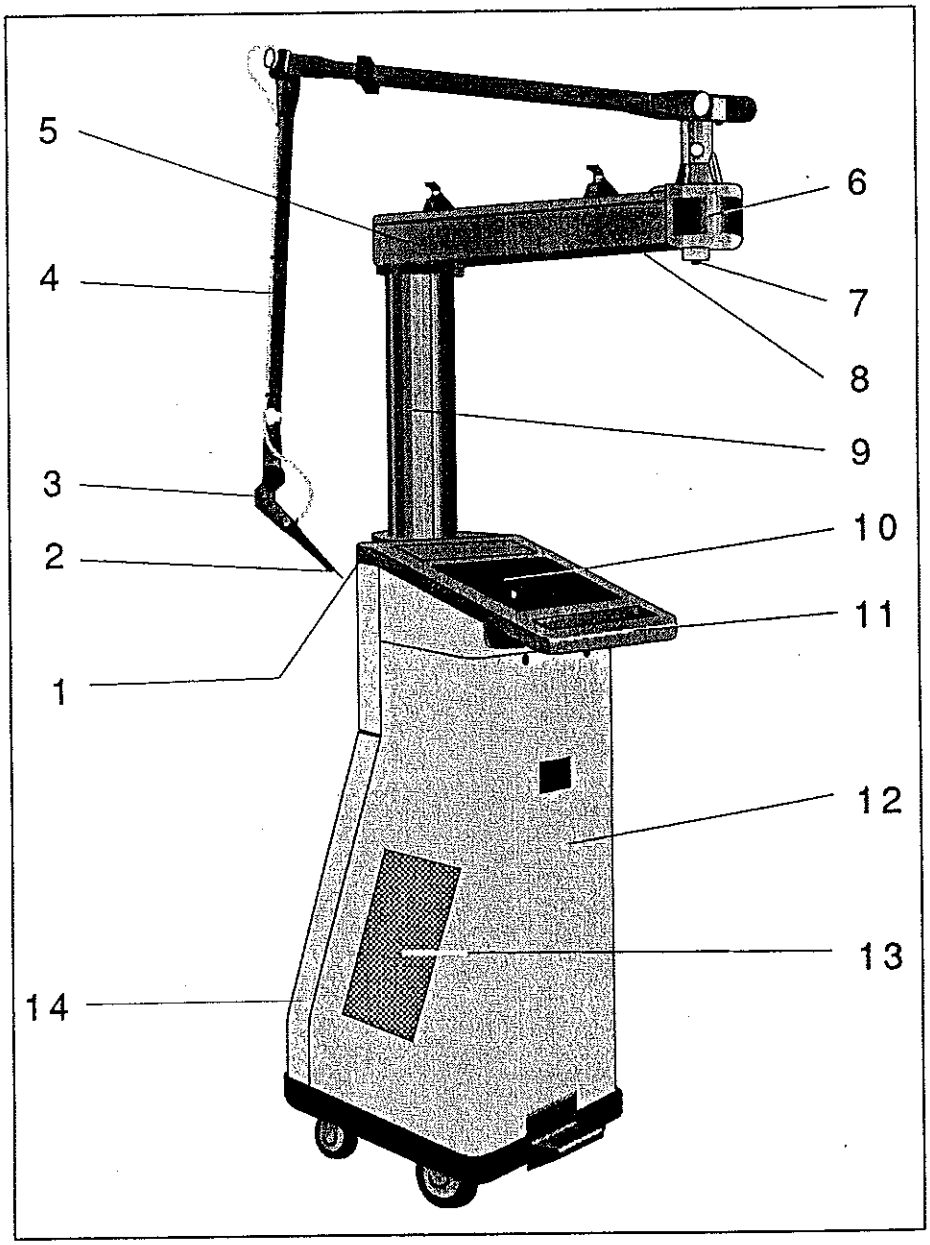


Figure 3-1. SHARPLAN 1041S System

1. Small handle
2. Handpiece
3. Endjoint
4. Articulated arm
5. Periscope
6. Repeater display
7. Laser emission indicator
8. He-Ne shutter control
9. Column
10. Control panel
11. Large handle
12. Main cabinet
13. Cooling vents
14. Service panel access door

3.5. *Main Cabinet*

3.5.1. *General*

The main cabinet includes the following:

1. Optical bench assembly (located within the column)
2. Power supply
3. Laser cooling system
4. Electronic control module
5. Compressed air/inert gas flow system
6. Footswitch compartment
7. Service panel.

3.5.2. *Optical Bench Assembly*

The optical bench assembly is positioned vertically within the column at the rear of the main cabinet, as illustrated in Figure 3-2, and is comprised of the sealed-off laser tube and its optical resonator.

3.5.3. *Power Supply*

The SHARPLAN 1041S is equipped with a switching-mode power supply which converts the input line voltage to the high voltage required for laser operation.

The inherent advantages of the switching-mode power supply over the conventional dc power supply are its small physical dimensions, high energy conversion efficiency and increased safety from high voltage hazards, since the high voltage components are activated only during laser emission.

3.5.4. *Laser Cooling System*

The laser tube cooling system is a closed-loop pressurized system. The coolant is circulated by a pump through a fan-cooled heat exchanger.

3.5.5. *Electronic Control Module*

The electronic control module contains the microprocessor circuits and the control panel. The microprocessor is responsible for the registration and execution of the system operation modes, and for monitoring the unit operation conditions. The control panel is used to control all operating functions. It includes soft-touch keys, power and time displays, and a built-in message display which provides direct on-line monitoring of all functions for safe system operation.

The alphanumeric display messages guide the user through each phase of operation, making the SHARPLAN 1041S unit exceptionally simple and safe to operate.

3.5.6. *Compressed Air/Inert Gas Flow System*

The compressed air/inert gas is used to remove the smoke from the target site in order to maintain a clear field of view for the surgeon, and to prevent damage to optical components of the accessory in use.

The air flow system consists of: an air compressor, a medical grade, sterilizable silicone tube that runs along the articulated arm and a bacteriological filter clipped to the arm.

The system can also be connected to a regulated external supply containing hospital grade N_2 or CO_2 gas with the compressed air/inert gas switch set to EXT. GAS. For detailed information, refer to 2.8.

The compressed air/inert gas flow rate is adjustable and can be set by the control knob on the flow meter located on the service panel. For detailed information, refer to 5.5.

3.5.7. *Footswitch Compartment*

The footswitch compartment, located above the service panel, is used for stowing the footswitch and its cord when the laser unit is not in use. The footswitch assembly contains the footswitch pedal and a metal guard. Access to the footswitch compartment is through the service panel door.

3.5.8. *Service Panel*

The service panel contains ports and controls for compressed air/inert gas flow and smoke evacuation, connection points for various auxiliary devices, fuse housings and a circuit breaker (for a detailed description, see Figure 4-5).

Access to the service panel is through the service panel door.

3.6. ***Periscope Assembly***

The SHARPLAN 1041S configuration includes a horizontal periscope mounted on a motorized telescopic column. The periscope together with the articulated arm provides a most convenient working distance for use in the O.R.

The periscope can be rotated up to 200° around the column. When the column is fully raised, the periscope is at a height of 185cm (73"); with the column fully lowered (stowing position), the periscope is at a height of 158cm (62"). In the stowing position, a built-in pin located within the column locks the periscope to prevent it from rotating.

Except for the sealed-off laser tube with its optical resonator and the articulated arm folding mirrors, all of the optical components are located within the periscope assembly. These include the CO_2 shutter assembly, the power detector, the He-Ne aiming beam laser tube, the He-Ne intensity control system and the beam combiner assembly (see Figure 3-2).

The beam combiner combines the CO_2 and He-Ne beams, and guides them into the articulated arm delivery system.

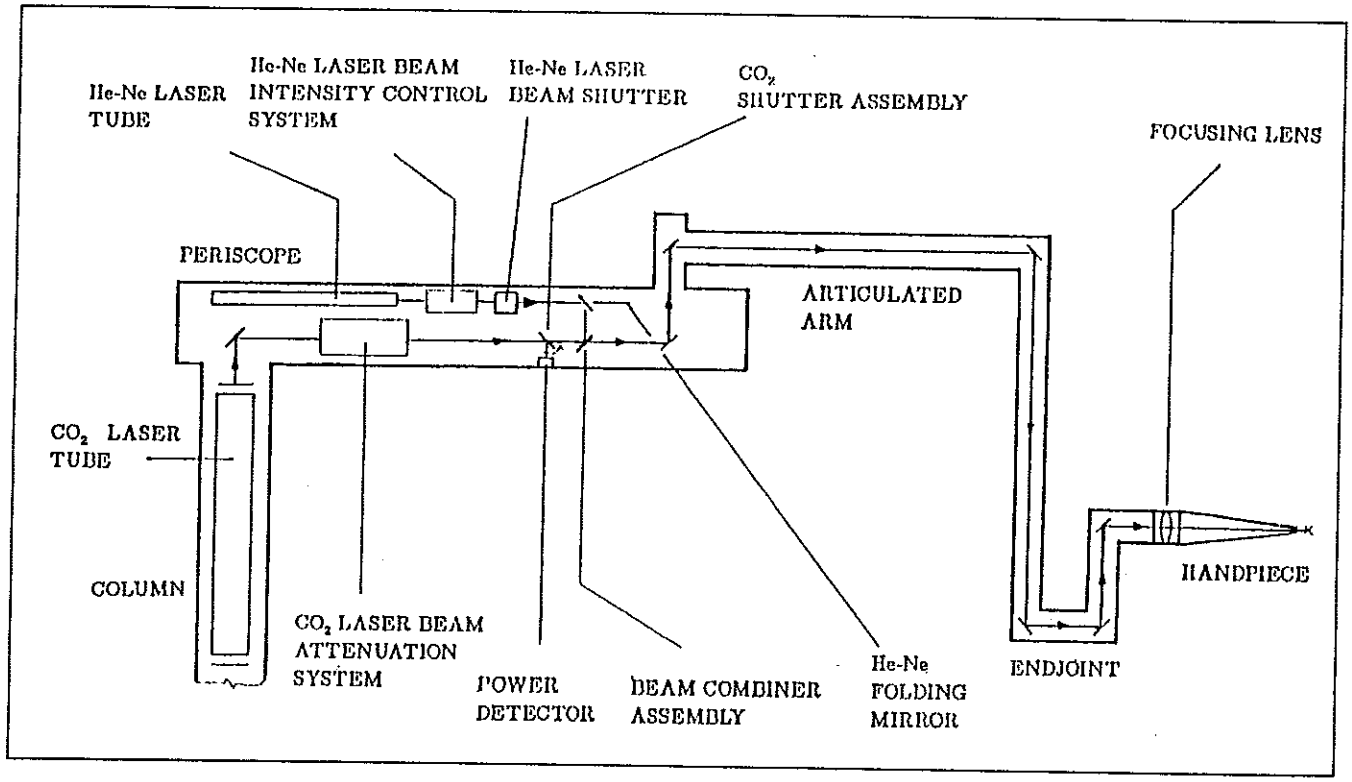


Figure 3-2. Optical System

A special built-in repeater display on the front end of the periscope assembly provides the user with vital laser emission parameters, including power setting, laser operation mode, tissue exposure mode, fault messages and ON time. The repeater display can be rotated up to 30° in each direction, to be fully visible from the farthest end of the delivery system.

3.7. *Articulated Arm Beam Delivery System*

The beam delivery system is a lightweight spring-balanced, 7-joint carbon-fiber articulated arm. The SHARPLAN 1041S articulated arm beam delivery system offers excellent maneuverability, balance and low-inertia movement. Arm balance is obtained through an arm tension control. As a result of the fixed mirror design, the arm maintains permanent and precise alignment. The arm subscribes a convenient working radius of 165cm (65"), measured from the column. At full arm extension, the arm subscribes a radius of 200cm (79").

The attachable endjoint at the end of the articulated arm consists of three rotating knuckles, providing the surgeon with the full wrist motion needed for comfortable manipulation of the various surgical accessories which attach to it.

3.8. *Laser Accessories*

A wide range of exclusive SHARPLAN laser surgical accessories easily attach to the beam delivery system for both freehand and microsurgery through a proprietary quick-connect design.

For freehand surgery, the standard handpiece supplied with the SHARPLAN 1041S unit is the 125mm focusing handpiece set. Other optional accessories available for freehand surgery are the 50mm and 200mm focusing handpiece sets and the 50mm and 250mm defocusing handpiece sets.

For microsurgery, the standard laser accessory supplied with the laser unit is the SHARPLAN 719 Microslad, which easily attaches to standard operating microscopes.

Double-headed microscopes require the optional SHARPLAN Microslads with side laser beam entry port. The SHARPLAN 715 Microslad is required for ZEISS MD and OPMI 11 microscopes. For reduced spot size, the optional SHARPLAN 710/711 Acuspot™ is available for most standard operating microscopes.

For laser surgery in colposcopic procedures, SHARPLAN Colposlads are available for ZEISS, OLYMPUS, LEISEGANG, JEDMED/KAPS, CODMAN, SHIMA, WOLF and KAMIYA TSUSHO KAISHA colposcopes.

The SHARPLAN 779 CO_2 laser colposcopic system, comprised of a SHARPLAN Colposlad integrated within a LEISEGANG ID300 colposcope, permits the use of the CO_2 laser under direct colposcopic guidance.

For endoscopic surgery, the following optional SHARPLAN laser endoscopes and auxiliary endoscopic devices are available:

1. SHARPLAN 781 CO_2 laser bronchoscope set
2. SHARPLAN 782 CO_2 laser single and double puncture laparoscope set
3. SHARPLAN 783 CO_2 laser second puncture laparoscope set
4. SHARPLAN 784 CO_2 laser rectoscope set
5. SHARPLAN 785 CO_2 laser anoscope set.
6. The SHARPLAN 793 CO_2 Laprobe™ laser laparoscopic probe is a laser delivery system which can be inserted into standard operating laparoscopes for laser surgical applications.
7. The SHARPLAN 794 ArthroLase™ probe system is a laser delivery system for use in various arthroscopic procedures.
8. The SHARPLAN Microguide system for Arthroscopy is a laser delivery system for use in orthopedics. Also available are fine waveguide sets for laparoscopic applications.

The SHARPLAN CO_2 laser FlexiLase™ fibers are laser delivery systems available in a variety of hand applicator configurations for freehand and/or laparoscopic applications.

SHARPLAN's SwiftLase™ Flashscan for char-free ablation includes a control box and motorized mirrors.

See Chapter 6 for more detailed information regarding accessories.

3.9. *System Modes of Operation*

The SHARPLAN 1041S 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 as follows:

Laser Operation Modes:	*Tissue Exposure Modes:*
1. CW (Continuous Wave)	1. Continuous
2. SUPERPULSE	2. Single Pulse
3. SHARPULSE	3. Repeat Pulse

Each laser operation mode may be paired with any of the three tissue exposure modes, thus yielding the following nine system modes of operation (see Figures 3-5 through 3-7), for a wide range of clinical applications:

1. CW – Continuous
2. CW – Single Pulse
3. CW– Repeat Pulse
4. SUPERPULSE – Continuous
5. SUPERPULSE – Single Pulse
6. SUPERPULSE – Repeat Pulse
7. SHARPULSE – Continuous
8. SHARPULSE – Single Pulse
9. SHARPULSE – Repeat Pulse

Note

The TEMoo mode structure (bell-shaped power distribution) is preserved in all modes of operation.

3.9.1. *Basic Concepts and Definitions*

1. **Frequency (f)** – number of pulses per second
2. **Period or cycle time (T)** – the time interval between the onset of two consecutive pulses. (T = 1/f ; T is inversely proportional to f.)
3. **ON time and OFF time** – the time duration that the laser is operative within the cycle time (T) is called the ON time, whereas the time duration that the laser is inoperative within the cycle time (T) is called the OFF time. Thus,

   Cycle time (T) = ON time + OFF time

4. **Duty cycle (%)** – the ratio between the ON time and the total cycle time (T), given as percentage:

$$\text{Duty cycle (\%)} = \frac{\text{ON time}}{T} \times 100$$

5. **Peak power (P peak)** – the maximum power delivered by the laser beam during emission.
6. **Average power (P av)** – the total power delivered, averaged over time.
7. **Pulse width (τ)** – the pulse duration at half peak power level.

The peak power and average power are rated as follows:

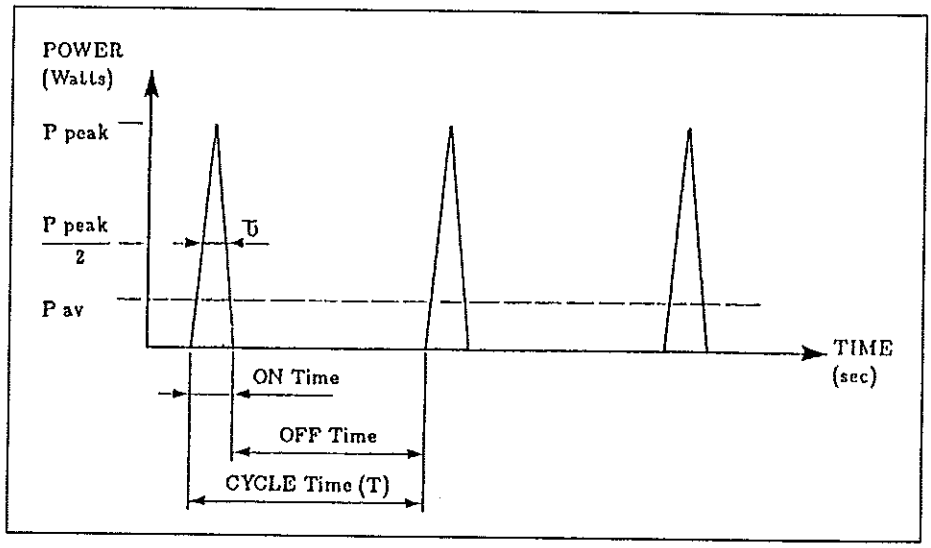


Figure 3-3. Basic Concepts of General Periodic Functio

a. For a square wave periodic function, the exact relationship is:

$$P_{av} = P_{peak} \times \frac{\text{duty cycle}}{100}$$

> **Note**
>
> In this section, "ON time", "OFF time", and "duty cycle" refer only to the laser operation mode, and not to the tissue exposure mode.

Thus, to obtain a variation in average power at a constant peak power, the duty cycle is adjusted accordingly.

b. For a general periodic function (such as in the SUPERPULSE laser operation mode), a close approximation of this equation is:

$$P_{av} = P_{peak} \times \tau \times f$$

Thus, the average power can be controlled either by varying the peak power, the pulse width, the frequency or any combination of these parameters.

In the SUPERPULSE laser operation mode, the system provides the highest possible peak power, obtaining the requested average power by varying the frequency and the ON time.

In the SHARPULSE laser operation mode, the system provides a high peak power, slightly lower than in SUPERPULSE, but with a longer pulse width, thus obtaining a higher average power than in the SUPERPULSE laser operation mode. The system reaches the requested average power by varying the frequency and maintaining a constant ON time.

3.9.2. *Laser Operation Modes*

The laser operation modes are CONTINUOUS WAVE (CW), SUPERPULSE and SHARPULSE (see Figure 3-4).

In the CW laser operation mode, the laser beam is emitted in a Continuous Wave, whereas in the SUPERPULSE and SHARPULSE laser operation modes, the laser beam is emitted as a train of very narrow pulses.

The CW laser operation mode is activated by "default" – i.e., when neither the SUPERPULSE nor the SHARPULSE laser operation modes are selected. In this mode, a Continuous Wave laser beam is emitted in the power range of 0.1-40W.

In the SUPERPULSE laser operation mode, the laser beam is emitted in a train of very narrow high-peak-power pulses. The SUPERPULSE frequency and ON time are adjusted by the microprocessor to obtain the desired average power . The power display shows the SUPERPULSE average power, which ranges between 0.5-17W.

In the SHARPULSE laser operation mode, the laser beam is emitted in a train of narrow square-wave high-peak-power pulses, with high energy per pulse (150mJ). The SHARPULSE frequency is adjusted by the system to obtain the desired average power, while the pulse width is maintained constant (~770 microsecond). The average power, ranging between 5-40W, is shown on the power display.

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 SUPERPULSE and SHARPULSE laser operation modes enable these tissue effects to be achieved through their constant high peak power level and variation of the duty cycle for control of the average power.

The Superpulse laser operation mode, used with a small beam diameter (<1mm), is appropriate for incision and, with low power, for precise vaporization of minute tissue structures. The Sharpulse laser operation mode is appropriate for incision at high power with a small beam diameter, and for vaporization of areas up to 2mm with minimal char. Higher average powers are available with the Sharpulse mode as compared to the Superpulse mode. CW laser operation mode provides the most hemostasis during incisions and, with a defocused beam, is useful for bulk coagulation. The rate of beam manipulation (time on tissue) also affects the depth of incision, vaporization or coagulation. Generalized information is summarized in Table 3-1, and is relevant for all tissue exposure modes.

Table 3-1. Laser Operation Mode Applications

Tissue Effects	*Average Power*	*Spot Size*	*Beam Manipulation*	*Preferred Mode*
Deep Incision	High	Focused	Slow	CW, Sharpulse Superpulse
Shallow Incision	Low	Focused	Slow	Sharpulse Superpulse
Shallow Incision	High	Focused	Fast	CW, Sharpulse Superpulse
Bulky Vaporization	High	Defocused	Slow	CW, Sharpulse
Superficial Vaporization	Low	Defocused	Slow	CW, Sharpulse
Superficial Vaporization	High	Defocused	Fast	CW, Sharpulse
Coagulation	Low	Defocused	Slow	CW
Coagulation	High	Defocused	Fast	CW

Note

The clinician should use the appropriate laser parameters for the treatment desired, taking into account individual preferences and techniques. The knowledge and expertise needed to make appropriate treatment decisions is developed through review of the published literature, clinical training, the hospital credentialing process, and general experience in the use of surgical lasers.

Figure 3-4 illustrates the different power versus time patterns generated for each of the laser operation modes. Note that although the average power can be identical in all three laser operation modes, the peak power, ON time and OFF time differ. The treated tissue reflects these differences in terms of incision/ablation effects, and of thermal conduction to adjacent tissue.

Note

In Figure 3-4, "ON time" and "OFF time" refer only to the laser operation mode.

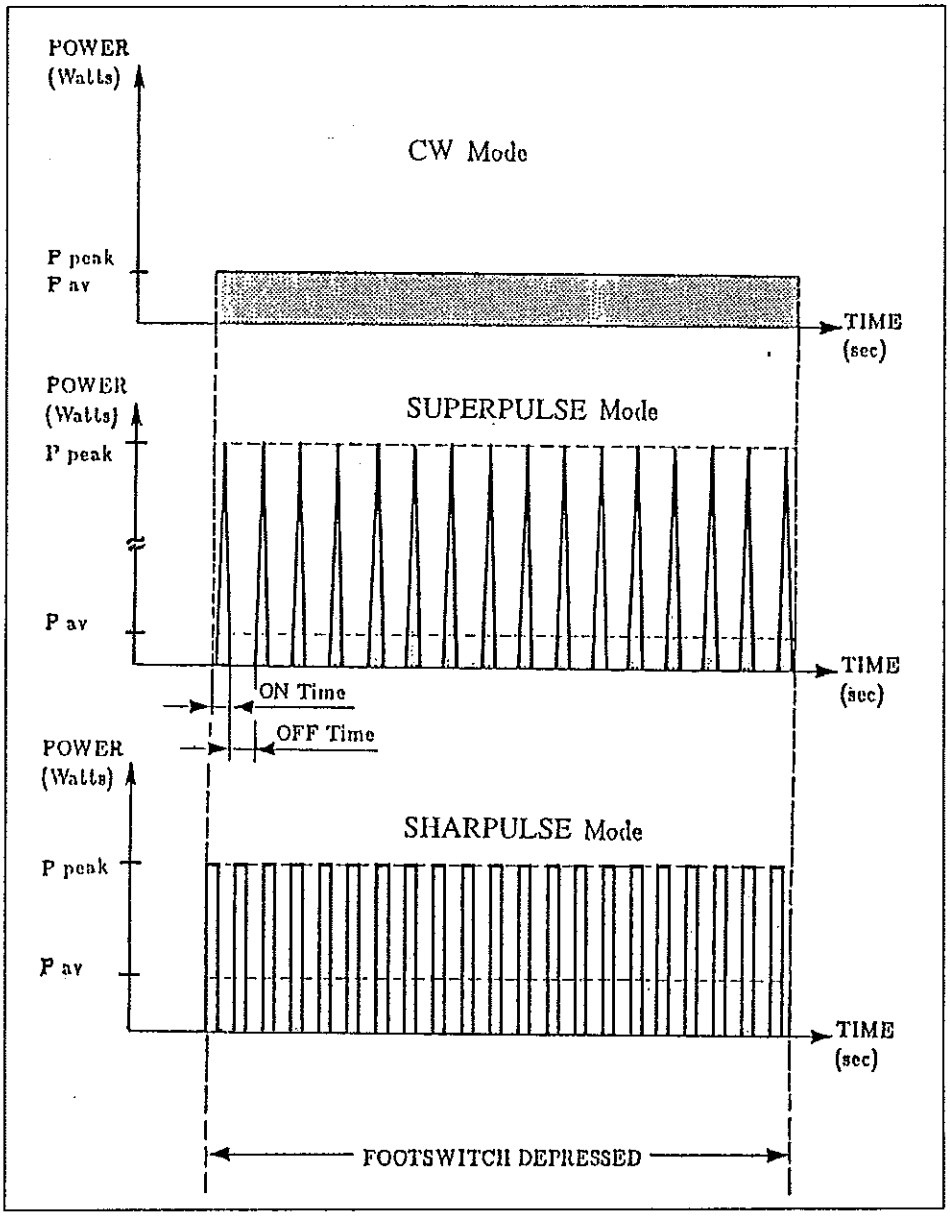


Figure 3-4. Laser Operation Modes

3.9.3. *Tissue Exposure Modes*

The tissue exposure modes control the duration pattern of the laser beam delivered to tissue. The three tissue exposure modes are CONTINUOUS, SINGLE PULSE and REPEAT PULSE. The unique power versus time pattern of each tissue exposure mode in the three laser operation modes is illustrated in Figures 3-5 through 3-7.

In the CONTINUOUS tissue exposure mode, the laser beam is emitted for as long as the footswitch is pressed.

In the SINGLE PULSE tissue exposure mode, the laser beam is emitted as a single pulse (for CW laser operation mode) or as a single burst (for SUPERPULSE and SHARPULSE laser operation modes), for a preset duration (ON time), or until the footswitch is released, whichever comes first. The ON time range in the various laser operation modes and power ranges is outlined in Table 5-1.

In the REPEAT PULSE tissue exposure mode, the laser beam is delivered intermittently as a series of bursts, for as long as the footswitch is pressed. The duration of each burst (pulse) is determined by the ON time selection (emission duration). The time interval between bursts (pulses) is determined by the OFF time selection.

Note

In Figures 3-5 through 3-7, "ON time" and "OFF time" refer only to the tissue exposure mode.

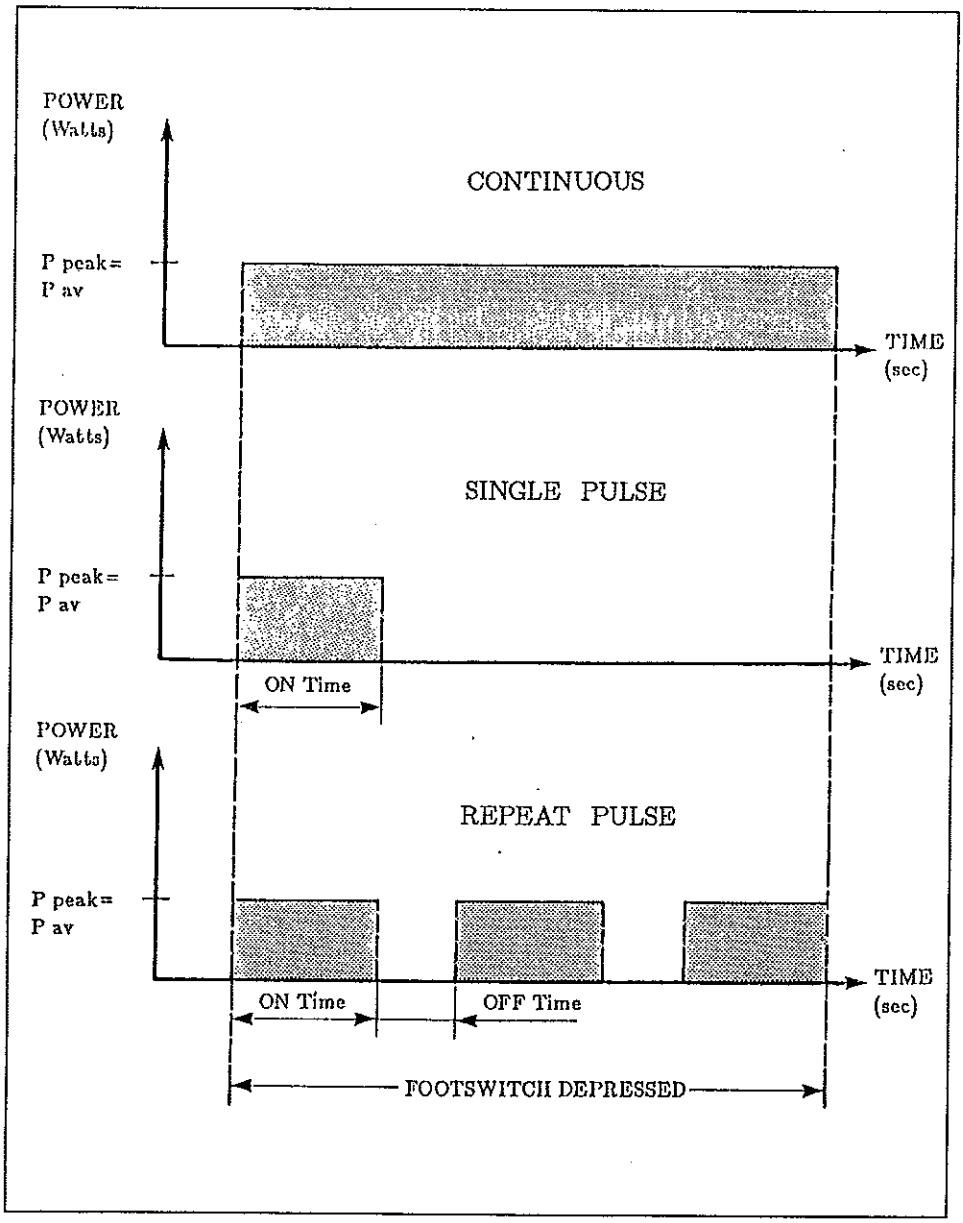


Figure 3-5. Tissue Exposure Modes in CW Laser Operation Mode

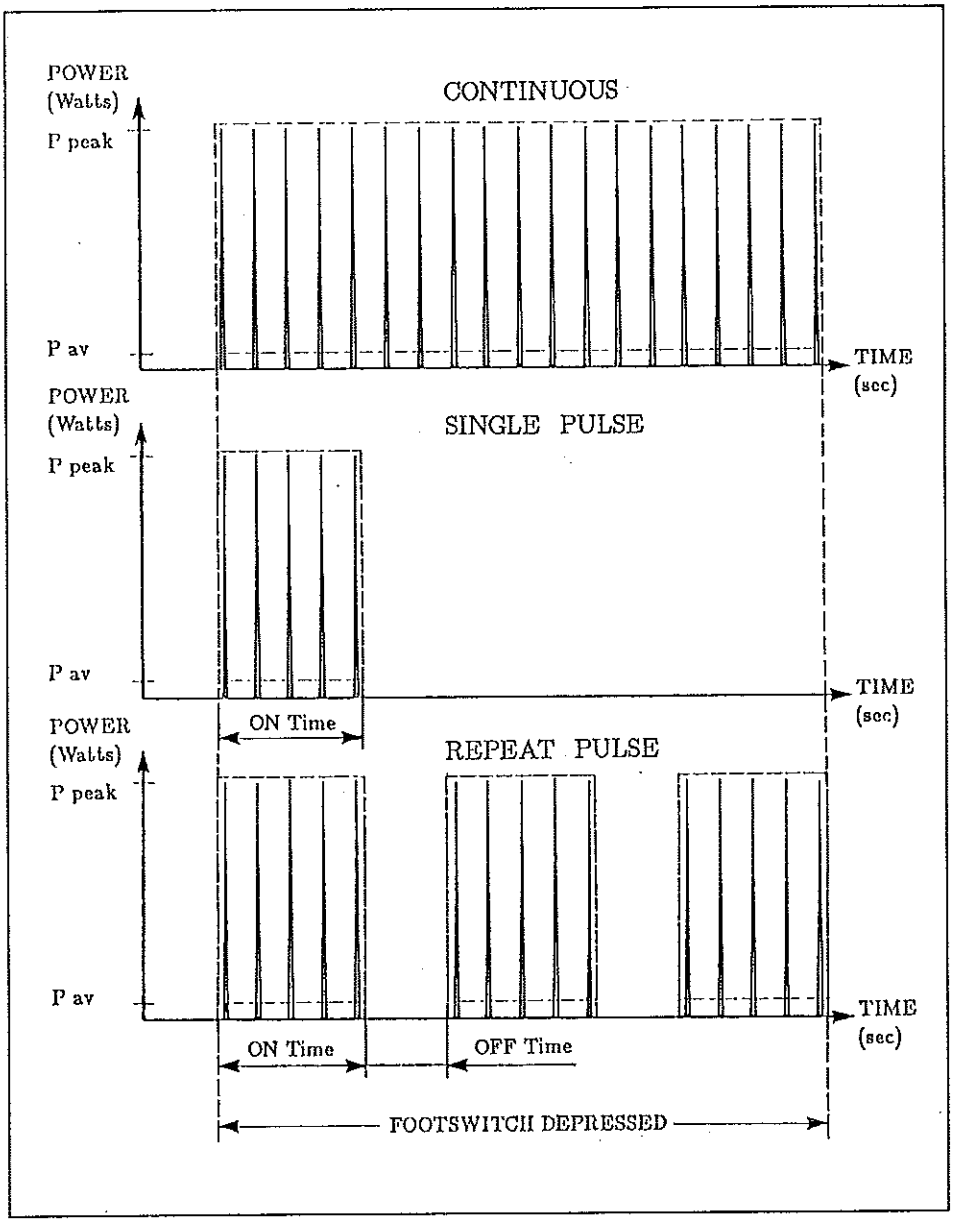


Figure 3-6. Tissue Exposure Modes in SUPERPULSE Laser Operation Mode

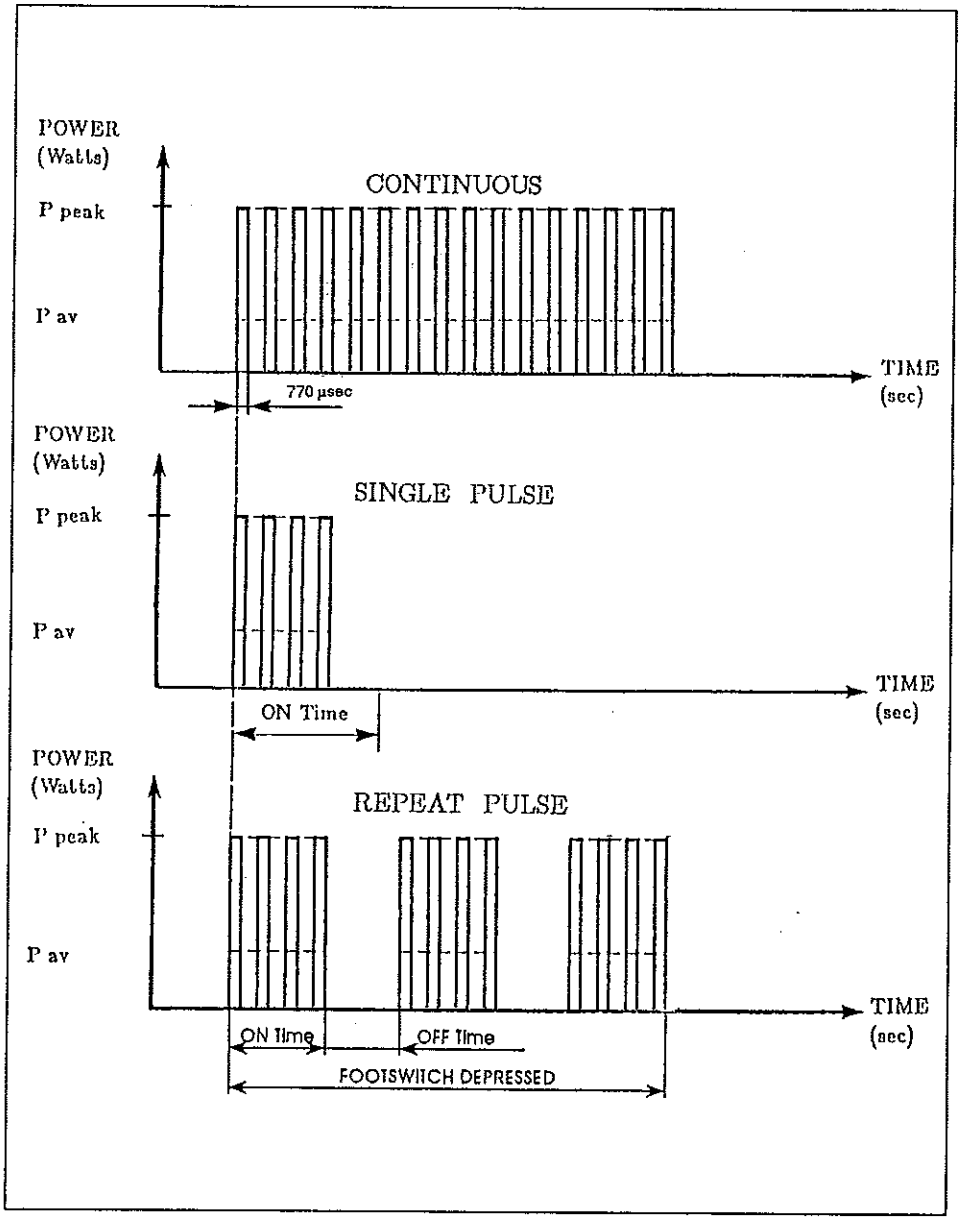


Figure 3-7. Tissue Exposure Modes in SHARPULSE Laser Operation Mode

Chapter 4

Controls, Indicators and Connections

4.1. General

The following is a list of the SHARPLAN 1041S controls, indicators and connection points, grouped according to location.

4.2. Periscope And Articulated Arm

Refer to Figures 4-1 and 4-2 for items 1 through 12.

1. ***Articulated Arm Endjoint*** – contains a threaded quick-connection for attachment of the laser surgical accessories discussed in Chapter 6.
2. ***Disposable Bacteriological Filter*** – for compressed air/inert gas filtration.
3. ***Arm Tension Control Grip*** – located at the end of the horizontal arm, used to balance the articulated arm. Proper arm tension adjustment is essential to achieve lightweight easy maneuverability of the attached laser accessory. Rotating the knurled tension control grip counterclockwise tightens the tension on the arm, reducing its weight at the endpiece. Rotating it clockwise loosens the tension on the arm, adding weight to the endpiece. When properly balanced, the articulated arm remains suspended and stationary in position.
4. ***Arm Clips*** – for stowing the articulated arm. The arm should be handled carefully and returned to its two arm clips on the upper section of the periscope when not in use.
5. ***Endjoint Knuckles Holder*** – secures the endjoint knuckles whenever the articulated arm is held by the arm clips. This protects the articulated arm optical components from dust particles and from jolts when the unit is being moved.
6. ***Articulated Arm Friction Adjustement Screw*** – used to adjust the rotation friction of the articulated arm. Tightening the screw increases friction and prevents undesired rotation of the articulated arm.
7. ***Compressed Air/Inert Gas Connection*** – connection point for the clear silicone flow tube attached to the articulated arm.

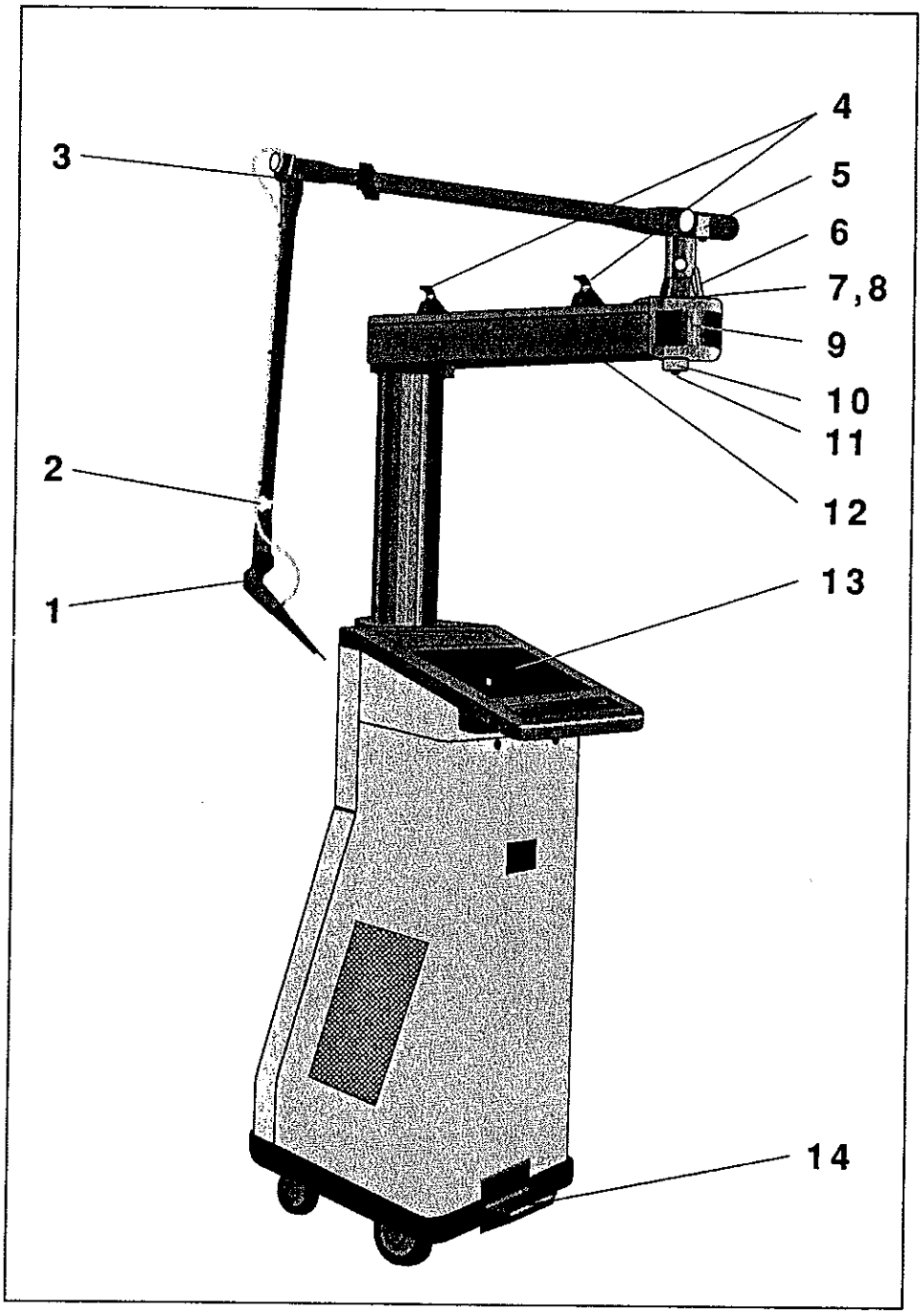


Figure 4-1. Controls, Indicators and Connections

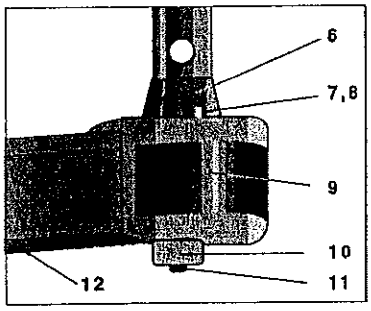


Figure 4-2. Controls, Indicators and Connections on Periscope Front End

8. ***R.C.U. Connection*** – Connection point for the optional SHARPLAN 750 Remote Control Unit.

9. ***Repeater Display*** – contains the following displays (see Figure 4-3):

a. ***Laser Operation Mode Display*** – 2-digit LED display showing the laser operation mode selected (**C.W.** for Continuous Wave, S.R. for SHARPULSE and **S.P.** for SUPER PULSE).

b. ***Tissue Exposure Mode and Fault Messages Display*** – 4-digit LED display showing the tissue exposure mode selected (**STBY** for STANDBY, **CONT** for CONTINUOUS, **SNGL** for SINGLE PULSE, **REPT** for REPEAT PULSE and **FAIL** when a system fault occurs).

c. ***Power Display*** – 3-digit LED display showing the average power in watts to be delivered on tissue.

d. ***Time Display*** – 3-digit LED display showing the selected ON time in seconds (only for SINGLE PULSE or REPEAT PULSE).

e. ***Flashing red dot*** – verifies that the data displayed is valid and updated.

Notes

1. The repeater display readings correspond to the control panel display readings.

2. A **FAIL** message on the repeater display is accompanied by a specific fault message on the control panel message display.

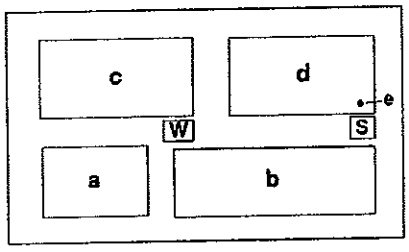


Figure 4-3. Repeater Display

10. ***Repeater Display Rotation Knob*** – used to rotate the repeater display to be conveniently visible from the distal end of the delivery system.

11. ***Laser Emission Indicator*** – amber LED indicator with three operational states - off, flashing and continuous:

a. ***Off*** – during unit turn-on or when the system is in STBY mode, the indicator is off.

b. ***Flashing*** – when the system is in the "ready" state (i.e., after the emission parameters are selected and the READY key is pressed), the indicator flashes, indicating that laser emission will occur if the footswitch is pressed.

c. ***Continuous*** – during laser emission, the indicator is continuously illuminated.

Note

The internal CO_2 laser shutter opens in conjunction with laser emission indication, and is heard as a click from the periscope just before laser emission. The shutter safeguards against beam emission when no laser emission request is present. The shutter is opened only by depression of the footswitch, and only when the system is in "ready" state.

12. ***He-Ne Shutter Control*** – 2-position aiming beam control permitting the He-Ne beam to be emitted at the intensity determined by the intensity control system, or to be blocked.

4.3. Main Cabinet

Refer to Figure 4-1 for items 13 and 14.

13. ***Control Panel*** – see 4.3.1.

14. ***Brake Pedal*** – for locking the wheels of the unit.

4.3.1. Control Panel

The control panel is designed to provide direct, simple and comprehensive control of the unit through soft-touch keys and display messages. These messages guide the user through each phase of operation, either by indicating the next step to be followed, or by indicating the system parameters (TIME and POWER settings) for verification.

The STBY, READY, SET PWR, SET TIME, laser operation mode, tissue exposure mode, and He-Ne aiming beam keys each have a LED indicator, which illuminates when the key function is in operation. For all keys, except the CLMN up/down ramps, a positive key contact is indicated by a brief beep.

Refer to Figure 4-4 for items 15 through 37.

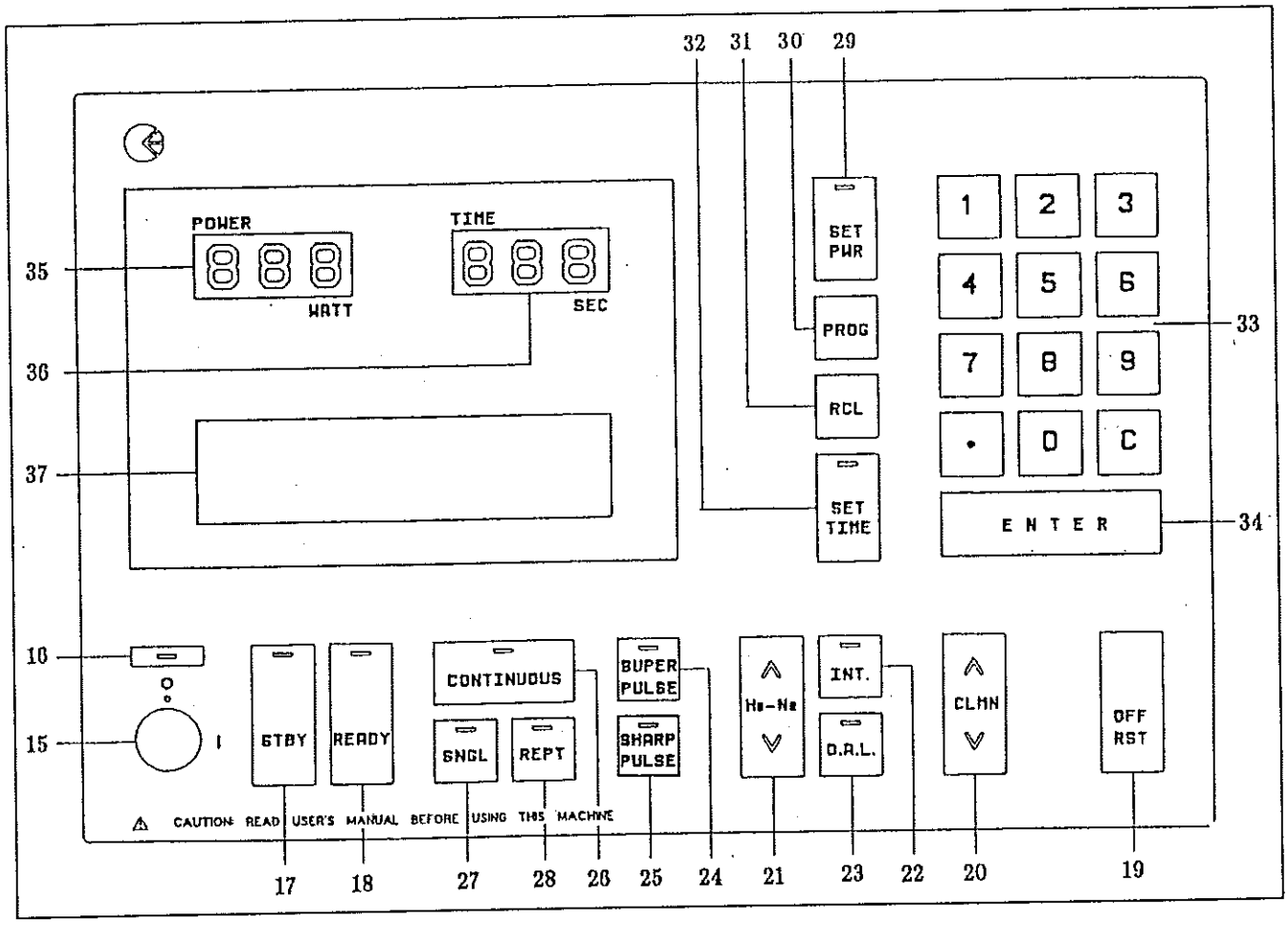


Figure 4-4. Control Panel

4.3.1.1. Keyswitch and Power-On Indicator

15. Keyswitch – when the master key is inserted into the keyswitch and turned clockwise to the "**I**" position, power is supplied to the unit. Turning the key counterclockwise to the "**O**" position turns off the unit. The key should be removed whenever the unit is left unattended.

16. Power-On Indicator – illuminates after the keyswitch is turned on, indicating that electrical power is being supplied to the unit. It remains illuminated until the keyswitch is turned off.

4.3.1.2. STBY, OFF/RST and READY Keys

17. ***STBY Key*** – when pressed while the system is in the "ready" state, this key returns the system to the STBY mode (STBY indicator illuminates), in which all selected parameters are maintained, but in which the footswitch is disabled.

18. ***READY Key*** – when pressed (indicator illuminates), the system enters the "ready" state (ready for laser emission); the laser emission indicator flashes, an appropriate system status/user instruction message appears on the display, and a laser beam is emitted when the footswitch is pressed.

19. ***OFF/RST Key*** – when pressed, the power to the high voltage power supply is cut off, the POWER and TIME displays are reset, any fault message appearing on the message display is deleted and the microprocessor is reset so that unit operation can be reinitiated.

4.3.1.3. Column Keys

20. ***CLMN Up (▲)/Down (▼) Keys*** – used to adjust the height of the periscope.

4.3.1.4. He-Ne Aiming Beam Mode Keys

21. ***He-Ne Up (▲)/Down (▼) Keys*** – used to set the He-Ne aiming beam intensity level.

22. ***INT Key*** – when pressed (indicator illuminates), the He-Ne aiming beam flashes intermittently. When repressed (indicator extinguishes), the He-Ne aiming beam illuminates continuously.

23. ***O.A.L. (Off At Lasing) Key*** – when pressed (indicator illuminates), the He-Ne aiming beam extinguishes during laser emission – i.e., when the footswitch is pressed. When repressed (indicator extinguishes), pressing the footswitch will not affect He-Ne aiming beam emission.

4.3.1.5. Laser Operation Mode Keys

24. ***SUPER PULSE Key*** – when pressed (indicator illuminates), sets the system for operation in the SUPERPULSE laser operation mode. When repressed (indicator extinguishes), sets the system to operate in the CW laser operation mode.

25. ***SHARP PULSE Key*** – when pressed (indicator illuminates), sets the system for operation in the SHARPULSE laser operation mode. When repressed (indicator extinguishes), sets the system to operate in the CW laser operation mode.

4.3.1.6. Tissue Exposure Mode Keys

26. ***CONTINUOUS Key*** – when pressed (indicator illuminates), sets the system for operation in the CONTINUOUS tissue exposure mode, wherein the CO_2 laser beam is continuously emitted for as long as the footswitch is depressed.

27. ***SNGL Key*** – when pressed (indicator illuminates), sets the system for operation in the SINGLE PULSE tissue exposure mode, wherein the CO_2 laser beam is emitted for the selected ON time when the footswitch is pressed. Laser emission ceases at the end of the ON time, or upon release of footswitch, whichever comes first.

28. ***REPT Key*** – when pressed (indicator illuminates), sets the system for operation in the REPEAT PULSE tissue exposure mode, wherein the CO_2 laser beam is emitted as a train of pulses for as long as the footswitch is depressed. The pulse duration and the time interval between pulses are determined by the ON and OFF time settings.

4.3.1.7. Set Keys

29. ***SET PWR Key*** – when pressed (indicator illuminates), sets the system to accept a new power level value through the numeric keyboard.

30. ***PROG Key*** – initiates a routine for storing the preselected emission parameters as a program. For additional information, refer to 5.9.

31. ***RCL Key*** – initiates a routine for recalling a stored program. For additional information, refer to 5.9.

32. ***SET TIME Key*** – when pressed (indicator illuminates), sets the system to accept new time values (ON and OFF times) through the numeric keyboard.

4.3.1.8. Numeric Keyboard and ENTER Keys

33. ***Numeric Keyboard Keys*** – set the values for time and power, for the programs being stored or recalled, and for selection of User Codes.

The "C" key cancels the last number entered.

The "." key inserts a decimal point.

Any value entered through the keys appears on the message display for verification.

34. ***ENTER Key*** – sets the system to accept numeric values entered through the numeric keyboard.

4.3.1.9. Displays

35. ***POWER Display*** – red 3-digit LED display, calibrated to display the average power in watts to be delivered on tissue. Power in the range of 10-40W is displayed in two digits. Below 10W, a decimal point appears, and power is displayed to one decimal. Below 1W, power is displayed to two decimals. The POWER display resolution (increment) varies with the power range and is given in Table 4-2.

Table 4-1. Power Display Resolution

POWER RANGE (In watts)	POWER INCREMENT (In watts)
10-40	1
1.0-10	0.5
0.5-1.0	0.1
0.1-0.5	0.05

36. ***TIME Display*** – red 3-digit LED display, showing the selected ON time in seconds. The TIME display resolution (increment) varies with the ON time range and is given in Table 4-3.

Table 4-2. Time Display Resolution

ON TIME RANGE (In seconds)	ON TIME INCREMENT (In seconds)
0.05-0.1	0.01
0.1-1.0	0.05

37. ***Message Display*** – a green fluorescent, 20-character, 2-line alphanumeric display, displaying messages relevant to the operation of the system. These include:

a. Instruction messages indicating the procedure to be followed.

b. System parameters (laser operation mode, tissue exposure mode, time and power settings) for verification prior to entry.

c. Fault messages indicating a condition critical to the system.

4.3.2. Service Panel

The service panel and the footswitch compartment are located at the rear of the unit and are accessible through the service panel access door

Refer to Figure 4-5 for items 38 through 52.

38. ***Service Panel Access Door.***
39. ***Footswitch Compartment*** – dedicated compartment for storing the footswitch.
40. ***PATIENT port*** – for connecting to an endoscope to allow synchronization of smoke evacuation with laser emission during endoscopic procedures.
41. ***VACUUM port*** – for connecting to a smoke suction unit to allow synchronization of smoke evacuation with laser emission during endoscopic procedures.
42. ***EXT. GAS/INT. AIR Switch*** – enables synchronization of either inert gas or compressed air flow with laser emission.
43. ***GAS INLET Connection*** – input for inert gas from a regulated external gas supply.
44. ***FOOTSWITCH Connection*** – connection point for the footswitch cable. A polarizer on the receptacle prevents incorrect cable connection.

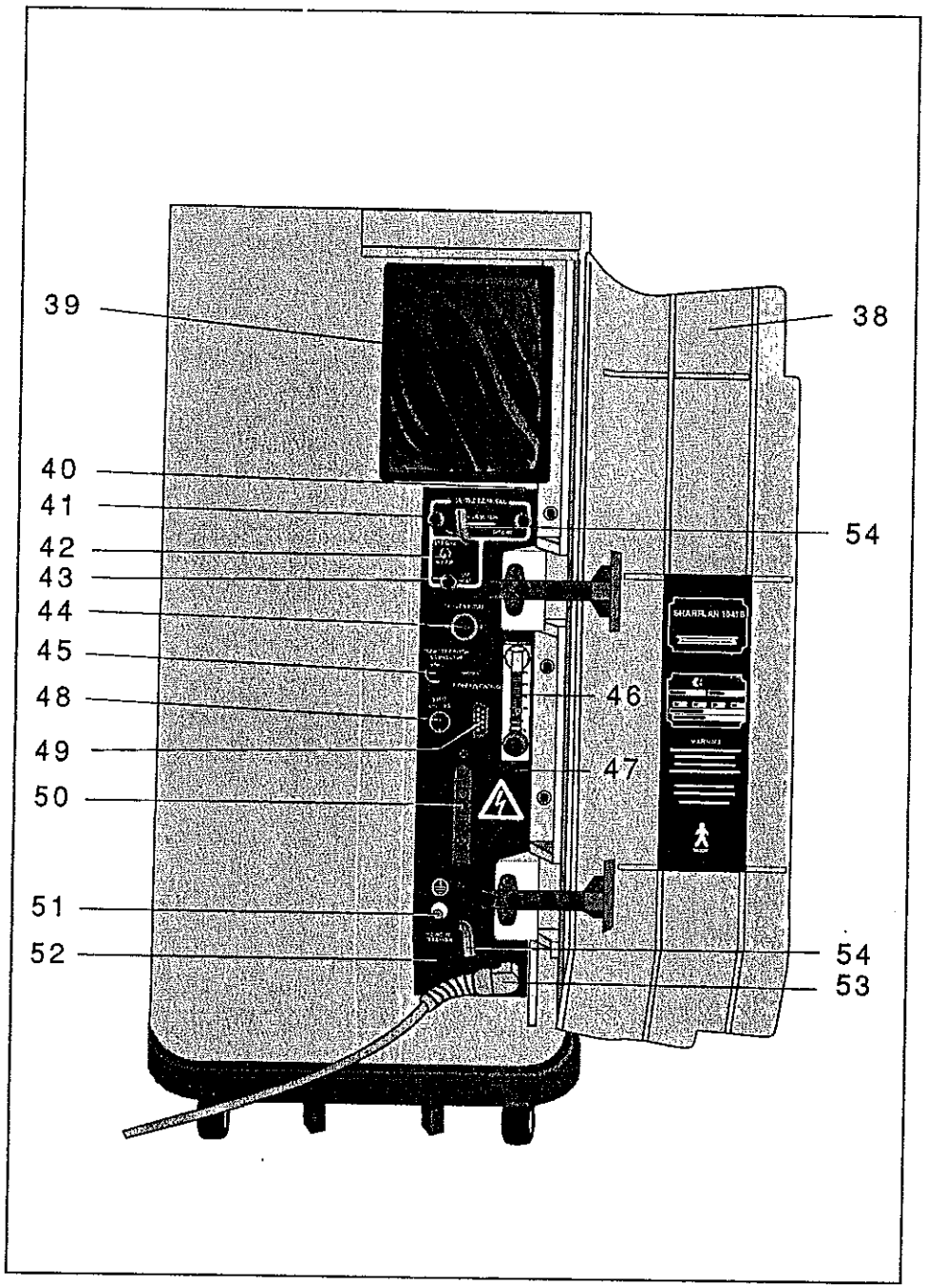


Figure 4-5. Service Panel

45. ***REMOTE SWITCH CONNECTOR Connection*** – connection point for an external interlock switch.
46. ***Compressed Air/Inert Gas Flow Meter*** – meter with a control knob, used to set the compressed air/inert gas flow rate in liters per minute.
47. ***Column Down Emergency Button*** – used to lower the column whenever the CLMN down key is disabled due to a fault situation (fault message appears on display).
48. ***Voltage Supply for SilkTouch*** – provides voltage for the SilkTouch char-free scanner.
49. ***Communication port for SilkTouch*** –Input/Output data port for the SilkTouch char-free scanner.
50. ***Fuse Housings.***
51. ***External Ground Connection*** – additional ground connection point for grounding the unit externally.
52. ***Circuit Breaker.***
53. ***Power Cable.***
54. ***Power Cable Hooks*** – for coiling the power cable when unit is not in use.

Chapter 5

Operating Instructions

5.1. *General*

This chapter contains detailed operating instructions for the unit. For easy reference, a checklist-type summary of procedures for the entire operation is also included at the end of the chapter.

5.2. *Preparing the Unit for Operation*

1. Push/pull the unit, using the large handle, into its desired position in the O.R. Use the small handle to rotate the unit to the required orientation. Press the brake pedal to lock the wheels of the unit. The recommended O.R. layout is shown in Figure 5-1.
2. Connect external ground (see 2.4), and the remote interlock system (see 2.5), if required.
3. Prepare the articulated arm:

   a. Release the articulated endjoint from its holder.

   b. Release the articulated arm from the two arm clips.
4. Inspect the bacteriological filter to verify that it is clean and properly installed, as described in 2.7.
5. Attach the desired laser surgical accessory. For details, refer to Chapter 6.
6. Balance the articulated arm by rotating the tension control grip. When in balance, the articulated arm should remain suspended and stationary with the laser accessory attached, and should convey a lightweight, freehand feeling to the user.
7. Remove the footswitch from its compartment and plug its cable into the FOOTSWITCH connection on the service panel (see 2.6).
8. Unhook the power cable and connect to a power receptacle.
9. If using a regulated external inert gas supply, connect the gas cylinder, and slowly open the cylinder valve. Set the line pressure at the required level, up to 4 atm/60 psi. Set the EXT. GAS/INT. AIR switch to EXT. GAS (for details, see 2.8). If compressed air is preferred to inert gas, set the switch to INT AIR.

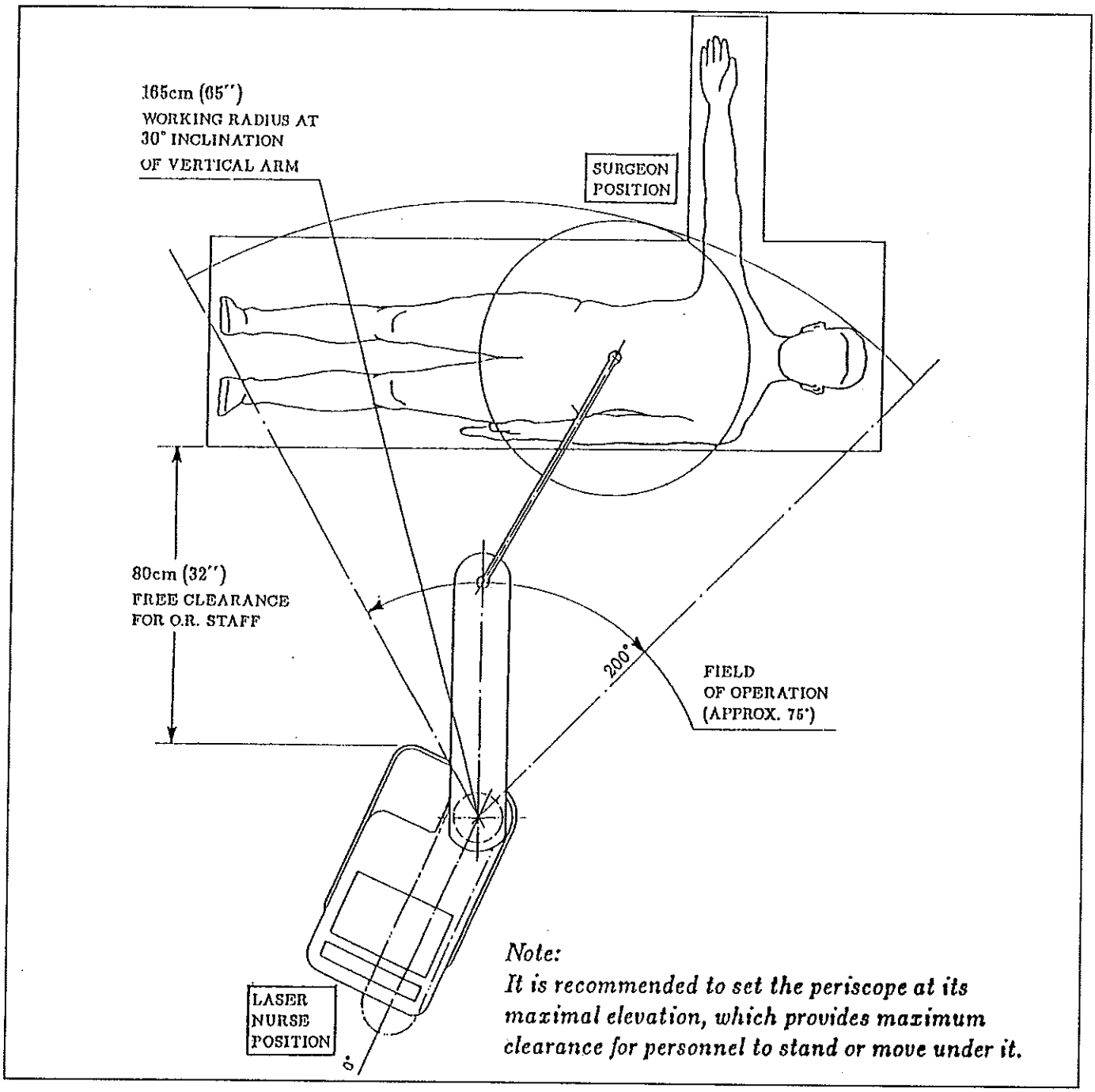


Figure 5-1. Recommended O.R. Layout

Warning

Do not use the compressed air/external gas system in sensitive endoscopic procedures requiring insufflation of CO_2 gas. This system is not intended for such applications.

10. If using an external smoke evacuation system, connect the appropriate tubing and set the EXT. GAS/INT. AIR switch on the service panel to EXT GAS. For synchronized smoke evacuation in endoscopic procedures, connect the tubing as described in 2.9.

5.3. Turn-On Procedure

1. Set the He-Ne shutter control to ON position.

2. Turn on the unit by turning the key clockwise to the "I" position. The power-on indicator illuminates to indicate that line voltage is supplied to the unit. The He-Ne aiming beam appears at the target site after a few seconds. The message display reads **SHARPLAN 1041S,** together with the current date and time. If the He-Ne shutter control is set to OFF during system turn-on, the message display will read OPEN HE-NE until the He-Ne shutter control is set to ON position. The message display reads **SYSTEM CHECK**, followed by a series of squares illuminating in sequence, indicating the process of the autómatic turn-on check procedure. All key indicators illuminate briefly, and the POWER and TIME displays momentarily read **8.8.8** to verify that all segments illuminate. The message display reads **FlexiLase USE? "1" – YES, "0" – NO.** Press "1" if FlexiLase fibers are in use; otherwise press "0". A small red dot flashes repeatedly on the right side of the LDU, indicating that the LDU is connected to the system, and that the message display is valid. The dot will continue to flash as long as the unit functions properly.

3. Set the He-Ne aiming beam parameters as follows:

a. Set the He-Ne beam intensity, using the He-Ne up/down keys.

b. For intermittent illumination of the He-Ne aiming beam, press the INT key. Repressing the INT key resets the aiming beam to operate in a continuous mode of illumination.

c. To block the He-Ne aiming beam upon pressing the footswitch for CO_2 laser emission, press the O.A.L. (Off At Lasing) key. Press this key again to cancel this function.

Notes

1. Upon unit turn-on, the He-Ne intensity level is automatically set to maximum illumination.

2. The He-Ne intensity level is indicated on the message display as a line of illuminated squares (appears upon depression of the He-Ne up/down ramp).

3. When the intensity level reaches maximum illumination, a beeping sound is heard (a complete line of illuminated squares appears). The minimum intensity level is indicated by only two illuminated squares on the message display, and a beeping sound is heard.

4. Adjust the periscope height, using the CLMN up/down ramp.

5. The message display will then read **CW POWER: WATTS, from .10 to 40 watts.**

5.4. *Checking for Proper Beam Alignment*

Before each surgical procedure, a beam alignment check should be performed. If using a handpiece, refer to 6.2.3 for a step-by-step alignment check.

5.5. *Checking and Adjusting Compressed Air/ Inert Gas Flow Rate*

Ensure that the compressed air/inert gas starts to flow when the unit is in the READY state (if in FlexiLase mode), or when the footswitch is pressed while the unit is in STBY state (if not in FlexiLase mode). The flow is verified by a hissing sound at the tip. Note that for inert gas supply, the compressed air/inert gas switch should be set to EXT. GAS, and for compressed air flow it should be set to INT. AIR. Set the flow meter control knob for the desired flow rate. For an initial setting, 2-3 liters/ minute is recommended.

If there is no compressed air/inert gas flow, refer to the Troubleshooting Guide in Chapter 8.

Caution

When using a handpiece, compressed air/inert gas must always be applied in order to protect the handpiece lens.

5.6. *Operating the System*

Whenever relevant, the first line of the message display reads the selected system parameters, as follows:

- ☐ Current laser operation mode (CW, SHARPULSE, or SUPERPULSE)
- ☐ Current tissue exposure mode (CONTINUOUS, SINGLE PULSE or REPEAT PULSE)
- ☐ ON time level for SINGLE PULSE (while in that mode)
- ☐ ON and OFF time level for REPEAT PULSE (while in that mode).

5.6.1. *Laser Operation Mode Selection*

Select the desired laser operation mode. CW is available by "default" upon unit turn-on. SUPERPULSE or SHARPULSE are available by pressing the appropriate key (key indicator illuminates). The system returns to CW whenever SHARPULSE or SUPERPULSE are cancelled by repressing the key (key indicator extinguishes).

The user may subsequently select a different laser operation mode whenever desired (provided that the CO_2 laser beam is not being emitted), by pressing the appropriate laser operation mode key.

The current laser operation mode is displayed on the message display and is also indicated by the key indicator.

5.6.2. *Power Setting*

The power displayed is the average power delivered on tissue.

Power setting is a two-stage procedure in which the user first selects the desired power level through the numeric keyboard. Then the microprocessor initiates a "power search" procedure in order for the system to operate at the requested power level. When the STBY key is initially pressed, or whenever the SET PWR key is pressed while in CW laser operation mode, the message display reads:

CW POWER: WATTS
from .10 to 40 watts.

When the SUPERPULSE laser operation mode is initially selected, or whenever the SET PWR key is pressed while in SUPERPULSE laser operation mode, the message display reads:

SP POWER: WATTS
from .50 to 17 watts.

When the SHARPULSE laser operation mode is initially selected, or whenever the SET PWR key is pressed while in SHARPULSE laser operation mode, the message display reads:

SHRPULSE: WATTS
from 5.0 to 40 watts.

When one of the above messages appears, the user should set the desired power level through the numeric keyboard. When a value is inserted, it appears on the first line of the message display. The second line reads **IF OK PRESS ENTER.** The user should then press the ENTER key for verification, or the " C " key to delete the inserted value.

If the value inserted is irrelevant, the message display reads **INVALID ENTRY!**

Note that the user may subsequently change the power setting whenever desired (provided that the CO_2 laser beam is not being emitted), by pressing the SET PWR key and setting the power level through the numeric keyboard.

Also note that in any subsequent selection of a laser operation mode, the system is automatically set to operate at the last power level set for the laser operation mode selected.

At this stage, the system initiates the "power search" procedure; the message display will read **POWER SETTING X.XXW, PLEASE WAIT** and the power level set will flash on the POWER display. When the "power search" procedure is ended, the POWER display illuminates continuously, and the message display reads **SELECT MODE, CONT. REPT. SNGL.** Note that if power setting is performed after the tissue exposure mode has already been selected, the message display will read the selected system parameters and **PRESS READY.**

If for any reason the requested power is not obtained, the message **POWER REACHED X.XXW, IF OK PRESS ENTER** will appear on the display, indicating the power level actually obtained. The system thus provides the operator with the possibility of deciding whether to resume operation at the power level obtained or to initiate a new power setting by pressing the SET PWR key.

5.6.3. *Tissue Exposure Mode Selection*

After the power level is selected and set, the message display reads **SELECT MODE CONT. REPT. SNGL.** (provided that a tissue exposure mode has not already been selected).

At this stage, the user should select the desired tissue exposure mode (CONTINUOUS, SINGLE PULSE or REPEAT PULSE) by pressing the appropriate key.

After a tissue exposure mode is selected, its indicator illuminates, and the message display reads the selected system parameters on one line, and on the other **PRESS READY.** In addition, for SINGLE PULSE and REPEAT PULSE tissue exposure modes, the ON time level is also displayed on the TIME display.

> **Warning**
>
> In READY state (READY key indicator illuminates), the laser emission indicator flashes and, if the footswitch is pressed, laser emission will occur.

5.6.4. *Time Selection*

In SINGLE PULSE or in REPEAT PULSE tissue exposure mode, the operator can set the desired ON time (and OFF time for REPEAT PULSE) through the SET TIME key and the numeric keyboard. The ON time ranges for the various laser operation modes and power ranges are provided in Table 5-1. The OFF time range is 0.01-1.0 second for all laser operation modes.

Table 5-1. ON Time Ranges

CW		SHARPULSE	SUPERPULSE	
Power Range (in watts)	*ON Time (in sec)**	*ON Time (in sec) **	*Power Range (in watts)*	*ON Time (in sec)*
Entire Range	0.01-1.0	0.05-1.0	0.5-0.9	0.5-1.0
			1.0-1.5	0.2-1.0
			2.0-3.5	0.1-1.0
			4.0-17	0.05-1.0

* Refers to entire SHARPULSE or CW power range.

Note

The ON and OFF time resolutions are given in Table 4-2.

In SINGLE PULSE tissue exposure mode, after the SNGL key is pressed, the ON time is automatically set to the minimal value permitted for the actual laser operation mode and power range (if a different ON time has not already been set since unit turn-on), or to the last setting selected by the user (provided it is within the acceptable ON time ranges in 5.6.4). The TIME display reads the ON time level and the message display reads the selected system parameters and **PRESS READY.**

The user should then press the READY key to enable the footswitch or the SET TIME key to change the ON time. When the SET TIME key is pressed, the message display reads **ON TIME SEC, from X.XX to 1.0 second** (where X.XX is the minimal ON time value permitted for the actual laser operation mode and power range as outlined in 5.6.4). Use the numeric keyboard to insert the desired value. When a value is inserted, it appears on the first line of the message display. The second line reads **IF OK PRESS ENTER.** The user should then press the ENTER key for verification, or the " C " key to cancel the inserted value. If the value inserted is irrelevant, the message display reads **INVALID ENTRY!**

Once a value is inserted and verified, the TIME display is updated and the message display reads the selected system parameters and **PRESS READY.**

In REPEAT PULSE tissue exposure mode, after the REPT key is pressed, the ON time is automatically set to the minimal value permitted for the actual laser operation mode and power range, and the OFF time is automatically set to 0.05 second (if a different ON or OFF time has not already been set since unit turn-on), or to the last setting selected by the user (provided it is within the acceptable time ranges in 5.6.4). The TIME display reads the ON time level and the message display reads the selected system parameters and **PRESS READY.**

The user should then press the READY key to enable the footswitch or the SET TIME key to change the ON and OFF time levels. When the SET TIME key is pressed, the message display reads **ON TIME SEC, from X.XX to 1.0 second** (Where X.XX is the minimal ON time value permitted for the actual laser operation mode and power range as outlined in 5.6.4). When value is inserted and verified, the TIME display is updated and the message reads **OFF TIME SEC, from 0.05 to 1.0 second.** When the new value for OFF time is entered and verified, the message display reads the selected system parameters and **PRESS READY.**

Note that the user may subsequently initiate a change in the time settings whenever desired (provided that the CO_2 laser beam is not being emitted), by pressing the SET TIME key.

5.6.5. *Footswitch Operation*

When the READY key is pressed, its indicator illuminates, the laser emission indicator flashes, and the unit is ready to emit the laser beam whenever the footswitch is pressed. The message display reads the selected system parameters and **PRESS FOOTSWITCH.**

Note

If the system is in the FlexiLase mode, compressed air/inert gas flow and suction is active for as long as the the unit is in READY state. When the system is not in the FlexiLase mode, compressed air/inert gas flow and suction will be activated by pressing the footswitch, and will continue for 2 seconds after footswitch release.

Table 5-2. Message Displays in Ready State

Tissue Exposure Mode	*Message Display Reading (in CW laser operation mode)*
CONTINUOUS	**CW CONTINUOUS PRESS FOOTSWITCH**
SINGLE PULSE	**CW SNGL X.XXS* PRESS FOOTSWITCH**
REPEAT PULSE	**CW RPT X.XX/Y.YY* PRESS FOOTSWITCH**
*X.XX represents the ON time level set and Y.YY represents the OFF time.	

Note

For SUPERPULSE or SHARPULSE laser operation modes, the message display reads **SP**or **SHRPULSE**, respectively, instead of **CW**.

> Warning
>
> Before pressing the footswitch, ensure proper power setting. If SINGLE PULSE or REPEAT PULSE is selected, ensure proper ON time and OFF time settings. Make sure that the beam is aimed at an appropriate target.

Press the footswitch to emit the laser beam. The message display reads **LASER EMISSION**, and the laser emission indicator illuminates continuously to warn personnel in the vicinity of the unit that CO_2 laser radiation is being emitted.

> **Note**
>
> An additional audio warning of laser emission is provided by initiating User Code 4, ACTIVATION OF AUDIBLE INDICATOR (see 5.8).

The opening of the shutter for CO_2 laser beam emission is heard as a distinct click from the periscope.

When the footswitch is released in a CONTINUOUS or REPEAT PULSE tissue exposure mode, laser emission ceases, the shutter closes, the emission indicator flashes again, and the message display reads the selected system parameters and **PRESS FOOTSWITCH.**

In a SINGLE PULSE tissue exposure mode, laser emission ceases upon termination of the ON time or when the footswitch is released, whichever comes first. At this point the shutter closes, the emission indicator flashes again, and the message display reads the selected system parameters on one line, and on the other **PULSE COMPLETED** (only if the pulse ON time was up before the footswitch was released), followed by **PRESS FOOTSWITCH.**

5.6.6. Pause in Operation

If a short pause in operation is desired, press the STBY key. The system exits the "ready" state, disabling the footswitch but preserving all settings. The message display reads the selected system parameters and **PRESS READY** until the READY key is pressed to return to "ready" state.

5.7. *Fault Messages*

The unit incorporates alarm circuits and self-test routines which continuously monitor unit operation. If a critical condition is detected, the microprocessor alerts the user by displaying an appropriate self-explanatory message on the message display, the audio indicator beeps and unit operation is disabled until the malfunction is repaired. For detailed information regarding each fault message, refer to the Troubleshooting Guide in Chapter 8.

> Note
>
> When a fault message is displayed, the CLMN up/down ramp is disabled. Press the column down emergency button on the service panel (see Figure 4-5, item 47) to lower the column, should the need arise.

5.8. *User Codes*

The SHARPLAN 1041S unit offers the possibility of changing some of the system functions for a more individualized operation, through the User Codes menu shown in Table 5-3.

To initiate the User Codes routine, perform the following:

1. Turn on the keyswitch. Verify that the message display reads **SHARPLAN 1041S,** together with the current date and time, followed by **SYSTEM CHECK** and a series of squares, indicating the process of the automatic turn-on check procedure. The message display will then read **FlexiLase USE? "1" – YES, 0 – NO.** Choose the appropriate key, according to the requested mode. The message display reads **CW POWER: WATTS, from .10 to 40 watts.**
2. Key in 1, 0 and 1 (101) on the numeric keyboard, and press the STBY key. The message display reads **USER CODE PRESS HENE UP/DN OR KEYPAD.**

> Note
>
> The user may subsequently enter the User Codes menu, whenever in the READY state, by entering 101 on the numeric keyboard, followed by STBY, provided that the CO_2 laser beam is not being emitted.

Table 5-3. User Codes Menu

Code No.	Function	Explanation
1	EUROPEAN MODE CALENDAR	Date displayed as DD/MM/YY.
2	AMERICAN MODE CALENDAR	Date displayed as MM/DD/YY.
3	SET TIME/DATE	Updates time and date.
4	ACTIVATION OF AUDIBLE INDICATOR	Beeps during CO_2 laser emission.
5	DEACTIVATION OF AUDIBLE INDICATOR	Cancels beeping during CO_2 laser emission.
6	USER I.D. CANCEL	Clears memory space (see 5.9).
7	ENGLISH	Sets message display language to English.
8	FRENCH	Sets message display language to French.
9	GERMAN	Sets message display language to German.
10	SPANISH	Sets message display language to Spanish
11	ITALIAN	Sets message display language to Italian
12	PULSE COUNTER ACTIVATION	Activates pulse counter
13	PULSE COUNTER DEACTIVATION	Deactivates the pulse counter

3. Press the appropriate code number, obtained from Table 5-3, using the numeric keyboard (or the He-Ne up/down ramp to continuously increase/reduce the User Code number on the menu to the desired number). To cancel a User Code selection, press the " C " key; the system returns to the User Codes menu and the message display reads **USER CODE PRESS HENE UP/DN OR KEYPAD.**

4. For User Codes 1, 2, 4, 5, 7, 8 or 9, with the appropriate code on the message display, the unit can be set for that function by pressing the ENTER key once. Return to normal operation by pressing the " C " key twice.

For User Code 3, SET TIME/DATE; and User Code 6, USER I.D. CANCEL, follow the instructions on the message display. When setting is completed, press the ENTER key once. Return to normal operation by pressing the " C " key twice.

For User Codes 12 and 13, after the user enters 12 and 13, the display will show **ACTIVATION** (or **DEACTIVATION**) **OF DISPLAY COUNTER.** Press the ENTER kay to activate or deactivate the pulse display counter.

The number of pulses is preserved, even if the unit is turned off, as long as the pulse display counter is activated. When the pulse display counter is deactivated, the counter is zeroed.

5.9. *Programming the System*

The SHARPLAN 1041S unit offers the user the possibility to reduce the time for setting procedures, by programming combinations of frequently used emission parameters. Up to one hundred different programs (ten programs per user, for ten different users) can be stored for easy retrieval when needed.

5.9.1. *Storing a Program*

1. Following initial unit turn-on, select the desired laser emission parameters in the following sequence;

   a. Laser operation mode
   b. Power level
   c. Tissue exposure mode
   d. Time settings (for SINGLE PULSE or REPEAT PULSE tissue exposure mode).

2. To store these parameters, first ensure that the message display reads the selected system parameters and **PRESS READY;** then, press the PROG key to enter the storing routine. The message display will read **USER ID: , PROGRAM STORAGE.**

Notes

1. The storing routine is available only after all the emission parameters are set and the message display reads the selected system parameters and **PRESS READY.** When pressing the PROG key before all emission parameters are set, the message reads **PROG: ACTIVE ONLY AFTER MODE SETTING.**

2. The **USER ID: , PROGRAM STORAGE** message is displayed the first time the storing routine is entered after unit turn-on. If the user wishes to enter additional programs, the system omits the message and allows direct selection of a program number, provided that the unit has not been turned off since initial turn-on.

3. Key in the I.D. or other code on the numeric keyboard (up to 8 digits) and press the ENTER key. The message display will then read **PROGRAM NO. _(0 to 9), PROGRAM STORAGE.**

Note

A situation may arise whereby the memory space for storing programs is full. In this case, when the user I.D. is keyed in, the message display reads **USER ID: BUFFER FULL.** To provide memory space for a new user, delete irrelevant user I.D. codes by entering User Code 6, USER I.D. CANCEL (see 5.8).

4. Key in a number from 0 to 9 on the numeric keyboard.

Note

Keying in a number already used will delete the program stored under that number.

5. The message display indicates the following system parameters: selected program No., laser operation mode, tissue exposure mode, ON time or ON time/OFF time, if in the SINGLE tissue exposure mode or REPEAT tissue exposure mode, respectively, followed by **IF OK PRESS ENTER.**

The POWER display flashes and reads the power level set.

The TIME display reads the ON time set (for SINGLE PULSE or REPEAT PULSE tissue exposure mode).

6. Press the ENTER key to store the program and return to normal operation, or press the " C " key to delete the program and return to normal operation.

5.9.2. *Recalling a Program*

1. Turn on the keyswitch and press the RCL key to enter the recall routine. The message display reads
USER ID: , PROGRAM RECALL.

Notes

1. The user may subsequently request the recall routine, by pressing the RCL key whenever desired, provided that the laser beam is not being emitted.

2. If the unit has not been turned off since a program was stored in the storing routine or recalled from storage, the recall routine omits the message **USER ID: ,PROGRAM RECALL**, allowing direct selection of a program number.

2. Key in the same code used for storing the program (up to 8 digits), and press the ENTER key. The message will then read
PROGRAM NO.__ (0 to 9), PROGRAM RECALL.

Note

If the user ID is not listed in the system memory, the message display will read **USER ID: NOT EXIST!**

3. Key in the desired program number. The system will automatically display the selected emission parameters stored in the program, followed by **PRESS ENTER**. The power display flashes and displays the power, and the TIME display reads the **ON TIME** (for SINGLE and REPEAT tissue exposure modes). When the ENTER key is pressed, the system will be set to operate according to the parameters displayed, and the power display will illuminate continuously.

Note

If the program number is not listed in the system memory, the message display will read **NOT PROGRAMMED!**

4. The message display will read **PRESS READY**. Press the READY key to enable the footswitch.

5.10. Turn-Off Procedure

To turn off the unit, proceed as follows:

1. Lower the periscope to the stowing position. The built-in column locking pin is engaged when the periscope repeater display points towards the large handle.

Note

If the CLMN down key is disabled, press the column down emergency button on the service panel.

2. Turn off the keyswitch and remove the key.
3. If the unit is connected to an external inert gas supply, close the inert gas cylinder valve and disconnect the gas hose. Set the INT. AIR/EXT. GAS switch on the service panel to INT. AIR.
4. If the unit is connected to a smoke evacuation system, disconnect the appropriate tubing and set the INT. AIR/EXT. GAS switch on the service panel to INT. AIR.
5. Disconnect all electrical connections (if necessary).
6. Remove the laser surgical accessory used (if necessary).
7. Lock the articulated arm in its two clips and screw the endjoint knuckles onto their holder.

5.11. Operating Procedures Summary

Table 5-4. Operating Procedures Summary

Action	Indications
1. Prepare unit for operation (see 5.2).	
2. Set He-Ne shutter control to ON, insert key and turn on keyswitch.	a. Power-on indicator illuminates. b. He-Ne aiming beam appears on the target site. c. Message display reads **SHARPLAN 1041S** with current date and time, followed by **SYSTEM CHECK** and a series of squares which illuminate one by one, indicating that the system is performing turn-on check procedure. d. Message display reads **FLexiLase USE? "1" – YES, "0" – NO.** Press appropriate key. e. Message display reads **PLEASE WAIT**, followed by **CW POWER: WATTS, from .10 to 40 watts**
3. Set He-Ne aiming beam intensity (intensity is set to maximum by "default").	He-Ne aiming beam intensity changes accordingly and a series of illuminated squares on message display indicates the intensity level.
4. Set He-Ne aiming beam mode of illumination (continuous mode of illumination is available by "default"). Press INT for intermittent illumination. Press O.A.L. to block He-Ne beam during CO_2 laser emission	 a. INT key indicator illuminates. b. He-Ne aiming beam flashes. O.A.L. key indicator illuminates.
5. Press CLMN up (down) key to adjust periscope height.	Periscope height is adjusted accordingly.
6. Check for proper beam alignment and compressed air/inert gas flow (see 6.2.3 and 5.5).	

Action	Indications
7. For CW laser operation mode, proceed to step 8. For SHARPULSE laser operation mode, press SHARP PULSE key. For SUPERPULSE laser operation mode, press SUPER PULSE key.	 a. SHARP PULSE key indicator illuminates. b. Message display reads **SHRPULSE: WATTS from 5.0 to 40 watts.** a. SUPER PULSE key indicator illuminates. b. Message display reads: **SP POWER: WATTS, from .50 to 17 watts.**
8. Set power, using the numeric keyboard and the ENTER key.	a. System enters "power search" procedure. b. Message display reads **POWER SETTING X.XXW, PLEASE WAIT.** c. Selected power level flashes on POWER display. d. At end of "power search" procedure: POWER display illuminates continuously. Message display reads **SELECT MODE, CONT. REPT. SNGL.**
9. Set tissue exposure mode.	a. The respective key indicator illuminates. b. Message display reads the selected system parameters and **PRESS READY.** c. In SINGLE PULSE and REPEAT PULSE tissue exposure mode: TIME display reads ON time (default value, or the last setting).
10. For CONTINUOUS tissue exposure mode, proceed to step 11. For SINGLE PULSE and REPEAT PULSE tissue exposure modes, perform time settings. For SINGLE PULSE tissue exposure mode:	

Action	Indications
Press SET TIME key.	a. SET TIME key indicator illuminates. b. Message display reads **ON TIME: SEC,** **from X.XX* to 1.0 sec.**
Set ON time, using the numeric keyboard.	Message display reads **ON TIME: X.XX SEC,,** **IF OK PRESS ENTER.**
Press ENTER.	a. TIME display is updated. b. Message display reads the selected system parameters and **PRESS READY.**
For REPEAT PULSE tissue exposure mode:	
Press SET TIME key.	a. SET TIME key indicator illuminates. b. Message display reads **ON TIME: SEC,** **from X.XX* to 1.0 sec.**
Set ON time, using the numeric keyboard.	Message display reads **ON TIME: X.XX SEC,** **IF OK PRESS ENTER.**
Press ENTER.	a. TIME display is updated. b. Message display reads **OFF TIME: SEC,** **from 0.05 to 1.0 sec.**
Set OFF time, using the numeric keyboard.	Message display reads **OFF TIME: X.XX SEC,** **IF OK PRESS ENTER.**
Press ENTER.	Message display reads the selected system parameters and **PRESS READY.**

* X.XX represents the minimal ON time value permitted for the actual laser operation mode and power range, as indicated in 5.6.4.

Action	Indications
11. Press READY.	a. READY key indicator illuminates. b. Laser emission indicator flashes. c. Compressed air/inert gas flow begins. d. Message display reads the selected system parameters and **PRESS FOOTSWITCH.**
12. Aim laser accessory and press footswitch.	a. Message display reads **LASER EMISSION.** b. Laser emission indicator illuminates. c. CO_2 shutter opens. d. Laser beam is emitted.
13. Release footswitch.	a. Laser emission ceases. b. CO_2 shutter closes. c. Laser emission indicator flashes. d. Message display reads the selected system parameters and **PULSE COMPLETED** (only if the system is in SINGLE PULSE mode and the pulse ON time was up before footswitch was released), followed by **PRESS FOOTSWITCH.**
14. For a pause in operation, press STBY.	a. STBY key indicator illuminates. b. Message display reads the selected system parameters and **PRESS READY.** c. READY key indicator and laser emission indicator extinguish. d. Compressed air/inert gas flow stops.

Action	Indications
15. To turn off unit: a. Lower periscope to stowing position. b. Turn off keyswitch and remove key. c. Close external inert gas cylinder valve (if relevant) and disconnect gas hose. d. Set INT. AIR/EXT. GAS switch on service panel to INT. AIR. e. Disconnect electrical connections. f. Detach the laser surgical accessory. g. Lock articulated arm in its clips and screw endjoint knuckles onto their holder.	Power-on indicator extinguishes.

Note:

It is recommended to set the periscope at its maximal elevation, which provides maximum clearance for personnel to stand or move under it.

Chapter 6

Laser Surgical Accessories

6.1. General

In this chapter, the standard laser surgical accessories, the 125mm focusing handpiece set and the SHARPLAN 719 Microslad are discussed in detail.

A brief description is also given of the other SHARPLAN optional laser surgical accessories for the unit. For more information about the various optional accessories, contact your SHARPLAN distributor.

6.2. Handpiece Set

6.2.1. Description

The standard focusing handpiece set supplied with the unit is the 125mm focusing handpiece.

The focusing handpiece set includes the following items (see also Figure 6-1):

1. 125mm Lens holder, including lens
2. 125mm Extender
3. Straight focus-indicating tip
4. 90° Reflector tip
5. 120° Reflector tip.

In the 125mm focusing handpiece, the CO_2 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.

> **Note**
>
> The focal distance of the He-Ne aiming beam is 88% of the CO_2 laser beam focal distance. The straight focus-indicating tip indicates the focal point of the CO_2 laser beam.

Table 6-1 shows the spot sizes for the standard 125mm focusing handpiece assembly as well as for the other optional SHARPLAN handpiece assemblies.

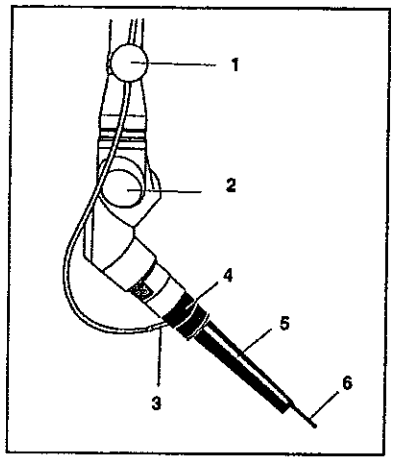
*Table 6-1. Handpiece Spot Sizes**

TYPE OF HANDPIECE AND WORKING DISTANCE (in mm)	SPOT DIAMETER (in mm)
50 Focusing	0.08
125 Focusing	0.20
200 Focusing	0.31
50 Defocusing	0.08-2.9
250 Defocusing	0.54-2.67

* Beam diameter containing 86.5% of the beam power.

6.2.2. Assembly

To assemble the handpiece:



1. *Bacteriological filter*
2. *Endjoint knuckles*
3. *Compressed air/inert gas nipple*
4. *Lens holder*
5. *Extender*
6. *Focus-indicating tip*

Figure 6-1. 125mm Handpiece Assembly Attached to Endjoint Knuckles

Notes

1. A sterile disposable drape (Cat. No. MD1446300) for the articulated arm and the handpiece is available as an option from your SHARPLAN representative.

2. The handpiece and its drape are assembled by a **Scrubbed Person** and a **Nonsterile Assistant.**

1. **Nonsterile Assistant:** Screw the lens holder into the endjoint knuckles quick-connection.
2. **Nonsterile Assistant:** Connect the inlet (free end) of the bacteriological filter to the compressed air/inert gas silicone tube, and the filter outlet (short flexible tube) to the compressed air/inert gas nipple on the lens holder.
3. **Scrubbed Person:** Screw the sterilized extender into the lens holder, while the **Nonsterile Assistant** holds the lens holder.
4. **Scrubbed Person:** Screw the desired tip (one of three types) into the extender.

Note

Make sure all components are tightly secured.

5. **Scrubbed Person:** Unwrap the drape and feed it over the handpiece.
6. **Nonsterile Assistant:** Starting at the endjoint knuckles, feed the drape along the entire length of the arm. Then secure the upper end of the drape around the articulated arm.
7. **Scrubbed Person:** Include the entire lens holder and the flow tube within the drape, and secure the lower end of the drape at the point where the lens holder is attached to the handpiece extender.

Note

For more detailed instructions, refer to those specified for the drape.

6.2.3. Optical Checks

To ensure proper operation of the handpiece with the laser unit, perform the following check:

1. Set the He-Ne beam intensity to the desired level, using the He-Ne up/down keys at a continuous mode of illumination. Aim the He-Ne beam at a cross marked on a moistened wooden tongue depressor placed on an appropriate thermal barrier.
2. Set the system at CW laser operation mode, 10W power level, SINGLE PULSE tissue exposure mode with ON time of 0.1 second.
3. Aim the He-Ne beam at the cross mark. Press the READY key, and then press the footswitch. The resulting burn mark on the tongue depressor should be concentric with the cross. Some displacement is permitted, provided that the burn mark perimeter covers the center of the cross.

Caution

Ensure compressed air/inert gas flow through the handpiece. Performing the check without compressed air/gas flow may damage the handpiece lens.

If the check is unsatisfactory, refer the problem to SHARPLAN-authorized technical personnel.

6.2.4. *Cleaning, Disinfection, Sterilization and Storage*

The following describes the cleaning, disinfection, sterilization and storage procedures for the 125mm focusing handpiece. The procedures for external cleaning and disinfection of the laser unit itself appear in Chapter 7 and in Appendix A. Procedures for cleaning, disinfecting and sterilizing the optional SHARPLAN accessories appear in specific manuals supplied with each accessory.

Note

Always clean/disinfect directly after use, before soils, stains and impurities dry on the parts.

Cautions

1. Before cleaning, disinfecting or sterilizing, the handpiece **must be disassembled and the lens holder separated** from the other components.

2. Disinfectants containing peracetic acid or chlorine components **should not be used.**

3. The handpiece **should not** be cleaned/disinfected by means of ultrasonic cleaners, washer-sterilizers or similar devices.

To clean/disinfect the handpiece, first remove the lens holder. Only then may the remaining handpiece parts, including the 90° and 120° reflector tips, be cleaned with water or instrument detergent. These parts may be disinfected using a standard hospital disinfectant solution. They should then be rinsed thoroughly inside and out with sterile water, and be carefully dried inside and out with a sterile cloth or swab.

The handpiece lens may be cleaned with a cotton swab dipped in high-grade acetone (such as Chemically Pure). This process should be repeated until the lens is clean.

Caution

Never allow the lens to come into contact with water.

The lens holder may be cleaned with a cotton ball dipped in hospital grade 70% alcohol solution, and may be cold gas sterilized.

Note

A stained lens must be cleaned before sterilization.

Except for the lens holder, all handpiece parts, including the 90° and 120° reflector tips, may be steam autoclaved at settings recommended by the autoclave manufacturer for metal instrumentation, or sterilized by ETO gas, according to hospital protocol.

Cautions

1. Although the reflector tips may be steam autoclaved, cold gas sterilization will better preserve the finish of the reflector tips.

2. **Do not steam autoclave the lens holder**, as the temperature and moisture will damage the lens.

6.3. SHARPLAN 719 Microslad

The SHARPLAN **Microslad** (**Micro**scope **L**aser **A**daptor **D**evice) for laser microsurgery is a CO_2 laser micromanipulator for coupling the SHARPLAN laser system to a microscope, thus enabling the application of the CO_2 laser beam under direct microscopic guidance. The Microslad incorporates a Continuously Variable Defocus (CVD) optical system for varying the spot size, and a joystick control for controlling the beam position at the target site.

Mounted onto the microscope, the SHARPLAN 719 Microslad delivers the laser beam from the articulated arm of the SHARPLAN 1041S surgical laser unit to the working plane determined by the microscope objective lens. A joystick is used to control the laser beam at the working plane within the microscope field of view. The red He-Ne aiming beam indicates the exact position of the CO_2 laser beam.

The 719 Microslad set includes the following items (see also Figure 6-2):

1. Microslad unit
2. 400mm Lens slide
3. 300mm Lens slide
4. Hand rest
5. Ring clip
6. Lens adaptor.

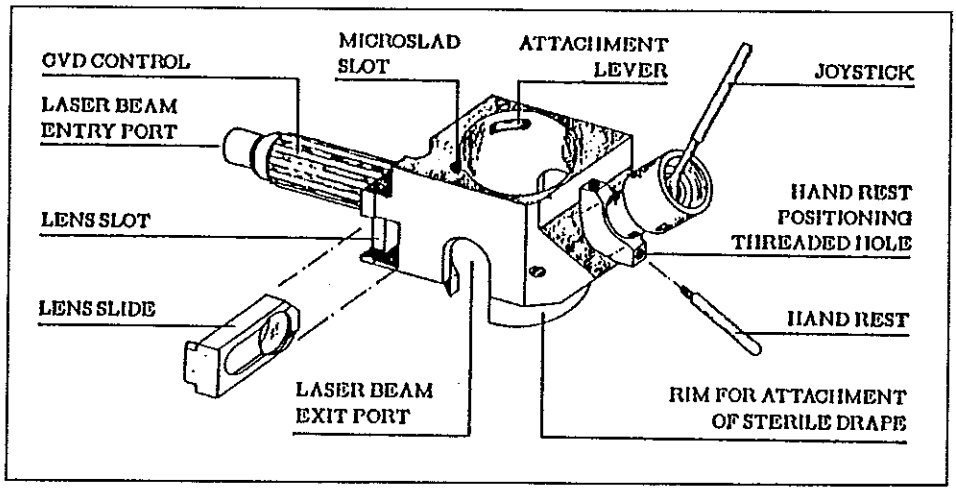


Figure 6-2. SHARPLAN 719 Microslad

The working distance of the SHARPLAN 719 Microslad is set to coincide with the focal distance of the microscope objective lens through the use of a lens slide. The standard lenses supplied with the Microslad are for 300mm and 400mm working distances. Lenses for 200mm, 250mm, 275mm and 350mm working distances are available as an option from your SHARPLAN representative.

Table 6-2 gives the beam spot diameters of the SHARPLAN 719 Microslad when coupled with the SHARPLAN 1041S laser unit, for various working distances, with the CVD at the focused and fully defocused settings.

*Table 6-2. Sharplan 719 Microslad Focal Spot Diameters**

WORKING DISTANCE (in mm)	CVD AT FOCUSED SETTING (spot diameter in mm)	CVD AT FULLY DEFOCUSED SETTING (spot diameter in mm)
200	0.35	4.6
250	0.42	5.6
275	0.45	6.1
300	0.49	6.8
350	0.58	7.7
400	0.64	8.6

* Beam diameter containing 86.5% of the beam power

The rim around the Microslad laser beam exit port allows convenient attachment of a sterile drape.

For user convenience, the Microslad includes a hand rest which can be connected in a horizontal (H) or in a vertical (V) orientation, as desired.

Special adaptors are available for coupling the SHARPLAN 719 Microslad to the following operating microscopes:

7. ZEISS* OPMI 1, 6, 9 and 19
8. WILD M600 series
9. OLYMPUS model OME
10. WECK OMS-15 series
11. JEDMED/KAPS, SOM series (not equipped with a fan housing)
12. MOLLER-WEDEL
13. TOPCON M300 series.

* The SHARPLAN 719 Microslad may be used as a Colposlad when mounted on ZEISS 1, 6, 9, 19, 90 and 99 colposcopes, and on the ZEISS photocolposcope.

Note

For more information about the 719 Microslad, and for installation and operation instructions, refer to the User's Manual for the SHARPLAN 719 Microslad.

6.4. Optional Accessories

6.4.1. SHARPLAN Handpieces

Focusing handpiece assemblies for 50mm (Model No. 15050) and 200mm (Model No.15200) working distances, and defocusing handpiece assemblies with Continuous Variable Defocus (CVD) optics, for 50mm (Model No.15051) and 250mm (Model No.15201) working distance, are available as options.

6.4.2. SHARPLAN Microslads

The SHARPLAN 717 (old Model No.719SL) and the SHARPLAN 718 (719SR), are Microslads equipped with a left or right side laser beam entry port, respectively. This configuration is recommended in the following circumstances:

1. When coupling to a double-headed microscope such as the ZEISS OPMI 6-SDFC, OPMI 6-SD, or OPMI 7-D.
2. Under constraints of space due to protruding elementary microscope parts, as in the cases of JEDMED/KAPS, SOM series microscopes equipped with a fan housing.
3. Under special constraints of space, surgeon convenience or requirements of the clinical procedure.

The SHARPLAN 715 Microslad is adaptable to the ZEISS OPMI MD, OPMI 11 and CS Varispot microscopes.

The SHARPLAN Acuspot™ laser micromanipulator provide surgeons with the exceptional precision of a very small spot size and perfect coaxial alignment of the He-Ne and CO_2 beams. The 710/711 are available for working distances of 250mm, 300mm and 400mm. The 710 Acuspot is compatible with ZEISS OPMI 1, 6, 9, and 19. Equipped with appropriate adaptors, it is compatible with WILD, OLYMPUS, WECK, JEDMED/KAPS, MOLLER-WEDEL and TOPCON microscopes.

The 711 Acuspot is compatible with ZEISS MD, OPMI 11 and CS Varispot microscopes. The Acuspot spot sizes range from 160 microns at 250mm working distance to 5mm, fully defocused at 400mm working distance.

6.4.3. *SHARPLAN Colposlads*

The most applicable Colposlads are the SHARPLAN 729 (old Model No.719), SHARPLAN 727 (719SL) with left side laser beam entry port, and SHARPLAN 728 (719SR) with right side laser beam entry port. These Colposlads are adaptable to ZEISS colposcopes 1, 6, 9, 19, 90, 99, and to the photocolposcope, as well as to JEDMED/KAPS, CODMAN, SHIMA, WOLF and KAMIYA TSUSHO KAISHA colposcopes.

Note

The SHARPLAN 717 (719SL), 718 (719SR) and 719 Microslads may be used as Colposlads when mounted on the colposcopes listed above.

Additional Colposlads available as options for colposcopic laser surgery are the SHARPLAN 725(719-L) for LEISEGANG colposcope models I, II and ID300, and the SHARPLAN 726 (719-0) for OLYMPUS OCS and OCS-2 colposcopes.

The SHARPLAN 779 CO_2 Laser Colposcopic System is an integral unit, comprising a SHARPLAN Colposlad incorporated in a LEISEGANG ID300 colposcope on a tiltable or swivel LEISEGANG stand with an illumination transformer.

6.4.4. *SHARPLAN Endoscopes and Auxiliary Endoscopic Devices*

The optional accessories used for laser endoscopic surgery are special laser-coupled endoscopes, which attach to the beam delivery system, and transmit the laser beam to their distal end. The SHARPLAN laser endoscopes include: SHARPLAN 781 Bronchoscope set for E.N.T., SHARPLAN 782/783 single and double puncture Laparoscope sets for OB/GYN, and the SHARPLAN 784/785 Rectoscope and Anoscope sets for Proctology.

Note

For 782/783 laparoscopes, as well as for any commercial laparoscope, the SHARPLAN BeamAlign direct laparoscopic coupler enables consistent alignment of the laser beam trajectory within its internal space. Equipped with the CVD optical system, the BeamAlign enables continuous varying of the spot size, eliminating the need to retract the laparoscope.

The SHARPLAN 793 Laprobe™ CO_2 laser laparoscopic probe is a laser delivery system which can be inserted into standard operating laparoscopes for laser surgical applications. The set includes two rigid endoscopic probes: a long probe for single puncture laparascopy and a short probe for double puncture laparoscopy. A laser coupler is included for attachment to the articulated arm of the SHARPLAN laser unit to focus and guide the beam into the Laprobe.

The SHARPLAN 794 ArthroLase™ probe system is a laser delivery system used for meniscectomies, synorectomies and meniscus, among others. The set includes short probes, sheaths and a laser coupler.

The SHARPLAN Microguide™ probes are available in straight, curved and mirrored configurations, either in lengths of 450 and 300mm for laparoscopic use or 120mm lengths for general use.

6.4.5. *SHARPLAN FlexiLase Fibers*

The SHARPLAN CO_2 laser FlexiLase™ fibers are lightweight, flexible delivery systems for freehand and/or endoscopic applications. They are based on a flexible plastic hollow waveguide, the internal surface of which is specially coated to provide superior reflection in the CO_2 laser wavelength of 10.6 micron. The FlexiLase fiber is a reliable and precise accessory for performing ablation of tissue, debulking of tumors or dissection of large structures.

The FlexiLase fibers are available in a variety of hand applicator configurations, to provide the surgeon with easy access to narrow cavities.

6.4.6. *SHARPLAN SwiftLase™*

The SHARPLAN SwiftLase™ flashscan provides the ideal device for many surgical applications in which char-free laser ablation over a relatively large area of extended lesions is required.

Chapter 7

Maintenance

7.1. *Introduction*

This chapter contains the SHARPLAN 1041S laser unit routine inspection and maintenance instructions. The maintenance procedures may be performed by hospital staff, unless specified otherwise. Any maintenance or repair not mentioned in this chapter may be performed **only** by SHARPLAN-authorized technical personnel.

> **Warning**
>
> Any unauthorized service or modification of this unit can cause serious injury and may invalidate the SHARPLAN Service Warranty Agreement.

7.2. *Service Information*

> **Warning**
>
> The SHARPLAN 1041S unit generates high voltages within the main cabinet. Therefore, the interior of the unit should be checked only by SHARPLAN-authorized technical personnel.

All correspondence with your SHARPLAN distributor regarding the unit should include the model and serial numbers appearing on the identification label.

7.3. *Routine Maintenance*

The SHARPLAN 1041S laser unit should be periodically inspected and serviced to maintain it in optimum condition. A recommended routine inspection and maintenance schedule is given in Table 7-1.

Table 7-1. Recommended Routine Inspection and Maintenance Schedule

INSPECTION/SERVICE	FREQUENCY	PERFORMED BY
Check pressure in inert gas cylinder.	Before every operation	Staff
Check beam alignment.*	Before every operation	Staff
Check for proper compressed air/inert gas flow.	Before every operation	Staff
Inspect general condition of handpiece and other laser surgical accessories. Also check optical components for dust smudges and scratches.*	Before every operation	Staff
Replace disposable bacteriological filter.	Whenever insufficient air/gas flow is detected.	Staff
Inspect unit exterior for loose gas or electrical connections and damage.	Weekly	Staff
Check power meter calibration.	Every six months	Hospital technical staff or SHARPLAN-authorized technical personnel
Perform power meter calibration.	As required by power meter calibration check	SHARPLAN-authorized technical personnel
Check maximum power output.	Every six months	SHARPLAN-authorized technical personnel
Check coating and condition of all mirrors and lenses.	Every six months	SHARPLAN-authorized technical personnel
Check cooling system for leaks and obstructions and air pressure in the expansion balloon.	Every six months	SHARPLAN-authorized technical personnel

* If CO_2 laser and He-Ne aiming beams are misaligned, or if any surgical accessory problem is apparent, except for dust and smudges on the the optical components, the problem should be referred to SHARPLAN-authorized technical personnel.

7.4. *Fuse Replacement*

To check and/or replace the fuses on the service panel, turn off the unit and disconnect the power cable from the power receptacle.

> **Warning**
>
> Before removing a fuse, turn off the keyswitch, remove the power cable from the power receptacle and wait approximately two minutes to allow high voltage discharge.

> **Caution**
>
> For continuous protection against fire hazard, replace fuses only with the same type and rating of fuse. Fuse type is LITTLEFUSE No.212 slow-blow, or equivalent.

For exact fuse rating, refer to the fuse listing on the service panel. (Note that the fuse labelled originally as 3A may be replaced by a slow-blow fuse rated for 3.15A.)

7.5. *Power Meter Calibration Check/Procedure*

The power meter calibration must be checked every six months. Though not mandatory, it is recommended that SHARPLAN-authorized technical personnel perform the power meter calibration check.

> **Note**
>
> **Only** SHARPLAN-authorized technical personnel may perform the actual calibration procedure, if required.

7.5.1. Calibration Check

The equipment required for the calibration check is a calibrated power meter. Ophir model 300A, Ophir model F-150A CAL ANHH MED, Laser Precision model RT-150, Coherent Radiation model 201, or an equivalent power meter should be used.

To check the power meter calibration:

1. Remove any surgical laser accessory attached to the articulated arm. Turn on the unit and aim the unfocused He-Ne aiming beam at the external power meter.

2. Ensure CW laser operation mode (available by "default").
3. Set power to 1W. Select CONTINUOUS tissue exposure mode and press the READY key. Press the footswitch and check whether the power measured by the external power meter matches the power read on the POWER display to within ±10%. If not, the power meter must be calibrated by SHARPLAN-authorized technical personnel.
4. Repeat step 3 for power settings of 5W, 10W, 30W and 40W.
5. Select SUPERPULSE laser operation mode.
6. Repeat step 3 for power settings of 0.5W, 2W, 5W, 10W, 15W and 17W.

7.5.2. Calibration Procedure

The power meter calibration procedure may be performed **only** by SHARPLAN-authorized technical personnel. The equipment required is a calibrated external power meter, a small screwdriver and a Digital Volt Meter (DVM).

1. Turn off the unit and remove any surgical laser accessory attached to the articulated arm.
2. Gain access to the head board by removing the periscope covers. Connect the ground (black) probe of the DVM to TP4 and the voltage (red) probe to TP6.

> **Caution**
>
> Take care not to accidentally touch any of the board components in order to avoid any damage to electronic components.

3. Turn on the unit and aim the unfocused He-Ne aiming beam at the external power meter.
4. Select SUPERPULSE laser operation mode.
5. Enter Service Mode. The message display reads **DIAGNOSTIC: PRESS HENE UP/DN OR KEYPAD.**
6. Press the 9 key. The message display reads **9) CALIBRATION MODE.**
7. Press ENTER. The message display reads **SP POWER: WATTS, IN CALIBRATION MODE.**

7. Press ENTER. The message display reads **SP POWER: WATTS, IN CALIBRATION MODE.**

8. Set power at 0.5W and press the ENTER key. The message display reads **PLEASE WAIT, IN CALIBRATION MODE**, followed by **IN CALIBRATION MODE, PRESS FOOTSWITCH.**

9. Using the screwdriver, adjust trimmer potentiometer P2 on the head board until the DVM reading is 100mV. If the reading is lower, turn P2 clockwise; if it is higher, turn counterclockwise.

10. Press the "C" key twice. The message display reads **SP POWER: WATTS, from .50 to 17 watts.**

11. Select CW laser operation mode and enter the service mode. The message display reads **DIAGNOSTIC: PRESS HENE UP/DN OR KEYPAD.**

12. Press the 9 key. The message display reads **9) CALIBRATION MODE.**

13. Press ENTER. The message display reads **CW POWER: WATTS, IN CALIBRATION MODE.**

14. Set power at 40W.

15. The message display reads **PLEASE WAIT, IN CALIBRATION MODE,** followed by **IN CALIBRATION MODE, PRESS FOOTSWITCH.**

16. The DVM offset reading should always be positive. If the reading is negative, press the OFF/RST key and repeat steps 4 through 9.

17. Press the "C" key and repeat steps 12 and 13. Set power at 0.05W, and proceed with steps 15 and 16.

18. Remove the DVM.

19. Press the 9 key. The message display reads **9) CALIBRATION MODE.**

20. Press ENTER. The message display reads **CW POWER: WATTS, IN CALIBRATION MODE.**

21. Set power to 10W and press the ENTER key. The message display reads **PLEASE WAIT, IN CALIBRATION MODE**, followed by **IN CALIBRATION MODE, PRESS FOOTSWITCH.**

22. Press the footswitch. The laser beam is emitted and the message display reads **LASER EMISSION.** Record the power level on the external power meter and release the footswitch. The message display will then read **EXT POWER: WATTS.**

23. Key in the power level recorded in step 22 and press ENTER. The message display reads **SHUT. (0=IN 1=OUT).**

24. Press the "O" key. The message display reads **SHUT.IN (0=IN 1=OUT), PRESS FOOTSWITCH.**

25. Press the footswitch. The laser beam is emitted internally and the message display will read **adj head P1 CW >>** (or **CCW<<**). The POWER display shows the actual power level.

26. If the POWER display reading and the power level on the external power meter (recorded in step 22) are not within ±10%, press the footswitch intermittently (at 5-sec intervals) while adjusting trimmer potentiometer P1 on the head board until the reading on the POWER display coincides with the power level recorded on the external power meter in step 22.

    If the message display, when pressing the footswitch, reads CW with the arrow poiting to the right, turn P1 clockwise; if it reads CCW with the arrows pointing to the left, turn counterclockwise.

    If a deviation of ±10% can not be obtained by adjusting P1, repeat steps 1 through 16.

Note

For proper calibration, allow a 5-second interval between measurements (footswitch depressions).

Caution

Take care not to touch any of the board components in order to avoid any damage to electronic components.

27. Press the OFF/RST key and repeat the calibration check in 7.5.1.

7.6. *External Cleaning/ Disinfection*

The external surfaces of the unit and the footswitch should be disinfected when the unit is initially received, and thereafter as required by hospital protocol. The surfaces may be wiped with a damp cloth or cotton dipped in hospital grade 70% alcohol solution or a disinfectant solution.

Cautions

1. Remove the power cable from the power receptacle before cleaning/ disinfecting with solutions.

2. Only the external surfaces of the unit may be cleaned by hospital staff. Do not attempt to remove any panels or to reach into the articulated arm to clean the mirror surfaces.

When the unit is not in use, it may be covered with a cloth or plastic drape.

See Chapter 6 for care and cleaning of the laser surgical accessories.

7.7. *Lens and Mirror Cleaning*

The lenses and mirrors within the unit may be cleaned **only** by Laser Industries-authorized technical personnel .

The handpiece lens and mirrors may be cleaned by hospital staff, following the procedures in Chapter 6.

7.8. *Moving the Unit*

Before moving the unit within the hospital, perform the following procedure:

1. Lower the periscope to the stowing position. (Note that the built-in column locking pin is engaged only when the periscope repeater display points towards the large handle.)
2. Disconnect the laser accessory from the articulated arm, disassemble and clean.
3. Lock the articulated arm in its arm clips, and screw the endjoint knuckles onto the endjoint holder.
4. Disconnect all external gas and electrical connections. Store the footswitch in its compartment and coil the power cable around its hooks.
5. Release the brake pedal to unlock the wheels of the unit.

On **flat** surfaces, push/pull the unit slowly, using the large handle located at the top of the main cabinet.

On **inclined** surfaces such as ramps, the following instructions must be followed:

Note

On inclined surfaces, it is necessary that two people move the unit.

- ☐ To move **down** a ramp, position the unit so that the large handle faces the ramp. One person should grasp the large handle firmly with both hands, and facing the unit, move backwards, allowing the unit to roll down. At the same time, the second person should grasp the small handle on the opposite end, restraining the unit so that movement down the ramp is slow and well-controlled.
- ☐ To move **up** a ramp, position the unit so that the small handle faces the ramp. One person should firmly grasp the large handle on the opposite end and push the unit. At the same time, the second person should firmly grasp the small handle, and moving backwards, pull the unit up the ramp.

Warnings

1. The unit should never be moved up or down ramps having a slope of more than 17% (10^{o}).

2. The unit should never be moved sideways across ramps having a slope of more than 10% (8.5^{o}).

To move the unit over uneven surfaces (i.e., elevator entrances, electric cables, etc.), position the unit so that the front wheels (the larger wheels) and the large handle face the direction of movement. Then pull the unit, firmly grasping the large handle with both hands.

If the unit must be moved to another location, it must be prepared for transport and reinstalled by SHARPLAN-authorized technical personnel.

Chapter 8

Troubleshooting

8.1. *General*

If the unit should malfunction, consult the Troubleshooting Guide in this chapter to identify the possible cause. Hospital staff may perform these troubleshooting procedures, except where stated that corrective action must be performed by SHARPLAN-authorized technical personnel.

Warning

This unit generates high voltages and emits high intensity laser radiation. Improper handling of the unit can cause serious injury.

Caution

Improper use or adjustment of this device may invalidate the SHARPLAN service warranty agreement. Contact your authorized SHARPLAN representative before any attempt to troubleshoot this unit in any manner other than those specified in this manual.

8.2. *Troubleshooting Guide*

The Troubleshooting Guide, Table 8-1, attempts to provide a guide for identifying malfunctions, some of which can be repaired by hospital staff. It does not attempt to anticipate all possible failures. Any malfunction not listed in the table **must** be referred to SHARPLAN-authorized technical personnel.

Table 8-1. Troubleshooting Guide

SYMPTOM	PROBABLE CAUSE	ACTION
HEAD TEMPERATURE FAILURE message	Cooling system malfunction	Press OFF/RST and wait a few minutes.* Reinitiate unit operation. If message persists, refer to SHARPLAN-authorized technical personnel.**
POWER SUPPLY FAILURE PS OVER CURRENT, OR **PS NO IGNITION FAILURE,** message	High voltage circuit problem	Press OFF/RST and wait a few minutes.* Reinitiate unit operation. If message persists, refer to SHARPLAN-authorized technical personnel.**
DISC OFFSET FAILURE message	Power detection problem	Press OFF/RST and wait a few minutes.* Reinitiate unit operation. If message persists, refer to SHARPLAN-authorized technical personnel.**
SHUTTER FAILURE message	CO_2 shutter problem	Press OFF/RST and reinitiate unit operation. If message persists, refer to SHARPLAN-authorized technical personnel.**
LOW COOLANT FLOW message	Cooling system malfunction	Press OFF/RST and turn off keyswitch. Reinitiate unit operation. If message persists, refer to SHARPLAN-authorized technical personnel.**
REMOTE INTERLOCK FAILURE message	External switch contacts of remote interlock system are disconnected or short is not installed on remote interlock connector	Reconnect external switch contacts, or turn off unit and install short on remote interlock connector.**

* Do not turn off the keyswitch.
** If the problem ceases, the message display reads **PRESS C TO CONTINUE.** Press the "C" key to continue operation.

SYMPTOM	PROBABLE CAUSE	ACTION
COLUMN OVERLOAD FAILURE message	Motorized column motor malfunction	Release CLMN up(down) key and wait a few seconds. Press CLMN up(down) key again. If message persists, refer to SHARPLAN-authorized technical personnel.**
POWER REACHED X.XXW, IF OK PRESS ENTER message appears when the "power search" procedure is completed.	"Power search" failure	Reselect power level. If message persists, press OFF/RST and reinitiate unit operation and reselect power level. If message persists, refer to SHARPLAN-authorized technical personnel.
NO POWER READING message	"Power search" failure	Press OFF/RST and reinitiate unit operation. If message persists, refer to SHARPLAN-authorized technical personnel.**
RELEASE FOOTSWITCH message	Footswitch depressed when system is not in "ready" state	Release footswitch.
FOOTSWITCH FAILURE RELEASE FOOTSWITCH message	Footswitch problem	Release footswitch. If message persists, refer to SHARPLAN-authorized technical personnel.
KEYBOARD TEST FAILURE message	Keyboard malfunction	Press OFF/RST and reinitiate unit operation. If message persists, refer to SHARPLAN- authorized technical personnel.**
OPEN HE-NE message	He-Ne shutter control is set to OFF position during system turn-on	Set He-Ne shutter control to ON position.
PROG. ACTIVE ONLY AFTER MODE SETTING message when initiating program storing	Emission parameters are not set	Set laser emission parameters and press PROG key only after message display reads **PRESS READY TO ENABLE.**
BUFFER FULL message when initiating program storing.	No memory space available	Clear memory space. See 5.9.1.

** If the problem ceases, the message display reads **PRESS C TO CONTINUE.** Press the "C" key to continue operation.

SYMPTOM	PROBABLE CAUSE	ACTION
NOT EXIST! message when initiating a program recall.	User I.D. not listed in system memory	Reinsert the user I.D. code.
NOT PROGRAMMED! message when initiating a program recall.	Program number not listed in system memory	Reinsert program number.
He-Ne aiming beam is not present or one of the He-Ne modes is not available.	He-Ne system problem	Refer problem to SHARPLAN-authorized technical personnel.
Very poor He-Ne aiming beam is present at handpiece tip.	1. He-Ne aiming intensity set too low	Adjust He-Ne aiming intensity
	2. Optical problem	Refer problem to SHARPLAN-authorized technical personnel.
Power-on indicator does not illuminate when switch is turned on, and unit is inoperable.	1. Tripped circuit breaker	Reset circuit breaker.
	2. No ac line power	Ensure that ac power is available and that power cable is properly connected to power receptacle.
	3. Blown fuse(s)	Check fuses F7 through F10 on the service panel. Replace, if necessary.
	4. Power supply problem or electronic problem	Refer problem to SHARPLAN-authorized technical personnel.
Power-on indicator illuminates when keyswitch is turned on, but unit is inoperable.	1. Blown fuse(s)	Check fuses F7 through F10 on service panel. Replace, if necessary.
	2. Electronic malfunction	Refer problem to SHARPLAN-authorized technical personnel.
Laser beam not emitted when footswitch is pressed.	1. System not in "ready" state	Ensure proper settings and press the READY key.
	2. Footswitch cable improperly connected	Connect footswitch cable properly.
	3. Electronic malfunction	Refer problem to SHARPLAN-authorized technical personnel.

SYMPTOM	PROBABLE CAUSE	ACTION
Laser emission indicator does not illuminate when footswitch is pressed, or does not flash when the system is in "ready" state.	Blown LED or electronic malfunction	Refer problem to SHARPLAN-authorized technical personnel.
No compressed air/inert gas flow in READY state (when in FlexiLase mode) or when the footswitch is pressed.	1. Int air/ext gas switch on service panel is set to EXT GAS position and an external gas cylinder is not connected. 2. If using external inert gas, external gas cylinder is closed or depleted, or flow control knob is turned off 3. Blocked bacteriological filter 4. If using the built-in compressed air system, air compressor problem	Set switch to INT. AIR position if using compressed air, or connect an external inert gas cylinder. Open the gas cylinder (if applicable) or replace cylinder if necessary. Adjust flow rate. Replace filter. Refer problem to SHARPLAN-authorized technical personnel.
Mode can be selected, but its indicator does not illuminate.	Blown LED	Refer problem to SHARPLAN-authorized technical personnel.
Mode, power or time cannot be selected.	Electronic malfunction	Refer problem to SHARPLAN-authorized technical personnel.
Periscope column does not move when column up/down key(s) is pressed.	Electronic malfunction or mechanical problem	If the symptom is accompanied by a fault message, the column can be lowered by pressing the column down emergency button on the service panel. If problem persists, refer to SHARPLAN-authorized technical personnel.
Periscope column does not move smoothly.	Mechanical problem	Refer problem to SHARPLAN-authorized technical personnel.
When coupling with smoke evacuation unit, suction does not occur in READY state (when in FlexiLase mode) or when footswitch is pressed.	1. Int air/ext gas switch on service panel is set to INT. AIR. 2. Electronic malfunction	Set switch to EXT. GAS. Refer problem to SHARPLAN-authorized technical personnel.

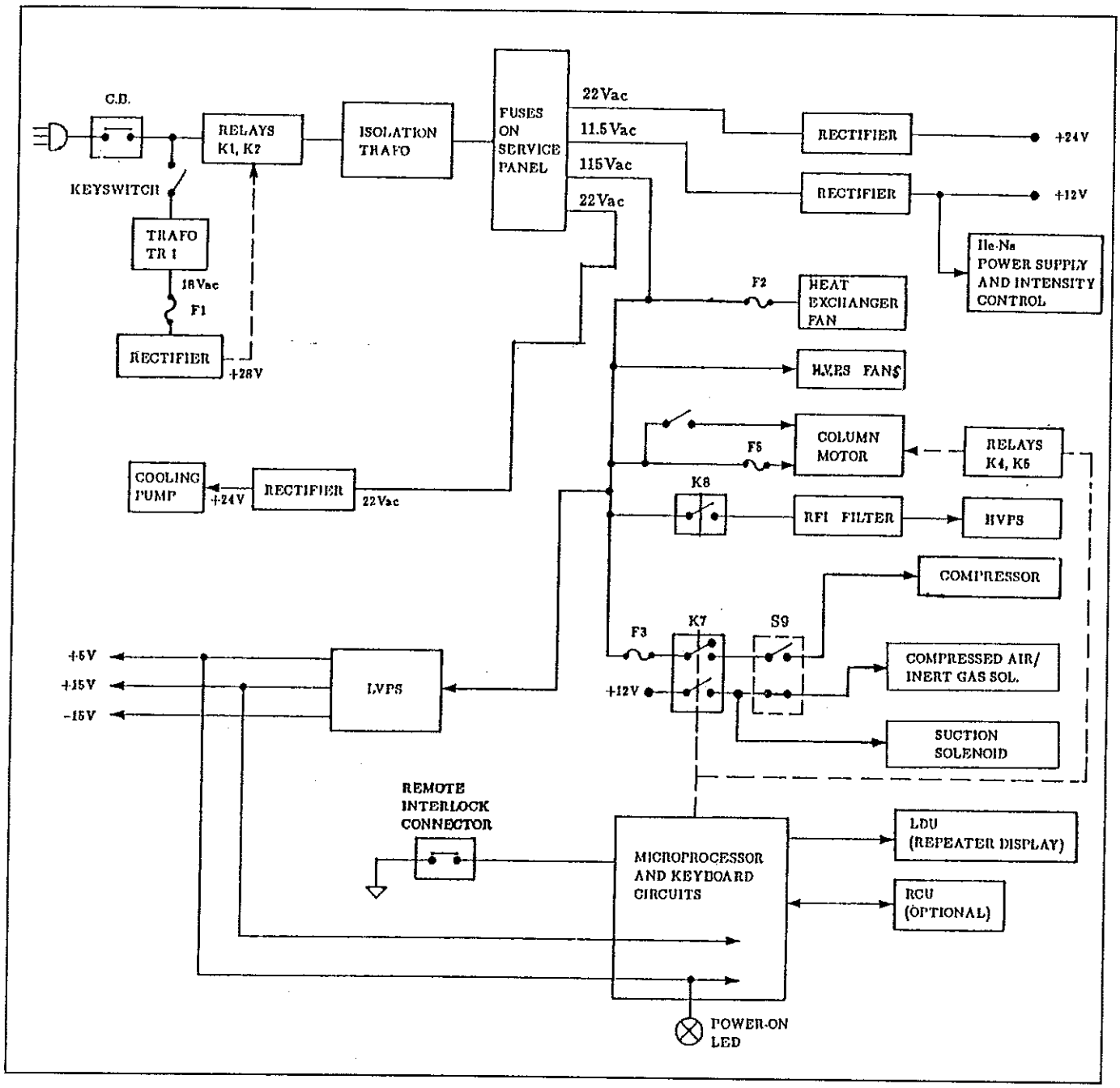


Figure 8-1. Power Distribution Schematic

Chapter 9

Specifications

9.1. Outputs

Laser
Sealed-off, DC-excited CO_2 laser.

Wavelength
10.6 microns, infrared.

Mode Structure
TEMoo.

Power on Tissue
Continuously adjustable power on tissue in the following ranges:

- ☐ CW:
  0.1-40W
- ☐ Superpulse:
  Average power range – 0.5-17W
  Peak power – 430W.
  Frequency and duty cycle – automatically set by system.
- ☐ Sharpulse:
  Average power – 5-40W
  Peak power – 200W
  Energy per pulse – 150mJ
  Pulse width – 770 µsec
  Frequency – automatically set by system.

Aiming Beam
5mW red helium-neon laser with a continuously variable intensity control.

Mode of operation:
continuous or intermittent at 5Hz.
Extinguishable during CO_2 laser emission.

Spot Sizes
From 0.08mm, at 50mm focus handpiece to 8.6mm,
at fully defocused setting of 719 Microslad with 400mm working distance.

Delivery System
Lightweight, carbon fiber, 7-joint, fixed mirrors, spring-balanced articulated arm designed for freehand, microscopic and endoscopic surgery.

9.2. Inputs

Electrical Power
100-140Vac/10A, 50 or 60Hz;
200-240Vac/5A, 50 or 60Hz.

Cooling System
Closed loop, pressurized liquid-to-air heat exchanger.

Purge Gas System
Dual system for inert gas/compressed air flow at surgical accessory via the bacteriological filter:

- ☐ Built-in air compressor
- ☐ Port for connection to a regulated external supply of inert gas; line pressure up to 4 atm/60 psi.
- ☐ Adjustable flow rate: 0-25 lit/min.

9.3. Operation and Control

Control
Microprocessor-based, soft-touch control panel.

Laser Operation Modes
CW (Continuous Wave)
Superpulse
Sharpulse

Tissue Exposure Modes

- ☐ Continuous
- ☐ Single Pulse :
  Continuously adjustable
  ON time (CW & Sharpulse) – min: 0.01 sec, max: 1.0 sec
  ON time (Superpulse) – min: 0.05 sec, max: 1.0 sec
  (Range varies according to power. See Table 5-1.)
- ☐ Repeat Pulse:
  Continuously adjustable
  ON time (CW & Sharpulse) – min: 0.01 sec, max: 1.0 sec
  ON time: (Superpulse) – min: 0.05 sec, max: 1.0 sec
  (Range varies according to power. See Table 5-1.)
  OFF time (all modes) – min: 0.01 sec, max: 1.0 sec

Control Panel Displays

- ☐ Green fluorescent, 20-character, 2-line alphanumeric display for operating instructions, system parameters and maintenance information.
- ☐ POWER: 3-digit, red LED.
- ☐ TIME : 3-digit, red LED.

Repeater Display (LDU)

- ☐ Laser operation mode: 2-digit, red LED
- ☐ Tissue exposure mode and fault messages: 4-digit, red LED
- ☐ Power: 3-digit, red LED
- ☐ Time: 3-digit, red LED.

Unit Turn-On

Keyswitch.

Laser Emission Control

Footswitch.

Laser Emission Indicator

Amber LED dual-function indicator:

- ☐ Flashes to indicate that unit is ready for laser emission
- ☐ Continuously illuminated during CO_2 laser emission.

Smoke Evacuation Interface System for Endoscopic Procedures

Built-in solenoid and ports; enables synchronization of smoke evacuation with laser emission.

Special Software Features

- ☐ Possibility of changing preset system functions for more individualized operation
- ☐ Store and recall capability for 100 laser protocols.
- ☐ Pulse Counter

9.4. Physical

Dimensions

Width: 38cm (15")
Depth: 52cm (21")
Height:
Main cabinet – 109cm (43")
Column fully raised – 205cm (81")
Column fully lowered – 178cm (70")
Radius from column at full arm extension: 200cm (79")
Periscope horizontal rotation: 200°.

Weight

132 kg (290 lbs).

9.5. *Standard Accessories*

Handpiece
Quick-connect focusing handpiece assembly for 125mm working distance with two straight tips, one 90° and one 120° reflector tips (Model No.15125).

9.6. *Optional Accessories*

Oral Pharyngeal Delivery System
The system combines the 230mm SHARPLAN defocusing handpiece with the unique SwiftLase technology for char-free tissue ablation.

Handpieces
Focusing handpiece assemblies for 50mm (Model No.15050) and 200mm (Model No.15200) working distances.

Defocusing handpiece assemblies with Continuously Variable Defocus (CVD) optics, for 50mm (Model No.15051) working distance and 250mm working distance (Model No.15201).

FlexiLase
SHARPLAN FlexiLase™ CO_2 laser hollow fiber system consists of a variety of long and short CO_2 fibers and a focusing coupler which attaches to the articulated arm of all SHARPLAN CO_2 laser units. The FlexiLase™ system allows work in normally inaccessible areas - such as the oral cavity, nasal sinuses, esophagus, trachea, rectum, vagina and cervix.

Microslads*
SHARPLAN 712 Acuspot™ provides a miniscule spot size and convenient working distance adjustment. For WILD, ZEISS, and other microscopes.

SHARPLAN 717 (719SL) and 718 (719SR) Microslads with side laser beam entry port.

SHARPLAN 719 Microslad for most standard operating microscopes.

SHARPLAN 715 for ZEISS OPMI MD and OPMI 11 microscopes.

Colposlads*
SHARPLAN 729 (719) for ZEISS, JEDMED/KAPS, CODMAN, SHIMA, WOLF and KAMIYA TSUSHO KAISHA colposcopes.

SHARPLAN 727 (719SL) and 728 (719SR) Colposlads with side laser beam entry port.

SHARPLAN 725 (719-L) and 726 (719-O) for LEISEGANG and OLYMPUS colposcopes, respectively.

SHARPLAN 779 Laser Colposcopic System comprised of a SHARPLAN Colposlad incorporated within a LEISEGANG ID300 colposcope on a tiltable or swivel stand with an illumination transformer.

Endoscopes and Auxiliary Endoscopic Devices
SHARPLAN 781 Bronchoscope set includes four tube sizes, coupler with joystick control, CVD and X4 proximal magnifier.

SHARPLAN 782 Laparoscope set includes single and double puncture tubes, trocars, sleeves, and two BeamAlign™ direct couplers for 200mm and 300mm working distances.

SHARPLAN 783 Laparoscope set includes double puncture tubes, trocar, sleeve and BeamAlign direct coupler for 200mm working distance.

SHARPLAN 787 Laparoscope set includes a 300mm single puncture tube with telescope, trocar, sleeve, and a BeamAlign direct coupler.

BeamAlign direct coupler for free beam CO_2 laser laparoscopy for absolute alignment with any operative laparoscope, includes CVD optical unit, aligning connector and adaptors.

SHARPLAN 793 Laprobe CO_2 laser laparoscopic probe set includes single puncture probes, second puncture probes, sheaths and laser coupler.

SHARPLAN 794 ArthroLase Set, includes short probes, sheaths and laser coupler.

SwiftLase
SHARPLAN SwiftLase is the ideal device for char-free laser ablation in ENT, Gynecology, Neursurgery, & General Surgery. Several models are available.

SilkTouch
SHARPLAN SilkTouch is the ideal device for single layer char-free tissue ablation in plastic surgery anddermatology.

Smoke Evacuation
SHARPLAN XPlume smoke evacuator system provides efficient smoke evacuation from surgical sites.

Remote Control Unit
SHARPLAN 750 Remote Control Unit for control of main functions from the articulated arm endjoint.

(* Old model numbers are given in parentheses)

9.7. Maintenance Accessories

	Description	Part Number
1.	Footswitch assembly	AA2056300
2.	Key for keyswitch lock	ES1452500
3.	Straight tip, 125mm	PM0163930
4.	90° Tip, 125mm	AA0198900
5.	120° Tip, 125mm	AA0198800
6.	Endjoint cap	PM0163830
7.	Lens holder	AA0742900
8.	Extender	AA2171600
9.	Bacteriological filter, 10 pack	MD1475000
10.	Flexible clear silicon tube, ID=3mm/OD=5mm/L=2.5m	MP1177200
11.	Suction/inert gas hose adaptor	PM2378630
12.	Hose clamping clip	PS0139140
13.	O.R. laser radiation warning sign	PL2242800
14.	SHARPLAN 1041S User's Manual	PB2395300
15.	SHARPLAN 719 Microslad™ User's Manual	PB0763100

Appendix A

Sharplan 1041S Laser Unit Operation and Safety Checklist

A.1. Pre-Operative

1. Ensure that the following fire retardant materials/equipment are present in the operating room (O.R.):
   - ☐ sterile, saline solution in both syringe and larger container
   - ☐ suitable fire extinguisher.
2. Check all instruments and surrounding surfaces for nonreflectivity. Use of nonreflective instruments is a recommended safety measure in laser procedures.
3. Ensure that the following are nonflammable:
   - ☐ Anesthetics
   - ☐ Endotracheal tubes
   - ☐ Prep solutions.
4. Thoroughly moisten all of the following:
   - ☐ Towels, gauze, and flammable materials used as drapes
   - ☐ Sponges.
5. Each member of the O.R. team must use appropriate safety eyewear.
6. Provide an appropriate vacuum suction unit for evacuation of fumes and debris.
7. Place a "LASER IN USE" safety sign on all entrance doors to the O.R. theater.
8. Obtain the key to the unit.
9. If the laser unit must be moved to the O.R.:
   - ☐ Ensure that the two long articulated arm sections are secured by the securing clip, and that the endjoint knuckles are locked onto the holder.
   - ☐ Ensure that the periscope is locked in its lowest position.

- ☐ Release the brake pedal to unlock the wheels of the unit.
- ☐ Move the unit to the O.R., following the instructions in 7.8.

10. Inspect all cables, including the footswitch cable, for torn areas or exposed wires; check cable connection for cracks or loose prongs.

11. Connect a remote interlock switch, if required (see 2.5).

12. Remove the footswitch from its compartment and connect the footswitch cable to the unit.

13. Connect external ground, if required (see 2.4).

14. Prepare an external suction unit. To synchronize smoke evacuation with footswitch activation for endoscopic procedures, connect the tubing as described in 2.9).

Note

The suction is active as long as the unit is in READY state. When the system is not in the FlexiLase mode, suction is activated in READY state, **only** by pressing the footswitch, and will continue for 2 seconds after footswitch release.

15. Uncoil the power cable from its hooks and connect to a suitable power receptacle (see 2.4). (U.S.A.: Use 120Vac, 10A power receptacle.)

16. If an external inert gas supply is required: Check for sufficient gas pressure in the cylinder (minimum 10 atm/150 psi), and replace, if necessary. Connect the inert gas (N_2 or CO_2) cylinder. Set the smoke evacuation/inert gas switch to EXT. GAS. Open the cylinder valve (turn counterclockwise), and adjust line pressure at the required level, up to 4 atm/60 psi (see 2.8).

If compessed air is preferred, set the compressed air/inert gas switch to INT. AIR.

17. Press the brake pedal to lock the wheels of the unit.

18. Release the articulated arm from its clips and the endjoint knuckles from their holder.

19. Inspect the disposable bacteriological filter for any changes in clarity, and attach it according to 2.7). Attach the laser accessory to the articulated arm (see Chapter 6). Check and adjust balance, if necessary.

Notes

1. If using a handpiece, verify that all its components are tightened securely.

2. When using the optional Microslad, verify that the lens within the lens slide is clean. If not, clean it with a cotton swab dipped in high-grade acetone (such as Chemically Pure).

20. Turn on the keyswitch.

21. The message display reads **SHARPLAN 1041S** and the current date and time, followed by **SYSTEM CHECK** and a series of squares illuminate one by one, indicating that the system is performing the turn-on check procedure. The message display reads **FlexiLase USE? "1" – YES, "0" – NO.** Press the appropriate key according to the desired option.

22. Verify emission of the red He-Ne aiming beam. Set the He-Ne aiming beam parameters (intensity, INT, O.A.L.).

23. Raise and lower the column to confirm that it operates properly. Rotate the periscope manually to check for proper movement. Note that in its lowest position, with the repeater display pointing towards the large handle, the periscope is fixed in place and cannot be rotated..

24. Message display reads
CW POWER: WATTS, from .10 to 40 watts.

25. Using safety eyewear, check for proper beam alignment and for compressed air/inert gas flow. (Beam alignment check with a handpiece is described in 6.2.3; compressed air/inert gas flow check and adjustment is described in 5.5.)

26. With a power setting of 10W, test fire the laser in CW - SINGLE PULSE at 0.05, 0.1, 0.2, 0.5 and 1.00 second ON time settings; then test fire in REPEAT PULSE, for identical ON time and OFF time settings of 0.05, 0.1, 0.2, 0.5 and 1.00 second. Repeat tests, firing in SUPERPULSE and SHARPULSE laser operation mode.

27. After testing of the unit is completed, lower the periscope and remove the laser accessory from the articulated arm.

Note

If the CLMN down key is disabled, press the column down emergency button on the service panel.

28. If the unit is to remain inactive for an extended period of time, turn off the keyswitch.
29. Lock the articulated arm in its arm clips, and screw the endjoint knuckles onto their holder.

A.2. Intra-Operative

1. According to hospital protocol, attach the cleaned, disinfected and/or sterilized accessory to be used to the articulated arm. The draping of the handpiece and the articulated arm is described in Chapter 6.
2. Provide safety eyewear for the staff, and for the patient (if conscious).

Notes

1. If performing surgery close to the endotracheal tube (oral, laryngeal, tracheal), appropriate precautions must be followed, according to hospital policy, to prevent perforation of the tube by the laser beam.

2. For facial surgery, completely cover the patient's eyes with moistened eye pads.

3. For surgery on perineal or anal areas, in order to prevent the possibility of methane gas explosion/fire, insert a wet sponge into the rectum.

3. Surround the surgical area with wet towels.
4. Position the laser unit near the patient, and press the brake pedal to lock the wheels. (The recommended configuration for surgical procedures is described in Figure 5-1.)
5. Position the footswitch near the surgeon.
6. Activate the vacuum suction unit for evacuation of fumes and debris from the treatment site.
7. Turn on the unit.
8. Set the laser operation mode.
9. Set the desired power level.

10. Set the tissue exposure mode (for SINGLE PULSE and REPEAT PULSE, also select time settings) and press the READY key.
11. When a pause in the surgical procedure is required, press the STBY key to disable the footswitch for short intervals, and OFF/RST to disable the unit for long intervals.

A.3. Post-Operative

1. Lower the periscope to the stowing position.

> **Note**
>
> If the CLMN down key is disabled, press the column down emergency button on the service panel.

2. Turn off the keyswitch and remove the key.
3. Remove the laser surgical accessory used. Clean and/or sterilize, according to hospital policy (see Chapter 6). Remove the optional RCU, if used. Check the bacteriological filter and replace, if necessary (see 2.7).
4. Secure the two long arm sections with the securing clip (for earlier models only), lock the articulated arm in its two clips, and screw the endjoint knuckles onto their holder. Release the brake pedal to unlock the wheels and move the unit away from the patient.
5. Close the inert gas cylinder valves (turn clockwise), if used. Disconnect the gas hose.
6. Disconnect the power cable, and coil it on its hooks.
7. Collect and store safety eyewear.
8. Wipe the laser unit and footswitch (and optional RCU, if used) with a damp cloth or sponge. Disinfect the unit, according to hospital policy. If bleach is recommended for disinfection, it may be used externally on surfaces too large to be disinfected by any other method. It must be noted that the bleach may dull or mar the finish/paint of the unit. This will in no way affect the performance of the laser unit, only its esthetic appearance. However, if the laser unit was used to treat a patient with an infectious disease, follow hospital protocol (i.e., infection control policy).
9. Coil the footswitch cable into the footswitch metal guard and store in its compartment.
10. Drape the end of the compressed air/inert gas tube at the outlet of the filter, with a suitable cover (i.e., a small plastic bag) to protect the tube from contamination.
11. Disconnect the remote interlock switch cables, if used.

12. Disconnect the external ground, if used.

13. Disconnect the suction unit tubing, if used.

14. Return the laser unit to storage (see 7.8).

15. Return the master key to an appropriate location.

16. If any part of the laser unit did not function properly during surgery, contact the hospital Biomedical Department or Laser Industries-authorized technical personnel.

Appendix B

Electrical Schematic

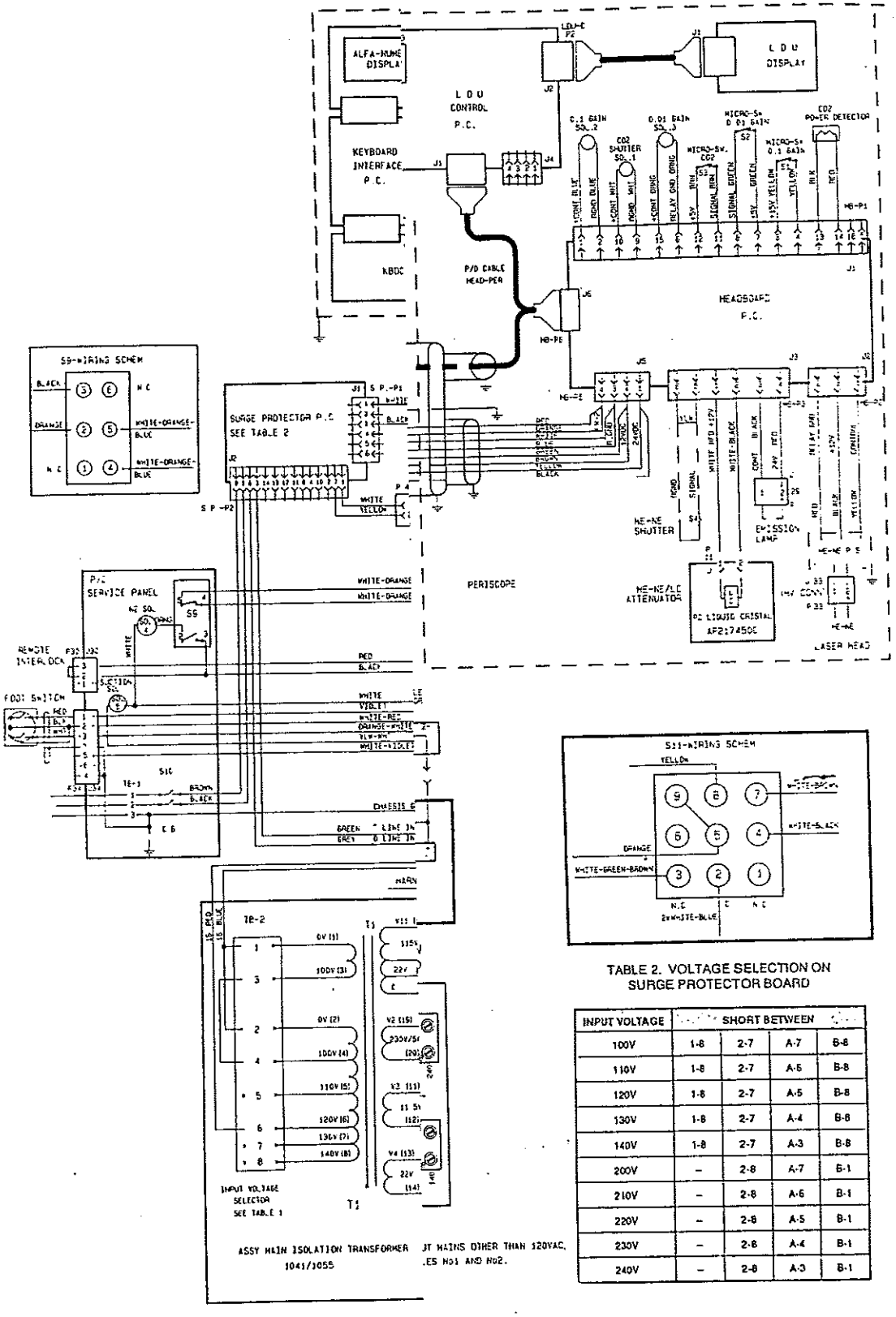


TABLE 2. VOLTAGE SELECTION ON SURGE PROTECTOR BOARD

INPUT VOLTAGE	SHORT BETWEEN			
100V	1-8	2-7	A-7	B-8
110V	1-8	2-7	A-6	B-8
120V	1-8	2-7	A-5	B-8
130V	1-8	2-7	A-4	B-8
140V	1-8	2-7	A-3	B-8
200V	–	2-8	A-7	B-1
210V	–	2-8	A-6	B-1
220V	–	2-8	A-5	B-1
230V	–	2-8	A-4	B-1
240V	–	2-8	A-3	B-1

Figure B-1.
SHARPLAN 1041S
Wiring Diagram

Appendix C

SHARPLAN 750 Remote Control Unit

Operating Instructions

C.1. Operating Safety Precautions

When using the SHARPLAN 750 RCU, all safety precautions pertaining to the SHARPLAN 1041S CO_2 surgical laser unit must be observed.

Warning

Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure. Therefore, personnel operating the SHARPLAN unit must be thoroughly familiar with all of its safety requirements and operating procedures.

The unit is intended for use only when mounted on the articulated arm of the SHARPLAN 1041S CO_2 surgical laser unit, and does not function as an independent unit.

Note

The RCU is intended to supplement, and not replace, the main control panel of the SHARPLAN 1041S CO_2 laser unit.

C.2. Unpacking

Note

Any damage incurred to the package of the unit or to the unit itself prior to, or during unpacking, installation or testing of the unit, should be immediately reported to your SHARPLAN distributor.

The SHARPLAN 750 system includes the following:

1. SHARPLAN 750 Remote Control Unit
2. Cable for connection to the SHARPLAN 1041S CO_2 laser unit
3. Clips for securing the cable to the SHARPLAN 1041S articulated arm
4. Instruction sheet.

C.3. Unit Description

C.3.1. General

The SHARPLAN 750 Remote Control Unit (RCU) is a small lightweight unit adaptable to the SHARPLAN 1041S CO_2 surgical laser unit.

The RCU is designed for attachment to the distal end of the vertical section of the articulated arm, thereby enabling the surgeon to easily control the main unit functions (i.e., system operation modes, time and power settings) from a convenient location near the surgical site.

C.3.2. Controls and Indicators

The RCU is designed to provide direct, simple and fast control of the SHARPLAN 1041S through soft-touch keys and displays which indicate main system parameters (TIME and POWER settings) for verification.

The SBY, RDY, laser operation mode and tissue exposure mode keys each have a LED indicator which illuminates when the key function is in operation.

The laser operation mode keys are "press to set/press to cancel" keys.

For all keys, except for the PWR and TIME up/down ramps, a positive key contact is indicated by a brief beep.

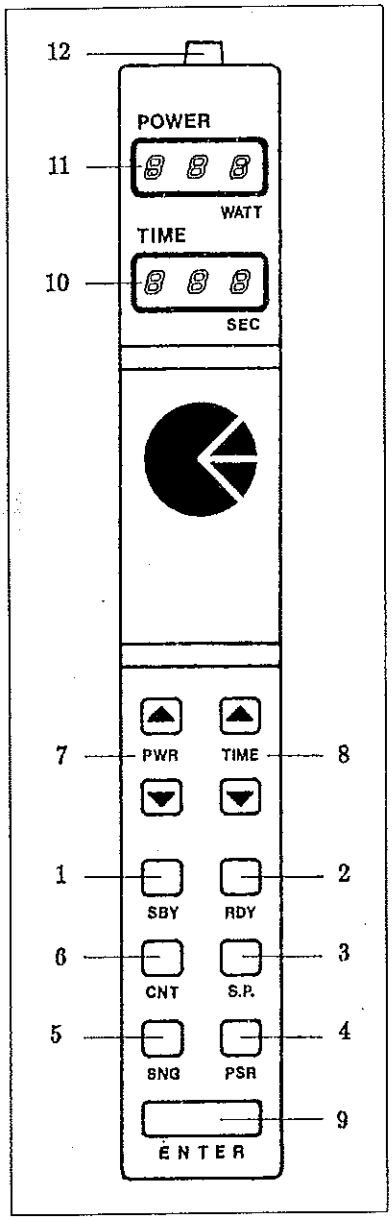


Figure C-1. SHARPLAN 750 Remote Control Unit

Note

The POWER and TIME display readings and the key LED indications correspond to the readings and indications on the SHARPLAN 1041S repeater display and control panel.

Refer to Figure C-1 for items 1 through 12.

1. **SBY Key** –when pressed while the system is in the "ready" state, returns the system to the STBY mode in which all selected parameters are maintained, but the footswitch is disabled.
2. **RDY Key** – when pressed (indicator illuminates), the system enters the "ready" state (ready for laser emission); the SHARPLAN 1041S laser emission indicator flashes, and a laser beam is emitted when the footswitch is pressed.
3. **S.P. Key** – when pressed (indicator illuminates), sets the system for operation in the SUPERPULSE laser operation mode. When repressed (indicator extinguishes), sets the system to operate in the CW laser operation mode.
4. **PSR Key** – when pressed (indicator illuminates), sets the system for operation in the SHARPULSE laser operation mode. When repressed (indicator extinguishes), sets the system to operate in the CW laser operation mode.
5. **SNG Key** – when pressed (indicator illuminates), sets the system for operation in the SINGLE PULSE tissue exposure mode, whereby the CO_2 laser beam is emitted for the selected ON time when the footswitch is pressed. Laser emission ceases at the end of the ON time, or upon release of footswitch, whichever comes first.
6. **CNT Key** – when pressed (indicator illuminates), sets the system for operation in the CONTINUOUS tissue exposure mode, whereby the CO_2 laser beam is continuously emitted for as long as the footswitch is depressed.

Note

The REPEAT PULSE tissue exposure mode is not available through the RCU and should be set through the SHARPLAN 1041S control panel, should the need arise.

7. **PWR Up (▲)/Down(▼) Keys** – up/down keys used to adjust the power level.

8. **TIME Up (▲) Down (▼) Keys** – up/down keys used to adjust the ON time.

9. **ENTER Key** – sets the system to accept the values reached through the PWR and TIME up/down keys.

10. **TIME Display** – red 3-digit LED display, showing the selected ON time in seconds. The TIME display resolution (increment) varies with the ON time range and is given in Table C-1.

Table C-1. TIME Display Resolution

ON Time Range (in seconds)	ON Time Increment (in seconds)
0.05-0.1	0.01
0.1-1.0	0.05

11. POWER Display – red 3-digit LED display, calibrated to display the average power in watts to be delivered on tissue. Power in the range of 10-40W is displayed in two digits. Below 10W, a decimal point appears, and power is displayed to one decimal. Below 1W, power is displayed to two decimals. The POWER display resolution (increment) varies with the power range and is given in Table C-2.

Table C-2. POWER Display Resolution

Power Range (in watts)	Power Increment (in watts))
10-40	1
1.0-10	0.5
0.5-1.0	0.1
0.1-0.5	0.05

12. **Connection Point** -- for the cable that plugs into the RCU connection point on the periscope of the SHARPLAN 1041S.

C.4. Operating Instructions

The procedures given in this section for operating the SHARPLAN 1041S with the RCU should be incorporated into the operating procedures outlined in Chapter 5 of the SHARPLAN 1041S User's Manual, beginning with Laser Operation Mode Selection (5.6.1).

C.4.1. Installation

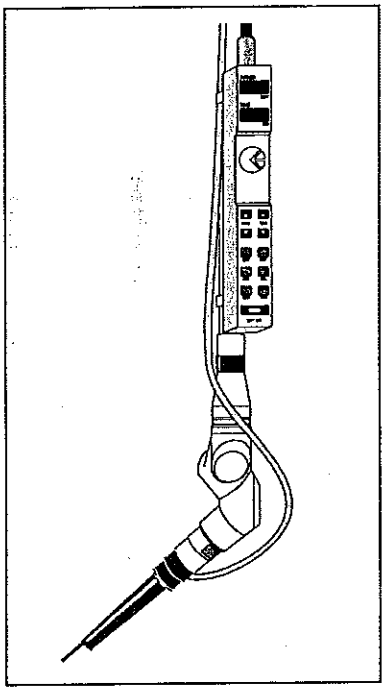


Figure C-2. SHARPLAN 750 RCU Clipped to Articulated Arm of SHARPLAN 1041S CO_2 Surgical Laser Unit

To couple the RCU to the SHARPLAN 1041S, perform the following procedure, referring to Figure C-2.

1. Turn off the SHARPLAN 1041S laser unit.
2. Connect one end of the RCU cable (female connector) to the connection point on the RCU unit (see Figure C-1, item 12).
3. Clip the RCU onto the vertical section of the articulated arm.
4. Connect the other end of the RCU cable (male connector) to the connection point on the periscope (see Figure 4-2, item 8).
5. Secure the cable along the articulated arm, using the clips supplied with the system.
6. Cover the RCU with the disposable drape for the articulated arm and handpiece (see 6.2.2.).

Note

Use two rubber bands to stretch the drape tightly over the unit in order to get a clear and unblurred view of the RCU controls.

C.4.2. Turn-On

To enable the RCU, set the He-Ne shutter control on the periscope of the SHARPLAN 1041S to ON position and turn the keyswitch to the "I" position. Select from the control panel whether or not FlexiLase fibers are in use.

Caution

System OFF/RST can be initiated only from the SHARPLAN 1041S control panel.

C.4.3. Laser Operation Mode Selection

Select the desired laser operation mode. CW is available by "default" upon unit turn-on. SUPERPULSE or SHARPULSE are available by pressing the appropriate key. The system returns to CW whenever SUPERPULSE or SHARPULSE is canceled by repressing the relevant key.

The user may subsequently select a different laser operation mode whenever desired (provided that the CO_2 laser beam is not being emitted), by pressing the appropriate laser operation mode key.

C.4.4. Power Setting

To set the desired power level, press the PWR increase or decrease key continuously until the displayed power is close to the desired level; then release and repress the key intermittently to obtain the precise power level reading desired. At this stage, press the ENTER key to indicate power level selection and to initiate the "power search" procedure for the power setting requested.

Note

The initial values which are displayed upon pressing the PWR increase/decrease key and from which the running change in power starts, are 40W for CW and SHARPULSE laser operation modes, and 17W for SUPERPULSE laser operation mode.

During the "power search" procedure, the POWER display flashes intermittently until the requested power is set, whereby it becomes continuously illuminated.

Note that the user may subsequently change the power setting whenever desired (provided that the CO_2 laser beam is not being emitted), by using the PWR up/down keys and the ENTER key.

Also note that in any subsequent selection of a laser operation mode, the system is automatically set to operate at the last power level set for the laser operation mode selected.

C.4.5. Tissue Exposure Mode Selection

After the power level is selected and set, the user should select the desired tissue exposure mode (CONTINUOUS or SINGLE PULSE) by pressing the appropriate key.

Note

The REPEAT PULSE tissue exposure mode is not available through the RCU and should be set through the SHARPLAN 1041S control panel, should the need arise.

After a tissue exposure mode is selected, its indicator illuminates. In addition, for SINGLE PULSE and REPEAT PULSE tissue exposure modes, the TIME display shows the ON time level.

C.4.6. Time Selection

In SINGLE PULSE tissue exposure mode, the operator can set the desired ON time through the TIME up/down keys and the ENTER key in the ranges provided in Table C-3.

Table C-3. ON Time Ranges

CW		SHAR-PULSE	SUPER PULSE	
Power Range (in watts)	ON Time (in sec)	ON Time (in sec)	Power Range (in watts)	ON Time (in sec)
0.1-3.5	0.1-1.0	0.05-1.0	0.5-0.9	0.5-1.0
4.0-40	0.05-1.0		1.0-1.5	0.2.-1.0
			2.0-3.5	0.1-1.0
			4.0-17	0.05-1.0

Note

The ON time resolutions (increments) are given in Table C-1.

When SINGLE PULSE tissue exposure mode is selected by pressing the SNG key, the ON time is automatically set to the minimal value permitted for the actual laser operation mode and power range (if a different ON time has not already been set since unit turn-on), or to the last setting selected by the user (provided it is within the acceptable ON time ranges in Table C-3). The TIME display reads the ON time level.

The user should then press the RDY key to enable the footswitch, or use the TIME up/down keys to change the ON time. When the ON time reading on the TIME display reaches the desired level, the user should press the ENTER key to confirm the selection and the ON time level is updated.

Note that the user may subsequently initiate a change in the ON time setting whenever desired (provided that the CO_2 laser beam is not being emitted), by pressing the TIME up/down keys.

C.4.7. Footswitch Operation

When the RDY key is pressed, its indicator illuminates, the SHARPLAN 1041S laser emission indicator flashes, and the unit is ready to emit the laser beam whenever the footswitch is pressed.

> **Warning**
>
> Before pressing the footswitch, ensure proper power setting. If SINGLE PULSE is selected, ensure proper ON time setting. Make sure that the beam is aimed at an appropriate target.

Press the footswitch to emit the laser beam. The SHARPLAN 1041S laser emission indicator stops flashing and illuminates continuously to warn personnel in the vicinity of the unit that CO_2 laser radiation is being emitted.

When the footswitch is released in the CONTINUOUS tissue exposure mode, laser emission ceases, and the SHARPLAN 1041S laser emission indicator flashes again.

In the SINGLE PULSE tissue exposure mode, laser emission ceases upon termination of the ON time or when the footswitch is released, whichever comes first. At this point the SHARPLAN 1041S laser emission indicator flashes again.

C.4.8. Pause in Operation

If a short pause in operation is desired, press the SBY key. The system exits the "ready" state, disabling the footswitch but preserving all settings. If the SBY key is pressed again, the system cancels the tissue exposure mode, while preserving the power and time settings and the laser operation mode.

C.4.9. Turn-Off

To disable the RCU, press the OFF/RST key on the SHARPLAN 1041S control panel. The TIME and PWR displays momentarily read **8.8.8.** and then blank, and all key indicators extinguish.

C.4.10. Operating Procedures Summary

Table C-4. Operating Procedures Summary

Action	Indications
1. Prepare the SHARPLAN 1041S for operation and attach the RCU (see 5.2 and C.4.1).	
2. Turn on the keyswitch of the SHARPLAN 1041S.	TIME and POWER displays momentarily read **8.8.8.** and then blank.
3. Perform all preliminary procedures as described in Table 5-4, steps 3 through 5.	
4. For CW laser operation mode proceed to step 6. For SUPERPULSE/SHARPULSE laser operation mode, press the appropriate key.	S.P./PSR key indicator illuminates.
5. Adjust power level using the PWR up/down keys.	POWER display shows running change as power is adjusted.
6. When the POWER display shows the desired power level, press ENTER.	a. System enters the "power search" procedure. b. The selected power level flashes on the power display. c. At the end of the "power search" procedure, the power display illuminates continuously.

Action	*Indications*
7. Set tissue exposure mode. Press SNG for SINGLE PULSE or CNT for CONTINUOUS.	a. The respective key indicator illuminates b. In SINGLE PULSE tissue exposure mode, TIME display reads the ON time (the default value or the last setting).
8. For CONTINUOUS tissue exposure mode, proceed to Step 10. For SINGLE PULSE tissue exposure mode, perform the ON time setting as follows: Adjust ON time level using the TIME up/down keys. When the TIME display shows the desired ON time level, press ENTER.	 Time display shows running change as ON time is adjusted. Time display shows the selected ON time level.
9. Press RDY	a. SBY key indicator extinguishes. b. RDY key indicator illuminates. c. The SHARPLAN 1041S laser emission indicator flashes.
10. Aim the laser accessory and press the footswitch.	The SHARPLAN 1041S laser emission indicator illuminates and the CO_2 laser beam is emitted.
11. Release footswitch.	The SHARPLAN 1041S laser emission indicator flashes.
12. For a pause in operation, press SBY.	a. SBY key indicator illuminates. b. RDY key indicator extinguishes. c. The SHARPLAN 1041S laser emission indicator extinguishes.
13. To disable the RCU, press OFF/RST on the SHARPLAN 1041S control panel.	TIME and POWER displays momentarily read **8.8.8.** and then blank.

C.5. Cleaning and Disinfection

The external surfaces of the RCU should be disinfected when the unit is initially received, and thereafter as required by hospital protocol. The surfaces may be wiped with a damp cloth or cotton dipped in a hospital grade 70% alcohol solution or a disinfectant solution.

Cautions

1. Disconnect and remove the RCU from the SHARPLAN 1041S articulated arm before cleaning/disinfecting with solutions.

2. Only the external surfaces of the unit may be cleaned by hospital staff. Do not attempt to disassemble the unit.

3. The unit is not sterilizable.

C.6. Maintenance

The unit requires no maintenance.

C.7. Troubleshooting

An RCU malfunction exists if one or more of the following indications are observed:

1. One or more display LEDs do not illuminate.
2. An incorrect value appears on the TIME or POWER display.
3. One or more keys do not function.

In the event of RCU malfunction during a surgical procedure, disconnect the RCU cable at the periscope (see Figure 4-2) and continue the surgical procedure, controlling the SHARPLAN 1041S through its control panel. When the surgical procedure is completed, refer the problem to Laser Industries-authorized technical personnel.

Appendix D

Professional Information

TABLE OF CONTENTS

Appendix D

Professional Information

D.1. Introduction

This appendix is provided to aid professionals in the use of this SHARPLAN CO_2 laser system in specific surgical specialties. It supplements or is redundant with information presented in the User's Manual concerning instructions for use, precautions, and warnings necessary to improve patient outcome and reduce the risk of injury or death to the patient, professional, or staff.

To gain the full benefit of this material, all users must read the entire User's Manual before reviewing this section and before operating the laser. While all sections of the Manual are important, the following sections include specific and general professional information:

Chapter 1	Operating Safety Precautions
Chapter 3	System Description
Chapter 3.1	General Laser Theory
Chapter 3.2	Intended Use
Chapter 3.3	CO_2 Laser Theory
Chapter 3.4	General System Description
Chapter 3.8	Laser Accessories
Chapter 3.9	System Modes of Operation
Chapter 4	Controls, Indicators and Connections
Chapter 5	Operating Instructions
Chapter 6	Laser Surgical Accessories

Before using the SHARPLAN CO_2 laser, the physician or professional must fully understand the surgical effect produced by the laser at the 10.6 micron wavelength when using the intended accessory. (See *Physician Training.*) A review of the clinical literature published on the use of CO_2 lasers is strongly encouraged.

The laser system should be used only by physicians and staff who have been appropriately trained and who are thoroughly familiar with the instructions, cautions and warnings in the User's Manual.

The information provided in this section is not intended to be all-inclusive and is not intended to replace physician or professional training or experience.

D.2. Physician Training

Physician and other professional (dentists, veterinarians, podiatrists, etc.) training should include all of the following elements:

- A review of published literature should be conducted in the specific surgical specialty of interest concerning CO_2 laser applications. A thorough understanding of laser tissue interactions and treatment techniques and options should gained. The professional should also review comparable non-laser techniques and treatment with other laser wavelengths (e.g. Nd:YAG, Argon, Holmium, etc.)

- Professionals should attend organized meetings, seminars, and conferences concerning the use of the laser in the surgical specialty of interest.

- Laser workshops that include didactic lectures covering laser physics and tissue interactions, laboratory and hands-on experience should be attended. Workshops and courses that are organized and structured to offer continuing medical education (CME) credits are recommended. Please contact SHARPLAN at 1-800-394-2000 or 1-201-327-1666 for current information on courses.

- Visits and preceptorships with other experienced physicians or professionals who are performing laser therapy should be made as frequently as possible to maintain current skills.

D.3. General Surgical Characteristics of CO_2 Lasers

Emitted energy at the CO_2 wavelength is highly absorbed by the water content of tissue.

There are several interrelated characteristics of the CO_2 laser beam that produce the thermal effects necessary to incise, vaporize, coagulate, etc. soft tissue. The following characteristics must be considered in the treatment of tissue:

- Average power
- Spot size
- Power density (average power/spot size)
- Energy fluence (power x time on tissue)
- Beam pulsing technique (e.g. SuperPulse)
- Peak power

These characteristics are comprehensively explained in any book on clinical lasers and in this SHARPLAN User's Manual.

Tissue incision capability is generally enhanced with a small spot size and higher peak power of the laser beam. (See Figure D-1.)

Thermal damage to surrounding tissue is usually reduced with shorter laser activation durations, whereby less heat is lost to surrounding healthy tissue through conduction.

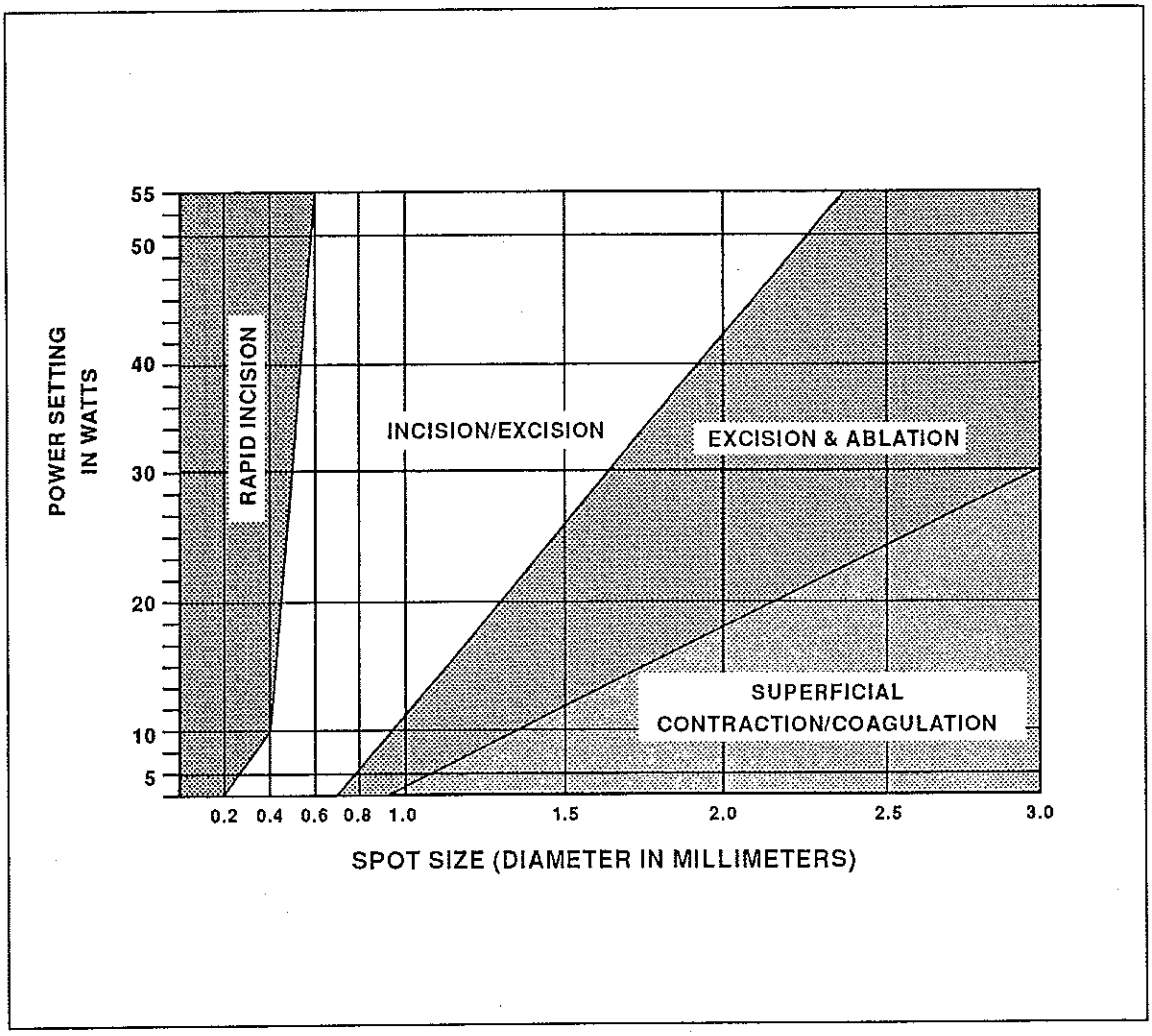


Figure D-1. Tissue Effects at Varying Power Settings and Spot Sizes

Table D-1. Power Density (in W/cm²) for various Spot Sizes and Power Settings

Spot Size (mm)	Power in Watts					
	5	10	20	30	40	55
0.2	15924	31847	63694	95493	127389	175070
0.4	3979	7958	15915	23873	31830	43768
0.6	1768	3537	7074	10610	14147	19452
0.8	995	2265	3981	6794	7962	10942
1.0	637	1273	2546	3820	5093	7003
1.5	283	566	1132	1698	2264	3112
2.0	159	318	637	955	1274	1751
2.5	102	204	407	611	815	1120
3.0	71	141	283	424	566	778

Tissue Effects of Different Power Densities	
5-300 W/cm²	Superficial contraction/coagulation
300-1,200 W/cm²	Excisional vaporization
1,200-15,000 W/cm²	Incisional vaporization
15,000-100,000 W/cm²	Rapid incision

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D.3.1. Pulsed Modes

Through their high peak power level, short pulse durations and varying average power, pulsed laser operation modes enable the surgeon to cause the tissue effects mentioned in the previous section.

The **SUPERPULSE** mode used with a small beam diameter (<1mm) is appropriate for incision and, with low power, for precise vaporization of minute tissue structures.

The **SHARPULSE** mode is appropriate for incision at high power with a small beam diameter, and for vaporization of areas up to 2mm with minimal char. Higher average powers are available with the Sharpulse mode, as compared to the Superpulse mode.

The **CW** (Continuous Wave) mode provides the most hemostasis during incisions and, with a defocused beam and low powers, is useful for bulk coagulation.

D.3.2. Beam Manipulation

The rate of beam manipulation (time on tissue) also affects the depth of incision, vaporization or coagulation. Generalized information is summarized in Table D-2, below, and is relevant for all laser modes.

Table D-2. Laser Characteristics for Desired Tissue Effects

Tissue Effects	*Average Power*	*Spot Size*	*Preferred Mode*	*Beam Manipulation*
Deep Incision	High	Focused	CW, SP, ShP	Slow
Shallow Incision	Low	Focused	ShP, SP	Slow
Shallow Incision	High	Focused	CW, ShP, SP	Fast
Bulky Vaporization	High	Defocused	CW, ShP	Slow
Superficial Vaporization	Low	Defocused	CW, ShP	Slow
Superficial Vaporization	High	Defocused	CW, ShP	Fast
Coagulation	Low	Defocused	CW	Slow
Coagulation	High	Defocused	CW	Fast

CW = *Continuous Wave* Mode SP = *Super Pulse* Mode ShP = *Sharpulse* Mode

The clinician should use the appropriate laser parameter for the treatment desired, taking into account individual preferences and techniques. The knowledge and expertise needed to make appropriate treatment decisions is developed through review of the published literature, clinical training, the hospital credentialing process, and general experience in the use of surgical lasers.

This SHARPLAN CO_2 laser unit is capable of producing all of the above tissue effects. The Specifications section of the User's Manual lists exact power ranges.

D.3.3. Delivery System & Laser Accessories

The laser delivery system and specific accessory used also play a role in tissue effects.

Accessories that produce a very small laser spot size, such as the *Acuspot* and *Microslad* micromanipulators and focusing handpieces, are capable of spot sizes in the range of 200-4,000 microns. These accessories can produce high power densities for incision at relatively low average power settings.

Other delivery systems and accessories such as the *FlexiLase* flexible fibers, *Microguides* and some endoscopic couplers allow spot sizes of 0.8 to 1.2 mm and require higher average powers for equivalent power densities.

Accessories that allow defocusing or can be physically moved to adjust the spot size (focal point) allow tissue treatment with small or large spot sizes (high or low power density, respectively).

The *SwiftLase* vaporization accessory scans the laser beam over the treatment site and permits superficial vaporization with minimal char. Users must refer to the Accessories Chapter in the User's Manual to gain a full understanding of the capabilities of each accessory.

D.4. General Directions for Use

Refer to the Operating Instructions Chapter of this manual for complete instructions on operating this CO_2 laser.

Refer to the Operating Safety Precautions Chapter and the Safety Checklist Appendix for laser safety precautions.

D.5. General Warnings

The physician and attending staff must be trained in all aspects of the listed surgical procedures and in the effective use of the laser through a comprehensive training program.

D.5.1. Eyewear

All persons in the treatment room, including the patient, must wear wavelength-specific protective eye wear. Laser protective (e.g. metal) corneal protectors should be worn by the patient if the treatment area precludes the use of conventional laser safety eye wear.

D.5.2. Tissue Effects

Physicians using this CO_2 laser must assume responsibility for understanding all tissue effects as a result of the power, spot size, laser delivery accessory system and the duration of application selected.

D.5.3. Fire

To avoid accidental laser fires:

1. Use the audible activation tone provided by the laser to alert all staff whenever the laser is energized.
2. Use only drapes soaked in sterile water near the operative site.
3. Ready a basin of sterile water to extinguish any small fires.
4. Make sure an appropriate fire extinguisher is available at all times.
5. Activate the laser footswitch only when the He-Ne beam is aimed at target tissue under direct visualization.
6. Avoid tenting of drapes and materials that may collect oxygen-enriched gases. Oxygen-enriched environments increase the combustibility of materials (e.g. drapes).
7. Avoid the use of flammable skin-prepping agents, or allow this material to completely evaporate before using the laser.
8. Do not use the laser in the presence of flammable or explosive anesthetic gases.

D.5.4. Smoke Evacuation

Always use an appropriate smoke evacuator with the intake directed at the laser plume or removed through an accessory suction port to prevent inhalation of smoke, vaporization by-products and aerosols.

D.5.5. Direction of Laser Beam

Always use surgical instruments with anti-reflective properties to prevent misdirection of the laser beam.

Appendix E

Clinical Applications

TABLE OF CONTENTS

TABLE OF CONTENTS (cont'd)

TABLE OF CONTENTS (cont'd)

Appendix E

Clinical Applications

E.1. Introduction

This appendix is provided to aid professionals in the use of this SHARPLAN CO_2 laser system in specific surgical specialties. It supplements or is redundant with information presented in the User's Manual concerning instructions for use, precautions, and warnings necessary to improve patient outcome and reduce the risk of injury or death to the patient, professional, or to the staff.

Note

This SHARPLAN CO_2 laser is a surgical tool. As with any surgical instrument, the success of a surgical procedure is dependent upon the operative skills and knowledge of the surgeon. SHARPLAN makes no claim that any disease, state, or condition can be completely eradicated with the use of the laser.

E.2. Otolaryngology – General

E.2.1. Indications

The Sharplan CO_2 laser is indicated for incision/excision, vaporization and coagulation of soft tissue in otolaryngological (ENT) surgery including head, neck and oral surgery.

E.2.2. Contraindications

The CO_2 laser should only be used in conditions where its use is appropriate and of proven efficacy.

E.2.3. Specific Precautions & Recommendations

1. Select the appropriate delivery system for the intended application after consulting with surgical experts, reviewing the published literature, and attending procedure-specific training programs. Possible delivery systems include CO_2 focusing handpieces, the Microslad or Acuspot micro-manipulators, the FlexiLase fiber, the Microguide waveguides, and the laser bronchoscope.

2. Middle ear surgery should be performed with an appropriate spot size at powers below 4 watts with pulse durations that deliver 200 millijoules or less. Higher energies increase the risk of excessive thermal injury. Test fire the laser on a wet sterile tongue depressor before use.

3. As with conventional non-laser surgery, there is no guarantee that treatment with the CO_2 laser will entirely eliminate any disease entity. Repeat treatment or alternative therapies subsequently may be required.

E.2.4. Complications

Complications may include the following:

- Endotracheal tube fires
- Excessive bleeding
- Infection
- Edema

Warning

Use only laser-resistant endotracheal tubes appropriate for the CO_2 wavelength. Avoid directing the CO_2 laser at any tracheal tube in an oxygen-enriched environment. Review all endotracheal tube instructions for use with the CO_2 laser.

E.2.5. References

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E.3. Laser Assisted Uvulopalatoplasty (LAUP)

E.3.1. Indications

With respect to Uvulopalatoplasty, this SHARPLAN CO_2 laser system is indicated for the following conditions:

- For incision, excision, coagulation, and vaporization of tumors and other disease specific lesions on the uvula, palate, and upper lateral pharynx including, but not limited to, papillomas, leukoplakia, and carcinoma.
- For surgical incision, excision, and vaporization of hypertrophic uvula, palate or pharyngeal tissue associated with chronic palatal snoring after weight reduction, avoidance of alcoholic beverages and tranquilizers, and other medical and dietary treatments are not effective.
- For palliative surgical enlargement of the airway in obstructive sleep apnea patients, where excessive palatal snoring is *known to be* the cause of the airway obstruction.

Any other use may be considered investigational by the FDA. Please contact SHARPLAN's Regulatory Affairs Department to discuss other applications.

E.3.2. Directions for Use

For treatment of disease specific lesions (e.g., leukoplakia, papilloma), a focused beam should be used for excision of tissue that ensures an appropriate margin of healthy tissue. Vaporization techniques should be used for sessile lesions.

Laser Assisted Uvulopalatopharyngoplasty (LAUP) techniques for palatal snoring follow techniques used by Carenfelt and Kamami. The basic surgical technique may include resection of the uvula, distal margins of the soft palate, palatine tonsils, and excess lateral pharyngeal tissue to produce a box-like enlarged airway that is resistant to collapse during sleep.

→ **Carenfelt**'s (and others') technique follows a simplified UPPP approach and basically uses the CO_2 laser for incision and vaporization of tissue. Powers of 10-20 watts are used with a fixed focusing handpiece throughout the procedure. In his technique, the tonsillar tissue is usually preserved.

→ **Kamami**'s surgical laser technique is to incise the palate slightly on both sides of the uvula and to vaporize a volume of palatal tissue along the uvula and distal margin of the palate. This procedure is repeated until snoring is reduced to a level acceptable to the patient.

The patient is seated comfortably and oral analgesia (e.g., 15% Lidocaine spray) is applied. A local anesthetic (e.g., Lidocaine with 2% epinephrine) is injected at the root of the uvula and along the soft palate to be resected or vaporized. Two vertical incisions ~1 cm long are made on either side of the uvula using a focused CO_2 laser beam, and the uvula and palatal tissue is vaporized to ~1/2 to 2/3 its original size. Laser power of 12-20 watts is used for incisions and vaporization.

The procedure normally takes 10-20 minutes to complete and the patients may be discharged home immediately following the procedure. Patients receive oral antibiotics and NSAD analgesic, and are asked to gargle with hydrogen peroxide and non-alcoholic mouthwash.

E.3.3. Laser Delivery Systems

Laser incisional and vaporization techniques in LAUP rely solely on the high power density of the CO_2 laser beam and the ability to aim or deliver this beam precisely to the operative site. The laser accessory (e.g., handpiece or microscope micromanipulator) chosen by the surgeon is **based on his or her preference,** since all Sharplan standard delivery systems produce acceptable spot sizes.

Specifically, the following standard Sharplan accessories are the most suitable for uvulopalatoplasty, based on convenience to the posterior oral space.

SHARPLAN Accessory	*Spot Size*
Model 15125 125mm Handpiece defocus	0.26mm / positional
Model 15200 200mm Handpiece defocus	0.41mm / positional
Model 15051 50mm Handpiece control	0.10-2.28mm focus
Model 15201 250mm Handpiece control	0.53-2.54mm focus
Model 719 Micromanipulator control	0.56-6.7mm focus
Model 710/711 Micromanipulator	0.16-5mm focus control

Other Sharplan accessories may be used or have advantages in the procedure. The Swiftlase vaporization accessory, which produces an incisional beam or a small circular scanning beam, is adaptable to each of the above accessories and may be used to incise, vaporize, and debulk tissue with minimal carbonization. Also, the Sharplan Short Microguide (120mm) or FlexiLase waveguide systems are suitable for the vaporization portions of the procedure.

E.3.4. Contraindications

The following contraindications include general CO_2 laser surgical contraindications as well as recognized relative contraindications for uvulopalatoplasty for palatal snoring that also apply to the SHARPLAN CO_2 laser system used for incision, excision, and vaporization in uvulopalatoplasty (LAUP).

1. The CO_2 laser should only be used in conditions where its use is appropriate and of proven efficacy, and never operated unless under the direct supervision of a trained physician with certification in laser safety.

2. LAUP for palatal snoring is contraindicated without demonstrated obstruction by uvulopalatal tissue using a fiberoptic endoscope or other means.

3. The use of the CO_2 laser for cutting, ablation or vaporization of dense, healthy bone or bone marrow (hard palate/mandible).

4. LAUP for palatal snoring is contraindicated in pediatric patients (less than 16 years) because the upper airway is not fully developed.

5. LAUP for palatal snoring is contraindicated in obese patients, in patients with severe tonsillar hyperplasia, and in patients with disproportionally short necks.

E.3.5. Specific Precautions & Recommendations

1. All patients presenting with chronic palatal snoring and other significant symptoms of sleep apnea should be evaluated for OSA syndrome by a qualified physician. A comprehensive sleep study (polysomnography) is strongly recommended for these cases. If LAUP is performed, a polysomnography should be repeated in each of these patients.

2. Use the lowest power setting that will achieve the desired effect. Begin treatment with low to moderate powers (e.g., 10 watts) and short exposure times until the effect of the laser beam on tissue can be judged.

3. Confine the tissue vaporization areas to specific locations such as the actual lesion under treatment or, for palatal snoring, the leading lateral edge of the soft palate or the most distal surface of the uvula. Avoid treating large ares of tissue mucosa to reduce the risk of post-operative infection.

4. Always use an anodized or ebonized matte-finished metal tongue depressor, laser backstop or other surgical instrument behind the area of treatment to avoid injury to the posterior nasopharynx.

5. Activate the laser only when the He-Ne aiming beam is directed at the targeted lesion or structure and there is a clear view of the treatment site.

6. Select the appropriate delivery system for the intended application after consulting with surgical experts, reviewing the published literature, and attending procedure-specific training programs. Possible delivery systems include CO_2 focusing handpieces, the Microslad or Acuspot micromanipulators, the FlexiLase fiber, the Microguide waveguides, and the laser bronchoscope.

7. Always use a filtered smoke evacuator system to suction vaporization plume. Dispose of the system accessories (e.g. filter, tubing) as infectious waste.

8. As with conventional non-laser surgery, there is no guarantee that treatment with the CO_2 laser will entirely eliminate any disease entity. Repeat treatment or alternative therapies (e.g., nasal turbinectomy) subsequently may be required.

Warnings

1. For procedures performed in the operating room under general anesthesia, use only laser-resistant endotracheal tubes appropriate for the CO_2 wavelength. Avoid directing the CO_2 laser at any tracheal tube in any oxygen enriched environment to prevent airway fires. Review all endotracheal tube instructions for use with the CO_2 laser.
2. To avoid fire, do not use the Sharplan CO_2 Laser Systems in the presence of flammable anesthetics. Allow all alcohol-based prepping and disinfection agents to thoroughly dry before laser activation.
3. Always test fire the laser before use on a wet wooden tongue blade placed on a wet cloth towel on a metal tray. Recommended settings are 10 watts/0.1 sec pulse duration.

E.3.6. Complications

Although rare, mild surgical complications are associated with laser UPPP and may include bleeding, mild infection, swelling, and post operative stenosis.

Complications associated with all uvulopalatoplasty techniques may include the following:

- Post-operative pain for up to 10 days
- Excessive bleeding
- Infection
- Edema
- Rhinophonia
- Nasopharyngeal stenosis
- Velopharyngeal incompetence

As with any surgical procedure, certain complications, such as excessive bleeding or infections, if not promptly treated, may lead to more serious complications or death.

E.3.7. References

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E.5.4. Complications

Complications may include:

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

E.5.5. References

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E.6. Neurosurgery

E.6.1. Indications

The Sharplan CO_2 laser is indicated for incision/excision, vaporization and coagulation of soft tissue in Neurosurgery.

E.6.2. Contraindications

Relative contraindications include laser application on tumors that are inoperable or inaccessible with the laser beam.

E.6.3. Specific Precautions & Recommendations

1. Hemostasis with the CO_2 laser alone may not be effective in vessels larger than 1 mm. Use alternate methods (e.g. ligatures) to provide hemostasis.

2. Use low to moderate laser power and brief pulse durations until the tissue effect can be clinically judged. Increase power in small increments to achieve greater effect.

Warnings

1. Purge gases used with CO_2 handpieces and FlexiLase waveguides may increase the risk of gas embolisms where large, open, cranial veins are present and are not recommended. Monitor all patients undergoing cranial procedures for gas embolism which may occur even without the use of the laser.
2. When ablating lipoma, exercise care to avoid ignition of pooled lipids.
3. Aim the laser only at fully observable tissue intended for treatment to prevent damage to surrounding healthy tissue.
4. Prior to the procedure, test fire the laser through the microscope and micromanipulator at 10 watts for 0.1 seconds on a sterile wooden tongue depressor away from the surgical area to confirm the spot size and location of the laser beam.
5. Using the laser to open the dura matter may cause shrinkage which can make closure difficult or impossible.

E.6.4. Complications

None known

E.6.5. References

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E.7. Orthopedics

E.7.1. Indications

The Sharplan CO_2 laser is indicated for incision/excision, vaporization soft tissue in Orthopedic surgery.

E.7.2. Contraindications

1. Arthroscopic surgery with the Microguide, Endoguide or FlexiLase where the required purge gas cannot be released or controlled with a tourniquet and would pressurize an enclosed space (e.g. shoulder) resulting in gas embolism or systemic subcutaneous emphysema.

2. The use of the CO_2 laser for cutting, ablation or vaporization of dense, healthy bone or bone marrow.

E.7.3. Directions for Use

When using the Microguide or Endoguide waveguides, read the specific User's Manual for these products.

E.7.4. Specific Precautions & Recommendations

1. Recommended power levels through the waveguide delivery systems are 15-25 watts. CO_2 laser energy may be moderately absorbed by the CO_2 purge gas. Adjust power levels in response to observed tissue effects.

2. Use only CO_2 gas supplied by a low pressure regulated gas source specifically designed for waveguide use. Recommended pressures are 0.5-1.5 PSI. Do not exceed 2 PSI. Recommended purge flow rates are 0.5-1.5 L/min.

3. 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 surfacing following use of the laser.

Warning

Specific safety considerations and techniques are required to prevent subcutaneous emphysema and gas embolism which may be life-threatening. In CO_2 laser arthroscopy of extremities, use of an appropriate gas regulated tourniquet is strongly recommended. Unique techniques for ambient air pressure environments using loosely fitting access ports for rapid release of purge gas pressure have been developed. Consult appropriate medical experts on this technique before attempting this procedural variation.

E.7.5. Complications

Complications may include the following:

- Subcutaneous emphysema
- Synovitis

E.7.6. References

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E.8. General/Thoracic Surgery

E.8.1. Indications

The Sharplan CO_2 laser is indicated for incision/excision, vaporization and coagulation of soft tissue in General and Thoracic surgery including endoscopic and open procedures.

E.8.2. Contraindications

The CO_2 laser should only be used in conditions where its use is appropriate and of proven efficacy. Other contraindications include:

- Procedures requiring general anesthesia where general anesthesia is contraindicated.
- Laparoscopic procedures where laparoscopy is contraindicated.

E.8.3. Specific Precautions,Recommendations, & Warnings

1. Begin treatment with low to moderate power settings and short exposure times until the effect of the laser beam on tissue can be judged.
2. For superficial debridement and vaporization, pulsed laser modes or the SwiftLase accessory are recommended.
3. For laparoscopic applications consult the Clinical Applications: Gynecology Section.

E.8.4. Complications

None known

E.8.5. References

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E.9. Dentistry

E.9.1. Indications

The Sharplan CO_2 laser is indicated for incision/excision, vaporization and coagulation of soft tissue in dentistry and oral surgery.

> *Note*
>
> ***The Sharplan CO_2 lasers are not cleared by the FDA for tissue applications on or within the tooth structure or sulcus.***

E.9.2. Contraindications

Hard tissue application (in the U.S.).

E.9.3. Specific Precautions, Recommendations & Warnings

1. Use the lowest power setting that will achieve the desired effect. Begin treatment with low to moderate power and short exposure times until the effect of the laser beam on tissue can be judged.

2. Available delivery systems include focused and variable focused handpieces, the FlexiLase fiber, the Microguide waveguide and the SwiftLase accessory. Consult the specific accessory User's Manual for additional instructions and warnings.

3. While directing the laser beam near the tooth, shield the tooth from laser energy using thin, non reflecting metal or instruments inserted between the tooth and gum.

E.9.4. Complications

- Laser damage to teeth through inappropriate use
- Infection

E.9.5. References

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E.10. Podiatry

E.10.1. Indications

The Sharplan CO_2 laser is indicated for incision/excision, vaporization and coagulation of soft tissue in podiatry.

E.10.2. Contraindications

The use of the CO_2 laser for cutting or ablating dense, healthy bone or bone marrow.

E.10.3. Specific Precautions, Recommendations, & Warnings

1. Begin treatment with low to moderate power settings and exposure times until the effect of the laser beam on tissue can be judged.
2. For superficial ablation, pulsed laser modes or the SwiftLase accessory are recommended.
3. Always use an appropriate smoke evacuation system.

E.10.4. Complications

- Infection
- Ulceration of tissue

E.10.5. References

"Laser Benefits Neglected in Much of Podiatric Practice", Editors, Clinical Laser Monthly, July 1991 pp. 110-112.

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Caplin JS, MD; Kaplan I, MD; "The CO_2 Laser in Nail and Verruca Surgery." Journal of Clinical Laser Medicine and Surgery. pp.45-46, FeC. 1990.

Gorman JB, DPM. "Is the CO_2 Laser Efficacious for Podiatric Nail Surgery?" Jack C. Gorman, D.P.M. 399 N. York Rd., Warminster, Penn. 18974.

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Nelson CL, DPM. "CO_2 Laser to Remove Warts Results in Less Pain, Scarring, Recurrence." Laser Practice Report. p.4S, June 1987.

E.11. Genito-Urinary

E.11.1. Indications

The Sharplan CO_2 laser is indicated for incision/excision, vaporization and coagulation of soft tissue in genito-urinary procedures.

E.11.2. Contraindications

None known

E.11.3. Specific Precautions, Recommendations, & Warnings

1. Begin treatment with low to moderate power settings and exposure times until the effect of the laser beam on tissue can be judged.
2. Always use a smoke evacuator system.

E.11.4. Complications

None known

E.11.5. References

Carpiniello VL, Malloy TR, Sedlacer TV and Zederic SA. "Results of carbon dioxide laser and topical 5-fluorouracil for treatment of subclinical condyloma found by magnified penile surface scanning." J Urol. 140:53-54, 1988.

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Rosemberg, SK. "Further Clinical Experience with CO_2 Laser in Microsurgical Vasovasostomy." Urology. Vol. 32, No.3, pp 225-227, 1986.

4. **Duty cycle (%)** – the ratio between the ON time and the total cycle time (T), given as percentage:

$$\text{Duty cycle (\%)} = \frac{\text{ON time}}{T} \times 100$$

5. **Peak power (P peak)** – the maximum power delivered by the laser beam during emission.

6. **Average power (P av)** – the total power delivered, averaged over time.

7. **Pulse width (τ)** – the pulse duration at half peak power level.

The peak power and average power are rated as follows:

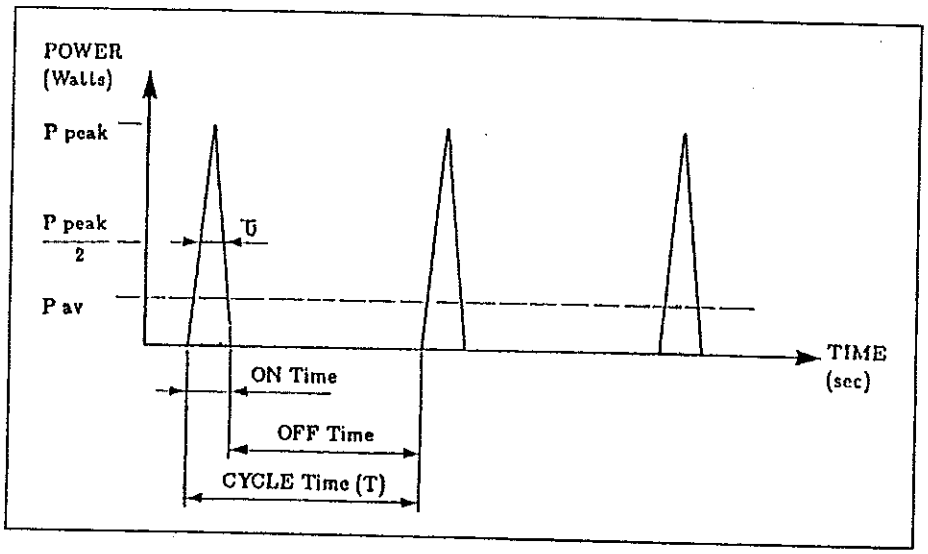

Figure 3-3. Basic Concepts of General Periodic Functio

a. For a square wave periodic function, the exact relationship is:

$$P_{av} = P_{peak} \times \frac{\text{duty cycle}}{100}$$

Note

In this section, "ON time", "OFF time", and "duty cycle" refer only to the laser operation mode, and not to the tissue exposure mode.

Thus, to obtain a variation in average power at a constant peak power, the duty cycle is adjusted accordingly.

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 SUPERPULSE and SHARPULSE laser operation modes enable these tissue effects to be achieved through their constant high peak power level and variation of the duty cycle for control of the average power.

The Superpulse laser operation mode, used with a small beam diameter (<1mm), is appropriate for incision and, with low power, for precise vaporization of minute tissue structures. The Sharpulse laser operation mode is appropriate for incision at high power with a small beam diameter, and for vaporization of areas up to 2mm with minimal char. Higher average powers are available with the Sharpulse mode as compared to the Superpulse mode. CW laser operation mode provides the most hemostasis during incisions and, with a defocused beam, is useful for bulk coagulation. The rate of beam manipulation (time on tissue) also affects the depth of incision, vaporization or coagulation. Generalized information is summarized in Table 3-1, and is relevant for all tissue exposure modes.

Table 3-1. Laser Operation Mode Applications

Tissue Effects	Average Power	Spot Size	Beam Manipulation	Preferred Mode
Deep Incision	High	Focused	Slow	CW, Sharpulse Superpulse
Shallow Incision	Low	Focused	Slow	Sharpulse Superpulse
Shallow Incision	High	Focused	Fast	CW, Sharpulse Superpulse
Bulky Vaporization	High	Defocused	Slow	CW, Sharpulse
Superficial Vaporization	Low	Defocused	Slow	CW, Sharpulse
Superficial Vaporization	High	Defocused	Fast	CW, Sharpulse
Coagulation	Low	Defocused	Slow	CW
Coagulation	High	Defocused	Fast	CW

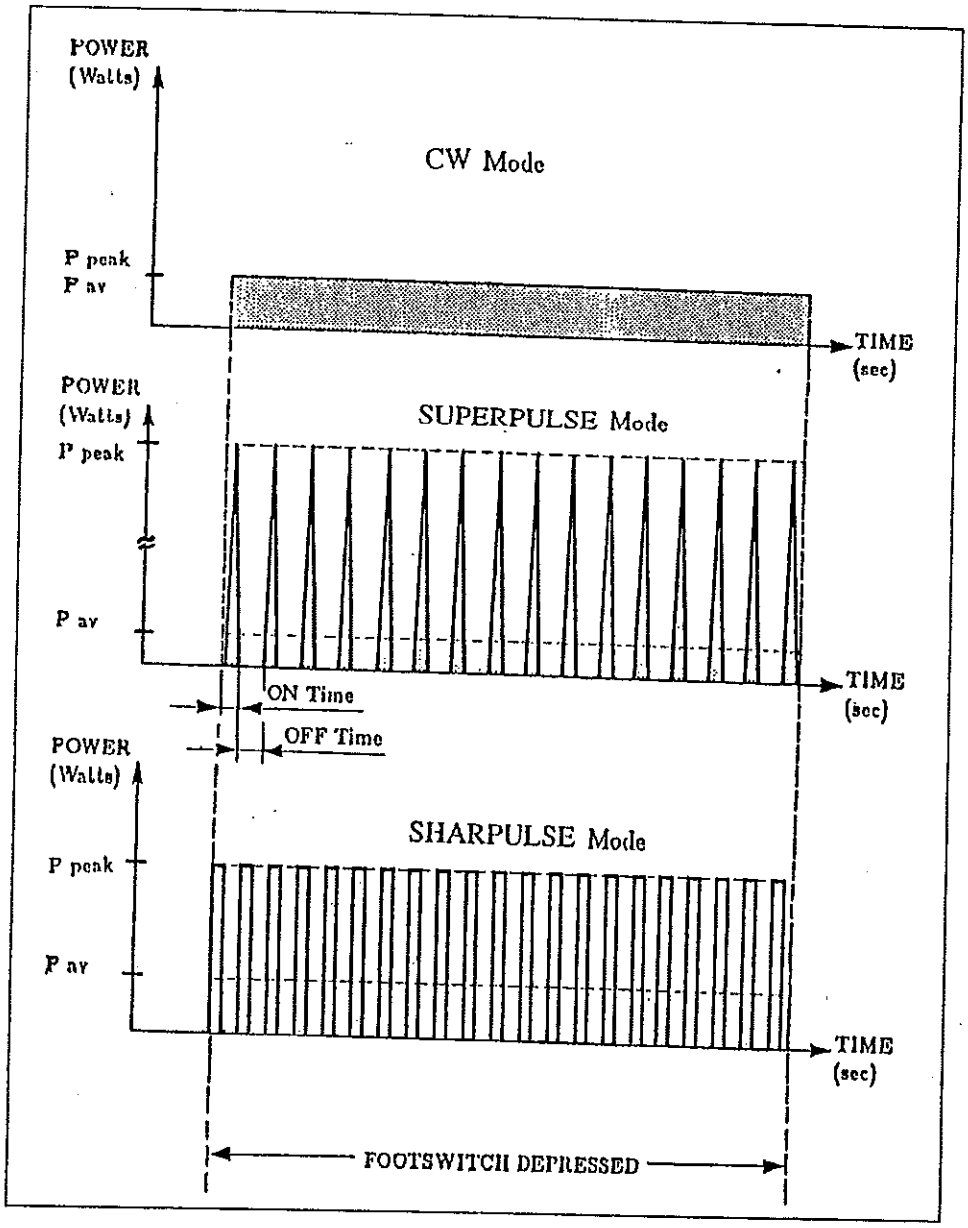

Figure 3-4. Laser Operation Modes

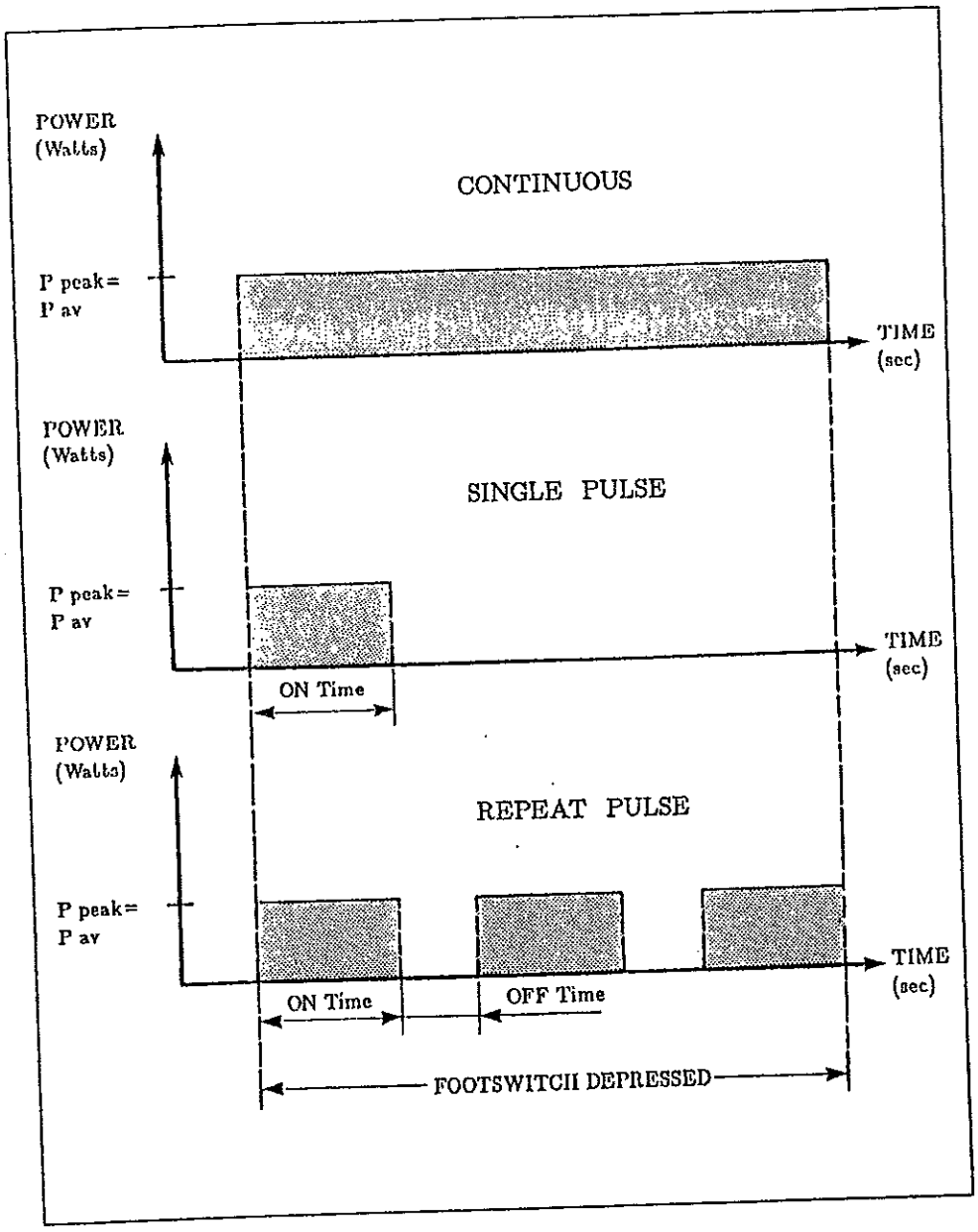

Figure 3-5. Tissue Exposure Modes in CW Laser Operation Mode

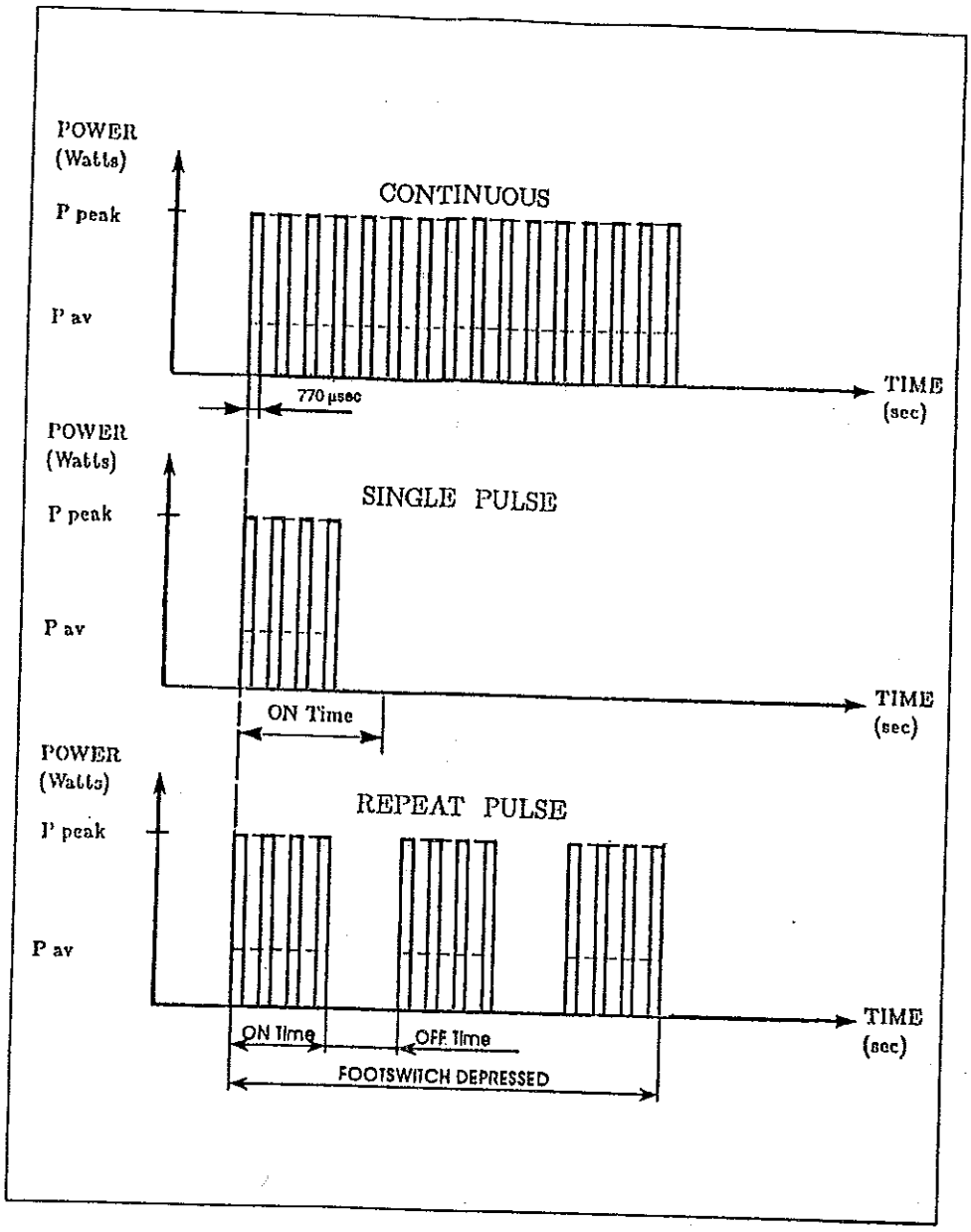

Figure 3-7. Tissue Exposure Modes in SHARPULSE Laser Operation Mode