constellation®
VISION SYSTEM

OPERATOR'S MANUAL

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MANUAL REVISION RECORD

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9/15/06	P1	
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9/1807	P3	

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FOREWORD

This Operator's Manual is designed to acquaint the operator and operating room personnel with the *Constellation®* Vision System. The manual presents an organized summary of the operating principles, main components, safety features, and instructions for care and use of the instrument.

The information in this manual should be supplemented with reference works on laser theory and the interaction of laser energy with biologic tissues. No attempt is made in this manual to answer all the questions that arise during the use of the instrument in medical procedures.

Questions concerning technique, safety and effectiveness should be referred to pertinent publications or recognized medical experts in laser surgery. Physicians should not attempt to treat patients with this instrument if not thoroughly familiar with its operation, or if in doubt as to its safe operation. All personnel authorized to use this instrument should be required to be thoroughly familiar with this manual.

Please contact Alcon for complete technical support and service if you have questions concerning any aspect of this instrument's operation or if it fails to perform satisfactorily.

To order supplies in U.S.A.:
800-862-5266
FAX: 800-241-0677

Outside U.S.A.: Contact your local Alcon representative for supplies.

IMPORTANT NOTICE

Equipment improvement is an on-going process and, as such, changes may be made to the equipment after this manual is printed.

Pay close attention to WARNINGS and CAUTIONS in this manual. WARNINGS are written to protect individuals from bodily harm. CAUTIONS are written to protect the instrument from damage. Illustrations contained in this manual are for reference only.

It is recommended that maintenance be performed by a qualified Alcon Field Engineer.

Alcon Surgical shall not be liable for any damage resulting from failure to comply with the enclosed instructions.

Alcon reserves the right to change specifications without further notice.

Operator Profile
The Constellation Vision System is designed to be operated by two basic groups; surgeons and nurses/scrub techs. The surgeon focus is primarily constrained to the footswitch and display panel. The design of the footswitch allows the surgeon to map any function to any switch position, assuming the function is valid in a particular scenario. The display screen was designed to mount on an articulating arm to allow optimum placement of the display so the surgeon can reference it at any time. The design also incorporated items specifically for nurses and scrub techs, who routinely control the machine via the front panel and remote control. The design incorporates color coding on all connectors and tubing to facilitate easy identification of the ports. In addition, the graphical user interface closely resembles controls commonly found on web sites, which this operator profile is expected to be highly proficient at using.

CAUTION

U.S. Federal Law restricts this device to sale by or on the order of a physician only.

WARNINGS!

For systems containing the optional laser module: Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

A qualified technician must perform a visual inspection of the following components every twelve months. In case of a deficiency, do not use the system; call Alcon Technical Services.

- **Warning Labels**
- **Power Cord**
- **Fuses**

A qualified technician must check ground continuity and both polarities for leakage current every twelve months to ensure they are within the applicable standard (for example: EN 60601-1/IEC 601-1). Values must be recorded, and if they are above the applicable standard, or 50% above your first measurement, do not use the system; call Alcon Technical Services.

Use of accessories and cables other than those provided may result in increased emissions or decreased immunity of the system. Portable and mobile RF communications equipment can affect this medical electrical equipment.

Comments or corrections concerning this manual should be addressed to:

Alcon
Technical Services Group
PO BOX 19587
Irvine, CA, USA 92623

SECTION ONE
GENERAL INFORMATION

Introduction

The *Constellation®* Vision System is a multifunctional surgical tool for use in anterior and posterior segment ophthalmic surgeries. The product's capabilities include driving a variety of handpieces that provide the ability to cut vitreous and tissues, emulsify the lens, illuminate the posterior segment of the eye, and apply diathermy to stop bleeding. Vacuum is used to remove ocular matter from the eye and is provided by connecting tubing from the handpiece to a port on the fluidics cassette. Irrigation/ infusion capability is provided to replace fluid in the eye, and enters the eye directly via either an infusion cannula or flows through a handpiece. The graphical operator interface is menu driven. The operator provides inputs using the touchscreen panel, the remote control, voice commands, and the footswitch.

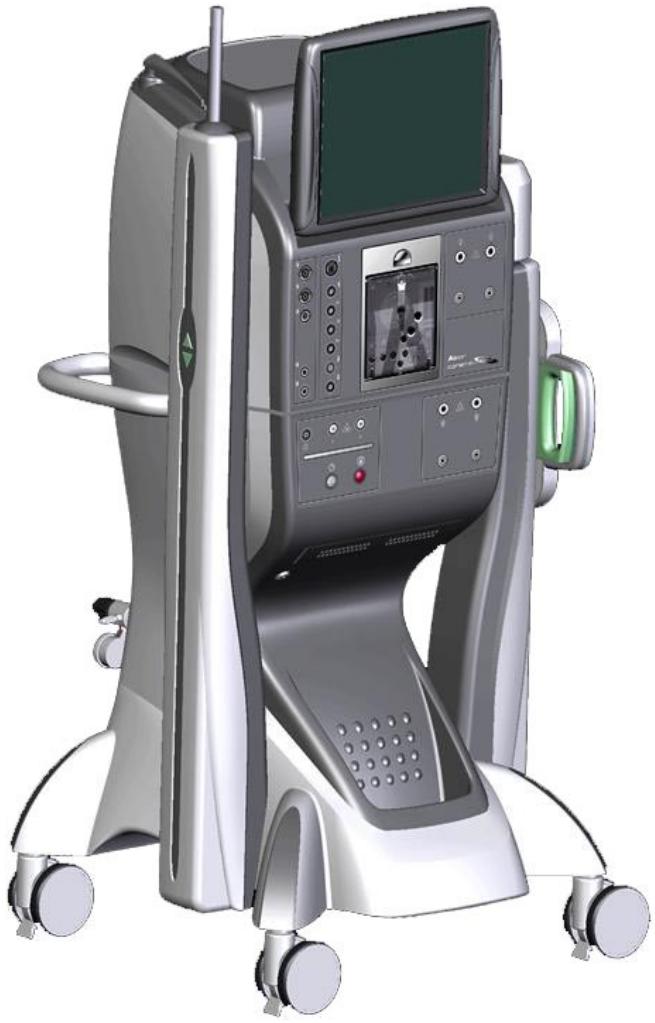


Figure 1-1 The *Constellation®* Vision System - The *Constellation®* Vision System is a multifunctional surgical tool is used in anterior and posterior segment ophthalmic surgeries.

Table 1-1 *CONSTELLATION*® VISION SYSTEM SPECIFICATIONS - This table is a quick reference point to identify system specifications, system requirements, and performance figures.

CONSOLE

DIMENSIONS:
Tabletop:

Height:	160.0 cm (63.0 inches)
Width:	76.2 cm (30.0 inches)
Depth:	77.5 cm (30.5 inches)

Base:

Height:	63.5 cm (25.0 inches)
Width:	53.3 cm (21.0 inches)
Depth:	57.2 cm (22.5 inches)

WEIGHT:

Tabletop:	61.2 kg (135 pounds)
Base:	72.6 kg (160 pounds)

ENVIRONMENTAL LIMITATIONS:

	Operating	Non-Operating
Altitude:	-125 to 2000 m (-410 to 6562 feet)	-125 to 3000 m (-410 to 9843 feet)
Temperature:	10° C to 35° C (50° F to 95° F)	-10 to 55°C (14° F to 131° F)
Relative Humidity:	10% to 95% without condensation	10% to 95% without condensation

ELECTRICAL REQUIREMENTS: The console accepts the following ranges or input commercial power voltages and frequencies and meets the leakage currents specified in IEC 60601-1. Protection against electrical shock is Class I.

100-120 Vac	50/60 Hz	12 A max.	Fuse: T 10 A / 250 V slow blow
220-240 Vac	50/60 Hz	7.5 A max.	Fuse: T 5 A / 250 V slow blow

FOOTSWITCH

DIMENSIONS:

Height:	14.0 cm (5.50 inches)
Width:	22.9 cm (9.00 inches)
Depth:	43.2 cm (17.0 inches)

WEIGHT: 5.4 kg (12 pounds)

ENVIRONMENTAL: The footswitch construction is water tight in compliance with IEC 60601-1 and IEC 60601-2-2, subclause 44.6 aa.

ELECTRICAL: The footswitch is connected to the console via electrical cable. All power and communications enter/exit the footswitch from this cable.

PERFORMANCE SPECIFICATIONS

PRESSURIZED INFUSION/IRRIGATION @SEA LEVEL:

Range:	0 to 120 mmHg
Accuracy:	±(2% of setpoint +5 mmHg)
Flow Rate:	0 - 20 cc/min. for infusion (20 Ga) 0 - 60 cc/min. for irrigation
Setpoint Transient:	500 ms maximum

IOP CONTROLLED INFUSION:

Setpoint Range:	0-120 mmHg
Repeatability[1]:	± 2 mmHg[2]
Setpoint Response Time:	<500 ms (20 Ga)
Transient Disturbance Response Time:	<500 ms[3]
Flow Range:	0-20 cc/min

[1] BSS Dual chamber mode.
[2] BSS medium, 20 gauge high flow Cannula, steady state condition at rated flow range
[3] Transient condition from no flow state to 10cc/min

ASPIRATION/SUCTION @SEA LEVEL:

Standard & Reduced Pressure Range:	0-650 mmHg Vacuum
Minimal Pressure Range:	0-600 mmHg Vacuum
Pressure Accuracy:	±(2% of Setpoint +5 mmHg)
Flow Range:	
Posterior Modalities:	0-20 cc/min
Anterior Modalities:	0-60 cc/min
Transient Response Time (Standard Pressure Range):	From– 0 to -400 mmHg @0 cc/min 10-90% Rise Time:300 msec max 90-10% Fall Time: 300 msec max

IRRIGATION/ASPIRATION @SEA LEVEL:

Sub Modes:	Cap Vac, I/A Max
Vacuum: Standard & Reduced Pressure Range:	0 to -650 mmHg
Minimal Pressure Range:	0 to -600 mmHg Vacuum
Vacuum Accuracy:	2% of displayed value + 5 mmHg
Flow Rate:	10 cc/min minimum + 1.5cc at 50 mmHg vacuum max

VACUUM @ SEA LEVEL:

Vitrectomy:	0 to 650 mmHg
Fragmentation:	0 to 650 mmHg
Extrusion:	0 to 650 mmHg
Extraction:	0 to 650 mmHg
Irrigation/Aspiration:	0 to 650 mmHg
Phacoemulsification:	0 to 650 mmHg

Table 1-1 *CONSTELLATION*® VISION SYSTEM SPECIFICATIONS...continued

PERFORMANCE SPECIFICATIONS...continued

LOW PRESSURE AIR SOURCE (LPAS) @SEA LEVEL:
- Pressure Range: 0 – 120 mmHg at rated flow
- Pressure Accuracy: ±3% of Setpoint +3 mmHg
- Flow Rate: 1.2 slpm minimum at 120 mmHg

VITRECTOMY:
- Submodes: 3D, Momentary, PropVac, VitWet
- Cut Rate:
  - *UltraVit*™ 5000 Probe: 100 to 5000 cpm
  - *UltraVit*™ 2500 Probe: 100 to 2500 cpm

DIATHERMY:
- Frequency: 1.5 Mhz ± 10%.
- Waveshape: Sinusoidal
- Output power: 10 Watts maximum at 100% setting with 75 ± 10% ohm non-inductive load
- Power range: 0 - 100% of maximum output power

ILLUMINATION:
- Lumen Accuracy: ±30%
- Light Output through 20GA 0.5 NA Fiber Probe: 0-200 hrs: 50 lumens minimum at 100% setting; 201-400 hrs:25 lumens minimum at 100% setting
- Light Output through 25GA 0.63 NA Fiber Probe: 0-200 hrs: 15 lumens minimum at 100% setting; 201-400 hrs:10 lumens minimum at 100% setting

FRAGMENTATION:
- Submodes: Linear, Fixed, Momentary
- Tip Stroke @ 100%: 3.1 ± 0.5 mils at 100% power
- Resonant Frequency: 39.0 ± 1.9 KHz
- Pulse Rate Range: 0 – 100 pps

SCISSORS:
- Submodes: Proportional, Multi-Cut
- Proportional Pressure: 0-50 psi @sea level
- Multi Cut Rate: single cut to 450 cpm

PROPORTIONAL AND CONTINUOUS REFLUX @SEA LEVEL:
- Pressure Range: 0 to 120 mmHg
- Pressure Accuracy: ±(2% of Setpoint +5 mmHg)

MICRO REFLUX:
- Pressure Range: 100 ± 15% mmHg[1]
- Volume: 50 ± 10 µL[1]

[1] measured with unoccluded *Accurus*® probe and aspiration tubing

VISCOUS FLUID CONTROL:
- Submodes: Inject, Dual, Extract
- Injection Pressure: 0 to 551.6 KPascal (0 to 80 psi); 0 to 482.7 KPascal @ Reduced (0 to 70 psi)
- Extract Vacuum at Sea Level: 0 to 650 mmHg

AUTO-GAS FILLING (AGF):
- Maximum Gas Pressure: 10 psig
- Fill Purity: 99.9% gas concentration following fill

AUTO-STOPCOCK:
- Response Time: 0.5 seconds minimum
- Pressure (Liquid): 0-120 mmHg
- Rated Flow (Liquid): 20 cc/min
- Pressure (LPAS): 0-120 mmHg
- Rated Flow (LPAS): 1.2 slpm

PHACOEMULSIFICATION:
- Submodes: Burst, Pulsed, Continuous
- Tip Stroke @ 100%: 3.5 ± 0.5 mils
- Resonant Frequency: 34khz – 42Khz ± 10%.
- Pulse Rate Range: 0-100 pulses per second
- Burst Length: 2.5 sec – user adjustable
- Burst Pulse durations: 5ms to 500ms

ANTERIOR VITRECTOMY:
- Submodes: Wet, Dry
- Cut Rate: 0 to probe maximum

LASER (optional):
- Treatment beam:
  - Class: IV
  - Power: 30 mW to 2 W (maximum)
  - Wavelength: 532 nm
- Aiming beam:
  - Class: II
  - Power: less than 1mW
  - Wavelength: 635 nm ± 5 nm

DOCTOR MEMORIES:
- Storage Capacity: xxx Doctors
- Memory Cells per Dr: xx (xx anterior, xx posterior, xx common)

TIMER:
- Range: 0 to xx h
- Resolution: 1 s

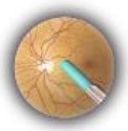
TONE VOLUMES @ 1 Meter:
- Errors/Faults/Invalid Key: 40 to 65 dB, short tones
- Diathermy: 40 to 65 dB, continuous tone
- Advisory/Timer Expire/Elev Infusion: 0 to 65 dB, short tones
- Frag/Phaco/Vacuum: 0 to 65 dB, continuous tone
- Valid Key: Factory set and not adjustable
- Volume Accuracy: 6 dB

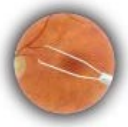
VOICE CONFIRMATION: 0 to 65 dB

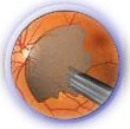
REMOTE CONTROL:
- Method: Infrared
- Channels: 4

Table 1-2 Terms and Abbreviations

Term or Abbreviation	Description
BSS PLUS®	Balanced Salt Solution enriched with bicarbonate, dextrose, and glutathione.
cmH_2O	Centimeters of water.
cpm	Cuts Per Minute.
Detent	A discrete footpedal position at which more force is required to depress the footpedal to the next position.
Diathermy	The production of heat in body tissues by electric current for therapeutic purposes.
Extrusion	A mode where vacuum is available to remove fluid/matter.
F/AX	Fluid Air Exchange.
Frag	Fragmentation.
Global Function	A function whose status and controls are independent of the current footpedal position and surgery mode.
Highlighted	To center attention by video reversing the function key and changing the key color from gray to blue.
I/A	Irrigation/Aspiration.
IEC	International Electromechanical Commission.
ISO	International Standards Organization.
IV	Intravenous.
LCD	Liquid Crystal Display.
mmHg	Millimeter of Mercury. A unit of vacuum.
N/A	Not Applicable.
PEL	Patient Eye Level. A difference in height between the cassette and the patient eye level.
PIN	Personal Identification Number.
psi	Pressure per Square Inch. A unit of pressure.
pps	Pulses Per Second.
slpm	Standard Liters Per Minute.
U/S	Ultrasound.
VFC	Viscous Fluid Control.
Vit	Vitrectomy. Extraction of the vitreous from the vitreous cavity.


Extrusion

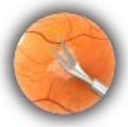

Forceps


Fragmentation


Irrigation/ Aspiration


Laser


Phaco


Scissors


Viscous Fluid Control (VFC)


Vitrectomy


Expand Window

Help Video


Modify


Power


Save


Air Pressure Input

Auto Gas Filling (AGF)


Alternating Current

Coagulation Connector


Connection Indicator


Dangerous Voltage


Eject


Equipotentiality


Footswitch

Forceps


Fuse


Hot

Illuminator


Laser Connection

Laser Emergency Stop Switch

Laser Port 1

Tethered Laser


Network Connection


Off

On


Consult Operator's Manual, or System Error or Advisory


Opens Operator's Manual


Video Recorder


Scissors Connector


Serial In/Out


Standby State

System Fault

System Information

Type BF Equipment

Type B Equipment

U/S Handpiece Connector

USB Connector

Use appropriate take-back system (see Environmental Considerations in this manual).

Viscous Fluid Control Connector

VGA Out

Video In/Out

Vitreous Cutter Connection

Figure 1-2 ICONS USED WITH THE *Constellation*® Vision System - Icons identifying modes, functions, etc., that are used with the *Constellation*® Vision System are identified in this chart.

constellation®
VISION SYSTEM

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

DANGER: RISQUE D'EXPLOSION. NE PAS EMPLOYER EN PRESENCE D'ANESTHESIQUES INFLAMMABLES.

CAUTION: GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED HOSPITAL GRADE.

CAUTION: RISK OF BURNS AND FIRE - DO NOT USE NEAR CONDUCTIVE MATERIALS. RENEW ELECTRODE CABLES UPON EVIDENCE OF DETERIORATION.

FCC ID: VMC212-1
IC: 7345A-2121

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Contains:
FCC ID: VMC212WIFI
IC: 7345A-212WIFI

OUTPUT	DIATHERMY
POWER (W)	10
IMPEDANCE (Ω)	75
FREQUENCY (MHz)	1.5

CAUTION

BF

100-120V 50/60 Hz 12A
MEDICAL/ELECTRICAL EQUIPMENT CLASSIFIED LR 103168
UL60601-1/CAN CSA C22.2 NO 601.1

220-240V 50/60 Hz 6A
0123

58-120 Psi
400-825 kPa

A G F
15-30 Psi
103-107 kPa

For applicable patents, please see the ABOUT screen on the monitor during operation.

Alcon®
ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TX 76134-2099 USA
MADE IN USA

WARNING
STORE TRAY PRIOR TO TRANSPORTATION
212-3019-001 REV P0

DANGER

Visible laser radiation.
Avoid eye or skin exposure to direct or scattered radiation.

Laser 532nm - 2W
DIODE LASER 635nm - 1mW
Class IV laser product

LASER 532 nm - 2W - CW
DIODE LASER 635nm - 1mW
CLASS 4 LASER PRODUCT
IEC 60601-2-22: 1995

LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION
CLASS 4 LASER PRODUCT

RAYONNEMENT LASER
EXPOSITION DANGEREUSE DE LÔEIL OU DE LA PEAU AU RAYONNEMENT DIRECT OU DIFFUS
APPAREIL À LASER DE CLASSE 4

USE OF THIS LASER WITHOUT A SAFETY FILTER MAY RESULT IN DAMAGE TO THE OPERATOR'S EYES

WARNING

L'USAGE DE CE LASER SANS FILTRE MEDECIN PEUT ENDOMAGER LES YEUX DE L'UTILISATEUR

POSSIBLE EXPLOSION HAZARD IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETIC

DANGER

RISQUE D'EXPLOSION SI UTILISATION EN PRESENCE D'ANESTHETIQUE INFLAMMABLE

Labels for gas containers

Figure 1-3 **LABELING USED ON THE *CONSTELLATION*® VISION SYSTEM - Labels used on the *Constellation*® Vision System console are identified and illustrated here.**

System Installation

In the USA contact the Alcon Technical Services Department for uncrating and installation at (800) 832-7827. Outside the USA contact your local Alcon affiliate.

Source Air Pressure Requirements

The *Constellation®* Vision System is designed to operate using different levels of source air pressure. The system operates automatically with pressures of 58 (4 bar) to 120 psi (8.3 bar). Between 4 bar and 5 bar, vacuum performance is reduced. Between 4 bar and 5.5 bar, VFC inject performance is reduced.

Accessory equipment connected to or used with this equipment must be certified according to the respective IEC Standard (e.g., IEC 60950 for data processing equipment, and IEC 60601-1 for medical equipment). The *Constellation®* is shipped with English and metric air fittings compliant with EN739:1998. Anyone connecting additional equipment or otherwise causing a different system configuration than provided by Alcon is responsible for continued compliance to the requirements of System Standard IEC 60601-1-1. If in doubt, consult the Technical Services department or your local Alcon representative.

Settings Restoration

When a loss of power occurs, the *Constellation®* Vision System retains its current settings and mode in memory. When power is reestablished a System Information popup window appears asking:

"Do you want to restore the system's previous settings and mode?"

The user can press **Yes** to restore the previous settings, or **No** to enter the default settings. Disconnecting the power cord, or turning the system off using the rear panel power switch, is considered a loss of power; using the rear panel standby switch is not.

Environmental Issues

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

WARNINGS!

***Laser*: There are potential hazards when inserting, steeply bending, or improperly securing the fiberoptic. Not following the recommendations of the manufacturer may lead to damage of the fiber or delivery system and/or harm to the patient or user.**

Since the aiming beam passes down the same delivery system as the treatment beam, it provides a good method of checking the integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, or its intensity is reduced or it looks diffused, this a possible indication of a damaged or not properly working delivery system. If there is any doubt, contact Alcon Technical Services.

The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen should be avoided. Some materials - for example cotton wool when saturated with oxygen - may be ignited by the high temperatures produced in normal use of the laser equipment. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. There is also danger of ignition of endogenous gases.

User Information - Environmental Considerations

The equipment that you have purchased requires the use of natural resources for its production. This equipment may also contain hazardous substances which could have potential effect on the environment and human health if disposed of improperly.

In order to avoid the entry of any such substances into our environment and to promote natural resource conservation, we encourage you to use the appropriate take-back systems. Such take-back systems reuse or recycle many of the materials in your end-of-life equipment in a beneficial way. Please contact your local Alcon office for assistance in take-back options through Alcon or other providers.

The crossed-bin symbol located on this equipment reminds you to use take-back systems, while also emphasizing the requirement to collect waste equipment separately, and not dispose of it as unsorted municipal waste.

If you need more information on the collection, reuse or recycle systems available to you, please contact your local or regional waste administration, or contact your local Alcon office for more information.

Universal Precautions

Universal precautions shall be observed by all people who come in contact with the instrument and/or accessories to help prevent their exposure to blood-borne pathogens and/or other potentially infectious materials. In any circumstance, wherein the exact status of blood or body fluids/tissues encountered are unknown, it shall be uniformly considered potentially infectious and handled in accordance with OSHA guidelines.

EMC Statement

It is important to install and use the equipment in accordance with the instructions in order to prevent harmful interference with other devices in the vicinity. If this equipment causes harmful interference to other devices (determined by turning the equipment off and on), the user is encouraged to try to correct the interference by one or more of the following measures:
Reorient or relocate the other device(s).

- Increase the distance between the equipment.
- Connect this equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer or your Alcon field service engineer for help.

Table 1-2 Guidance and Manufacturer's Declaration - Electromagnetic Emissions - The *Constellation*® Vision System is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	The *Constellation*® Vision System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Based on extensive field experience the *Constellation*® Vision System is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. The EMC Statement provides guidance on steps to take in case of electromagnetic interference.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Table 1-3 Guidance and Manufacturer's Declaration - Electromagnetic Immunity - The *Constellation*® Vision System is intended for use in the electromagnetic environment specified below. The customer or the user of the *Constellation*® Vision System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	• ±6 kV contact • ±8 kV air	• ±6 kV contact • ±8 kV air	Floors should be wood, concrete, or ceramic tile. Do not use around floors that are covered with synthetic material to avoid laser stoppage due to ESD.
Electrical fast transient/burst IEC 61000-4-4	• ±2 kV for power supply lines • ±1 kV for input/output lines	• ±2 kV for power supply lines • ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment. To avoid laser stoppage due to fast transients avoid powering the *Constellation*® Vision System on the same branch circuit with sources that can generate fast transients (inductive switching; e.g., high current motors).
Surge IEC 61000-4-5	• ±1 kV differential mode • ±2 kV common mode	• ±1 kV differential mode • ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment. To avoid laser stoppage due to power-line surges consider powering the *Constellation*® Vision System through branch circuit that has surge suppressor for protection against lightning surges (e.g., at power panel to surgical/office suite).
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	• <5% U_T (>95% dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% (30% dip in U_T) for 25 cycles • <5% (>95% dip in U_T) for 5 sec	• <5% U_T (>95% dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% (30% dip in U_T) for 25 cycles • <5% (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the uses of the *Constellation*® Vision System require continued operation during power mains interruptions, it is recommended that the *Constellation*® Vision System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *Constellation*® Vision System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency to the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz *Constellation*® Vision System where P is the maximum output power rating to the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with following symbol. 

Note: U_T is the a.c. mains voltage prior to application of the test level.
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Constellation*® Vision System is used exceeds the applicable RF compliance level above, the *Constellation*® Vision System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Constellation*® Vision System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 1-4 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the *Constellation*® Vision System - The *Constellation*® Vision System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Constellation*® Vision System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Constellation*® Vision System as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	**150 kHz to 80 MHz $d = 1.2\sqrt{P}$**	**80 MHz to 800 MHz $d = 1.2\sqrt{P}$**	**800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rates at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

USA – Federal Communications Commission (FCC) Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

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

Caution

Change or modifications made to this equipment not expressly approved by Alcon may void the FCC authorization to operate this equipment.

FCC Radiation Exposure Statement

Caution

To ensure that the radio transmitter complies with current FCC regulations limiting both maximum output RF power and human exposure to radio frequency radiation, a separate distance of at least 20 cm must be maintained between the unit's antenna and the body of the user and any nearby persons at all times, and unit's antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

Canada – Industry of Canada (IC) Compliance Statement

This device complies with Industry Canada Radio Standards Specification RSS-210. Operation is subject to the following two conditions:

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

This ISM device complies with Canadian ICES-001.
Cet appareil ISM est conforme à la norme NMB-001 du Canada.

Antenna Notices

This device has been designed to operate with the antenna having a maximum gain of 5 dBi. Antenna having a gain greater than 5 dBi is strictly prohibited for use with this device. The required antenna impedance is 50 ohms.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (EIRP) is not more than that required for successful communication.

Exposure of Humans to RF Fields

This device complies with the RF exposure limits for humans as called out in RSS-102.

Europe – R&TTE Directive 99/5/EC

This device complies with the requirements of the Council Directive 99/5/EC (R&TTE).

Caution

The radio equipment is intended to be used in all EU and AFTA countries. Outdoor use may be restricted to certain frequencies and/or may require a license for operation. Contact local Authority for procedure to follow.

Note: Combinations of power levels and antennas resulting in a radiated power of above 100mW equivalent isotropic radiated power (e.i.r.p) are considered as not compliant with the above mentioned directive and are not allowed for use within the European community and countries that have adopted the European R&TTE directive 1999/5/EC.

For more details on legal combinations of power levels and antennas, contact Alcon Compliance.

Equipment contains radio transmitters:

Wireless LAN device (WiFi)

- Frequency or frequency band of transmission: 2.412 – 2.462 GHz
- Type and frequency characteristics of the modulation: CCK, DQPSK, DBPSK, OFDM
- The Effective Radiated Power (ERP): 17 – 18dBm (50 – 64mW)

Radio Frequency Identification (RFID) device

- Frequency or frequency band of transmission: 13.56 MHz
- Type and frequency characteristics of the modulation: ASK
- The Effective Radiated Power (ERP): -119 dBm (1260 pW)

Australia and New Zealand

This device complies with the Australian/New Zealand Standard AS/NZS 4268: 2003 Radio Equipment and Systems – Short Range Devices – Limits and methods measurement, and AS/NZS 4771 (2000 + A1: 2003) Technical characteristics and test conditions for data transmission equipment operating in the 900 MHz, 2.4 GHz and 5.8 GHz bands and using spread spectrum modulation techniques.

Cautions and Warnings

Please contact Alcon for instrument setup and in-service training.

If you have any questions or require additional information, please contact your local Alcon representative or the Technical Services Department. For locations outside the USA, please contact your local authorized Alcon Service/Sales office.

- Good clinical practice dictates the testing for adequate irrigation, aspiration flow, and operation as applicable for each handpiece prior to entering the eye.
- Do not use the *Constellation®* Vision System system near flammable anesthetics.
- Use only Alcon-supplied A.C. power cords. Prior to plugging the power cord into its power source, ensure that the proper voltage selection has been made. See Care and Maintenance section of this manual for instructions.
- Provide at least two feet of clearance at the rear of the unit for fan intakes and exhausts. This ensures unrestricted air flow for adequate console cooling.
- A handle on the instrument cart is used for moving the instrument. The cart should be pulled, not pushed, over elevator and door thresholds.

WARNING!

The *Constellation®* Vision System power cord is a medical grade power cord with the least leakage current per foot rating available. Extension of the power cord by hospital staff is not recommended. Unauthorized extension of the power cord could result in injury.

Presurgical Setup Instructions

Presurgical setup instructions must be performed as outlined in this manual. If an error message is displayed on the front panel, refer to Troubleshooting of this Manual. If a problem persists, DO NOT PROCEED. Contact your local Alcon Surgical Service Representative.

NOTE: If an inconsistency exists between the setup instructions in this manual and the Directions For Use (DFU) supplied with a consumable pak, follow the DFU.

Vitreous Probes

Do not operate vitreous probes in air. This could result in performance degradation and/or potential hazard.

Ultrasonic Handpieces

Power loss may occur if handpiece tip is not securely tightened into Fragmentation and Phaco handpieces.

WARNING!

Use of a Phaco handpiece at power settings greater than 80% continuously for over 4 minutes can result in ultrasonic system failure. Allow the system to cool for 8 minutes between heavy usage of this type.

If proper cleaning procedures are not performed immediately after each surgical procedure, tissue debris and salts from irrigating solution may collect. This could permanently damage the handpiece and could jeopardize cleanliness and/or create biohazard conditions for the patient. Remove all debris prior to autoclaving handpiece.

CAUTION

Never ultrasonically clean the Fragmentation and Phaco handpieces; irreparable damage will result.

WARNINGS!

Use of the phaco handpiece in the absence of irrigation flow and/or in the presence of reduced or lost aspiration flow can cause excessive heating and potential corneal and/or scleral burns.

Use of the Fragmentation handpiece in the absence of aspiration flow can cause excessive heating and potential scleral burns.

Handpiece Tips

Scissors, frag, and phaco handpiece tips must be fully tightened to their handpieces. If not secured properly, the handpieces may not operate correctly. Ensure, however, that tips are not so tight that they cannot be removed after use. Use only Alcon supplied fragmentation tip wrenches; otherwise, damage to tips and/or handpiece may occur.

WARNING!

For phaco surgery use only Alcon-certified *Turbosonics® MicroTip™* configurations (.9 mm). Alcon does not recommend the use of standard *Turbosonics®* tips (1.0 mm) with the *Constellation®* Vision System.

Diathermy Function

To ensure safe operation of the Diathermy function, use only Alcon cables and accessories. Diathermy performance can be guaranteed only when using Alcon Surgical components or Alcon-endorsed components. Cables should always be positioned in such a way that contact with the patient is prevented.

See Figures 1-4 through 1-6 for diathermy power specifications.

WARNING!

- **Do not use the diathermy function on patients with pacemakers or implanted defibrillatory devices. If electrosurgery is used on patients with implanted cardiac pacemakers or defibrillatory devices or pacemaker electrodes, be aware that irreparable damage to the pacemaker or defibrillatory device and its function may occur and lead to ventricular fibrillation. Please check with the pacemaker or defibrillatory device manufacturers for their recommendations.**
- **Failure of the HF surgical equipment (diathermy circuitry) could result in an unintended increase of output power.**

Listed below are general precautions to be followed when using the Diathermy function:

- To ensure safe operation of the Diathermy function, only approved cables and accessories must be used (See your Alcon representative). Diathermy performance can be guaranteed only when using Alcon components or Alcon-endorsed components.
- To reduce the risk of accidental burns, caution should always be taken when operating high-frequency surgical equipment.
- Interference produced by the operation of high-frequency surgical equipment may adversely influence the operation of other electronic equipment.
- Accessories should be checked regularly; electrode cables should particularly be checked for possible damage to the insulation.
- The lowest power level in Diathermy step should always be selected for the intended purpose.
- Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
- When HF (high frequency) surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.
- In all cases, monitoring systems incorporating high frequency current-limiting devices are recommended.
- The cables to the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided.
- Temporarily unused active electrodes should be stored so that they are isolated from the patient.

- The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.
- Non-flammable agents should be used for cleaning and disinfection wherever possible.
- Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of the HF surgical equipment.

Illuminator Function

Housed inside *Constellation®* tabletop, the illuminator provides two channels of illumination from a single xenon arc lamp. Two front panel sockets accept ACMI compatible fiber optic light guides to provide intraocular illumination.

When installed, an optional illuminator is housed inside *Constellation®* base and provides two channels of illumination from a single xenon arc lamp.

To gain access for bulb replacement or servicing, follow directions in section four of this manual. Be aware that using the illuminator at high settings will reduce the life of the bulbs.

WARNING!

The illuminator bulbs become extremely hot. Never handle a bulb until it has cooled considerably from its operating temperature. Do not touch bulb directly with fingers at any time.

The bulb of the xenon lamp is under constant high pressure. There is a risk it may burst with explosive force if knocked or damaged. Protective measures:
- **Keep the lamp in its protective sleeve at all times during installation**
- **If you are handling the lamp without its protective sleeve, always wear safety goggles, a face mask, gauntlets with wrist protectors and a breast protector.**

Cautions and Warnings

Footswitch
Never pick up or move the footswitch by holding the cable. Damage may result.

Cassette
During initialization the drain pump is rotated to the home position; therefore, keep hands and fingers clear of cassette well during power-on initialization. Manually rotating the hub roller in the cassette well when power is on and a cassette is not installed can cause incorrect cassette loading and/or can cause injury to fingers.

WARNINGS!

All fluids aspirated during surgery should be treated as biohazards. Take appropriate precautions when handling instruments and lines in contact with aspirated fluids.

Drain bag volume should not exceed 500cc "Max. Capacity." Exceeding this volume may result in a biohazardous condition.

Consumables
Do not use consumable paks beyond the expiration date stamped on the outer packaging. Sterile consumable medical devices should not be reused (Accreditation Manual for Hospitals, 1982); they are intended for single use only. Improper usage or assembly could result in a potential hazardous condition for the patient. Alcon assumes no responsibility for complications that may arise as a result of the reuse or improper usage of consumables.

The equipment used in conjunction with Alcon *Constellation®* Vision System consumables constitutes a complete system. Use of consumables other than Alcon consumables may affect system performance and create potential hazards, and if it is determined to have contributed to the malfunction of the equipment under service contract, could result in the voidance of the contract and/or invoicing at prevailing hourly rates.

WARNING!

Attach only Alcon supplied consumables to console and cassette luer fittings. Do not connect consumables to the patient's intravenous connections.

In all cases, the instrument setup instructions contained in this manual, and all label instructions in the package, should be thoroughly understood prior to using any of the *Constellation®* Vision System Pak configurations.

Ensure that tubing is not occluded during any phase of operation.

Cautions and Warnings

Consumable Paks

If any item in a consumable pak is received in a defective condition, Alcon is to be notified immediately. Do not use any of the contents if the sterile package is damaged or the seal is broken in any way. Paks are identified by lot number that provides traceability and should be given to the Customer Service Department.

Phone Alcon Customer Service At:
(800) 862-5266 or
(817) 293-0450

Please Write To Alcon At:
Alcon
Attn: Product Complaints
6201 South Freeway
Fort Worth, TX 76134-2099

Diathermy, Cautery, Coagulation

In the past, some of Alcon's products have referred to the feature "Cautery" or "Coagulation." The *Constellation®* Vision System and this operator's manual use the word "Diathermy" based on the following definitions:

- Diathermy - introducing an electric field into a body part to produce heat.
- Cautery - cutting and burning method associated with two hot wires passing a current between them; cutting away skin; halting bleeding.
- Coagulation - an isolated bipolar current supplied to conductors (e.g. forceps). Current passes between these electrodes, halting bleeding.

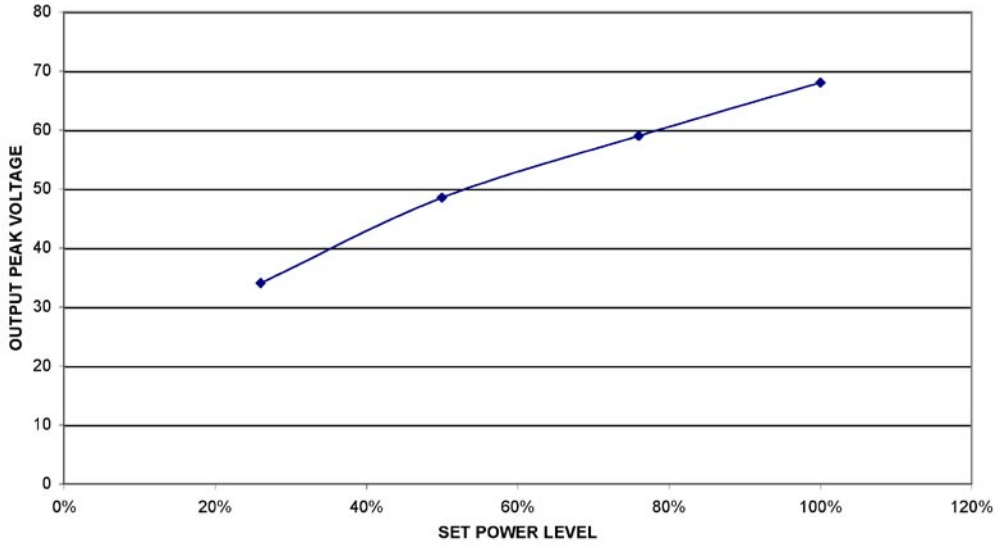


Figure 1-4 DIATHERMY POWER THROUGH 75 OHM LOAD

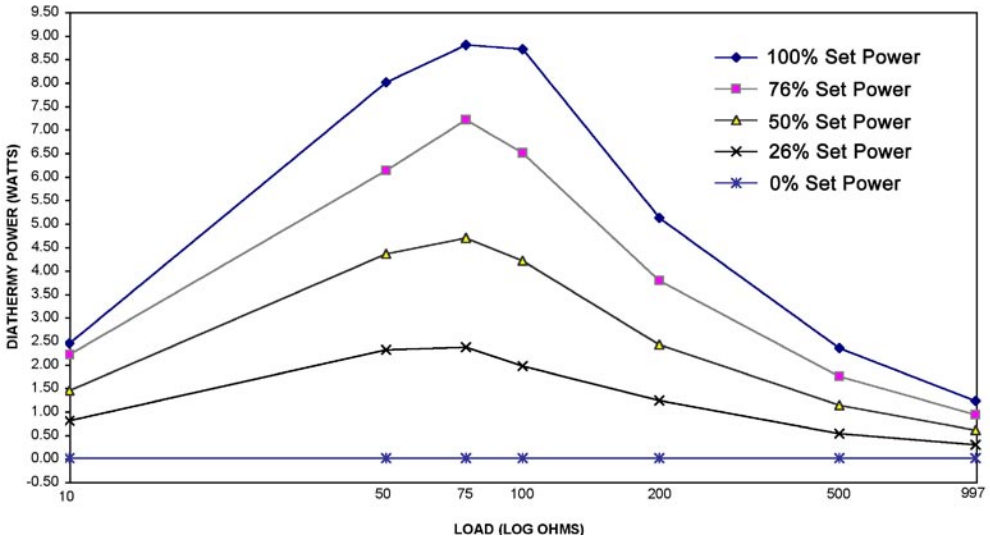


Figure 1-5 DIATHERMY POWER VS. LOAD IMPEDANCE

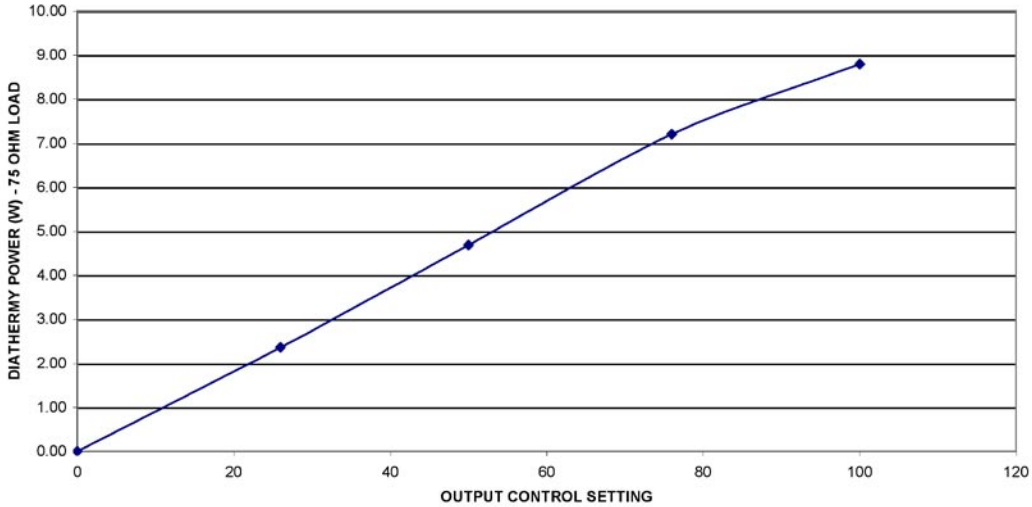


Figure 1-6 DIATHERMY OUTPUT VOLTAGE VS. OUTPUT CONTROL SETTING
Note: Maximum output peak-to-peak voltage is about 140V without resistive load.

PRODUCT SERVICE

For product service, please contact Alcon's Technical Services Department at the number provided below.

Operators experiencing problems with the system should refer to the Operating Instructions and Troubleshooting sections of this manual. A problem which persists should be referred to the Alcon Technical Services Department or your local authorized service representative.

For optimum performance, it is the user's responsibility to schedule preventive maintenance service on the system and its accessories one time each year. Alcon's Field Service Engineers are trained and equipped to provide the highest quality of workmanship.

Safety performance should be verified by the user (e.g., qualified service personnel) at least twice a year. Ground resistance must be under 0.1 ohms. Leakage current must be under 500 μA.

To avoid unnecessary shipping, please contact your Alcon Technical Services Department prior to the return of any system or accessories. If return of the equipment is deemed necessary, a Return Material Authorization will be issued with appropriate shipping instructions.

Alcon Laboratories, Inc.
Technical Services Department
15800 Alton Parkway
Irvine, California 92618-3818
(949) 753-1393
(800) 832-7827

LIMITED WARRANTY

Alcon Laboratories, Inc., will repair or replace at its option, any system or accompanying accessories (excluding the optical fiber) found to be defective in material and/or workmanship for a period of one (1) year from the date of initial installation. This warranty applies to the original purchaser of the system, when said system is properly installed, maintained, and operated in accordance with published instructions.

Alcon Laboratories shall not be obligated to provide services under this warranty for damage to or destruction of systems covered where such damage or destruction is (i) a result of or caused by fire or explosion of any origin, riot, civil commotion, aircraft, war, or any Act of God including, but not limited to lightning, windstorm, hail, flood, earthquake, or (ii) caused by customer's misuse or improper servicing of said systems.

The express warranty above is the sole warranty obligation of Alcon, and the remedy provided above is in lieu of any and all other remedies. There are no other agreements, guarantees, or warranties - oral or written, express or implied - including without limitation warranty of merchantability or fitness for a particular purpose. Alcon shall have no liability whatsoever for any incidental or consequential damages arising out of any defect, improper use, or unauthorized service or repair.

WARNING!

The disposables used in conjunction with Alcon instrument products constitute a complete surgical system. Use of disposables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards. If it is determined that disposables or handpieces not manufactured by Alcon have contributed to the malfunction of the equipment during warranty period, service will be provided at prevailing hourly rates.