



# Operator's Manual

**Manufacturer:**

Alcon Laboratories, Inc.  
6201 South Freeway  
Fort Worth, Texas 76134-2099  
U.S.A.



Alcon Laboratories (UK) Ltd.  
Frimley Business Park  
Frimley, Camberley  
Surrey, GU16 7SR, United Kingdom

**Produced By:**

Alcon Research, Ltd.  
15800 Alton Parkway  
Irvine, California 92618-3818  
U.S.A.



Telephone: 949/753-1393  
800/832-7827  
FAX: 949/753-6614

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**Centurion® Vision System Operator's Manual**  
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March 2011	P2	2011XXXX - Preliminary release of Centurion® Vision System Operator's Manual with catalog number 8065751772, and 905-2150-001 text (applies to Centurion® Vision System consoles with software version X.00).
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## PREFACE

This operator's manual is your written guide to the *Centurion*<sup>®</sup> Vision System and considers all options available to the customer; therefore, when reading this manual, ignore the options which do not apply to your specific unit.

Please read the entire manual carefully before operating the instrument. Recommended settings are given only as guidelines, and are not meant to restrict the surgeon; however, before trying other settings, the surgeon and support personnel should be experienced with the system and familiar with the new settings.

**NOTE: If an inconsistency exists between the instructions in the operator's manual and the Directions For Use (DFU) supplied with a consumable pack or accessory, follow the DFU.**

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, Cautions, and Notes in this manual. A WARNING! statement is written to protect individuals from bodily harm. A Caution statement, with the CAUTION heading centered above the text, is written to protect the instrument from damage. A NOTE: is written to bring attention to highlighted information.

If you have questions, or want additional information, please contact your local Alcon representative or the Alcon Technical Services Department at:

Alcon Research, Ltd.  
15800 Alton Parkway  
Irvine, California 92618  
(949) 753-1393  
FAX (949) 753-6614

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

## SECTION ONE GENERAL INFORMATION

### INTRODUCTION

Alcon's *Centurion*<sup>®</sup> Vision System is an ophthalmic surgical instrument designed to provide for cataract lens extraction using the CENTURION<sup>®</sup> *OZil*<sup>®</sup> handpiece and the INFINITI<sup>®</sup> *OZil*<sup>®</sup> handpiece.

The *Centurion*<sup>®</sup> Vision System is intended for use in small incision cataract lens extraction and IOL injection surgical procedures. This system allows the surgeon to emulsify and aspirate the lens in the eye, while replacing aspirated fluid and lens material with balanced salt solution. This process maintains a stable (inflated) eye chamber volume. Using system controls, the surgeon regulates the amount of power applied to the handpiece tip, the rate of aspiration, vacuum, and the flow of *BSS*<sup>®</sup> irrigating solution. The system includes a footswitch to enable the surgeon to control flow of fluidics, aspiration rate, phaco power, vitrectomy cut rate, IOL injection rate, anterior capsulotomy, and coagulation power.

## GENERAL INFORMATION

The *Centurion*<sup>®</sup> Vision System is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intra-ocular lens injection. The *AutoSert*<sup>®</sup> IOL Injector Handpiece is intended to deliver qualified *AcrySof*<sup>®</sup> intraocular lenses into the eye following cataract removal.

The *AutoSert*<sup>®</sup> IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The *AutoSert*<sup>®</sup> IOL Injector Handpiece is indicated for use with *AcrySof*<sup>®</sup> lenses SN60WF, SN6AD1, SN6AT3 through SN6AT9, as well as approved *AcrySof*<sup>®</sup> lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

The *Centurion*<sup>®</sup> Vision System, including accessories approved by Alcon, constitutes a complete surgical system and is intended exclusively for use by licensed ophthalmic surgeons and their surgical teams. These surgical teams are experienced at conducting phacoemulsification procedures in a properly maintained surgical environment (qualified personnel, availability of backup equipment) and are familiar with the operation of the equipment used as outlined in operator's manuals and directions for use (setup/checkout procedures to be completed before the surgical procedure; processing of reusable devices; maintenance; etc.).

Patient selection for use with the *Centurion*<sup>®</sup> Vision System (such as age, ophthalmic pathology, and other factors) is determined by the surgeon. The general patient age can range from newborn to geriatric, although there have been studies that have identified the mean age of patients that underwent cataract surgery was 72.32 yrs - men and 74.89 yrs - women.<sup>1</sup>

### Intended Use Environments

The *Centurion*<sup>®</sup> Vision System is intended for use in hospitals and ambulatory surgery centers.

### Phaco Handpiece Note

Throughout the rest of this manual the CENTURION<sup>®</sup> *OZil*<sup>®</sup> handpiece and the INFINITI<sup>®</sup> *OZil*<sup>®</sup> handpiece will be referred to as phaco handpieces, unless one or the other must be referred to exclusively.

### Trademark Note

A button, mode, or step labeled *OZil*<sup>®</sup>, *AutoSert*<sup>®</sup>, or *UltraChop* refers to a display screen control used with a phaco handpiece, INTREPID<sup>®</sup> *AutoSert*<sup>®</sup> IOL injector, or ALCON<sup>®</sup> *UltraChopper*<sup>®</sup> tip, respectively.

### Abbreviation Descriptions

Many of the abbreviations used in this manual and on the *Centurion*<sup>®</sup> Vision System are described in Table 1-x. Icons are identified in Figure 1-x.

### Accessory Equipment

Accessory equipment connected to or used with this equipment must be certified according to the respective IEC Standard (e.g., IEC 60950-1 for data processing equipment, and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with clause 16 of IEC 60601-1:2005 (as amended). Anyone connecting additional equipment or otherwise causing a different system configuration than provided by Alcon is responsible for continued compliance to the requirements of clause 16 of IEC 60601-1:2005 (as amended). If in doubt, consult the Technical Services department or your local Alcon representative.

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

1. "Age and sex profile of patients having cataract surgery between 1986 and 2003"  
Philip O'Reilly, FRCSI (Ophth), U. Mahmoud, FRCOphth, P. Hayes, FRCOphth, P. Tormey, FRCOphth, S. Beatty, MD.  
Journal of Cataract Refractive Surgery 2005; 31:2162-2166

## User Information – Environmental Considerations

The equipment that you have purchased requires the use of natural resources for its production and operation. 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, please install, maintain, and operate the equipment in accordance with the instructions. Information on the location of hazardous substances, resource consumption and emissions of the equipment can be found throughout this Operator's Manual. Please 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.



**Pb**

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. The Pb notation, if present, indicates that the labeled device contains greater than 0.004% lead.

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 or your own national guidelines.

## EMC Statements

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 equipment off and on), the user is encouraged to try to correct 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.

Users should be aware of known RF sources, such as radio or TV stations and hand-held or mobile two-way radios, and consider them when installing a medical device or system.

Portable and mobile RF communications equipment such as cellular telephones can affect medical electrical equipment (see Table 1-3 for recommended separation distances).

Be aware that adding accessories or components, or modifying the medical device or system, may degrade the EMI performance. Consult with qualified personnel regarding changes to the system configuration.

**WARNINGS!**

The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the system as replacement parts for internal components, may result in increased emissions or decreased immunity of the system.

The system should not be used adjacent to, or stacked with, other equipment; and that if adjacent to or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.


**MAGNETIC AND ELECTRICAL INTERFERENCE** - Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment, magnetic resonance tomography (MRT), nuclear magnetic resonance (NMR), or magnetic resonance imaging (MRI) devices are possible sources of interference as they may emit higher levels of electromagnetic radiation. See the Magnetic Resonance Unsafe icon in Figure 1-2.

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

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	The <i>Centurion</i> <sup>®</sup> 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	The <i>Centurion</i> <sup>®</sup> Vision System is suitable for use in all establishments other than domestic and those directly connected to a 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 1-2 Guidance and Manufacturer's Declaration - Electromagnetic Immunity - The *Centurion*® Vision System is intended for use in the electromagnetic environment specified below. The customer or the user of the *Centurion*® 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. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
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 hospital (including ambulatory surgery center) environment. To avoid pre-mature shutdown due to fast transients avoid powering the <i>Centurion</i> ® 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 hospital (including ambulatory surgery center) environment.
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 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles • < 5 % $U_T$ (> 95 % dip in $U_T$ ) for 5 s	• < 5 % $U_T$ (> 95 % dip in $U_T$ ) for 0.5 cycle • 40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles • 70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles • < 5 % $U_T$ (> 95 % dip in $U_T$ ) for 5 s	Mains power quality should be that of a typical hospital (including ambulatory surgery center) environment. If the use of the <i>Centurion</i> ® Vision System requires continued operation during power mains interruptions, it is recommended that the <i>Centurion</i> ® 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 hospital (including ambulatory surgery center) environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the <i>Centurion</i> ® Vision System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency to the transmitter.  <b>Recommended separation distance:</b>  $d = 1.2\sqrt{P}$  $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz  $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz  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 <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> .  Interference may occur in the vicinity of equipment marked with following symbol. 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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.

<sup>a</sup> 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 (equipment or system) is used exceeds the applicable RF compliance level above, the (equipment or 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 *Centurion*® Vision System.

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

**Table 1-3 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Centurion® Vision System - The Centurion® Vision System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Centurion® Vision System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Centurion® Vision System as recommended below, according to the maximum output power of the communications equipment.**

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	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.

## Equipment Contains Radio Transmitters

- ZigBee Radio Modular (Communication link with Footswitch, HUD and Media Center)
  - Frequency or frequency band of transmission: 2.405 – 2.480 GHz
  - Type and frequency characteristics of the modulation: OQPSK (Offset quadrature phase-shift keying)
  - The Effective Radiated Power (ERP): 12.91 dBm (19.54 mW)
  
- Wireless LAN device (Optional)
  - Frequency or frequency band of transmission: 2.412 – 2.484 GHz and 5.180 - 5.700 GHz
  - Type and frequency characteristics of the modulation: OFDM, DSSS, CCK, DQPSK, DBPSK, 64 QAM, 16 QAM
  - The Effective Radiated Power (ERP): 17.09 dBm (51.17 mW)
  
- Wireless Footswitch Charger
  - Frequency or frequency band of charging transmission: 50 kHz
  - Frequency or frequency band communication transmission: 115 kHz
  - Type and frequency characteristics of the modulation: FSK (Frequency Shift Keying)
  - The Effective Radiated Power (ERP): -14.89 dBm (53.18  $\mu$ W)

## USA – Federal Communications Commission (FCC)

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.

### CAUTION

**Change or modifications made to this equipment (including antenna) 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)

This device complies with Industry Canada licence-exempt RSS standards. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

*Cet appareil est conforme aux normes d'Industrie Canada RSS exemptes de licence. Son fonctionnement est soumis aux deux conditions suivantes: (1) Cet appareil ne doit pas provoquer d'interférences nuisibles, et (2) cet appareil doit accepter toute interférence, y compris les interférences pouvant provoquer un fonctionnement indésirable de l'appareil.*

### Transmitter Antenna:

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

*Conformément à la réglementation de l'industrie du Canada, cet émetteur de radio ne peut être utilisé qu'avec un type d'antenne approuvé pour l'émetteur par Industrie Canada et seulement avec une valeur de gain inférieure ou égale au gain maximum approuvé par Industrie Canada. Pour réduire les risques potentiels d'interférence à autrui, le type d'antenne et son gain doivent être choisis de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas la valeur qui est nécessaire pour une communication réussie.*

The radio transmitters, contained in the system, have been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

*Les émetteurs radio, contenues dans le système, ont été approuvés par Industrie Canada pour fonctionner avec les types d'antenne énumérés ci-dessous et ayant un gain admissible maximal et l'impédance requise pour chaque type d'antenne. Les types d'antenne non inclus dans cette liste, ou dont le gain est supérieur au gain maximal indiqué, sont strictement interdits pour l'exploitation de l'émetteur.*

Approved Antennas			
Part Number	Manufacturer	Description	Min. Separation
WPC25A	Taoglas	2.4 GHz Ceramic Patch Antenna	20 cm
GW.71.5153	Taoglas	2.4 / 5.8 GHz Dipole Antenna	20 cm
ANTB98-061A0	Sansei Denki	Sleeve antenna 2.4 / 5 GHz	20 cm

### Exposure of Humans to RF Fields:

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

*Cet appareil est conforme aux limites d'exposition RF pour les êtres humains comme elles le sont notifiées dans la norme 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 100 mW 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.

## Japan

This device complies with ARIB STD-66 Radio Standard in Japan.

**Table 1-4 Information on the Location of Hazardous Substances in the Centurion® Vision System - The Centurion® Vision System contains hazardous substances which could have potential effect on the environment and human health if disposed of improperly.**

Material Location	Hazardous Substances Contained
Printed Circuit Board Assembly	Lead, Polybrominated Biphenyls (PBB)
Other Electrical / Electronic Device	Lead, Polybrominated Biphenyls (PBB)
Cable Assembly	Lead
Power Supply	Lead, Polybrominated Biphenyls (PBB)
Host PC Module	Lead, Polybrominated Biphenyls (PBB)
Liquid Crystal Display	Lead
Battery	Lead, Lithium, Zn/MnO <sub>2</sub>
IV Pole Assembly	Lead, Polybrominated Biphenyls (PBB)
Remote Control	Lead
Fluidics Assembly	Lead
Pneumatic Assembly	Lead

## WARNINGS AND CAUTIONS

Many of these warnings are stated elsewhere in this manual; however, for easy reference they are repeated in greater detail here. If additional information is required, please contact your local Alcon service representative, or the Technical Services Department.

There are no user serviceable components inside the *Centurion*<sup>®</sup> Vision System console or footswitch. Refer all service issues to your factory-trained Alcon service engineer.

### **WARNINGS!**

**The *Centurion*<sup>®</sup> Vision System battery can only be serviced by a factory-trained Alcon service engineer. Access by untrained personnel can lead to injury.**

**A qualified technician must perform a visual inspection of the following components every twelve months:**

- **Warning Labels (see section one of this manual)**
- **Power Cord**
- **Fuses**

**In case of a deficiency, do not use the system; call Alcon Technical Services.**

**A qualified technician must check ground continuity and leakage current every twelve months to ensure they are within the limits of the applicable standards (for example: EN60601-1/IEC60601-1). Values must be recorded, and if they are above the limits of the applicable standards, or 50 % above initial measurement, do not use the system; call Alcon Technical Services.**

**If the *Centurion*<sup>®</sup> Vision System is used at the 220 V - 240 V range in the United States or Canada, it should be used on a center-tapped, 240 V single phase circuit.**

**Console isolation from mains is achieved through a two pole power switch. Turn OFF power switch or unplug the power cord from wall outlet to achieve isolation from mains.**

**Do not use the *Centurion*<sup>®</sup> Vision System near flammable anesthetics.**

**Do not exceed maximum capacity of drain bag (500 ml). Excessive pressure can result from exceeding drain bag maximum capacity and potentially result in a hazardous condition for the patient.**

**Inadvertent actuation of Prime or Tune while a handpiece is in the eye can create a hazardous condition that may result in patient injury.**

**Keep clear of display base when raising display from stored position to prevent skin, hair, and /or clothing from being trapped at the base.**

**The maximum allowable load on the instrument tray is 20 lb. (9 kg).**

**Place the instrument tray in the stored position prior to transportation to avoid a situation that could cause the system to tip.**

**Console might overbalance when it is pushed and its wheels are immobilized (blocked).**

**Route the footswitch cable, power cord and any other cables connected to the *Centurion*<sup>®</sup> Vision System to avoid tripping.**

### **WARNINGS!**

Appropriate use of *Centurion*<sup>®</sup> Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low bottle heights, high power settings, extended power usage, power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage.

Good clinical practice dictates testing for adequate irrigation, aspiration flow, reflux, and operation as applicable for each handpiece prior to entering eye.

Ensure that the tubings are not occluded during any phase of operation.

If the handpiece test chamber is collapsed after tuning, there is a potential of low irrigation flow through the handpiece and may result in a fluidic imbalance. This, in turn, may cause a shallowing or collapsing of the anterior chamber.

Avoid setting the patient above the FMS unless PEL is used. Operating with the patient above the FMS without PEL adjustment will result in a lower irrigation pressure than indicated on the display, and possible underventing.

Use of *BSS*<sup>®</sup> irrigating fluid bags other than those approved by Alcon for use in the active fluidics system can result in patient injury or system damage.

Use of appropriate technique and settings is important to minimize fragments and turbulence.

Do not remove the FMS during the surgical procedure.

In the event of a system error release footswitch to the up position.

Improper handling or removal of dual irrigation handpiece tip from eye may cause draining of the fluidics system.

### **CAUTIONS**

- **Modification of the equipment is NOT allowed without prior authorization from the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.**
- **Avoid spilling *BSS*<sup>®</sup> irrigating solution, or moisture of any kind, around the electrical handpiece connectors.**
- **Do not spray any liquid (i.e. cleaning solution or water) upward into the console vents.**
- **Do not push or pull the unit by the display, the tray, or the IV pole. Wrapping around the rear and sides of the system is a handle provided for moving the instrument. The unit should be pulled and not pushed, especially over elevator and door thresholds.**

## Handpiece Care

Phaco handpieces are surgical instruments and must be handled with care. The handpiece tip should not touch any solid object while in operation. Immediately following surgery the handpiece must be thoroughly cleaned. Be sure handpiece connector is completely dry before connecting it to console. For cleaning and sterilization procedures, see the Directions for Use (DFU) supplied with the handpiece.

### **WARNINGS!**

If in the medical opinion of the physician a patient with a prion related disease undergoes a high risk procedure, the instrument should be destroyed or be processed according to local requirements.

Use of a phaco handpiece in the absence of irrigation flow and/or in the presence of reduced or lost aspiration flow and/or sideways orientation of the *Kelman*® and *OZi*® 12 tips can cause excessive heating and potential thermal injury to adjacent eye tissues.

Appropriate use of *Centurion*® Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low bottle heights, high power settings, extended power usage, power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage.

Use of an ultrasonic handpiece other than an *OZi*® torsional handpiece, or use of a handpiece repaired without Alcon authorization, is not permitted, and may result in patient injury, including potential shock hazard to patient and/or operator.

The U/S tips supplied in the *Centurion*® Vision System pack are only to be used on an *OZi*® torsional handpiece. Each U/S tip is intended to be used only once per case, and then disposed of according to local governing ordinances.

Mismatching U/S tips and infusion sleeves may create potentially hazardous fluidic imbalances.

Directing energy toward non-lens material, such as iris or capsule, may cause mechanical and/or thermal tissue damage.

Perform visual inspection of accessories for burs or bent tips prior to use.

Use of appropriate technique and settings is important to minimize fragments and turbulence.



## CAUTIONS

**Never ultrasonically clean the phaco handpiece; irreparable damage may result.**

**Prior to sterilization, the phaco handpiece should always have the connector end cap secured and placed in the sterilization tray. This will prevent damage to the connectors and handpieces during handling, and especially during autoclaving.**

**The phaco handpiece and *INTREPID*<sup>®</sup> *AutoSert*<sup>®</sup> IOL Injector must be at room temperature just before use. Allow the handpiece to air cool for at least 15 minutes after autoclaving; never immerse the handpiece in liquid when hot.**

**Do not operate the phaco handpiece unless the tip is immersed in *BSS*<sup>®</sup> sterile irrigating solution or distilled water or is in surgical use. Irreparable damage to the handpiece and tip can result if run dry.**

**Ensure that test chamber is filled with *BSS*<sup>®</sup> sterile irrigating solution before tuning the phaco handpiece. Tuning a handpiece dry may result in premature tip failure and breakage.**

**Quenching a hot handpiece in water can cause damage and will void warranty.**

**Be sure handpiece is completely dry before connecting it to console. Damage to handpiece and console may result if plugged in when wet.**

### **Handpiece Tips**

Ensure that handpiece tip is fully tightened to the handpiece. If not securely attached, an error may be generated and/or inadequate tuning will occur. Ensure that the tip is not too tight so that it can be removed after use.

Use of a tool other than tip wrenches supplied by Alcon may cause damage to the tip and/or handpiece.

#### ***WARNING!***

**Poor clinical performance will result if tip is not secured tightly to the handpiece.**

**During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.**

## **Ultraflow® II (I/A) Handpiece**

Prior to each procedure inspect the two O-rings where the tip screws onto the *Ultraflow® II I/A* handpiece. If damaged or missing, replace the o-rings. If in doubt, contact Alcon's Technical Services Department.

### **WARNINGS!**

Use of non-Alcon surgical reusable or disposable I/A handpieces that do not meet Alcon surgical specifications, or use of an Alcon handpiece not specified for use with the *Centurion® Vision System*, may result in a fluidic imbalance. This, in turn, may cause a shallowing or collapsing of the anterior chamber.

Exceeding the recommended level of 100 mmHg (133 hPa) with a 0.5 mm or larger I/A tip may cause anterior chamber shallowing and/or incarceration or tearing of posterior capsule.

I/A tips are not to be used with a phaco handpiece.

## **Recommended Vacuum Range for I/A Tips**

It is important that only the proper size I/A tip be used when operating with maximum vacuum. Only 0.2 mm or 0.3 mm I/A tips should be used with vacuum limits above 100 mmHg (133 hPa). I/A adjustable vacuum range is 0 - 700 mmHg (0 - 933 hPa).

## **Centurion® Vitrectomy Probe**

The vitrectomy probe, a guillotine vitreous cutter, is intended for single use only.

Vitrectomy cutting performance may vary at high altitudes. Consult Alcon Technical Service for additional information.

### **WARNINGS!**

Do not test or operate vitrectomy probe unless tip of probe is immersed in *BSS®* sterile irrigating solution or distilled water or is in surgical use. Irreparable damage to the probe and tip can result if run dry.

Perform visual inspection of accessories for burs or bent tips prior to use.

Connect pneumatic tubing connectors from vitrectomy probe to console prior to initiating prime of probe. Initiating prime of the vitrectomy probe, or running the vitrectomy system, with one or both pneumatic connectors disconnected may cause the flow of non-sterile air over the sterile field for a brief moment.

Do not use vitrectomy probes that are not approved for use on *Centurion®* system.

After filling and testing, and before surgical use, verify that the probe is properly actuating and aspirating. This may require lowering cut rate to achieve good visualization. The port should always remain in open position in footpedal position 1. If cutting port is partially closed while in position 1, replace the probe. Prior to entry into the eye, and with tip of probe in sterile irrigating solution, the surgeon should step on the footpedal for visual verification that the probe is cutting:

- If the cutter is observed to not fully close, or does not move when the probe is actuated, replace the probe.
- If cutting port is partially closed while idle, replace the probe.
- If air bubbles are observed in the aspiration line or exiting the probe tip during priming, replace the probe.
- If a reduction of cutting capability or vacuum is observed during the surgical procedure, stop immediately and replace the probe.

## INTREPID® *AutoSert*® IOL Injector

### CAUTIONS

- Do not ultrasonically clean the *AutoSert*® IOL Injector connector. Ultrasonic cleaning will cause irreparable damage.
- Use care when handling *AutoSert*® IOL Injector, particularly when cleaning. Always clean handpiece over a surface cushioned with a pad or rubber mat.
- Be sure handpiece cable connector is dry before connecting it to the console.
- Do not disconnect cable connector from *Centurion*® system console until the IOL Injector plunger is fully retracted.
- Do not immerse the *AutoSert*® IOL Injector in any fluid when the plunger is not retracted.
- As part of a properly maintained surgical environment, it is recommended that a backup IOL injector be made available in the event the *AutoSert*® IOL injector handpiece does not perform as expected.

### **WARNINGS!**

- The *AutoSert*® IOL Injector is non-sterile and must be cleaned and sterilized prior to, and immediately after, each use.
- Never immerse the *AutoSert*® IOL Injector in liquid after autoclaving; allow it to air cool for at least 15 minutes. Quenching could result in a potentially hazardous condition for the patient.
- The *AutoSert*® IOL Injector delivery system is for the implantation of Alcon qualified *AcrySo*® foldable IOLs. Unqualified lenses shall not be used with the system. See DFU, or contact your Alcon representative, for qualified lens/cartridge combinations.
- The cartridge/IOL combination listed in the DFU, along with Alcon settings, has been validated per section 5 of BS EN ISO 11979-3:2006. Appropriate use of *AutoSert*® IOL Injector settings is important for successful IOL implantation. Inappropriate use of settings may lead to a potentially hazardous condition for the patient.

## Aspiration/Vacuum Adjustments

Adjusting aspiration rates or vacuum limits above the preset values may result in aspiration levels (volumes) exceeding irrigation inflow.

### **WARNING!**

**Adjusting aspiration rates or vacuum limits above the preset values, or lowering the IOP or IV pole below the preset values, may cause chamber shallowing or collapse which may result in patient injury.**

## Presurgical Check-out Tests

Presurgical check-out tests must be performed as outlined in the Operating Instructions section. If an Event message is displayed on the front panel, refer to the Troubleshooting section of this manual. If the problem persists, DO NOT PROCEED.

### **WARNINGS!**

When filling handpiece test chamber, if stream of fluid is weak or absent, good fluidics response will be jeopardized. Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye.

Ensure that tubings are not occluded or pinched during any phase of operation.

Perform visual inspection of accessories for burrs or bent tips prior to use.

## IV Pole

### **WARNINGS!**

Keep clear of the IV pole when it is in motion to prevent skin, hair, and/or clothing from being trapped in the IV pole mechanism. The IV pole moves during power on/off, priming, and bottle height adjustment.

IV pole rises automatically. To avoid stretching drip chamber tubing, and possibly pulling drip chamber out of bottle, tubing must hang freely with no interference.

When out of use, remove fluid bottle from IV pole and flip bottle hanger into its storage position to avoid injury.

Empirical numbers for bottle heights are not a replacement for competent surgical technique. The surgeon should visually and physically monitor intraocular pressure.

## Footswitch

If required, the footswitch may be wiped with alcohol, mild soap and water, or any germicidal solution that is compatible with the plastic parts.

### **WARNING!**

Route the footswitch cable properly to avoid tripping.

### **CAUTIONS**

Do not clean the footswitch using solvents, abrasives, or any cleaner that is not compatible with plastic parts made of GE Cycloy CU 6800 and LEXAN 920A. Damage may result.

Never pick up or move the footswitch by the cable. Dropping or kicking the footswitch can cause irreparable damage.

## Occlusion Tones

Two different occlusion tones (intermittent beeping tones during occlusion) indicate that the vacuum is near or at its preset limit, and aspiration flow is reduced or stopped to avoid exceeding the limit. The first type, the I/A occlusion tone, sounds when occlusion occurs during aspiration only (in the absence of ultrasonic power). The I/A occlusion tone is a lower, intermittent single beep. The second type of occlusion tone, the phaco occlusion tone, is a higher, intermittent double beep, and sounds when occlusion occurs during application of ultrasonic power.

The I/A occlusion and phaco occlusion tones indicate that the vacuum has reached its maximum allowed preset value. The I/A occlusion tone can be turned off, while the phaco occlusion tone cannot be turned off.

### **WARNINGS!**

**The phaco occlusion bell indicates no aspiration flow. Use of high U/S settings and/or prolonged use may lead to thermal injury.**

**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 thermal injury to adjacent eye tissues.**

**In the event of a persistent loss of aspiration during the application of U/S power, remove U/S power via footswitch control.**

## Vacuum Tone

A vacuum tone is provided. The pitch will vary relative to the amount of vacuum. A high vacuum can indicate that little to no flow is occurring. This tone can be reduced in volume, but not turned off.

### **WARNINGS!**

**A moderate to high vacuum tone may indicate little to no flow is occurring. 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 thermal injury to adjacent eye tissues.**

**Do not exceed maximum capacity of drain bag (500 ml). Excessive pressure can result from exceeding drain bag maximum capacity and potentially result in a hazardous condition for the patient.**

**In the event of a persistent loss of aspiration during the application of U/S power, remove U/S power via footswitch control.**

## Cautery, Diathermy, Coagulation Definition

The *Centurion*<sup>®</sup> Vision System uses the word “Coagulation” in place of Cautery or Diathermy, based on the following definition:

Coagulation - Isolated, bipolar, high frequency current supplied to conductors (e.g. forceps). Current passes between these electrodes, halting bleeding. (Abbreviated “Coag” in some of the text of this operator’s manual.)

## Coagulation Function

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

- To ensure safe operation of the coagulation function, only approved cables and accessories must be used (See your Alcon representative). Coagulation 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.
- Operation of the coagulation step is limited to extraocular uses only.
- The lowest power level in coagulation 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<sub>2</sub>O) 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.
- Accessories should have a rated voltage equal to or greater than the maximum coagulation output voltage.

### **WARNINGS!**

**Do not use the coagulation 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 (coagulation circuitry) could result in an unintended increase of output power.**

## VideOverlay System

### ***WARNINGS!***

**Do not remove VideOverlay cover; there are no user-serviceable parts inside. Refer servicing to qualified service personnel.**

**Do not simultaneously touch the VideOverlay enclosure and the patient.**

### **CAUTIONS**

- **Do not use multiple portable socket outlets with this system.**
- **Use only the Alcon-supplied serial cable to connect the *Centurion*<sup>®</sup> Vision System to the VideOverlay System.**

## Consumable Packs

Consumable items used with the *Centurion*<sup>®</sup> Vision System during surgery are designed to be used once and then discarded, unless labeled otherwise.

All *Centurion*<sup>®</sup> packs contain Directions for Use (DFU). It is important to read and understand the DFU's prior to use.

In all cases, the instrument setup instructions contained in the manual should be thoroughly understood prior to using any of the pack configurations.

**NOTE: If an inconsistency exists between the instructions in the operator's manual and the Directions For Use (DFU) supplied with a consumable pack or accessory, follow the DFU.**

### **WARNINGS!**

Mismatch of consumable components and use of settings not specially adjusted for a particular combination of consumable components may create a patient hazard.

Do not use packs that have exceeded the expiration date.

Sterile disposable medical devices should not be reused! These components have been designed for one time use only; do not reuse.

Potential risk from reuse or reprocessing the following products labeled for single use include:

- *Bipolar Coagulation Instruments* - Thermal injury or electrical shock caused by a damaged bipolar instrument, and foreign particle introduction into the eye.
- *Fluid Management Components* - Fluid path leaks or obstruction resulting in reduced fluidics performance, and foreign particle introduction into the eye.
- *Phacoemulsification Tips* - Reduced tip cutting performance, presence of tip burrs, fluid path obstruction, and foreign particle introduction into the eye.
- *Vitreous Cutting Instruments* - Reduced vitreous cutting performance, fluid path obstruction, and foreign particle introduction into the eye.

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

Perform visual inspection of accessories for burs or bent tips prior to use.

Do not remove the FMS during the procedure.

Do not use any Vitrectomy probes that have not been approved for use on the *Centurion*<sup>®</sup> Vision System.



## 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 a minimum of one time per year. Additional preventive maintenance may be required based upon system use. 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, leakage current, and dielectric withstand voltage must be checked to appropriate national standard.

To avoid unnecessary shipping, please contact your Alcon Technical Services Department prior to 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 Technical Services Department  
15800 Alton Parkway  
Irvine, California 92618-3818  
(800) 832-7827, or (949) 753-1393

## LIMITED WARRANTY

Alcon will repair or replace at its option, any system or accompanying accessories 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 shall not be obligated to provide services under this warranty for damage to or destruction of systems covered where such damage or destruction is 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 or an earthquake.

This warranty does not cover damage resulting from service repair or other alteration by any person other than an Alcon-authorized service person, and any warranties provided by Alcon with respect to this equipment shall become void and of no further force and effect if this equipment is serviced by anyone other than Alcon-authorized service personnel. In particular, Alcon shall have no obligation to replace, repair or credit customer's account for the cost of the equipment, which has been subject to service or other alteration by persons other than Alcon-authorized service personnel.

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, expressed or implied – including, without limitation, warranties 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 consumable products used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of consumable products and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards. If it is determined that consumable products 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.**

	Type BF equipment, providing both the attributes of basic insulation and "floated" isolation.		Eject FMS
	Follow Instructions for Use (white figure on blue background)		Lamp to illuminate instrument tray
	WARNING: The console might overbalance when it is pushed and its wheels are immobilized (blocked) (black symbol behind lined out red circle)		Connector for CENTURION® OZi® handpiece
	WARNING: Dangerous Voltage (black symbols on yellow background)		Connector for INFINITI® OZi® handpiece
	GENERAL WARNING (black symbols on yellow background)		Connector for INTREPID® AutoSert® IOL Injector
	Equipotential ground connection		Connector for Vitrectomy probe tubing
	AC Voltage		Connector for Autocapsulorhexis handpiece
	Power stand-by state for a part of equipment		Connector for Coagulation handpiece
	ON (POWER)		Connector for Cabled Footswitch
	OFF (POWER)		Magnetic Resonance Unsafe
	Fuse Size, Type, and Rating T10.0AH/250V		Non-ionizing electromagnetic radiation
	Use appropriate take-back system (see Environmental Considerations in this manual) Pb notation, if present, indicates lead content greater than 0.004%.		Date of Manufacture
	Pb		Manufacturer
	Catalog Number		OSHA recognized NRTL, TUV SUD America mark, providing electrical safety certification to North American requirements for Medical Devices.
	Serial Number		

**Figure 1-2 ICONS USED WITH CENTURION® VISION SYSTEM - Icons identifying modes, functions, etc., that are used with the Centurion® Vision System are identified in this chart. The icons shown on this page are for reference only.**

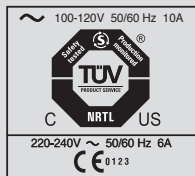


**DANGER:** RISK OF EXPLOSION IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

**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.



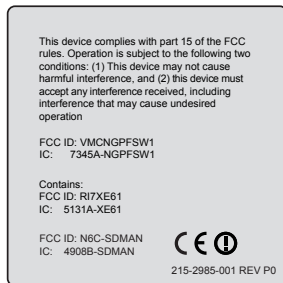
OUTPUT	DIATHERMY
POWER (W)	10
IMPEDANCE (Ω)	75
FREQUENCY (MHz)	1.5



For applicable patents, please see the ABOUT screen on the monitor during operation.  
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Label printed on rear panel of *Centurion<sup>®</sup>* Vision System



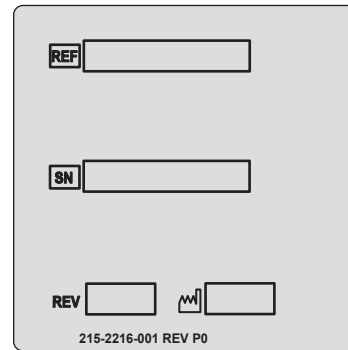
Label located on rear panel of *Centurion<sup>®</sup>* Vision System



**WARNING:** FOR CONTINUED PROTECTION AGAINST RISK OF FIRE, REPLACE ONLY WITH SAME TYPE AND RATING OF FUSE.



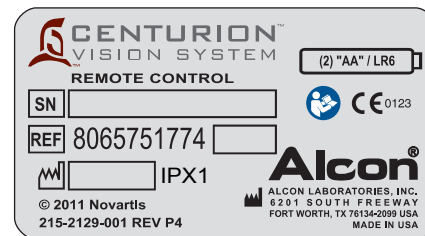
Label printed on power input module



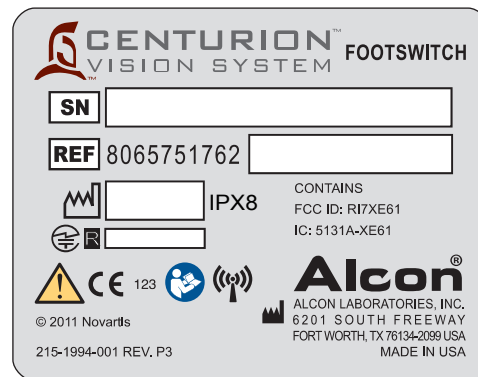
Label located on rear panel of *Centurion<sup>®</sup>* Vision System



Label located on instrument tray



Label located on back of remote control



Label located on bottom of footswitch

**Figure 1-3 LABELING ON *CENTURION<sup>®</sup>* VISION SYSTEM - Labels used on the *Centurion<sup>®</sup>* Vision System are illustrated here. The labels on this page are intended for reference only.**

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