UNFINITION SYSTEM Operator's Manual

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September 200	09 R	20091528 - Add note on text cover sheet to inspect per generic QIP manual.

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PREFACE

This operator's manual is your written guide to the *Infiniti®* 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 pak 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 Laboratories, Inc. 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 *Infiniti*® Vision System is an ophthalmic surgical instrument designed to be reliable, safe, and easy to operate. The *Infiniti*® Vision System provides four modes for cataract lens extraction using *AquaLase*®, *OZil*® torsional, *NeoSoniX*®, and high performance U/S handpieces. This instrument has been developed to be user friendly, combining hardware

that is easy to install and maintain along with software that increases the effectivity of the user.

The Infiniti® Vision System is intended for use in small incision cataract lens extraction 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® or BSS®Plus irrigation solution. The system controls include a footswitch to enable the surgeon to control irrigation flow, aspiration rate, phaco power, vitrectomy cut rate, and coagulation power.

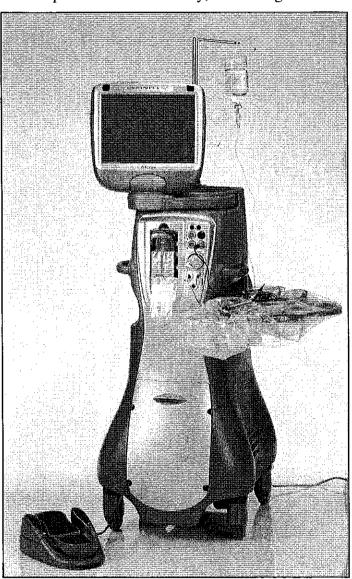


Figure 1-1 The Infiniti® Vision System

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GENERAL INFORMATION

The *Infiniti*® Vision System is designed for use in anterior segment procedures that require simultaneous cataract lens extraction, irrigation, and aspiration, as well as associated procedures such as vitrectomy and coagulation. It was developed with a dual purpose: to make it simple to operate, and to allow the surgeon tremendous versatility and control. The system is designed to allow the surgeon to customize the treatment of every patient.

Following are key features of the *Infiniti®* Vision System:

- Customized cataract lens removal options:
 - *OZil*[®] torsional handpiece with ultrasonic torsional oscillations which can be used exclusively or alternated with traditional phaco.
 - AquaLase® liquefaction device handpiece, technology, and accessories.
 - *Infiniti*[®] *NeoSoniX*[®] handpiece combining the features of a phaco handpiece with sonic oscillations.
 - High performance *Infiniti*® U/S handpiece: 40 kHz, piezoelectric, slim, lightweight, autoclavable.
- Advanced fluidics with quick, smooth control of peristaltic aspiration.
- Fully programmable, multi-microprocessor control.
- Modularized fluidic connections achieved with the disposable Fluidic Management System (FMS).
- Emulation of venturi-like fluidic performance.
- Ability to drive a high performance *Infiniti*® vitrectomy guillotine cutter.
- Bipolar coagulation capability.
- Several traditional modalities of ultrasonic power control including continuous, pulsed, and "burst" application of ultrasonic power, as well as duty cycle management.
- Automated IV pole, controlled via the front panel, footswitch, or remote control.
- Linear footswitch control of ultrasonic power in U/S steps (sophisticated control loop offers low-end control).
- Linear footswitch control of aspiration flow rate (AFR) in I/A, VIT, and lens removal modes.
- Linear footswitch control of vacuum in I/A, VIT, and lens removal modes.
- On-demand continuous irrigation.
- Programmable, pressurized reflux via the footswitch.
- Ability to set vacuum levels and aspiration flow rates to desired levels in phaco, I/A, and VIT steps.
- Ability to switch between surgical steps using touch screen, remote, or footpedal.
- Emission of variable tones for confirmation of system operational status.
- Voice confirmation during surgical step or mode changes.
- Flat screen, active matrix color LCD with touch screen display that is tiltable and rotatable.
- High-tech graphical user interface.
- Multi-channel wireless remote control.

Abbreviation Descriptions

Many of the abbreviations used in this manual and on the *Infiniti*® Vision System are described in Table 1-5. Icons are identified in Figure 1-2.

Accessory Equipment

Accessory equipment connected to or used with this equipment must be certified according to the respective IEC Standard (e.g., IEC 950 for data processing equipment, and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with System Standard IEC 60601-1-1. 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.

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

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 takeback 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 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 1-1 Guidance and Manufacturer's Declaration - Electromagnetic Emissions - The *Infiniti*® Vision System is intended for use in the electromagnetic environment specified below. The customer or the user of the *Infiniti*® 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 Infinitt® Vision 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 <i>Infiniti</i> ® Vision System is suitable for use in all establishments including domestic and those directly connected to the public low voltage power supply network that supplies buildings
Harmonic emissions IEC 61000-3-2	Class A	used for domestic purposes. The EMC Statement provides guidance on steps to take in case of
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	electromagnetic interference.

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

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 system 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 premature shutdown due to fast transients avoid powering the <i>Infinitt</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 commercial or hospital environment.		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	$ \begin{array}{lll} \bullet & <5\% \ \ U_{_T} \ (>95\% \ \ \ \ \ \ \) \\ U_{_T}) \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	• <5% U_{τ} (>95% dip in U_{τ}) for 0.5 cycle • 40% U_{τ} (60% dip in U_{τ}) for 5 cycles • 70% U_{τ} (30% dip in U_{τ}) for 25 cycles • <5% U_{τ} (>95% dip in U_{τ}) for 5 sec	commercial or hospital environment. If the use of the <i>Infiniti</i> ® Vision System requires continued operation during power mains interruptions, it is recommended that the <i>Infiniti</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 commercial or hospital 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>Infiniti</i> Vision System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency to the transmitter.		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	Recommended separation distance: d = 1.2√P d = 1.2√P 80 MHz to 800 MHz d = 2.3√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 ^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: \mathbf{U}_{τ} 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.

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

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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 Infiniti® Vision System.

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 Infiniti® Vision System - The Infiniti® Vision System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Infiniti® Vision System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Infiniti® Vision System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter (m)			
power of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 2.3√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.

WARNINGS AND CAUTIONS

Most 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 *Infiniti*® Vision System console or footswitch. Refer all service issues to your factory-trained Alcon service engineer.

WARNINGS!

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

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.

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.

Inadvertent pressing of Standby switch when system is active will cause unit to shut down.

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. Operating with the patient above the FMS will result in a lower irrigation pressure than indicated on the display, and possible underventing.

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

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.

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

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 for leakage current every twelve months to ensure they are within the applicable standards (for example: EN60601-1/IEC601-1). Values must be recorded, and if they are above the applicable standards, or 50% above initial measurement, do not use the system; call Alcon Technical Services.

WARNINGS!

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.

Handpiece Care

The *Infiniti® AquaLase®*, *OZil®* torsional, *NeoSoniX®*, and high performance U/S 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.

WARNING!

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.

The *Infiniti® NeoSoniX®*, *OZil®* torsional, and U/S handpieces must be at room temperature just before use. Allow the handpiece to <u>air cool</u> for at least 15 minutes after autoclaving; never immerse the handpiece in liquid when hot.

CAUTIONS

Never ultrasonically clean the *Infiniti*® *AquaLase*®, *OZil*® torsional, *NeoSoniX*®, or U/S handpieces; irreparable damage may result.

Prior to sterilization, the *Infiniti® AquaLase®*, *OZil®* torsional, *NeoSoniX®*, and U/S handpieces 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.

Do not operate $OZit^{\oplus}$ torsional, $NeoSoniX^{\oplus}$, or U/S handpieces unless the tip is immersed in BSS^{\oplus} 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 $BSS^{@}$ sterile irrigating solution before tuning $OZil^{@}$ torsional, $NeoSoniX^{@}$, or U/S handpieces. 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.

WARNINGS!

Use of the *OZil*® torsional, *Infiniti*® *NeoSoniX*®, U/S, or *AquaLase*® 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.

Appropriate use of *Infiniti*® 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 the *OZil*® torsional, *Infinitl*® *NeoSoniX*®, or U/S 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 *Infiniti*® Vision System pak are only to be used on the *OZif*® torsional, *Infiniti*® *NeoSoniX*®, or U/S handpieces. Each U/S tip is intended to be used only once per case, and then disposed of according to local governing ordinances.

Use 0.9 mm U/S tips exclusively with 0.9 mm infusion sleeves. Use 1.1 mm U/S and 1.1 mm liquefaction tips exclusively with 1.1 mm infusion sleeves. Mismatching U/S tips and infusion sleeves may create potentially hazardous fluidic imbalances.

Directing energy toward non-lens material may cause tissue damage.

IV Pole and Extender

WARNINGS!

Once the IV pole extender is installed, the upper hook is to be used. Do not change bottle height by manually hanging the bottle on the lower hook. Manually lowering the IV bottle to the lower hook will introduce an error in the displayed height indication and negatively impact the performance of the Infusion Pressure Drop detection feature, causing false indications at low bottle levels.

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

Ultraflow™* (I/A) Handpiece

Prior to each procedure inspect the two O-rings where the tip screws onto the *Ultraflow*TM * 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 *Infiniti*® 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 with a 0.5 mm or larger I/A tip may cause anterior chamber shallowing and/or incarceration or tearing of the posterior capsule.

I/A tips are not to be used with NeoSoniX®, OZiI® torsional, or U/S handpieces.

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.

I/A adjustable vacuum range is 0-650+.

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.

Check for the presence and correct position of the polymer tubing on the *Mackool*** tips. Never attempt to remove the tubing. Use of the *Mackool*** tips without polymer tubing may result in a hazardous condition for the patient.

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Infiniti® Vitrectomy Probe

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

WARNINGS!

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

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; alternatively, press the Test button on the Vitrectomy Setup Screen: 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.

Aspiration/Vacuum Adjustments

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

Dynamic Rise values of 1, 2, 3, or 4 will achieve vacuum in shorter periods of time. Care must be taken not to engage non-lens material.

WARNING!

Adjusting aspiration rates or vacuum limits above the preset values, or lowering the 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 error message or advisory 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.

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Footswitch

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

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

CAUTION

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

High Altitudes

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

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 or *AquaLase*® system magnitude). 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 or *AquaLase*® system magnitude.

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 NeoSoniX®, OZil® torsional, U/S, or AquaLase® 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.

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 occuring. 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 occuring. Use of the NeoSoniX®, OZiI® torsional, U/S, or AquaLase® 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.

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 Alconendorsed 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 (N₂O) 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.

Coagulation Function (from prior page)

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.

CAUTION

The *Infiniti*® Vision System is not protected against the effects of defibrillator discharge.

Cautery, Diathermy, Coagulation Definition

The *Infiniti*® 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.)

Infiniti® VideOverlay System (IVO)

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 *Infiniti®* Vision System to the IVO.

Consumable Paks

Consumable items used with the *Infiniti*[®] Vision System during surgery are designed to be used once and then discarded, unless labeled otherwise.

All *Infiniti*® paks contain Directions for Use (DFU). It is important to read and understand the DFU's prior to use.

NOTE: If an inconsistency exists between the instructions in the operator's manual and the Directions For Use (DFU) supplied with a consumable pak 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 paks 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.

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.

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

Read all package label material printed on the consumable paks prior to their use.

Miscellaneous

CAUTIONS

- Do not use the Infiniti® Vision System near flammable anesthetics.
- Avoid spilling BSS® solution, or moisture of any kind, around the electrical handpiece connectors.
- Do not push or pull the unit by the display, the tray, or the IV pole. Handles located at the rear and sides of the unit are provided for moving the instrument. The unit should be pulled and not pushed, especially over elevator and door thresholds.
- Do not place more than a 20 lb. load on tray support.
- The USB connector (•••) and *Infiniti*® port (•••) located on the rear panel are for use by Alcon trained personnel only. Failure to comply will void warranty.

WARNING!

Tray support must be set in its stored position when moving instrument.

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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.

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CONSOLE			PERFORMANCE SPECIFIC	CATIONS
DIMENSIONS	Height: Width: Depth:	160 cm (63 inches) 58.5 cm (23 inches) 76 cm (30 inches)	PHACOEMULSIFICATION Submodes: Tip Stroke @ 100%: Resonant Frequency:	Continuous, Pulse, Burst 88.9 ±27.0 um (.0035 ±.0005 in.) 38.0 ±1.9 KHz
WEIGHT	Unpacked: Packed:	107 kg (235 pounds) 150 kg (330 pounds)	Pulse Rate Range: Burst Length:	0-100 pps 5 to 500 mS
ENVIRONMENTAL			OZiji TORSIONAL HANDPIECE	<u>:</u>
LIMITATIONS	Operating	Non-Operating	Longitudinal Frequency: Torsional Frequency:	44.0 ±2.0 KHz 32.0 ±2.0 KHz
Altitude:	2438 meters (8,000 feet)	12,191 meters (40,000 feet)	Pulse Rate Range: Burst Length:	1-100 pps 20 to 500 mS
Temperature:	10° C to 35° C (50° F to 95° F)	-40° C to 60° C (-40° F to 140° F)	AquaLase [®] LIQUEFACTION DE Pulse Rate Range: Burst Time On:	VICE 10-75 pps 7-100 %
Relative Humidity:	10% to 95% without condensation	10% to 95% without condensation	ANTERIOR VITRECTOMY Submodes: 20 ga <i>Infiniti</i> ® Vit Probe:	Cut I/A, I/A Cut 10 to 800 cpm
ELECTRICAL REQUI) - 120 VAC, 50/60 Hz) - 240 VAC, 50/60 Hz	23 ga <i>Infiniti</i> ® <i>UltraVit</i> ® Probe	: 10 to 2500 cpm
REMOTE CONTROL	Method: Channels: Batteries:	Infrared 4 AAA (3)	COAGULATION 10 Watts max., 75 ohm load 76 Vpp @ 1.5 MHz ±5%, 75 of the common second	
MAXIMUM INPUT CU PROTECTION AGAIN CLASSIFICATION OF DATA CARD: MMC (M	ST ELECTRIC SHO ALL APPLIED PAR		VACUUM @ SEA LEVEL Phacoemulsification: Vitrectomy: Irrigation/Aspiration:	0 to 650 mmHg 0 to 650 mmHg 0 to 650 mmHg
			POWER IV POLE Height Range; With Alcon IV Pole Extender	13 to 110 cm 45 to 142 cm

Table 1-4 SPECIFICATIONS - This table is a quick reference point to identify basic system specifications, system requirements, and performance figures.

Abbreviat	ion Description	Abbreviat	ion Description
Abbreviat A AC AqL Asp BF C cc/min Coag CPM DFU ESD F FMS FTSW HIS HP	Amperes Alternating Current AquaLase® Aspiration Body Floating Centigrade Cubic centimeters per minute Coagulation Cuts Per Minute Directions for Use Electro Static Discharge Fahrenheit Fluidic Management System Footswitch High Infusion Sleeve Handpiece	IPX8 IRR IT IVO MMC	International protection code - solid objects X (not specified), water 8 (continuous immersion) Irrigation Interchangeable Tip Infiniti® VideOverlay MultiMedia Card Millimeters of Mercury Patient Eye Level Pulses Per Second
Hz I/A IEC	Hertz Irrigation/Aspiration International Electrotechnical Commission	Vac Vit	Vacuum Vitrectomy
	The Francisco Lieute Commission		

Table 1-5 ABBREVIATIONS USED WITH THE INFINITI® VISION SYSTEM

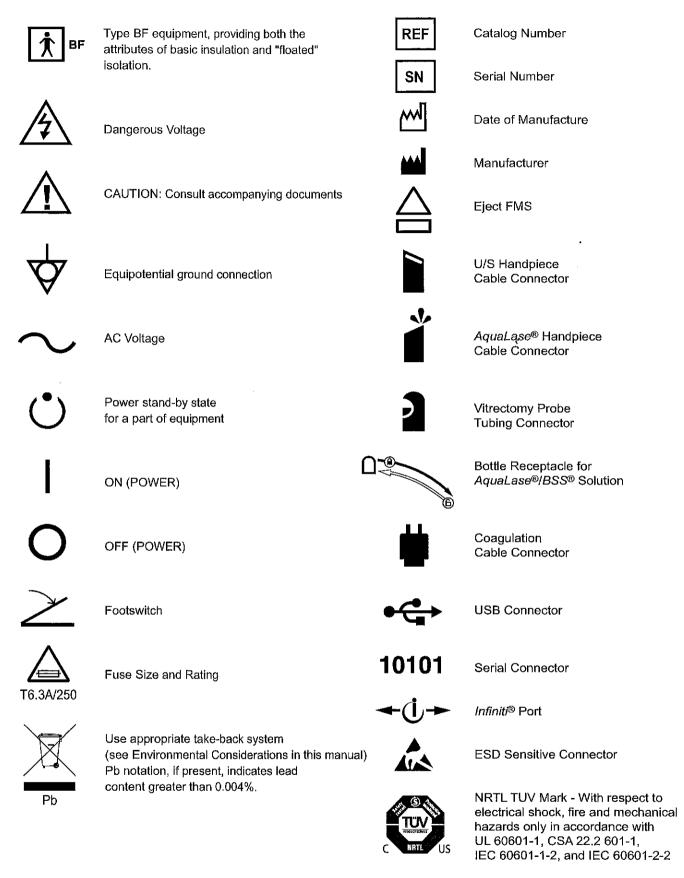
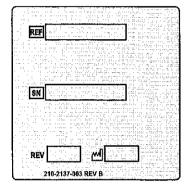
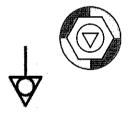


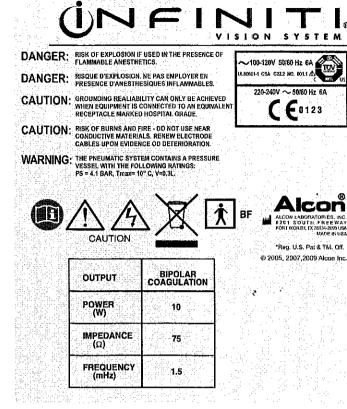
Figure 1-2 ICONS USED WITH THE INFINITI® VISION SYSTEM - Icons identifying modes, functions, etc., that are used with the Infiniti® Vision System are identified in this chart.



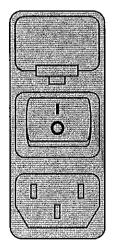








FOR APPLICABLE PATENTS, PLEASE SEE THE "ABOUT" SCREEN ON THE MONITOR DURING OPERATION.





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

Figure 1-3 LABELING ON *INFINITI*® VISION SYSTEM - Labels used on the *Infiniti*® Vision System are illustrated here. The labels on this page are intended for reference only.

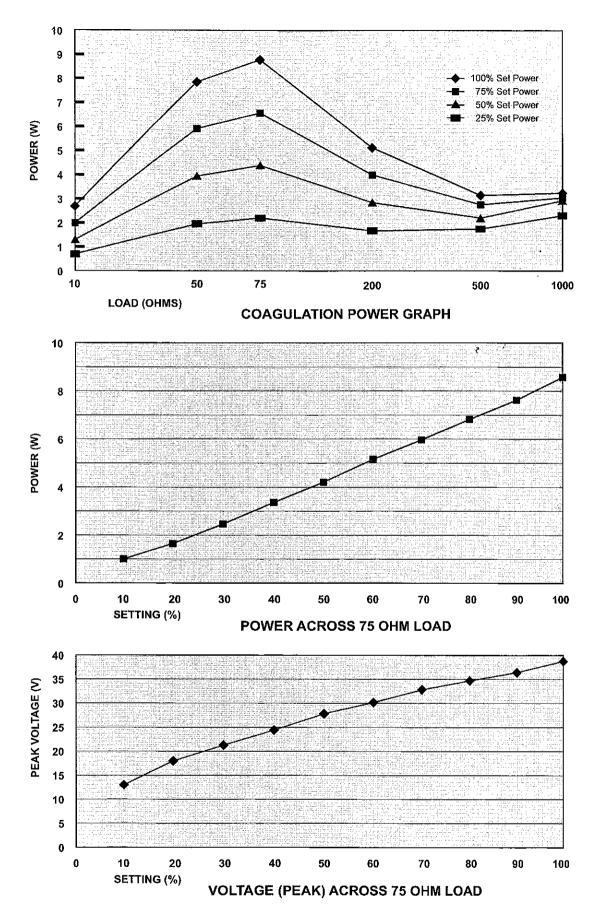


Figure 1-4 COAGULATION POWER OUTPUTS - Set coagulation power at the intended output control setting in the intended operating mode in reference to figures above.

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SECTION TWO DESCRIPTION

INTRODUCTION

Alcon's *Infiniti*® Vision System is a multi microprocessor-controlled ophthalmic surgical instrument with associated memory and input/output (I/O) circuitry. The system communicates to the user via its Front Panel display, with voice confirmations, and with tones. An automatic self-test is initiated each time system power is turned on.

This test performs a variety of functions including the following:

- Tests the Central Processing Unit (CPU)
- Tests the RAM and ROM memory, and the I/O circuits
- Initializes the system

When the system successfully completes the self-test, it automatically goes into the Setup mode. If the system fails the self-test, an error message is displayed.

This section of the manual is broken into two major parts. The first part describes the console and its accessories. All the parts of the system will be described, including the display panel, IV pole, connectors, fluidic interface, footswitch, remote control, and VideOverlay system. The second part of this section describes the operator interface. This is where the display screens for system setup, surgery, programming, and dialogs are shown.

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INFINITI® VISION SYSTEM CONSOLE AND ACCESSORIES

CONSOLE

Fluidics Module

The fluidics module is located at the top of the front panel. The module allows fast and easy insertion of the Fluidic Management System (FMS), and because the module contains all the connections required, surgery can be started without delay.

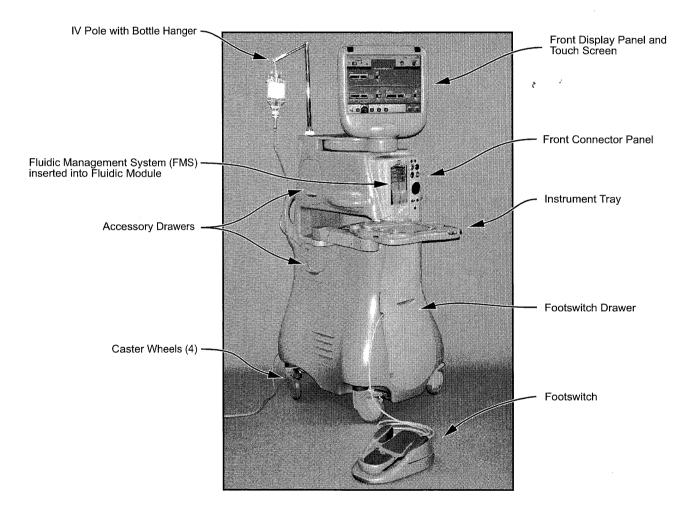


Figure 2-1 The Console - The console contains all the controls, connectors, and communication devices required by the surgeon to perform cataract lens extraction surgery.

Front Display Panel and Touch Screen

The front display panel tilts and rotates, allowing easy maneuverability during setup and surgery. For storage and transport the front panel folds down. The front display is the user's main source of system control, allowing fingertip command of system functions.

Front Connector Panel

The connector panel is located to the right of the fluidics module. It provides two self-locking U/S handpiece connectors, one *AquaLase*® handpiece connector, two connectors for bipolar coagulation handpieces, an *AquaLase*®/balanced salt solution bottle receptacle, and two luer lock pneumatic connectors for an anterior vitrectomy probe. Symbols near the connectors facilitate handpiece identification.

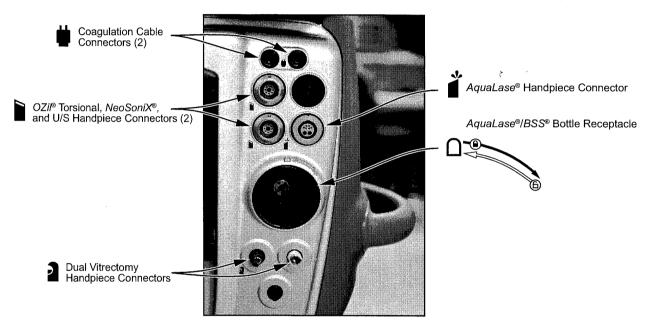


Figure 2-2 The Front Connector Panel - The front connector panel allow quick and easy connection of handpieces and consumables.

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Footswitch Drawer

The footswitch drawer is at the bottom of the front panel. When not in use, this drawer is used to store and protect the footswitch. The enhanced *Infiniti*® footswitch, identified by its ribbed rubber footpedal surface and two small holes in its heel, requires that a plastic insert be placed in the bottom of the drawer. This allows easy insertion and removal of the enhanced footswitch. If the *Accurus*®/*Legacy*® footswitch is used, remove plastic insert from bottom of drawer.

Two footswitch cable connectors are located behind this drawer. The left connector is for the *Infiniti*[®] and enhanced *Infiniti*[®] footswitch; the right for *Accurus*[®]/*Legacy*[®] footswitch. The footswitch cord is also stored in, and exits from, the drawer.

Instrument Tray

Provides a movable instrument tray within the sterile field. There is a curved metal rod on the tray arm that allows for creation of a sterile pouch when used with sterile tray support cover. The tray is capable of accommodating a variety of positions in the operating room environment: right, left, front and rear of the surgeon as well as the front of the bed. The tray is height adjustable.

IV Pole with Bottle Hanger

A bottle of BSS® or BSS Plus® irrigating fluid is hung from the hook on top of this pole. The IV pole is used to raise and lower the bottle height, causing irrigation pressure to increase or decrease.

Accessory Drawers

Two drawers allow storage of miscellaneous accessories.

Caster Wheels

Four large caster wheels support the *Infiniti*® Vision System. The wheels rotate 360° for ease of system mobility, and two wheels have a locking lever to secure the system in place. The wheels should always be locked when the unit is in use, and unlocked when being moved.

Handles

Handles are located on the sides and back of the instrument, and should always be used to move the unit. For greater safety and control, the unit should be pulled, not pushed.

CAUTION

The system must be moved carefully, otherwise the system could tip over and become damaged. Do not push or pull the unit by the display, the tray, or the IV pole. Handles located at the rear and sides of the unit are provided for moving the instrument. The unit should be pulled and not pushed, especially over elevator and door thresholds.

2.4

REAR PANEL

Power Module

The power module contains an AC power connector, AC power switch, and a fuse drawer. The power module is located at the bottom of the rear panel. A standby power switch is located at the top of the rear panel.

- AC Power Connector Power cord from AC power outlet connects here. A hospital grade power cord must be used.
- Main Power Switch Connects AC power to power supply.
- Fuse Drawer Holds fuse. Refer to label on back of system to identify size and type.

Equipotential Ground Connector

For Service personnel use.

Cord Wrap

Used to store the power supply cord. Located on the right side of the rear panel.

Connectors and CD/DVD Drive

This module, located in the middle of the rear panel, contains various connectors and outlets used for electrical interconnections. A CD/DVD drive, located next to the connectors, is used for software upgrades to the system.

- **USB** Connector Not used.
- 10101 Serial Connector Used for VideOverlay.
- **4** Infiniti® Port Not used.

CAUTION

The USBconnector (• and Infiniti® port (• •) located on the rear panel are for use by Alcon trained personnel only. Failure to comply will void warranty.

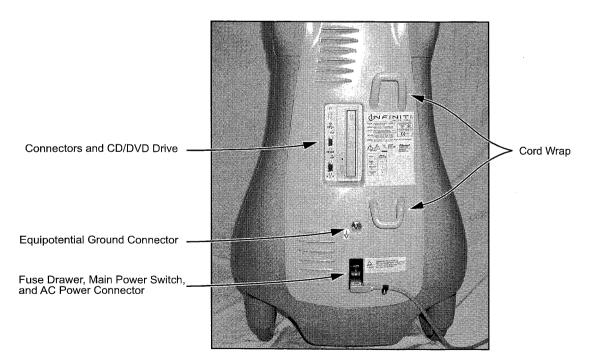


Figure 2-3 The Rear Panel - The rear panel contains the power module, electrical connectors, CD/DVD drive, cord wrap, and standby power switch (shown on next page).

Data Card Slot

A data card (e.g., Multi Media Card (MMC)) can be inserted into this data card slot when the user wants to back up or restore system settings. This is done by using the Copy/Delete option from the *Custom* drop list. The Copy/Delete dialog allows the user to copy data from the *Infiniti*® Vision System to a data card (backup), or copy data from a data card to the *Infiniti*® Vision System (restore).

Standby Power Switch

This pushbutton switch is used to turn secondary power ON and OFF. If system freezes and is unresponsive to operator commands, press Standby switch for five seconds to shut down system, then re-boot.

WARNING!

Inadvertent pressing of Standby switch when system is active will cause unit to shut down.

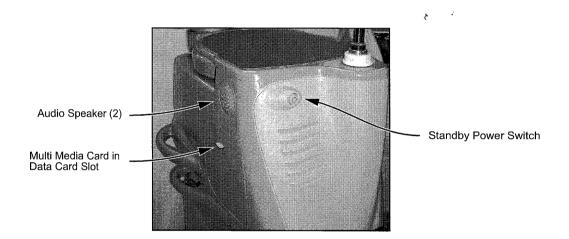


Figure 2-4 The Right Side Panel - The right side panel contains the data card slot and one-of-two audio speakers. The left side panel has the other speaker and two accessory drawers.

Audio Speaker

The audio speakers are located on each side of the console. These speakers produce voice confirmations, in conjunction with multiple tones, to allow the *Infiniti®* Vision System to communicate with the user. Audible tones are generated to indicate a change in the operating mode and to alert the operator of certain conditions such as an occluded line. Additionally, a varied pitch tone is generated to audibly indicate vacuum levels; the pitch increases as the vacuum level increases. Speaker volumes are adjustable via the *Custom* menus.

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FOOTSWITCH

The *Infiniti*® Vision System can utilize two different Alcon footswitches. The *Infiniti*® footswitch has a footpedal, on/off toe switches (horizontal and vertical), and on/off footpedal swivel switches. The *Accurus*®/*Legacy*® footswitch contains heel switches rather than a swivel footpedal.

The footswitch icon button on the display screen is a graphical representation of the footswitch connected. When connected, the icon's footpedal position (0, 1, 2, or 3) is displayed in the center of the icon, and a triangular arrow appears next to the icon each time a switch is activated. If a footswitch is not connected, no footpedal position is displayed in the icon.

Several functions within the system's operating modes are controlled by the surgeon using the footswitch. The footpedal enables the surgeon to control irrigation flow, aspiration rate; $OZil^{\circledast}$, $NeoSoniX^{\circledast}$, or U/S system power; $AquaLase^{\circledast}$ system energy, vitrectomy cutting, and coagulation power. The switches are used to turn functions on/off, to adjust function settings, and to progress through surgical steps.

The footswitch actions are shown in Figure 2-8. Footpedal positions are shown in Figure 2-7, and footpedal positions/functions in each mode of operation are listed in Table 2-1. To program the footswitch, see the *Custom* feature later on in this section of the operator's manual.

CAUTION

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

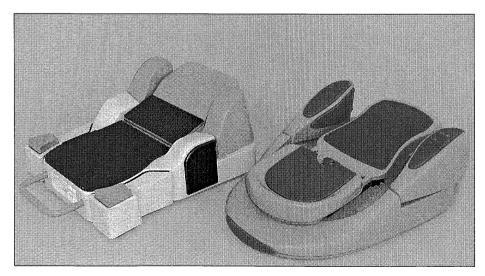


Figure 2-5 The Accurus®/Legacy® and Infiniti® Footswitches

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Plugging in the Footswitch

The footswitch plugs into one-of-two connectors behind the footswitch drawer. One connector is for the *Infiniti*[®] footswitch; the other is for the *Accurus*[®]/*Legacy*[®] footswitch. To plug in the footswitch follow the directions below.

- 1. Open the footswitch drawer.
- 2. Simultaneously press a metal drawer extension latch on each of two hinges to release the drawer and allow access to the footswitch cable connectors.
- 3. Grasping the footswitch cable connector, plug the cable into one of the two connectors. The red dot on the cable connector must be in alignment with the red dot on the console connector, and when the connector is in the correct position it will slide in smoothly.

NOTE: Only one footswitch connector is intended to be used at a time. If both connectors are used at the same time, only the *Infiniti*® footswitch connector is functional.

- 4. A cable restraint is located on the back of the drawer. Loosen'the two screws securing the cable restraint and place the cable through its center. Replace the cable restraint over the cable and secure it with the two screws. Ensure that a slight amount of excess cable exists between the connector and the restraint.
- 5. Loop the cable through the slot in the back of the drawer, then route it through the left or right slot of the cable management system in the front of the drawer. There are high and low slots on each side of the drawer.
- 6. Shut the footswitch drawer.

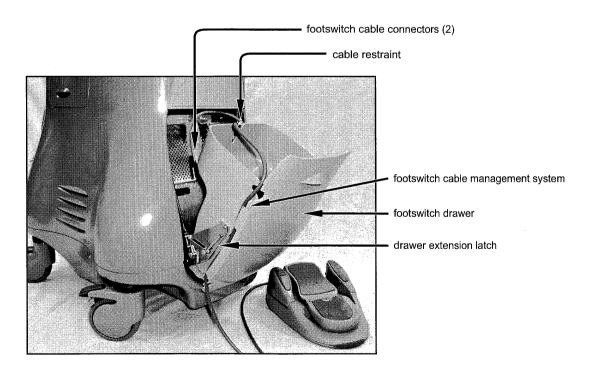


Figure 2-6 Footswitch Cable Routing

Footpedal Control

Depending on the surgery step, the user may have the option to select *linear* or *fixed* footpedal control of a surgical parameter (i.e., aspiration, vacuum, power, coagulation). With *linear* footpedal control, the angle of depression within the pedal range is directly proportional to the parameter output. The parameter output is 0

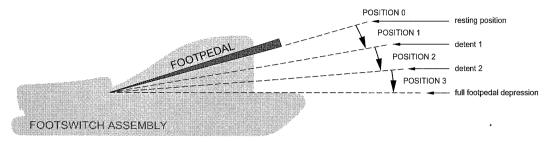


Figure 2-7 Diagram of Footpedal Positions

	Footpedal Control of Surgical Functions					
Mode	Position 0	Position 1		Position 2	Position 3	
Phaco or NeoSonix® or	Resting	Irrigation		Irrigation/Aspiration	Irrigation/Aspiration • Phaco Power • NeoSonix Amplitude • Torsional Amplitude • AquaLase Magnitude	
<i>OZiI</i> ® or AquaLase®	Continuous Irriç	gation		rrigation/Aspiration	Irrigation/Aspiration • Phaco Power • NeoSonix Amplitude • Torsional Amplitude • AquaLase Magnitude	
I/A	Resting	Irrigation		Irrigation/Aspiration		
	Continuous Irrigation			Irrigation/Aspiration		
Vit I/A Cut	Resting	Irrigation		Irrigation/Aspiration	Irrigation/Aspiration Cutting	
	Continuous Irrigation		l	rrigation/Aspiration	Irrigation/Aspiration Cutting	
Vit Cut I/A	Resting	Irrigation		Irrigation/Cutting	Irrigation/Cutting Aspiration	
	Continuous Irrigation			Irrigation/Cutting	Irrigation/Cutting Aspiration	
Coag	Resting			Coagulation Power		

Table 2-1 Table of Footpedal Positions - The footpedal is used by the surgeon to control several surgical functions. This table shows the functions controlled, dependent on mode of operation and type of irrigation selected. As the footpedal is depressed it travels from the resting position into its active positions.

at the very start of the treadle range, and the parameter output is equal to the limit value specified at the end of the treadle range. With *fixed* footpedal control, the parameter output is fixed at its limit value throughout the treadle range. Footpedal detents identify the transition from one footpedal position to another, and are felt by the operator when slightly more pressure is required to press the footpedal from one position into the next. Detents can also be accompanied by vibration if programmed to do so.

The footswitch's Buttons and Treadle adjustments are programmable and are available by pressing the Footswitch Button in the Main Window. The Footswitch Button is described later in this section of the manual.

Switch Control

The footswitch has six switches that can be programmed to control various surgical functions. The *Infiniti*® footswitch has left and right toe switches that operate horizontally and vertically, and footpedal switches that activate when the pedal is shifted left or right. The *Accurus*® /*Legacy*® footswitch has left and right toe switches that operate horizontally and vertically, and heel switches that activate when pressed down.

Switch functions are programmable by pressing the footswitch icon and making selections on the display. The left horizonal switch is the only switch with a factory default action: Reflux. The other five switches are listed as None, their functions are mutually exclusive, and must be programmed by the user. When a switch is given a function already designated to another switch, the other switch is given a None designation. Choices are Cont. Irr., Reflux, Irr. Up, Irr. Down, Step+, Step-, Step+/-, Grade+, Grade+/-, Vit Cutter, Video Overlay, and None.

If the footpedal is not depressed, any switch may be engaged; however, the assigned switches are mutually exclusive and cannot be engaged until all other assigned switches are disengaged. If the footpedal is depressed, depending on the mode of operation, certain switches may or may not be allowed to engage. Furthermore, even if a switch is permitted to be engaged with the treadle depressed, some functions are not available when the treadle is depressed, and the command will not be performed.

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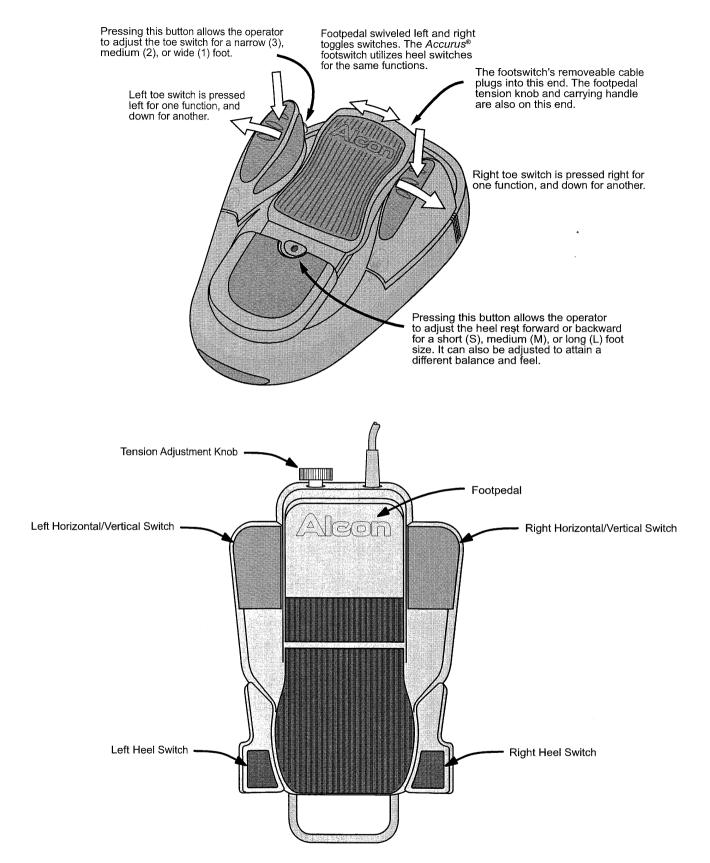


Figure 2-8 Footswitches Used with the *Infiniti*® Vision System - Shown at the top is the *Infiniti*® footswitch with its switch actions identified. Shown below is the *Accurus*®/Legacy® footswitch.

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The following sections indicate whether each switch function is permitted with the treadle depressed. If it is permitted, and the user intends to control that function when the treadle is depressed, the function must be assigned to a switch that is permitted to be engaged with the treadle depressed.

• Continuous Irrigation On/Off

When a switch assigned to Continuous Irrigation On/Off is toggled, the continuous irrigation status immediately activates/deactivates. Continuous irrigation toggling is available when the footpedal is in any position, but is not available in a Coagulation step.

• Reflux

The default reflux pressure is equal to the current bottle height pressure. The reflux pressure can be increased using the Reflux Offset control in the *Custom/Doctor* menu.

In all cases, reflux is not available when the footpedal is depressed, and is not available in a Coagulation step.

• Irrigation Up, Irrigation Down

A switch may be assigned as irrigation up or irrigation down. When the switch is pressed and immediately released, the IV pole position will increment up or down. If the switch is pressed and held for more than 1/2 second, the IV pole will move continuously up or down until the switch is released. Control of this irrigation function is available in all steps but coagulation, and in all footpedal positions.

• Step Advance, Step Back, Step Advance/Back A switch may be assigned as step advance (Step +), step back (Step -), or step advance/back (Step +/-). The Setup, Coagulation, and Anterior Vitrectomy steps are excluded from this stepping sequence.

If step advance or step back is assigned, when the switch is pressed, the next or previous step to the current step is selected in the surgery menu. If step advance/back is assigned to a switch, then step advance will be activated if the switch is pressed for less than 1/2 second. If the switch is pressed for more than 1/2 second, then the step back function will be activated.

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• Cataract Grade Increase, Decrease, Increase/Decrease
A switch may be assigned as cataract grade increase (Grade +), cataract grade
decrease (Grade -), or cataract grade increase/decrease (Grade +/-). Footswitch
control of the cataract grade is only available in phaco and AquaLase® steps, and is
available whether or not the footswitch treadle is depressed.

If cataract grade increase or cataract grade decrease is assigned, when the switch is pressed, the next or previous cataract grade to the current cataract grade is selected. If cataract grade increase/decrease is assigned to a switch, then cataract grade increase will be activated if the switch is pressed for less than 200 milliseconds. If the switch is pressed for more than 200 milliseconds, then the cataract grade decrease function will be activated.

If the highest cataract grade is currently selected, and cataract grade increase is selected, the lowest cataract grade will be selected. Similarly, if the lowest cataract grade is currently selected and cataract grade decrease is selected, the highest cataract grade will be selected.

When a new cataract grade is selected, surgical parameters will be updated with those specified for the new cataract grade.

Vit Cutter On/Off

A switch may be assigned to enable and disable the Vit Cutter (the left horizontal switch is an exception). The Vit Cutter function is available only in the Vit step; at all other times the designated button does nothing. The Vit Cutter is automatically enabled when the Vit step is selected. When the Vit Cutter is disabled, the I/A functionality in footpedal positions 2 and 3 is unchanged, but the Vit Cutter does not cut. The Vit Cutter switch may be pressed in footpedal positions 1, 2, or 3, and the function takes effect immediately. When the current step is Vit, and the Vit Cutter is disabled, the message "Vit Cutter Disabled" is displayed in the Surgery Screen.

• VideOverlay On/Off

When a switch assigned to VideOverlay On/Off is toggled, the video overlay output (including Alcon logo) is toggled on/off on the video display. Control of this function is available in any footpedal position when it is assigned to a switch in which activation is permitted with the pedal depressed.

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REMOTE CONTROL

The remote control for the *Infiniti*® system is wireless and can be used in one of two ways. It can be laid in its tray assembly receptacle and operated under the sterile tray support cover supplied in the disposable pak; this offers the Scrub Nurse or Sterile Assistant access to the controls from the sterile field. Alternatively, the Circulating Nurse can operate the remote control in a non-sterile manner. Programmability and custom user setup features are functions which are not accessible from the remote control.

CAUTIONDo not sterilize the remote control as it will damage the unit.



Figure 2-9 The Remote Control - The remote control fits securely in its tray assembly receptacle and allows rotation in any orientation. The sterile tray support cover is then draped over the remote and tray.

Remote Control Keys and Buttons

The following describes the remote control keys and buttons. The following sections will describe the function of each, and indicate when they are valid. When a remote control key or button is pressed, a valid or invalid key tone is generated as appropriate.

The remote control is divided into three sections from top to bottom. Each section of the remote approximately corresponds to its associated section of the *Infiniti®* Vision System display screen. The three sections of the display screen are 1) the setup status/surgery control window, 2) the main window, and 3) the setup steps/surgery menu. The Adjust button and items in the Adjust bar are not accessible with the remote.

• Irrigation Control Up/Down Keys



The Irrigation Control up/down keys on the remote function as they do on the touchscreen. Each individual press raises the IV pole 1 cmH2O up or down. To move rapidly up or down, a key is pressed and held until the desired height is reached. The irrigation control keys are only valid in the Setup and Surgery screens, and are not valid when any dialog is displayed.

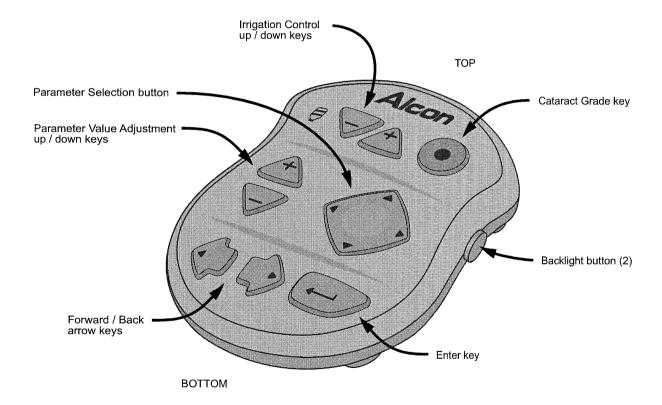


Figure 2-10 The Remote Control Keys



Cataract Grade Key

The Cataract Grade key is only valid in the setup screen and during lens removal surgery steps, and is not valid when any dialog is displayed. Each time this key is pressed it cycles the cataract grade upward until it reaches 4, and then begins again at grade 1. The Default Grade can be programmed in the Custom/Doctor/General menu.

The first press of the Cataract Grade key, or the first press after five seconds have elapsed from the last press, simply invokes the voice confirmation of the currently selected grade. Each subsequent press of the key within five seconds selects the next cataract grade, with voice confirmation of the grade.



• Parameter Selection Button

The Parameter Selection button is used to select parameters for adjustment, and to select Coag and Vit steps. The current selection is indicated with a yellow border. With this button the user can navigate up, down, left, and right to select the desired parameter. This button is valid when the footpedal and/or a footswitch button is up or depressed, but is invalid when a dialog is displayed.



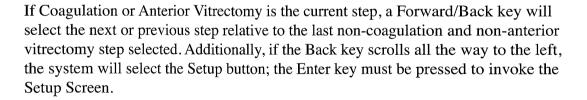
Parameter Value Adjustment Up/Down Keys

The Parameter Value Adjustment up/down keys affect settings in the Surgery Control Window that have adjustment arrows (i.e., power, vacuum, aspiration) and the linear/fixed toggle buttons. When a surgical parameter is selected via the Parameter Selection button, a yellow border indicates that the item is selected; the Parameter Value Adjustment up/down keys can then be used to adjust its value.

If a linear/fixed toggle button is selected, either of the parameter value adjustment up/down keys can be pressed to toggle the value between linear and fixed.

Forward/Back Arrow Keys

The Forward/Back Arrow keys are used to move left and right through the Setup Step buttons and the Surgery Menu steps. In the Surgery screens, when a step is selected using the Forward key or Back key on the remote, the step is immediately selected. The Forward key and Back key do not wrap around.



In the Setup Screen, when a Forward/Back key is used to move to a Setup Step button, the button will be highlighted, but the Enter key must be pressed to activate



the button. If the Forward key is pressed during the draw fluid portion of the priming sequence, the system will skip to the vacuum check.

The Forward key and Back key can also be used in an information dialog to select a button (e.g., OK, Cancel, Save, etc.).

• Enter Key



The Enter key is only valid to do the following: 1) select the Coag or Ant Vit step after it has been selected with the Parameter Selection button, 2) go to the Setup Screen when the Setup button has been selected with the Back key, 3) invoke a setup function (e.g. prime FMS, fill, test handpiece.) when the function has been selected in the Setup screen with the Forward/Back key, 4) invoke the highlighted button in dialogs, 5) toggle between Irrigation/Continuous Irrigation when the Irrigation Controls window is selected with the Parameter Selection button, and 6) select and Reset Metrics to zero when the Metrics window is selected with the Parameter Selection button.

Remote Control Batteries

When batteries in the remote control are low, the status message "Remote Battery Low" will appear below the irrigation controls each time a remote key is pressed. The message will disappear after new batteries are installed and a remote control key is pressed. After changing batteries, select remote control channel as instucted on next page.

A battery holder inside the remote holds three (3) AAA (LR3) batteries. To replace batteries, loosen two captive screws on the rear cover with a standard slotted screwdriver and remove cover. Replace old batteries and replace cover (correct battery positions are identified inside each battery slot). When closing cover it is important that rubber buttons slide into slots in other half of remote without binding (see Figure 2-11). To check correct installation of batteries, press a Backlight button on the side of the remote and verify that the remote control buttons illuminate, then turn off after a few seconds. If illuminated buttons don't turn off, rubber buttons are not properly inserted into slots, so you must repeat procedure. Dispose of batteries following local governing ordinances and recycling plans.

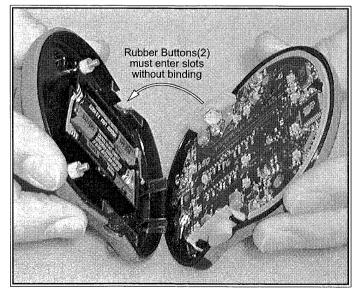


Figure 2-11 Proper Orientation of Two Halves of Remote Control

Select Remote Control Channel

The remote control can be configured to operate on one-of-four channels. This feature allows four remote controls to independently control four *Infiniti®* Vision Systems operating in the same room or area. Remote controls are factory preset to channel A. For proper remote operation, the *Infiniti®* Vision System must be set to the same channel as the remote.

The Custom/System Settings window allows the selection of four remote receive codes: A, B, C, & D. This selection must correspond to the channel selection on the remote control. Set the remote channel as instructed below.

To select a remote channel on the *Infiniti*® Vision System:

- 1. Press the *Custom* key to activate its drop-down menu.
- 2. Press the *System* key to bring up the System Settings window.
- 3. Press the *Remote Channel* button to bring up the Remote Control Settings dialog (see Figure 2-12).
- 4. Hold the remote control in front of the *Infiniti*® display screen and simultaneously press its *parameter value adjustment up/down* keys (labeled *1 & 2 on the screen). Simultaneously release the buttons.
- 5. Press the *parameter selection* button corresponding to the new channel (labeled A at 9:00, B at 12:00, C at 3:00, and D at 6:00 on the screen).
- 6. Press the *Enter* button on the remote (see Figure 2-10), then press *Save* on the screen.

No additional steps are needed once the remote channel is set, and only one remote channel is stored per unit.

NOTE: If necessary to distinguish between remote controls, identify the remote controls and the units with unique labels.

CAUTION

Do not sterilize the remote control as it will damage the unit.

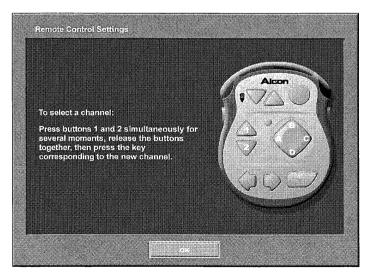


Figure 2-12 The Remote Control Settings Dialog

HANDPIECES, TIPS, AND INFUSION SLEEVES

Different handpieces, tips, and infusion sleeves are required for different procedural steps and/or functions. A full selection of handpieces, along with tip styles and sizes are available. Please contact your Alcon representative for information regarding the appropriate handpieces, tips, and infusion sleeves for your specific technique and needs.

Following is a general description of the various handpieces, tips, and infusion sleeves used to perform lens removal procedures.

Phaco Ultrasound Handpieces

Alcon's phaco handpieces integrate irrigation, aspiration and emulsification. The three functions of the lens extraction step enable the surgeon to simultaneously maintain or inflate the anterior chamber, emulsify the lens, and aspirate the lens material from the eye.

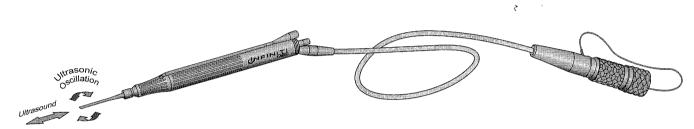


Figure 2-13 OZil® Torsional Handpiece

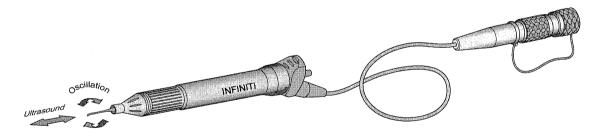


Figure 2-14 Infiniti® NeoSoniX® Handpiece

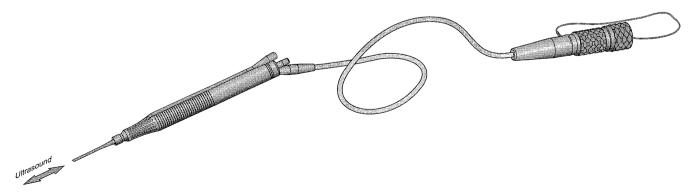


Figure 2-15 Infiniti® Ultrasonic (U/S) Handpiece

These handpieces require no disassembly other than removal of the disposable tubing, the ultrasonic tip, and the infusion sleeve with bubble suppression insert.

- OZil® Torsional Handpiece The OZil® torsional handpiece integrates all functions of the ultrasonic handpiece, and in addition provides ultrasonic oscillations. This handpiece uses many of the same tips as the U/S handpiece; for best performance of OZil® torsional handpiece, use tips recommended by your Alcon representative.
- Infiniti® Ultrasonic (U/S) Handpiece This handpiece is used for ultrasonic applications on the Infiniti® Vision System with 1.1 mm TurboSonics® tips or 0.9 mm TurboSonics® tips, including flared and/or ABS® tips.
- *Infiniti*® *NeoSoniX*® Handpiece The *NeoSoniX*® handpiece integrates all functions of the ultrasonic handpiece, and in addition provides sonic oscillations. This handpiece uses the same tips as the U/S handpiece.

CAUTIONS

Do not test or operate U/S, $OZil^{\otimes}$ torsional, or $NeoSoniX^{\otimes}$ handpieces unless the tip is immersed in BSS^{\otimes} 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 $BSS^{@}$ sterile irrigating solution before tuning U/S, $OZil^{@}$ torsional, or $NeoSoniX^{@}$ handpieces. Tuning a handpiece dry may result in premature tip failure and breakage.

WARNINGS!

Use of an ultrasonic handpiece other than the *OZiI*® torsional, *NeoSoniX*®, or U/S, 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.

Use of the *OZiI*® torsional, *NeoSoniX*®, U/S, or *AquaLase*® 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.

TurboSonics® Family of Tips

U/S tips are made of medical grade titanium alloy, and are attached to an $Ozil^{\circ}$ torsional, U/S, or $NeoSoniX^{\circ}$ handpiece to deliver mechanical energy to the lens, assisting in its removal by aspiration. Depending on the needs and technique preferred by the surgeon, various styles of tips and tip bevels are available (see Figure 2-16). Various U/S tip styles are color coded.

Each doctor selects the $Ozil^{\otimes}$, U/S, and $NeoSoniX^{\otimes}$ tips offered at the top of the surgery screen for his selected handpiece. The tips offered for each doctor are enabled or disabled from the Custom Copy/Delete feature.

- 1.1 mm U/S Tips The standard ultrasonic tips are the original 1.1 mm *TurboSonics*® tips. They are designed for use only with 1.1 mm infusion sleeves.
- 0.9 mm U/S Tips The 0.9 mm ultrasonic tips are designed to allow entry through a smaller incision. They are designed for use only with 0.9 mm infusion sleeves.
- *Mackool*** U/S Tips The *Mackool*** ultrasonic tips contain a polymer tubing over the main part of the tip shaft. This necessary part of the *Mackool*** tip provides additional thermal and fluidic advantages.
- Aspiration Bypass System The *ABS*® tip contains a small hole in the distal portion of the tip's wall. This helps to maintain flow through the system even during occlusion of the tip's main port.

WARNINGS!

Use 0.9 mm tips with 0.9 mm infusion sleeves. Use 1.1 mm tips with 1.1 mm infusion sleeves. Mismatch of consumable components and use of settings not specially adjusted for a particular combination of consumable components may create a patient hazard.

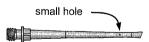
Read all package label material printed on the consumable paks prior to their use.



Standard U/S Tip - The 1.1 mm TurboSonics[®] tip with the round shaft is the original, classical U/S tip shape. The 0.9 mm has a smaller diameter shaft.



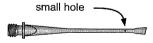
The Aspiration Bypass System - The *ABS*[®] tip contains a small hole in the distal portion of the tip's wall.



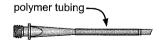
Tapered Tip - The tapered ABS^{\circledR} tip is a combination of the 0.9 mm tip and the flared ABS^{\circledR} tip. The shaft inner and outer diameters is equivalent to straight tips, while the distal end is comparable to flared tips. The tapered ABS^{\circledR} tip has the improved holding force of a flared tip, and the same aspiration flow characteristics as a straight tip.



Kelman[®] Tip - The *Kelman*[®] tip has a bent shaft which generates transverse ultrasound motion, in addition to the conventional longitudinal motion, to enhance cutting efficiency. In addition, the bend allows better visibility during the surgical procedure.



Flared ABS® Tip - The flared tip has a larger proximal port, providing increased holding force. They narrow in the middle of the shaft, thus allowing smaller incisions and improving occlusion breaks by reducing outflow from the anterior chamber, following occlusion breaks. Flared tips also have the Aspiration Bypass System feature, to further enhance performance.



Mackool Series U/S Tip** - The *Mackool*** ultrasonic tip contains a polymer tubing over the main part of the tip shaft.

Figure 2-16 *TurboSonics*® Tips - Shown here are samples of U/S tips used with the *OZil*® torsional, U/S, and *NeoSoniX*® handpieces.

AquaLase® Liquefaction Handpiece

The *AquaLase*[®] handpiece utilizes warmed high energy rapid pulses of fluid to perform liquefaction on the lens, while at the same time irrigating the anterior chamber and aspirating the lens material from the eye.

Each doctor selects the *AquaLase*[®] tips offered at the top of the surgery screen for his selected handpiece. The tips offered for each doctor are enabled or disabled from the Custom Copy/Delete feature.

- 1.1 mm Liquefaction Tip Standard tip used with 1.1 mm infusion sleeves.
- 1.1 MI Liquefaction Tip Micro Incision tip used with 1.1 mm infusion sleeves for small incision surgery.



Figure 2-17 AquaLase® Liquefaction Handpiece

MicroSmooth® Infusion Sleeves

Infusion sleeves cover the tip of the handpiece to provide irrigation to the anterior chamber of the eye during surgery (see Figure 2-18). Infusion sleeves are used with the $Infiniti^{\text{@}}$ U/S, $Ozil^{\text{@}}$ torsional, $NeoSoniX^{\text{@}}$, and $AquaLase^{\text{@}}$ handpieces, and with some $Ultraflow^{\text{TM}}*I/A$ handpieces. Infusion sleeves used with $Infiniti^{\text{@}}$ U/S, $Ozil^{\text{@}}$ torsional, and $NeoSoniX^{\text{@}}$ handpieces require a BSI (bubble suppression insert). Infusion sleeves must be correctly matched to the specific tip type (see the following descriptions). $Infiniti^{\text{@}}$ paks contain only $MicroSmooth^{\text{@}}$ infusion sleeves.

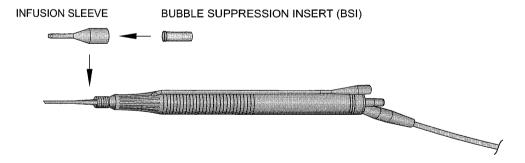


Figure 2-18 Infiniti® U/S Handpiece shown with Infusion Sleeve and Bubble Suppression Insert

Depending on the needs and technique preferred by the surgeon, various styles of infusion sleeves are available.

- Standard *MicroSmooth*® Infusion Sleeves These are the original infusion sleeves. Standard infusion sleeves are available in 1.1 mm (blue), to be used with 1.1 mm tips; and 0.9 mm (purple), to be used with 0.9 mm tips.
- *MicroSmooth*® High Infusion Sleeves High infusion sleeves (HIS) have a larger shaft diameter than original infusion sleeves. The larger shaft diameter of the high infusion sleeves is compatible with a larger incision. Reduced resistance to irrigation flow resulting from this larger shaft diameter creates a more stable anterior chamber. High infusion sleeves are available in semi-transparent blue, to be used with 1.1 mm tips; and semi-transparent purple, to be used with 0.9 mm tips.
- *MicroSmooth*[®] Ultra Infusion Sleeves Ultra infusion sleeves have a smaller shaft diameter than original infusion sleeves. The smaller shaft diameter of the Ultra infusion sleeves is compatible with a smaller incision. Ultra infusion sleeves are available in 1.1 mm (green), to be used with 1.1 mm tips; and 0.9 mm (rose), to be used with 0.9 mm tips.

WARNINGS!

Use 0.9 mm U/S tips exclusively with 0.9 mm infusion sleeves. Use 1.1 mm U/S and 1.1 mm liquefaction tips exclusively with 1.1 mm infusion sleeves. Mismatching U/S tips and infusion sleeves may create potentially hazardous fluidic imbalances.

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

Read all package labelling on the consumable paks prior to their use.

Ultraflow™* Handpieces and Tips

The *Ultraflow*TM * handpiece is used in I/A mode to maintain chamber pressure with irrigation while removing cortical material via aspiration. (See Figure 2-20 and note the band markings on the tips that identify size of tip aperture.) Some configurations of the *Ultraflow*TM * IT and SP handpieces also use infusion sleeves. The following *Ultraflow*TM * I/A handpieces and tips are available:

- *Ultraflow*[™] * IT Handpiece and Interchangeable Tips The *Ultraflow*[™] * IT consists of a handpiece body that accepts interchangeable tips. These tips do not require an adapter or infusion sleeve as they contain a built-in metal infusion sleeve.
- $Ultraflow^{\text{TM}} * \text{I/A}$ Handpiece and Threaded Tip Adapter Reusable I/A tips with $TurboSonics^{\text{@}}$ silicone infusion sleeves can be used with the $Ultraflow^{\text{TM}} * \text{I/A}$ handpiece with threaded tip adapter.
- *Ultraflow*[™] * SP I/A Handpiece (Single-Piece with fixed tips) The *Ultraflow*[™] * SP consists of a single-piece handpiece with aspiration tip and a built-in metal infusion sleeve. Various tip configurations are available.

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 *Infiniti*® 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 with a 0.5 mm or larger I/A tip may cause anterior chamber shallowing and/or incarceration or tearing of the posterior capsule.

I/A tips are not to be used with U/S, NeoSoniX®, or OZiI® torsional handpieces.

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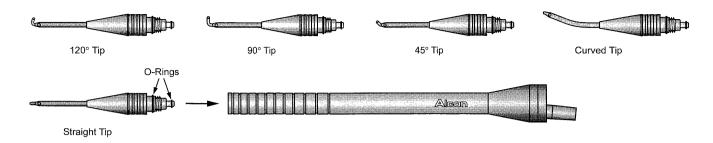


Figure 2-19 *ULTRAFLOW*™* I/A HANDPIECE AND TIPS - A wide variety of tips are available for use with the *Ultraflow*™* I/A handpiece.

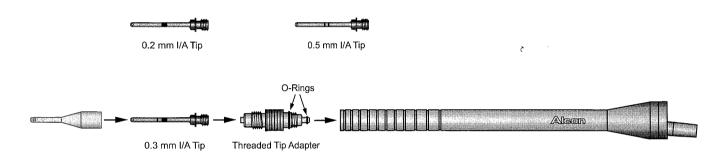


Figure 2-20 *ULTRAFLOW™** I/A HANDPIECE AND ACCESSORIES - Shown here is the *Ultraflow™** I/A handpiece with infusion sleeve, reusable I/A tip, and threaded tip adapter.

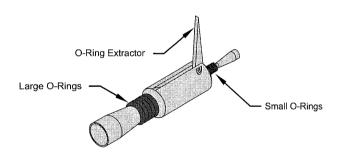


Figure 2-21 O-RING REPLACEMENT TOOL - This is the *Ultraflow*™* O-ring replacement tool with large and small O-rings.



Figure 2-22 *ULTRAFLOW*™* SP I/A HANDPIECE - Shown here is the *Ultraflow*™* single piece I/A handpiece with .3 mm 45° tip.

Infiniti® Vitrectomy Probes

The *Infiniti*® system supports two different vitrectomy probes: the 20 gauge *Infiniti*® vitrectomy probe, and the 23 gauge *Infiniti*® *UltraVit*® probe. Each probe is a sterile, single-use, vitreous cutter which provides for aspiration and cutting. An irrigating cannula is provided in each pak to allow for bimanual irrigation. The 20 gauge *Infiniti*® vitrectomy probe can be used with, as a separate accessory, an irrigation sleeve to allow for simultaneous coaxial irrigation. This sleeve is not for use with the 23 gauge *Infiniti*® *UltraVit*® probe.

The 23 gauge *Infiniti*[®] *UltraVit*[®] probe supports higher cut rates by utilizing an additional pneumatic actuation line.

Each probe is completely preassembled and requires no lubrication or cleaning prior to surgery. These guillotine vitreous cutters are intended for single use only.

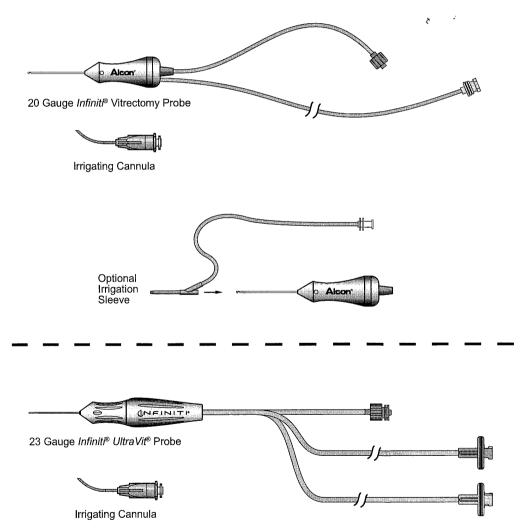


Figure 2-23 VITRECTOMY PROBES - The 20 gauge *Infiniti*® vitrectomy probe operates at up to 800 cpm and can be used with an optional irrigation sleeve. The 23 gauge *Infiniti*® *UltraVit*® probe operates at up to 2500 cpm and utilizes two pneumatic lines. Both handpieces are packaged with an irrigating cannula.

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WARNINGS!

Do not test or operate vitrectomy probes unless tip of probe is immersed in $BSS^{@}$ sterile irrigating solution or distilled water or is in surgical use. Irreparable damage to the handpiece and tip can result if run dry.

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; alternatively, press the Test button on the Vitrectomy Setup Screen: 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.

Bipolar Coagulation Handpieces

- <u>Bipolar Coagulation Forceps</u> are lightweight and ergonomically designed to reduce hand fatigue as well as to provide precise control and safety. The forceps are available with a wide variety of tip styles.
- <u>Bipolar Coagulation Brushes</u> are available in a wide variety of configurations: straight, curved, tapered, and widestroke. All disposable bipolar accessories are available both with and without cords.

Coagulation Cords are available in disposable and reusable configurations.

See your Alcon representative for a complete listing of products and accessories.



Figure 2-24 Single use bipolar brush

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FLUIDIC MANAGEMENT SYSTEM

The Fluidic Management System (FMS) is an interface between the *Infiniti*[®] console and the surgical handpiece. It is used to regulate *BSS*[®] irrigating fluid to the handpiece, aspirate debris from the handpiece, monitor irrigation and aspiration pressure, and deposit the debris in a sealed drainage bag for disposal. This single assembly contains a rigid plastic fluidic chamber, non-invasive pressure/vacuum sensor, drain bag, irrigation (clear) and aspiration (blue stripe) tubing, and a clear tubing with spike for connection to the bottle of *BSS*[®] irrigating solution. The type of FMS inserted is automatically identified by the system when it is inserted into the fluidics module. Inserting the FMS into the console fluidics module establishes fluidics system connections, contributing to quick and easy surgical setup.

Infiniti® FMS

This is the original FMS. The aspiration line has a blue stripe.

Intrepid® FMS

The *Intrepid*® FMS is designed to enhance microcoaxial techniques. The aspiration line is tinted blue.

AquaLase® FMS

The *AquaLase*[®] FMS offers an additional tubing (black stripe) for connection to the bottle of *AquaLase*[®] Solution CE. The user can also utilize either the *Infiniti*[®] or *Intrepid*[®] FMS used in conjunction with standalone *AquaLase*[®] kits with Injection Line.

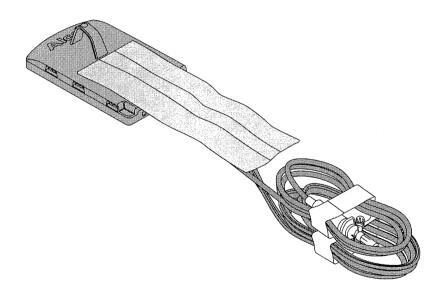


Figure 2-25 The Infiniti® Ultrasound Fluidic Management System (FMS)

INFINITI® AQUALASE® BALANCED SALT SOLUTION BOTTLE

When performing an *AquaLase*[®] liquefaction device procedure, the *Infiniti*[®] Vision System must be equipped with an *AquaLase*[®] bottle containing *BSS*[®] sterile irrigating solution. This solution is emitted in warm high energy pulses from the tip of the handpiece.

During the setup procedure the bottle is inserted into its receptacle on the front of the console, with its alignment arrow at the 12 o'clock position, and turned clockwise 1/4 turn to secure it in position

<u>CAUTION</u> To avoid damaging the bottle, take care not to overtighten.

To remove the bottle, press it in and turn counterclockwise before pulling it out from its receptacle. The spike on the black-striped tubing is inserted into the *AquaLase*[®] bottle and then connected to the *AquaLase*[®] handpiece.

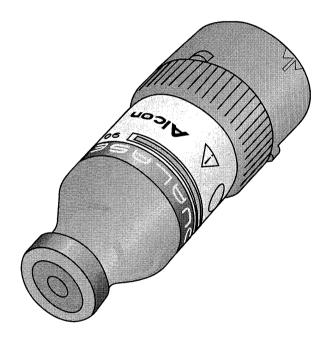


Figure 2-26 The AquaLase® Balanced Salt Solution Bottle

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CONSUMABLE PAK CONFIGURATIONS

The family of *Infiniti*® paks consist of various combinations of fluidic management systems (FMS), handpiece tips, infusion sleeves, and other components. *AquaLase*® complete paks include a bottle of *AquaLase*®/Balanced Salt Solution. Consumable items used with the *Infiniti*® Vision System during surgery are designed to be used once and then discarded, unless labeled otherwise.

Please contact your Alcon Sales representative for complete up-to-date listings, and for in-service information prior to initial use of Alcon paks. All *Infiniti®* paks contain Directions for Use (DFU). It is important to read and understand the DFU's prior to use.

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

Custom Pak® Surgical Procedure Pack Configurations

To better serve our customers we offer the opportunity for surgeons to specify a $Custom Pak^{\otimes}$ surgical procedure pack for their own individual needs. Please contact your Alcon Sales representative for more information on how to design your own $Custom Pak^{\otimes}$ surgical procedure pack.

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 paks 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.

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.

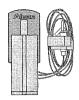
In all cases, the instrument setup instructions contained in the manual should be thoroughly understood prior to using any of the pak configurations.

Read all package label material printed on the consumable paks prior to their use.

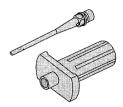
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Infiniti® U/S Fluidic Management System Paks

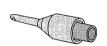
When performing a phacoemulsification procedure, one of the *Infiniti*® U/S family of paks with handpiece tip is used. The pak can contain all the items listed below:



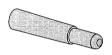
• Fluidic Management System (FMS) - This single assembly consists of irrigation (clear) and aspiration (striped) tubing, a plastic reservoir/pump device, and a drainage bag (maximum capacity of 500 cc). Inserting the FMS into its console receptacle establishes the *Infiniti*® fluidic system, allowing quick and easy surgical setup.



• U/S Tip with Tip Holder/Wrench - The tip attaches to the ultrasonic handpiece. Securely tighten the tip with the all-in-one tip wrench/ assembly, then remove the wrench from the tip. Several tip designs are available.



• Infusion Sleeve with BSI - This single-piece silicone sleeve fits over the handpiece tip to provide irrigation into the eye, protection to the surrounding tissues, and fluidic balance. One infusion sleeve contains a bubble suppression insert (BSI); a second infusion sleeve is included to be used with the I/A handpiece/tip.



• Test Chamber - The test chamber is a small elastomeric cap that fits over the handpiece tip to facilitate a functional irrigation and aspiration check of the handpiece and instrument prior to surgery.



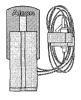
• I/A Tip Wrench - A separate wrench is required to securely fasten the I/A tip to its handpiece, and also to remove the tip when the surgery is completed.

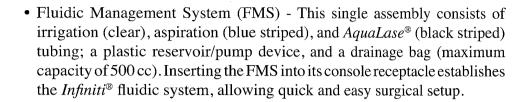


- Tray Support Cover The tray support cover is a sterile plastic bag that is
 placed around the instrument tray and support arm. The cover is used to
 form a pouch in the tray to provide storage for the handpiece and tubing
 during surgery.
- Directions for Use (DFU) Instructions for setup and removal of pak contents (not shown).

Infiniti® AquaLase® Fluidic Management System Paks

When performing a lens extraction procedure with the *AquaLase*[®] handpiece, a single-use *Infiniti*[®] *AquaLase*[®] pak is used. This pak can contain all the items listed below:



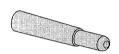




• AquaLase® Liquefaction Tip with integral Tip Holder/Wrench - The tip attaches to the AquaLase® handpiece. Securely tighten the tip with the all-in-one tip wrench/assembly, then remove the wrench from the tip.



• Infusion Sleeve - This single-piece silicone sleeve fits over the handpiece tip to provide irrigation into the eye, and fluidic balance. A second infusion sleeve is included to be used with the I/A handpiece/tip.



 Test Chamber - The test chamber is a small elastomeric cap that fits over the handpiece tip to facilitate a functional irrigation and aspiration check of the handpiece and instrument prior to surgery.



• I/A Tip Wrench - A separate wrench is required to securely fasten the I/A tip to its handpiece, and also to remove the tip when the surgery is completed.



• Tray Support Cover - The tray support cover is a sterile plastic bag that is placed around the instrument tray and support arm. The cover is used to form a pouch in the tray to provide storage for the handpiece and tubing during surgery.



- AquaLase® Balanced Salt Solution Bottle Liquefaction solution.
- Directions for Use (DFU) Instructions for setup and removal of pak contents (not shown).

INFINITI® VIDEOVERLAY SYSTEM (optional item)

Overview

The *Infiniti®* VideOverlay (IVO) system accepts operating parameters from the *Infiniti®* Vision System and overlays that information onto video accepted from the microscope camera. The IVO system then outputs a video signal to a monitor and/or VCR for retrospective viewing.

There are two models of IVO available: Standard and High Definition. The text below describes the Standard IVO. For a complete description of the High Definition IVO, please refer to Figure 2-31 and the operator's manual addendum which accompanied the High Definition IVO.

The Standard IVO will accept either Composite or S-Video inputs in either NTSC or PAL format (auto detecting). The IVO is powered by an external power supply. The external power supply can operate from a 100 VAC to 240 VAC source, and provides an output of 12 VDC at 1.25 amps to power the IVO.

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 Alcon-supplied serial cable to connect *Infiniti®* Vision System to IVO.

NOTES:

- This unit is not a medical device and should be located/stored with other video equipment (i.e., VCR, monitor, etc.).
- When connected to the *Infiniti®* Vision System, the IVO system does not increase the leakage current of the *Infiniti®* Vision System.
- The *Infiniti*® VideOverlay system is for information purposes only, and is not intended to substitute for the *Infiniti*® Vision System display.

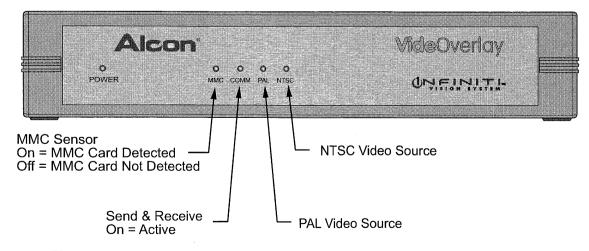


Figure 2-27 VideOverlay Front Panel

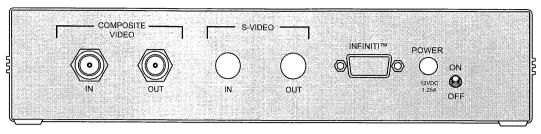


Figure 2-28 VideOverlay Rear Panel

Setup For Standard IVO (for HD IVO refer to Figure 2-31 and documentation that came with HD kit)

- 1. Ensure electric power to all systems is turned OFF. Attach the 12 V end of the external power supply to the IVO system.
- 2. Attach the appropriate wall outlet adapter (USA, United Kingdom, Australia, or Europe) to the AC end of the external power supply, and plug it into an appropriate wall outlet (see Figure 2-29).
- 3. The IVO can operate using either Composite Video inputs/outputs or S-Video inputs/outputs. Appropriate cables should be used to configure the IVO. Connect the microscope camera output to the Composite or S-Video input of the IVO (see Figure 2-30).

NOTE: If the microscope camera output has an RCA or BNC connector, connect the camera output to the VideOverlay Composite input. Do not use an adapter cable to connect the camera output to the VideOverlay S-Video input or loss of color will occur.

- 4. Connect the Composite or S-Video output of the IVO to a monitor or a VCR. The video output selected must be the same configuration as that used for the video input (Composite or S-Video).
- 5. With the video output connected to a monitor, turn the monitor and microscope camera power ON, and leave the IVO power OFF. If the video input and output cables are connected properly, the microscope camera image will appear on the monitor.
- 6. Connect the serial cable between the IVO and Infiniti® Vision System (see Figure 2-30).
- 7. Turn *Infiniti*® Vision System power ON. Turn IVO power ON with its rear panel switch. The MMC light and either the PAL or NTSC Video source light should be illuminated (if not illuminated, check power supply connections).
- 8. With the *Infiniti*® system touchscreen interface running, make sure the Send & Receive light blinks (if not blinking, check serial cable).
- 9. Observe the monitor video display. The *Infiniti®* Vision System logo should appear (see Figure 2-30) (if the *Infiniti®* Vision System logo does not appear, check serial cable connections). If the system does not operate correctly, contact an Alcon Technical Service representative.

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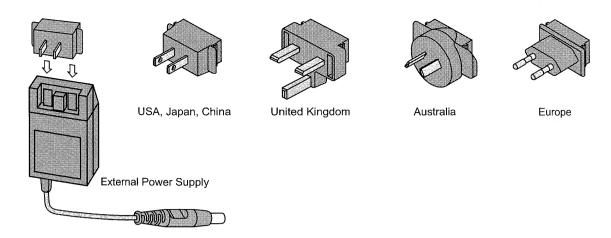


Figure 2-29 Wall Outlet Adapters

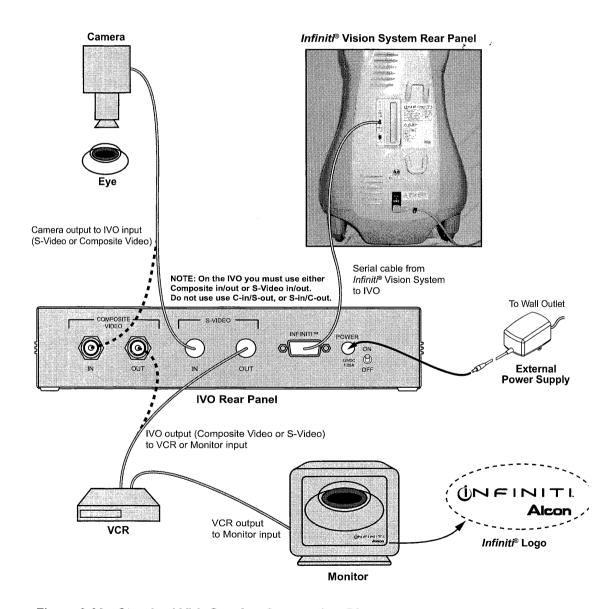


Figure 2-30 Standard VideOverlay Connection Diagram

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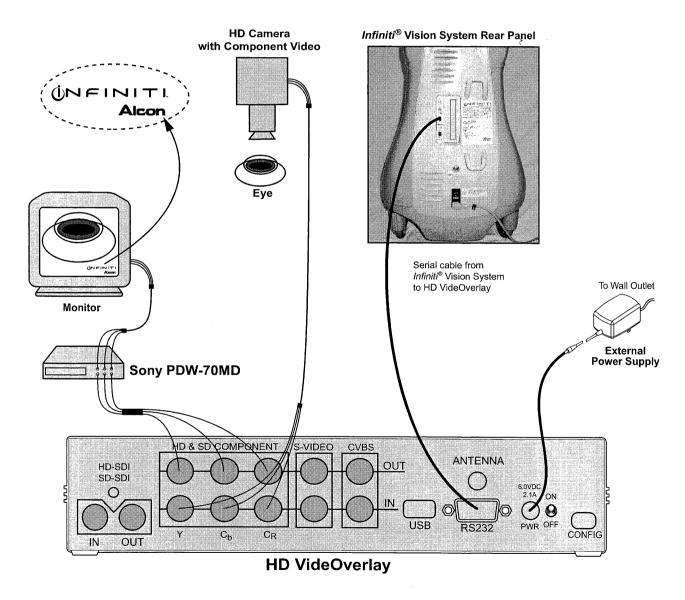


Figure 2-31 High Definition VideOverlay Connection Diagram

INFINITI® VISION SYSTEM OPERATOR INTERFACE

FRONT DISPLAY PANEL AND TOUCH SCREEN

The *Infiniti*® Vision System front display panel and touch screen has a flat, non-glare surface, and is mounted above the console. For ease of viewing the display panel swivels and rotates, and it folds down into a protected position for storage.

Control buttons are located within the active touch screen area. There are two basic types of pushbuttons on the display screen: up/down arrow buttons and momentary buttons. The user can press and hold the up/down arrow buttons until the desired adjustment is complete, and he can press the momentary buttons with a single push-and-release to activate a function.

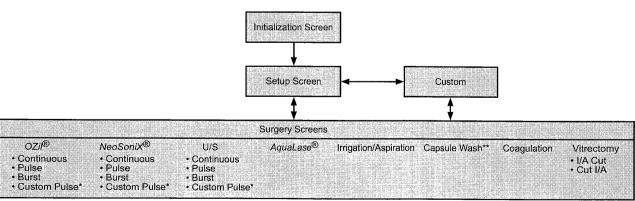
The *Infiniti*® Vision System emits an audible tone to indicate button activation. Activation of a valid touchscreen button or remote control button results in a valid key tone; an invalid button results in an invalid key tone, and sometimes its icon symbol is ghosted to indicate an invalid function.



Figure 2-32 The *Infiniti*® Vision System Front Display Panel and Touch Screen

There are three types of display screens: the Setup screen, Surgery screens, and Dialogs.

- The Setup screen is used to prepare for surgery; i.e., priming the fluidic management system and testing the handpiece.
- Surgery screens contain special surgical settings for each of the current surgical procedures. Pressing the touch screen buttons (or footswitch or remote control) allows the user to adjust the settings for his current step.
- Dialogs are displayed as a result of selecting an option from the Custom drop list (i.e., System, About, Doctor, etc.) or pressing the Metrics or Footswitch button. Dialogs enable the user to view and modify system settings, doctor settings, and some surgical settings. There is another class of dialogs that are displayed when the user needs to be advised or warned of a situation, or to indicate progress on a function in the Setup screen.



* Custom Pulse is enabled/disabled through the Advanced tab in the Custom/Doctor dialog.
 ** Capsule Wash is enabled/disabled through the Steps tab in the Custom/Doctor dialog.

Figure 2-33 Navigating the Infiniti® Vision System User Screens

SETUP SCREEN AND ITS FUNCTIONS

The Setup screen is displayed when one of the following occurs:

- The system is powered up and initialization is successful.
- The screen is explicitly invoked by pressing the Setup button from a Surgery screen.
- The FMS is removed while in a surgery screen other than Coagulation.
- The handpiece tip is changed in a surgery screen and the user indicates on the resulting popup message that he selects the Setup screen.
- A handpiece is selected in a surgery screen and the handpiece is not tuned.
- A valid FMS is inserted while the user is in a surgery screen.

The Setup screen is divided into three sections. At the top is the Main Window, below that is the Setup Status Window, and below that are the Setup Steps.

1. Main Window

The Main Window consists of buttons and readouts that are used to set up the system and then perform surgery (see Figure 2-34). The Setup Main Window is the same in most areas as the Surgery Main Window discussed later.

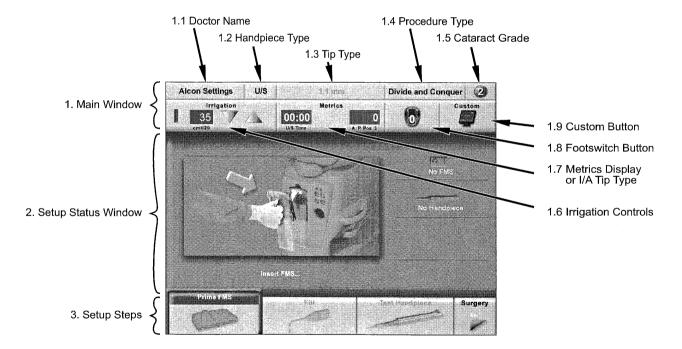


Figure 2-34 Functional Areas of the Setup Screen

1.1 Doctor Name

Alcon Settings

The Doctor Name button displays the currently-selected doctor. When pressed, and also when system is first turned on, this button displays a drop list of all the doctors entered in the system. The first doctor at the top of the list is the Alcon Settings doctor, which contains all the Alcon defaults. Listed in the second position from the top is the Add Doctor selection which allows the user to add a new doctor to the list. The remaining doctors will be listed with the most-recently-selected doctor in the third position from the top, or if enabled in the *Custom/System* drop list menu, alphabetically.

When a doctor is selected (other than Add Doctor), the following occurs:

- The drop list collapses and the selected doctor name is displayed.
- The surgical handpiece, phaco tip, procedure, and I/A tip are selected in accordance with the following:
 - The I/A tip is changed to that last used by the doctor.
 - If no handpiece is connected, the surgical handpiece, tip, and procedure are changed to those last used by the doctor, or the defaults selected in Doctor Settings.
 - If the currently-selected handpiece is connected but not tuned, the selected handpiece does not change. The tip and procedure change to those last used by the doctor for the selected handpiece. If the tip or procedure do change, a dialog is displayed notifying the doctor that the tip and/or procedure have changed.
 - If the currently-selected handpiece is tuned, the selected handpiece and tip do not change. The procedure changes to that last used by the doctor for the selected surgical handpiece and tip.
- The Cataract Grade is set to the doctor's default.

Add Doctor

When Add Doctor is selected from the doctor drop list, a dialog window with keyboard appears. The user can enter a doctor's name in the designated box using the alphanumeric keypad. When a doctor's name is typed and the OK button is pressed, the dialog window disappears and the doctor name is saved with Alcon's default parameters (names are not case-sensitive). When a new doctor is successfully saved, he becomes the current doctor and is entered in the third position from the top, or if enabled in the *Custom/System* drop list menu, alphabetically.

1.2 Handpiece Type



The Handpiece Type button displays the currently-selected surgical handpiece: $Ozil^{\otimes}$ torsional (OZil), $NeoSoniX^{\otimes}$ (Neo), Ultrasound (U/S), or $AquaLase^{\otimes}$ (AqL). Pressing this button displays a drop list of available surgical handpieces. When a handpiece is selected, the following occurs:

- The drop list collapses and the selected handpiece is displayed.
- The surgical tip and procedure are changed to those last used by the doctor for the selected handpiece. The current surgical steps in the Surgery Menu are replaced with the steps associated with the newly selected procedure, and the first step is entered.

During setup, the handpiece selection will automatically correspond to the installed handpiece. Automatic selection of the handpiece is disabled when the case is started.

2.40

The system has two surgical connectors for $Ozil^{\mathbb{B}}$ torsional, $NeoSoniX^{\mathbb{B}}$, and U/S handpieces; however, only one connector can be used at one time. There is a third connector for an $AquaLase^{\mathbb{B}}$ handpiece, and it can be connected at the same time as an $Ozil^{\mathbb{B}}$ torsional, $NeoSoniX^{\mathbb{B}}$, or U/S handpiece.

If handpieces are plugged into both of the $Ozil^{\$}$ / $NeoSoniX^{\$}$ / U/S connectors, the message "Two handpieces detected. Remove a handpiece." will appear. The message can be dismissed by pressing the OK button; however, U/S power will not be available until one of the handpieces is removed.

1.3 Tip Type

1.1 mm

The Tip Type button displays the currently-selected surgical tip. When pressed, this button displays a drop list of available tips for the selected handpiece. The tips displayed in the drop-down menu have been color-coded to assist in differentiating between 0.9 mm and 1.1 mm tips. The 0.9 mm tips are listed in purple, and the 1.1 mm tips are listed blue. When a tip is selected, the following occurs:

- The drop list collapses and the selected tip is displayed.
- The Procedure Type is changed to that last used by the doctor for the selected handpiece and tip.
- If there are unsaved changes to surgical parameters, a dialog will be displayed giving the user the option either to save or discard the changes, or just cancel the dialog. If the dialog is canceled, the surgical tip is not changed.

Each doctor selects the available tips offered at the top of the surgery screen for the selected handpiece. The tips offered for each doctor are enabled or disabled from the Custom Copy/Delete feature.

1.4 Procedure Type



The Procedure Type button displays the currently-selected surgical procedure name. When pressed, this button displays a drop list of the available procedures for the selected handpiece tip. When a procedure is selected, the following happens:

- The drop list collapses and the procedure is selected.
- If there are unsaved changes to surgical parameters, a dialog will be displayed giving the user the option to save or discard these changes, or just cancel the dialog. If the dialog is canceled, the procedure is not changed.

Procedures can be customized by using the Custom Copy/Delete feature.

1.5 Cataract Grade



The Cataract Grade button displays the currently selected cataract grade: 1, 2, 3, or 4. When selected, this button displays a drop list of the four cataract grades. When a new cataract grade is selected, the following occurs:

- The drop list collapses and the selected cataract grade is displayed.
- The cataract grade is enunciated.
- Surgical step parameters that are dependent upon the cataract grade are updated with the parameter values specified for the new cataract grade.

1.6 Irrigation Controls



Irrigation/Continuous Irrigation and PEL Indicators - Pressing the bottle height readout will toggle the readout from "Irrigation" to "Continuous Irrigation" and back to "Irrigation" again. Continuous irrigation can also be activated several other ways as described on the next page.



The Patient Eye Level (PEL) readout indicates the number of centimeters below the FMS that the patient's eye is located. The PEL is programmed in the *Custom/Doctor* menu. When the PEL is set to a value other than 0, "PEL= xx" is displayed in the lower-right corner of the box.

WARNING!

Avoid setting the patient above the FMS. Operating with the patient above the FMS will result in a lower irrigation pressure than indicated on the display, and possible underventing.

- Irrigation Pressure Bar Display This bar display is a visual indication of the irrigation pressure as measured by the fluidics mechanism, irrespective of the IV pole position.
- Bottle Height and Adjustment Arrows- The bottle height readout is representative of the actual bottle height, respective to the PEL. The adjustment arrows are pressed to adjust the IV pole height, and thus change the irrigation pressure value and readout.

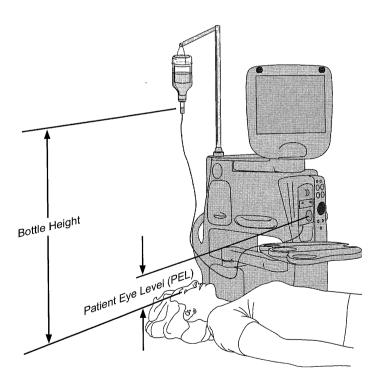


Figure 2-35 BOTTLE HEIGHT MEASUREMENT - Bottle height for gravity-fed irrigation is measured from the center of the drip chamber to the patient's eye. Default bottle height is 95 cm above the center of the round aspiration pressure sensor in the FMS. PEL is measured from the aspiration pressure sensor to the patient's eye.

Irrigation Control

Irrigation operates on a gravity-feed principle from the IV bottle to the FMS to the handpiece. The console's irrigation valve is normally closed when the fluidic interface device is inserted. In most modes of operation irrigation begins flowing when the footpedal transitions from position 0 to position 1.

Irrigation pressure is increased or decreased by raising or lowering the IV pole that holds the irrigation bottle. Default height for Ultrasound is 95 cm, and for I/A modes is 78 cm, measured from the center of the drip chamber to the center of the FMS aspiration pressure sensor; for Anterior Vitrectomy mode it is 55 cm. Patient Eye Level (PEL) is measured from the FMS aspiration pressure sensor to the patient's eye. Maximum bottle height of 110 cm results in maximum irrigation pressure. In the event of power loss, bottle position is maintained; however, if the unit is turned off using the Standby switch, the IV pole automatically retracts to its storage position.

Continuous Irrigation

Continuous irrigation is available in all applicable surgical steps and allows for continuous irrigation of the eye during surgery by opening the irrigation valve. Changing a doctor or handpiece shuts off continuous irrigation, allowing exchange of irrigation and aspiration tubing between handpieces without loss of irrigation solution. Continuous irrigation is not available in Setup or Coagulation modes.

The continuous irrigation feature is normally turned off. Continuous irrigation can be toggled from "Irrigation" to "Continuous Irrigation" and back to "Irrigation" again by using the four methods described below:

- Press the bottle height readout on the display.
- Use the remote control's Parameter Selection button to select the Irrigation window on the display, then press the Enter key on the remote control.
- Program a footswitch button for the Continuous Irrigation function, then press down on the designated footswitch button.
- Custom/Doctor/General tab/Continuous Irrigation can be turned On to activate continuous irrigation when the footpedal is depressed. It can be turned off using one of the other three methods.

When continuous irrigation is on, footswitch treadle range 1 is eliminated, and ranges 2 & 3 are expanded.

NOTE: Before switching handpieces it is advised to turn continuous irrigation off, after exiting the eye, to close the irrigation valve and prevent excess $BSS^{\$}$ sterile irrigating solution from flowing out of the handpiece.

1.7 Metrics Display



The Metrics display is available in the surgery screen during lens removal steps. During surgical procedures utilizing Ultrasound and *NeoSonix*® modes the metrics figures shown in this box display U/S Time and Average Power. During an *AquaLase*® procedure the metrics figures shown are *AquaLase*® Time, Pulses, and Average Magnitude. For the *Ozil*® mode it shows Cumulative Dissipated Energy. When the Metrics box is pressed, the Metrics dialog is displayed, and the metrics readouts can be reset to 0. The display will close when Reset is pressed.

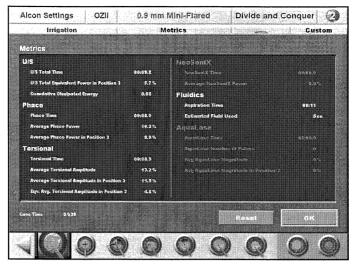


Figure 2-36 METRICS DIALOG SCREEN - Metric definitions are listed below.

U/S

U/S Total Time: Sum of Phaco Time and Torsional Time.

U/S Total Equivalent Power in Position 3:

CDE U/S Total Time

Cumulative Dissipated Energy: Total U/S energy in footpedal position 3 (both phaco and torsional) calculated as: (Phaco Time x Average Phaco Power) + (Torsional Time x 0.4 x Average Torsional Amplitude)

The factor 0.4 represents approximate reduction of heat dissipated at the incision as compared to conventional phaco.

Phaco

Phaco Time: Total time phaco power was active. This records the phaco On-time, displayed in minutes and seconds. **Average Phaco Power:** Average phaco power over the time when phaco power was applied. For example, if Ultrasound Burst mode was selected and 100 mS burst pulses at 70% stroke were generated once a second, the Average Power would record 70%.

Average Phaco Power in Position 3: Average phaco power over the time when phaco power was applied in footpedal position 3. This takes into account the U/S modulation aspects, resulting in a significantly lower reading than Average phaco Power. For example, if Ultrasound Burst mode was selected and 100 mS burst pulses at 70% stroke were generated once a second, the Average Power in Position 3 would record 7%.

Torsional

Torsional Time: Total time torsional power was active. This records the torsional On-time in minutes and seconds.

Average Torsional Amplitude: Average torsional amplitude over the time when torsional power was applied. For example, if *OZil*[®] Burst mode was selected and 100 mS burst pulses at 70% amplitude were generated once a second, the Average torsional amplitude would record 70%.

Average Torsional Amplitude in Position 3: Average torsional amplitude over the time when torsional power was applied in footpedal position 3. This takes into account the U/S modulation aspects, resulting in a significantly lower reading than Average Torsional Amplitude. For example, if Ultrasound Burst mode was selected and 100 mS burst pulses at 70% amplitude were generated once a second, the Average Torsional Amplitude in Position 3 would record 7%.

Eqv. Avg. Torsional Amplitude in Position 3: Average U/S energy in footpedal position 3 calculated as:

0.4 x Average Torsional Amplitude in Position 3.

NeoSoniX

NeoSoniX Time: Total time *NeoSoniX*[®] mode was active. On-time recording in minutes and seconds.

Average NeoSoniX Power: Average amplitude only when NeoSoniX® mode was active.

Fluidics

Aspiration Time: Total time the system was aspirating.

Estimated Fluid Used: An estimation of the volume of fluid aspirated based on system settings and time.

AquaLase

AquaLase Time: Total time when AquaLase® mode was active, displayed in minutes and seconds. This is a summation of all pulse On-times while in AquaLase® mode.

AquaLase Number of Pulses: Total number of AquaLase® mode pulses used in the case.

Avg. AquaLase Magnitude: Average magnitude only when AquaLase® mode was active.

Avg. AquaLase Magnitude in Position 3: Average magnitude over the time in footpedal position 3 when *AquaLase*® mode was active. This takes into account the burst control which sets the duty cycle. For example, if an 80% amplitude was used and a 60% burst (duty cycle) was set, Average Magnitude in Position 3 would record 48%.

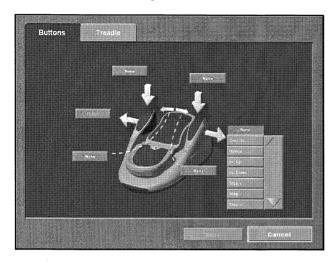
<u>Case Time:</u> The timer starts (Case Begin) when first step is chosen and footpedal is depressed. The timer stops (Case Ended) when the FMS <u>and</u> all active handpieces are removed (U/S, NeoSoniX®, AquaLase®, and OZil® handpieces). The timer pauses when system is placed in Set-up mode (Case is Inactive).

1.8 Footswitch Button



The Footswitch button is a graphical representation of the currently-installed footswitch (either $Infiniti^{\text{@}}$ or $Accurus^{\text{@}}/Legacy^{\text{@}}$ footswitch). The current footpedal position (0, 1, 2, or 3) is displayed in the center of the footswitch. Right/left and up/down arrows appear in the box whenever a momentary switch is activated.

When the Footswitch Button is pressed, the Footswitch Buttons dialog (see Figure 2-37) or Footswitch Treadle dialog (see Figure 2-38) appear. These dialogs allow the user to view and modify the current settings of the footswitch. Switching between the Buttons and Treadle dialogs is performed by pressing the corresponding tab on the viewing screen.



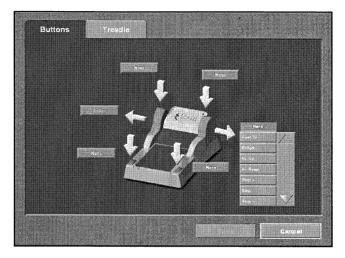
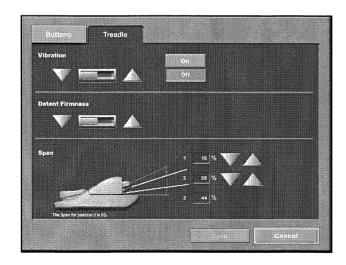


Figure 2-37 FOOTSWITCH BUTTONS DIALOGS - Pressing the Footswitch Button pulls up a dialog that corresponds to the footswitch connected to the *Infiniti*® Vision System. Pressing the Buttons tab activates one of these dialogs; on the left is the *Infiniti*® footswitch, and on the right is the *Accurus*®/*Legacy*® footswitch. Pressing a button next to a switch activates a drop-down list, as shown in these images, with functions that can be selected for that footswitch button.



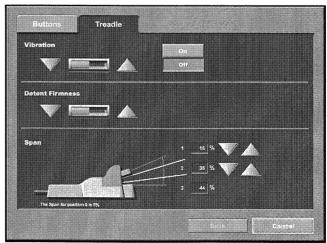


Figure 2-38 FOOTSWITCH TREADLE DIALOGS - Pressing the Footswitch Button pulls up a dialog that corresponds to the footswitch connected to the *Infiniti*® Vision System. Pressing the Treadle tab activates one of these dialogs; on the left is the *Infiniti*® footswitch, and on the right is the *Accurus*®/*Legacy*® footswitch. The buttons on the screen allow you to adjust the treadle settings to your own personal preferences.

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Treadle Function	Adjustment Method	Type of Adjustment	Description of Function			
Vibration	Horizontal Bar with Up/Down Arrow Keys	Minimum to Maximum Vibration	Treadle vibration level applied at both upward and downward treadle movement.			
	Button Selection	On	Vibration active during upward and downward treadle movement.			
		Off	Vibration not active during upward and downward treadle movement.			
Detent Firmness	Horizontal Bar with Up/Down Arrow Keys	Minimum to Maximum Firmness (0 to 100% of maximum firmness)	Detent firmness for all detents of the footswitch.			
Span 1	Value Adjust with Up/Down Arrow Keys	Percentage value (0 to 26) such that the total of Span 1, Span 2, and Span 3 equal 95% (the first 5% is always reserved for the 0 position)	The span of footpedal position 1. When the first set of arrow keys is used to increase or decrease the span 2 start position, span 1 is increased or decreased by the same amount.			
Span 2	Value Adjust with Up/Down Arrow Keys	Percentage value (19 to 95), such that the total of Span 1, Span 2, and Span 3 equal 95%	The span of footpedal position 2. When the first set of arrow keys is used to increase or decrease the span 2 start position, span 2 is decreased or increased by the same amount. When the second set of arrow keys is used to increase or decrease the span 3 start position, span 2 is increased or decreased by the same amount.			
Span 3	Value Adjust with Up/Down Arrow Keys	Percentage value (0 to 50), such that the total of Span 1, Span 2, and Span 3 equal 95%	The span of footpedal position 3. When the second set of arrow keys is used to increase or decrease the span 3 start position, span 3 is decreased or increased by the same amount.			

Table 2-2 PROGRAMMING THE FOOTSWITCH TREADLE - This table describes all the objects in the Footswitch Treadle tab, accessed by pressing the Footswitch Button in the display screen's Main Window.

2.46

1.9 Custom Button



The *Custom* button enables the user to view and modify system settings, doctor settings, and some surgical settings. When the *Custom* button is pressed, a drop list menu appears with the following options (see Figure 2-39). When one of the options is selected from the menu, the respective dialog for that option is displayed and the drop list menu disappears. If no selection is made, the drop list menu disappears after about five seconds.

The following describes the purpose of each drop list menu item, the function of the controls in its dialog, and how the selections are invoked. The selections may be invoked whether the footswitch treadle and/or a footswitch button is depressed or not depressed, and the footswitch is functional when the dialog is displayed. The drop list menu items provide the user with options relating to viewing, copying, deleting, modifying, backing up, and restoring doctor/system settings.

- Doctor
- Save
- Copy/Delete
- System
- Sound
- AqL Occlusion
- About
- Shutdown

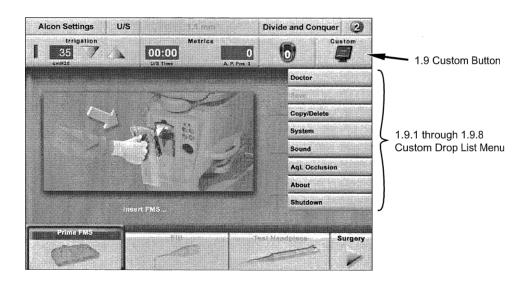


Figure 2-39 Setup Screen with Custom Drop List Menu

1.9.1 Doctor

The Doctor Settings dialog is invoked when the user presses Doctor on the *Custom* drop list menu (see Figure 2-40). The Doctor Settings dialog enables the user to view and modify surgeon preferences for the currently-selected doctor.

The dialog has Save and Cancel buttons. When Save is selected, all settings changed since the dialog was invoked are saved to persistent storage, the doctor dialog closes, and the settings take immediate effect. If the current doctor is the Alcon Settings default, the changes take immediate effect, but they are not saved to persistent storage; the changes are temporary. If Cancel is selected, the whole doctor dialog closes and the system returns to its prior settings.

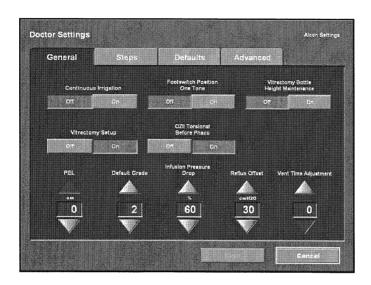


Figure 2-40 Doctor Settings Dialog Screen - General Tab

General Tab

Continuous Irrigation

Continuous irrigation is applicable for lens removal, I/A, and vitrectomy surgical steps. When Continuous Irrigation is set to On (enabled), continuous irrigation will be active following the first footpedal depression. When activated "Continuous Irrigation" is displayed in the irrigation section of the Main Window, and the continuous irrigation On tone is generated. When transitioning to another step of the same surgical type, continuous irrigation remains activated. When transitioning to a step that is a different surgical type, continuous irrigation is inactivated but then re-activated when the footpedal is depressed (except for Coagulation).

• Footswitch Position One Tone

When enabled, irrigation On tone will sound when transitioning from footpedal position 0 to 1 in any phaco, I/A, or vitrectomy step. Irrigation Off tone will sound when transitioning from footpedal position 1 to 0. This feature is mutually exclusive with Continuous Irrigation, as both cannot be enabled at the same time.

• Vitrectomy Bottle Height Maintenance

If the Vitrectomy Bottle Height Maintenance feature is enabled, and during vitrectomy surgery the footpedal is depressed, upon a transition to a non-vitrectomy step a confirmation dialog will appear. If the user confirms the desire to begin irrigation pressure maintenance, the irrigation pressure level used in the vitrectomy step will be maintained, and the following rules will be in effect until 1) a Vitrectomy step is reentered and then the desire to continue irrigation pressure maintenance is denied, or until 2) the Vitrectomy Bottle Height Maintenance feature is disabled in the Doctor Settings Dialog, or until 3) a new doctor is selected with the Vitrectomy Bottle Height Maintenance feature disabled, or until 4) the surgery ends:

- If the PEL is changed, the IV pole height will be adjusted up/down as needed to maintain the irrigation pressure.
- The user can manually change the irrigation pressure using the remote, footswitch buttons, or touchscreen buttons. If the user manually changes the irrigation pressure while in the Surgery mode, the new irrigation pressure value will be maintained until the surgery ends.
- Manual changes to irrigation pressure will not be saved to the doctor database.
- The IV pole height will be automatically moved when the Setup mode is entered, and to accommodate prime/tune/test while in Setup mode. When Surgery mode is re-entered, the irrigation pressure will revert back to the value being maintained for Vitrectomy Irrigation Pressure Maintenance.
- The IV pole height will be automatically moved when a Fill step is activated.

Vitrectomy Setup

When the Anterior Vitrectomy step is entered, an automated Vitrectomy Setup screen appears. This automated screen assists the user through the proper set up and test of the selected vitrectomy probe. If the doctor does not want the screen to guide him through the vitrectomy handpiece setup procedure when the Anterior Vitrectomy step is entered, press the Off button.

Ozil® Torsional Before Phaco

The *Infiniti*[®] system has an ON/OFF setting called "OZil Torsional Before Phaco" in the General tab of the Doctor Settings dialog that affects *Ozil*[®] Pulse and

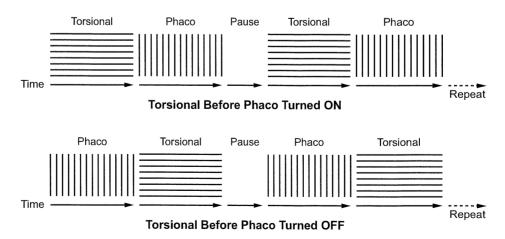


Figure 2-41 OZil® Torsional Function Before Phaco

Burst modes. When the "OZil Torsional Before Phaco" feature is turned ON, the torsional pulse of U/S energy leads the phaco (longitudinal) pulse, then there is a pause before repeating. When turned OFF, the progression is phaco/torsional/pause/repeat (as in prior software releases).

This feature is illustrated in the Figure 2-41. The top portion depicts the pulse sequence in which torsional comes before phaco; the bottom portion depicts the sequence in which phaco comes before torsional.

PEL

The Patient Eye Level (PEL) indicates the number of centimeters below the FMS that the patient's eye is located. The IV pole height is automatically adjusted to compensate for the PEL.

Default Grade

Indicates the initial cataract grade that will be selected when a doctor is selected.

• Infusion Pressure Drop

When the acquired value of the irrigation pressure sensor is below the value specified for the Infusion Pressure Drop, the system will display an advisory dialog. When this setting is 100%, this feature is disabled.

Reflux Offset

The software limits reflux pressure to a level equal to the current infusion pressure plus the value specified for the Reflux Offset, or the maximum infusion pressure the system is capable of, whichever is less.

Vent Time Adjustment

A vent time adjustment feature is used to tailor the degree of venting pressure at the tip that is adjusted in response to a vent (transition from footswitch position 2 to position 1). There are three settings: 0, 1, and 2. Zero is the default which provides unmodified venting performance. Settings 1 and 2 increase the net pressure experienced at the handpiece tip after a vent.

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Steps Tab

According to doctor's preferences the Irrigation Footswitch, Coag, Vit, and Fill steps can be placed at different locations in the surgery step sequence by enabling these buttons.

- Irrigation Footswitch Before Phaco Steps
 The Irrigation Footswitch step can be placed before phaco steps in the surgery step sequence by pressing the Enable button.
- Capsule Wash
 The Capsule Wash step uses the *AquaLase*® mode to clean the posterior capsule.
 When enabled, the Cap Wash step is placed before the last I/A step for all procedures. The *AquaLase*® handpiece must be primed and tuned prior to use.

procedures. The *AquaLase*[®] handpiece must be primed and tuned prior to use. Unlike the regular *AquaLase*[®] step, there is no burst control, and PPS maximum and Magnitude Limit are different.

- Coag Before Phaco Steps Coag After I/A Steps
 The Coag step can be placed before the phaco steps and/or after the I/A steps in
 the surgery step sequence by enabling these buttons. The Power and Fixed/Linear
 settings in the Coag Before Phaco Steps are unique, and are not shared with other
 coagulation steps.
- Vit Before I/A Steps Vit After I/A Steps
 The Vit step can be placed before and/or after the I/A steps in the surgery step sequence by enabling these buttons.
- Fill Before I/A Steps Fill After I/A Steps
 The Fill step can be placed before and/or after the I/A steps in the surgery step sequence by enabling these buttons. If Irrigation Fill is enabled in System Settings, this step will be Irrigation Fill.

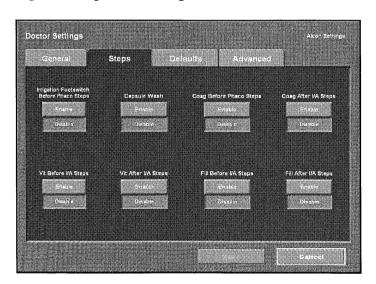


Figure 2-42 Doctor Settings Dialog Screen - Steps Tab

Defaults Tab

Selecting this tab allows the user to select default settings for the active surgeon, shown in the upper right corner of the screen (in this case the active surgeon is Alcon Settings). Enabling the options in this screen will activate the selected Handpiece, Tip, and Procedure each time the associated doctor name is activated. If Defaults are not enabled, the doctor's settings will return to those "last used."

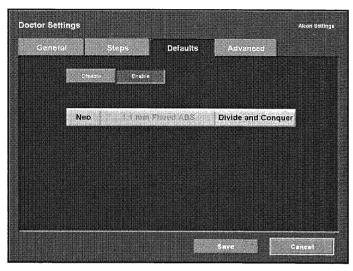


Figure 2-43 Doctor Settings Dialog Screen - Defaults Tab

Advanced Tab

Selecting this tab from within the Doctor Settings screen allows the user to enable or disable the Custom Pulse feature, and to change the settings for the *OZil*[®] IP feature.

• Custom Pulse

Use this button to enable or disable the Custom Pulse feature in phaco steps. (Refer to the Ultrasound (U/S) mode of operation section of this manual for details on the Custom Pulse feature.)

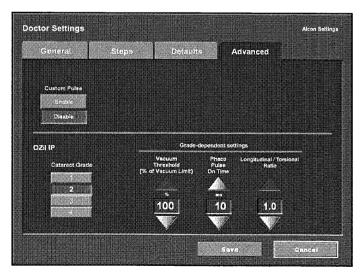


Figure 2-44 Doctor Settings Dialog Screen - Advanced Tab

$OZil^{\otimes}$ IP

Use these controls to adjust settings for the $OZil^{\otimes}$ IP (Intelligent Phaco) feature (see Figure 2-44). The settings allow the user to specify the $OZil^{\otimes}$ IP control parameters used in the enabled steps.

This $OZil^{\otimes}$ IP feature can be enabled or disabled for individual phaco steps. In addition, the $OZil^{\otimes}$ IP settings can be tailored for each cataract grade. (Refer to the $OZil^{\otimes}$ Mode of Operation in this manual for instructions on enabling and disabling this feature.) The settings specified in this screen are applied to the phaco steps for which the $OZil^{\otimes}$ IP feature is enabled.

- Cataract Grade
 Each of the *OZil*® IP settings can be established as a function of cataract grade.
- Vacuum Threshold (% of Vacuum Limit)

 The Vacuum Threshold setting determines the percentage of the vacuum limit set value at which the $OZil^{\circ}$ IP feature is activated and its specified phaco power is applied. When vacuum reaches and/or exceeds the vacuum threshold, then the $OZil^{\circ}$ IP feature, if enabled, is activated. When the vacuum drops below the vacuum threshold value, then the $OZil^{\circ}$ IP feature is deactivated.
- Phaco Pulse On Time
 The Phaco Pulse On Time specifies the on-time of an applied phaco pulse during activation. These phaco pulses are applied at 10 pulses per second until either the vacuum level falls below the threshold or the total accumulated pulse time exceeds 200 mS. *OZil*® IP functionality can be turned off for a particular cataract grade if the Phaco Pulse On Time is set to Off.
- Longitudinal / Torsional Ratio
 The Longitudinal / Torsional Ratio establishes the applied phaco power level
 relative to the applied torsional amplitude. This ratio is expressed as a decimal
 fraction and ranges from 0.7 to 1.0.

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1.9.2 Save

The Save dialog can be invoked when a change has been made to the current surgical parameters and the user selects the Save option from the *Custom* drop list menu. If there are no unsaved changes, the Save button is disabled.

The Save dialog provides the user with three buttons: Save, Discard Changes, and Cancel. If the Save button is pressed, the changes are saved to the current doctor. If Discard Changes is selected, the unsaved changes to the surgical parameters for the current doctor will be discarded and the dialog will be closed. If Cancel is selected, surgical parameters will not be saved to the current doctor and the dialog will close.

The Alcon Settings doctor is the factory default and cannot be permanently changed. When Alcon Settings is the current doctor, the Save dialog provides the user with three buttons: Save As, Discard Changes, and Cancel. If the Save As button is pressed, a keyboard appears allowing the user to add a new doctor. Once the new doctor is added, the changes are saved to the new doctor. Settings can be saved for up to 100 doctors. If Discard Changes is selected, the unsaved changes will be discarded and the dialog will be closed. If Cancel is selected, changes will not be saved and the dialog will close.

1.9.3 Copy/Delete

The Copy/Delete dialog is opened when the user selects Copy/Delete from the *Custom* drop list menu (see Figure 2-45). The Copy/Delete dialog allows the users to perform these actions:

- Copy data from the *Infiniti*® Vision System to a data card (backup).
- Copy data from a data card to the *Infiniti*® Vision System (restore).
- Save changes previously made to surgical parameters.
- Copy, delete, and rename groups of doctor settings on the *Infiniti*® Vision System. These settings include 1) surgical parameters for handpieces, tips, procedures, and steps; and 2) doctor preferences.
- Add, Remove, Rename, and change the order of steps.
- Select available tips to be offered at top of surgery screen for current doctor/handpiece.

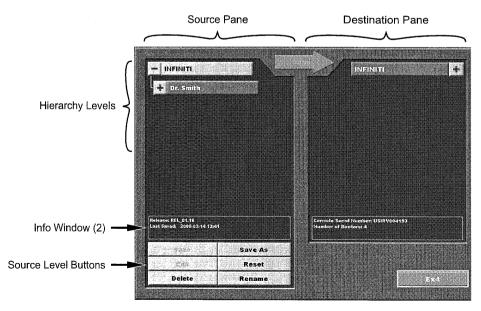


Figure 2-45 Copy/Delete Dialog

In the Copy/Delete dialog two hierarchies are shown: the left hierarchy is the *source pane* invoked with the Copy button, and the right hierarchy is the *destination pane*. The source pane can be manipulated using the source level buttons below it (Save, Save As, Edit, Reset, Delete, Rename). The destination pane cannot be similarly manipulated. The Info Window, immediately below each hierarchy, provides additional information about the selected hierarchy level.

Upon entry to the Copy/Delete dialog, the hierarchy of the source pane (on the left side) reflects the current surgical procedure. The destination hierarchy (on the right side) is not expanded and the destination pane is INFINITI.

Data Hierarchy

The first level of the hierarchy is either INFINITI or DATA CARD.

The second level under DATA CARD is either Full Backup or Doctors. The level under Full Backup is the doctor backup name, and all doctors included in that full

BACKUP / DELETE / RESTORE EXERCISE

Data card must be blank before beginning this procedure.

- 1. Backup data from *Infiniti*® console to data card.
- 1.1 Press Doctor Name (Alcon Settings) button in upper-left corner of screen.
- 1.2 Select Add Doctor from drop down list, type TEST DOC on keyboard, then press OK.
- 1.3 Select U/S handpiece, Cataract Grade 1, and press Surgery button to enter surgery screen. Select Ultrasound Continuous, and set Power Limit to 50.
- 1.4 Press the Custom button, then Save. The dialog "Save changes to the surgical step parameters of the current doctor?" appears. Press the Save button to save new doctor settings.
- 1.5 Insert data card into its slot on the right side of the Infinitf® console below the speaker.
- 1.6 Press the Custom button, then Copy/Delete.
- 1.7 Press the top-left source pane button to select **INFINITI**. Select **TEST DOC**.
- 1.8 Press the top-right destination pane button to select DATA CARD.
- 1.9 Press the **Backup** arrow button in the top-center of the screen. The system archives the TEST DOC data from the *Infiniti*® console to the data card.
- 2. Delete TEST DOC data from Infiniti® console.
- 2.1 Press **Delete** in the lower-left corner of the screen. The dialog "Delete selected doctor setting? It is currently in use" appears. Press the **OK** button.
- 2.2 Press Exit to leave Copy/Delete screen and return to surgery screen.
- 2.3 Press Alcon Settings and verify TEST DOC has been deleted from Infiniti® console drop down list.

- Restore TEST DOC data from data card to *Infiniti*[®] console.
- 3.1 Press the Custom button, then Copy/Delete.
- 3.2 Press top-left source pane button to select DATA CARD.
- 3.3 Press Doctors and select TEST DOC.
- 3.4 Press top-right destination pane button to select **INFINITI**.
- 3.5 Press the **Restore** arrow button in the top-center of the screen. The system restores the TEST DOC data from the data card to the *Infiniti*® console.
- 3.6 Press **Exit** to leave Copy/Delete screen and return to surgery screen.
- 3.7 To verify transfer of TEST DOC cataract grade 1 settings to Infinit® console, press Alcon Settings, select TEST DOC, select U/S handpiece, press Cataract Grade 1 button, Ultrasound Continuous, and verify Power Limit is 50.
- 4. Delete TEST DOC data from data card and *Infiniti*® console.
- 4.1 Press the Custom button, then Copy/Delete.
- 4.2 Press top-left source pane button to select **DATA CARD**.
- 4.3 Press **Doctors** and select **TEST DOC**.
- 4.4 Press **Delete** in the lower-left corner of the screen. The dialog "Delete doctor backup on Data Card" appears. Press the **OK** button.
- 4.5 Press the top-left source pane button to select **INFINITI**. Select **TEST DOC**.
- 4.6 Press **Delete** in the lower-left corner of the screen. The dialog "Delete selected doctor setting? It is currently in use" appears. Press the **OK** button.
- 4.7 Press top-left source pane button to select INFINITI. Press its "+" button to ensure TEST DOC is no longer on Infiniti® console.
- 4.8 Remove data card from its slot.

backup are displayed. The level under Doctors is the doctor backup name, and all doctors that have been individually backed up are displayed.

The second level under INFINITI is the doctor name. When the doctor name is selected, there is a third level which may be a handpiece, step, or preference. When a handpiece is selected, the fourth level is either an I/A tip or a phaco tip. When an I/A tip is selected, the fifth level is an I/A step. When phaco tip is selected, the fifth level is a phaco procedure, and the sixth level is a phaco step.

Collapse/Expand Buttons

The Collapse button (–) is displayed to the left of each non-selected level in the hierarchy. Touching this button hides all lower levels, making the label at that level the selected label. The Expand button (+) is displayed to the left of each level for which a lower level exists. Touching this button opens the node selection drop-down menu for the next lower level.

Label Selection Button

Each hierarchy level is a button which displays a drop-down menu of possible labels for that level when touched. Selecting an item from this list collapses all lower levels, changes to the selected label, and opens the drop-down menu for the next lower level. The system provides a visual indication in all levels to indicate there are unsaved parameters.

Copy/Delete - Handpiece Tip Selections

To ease setup, the system supports the ability to show only doctor-selected tips in the Tip Selection Dropdown display, at the top of the surgery screen, for the selected doctor and handpiece. Enabling /disabling occurs within this copy/delete screen where an enabled tip is highlighted while a disabled tip is grayed out. Disabled tips do not appear in the Tip Selection Dropdown display, nor do they appear in the Tip Selection Menu in the Defaults tab of the Doctor Settings Dialog.

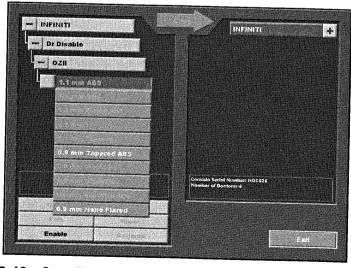


Figure 2-46 Copy/Delete Dialog with Enabled and Disabled Tips - For the selected doctor and handpiece, tips colored white are enabled and will be shown in surgery screen's Tip Selection Dropdown list, while grayed out tips will not be shown.

Copy Button

The Copy button, located above and between the left and right hierarchies, is used to copy data from the source (left) node to the destination (right) node. When the Copy button is touched the action taken is determined by the source and destination.

The button is labeled Copy when the source node is a surgeon, and the destination node is a surgeon. The button is labeled Back Up when the source node is INFINITI, and the destination node is DATA CARD. The button is labeled Restore when the source node is the DATA CARD, and the destination node is INFINITI.

Info Window

The Info Window, immediately below each hierarchy, provides additional information about the selected node. If a Backup doctor node or doctor node is selected, the Info Pane displays the date and time at which the parameters were archived and the software release. If the selected node has lower level nodes, the Info Pane provides a preview of the lower level nodes.

Source Node Manipulation Buttons

The Save, Save As, Edit, Reset, Delete, and Rename buttons are used to manipulate the source node. The destination node cannot be similarly manipulated.

- Save When parameters have been changed during surgery, this button can be pressed to update the procedure type with the new settings.
- Save As This button is pressed to save current settings under a new procedure type name using the on-screen keyboard.
- Edit To edit the steps of a procedure type, press this button to open an editing dialog. The sequence, names, icons, and number of steps can be manipulated in this dialog using its Delete, Rename, Add As, and Edit buttons.
- Reset Reset data to system default settings.
- Delete When enabled this button can be pressed to delete the highlighted label.
- Rename When this button is enabled it can be pressed to activate an on-screen keyboard. Typing in a new name will replace the old name.

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1.9.4 System

The System Settings dialog is invoked when the user selects System from the *Custom* drop list menu. This dialog enables the user to view and modify the current system settings such as Language, Remote Channel, IV Pole Extender, Alphabetize Doctor Menu, Irrigation Fill, Date, and Time. System settings apply to all doctors, and remain in effect until modified; the settings are not lost when the system is powered down. The System Settings dialog has a Save button and a Cancel button. If Save is selected, the current settings are saved to persistent storage, the dialog closes, and the settings take immediate effect. If Cancel is selected, the dialog closes and any changes made to the system settings are neglected.

Setting Remote Channel

The remote channel displayed in the System Settings dialog is for display only. To change the remote channel, press the Remote Channel button to bring up the remote control graphic with instructions to change the remote channel; this screen must be displayed while changing the remote channel. The newly-selected remote channel takes effect immediately. Pressing Cancel on the System Settings dialog returns the system to its previously-saved remote channel.

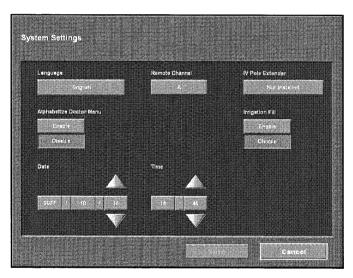


Figure 2-47 System Settings Dialog

IV Pole Extender

The *Infiniti*® system supports the use of the *Alcon*® IV pole extender. This extender has two hooks. Use of the upper hook extends the upper and lower limits of the IV pole by 32 cm (increased from 110 cm to 142 cm, and 13 cm to 45 cm). The maximum PEL is -39 cm.

Use of the IV pole extender applies to all users. Once the extender is physically attached to the system it must be enabled through the System Settings dialog, and the upper hook must be used by all users.

Enabling the use of the extender is done by depressing the IV Pole Extender button in the System Settings dialog. This brings up the IV Pole Extender Settings dialog where the extender can be "Installed" or "Not Installed." When Installed is selected, the

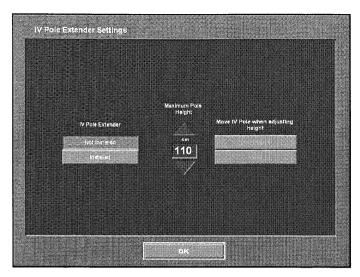


Figure 2-48 IV Pole Extender Settings

system automatically compensates for the additional height and the upper hook must be used. There is no need to adjust the PEL setting to account for the extender. When Installed is selected, the Maximum Pole Height setting feature is enabled, allowing the user to adjust the IV pole maximum height. This feature is used to protect against inadvertent damage to overhead structures. When the "Move IV Pole when adjusting height" is set to "Move," then the IV pole tracks to the maximum pole height setting while the adjustment is made.

WARNINGS!

Once the IV pole extender is installed, the upper hook is to be used. Do not change bottle height by manually hanging the bottle on the lower hook. Manually lowering the IV bottle to the lower hook will introduce an error in the displayed height indication and negatively impact the performance of the Infusion Pressure Drop detection feature, causing false indications at low bottle levels.

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

Alphabetize Doctor Menu

When enabled, the doctor names presented in a drop list at the top of the Setup and Surgery screens are alphabetized, starting after Alcon Settings and Add Doctor. If not enabled, the doctor last-used is presented after Alcon Settings and Add Doctor.

Irrigation Fill

When enabled, irrigation is activated without reflux to fill handpiece. The result is that the Irrigation Fill step replaces the Fill step, in all instances, for all users of the console.

1.9.5 **Sound**

The Sound dialog is invoked when the user selects Sound from the Custom drop list menu. The Sound dialog enables the surgeon to set a volume level for all tones and voice confirmations.

The volume levels are set individually. When an individual button is selected, the volume level adjustment will pertain only to the selected tone. Each selection; except for Vacuum Level, Phaco Occlusion, and Coagulation Power; may be turned Off so that no tone will be heard. Pressing the Play Sound button emits a sample of the volume level selected.

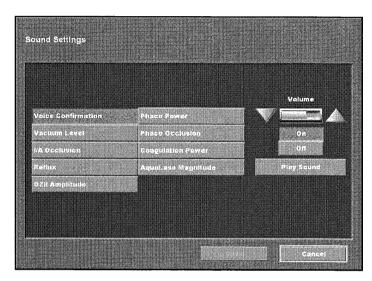


Figure 2-49 Sound Settings Dialog

1.9.6 AqL Occlusion

The AquaLase® Occlusion feature is invoked when the user selects Aql Occlusion from the Custom drop list menu. The AquaLase® Occlusion feature enables the surgeon to specify parameters (Magnitude and Burst) for reduction of AquaLase® power at the onset and full occlusion during AquaLase® surgery steps. The Total Power Reduction readout is the product of the Magnitude and Burst settings.

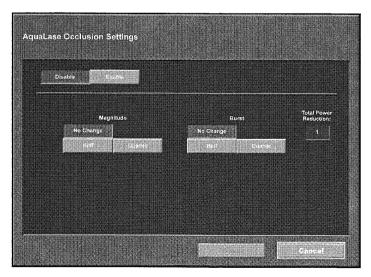


Figure 2-50 AquaLase® Occlusion Settings Dialog

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The *AquaLase*[®] Occlusion feature can be enabled and disabled by pressing the appropriate button in this menu. When enabled, a button in the surgery screen's horizontal Adjust bar indicates whether occlusion watch is off or on, and user is able to press this button to turn it on or off.

1.9.7 About

The About dialog is invoked when the user selects About from the *Custom* drop list menu. The About dialog displays the software and hardware revisions for system mechanisms, is for display only, and may not be modified by the user. Pressing OK closes the About dialog and returns the system to its prior state.

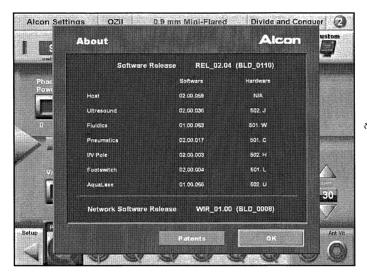


Figure 2-51 About Dialog

1.9.8 Shutdown

Pressing the Shutdown button invokes a message asking if the user wants to Shutdown system? Pressing the Cancel button in the dialog returns the system to its prior state; pressing OK turns standby power off. To turn system power off the user must then press the power switch at the bottom of the *Infiniti*® Vision System rear panel.

2. Setup Status Window

This area of the Setup Screen is used to display current system status during the setup phase of operation, and is for display only (see Figure 2-52). The user is alerted to situations like handpiece status ("Tuned," "Not Tuned," etc.), prime status, and type of FMS. The user can also be alerted when a remote control battery is low, or the *AquaLase*®/Balanced Salt Solution bottle is inserted. This area is also used for pictures to help the user perform a procedure (i.e., luers being connected to a handpiece).

If a valid FMS is not inserted, "No FMS" is displayed in the Setup Status area, and the Prime FMS, Fill, and Test Handpiece Setup Steps are unavailable. Text is displayed in the Setup Status area indicating "Insert FMS..."

When a valid FMS is inserted, "Calibrating FMS" is displayed while the fluidics mechanism performs a test of the aspiration pressure sensor. If the test fails, a dialog is displayed and the FMS is rejected. If the test succeeds, the FMS type and "Not Primed" is displayed, and the Prime FMS and Fill Setup Steps are available. The Test Handpiece button is not available until the system is primed and a valid handpiece is connected to the system.

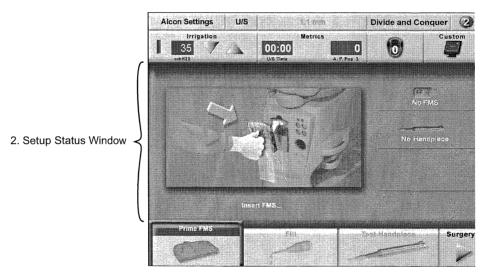


Figure 2-52 Functional Area of the Setup Status Window

3. Setup Steps

This area of the Setup Window is used for initiating setup functions as well as activating the surgery screen (see Figure 2-53). At power-up the system enters the grayed-out Setup Screen with the Doctor Name dropdown list displayed. One of the doctor names must be selected to continue with the system setup. After a doctor is selected the complete Setup Screen appears, and the Prime FMS button is highlighted. NOTE: It is important to follow the setup sequence as indicated on the *Infiniti*® Vision System display screen and/or as written in section three of this operator's manual. Not following the directions could lead to priming failures.

3.1 Prime FMS Button



The Prime FMS button may be selected as long as a valid FMS is installed, regardless of current prime and tune status. With the irrigation and aspiration luer fittings connected together, the priming sequence is 1) raise the IV pole, 2) draw fluid, and 3) vacuum/vent check. When selected, the Prime FMS button is highlighted, metrics are reset to 0, and a priming dialog box is invoked which contains the following:

- Progress bar to show the progress of the draw fluid priming sequence.
- Vacuum bar as well as the actual vacuum value to show the vacuum check progress and actual vacuum value.
- Text message indicating "Drawing Fluid...", "Checking Vacuum..."
- Two buttons; one for Advance to Vacuum Check, and another for Cancel.

Once the prime sequence is initiated and the system is raising the IV pole or drawing fluid, then pressing Advance to Vacuum Check on the dialog will immediately skip to the vacuum/vent check. Once the prime sequence is initiated it can be aborted by pressing Cancel or by removing the FMS.

When the priming and vacuum checks are completed successfully, the prime status becomes "Primed" and the Fill Button is highlighted.

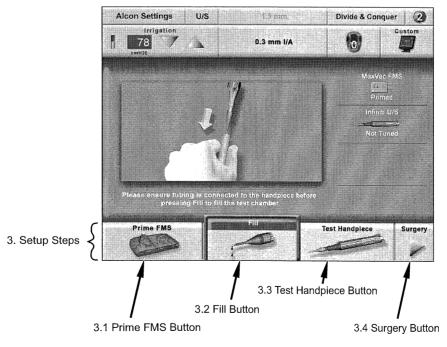
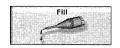
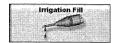


Figure 2-53 Functional Areas of the Setup Steps Window

3.2 Fill or Irrigation Fill Button





The Fill button is automatically highlighted when the priming sequence has completed successfully (if Irrigation Fill is enabled in System Settings, this button will be Irrigation Fill). Pressing the Fill Button activates the fluidics system to fill the handpiece. During the fill process a text message indicating "Filling Handpiece..." appears on the screen. Also displayed is a dialog with a Cancel button and an Advance To Test button. (Note that the Advance to Test button is ghosted if the conditions for testing are not met.)

Once the fill sequence is initiated it can be aborted by pressing Cancel or by removing the FMS, whereby the Fill dialog closes and the Fill Button remains highlighted. If Advance To Test is pressed, or if the system is left to proceed to completion, the Fill dialog closes and the Test Handpiece function is selected.

The Fill step activates both irrigation and reflux to clear air bubbles from the fluidics system. If Irrigation Fill is enabled, irrigation is activated without reflux.

3.3 Test Handpiece Button



The Test Handpiece button may be selected only when the FMS is primed and the selected handpiece is inserted. In addition, if an *AquaLase*[®] handpiece is selected, the *AquaLase*[®] bottle must be inserted.

The *Infiniti*[®] Vision System allows an *AquaLase*[®] and a U/S, *NeoSoniX*[®], or *Ozil*[®] torsional handpiece to be connected at the same time, but the user must perform the Test Handpiece sequence for each handpiece; once when the U/S or *NeoSoniX*[®] handpiece is selected, and once when the *AquaLase*[®] handpiece is selected.

When the Test Handpiece button is selected the test handpiece dialog will display progress of the flow check with a vacuum bar as well as the actual vacuum value. A Cancel button also appears. Once the test sequence is initiated, it can be aborted by the user by pressing Cancel or removing the FMS, or it can be left to proceed to completion. For the *AquaLase*® handpiece only, a momentary collapse of the test chamber is normal.

Upon successful completion of the handpiece test sequence, the system exits the Setup Screen and enters the appropriate Surgery Screen.

3.4 Surgery Button



If the Surgery button is pressed the system goes to the appropriate Surgery Screen as determined by the procedure selected. The first surgery step for the doctor's procedure is entered.

SURGERY SCREEN AND ITS FUNCTIONS

The Surgery Screens contain the buttons, readouts, and controls that allow the user to perform surgical functions. This screen is displayed when one of the following occurs:

- The Surgery button is pressed from the Setup Screen.
- The Test Handpiece function is completed in the Setup Screen and no other connected handpieces are "Not Tuned."

The Surgery Screen is divided into three sections (see Figure 2-54). At the top is the Main Window, below that is the Surgery Control Window, and below that is the Surgery Menu. Depending on the handpiece, procedure type, and surgery step selected, the Surgery Screen is updated with the buttons and surgical parameters corresponding to the selections. Although several representative surgery screens are shown in this section of the manual, screens showing all handpiece/procedure/steps are not shown.

1. Main Window

The buttons in the Surgery Main Window for U/S are nearly the same as the buttons in the Setup Main Window (see Setup Screen earlier in this section of the manual for descriptions). The Main Window for I/A, Coagulation, and Vitrectomy are discussed later in this section.

Depending on the active surgery step, the buttons available in the Main Window vary; however, the behavior of a button is consistent, regardless of the surgery step from which it is pressed. All buttons are available regardless of whether the footpedal and/or

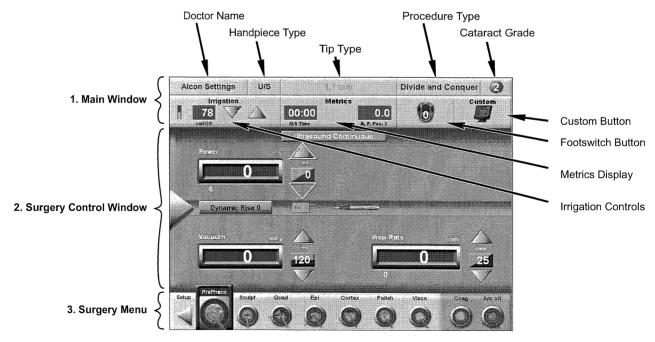


Figure 2-54 Functional Areas of the *Infiniti*® Vision System Surgery Screen - This screen is for the Ultrasound Continuous mode of operation. Other modes of operation look similar to this, but may have more or fewer buttons and surgical parameters corresponding to the surgery step.

a footswitch button is depressed or not depressed, and the functionality provided by the footswitch will continue.

- Doctor Name
 When a new doctor is selected, the system setup is changed to the settings associated with the newly-selected doctor.
- Handpiece Type, Tip Type, Procedure Type, and Cataract Grade
 These selections along the top row of the Main Window are displayed during
 U/S, NeoSoniX®, Ozil®, and AquaLase® steps. The selections change during I/A,
 Vitrectomy, and Coagulation steps.
- Irrigation Controls, Metrics Display, Footswitch Button, and Custom Button These selections along the second row of the Main Window are displayed in all step types. Their descriptions, except for Metrics, are the same as in the Setup Screen.

2. Surgery Control Window

This window contains an Information Bar. Surgical parameters are situated above and below the bar. Parameters related to the fluidics, vacuum, and aspiration flow rate are located below the bar. Parameters related to the chosen mode, for example ultrasound power, are located above the bar. Parameters above the bar are independent of the fluidics parameters. The content of these areas is determined by the active surgical step.

The actual values for certain parameters are shown using Display Bars. With the exception of the Vacuum parameter, the upper limits of the Display Bars are equal to their maximum settings. For the Vacuum parameter, if the vacuum limit is set to 650+, then the upper limit does not exist; otherwise, the upper limit is equal to the vacuum limit setting.

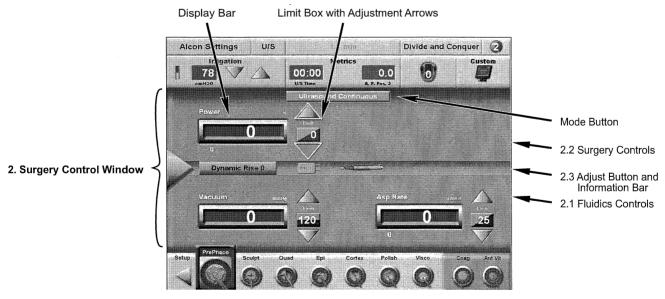


Figure 2-55 Surgery Control Window - Above the Adjust bar is the area reserved for Surgery Controls, and below the bar is the area reserved for Fluidics Controls. This Surgery Control Window is used to adjust system settings with the up/down arrows, and to observe current performance levels on the Display Bars. Depending on the mode of operation, the Adjust Button is used to adjust other settings.

Saving Modifications to Surgical Parameters

Each surgery step has surgical parameter values that are established by default. During surgery the user may change surgical parameters in any of the steps. Any parameter changes made may be explicitly saved by the user using the Save option in the Custom drop list. Also, if there are unsaved changes to the surgery steps and the user changes the doctor, phaco handpiece, phaco tip, I/A tip, or lens removal procedure, a dialog box appears asking the user to save or discard any unsaved changes. Powering down the system automatically dismisses any unsaved changes.

2.1 Fluidics Controls

Below the Information Bar in the Surgery Control Window are the Fluidics Controls. These parameters are always vacuum and aspiration and are independent of the Surgery Controls. Fluidics Controls are available in all steps but Coagulation.

2.2 Surgery Controls

For Phaco steps, the area above the Information Bar contains the Surgery Controls for U/S functions. The surgery controls available are dependent on the type of lens removal step and mode selected. The possible parameters are a power bar to display a real-time representation of the actual power level, a linear/fixed button to toggle between linear (/) or fixed (-) footswitch-controlled power, and limit boxes with adjustment arrows to display and set maximum or minimum settings (see Table 2-3).

The Mode button in the top-center of this area displays the current mode (continuous, pulse, custom pulse, burst) for the step. The mode can be changed by pressing the Mode Button and selecting another from a drop list. Depending on the current handpiece the mode selections are:

- Ozil® Continuous
- *NeoSoniX*® Continuous
- Ultrasound Continuous
- Vit Cut I/A

- Ozil® Pulse
- NeoSoniX® Pulse
- Ultrasound Pulse
- Vit I/A Cut

- Ozil® Burst
- NeoSoniX® Burst
- Ultrasound Burst
- Ozil® Custom Pulse NeoSoniX® Custom Pulse Ultrasound Custom Pulse

For *AquaLase*[®], Irrigation/Aspiration, Coagulation, and Capsule Wash, the top-center of this area displays the current mode, but is not a button.

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Ultrasound, NeoSoniX®, AquaLase®, Coagulation, Vitrectomy

MODE	Power % Bar	Power Limit Linear/Fixed Button	Burst % Time On Bar	Burst % Time On Limit Linear/Fixed Button	pps Box	% Time On Box	On ms Box	On ms Limit	Off ms Limit	Amplitude Box	Threshold Box	Cut Rate cpm Bar	Cut Rate Limit Box
Ultrasound Continuous	Х	×											
Ultrasound Pulse	х	×			х	Х							
Ultrasound Burst	х	×					Х		Х				
U/S Custom Pulse	Х	×						Х	X			•	
NeoSoniX® Continuous	х	×								Х	Х		
NeoSoniX® Pulse	х	×			х	Х				Х	Х		
NeoSoniX® Burst	х	×					х		Х	Х	*		
NeoSoniX® Custom Pulse	х	х						Х	Х	Х	Х		
AquaLase®	X*	X*	Х	Х	Х								
Coagulation	Х	Х											
Vitrectomy												х	Х

 $^{^{\}star}$ For $\textit{AquaLase}^{\text{@}}$ these labels are Magnitude instead of Power.

OZil®

Mode	Phaco Power/ Torsional Amplitude									
	% Bar	Limit Linear/Fixed Button	On ms Limit Linear/Fixed Button	l .	On ms	% Time On	Off ms Limit	PPS		
<i>OZil[®]</i> Continuous	Х	х								
<i>OZil</i> ® Pulse	х	Х				х		х		
<i>OZil</i> ® Burst	x	x			х		Х			
<i>OZil</i> ® Custom Pulse	Х	х	х	x						

Table 2-3 PARAMETERS IN SURGERY CONTROLS AREA - The top half of the Surgery Control Window contains surgery controls; fluidics controls are in the lower half. Listed here are the operating parameters in the surgery controls section for identified surgical modes.

Lower and Upper Limits

The system now allows for lower limits to be established for any parameter setting in which linear mode is supported. This lower limit can be set between 0 and the upper limit. Once a linear footpedal position is entered, the parameter starts at the lower limit and increases to the upper limit at the end of that footpedal position.

To adjust the lower limit, touch the active bar graph; an adjustment window appears on top of the value being adjusted (see Figure 2-56). Press the up and down arrows to select the desired lower limit setting, then press OK. (Lower and upper limits can both be adjusted in this window. The upper limit can also be adjusted in the surgery screen without entering this adjustment window.)

The lower limit setting is shown in the surgery screen below the lower-left corner of the bar graph.

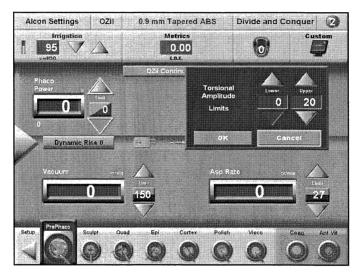


Figure 2-56 Lower and Upper Limits - This is an example of an adjustment window with upper and lower linear control limits that is displayed by pressing an active bar graph; in this case the Torsional Amplitude bar graph was pressed.

2.3 Adjust Button and Information Bar

When the Adjust button is pressed, the Display Bar is depicted with buttons representing the current settings of each of the Adjust parameters. The Adjust parameters may be changed at this time. If the parameter is a drop down type, when the parameter button is pressed, a drop down list appears and the user can select the option desired. If the parameter is a toggle type, when the parameter button is pressed, the value will be toggled. The Display Bar can be removed manually by pressing the Adjust Button again, or by waiting five seconds and it will be disappear automatically. The Display Bar is available in all surgery steps except Coagulation.

Dynamic Rise - The value in the display bar indicates the current rise time for the aspiration pump rate adjustment at occlusion onset. The Dynamic Rise setting can vary from -2 to 4, in increments of 1. When Dynamic Rise -2 is displayed in the Adjust Bar, it indicates that the rise time in aspiration pump rate adjustment is

slowest. When Dynamic Rise 4 is displayed in the Adjust Bar, it indicates that the rise time in aspiration pump rate adjustment is fastest. The Alcon default setting is 0.

WARNING!

The use of Dynamic Rise setting 1, 2, 3, or 4 may result in aspiration levels (volumes) exceeding irrigation flow. This may cause chamber shallowing or collapse which may result in patient injury.

Occlusion Watch Off/On - Occlusion Watch is enabled in the *Custom/AqL Occlusion* menu. When enabled it can be turned on and off in this information bar. When Occlusion Watch On is displayed in the Adjust Bar, it indicates that auto-attenuation of occlusion-based power is active. When Occlusion Watch Off is displayed in the Adjust Bar, it indicates that auto-attenuation of occlusion-based power is inactive.

Status Icons - These icons indicate the presence and status of the active handpiece, FMS, and bottle of *AquaLase*® *BSS*® sterile irrigating solution.

OZil® IP Icon - When the OZil® IP feature is enabled for a particular surgical step, this icon is colored and animated; when disabled, this icon is greyed out. Pressing this icon button displays the OZil® IP dialog which allows the feature to be enabled/disabled for the currently-active surgical step. Refer to the OZil® IP Feature later in this section of the manual.

2.4 Surgery Controls Window with I/A Steps

All I/A steps contain the same Fluidics Controls for vacuum and aspiration. The Surgery Controls area above the Display bar does not contain any surgical parameters, but does display a mode indicator showing Irrigation/Aspiration.

2.5 Surgery Controls Window with Vitrectomy Steps

All Vitrectomy steps contain Surgery Controls for cut rate parameters, and Fluidics Controls for vacuum and aspiration parameters. The Surgery Controls area also contains a Mode Button indicating the current Vitrectomy step type (Vitrectomy I/A Cut or Vitrectomy Cut I/A).

2.6 Surgery Controls Window with Coagulation Steps

All Coagulation steps contain just one surgical parameter: Power. This parameter is displayed in the upper portion of the Surgery Control Window. This window also contains a mode indicator showing Coagulation.

The Power and Fixed/Linear settings in Pre-Phaco Coagulation (enabled in Steps tab of Custom/Doctor dialog) are unique and are not shared with other coagulation steps.

2.70

3. Surgery Menu

The Surgery Menu consists of the buttons at the very bottom of the surgery display (see Figure 2-57). These buttons represent all the surgery steps for the currently selected surgery mode, plus a Setup button to quickly return to the Setup screen.

The Surgery Menu allows up to 10 visible buttons across the bottom of the surgery display screen. The Setup button is always on the far left, followed by up to 7 buttons corresponding to the lens removal and I/A steps. The last two buttons are for the coagulation and anterior vitrectomy steps. The Setup, coagulation, and anterior vitrectomy buttons are fixed, however the 7 buttons corresponding to lens removal and I/A steps are scrollable to the left and right. This scrolling is necessary since more than 7 lens removal and I/A steps may be specified.

The lens removal steps correspond to the selected tip, procedure, and handpiece. The I/A steps correspond to the selected I/A tip and procedure. When selecting the step that is furthest left (e.g. next to the Setup button) or furthest right (e.g. next to the stationary coagulation button), the lens removal and I/A steps will scroll so that all steps before or after the selected step, respectively, can be seen.

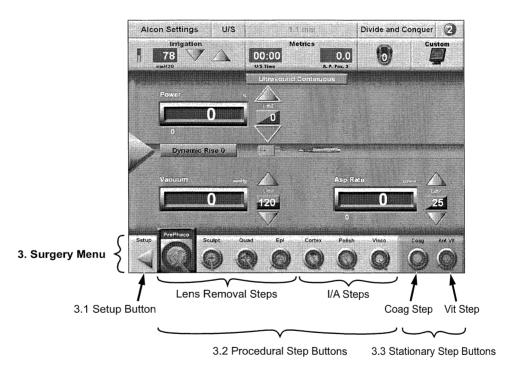


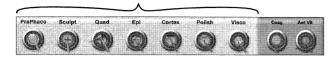
Figure 2-57 Surgery Menu - At the bottom of the display screen is the Surgery Menu. The buttons in this area allow the surgeon to control the surgical step progression.

3.1 Setup Button



When the Setup button is pressed, the user will be taken to the Setup screen. To enter the Setup screen the footpedal must be released, and the footswitch buttons must not be activated.

3.2 Procedural Step Buttons



When a surgery step is selected, its button is highlighted with a frame, and the surgical parameters for the surgery step are displayed in the Surgery Control Window. In addition, the Surgery Main Window is updated with the buttons that are applicable for the selected step.

Step changes in lens removal and I/A modes are allowed regardless of footpedal position. A step change into Coag or Vit is allowed with the footpedal depressed, but the footpedal must be released to exit.

Procedural Steps

The *Infiniti*® Vision System provides operational surgical steps to support efficient lens removal. Each step allows for the adjustment of surgical parameters such as power, aspiration, and vacuum settings according to doctor preferences. These steps are arranged in sequential order from left to right across the bottom of the screen to provide a complete surgical procedure of different settings associated with different aspects of the procedure. Complete procedures can be saved for future use without having to re-program the instrument. Coag and Ant Vit steps can be added to the procedural sequence by enabling them from the Doctor Settings dialog (see 1.9.1). U/S, Aql, and I/A steps can be added or deleted from the Copy/Delete dialog (see 1.9.3).

The procedural steps are selectable from the unit's front display screen, from the remote control unit, or from the footswitch. Step changes will result in voice confirmation. (The user has the ability to turn this feature off via the *Custom/Sound* menus.)

Preset operating parameters for each step are programmed into the system as "Alcon Settings." These default operating parameters can be temporarily modified by using the front panel or remote. These parameters can then be permanently saved by using the Custom/Save/Save As option.

3.3 Stationary Step Buttons



Steps are always present to support Coag and Ant Vit. These two steps are selectable from the display screen and remote control, but can be exited using either the display screen, remote control, or footswitch (if footswitch button programmed for Step+, Step-, or Step±) when pedal is in position 0 or 1.

SURGERY MODES

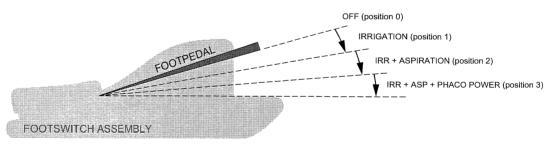
Ultrasound (U/S) Mode of Operation

When the U/S handpiece is selected, irrigation, aspiration, and phaco power are provided to the handpiece tip. Phaco power is defined as being proportional to ultrasound displacement of the phaco tip. Amplitude of the ultrasound displacement of the phaco tip is proportional to the ultrasound power displayed on the console front panel. The user has the ability to adjust the aspiration rate, vacuum levels, and phaco power at any time during the surgical procedure via their respective adjustment arrows or remote control.

Power

The phaco Power Limit is increased or decreased via the front panel in increments of 5% from a minimum of 0% to a maximum of 100%. The amount of phaco power delivered to the handpiece is controlled by one of two methods: linear or fixed footpedal control.

- If linear footpedal control is selected (diagonal button graphic), the power readout button indicates the maximum power available in footpedal position 3. In footpedal position 3, power starts at the lower limit and increases linearly until power reaches the upper limit at full footpedal depression. To change the lower and upper limits, press the active power bar to bring up the adjustment window, then press the up or down arrows which will increase or decrease the lower and upper limits.
- If fixed footpedal control is selected (horizontal button graphic), the Power Limit button indicates the power applied in footpedal position 3. To increase or decrease power, the arrow buttons must be pressed. The selected power is fully activated on transition of the footpedal into and throughout position 3.



Power

Linear or Fixed Power

Timing

Continuous: Continuous Power with No Rest Period

Pulse: Adjustable Pulse Rate Setting

Adjustable Duty Cycle

• Burst: Fixed On-Time

Decreasing Off-Time

Custom Pulse: Fixed, Increasing, or Decreasing On-Time

Fixed or Decreasing Off-Time

Figure 2-58 U/S Footpedal Control - Phaco power is delivered with the power and timing methods listed above when the footpedal enters, and then travels through, footpedal position 3.

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Timing

Phaco power is delivered to the phaco tip through a variety of timing configurations when in footpedal position 3. Depending on the mode selected the timing can be continuous, or can include moments of rest between power pulses.

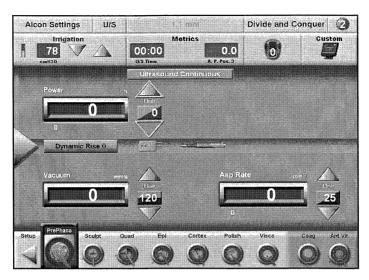


Figure 2-59 The Ultrasound Continuous Surgery Screen

• Ultrasound Continuous - This mode of operation provides continuous phaco power to the handpiece.

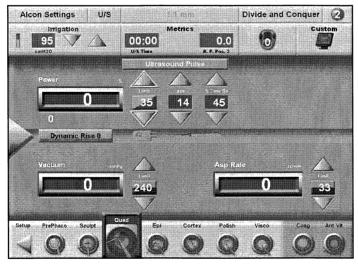


Figure 2-60 The Ultrasound Pulse Surgery Screen

• Ultrasound Pulse - When operating in this mode of operation, phaco power is turned On and Off at a frequency determined by the pulse rate setting in pulses per second (pps), and on a duty cycle adjustable by the operator (% Time On).

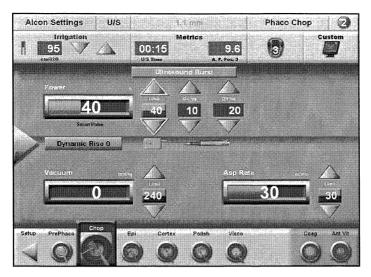


Figure 2-61 The Ultrasound Burst Surgery Screen - This is an example of the screen when the footpedal is depressed into footpedal position 3 and is delivering power for less than 20 ms. The Smart Pulse text flickers under the Power bar when power is delivered for less than 20 ms.

- Ultrasound Burst Ultrasound Burst control allows fixed or linear controlled phaco power in footpedal position 3. The power is delivered in bursts, separated by off-times. The timing of the burst and off-times occur for an operator-set duration.
 - The duration of each burst (On ms) can be increased or decreased by pressing the up or down arrows.
 - The off-time between each burst (Off ms), during which no phaco power is applied, is 2.5 seconds (2500 ms) at the beginning of footpedal position 3. The user can adjust the minimum off-time (Off ms) at the bottom of footpedal position 3 from between 500 to 0 ms (0 ms results in continuous phaco power). When in footpedal position 3 the readout displays the actual off-time.

Smart Pulse

When in footpedal position 3, and the duration of ultrasound pulse becomes less than 20 ms, a proprietary algorithm becomes active. This is indicated by the Smart Pulse message appearing on the screen below the Power bar (see Figure 2-61).

When the algorithm is active, ultrasound power will be generated at 10% or half of the commanded power, whichever is lower, prior to the application of the main power pulse. This low-powered pulse contributes a negligible amount of energy to the procedure, but it allows the electronic equipment to determine the optimum operating parameters for the main power pulse, thus making it more efficient, even for the shortest duration of ultrasound. The Smart Pulse algorithm can be active in Pulse, Burst, or Custom Pulse modes when used with the U/S, *NeoSoniX*®, or *OZil*® torsional handpieces. The minimum duration of the main pulse in ultrasound is 5 ms; the minimum duration of torsional pulse is 20 ms.

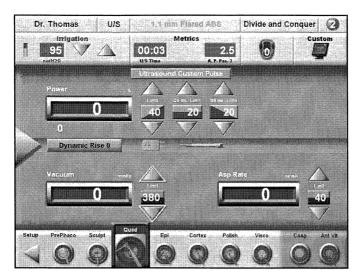


Figure 2-62 The U/S Custom Pulse Surgery Screen

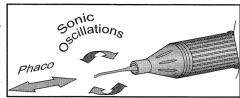
- Ultrasound Custom Pulse When operating in this mode of operation, phaco power is turned On and Off for a period of time determined by the milliseconds (ms) selected by the user (On ms Limit / Off ms Limit) and the position of the footswitch in position 3. This screen can only be accessed if it is enabled in the doctor's preferences (Custom/Doctor/Advanced/Custom Pulse Enable).
 - The on-time can be fixed at the selected setting throughout position 3, set to increase from one-fifth the set limit (ms) at the beginning of position 3 to the set limit at the end of position 3, or set to decrease from five times (ms) the set limit at the beginning of position 3 down to the set limit at the end of position 3.
 - The off-time can be fixed at the selected setting throughout position 3, or set to decrease from 2500 ms at the beginning of position 3 down to the set limit at the end of position 3. When not in footpedal position 3 the user setting is displayed; when in position 3 the actual value reported by the subsystem is displayed.

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NeoSoniX[®] Mode of Operation

When the *NeoSoniX*® handpiece is selected, irrigation, aspiration, phaco power and sonic oscillations are provided by the handpiece. In this mode of operation phaco power and

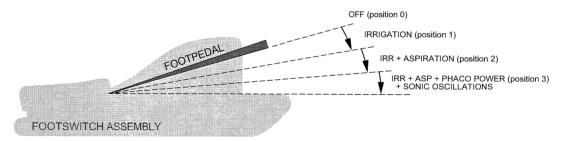
sonic oscillations alternately turn On and Off. The user has the ability to adjust the aspiration rate, vacuum levels, phaco power, and sonic oscillations (via Amplitude/Threshold settings) at any time during the surgical procedure via their respective adjustment arrows or remote control.



Power

The phaco Power Limit is increased or decreased via the front panel in increments of 5% from a minimum of 0% to a maximum of 100%. Power to the handpiece is controlled by one of two methods: linear or fixed footpedal control.

• If linear footpedal control is selected (diagonal button graphic), the power readout button indicates the maximum phaco power delivered with the footpedal fully depressed. In footpedal position 3, power starts at the lower limit and increases



Power and Sonic Oscillations

- Linear or Fixed Phaco Power
- Fixed Sonic Oscillations when U/S Power Threshold Reached

Timing

• Continuous:

Continuous Power with No Rest Period

Pulse:

Adjustable Pulse Rate Setting

Adjustable Duty Cycle

Burst:

Fixed On-Time

Decreasing Off-Time

• Custom Pulse: Fixed, Increasing, or Decreasing On-Time

Fixed or Decreasing Off-Time

Figure 2-63 NeoSoniX® Footpedal Control - Phaco power and sonic oscillations are delivered with the power and timing methods listed above when the footpedal enters, and then travels through, footpedal position 3.

linearly until power reaches the upper limit at full footpedal depression. To change the lower and upper limits, press the active power bar to bring up the adjustment window, then press the up or down arrows which will increase or decrease the lower and upper limits.

- If fixed footpedal control is selected (horizontal button graphic), phaco power is fully activated on transition of the footpedal into and throughout position 3. To increase or decrease power, the arrow buttons must be pressed.
- Sonic oscillations are activated when phaco power reaches or exceeds the (phaco power) Threshold set on the screen. At that point sonic oscillations are activated at the Amplitude set on the screen. If phaco power control is fixed, and is lower than the Threshold setting, sonic oscillations will not turn On; alternatively, if phaco power control is fixed, and is higher than the Threshold setting, oscillations turn On when the footpedal enters position 3.

Timing

Phaco power and sonic oscillations are delivered to the phaco tip through a variety of timing configurations when in footpedal position 3. Depending on the mode selected the timing can be continuous, or can include off-times between power/sonic pulses.

• *NeoSoniX*® Continuous - This mode of operation provides continuous phaco power and sonic oscillations (if Threshold reached) to the handpiece.

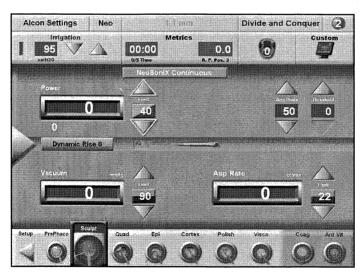


Figure 2-64 The NeoSoniX® Continuous Surgery Screen

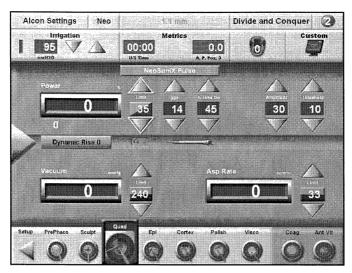


Figure 2-65 The NeoSoniX® Pulse Surgery Screen

• *NeoSoniX*® Pulse - When operating in this mode of operation, phaco power and sonic oscillations are turned On and Off with a frequency determined by the pulse rate setting in pulses per second (pps), and on a duty cycle adjustable by the operator (% Time On). Sonic oscillations are applied at the limit value specified in the Amplitude box when phaco power meets or exceeds the power value specified in the Threshold box.

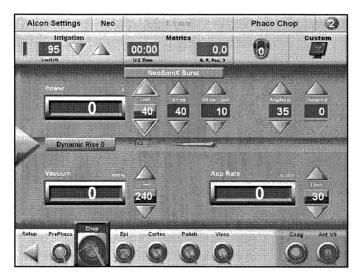


Figure 2-66 The NeoSoniX® Burst Surgery Screen

- *NeoSoniX*® Burst *NeoSoniX*® Burst control allows fixed or linear controlled phaco power and sonic oscillations in footpedal position 3. The power is delivered in bursts, separated by off-times. The timing of the burst and off-times occur for an operator-set duration.
 - The duration of each burst (On ms) can be increased or decreased by pressing the up or down arrows.
 - The off-time between each burst (Off ms), during which no phaco power or sonic oscillations are applied, is 2.5 seconds (2500 ms) at the beginning of

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footpedal position 3. The user can adjust the minimum off-time (Off ms) at the bottom of footpedal position 3 from between 500 to 0 ms (0 ms results in continuous power). When in footpedal position 3 the readout displays the actual off-time reported by the subsystem.

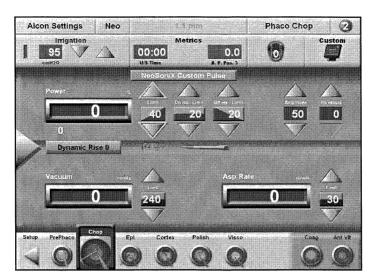


Figure 2-67 The NeoSoniX® Custom Pulse Surgery Screen

- *NeoSoniX*[®] Custom Pulse When operating in this mode of operation, phaco power and sonic oscillations are turned On and Off for a period of time determined by the time (ms) selected by the user (On ms Limit / Off ms Limit) and the position of the footswitch in position 3. This screen can only be accessed if it is enabled in the doctor's preferences (Custom/Doctor/Advanced/Custom Pulse Enable).
 - The on-time can be fixed at the selected setting throughout position 3, set to increase from one-fifth the set limit (ms) at the beginning of position 3 to the set limit at the end of position 3, or set to decrease from five times (ms) the set limit at the beginning of position 3 down to the set limit at the end of position 3.
 - The off-time can be fixed at the selected setting throughout position 3, or set to decrease from 2500 ms at the beginning of position 3 down to the set limit at the end of position 3. When not in footpedal position 3 the user setting is displayed; when in position 3 the actual value reported by the subsystem is displayed.

OZil® Mode of Operation

When the $OZil^{\otimes}$ torsional handpiece is selected, irrigation, aspiration, phaco power and ultrasonic oscillations are provided by the handpiece. In this mode of operation phaco

power and ultrasonic oscillations alternately turn On and Off. Amplitude of the ultrasound and torsional displacement of the phaco tip is proportional to the ultrasound power and torsional amplitude displayed on the console front panel. The user has the ability to adjust the aspiration rate, vacuum levels, phaco

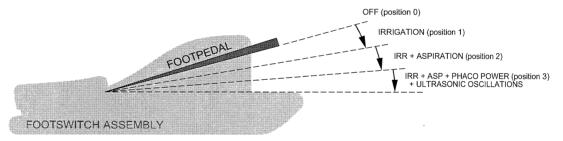


power, and torsional amplitude (ultrasonic oscillations) at any time during the surgical procedure via their respective adjustment arrows or remote control. For best performance of the $OZil^{\otimes}$ torsional handpiece, use tips recommended by your Alcon representative.

Power/Amplitude

The Phaco Power Limit and Torsional Amplitude Limit are increased or decreased via the front panel in increments of 5% from a minimum of 0% to a maximum of 100%. Power/Amplitude to the handpiece is controlled by one of two methods: linear or fixed footpedal control.

• If linear (increasing) footpedal control is selected (rising diagonal button graphic), the Limit buttons indicate the maximum phaco power and ultrasonic oscillations (Torsional Amplitude) delivered with the footpedal fully depressed. In footpedal position 3, power and oscillations start at the lower limit and increases linearly until



Power

- Linear or Fixed Phaco Power
- Increasing or Fixed Torsional Amplitude

Timing

• Continuous: Continuous Power with No Rest Period

Pulse: Adjustable Pulse Rate Setting

Adjustable Duty Cycle

Burst: Fixed On-Time

Decreasing Off-Time

Custom Pulse: Fixed, Increasing, or Decreasing On-Time

Fixed or Decreasing Off-Time

Figure 2-68 *OZII*® Footpedal Control - Phaco power and ultrasonic oscillations are delivered with the power and timing methods listed above when the footpedal enters, and then travels through, footpedal position 3.

power reaches the upper limit at full footpedal depression. To change the lower and upper limits, press the active power bar to bring up the adjustment window, then press the up or down arrows which will increase or decrease the lower and upper limits.

• If fixed footpedal control is selected (horizontal button graphic), the Limit buttons indicate the phaco power and ultrasonic oscillations delivered throughout footpedal position 3. To increase or decrease power, the arrow buttons must be pressed.

Timing

Phaco power and ultrasonic oscillations are delivered to the phaco tip through a variety of timing configurations when in footpedal position 3. Depending on the mode selected the timing can be continuous, or can include off-times between phaco/torsional pulses.

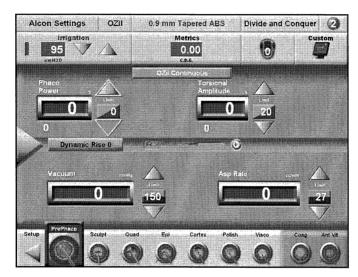


Figure 2-69 The OZil® Continuous Surgery Screen

• OZil® Continuous - When the Phaco Power default setting is set to 0 (no phaco power), then only torsional ultrasonic oscillations at the preset Torsional Amplitude are delivered, for 100% of the time, to the handpiece tip. This allows the user to have continuous torsional ultrasonic oscillations if so desired. If U/S power is added, then this mode of operation provides 20% of its duty cycle for phaco power, then torsional ultrasonic oscillations for the remaining 80% when in footpedal position 3, and repeats this cycle over and over again as long as the footpedal is in position 3. This produces continuous U/S alternations between phaco power and torsional amplitude.

The user can select between fixed (horizontal button display) or linear (diagonal button display) Phaco Power, and fixed or increasing Torsional Amplitude when in footpedal position 3 by pressing their associated buttons.

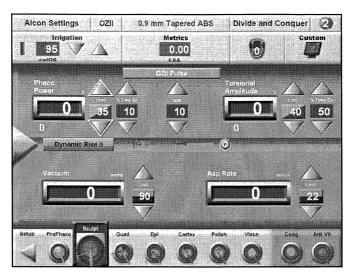


Figure 2-70 The OZil® Pulse Surgery Screen

• OZil® Pulse - When operating in this mode of operation, phaco power and ultrasonic oscillations turn On and Off at a frequency determined by the pulse rate (pps) setting, and on a duty cycle adjustable by the operator (% Time On). The remaining pulse time, or percent time Off, is an off-time. The sum of phaco duty cycle and torsional duty cycle cannot exceed 100%.

For example, in the figure above the entire cycle of phaco, torsional, and off-time is 100 ms duration because of the selected pulse rate of 10 pps. Duration of the phaco, therefore, is $100 \text{ ms } \times 10\% = 10 \text{ ms}$, and duration of the torsional is $100 \text{ ms } \times 50\% = 50 \text{ ms}$. The remaining 40 ms is an Off period. Note that the Off period follows application of torsional ultrasound, while torsional ultrasound follows application of phaco immediately with no pause.

If Phaco Power Limit (see figure below) and/or Torsional Amplitude Limit are set to zero, then there are no phaco nor torsional contributions to the pulse, and the duty cycles (% Time On) are not adjustable.



Figure 2-71 Phaco Duty Cycle (% Time On) Not Adjustable

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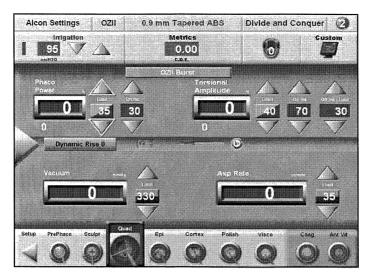


Figure 2-72 The OZil® Burst Surgery Screen

• *OZil*® Burst - When operating in this mode, phaco burst is followed immediately by torsional burst, followed by an off-time. Duration of the phaco burst is determined by the setting on the panel, for example 30 ms in the figure above; duration of the torsional burst is 70 ms. Duration of the off-time is determined by the footpedal in position 3. At the beginning it is equal to 2500 ms, and gradually reduced as the footpedal is depressed. When the footpedal is depressed all the way, the off-time will be equal to that set on the panel – 30 ms in the given example.

If Phaco Power Limit and/or Torsional Amplitude Limit are set to zero, then there are no phaco or torsional contributions to the burst, and the duty cycles (On ms) are not adjustable.

• *OZil*® Torsional Before Phaco

The *Infiniti*® system has an ON/OFF setting called "OZil Torsional Before Phaco" which affects the order of the phaco and torsional pulses/bursts in the *OZil*® Pulse and Burst modes. This feature has been previously described in the "General Tab" section of the manual.

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• OZil® Custom Pulse - When operating in this mode of operation, phaco power and ultrasonic oscillations are turned On and Off for a period of time determined by the time (ms) selected by the user (On ms - Limit / Off ms - Limit) and the position of the footswitch in position 3. The system repeats this sequence of events: phaco power on then off-time, ultrasonic oscillations on then off-time. This screen can only be accessed if it is enabled in the doctor's preferences (Custom/Doctor/Advanced/Custom Pulse Enable).

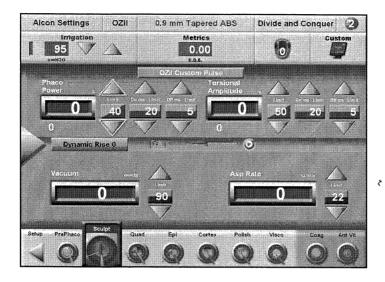


Figure 2-73 The *OZII*® Custom Pulse Surgery Screen - In this mode of operation there is a repeating sequence of events as follows: phaco power, then an off-time, ultrasonic oscillations, then an off-time. The Phaco Power Limit and Torsional Amplitude Limit set the strength of each. The duration of each is set with the On ms - Limit and Off ms - Limit settings.

- The on-time can be fixed at the selected setting throughout position 3, set to increase from one-fifth the set limit (ms) at the beginning of position 3 to the set limit at the end of position 3 (rising diagonal button graphic), or set to decrease from five times (ms) the set limit at the beginning of position 3 down to the set limit at the end of position 3 (falling diagonal button graphic).
- The off-time can be fixed at the selected setting throughout position 3, or set to decrease from 2500 ms at the beginning of position 3 down to the set limit at the end of position 3 (falling diagonal button graphic). When not in footpedal position 3 the user setting is displayed; when in position 3 the actual value is displayed.

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OZil® IP Feature

This feature can be enabled when performing surgery in the $OZil^{\odot}$ phaco mode. It is used to intelligently deliver energy combinations of phaco (longitudinal) power of equal or less magnitude when a programmable vacuum threshold is exceeded. These additional longitudinal pulses are applied only as necessary to enhance the delivery of energy, and continue until the vacuum drops below the Trigger or the maximum number of pulses has been reached.

While in the $OZil^{\otimes}$ mode of operation, the $OZil^{\otimes}$ IP feature can be enabled or disabled for each individual phaco step by pressing the $OZil^{\otimes}$ IP button icon located in the Information Bar (see Figure 2-74). When pressed, the $OZil^{\otimes}$ IP dialog appears (see Figure 2-75). $OZil^{\otimes}$ IP for the current $OZil^{\otimes}$ step is enabled by pressing the On button; disabled by pressing the Off button. Press the OK button to close the $OZil^{\otimes}$ IP dialog or it will be automatically dismissed after about three seconds of inactivity.

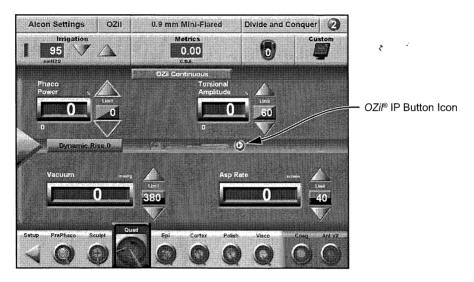


Figure 2-74 Surgery Screen with *OZil*[®] IP Enabled - When enabled for the current step, the *OZil*[®] IP button icon is colored and animated (when not enabled it is dull and gray). The user can press the button icon to pull up the *OZil*[®] IP dialog, shown below.

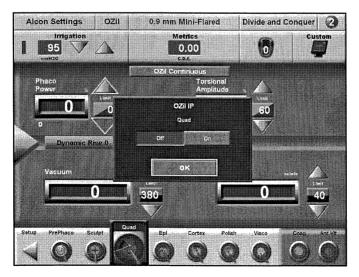


Figure 2-75 *OZil*® IP Dialog - This dialog is used to turn the *OZil*® IP feature On (enabled) and Off (disabled).

When the $OZil^{@}$ IP feature is enabled, the $OZil^{@}$ IP button icon is colored and animated for the current step. When $OZil^{@}$ IP is disabled for the selected $OZil^{@}$ phaco step, the $OZil^{@}$ IP button icon is grayed out.

The $OZil^{\$}$ IP settings are specified, and can be changed, in the Advanced tab of the Custom/Doctor dialog (see the description of the Advanced tab earlier in this section of the manual). These settings are user-adjustable so the user can specify the vacuum limit at which the $OZil^{\$}$ IP feature is activated, and the amount of pulsed phaco power that is delivered when activated. In addition, the $OZil^{\$}$ IP settings can be tailored for each cataract grade.

Even though the $OZil^{\otimes}$ IP feature may be enabled for a particular surgical step, it can be turned Off for a particular cataract grade. If it is turned Off for a particular cataract grade (turned Off by adjusting the Phaco Pulse On Time to Off) and the user presses the $OZil^{\otimes}$ IP button icon, then the user is notified that the $OZil^{\otimes}$ IP feature has been turned Off for that cataract grade (see Figure 2-76). The advisory instructs the user how to turn it On if desired.



Figure 2-76 *OZII*® IP Dialog - This dialog shows that *OZII*® IP feature is turned Off for this cataract grade. To turn it On for this cataract grade, it must first be enabled in the Custom / Doctor / Advanced window.

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AquaLase® Liquefaction Mode of Operation

When the *AquaLase*[®] handpiece is selected, irrigation, aspiration, and liquefaction energy are provided by the handpiece.

The Magnitude Limit, Pulse Rate, and Burst % are increased or decreased via the front panel adjust arrows in increments of 5% from a minimum of 0% to a maximum of 100%. Power to the *AquaLase*® handpiece is controlled by one of two methods: linear or fixed footpedal control of magnitude.

- If Fixed is selected, the output setting is displayed in the Magnitude Limit box. To increase or decrease magnitude, press the arrow buttons. The selected magnitude is fully activated on transition of the footpedal into position 3.
- If Linear control is selected, the Magnitude Limit box indicates the maximum output available. In footpedal position 3, magnitude starts at the lower limit and increases linearly until power reaches the upper limit at full footpedal depression. To change the lower and upper limits, press the active control bar to bring up the adjustment window, then press the up or down arrows which will increase or decrease the lower and upper limits.

Liquefaction energy is delivered to the *AquaLase*[®] handpiece tip through a variety of timing configurations when in footpedal position 3. Depending on the mode selected the timing can be in pulses, or can be in bursts of pulses which include off-times between sets of pulses.

PPS - The pulse frequency, or pulses per second (PPS) may be set using the up/down keys. PPS can be adjusted in increments of 5 from 10 to 50, and then jumps to 75.

• Fixed control - When Fixed is selected liquefaction energy is supplied at the selected pulse rate upon transition of the footpedal into position 3.

Burst - Burst percentage indicates the percentage of a fixed time period that is spent applying pulses of liquefaction energy, and may be adjusted in 5% increments using the control labeled "Burst." The remainder of the time period is spent off. When the limit is set to 100% the pulses are uninterrupted.

NOTE: Burst is limited to a maximum of 67% when PPS is set to 75.

- Fixed control When Fixed is selected liquefaction energy is supplied at the selected burst upon transition of the footpedal into position 3.
- Linear control If Linear is selected, the Burst Limit box indicates the maximum output available. Upon transition to footpedal position 3, burst starts at the lower limit and increases linearly until power reaches the upper limit at full footpedal depression. To change the lower and upper limits, press the active control bar to bring up the adjustment window, then press the up or down arrows which will increase or decrease the lower and upper limits.

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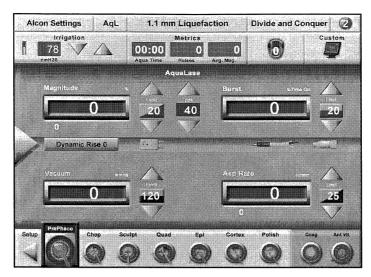


Figure 2-77 The AquaLase® Surgery Screen

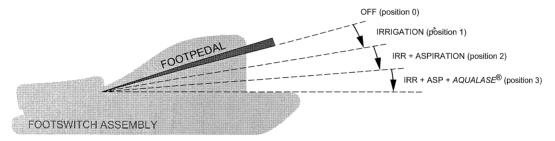


Figure 2-78 AquaLase® Footpedal Control - Liquefaction energy is delivered with the magnitude and timing methods listed above when the footpedal enters footpedal position 3.

WARNINGS!

Use of the OZil® torsional, Infiniti® NeoSoniX®, U/S, or AquaLase® 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.

Appropriate use of *Infiniti*® 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 the *OZiI*® torsional, *Infiniti*® *NeoSoniX*®, or U/S 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 *Infiniti*® Vision System pak are only to be used on the *OZil*® torsional, *Infiniti*® *NeoSoniX*®, or U/S handpieces. Each U/S tip is intended to be used only once per case, and then disposed of according to local governing ordinances.

Use 0.9 mm U/S tips exclusively with 0.9 mm infusion sleeves. Use 1.1 mm U/S and 1.1 mm liquefaction tips exclusively with 1.1 mm infusion sleeves. Mismatching U/S tips and infusion sleeves may create potentially hazardous fluidic imbalances.

Directing energy toward non-lens material may cause tissue damage.

Irrigation/Aspiration Mode of Operation

I/A provides gravity-fed irrigation and simultaneous peristaltic aspiration for use with I/A handpieces and tips. I/A control supports all surgical steps except coagulation.

In Irrigation/Aspiration mode there are only two footpedal positions. Irrigation is provided in footpedal positions 1 and 2; Aspiration is provided in footpedal position 2. To change the lower and upper linear limits in footpedal position 2, press the active power bar to bring up the adjustment window, then press the up or down arrows which will increase or decrease the lower and upper limits.

All I/A steps contain vacuum and aspiration Fluidics Control Parameters. These parameters are displayed in the portion of the Surgery Control Window below the Adjust bar. The Surgery Control Window above the Adjust bar does not contain any surgical parameters, but does contain an indication of the step type (i.e. Irrigation/Aspiration).

The following is an example of an I/A step surgery screen with the Adjust bar displayed.

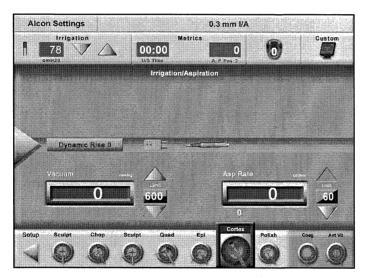


Figure 2-79 The Irrigation/Aspiration Surgery Screen

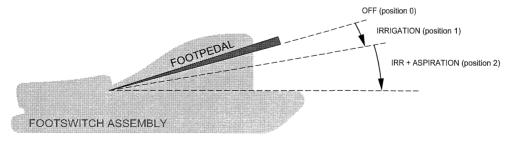


Figure 2-80 Irrigation/Aspiration Footpedal Control

Vacuum Control

The operator can adjust the vacuum limit using the front display panel or the remote. The adjustable vacuum limit range is 0 to 650+ mmHg, where 650+ is limited by atmospheric pressure.

- <u>Fixed Vacuum Control</u> Fixed vacuum control provides a fixed vacuum limit when aspirating in footpedal position 2.
- <u>Linear Vacuum Control</u> Linear vacuum control provides linear control of vacuum in footpedal position 2 where the actual vacuum limit is proportional to the footpedal position. The upper vacuum limit is the set vacuum limit displayed.

Aspiration Control

The operator can adjust the aspiration limit using the front display panel or the remote. The adjustable aspiration limit range is 5 to 60 cc/min.

- Fixed Aspiration Control Fixed aspiration control provides a fixed aspiration flow rate when in footpedal position 2.
- <u>Linear Aspiration Control</u> Linear aspiration control provides linear control of aspiration flow rate in footpedal position 2 where the flow rate is proportional to the footpedal position.

Fill Mode of Operation for Irrigation/Aspiration

The Fill step can be added before and/or after the I/A steps. When transitioned into the Fill step, irrigation and reflux will be enabled simultaneously for up to 10 seconds (if Irrigation Fill is enabled in System Settings, this step will be Irrigation Fill, and irrigation will be enabled without reflux). It is recommended to add the Fill step before the first I/A step to facilitate removal of air from the I/A handpiece. Adding the Fill step after the last I/A step will simplify cleaning of the I/A tip and handpiece. Refer to Custom/Doctor in section 1.9 for details of how to add/remove the Fill step.

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Coagulation (Coag) Mode of Operation

The Coagulation mode provides approximately 1 MHz frequency bipolar coagulation to drive Alcon brush and forceps up to the preset limit upon travel through footpedal position 2. The preset lower and upper limits are the available percentage of maximum available coagulation power from 0% to 100%. To change the lower and upper limits in footpedal position 2, press the active power bar to bring up the adjustment window, then press the up or down arrows which will increase or decrease the lower and upper limits.

The Power and Fixed/Linear settings in Pre-Phaco Coagulation (enabled in Steps tab of Custom/Doctor dialog) are unique and are not shared with other coagulation steps.

In Coagulation mode there are only two footpedal positions. In footpedal position 2 coagulation is displayed and an audible tone is initialized. As in all other steps, settings in Coag are retained in memory so that when <u>re-entering</u> the Coagulation step, the previous settings are displayed.

- <u>Fixed Coag Control</u> provides bipolar coagulation at the preset limit when the footpedal enters position 2.
- <u>Linear Coag Control</u> The control power is varied linearly from the lower limit to the upper limit. Power begins when entering footpedal position 2 and ends when the footpedal is fully depressed.



Figure 2-81 The Coagulation Screen

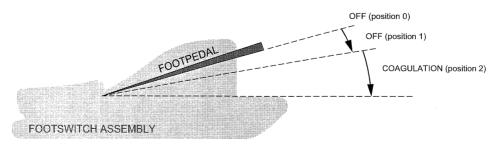


Figure 2-82 Coagulation Footpedal Control

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.

CAUTION

The *Infiniti*® Vision System is not protected against the effects of defibrillator discharge.

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Anterior Vitrectomy Mode of Operation

The Anterior Vitrectomy (Ant Vit) mode is used to drive a pneumatically operated vitrectomy cutter. The Cut Rate is adjustable from 10 to 800 cuts per minute for the 20 gauge *Infiniti®* vitrectomy probe, and from 10 to 2500 cuts per minute for the 23 gauge *Infiniti®* UltraVit® probe. Fixed and linear control of aspiration and vacuum is provided in both Vitrectomy Cut I/A and Vitrectomy I/A Cut control modes. The currently-selected vitrectomy probe is displayed in a button at the top of the vitrectomy surgery screen. When pressed, a drop down list of available vitrectomy probes appears. When a probe is selected the drop down list collapses and the selected probe is displayed.

A switch on the footswitch may be assigned to enable and disable the Vit Cutter (the left horizontal switch is an exception). When the Vit Cutter is disabled, I/A functionality in footpedal positions 2 and 3 is unchanged, but the Vit Cutter does not cut, and the message "Vit Cutter Disabled" is displayed. The assigned Vit Cutter switch may be pressed in footpedal positions 1, 2, or 3, and the function takes effect immediately.

- <u>Vitrectomy Cut I/A</u> Irrigation is provided in footpedal position 1; irrigation and guillotine-motion cutting in position 2; and irrigation, cutting, and aspiration in position 3.
- <u>Vitrectomy I/A Cut</u> Irrigation is provided in footpedal position 1; irrigation and aspiration in position 2; and irrigation, aspiration, and cutting in position 3. The operator can adjust the preset aspiration and vacuum limits using the adjustment control buttons on the control panel or on the remote control.

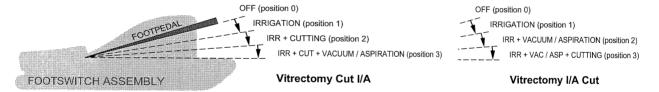


Figure 2-83 Anterior Vitrectomy Footpedal Control

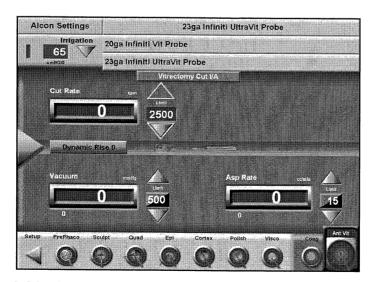


Figure 2-84 Anterior Vitrectomy Screen With Vit Probes In Drop Down List

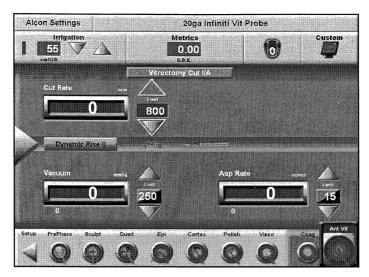


Figure 2-85 Anterior Vitrectomy Surgery Screen Using 20 Gauge Infiniti® Vitrectomy Probe

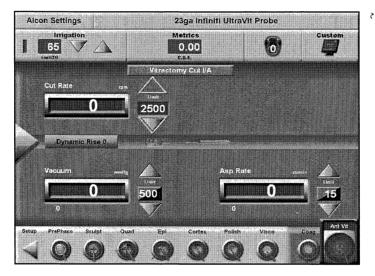


Figure 2-86 Anterior Vitrectomy Surgery Screen Using 23 Gauge Infiniti® UltraVit® Probe

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Anterior Vitrectomy Setup Screen

When the Anterior Vitrectomy step is entered, the Vitrectomy Setup screen appears (see Figure below) unless turned Off in the Doctor Settings screen. This setup screen assists the user through the proper set up and test of the selected probe.

The *Switch Probe* button allows the user to change selected probes if the desired probe is not displayed (this button appears only if hardware for *UltraVit®* probe upgrade is installed). After performing a procedural step, pressing the *Next Step* button brings up the screen for the next step. The *Fill* button allows the user to prime the irrigation and aspiration tubings and fill a test vessel for proper testing of the probe. Pressing the *Test* button initiates an automated test sequence which verifies secure pneumatic connections, then applies pneumatic activation at a reduced cut rate for visual verification of probe cutting.

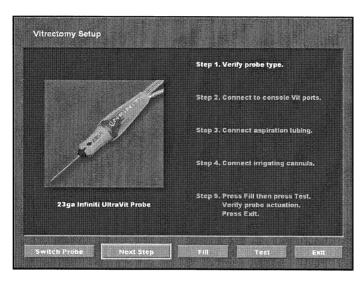


Figure 2-87 Vitrectomy Setup Screen

SECTION THREE OPERATING INSTRUCTIONS

INTRODUCTION

This section details a recommended setup and check-out procedure for the *Infiniti*® Vision System. The steps on the following pages cover preparation for cataract lens removal surgery including irrigation and aspiration, coagulation, and vitrectomy using Alcon-supplied paks.

The *Infiniti*® Vision System, including Alcon-approved consumables and accessories, 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.).

The procedures are divided into two columns and presume a surgical team of three people: Surgeon and Scrub Nurse in the sterile field, and a Circulating Nurse in the non-sterile field. In the left column a directive is given; in the right column the responsible team member is identified.

Any problems pertaining to setup and check-out procedures should first be directed to the Troubleshooting section of this manual. If questions still exist, contact the Alcon Technical Services Department or your local Alcon representative.

POWER UP SEQUENCE

When the Power switch is turned on, and the Standby switch is pressed, the *Infinitt*[®] logo screen appears while the system performs its self-test diagnostics. The *Infinitt*[®] Vision System is capable of detecting and reporting a wide range of fault and error conditions. Many of these are checked during the power up procedure. If a fault is detected during power up, the instrument becomes non-operational until the failure/problem is corrected. Upon successful completion of the self-tests, the system enters the Setup screen.

8065751606 3.1

INITIAL SYSTEM SETUP

1. Matching the red dot on the footswitch cable connector to the red dot on the footswitch, plug cable into footswitch. Place footswitch on the floor. Ensure treadle and switches are not depressed/activated.

Circulating Nurse

2. Plug main power cord into a suitable wall outlet or receptacle. Turn Power switch ON located at the bottom of the rear panel next to the power cord (this switch remains ON in the I position). Turn system power ON using the Standby switch located at the top of the rear panel.

Circulating Nurse

CAUTION

Do not use multiple portable socket outlets with this system.

WARNING!

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

3. Extend the IV pole hook. Do not extend while IV pole is in motion.

Circulating Nurse

4. The grayed-out Setup screen appears with the Doctor Name dropdown list displayed. Press a Doctor Name button (Alcon Settings) to select an available doctor, or add a doctor by following the steps presented on the display. If desired, select a Handpiece, Tip, and Procedure Type.

Circulating Nurse

5. Inspect the O-rings on the $Ultraflow^{TM} * I/A$ handpiece tip. If damaged, the O-rings must be replaced using the $Ultraflow^{TM} * O$ -ring tool prior to sterilization.

Circulating Nurse

6. Sterilize the instruments according to hospital procedure.

Circulating Nurse

CAUTION

The U/S, $OZil^{\otimes}$ torsional, $NeoSoniX^{\otimes}$, and $AquaLase^{\otimes}$ handpieces must be at room temperature before use. Allow handpiece to air cool after steam autoclave (at least 15 minutes). Never immerse in liquid to cool.

STANDARD PHACOEMULSIFICATION SETUP

Prepare Contents of U/S Surgical Pak

- 1. Extend instrument tray out from the right or left side of console. Pull to Circulating Nurse extend wire loop on tray.
- 2. If remote control is to be used during surgery, place it in the instrument tray well. Verify remote control is functional by slightly raising or lowering the IV pole.
- 3. Peel lid from U/S surgical pak and aseptically transfer contents to sterile Circulating Nurse field.
- 4. Drape the tray support cover over the tray, remote control, and support arm. Push tray support cover downward through open wire loop to form pouch.
- 5. Grasp Fluidic Management System (FMS), remove paper band from Scrub Nurse irrigation/aspiration (I/A) tubing, uncoil tubing and place in pouch.
- 6. Hold FMS by handle, angle it toward the lip on bottom of fluidic module, and press top forward to insert into housing, all in one motion. Ensure that the drain bag hangs freely, and that tubing does not fall out of pouch.
- 7. Remove band from irrigation drip chamber tubing and aseptically present drip chamber to Circulator.
- 8. Accept the drip chamber. Spike the irrigation bottle and hang it from the irrigation pole. Squeeze drip chamber until it fills approximately 2/3 to 3/4 full.

CAUTION

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 on left side of console.

WARNING!

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.

3.3

Prime, Vacuum, and Vent Test

9. Connect the blue aspiration tubing luer to the white irrigation tubing luer.

Scrub Nurse

10. The setup screen is automatically entered at startup or upon removal of the FMS after completion of a procedure. If not in setup screen, press the Setup button, or access the setup screen via the remote control.

Scrub Nurse or Circulating Nurse

11. Press Prime FMS on the setup screen or Enter on the remote control. The IV pole automatically goes to the priming position and the system performs three functions: prime, vacuum test, and vent test.

Scrub Nurse or Circulating Nurse

NOTE: After completion of priming, the vacuum test is performed. This is immediately followed by a vent test. After successful completion of vacuum and vent tests the prime status indicator will change from U/S FMS Not Primed (red) to U/S FMS Primed (blue).

If the vacuum or vent test is not successful the system will display an advisory.

U/S, OZil® Torsional, or NeoSoniX® Handpiece Setup and Test

12. Thread U/S tip onto U/S, $OZil^{\circ}$ torsional, or $NeoSoniX^{\circ}$ handpiece. Tighten firmly using the tip wrench. Remove tip wrench and retain for future tip removal. If tip is not securely attached, an error may be generated and/or inadequate tuning will occur.

Scrub Nurse

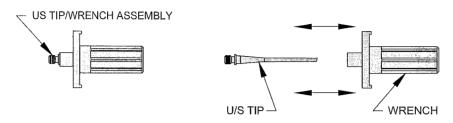


Figure 3-1 U/S Tip/Wrench Assembly

*Mackool*** series ultrasonic tips contain a polymer tubing. This necessary part of the *Mackool*** tip provides additional thermal and fluidic advantages.

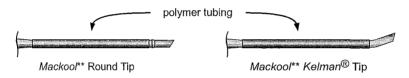


Figure 3-2 Mackool** Tips

WARNING!

Check for the presence and correct position of the polymer tubing on the *Mackool*** tips. Never attempt to remove the tubing. Use of the *Mackool*** tips without polymer tubing may result in a hazardous condition for the patient.

CAUTION

Do not use the disposable tip wrench for <u>subsequent</u> cases; stripping of the tip wrench may occur.

13. Thread infusion sleeve containing the BSI onto handpiece over the U/S tip. Match the proper color coding between the tip and sleeve. Adjust sleeve so it clears bevel on tip by approximately 1-2 mm, and orient port holes correctly.

Scrub Nurse

14. Connect irrigation and aspiration tubing to U/S, $OZil^{\textcircled{m}}$ torsional, or $NeoSoniX^{\textcircled{m}}$ handpiece.

Scrub Nurse

Scrub Nurse

15. Remove protective cap from connector by retracting the sheath of the connector and releasing cap. Line up red dot on handpiece cable connector with red dot on *Infiniti*® Vision System front panel and plug cable into console connector.

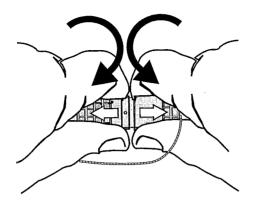


Figure 3-3 Protective Cap Removal

16. Hold handpiece with tip pointed down into test chamber. Press Enter on the remote control (or Circulator press Fill on the setup screen). Fill test chamber completely and slide it over end of handpiece. Ensure no air bubbles are present in test chamber. Press handpiece into tray pouch with tip pointed up. Ensure tubing is not kinked.

Scrub Nurse

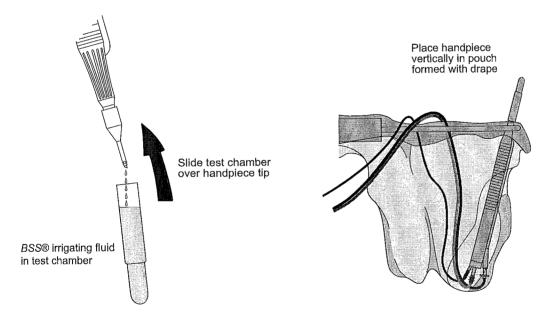


Figure 3-4 Preparing Test Chamber and Placing Handpiece in Pouch.

WARNINGS!

If stream of fluid is weak or absent while filling test chamber, 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 the tubings are not occluded during any phase of operation.

When using a bimanual procedure, ensure the irrigation handpiece and settings have sufficient flow characteristics. Use of irrigation handpieces or settings with insufficient flow characteristics may result in a fluidic imbalance and may cause a shallowing or collapsing of the anterior chamber.

17. Press Enter on the remote control (or Circulator press Test Handpiece on the setup screen). After a very brief and successful tuning of the handpiece, flow check will follow automatically. After a successful flow check, the tune status indicator will change from Not Tuned (red) to Tuned (green). The system will then advance to the surgery screen.

Scrub Nurse or Circulating Nurse

The IV pole returns to its last selected height, but if no memory has been selected it returns to its default position.

WARNINGS!

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.

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

STANDARD AQUALASE® SYSTEM SETUP

Prepare Contents of AquaLase® Surgical Pak

- 1. Extend instrument tray out from the right or left side of console. Pull to Circulating Nurse extend wire loop on tray.
- 2. If remote control is to be used during surgery, place it in the surgical tray well. Verify remote control is functional by slightly raising or lowering the IV pole.
- 3. Peel lid from *AquaLase*® surgical pak and aseptically transfer contents to Circulating Nurse sterile field.
- 4. Drape the tray support cover over the tray, remote control, and support Scrub Nurse arm. Pull to extend wire loop on tray. Push drape downward through open wire loop to form pouch.
- 5. Grasp Fluidic Management System (FMS), remove paper band from all scrub Nurse tubing, uncoil tubing and place in pouch.
- 6. Hold FMS by handle, angle it toward the lip on bottom of fluidic
 interface module, and top press forward to insert into housing, all in one
 motion. Ensure that the drain bag hangs freely, and that tubing does not
 fall out of pouch.
- 7. Insert *AquaLase*®/Balanced Salt Solution bottle into bottle receptacle on front panel, then push and rotate 1/8 turn clockwise to secure. When inserting bottle, etched arrow on bottle must be in alignment with top of receptacle.
- 8. Aseptically present drip chamber/irrigation tubing to Circulator. Scrub Nurse
- 9. Accept the drip chamber. Spike the irrigation bottle and hang it from the irrigation pole. Squeeze drip chamber until it fills approximately 2/3 to 3/4 full.

CAUTION

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 on left side of console.

WARNING!

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.

Prime, Vacuum, and Vent Test

10. Connect the blue aspiration line luer to the white irrigation line luer.

Scrub Nurse

11. The setup screen is automatically entered at startup or upon removal of the FMS after completion of a procedure. If not in setup screen, press the Setup button.

Circulating Nurse

12. Press Enter on the remote control (or Circulator press Prime FMS on the setup screen). The IV pole automatically goes to the priming position and the system performs three functions: prime, vacuum test, and vent test.

Scrub Nurse

After completion of priming, the vacuum test is performed. This is immediately followed by a vent test. After successful completion of vacuum and vent tests the prime status indicator will change from *AquaLase*® FMS Not Primed (red) to *AquaLase*® FMS Primed (green).

If the vacuum or vent test is not successful the system will display an advisory.

AquaLase® Handpiece Setup and Test

13. Prepare AquaLase® handpiece for use as described in the AquaLase® handpiece DFU.

Staff

14. Install *AquaLase*[®] tip onto *AquaLase*[®] handpiece. Tighten firmly using the tip wrench. Remove tip wrench and retain for future tip removal.

Scrub Nurse

15. Install infusion sleeve over tip and onto end of *AquaLase*® handpiece. Adjust sleeve so it clears bevel on tip by approximately 1 mm, and orient port holes correctly.

Scrub Nurse

16. Connect irrigation, aspiration, and black-striped *AquaLase*® tubing to the *AquaLase*® handpiece.

Scrub Nurse

17. Grasp black-striped *AquaLase*® tubing spike from the pouch and spike the *AquaLase*®/Balanced Salt Solution bottle.

Scrub Nurse

18. Remove protective cap from connector by retracting the sheath of the connector and releasing cap. Line up red dot on handpiece cable connector with red dot on *Infiniti*® Vision System front panel connector and plug cable into console connector.

Scrub Nurse

19. Hold handpiece with tip pointed down into test chamber. Press Enter on the remote control (or Circulator press Fill on the setup screen). Fill test chamber completely and slide it over end of handpiece. Ensure no air bubbles are present in test chamber. Press handpiece into tray pouch with tip pointed up. Ensure that tubing is not kinked.

Scrub Nurse

WARNING!

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

20. Press Enter on the remote control (or Circulator press Test Handpiece on the setup screen). After a very brief and successful tuning of the handpiece, flow check will follow automatically. For the *AquaLase*® handpiece, a momentary collapse of the test chamber is normal. After a successful flow check, the tune status indicator will change from Not Tuned (red) to Tuned (green). The system will advance to the surgery screen.

Scrub Nurse

The IV pole returns to its last selected height, but if no memory has been selected it returns to its default position.

WARNING!

Use of the U/S, *OZil*® torsional, *NeoSoniX*®, or *AquaLase*® 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.

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.

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

IRRIGATION/ASPIRATION HANDPIECE SETUP

1. Remove the blue luer aspiration line and white luer irrigation line from the U/S, $OZil^{\textcircled{@}}$ torsional, $NeoSoniX^{\textcircled{@}}$, or $AquaLase^{\textcircled{@}}$ handpiece and connect to the I/A handpiece.

Scrub Nurse

2. This step is required when using $Ultraflow^{TM} * I/A$ handpiece with threaded tip adapter.

Attach sterile I/A tip to I/A handpiece using tip wrench supplied in the phaco pak.

Scrub Nurse

CAUTION

Use of a tool other than Alcon tip wrench may cause damage to the I/A tip and handpiece.

Thread infusion sleeve, without bubble suppression insert (BSI), over the I/A tip until sleeve clears the tip's aspiration opening. Orient the irrigation port holes on the sleeve.

Scrub Nurse

3. Press Fill until fluid streams from both irrigation and aspiration ports (if Irrigation Fill is enabled in System Settings, fluid will only stream from irrigation port). Ensure no air bubbles remain in irrigation or aspiration pathways before continuing procedure.

Circulating Nurse

WARNING!

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

ANTERIOR VITRECTOMY PROBE SETUP

(using Vitrectomy Setup screen)

When the Anterior Vitrectomy step is entered, the Vitrectomy Setup screen appears (see Figure below) unless turned Off in the Doctor Settings screen. This setup screen assists the user through the proper set up and test of the selected probe.

If the Vitrectomy Setup screen is turned Off, you can either turn the Vitrectomy Setup screen On (Custom/Doctor/General), or proceed to **ANTERIOR VITRECTOMY PROBE SETUP** (without using Vitrectomy Setup screen).

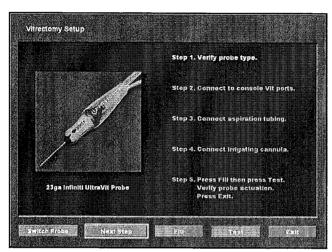


Figure 3-5 Vitrectomy Setup Screen - The *Switch Probe* button allows the user to change selected probes if the desired probe is not displayed; this button appears only if hardware for *UltraVit®* probe upgrade is installed. After performing a set up step, pressing the Next Step button brings up the screen for the next step. The *Fill* button allows the user to prime the probe and to fill a test vessel for proper testing of the probe. Pressing the *Test* button initiates an automated test sequence which verifies secure pneumatic connections, then applies pneumatic activation at a reduced cut rate for visual verification of probe actuation.

1. Peel lid and aseptically transfer contents of pak to sterile field.

Circulating Nurse

2. Press the Ant Vit step button; the Vitrectomy Setup screen appears.

Circulating Nurse/ Scrub Nurse

NOTE: In the next few steps the user will be instructed to press buttons on the display screen. These buttons can be pressed on the display screen, or they can be activated using the Forward/Back Arrow keys and Enter key on the remote control.

3. **Verify probe type** - If desired probe is not displayed, press the *Switch Probe* button to select probe being used. Press *Next Step* button.

Circulating Nurse/ Scrub Nurse

4. **Connect to console Vit ports** - For 20 gauge *Infiniti*® vitrectomy probe, connect clear tubing connector to left Vit port. For 23 gauge *Infiniti*® *UltraVit*® probe, connect black and purple tubing connectors to left and right Vit ports, respectively. Press *Next Step* button.

Scrub Nurse

5. **Connect aspiration tubing** - Disconnect FMS irrigation and aspiration tubing connectors from lens removal handpiece. Connect FMS blue aspiration tubing connector to probe's blue aspiration tubing connector. Press *Next Step* button.

Scrub Nurse

6. **Connect irrigating cannula** - Connect FMS white irrigation tubing connector to irrigating cannula, or optionally for a 20 gauge *Infiniti*® vitrectomy probe, to an irrigation sleeve added to probe's tip. Press *Next Step* button.

Scrub Nurse

7. **Press Fill then press Test** - Priming of the vitrectomy probe is required prior to use. With tip of probe and irrigating cannula in a cup of sterile fluid, press the *Fill* button. Ensure all air bubbles have been removed from all tubing connected to the probe prior to use.

Scrub Nurse

Verify probe actuation - While observing cutting port of probe, held under surface of sterile fluid, press the *Test* button. The system intitiates an automated test sequence confirming secure connections and facilitates visualization of probe cutter by applying a brief period of reduced cut rate. The cutter should fully open and close when actuated. Press the *Exit* button.

Scrub Nurse

8. The Vitrectomy Cut I/A or I/A Cut surgery screen appears on the front display panel. Switching between Cut I/A and I/A Cut is done with the Mode button at top center of surgery screen.

Circulating Nurse

9. Press Irrigation Control up/down keys on the remote control (or Circulator press Bottle Height Adjustment Arrows on the setup screen) to adjust bottle height. Vitrectomy probe is ready.

Scrub Nurse/ Circulating Nurse

WARNINGS!

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

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; alternatively, press the Test button on the Vitrectomy Setup Screen: 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.

ANTERIOR VITRECTOMY PROBE SETUP (without using Vitrectomy Setup screen)

To set up the vitrectomy probe without using the Vitrectomy Setup screen, follow the instructions below.

1. Peel lid and aseptically transfer contents to sterile field. Circulating Nurse 2. Press the Ant Vit step button; the vitrectomy surgery screen appears. Circulating Nurse/ Scrub Nurse 3. If desired probe is not displayed in the button at the top of the vitrectomy Circulating Nurse/ surgery screen, press the button to select probe being used. Scrub Nurse For 20 gauge *Infiniti*® vitrectomy probe, connect clear tubing connector Scrub Nurse 4. to left Vit port. For 23 gauge Infiniti® UltraVit® probe, connect black and purple tubing connectors to left and right Vit ports, respectively. 5. Disconnect FMS irrigation and aspiration tubing connectors from lens Scrub Nurse removal handpiece. Connect FMS blue aspiration tubing connector to blue connector of vitrectomy probe. 6. Connect FMS white irrigation tubing connector to irrigating cannula, Scrub Nurse or optionally for a 20 gauge Infiniti® vitrectomy probe, to an irrigation sleeve added to probe's tip. 7. Priming of the vitrectomy probe is required prior to use, and can be Scrub Nurse performed using one of two methods. With tip of probe and irrigating cannula in a cup of sterile fluid: • Independently use irrigation by depressing the footpedal to position 1 to remove air bubbles from the probe's irrigation line, and then use reflux to remove air bubbles from the probe's aspiration tubing. • Use the Fill command, if enabled in Doctor Settings, to simultaneously remove air bubbles from the irrigation and aspiration lines, then return to Ant Vit mode. Ensure all air bubbles have been removed from all tubing connected to the probe prior to use. 8. Testing of the vitrectomy probe should be performed prior to use. With Scrub Nurse tip of probe and irrigating cannula in a cup of sterile fluid, depress footpedal to the cut position and observe probe's cutting port (to facilitate visualization, reduce cut rate). The cutter should fully open and close when actuated, and remain open when footpedal is released to position 0. Circulating Nurse 9. Switching between Cut I/A and I/A Cut is done with the Mode button at top center of surgery screen. Press Irrigation Control up/down keys on the remote control (or Scrub Nurse/ 10.

- Always observe Warnings on previous page -

to adjust bottle height. Vitrectomy probe is ready.

Circulator press Bottle Height Adjustment Arrows on the setup screen)

Circulating Nurse

COAGULATION HANDPIECE SETUP

1. Using aseptic techniques, plug new or sterilized handpiece cable connectors into *Infiniti*® Vision System front connector panel.

Scrub Nurse

2. Plug connector into new or sterilized coagulation handpiece.

Scrub Nurse

3. Coagulation handpiece is ready.

SECTION FOUR CARE AND MAINTENANCE

INTRODUCTION

This section of the manual is designed to inform the operator of basic care and maintenance of the instrument. If a problem occurs on the instrument, contact Alcon Technical Support or your local Alcon representative and give details of the breakdown circumstances and effects. If there is an error message, write down the number and message exactly as it appears on the screen. From these elements, a specialized technician will evaluate the problem and determine the maintenance requirements.

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

CAUTION

There are no operator replaceable parts other than the fuse. Contact Alcon Technical Services for all servicing issues.

WARNING!

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

UPON COMPLETION OF THE DAY'S SURGERY SCHEDULE

STEP ONE: Clean handpieces, cables, forceps, etc., as instructed in DFU's supplied with each accessory.

WARNING!

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.

STEP TWO: Remove irrigation bottle from hanger and set aside. Remove spike from irrigation bottle and discard tubing.

STEP THREE: Eject FMS and discard.

STEP FOUR: Flip the irrigation bottle holder to its storage position.

STEP FIVE: Select Custom/Shutdown from the Surgery Screen. Select OK. IV pole will go down to storage position before unit shuts off.

<u>or</u>

Press Standby power switch located at top of rear panel to remove operating power from the system. IV pole will go down to storage position before unit shuts off.

WARNING!

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.

STEP SIX: Turn the Main power switch OFF. It is located at the bottom of the rear panel above the power cord.

STEP SEVEN: Disconnect the power cable from the wall receptacle and wind the cable around the cord wrap.

4.2

STEP EIGHT: Inspect, and if required, clean footswitch bottom cover and under rear section of treadle with water, alcohol, or mild soap and water. Remove any debris (see Figure 4-1).

CAUTION

Debris, including fluid residue, stuck on footswitch bottom or under rear section of treadle may cause temporary malfunction of the footswitch.

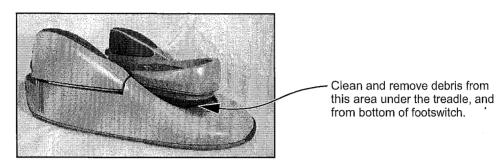


Figure 4-1 Footswitch Cleaning - Clean under rear section of footswitch treadle to remove debris that can interfere with its operation.

STEP NINE: If required, the console panels, the footswitch, and the remote control may be wiped with alcohol, mild soap and water, or any germicidal solution that is compatible with the plastic parts.

CAUTIONS

- Do not clean console or accessories using solvents, abrasives, or any cleaner that is not compatible with plastic parts made of GE Cycoloy CU 6800 and LEXAN 920A. Damage may result.
- Avoid spilling BSS^{\circledast} solution, or moisture of any kind, around the electrical handpiece connectors.

STEP TEN: Place the footswitch and cable in its drawer at the bottom of the front panel.

CARE AND CLEANING

The following tips are recommended for proper care of the *Infiniti*® Vision System:

- The console panels, the footswitch, and the remote control may be wiped with alcohol, mild soap and water, or any germicidal solution that is compatible with the plastic parts; instructions begin on the prior page.
- The touch screen may be cleaned with a soft, non-abrasive cloth towel and a mild commercially-available window cleaner. Apply the cleaner to the towel rather than the touch screen.
- Follow cleaning and maintenance schedules outlined in this section of the manual.
- Periodically check chassis appearance.
- Pay attention to correct operation of controls, connectors, and indicators.
- Damaged hardware must be replaced to ensure safe operation. Call Alcon Technical Services for assistance.

WARNING!

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 for leakage current every twelve months to ensure they are within the applicable standards (for example: EN60601-1/IEC601-1). Values must be recorded, and if they are above the applicable standards, do not use the system; call Alcon Technical Services.

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STERILIZATION INSTRUCTIONS

Please consult the accompanying Directions For Use (DFU) for cleaning, reprocessing, and sterilization instructions for Alcon approved reusable accessories. The DFU will provide the recommended time and temperature guidelines for steam autoclave cycles performed by Alcon, Inc. **The sterility assurance level achieved with these parameters must be validated by each surgical facility**. Please refer to Association for the Advancement of Medical Instrumentation (AAMI) Standards or your facility's standard procedures for the most current specifications.

Additionally, per the Sterilizer Equipment Manual, the sterilizer reservoir is to be filled with distilled or deionized water.

NOTE: The reusable items will withstand steam autoclave cycles at 134° C (273°F). Due to the variations found in steam autoclaves and the variable bioburden on devices in clinical use, it is not possible for Alcon to provide specific parameters to ensure an adequate sterility assurance level. Validation of the individual autoclave, and verification of the sterility assurance level achieved with a given steam sterilization cycle, must be performed by each surgical facility. Please refer to below AAMI Standards or your facility's standard procedures for the most current specifications.

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FUSE REPLACEMENT

- 1. Turn the Main power switch OFF. It is located at the bottom of the rear panel above the power cord. Unplug power cord from power source.
- 2. Insert a flat surfaced instrument into opening located just below the fuse drawer.
- 3. Gently push tab up until it releases fuse drawer.

CAUTION

The tab must be pressed gently to ensure it does not break.

- 4. Remove the fuse drawer from the fuse module.
- 5. Gently remove and replace fuses. Contact Alcon Technical Services for the correct rating and size.
- 6. Reinsert fuse drawer. A snap is heard when it is secured inside module.
- 7. Plug power cord into power source.

SECTION FIVE TROUBLESHOOTING

INTRODUCTION

Table 5-1 is a general troubleshooting guide that addresses symptoms/observations and what the operator can do to try and solve the observed problem. Figure 5-4 and Table 5-2 are presented as aids to rapid location of failed or malfunctioning parts or components in the *Infiniti*® Vision System; they are not meant to replace standard troubleshooting methods. In all cases, should the corrective actions not provide the desired result, call your Alcon Technical Services Department.

Equipment Malfunction

The system communicates equipment malfunctions through the display of Advisories, Warnings, and Faults based on the level of severity. Listed below is a general sequence of events for each.

Advisories

An advisory is a message to the user (see Figure 5-1). The advisory may require user intervention, or it may be for information purposes only. When an advisory condition is detected, the following occurs:

- A tone is generated.
- A dialog is displayed indicating the advisory.

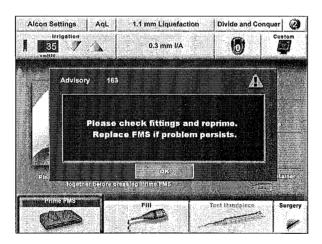


Figure 5-1 ADVISORIES SCREEN - This is a typical example of an Advisories dialog.

Warnings

Warnings are generated to indicate a non-system fault (see Figure 5-2). When a warning is detected, the following occurs:

- A tone is generated.
- Affected mechanisms are placed in a safe state.
- A dialog is displayed indicating the warning.

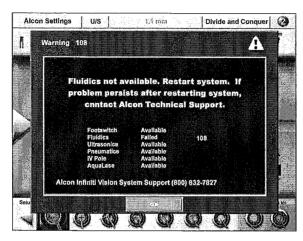


Figure 5-2 WARNINGS SCREEN - This is a typical example of a Warnings dialog.

Faults

System faults are the result of an exceptional condition resulting from an error or a hardware failure that renders the software unable to carry out a requested service, or one that results in unacceptable risk (see Figure 5-3). When a system fault is detected, the following occurs:

- A tone is generated.
- All mechanisms are disabled.
- A dialog is displayed indicating the fault. If the fault occurs during system initialization, shutdown, or when the touchscreen graphics software is unavailable, the fault dialog will be displayed in English.
- All requests for functions are ignored, including key activations.



Figure 5-3 FAULTS SCREEN - This is a typical example of a Faults dialog.

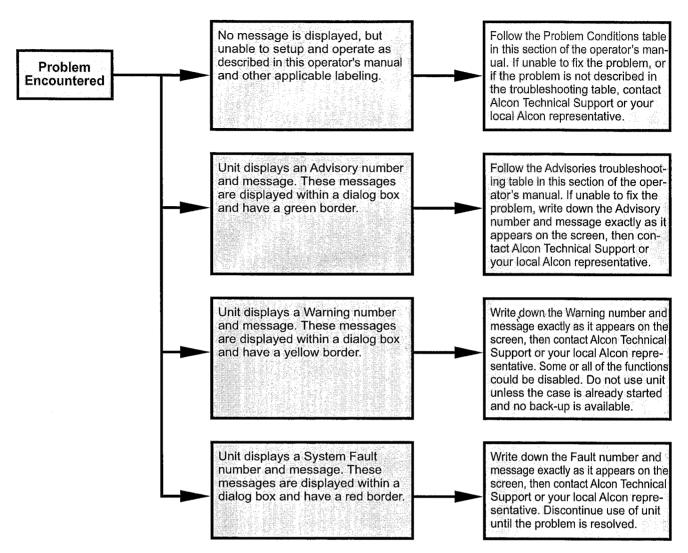


Figure 5-4 TROUBLESHOOTING GUIDE - When a problem is encountered, refer to this chart first.

PROBLEM CONDITIONS

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
Test chamber does not fill— nsufficient irrigation.	1. Restriction to irrigation inflow.	Check for kinks in irrigation line or twisted infusion sleeve.
	Bottle too low or handpiece too high.	2. Put bottle at 78 cm and put handpiece at patient eye level.
	Drip chamber not adequately filled with fluid.	3. Squeeze drip chamber until 2/3 to 3/4 full.
	4. Clogged handpiece or tips.	4. Check handpiece and tips.
	5. Drip chamber valve stuck.	Tap drip chamber with finger to free ball valve.
	6. Faulty Fluidic Management System (FMS).	6. Replace FMS.
Vacuum check failure.	1. Improper FMS insertion.	1. Reinsert FMS.
Advisory 162	2.IRR and ASP fittings are not connected together securely.	2. Ensure both fittings are tightly connected together.
	3. Drip chamber not 2/3 to 3/4 full.	 Flush irrigation line and fill drip chamber halfway using Fill button in Setup mode. Reprime.
	Test chamber not on handpiece, or not secured tightly onto handpiece.	 Secure test chamber tightly onto handpiece.
	5. Priming with HP attached.	Remove HP, then connect blue and white luer fittings together.
	6. Cracked blue luer fitting.	Check fitting and replace FMS as necessary.
	7. Faulty FMS.	7. Replace FMS.
Vent test failure or vacuum and vent check failure.	Restriction in irrigation or aspiration lines.	Check kinked irrigation or aspiration lines or twisted tip cap sleeve.
Advisory 161, 164	2. Machine insufficiently primed.	2. Press Test to reprime.
	3. Drip chamber vent valve stuck.	Tap drip chamber with finger to free ball valve.
	4. Faulty FMS.	 Reinsert FMS. Replace FMS if problem persists.
Ultraflow™* I/A handpiece leaking at	1. Loose tip.	1. Retighten tip.
tip and handpiece connection.	2. Damaged O-ring.	 2. Retest. Inspect O-rings and replace, as necessary. To replace: Using the special O-ring tool, remove damaged O-ring. Roll new O-ring off tool and roll it into place on tip.
	3. Leak in tubing.	3. Replace tubing.

Table 5-1 PROBLEM CONDITIONS - Listed in this table are problem conditions that may be observed. The observed Symptom is followed by the Probable Cause and its Corrective Action.

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
System does not power-up.	1. Main power switch in OFF position.	Turn main power switch near power cord to ON position.
	2. Blown power fuse.	2. Replace power fuse near power cord.
Test chamber collapses after tuning completed—does not refill.	1. Clogged handpiece or tips.	Check handpiece and tips irrigation flow.
	2. Drip chamber valve stuck.	Tap drip chamber with finger to free ball valve.
	3. Restriction to irrigation flow.	Check for kinks in irrigation line or twisted infusion sleeve.
	4. Wrong sleeve on tip.	4. Check for proper sleeve and tip size.
Backflow regurgitation.	Machine insufficiently primed.	Reprime.
Insufficient aspiration.	1. Loose blue luer fittings.	1. Reconnect securely.
	 Damaged O-ring (<i>Ultraflow™*</i> I/A handpiece only). 	2.Inspect O-ring and replace, as necessary.
	3. Clogged tip.	 3. • Flush tip with sterile water or BSS[®] sterile irrigating solution. Retest. • Replace tip. Retest.
	4. Kinked or damaged tubing.	4. Check tubing and/or replace FMS.
	5. Cracked blue luer fitting.	5. Check fitting and/or replace FMS.
Test Handpiece Failed: Loose Tip.	Loose tip.	Retighten and retune.
Test Handpiece Failed: Tuning in Air.	Attempted to tune tips in presence of air.	Fill test chamber completely. Retune.
Prime Complete / Test Handpiece Failed.	1. Faulty Handpiece.	1. Replace handpiece. Retest.
i alicu.	2. Faulty Connector.	2. Unplug, reinsert into socket, retest.
	3. Faulty tip.	Remove tip and replace if faulty. Retighten. Retest.
	4. Other.	 Record the failed code number and contact Alcon Technical Services Department.
	5. AquaLase® handpiece injection path clogged.	5. Flush path with syringe and sterile fluid.
No tune or loss of U/S power.	1. Handpiece tuned while hot.	1. Retune.
	2. Loose tip.	2. Retighten and retune.
	2 LID compostor not costed compostly.	3. Disconnect and reinsert HP connector
	HP connector not seated correctly.	3. Disconnect and remsert HP connector

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
Irrigation does not stop.	System in Continuous Irrigation mode.	Turn Continuous Irrigation off.
Air in irrigation line causing bubbles.	1. Drip chamber not sufficiently full.	Fill drip chamber 2/3 to 3/4 full. Flush irrigation line in Free Flow or footpedal position 1.
	2. Air in line or handpiece.	2. Tap handpiece 2-3X during flow test.
	3. Loose irrigation luer fitting.	3. Check irrigation line and reseat.
	4. Improper priming.	4. Reprime per setup procedure.
Ant Vit probe does not work at all (no	1. Faulty probe.	1. Replace probe.
movement).	2. An actuation line filling with BSS® fluid due to improper setup.	Check for correct tubing connections, then replace probe.
Ineffective or poor Vit cutting.	Port not closing fully as the inner cutter moves.	Reduce cutting speed until port closes completely.
	Kinked, damaged or loose actuation tubing.	 Check for damaged or kinked tubing; straighten if necessary. Tighten any loose luer fittings. Replace probe if visual inspection shows any damaged components.
	Faulty probe (activated in air instead of fluid).	3. Replace probe.
"Calibration failed. Vitrectomy cut rate will be limited to 800 cpm" Advisory is displayed at power up. Error code 752 or 753.	Internal pneumatics valve calibration has failed.	Continue vitrectomy procedure with limited cut rate and contact Alcon Technical Services Department.
Remote control does not work.	Remote and system set on different channels.	Verify system channel selection and remote channel select are set to same channel (A, B, C, or D).
	2. Batteries discharged.	2. Replace batteries in remote control.
IV pole does not retract completely upon shutdown.	System error.	Turn system on, wait until system powers up, then turn system off using Standby power switch located on upper rear panel.
Footpedal not responding properly.	Footpedal was pressed when system was powered up, or footpedal was pressed when footswitch was plugged in.	Release footpedal and power off system. Make sure footswitch is properly connected to system, and turn power back on, with footpedal in full up position.
	Footswitch connector not seated properly.	Disconnect and reconnect footswitch cable connector.
	3. Debris or BSS® fluid residue under rear section of treadle.	3. Clean and remove debris.
	4. Console malfunction.	Disconnect and reconnect footswitch cable connector.
	5. Faulty footswitch.	5. Replace footswitch.

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
"Please Install Footswitch" Advisory is displayed. Error code 460.	Improperly connected or discon- nected footswitch.	Verify proper insertion of footswitch connector (while footpedal/treadle is in full up position).
	Footswitch connector not seated properly.	Disconnect and reconnect footswitch cable connector.
	3. Faulty footswitch.	3. Replace footswitch.
System Fault occurs; entire system inoperative, red screen with stop sign is displayed.	System Fault has several possible causes.	Carefully record all text appearing in Fault screen, on display. Press and hold Standby switch for a few seconds to turn system off, wait until screen goes dark, then turn system back on to see whether fault clears. Contact Technical Services.
AquaLase® handpiece test failed.	1. Short circuit error.	1. Replace handpiece.
	2. Open circuit error.	2. Ensure AquaLase® fluid is flowing to haridpiece.
		Replace handpiece.
	3. Flow obstruction.	3. Ensure <i>AquaLase</i> ® fluid is flowing to handpiece.
		Flush injection flow path per hand- piece DFU and verify fluid exits tip.
AquaLase® handpiece leak at tip interface.	1. Loose tip.	1. Reapply wrench and tighten tip.
interrace.	2. Missing or damaged gasket.	2. Replace tip.
Diminished pulsing performance.	AquaLase® fluid container near empty.	Replace AquaLase® fluid container.
Low irrigation flow.	Irrigation sleeve too distal.	Move sleeve so holes are proximal to tip flare.
"Doctor data invalid, U/S Occlusion, Dr. XXXX" Advisory is displayed. Error code 471.	User restores, or selects Doctor Name that contains U/S Occlusion settings which are no longer available.	Save data. U/S Occlusion settings will be removed.

ADVISORIES

ERROR CODE	MESSAGE DISPLAYED	ERROR CODE	MESSAGE DISPLAYED
160	Advisory xxx: Reinsert FMS. Replace FMS if problem persists.	278	Advisory xxx: Replace handpiece. If problem persists after restarting system, contact Alcon Technical Services.
161-164	Advisory xxx: Please check fittings and reprime. Replace FMS if problem persists.	279	Advisory xxx: Unknown handpiece detected.
165-167	Advisory xxx: Flow obstruction. Please check handpiece free flow.	280	Advisory xxx: Unsupported handpiece detected.
169	Advisory xxx: Irrigation pressure is low. Please check bottle and fittings.	281	Advisory xxx: Cautery compliance error. If problem persists after restarting system, contact Alcon Technical Services.
170	Advisory xxx: Reflux terminated. Reflux fluid volume depleted.	282	Advisory xxx: Coagulator error: If problem persists after restarting system, contact Alcon Technical Services.
171	Advisory xxx: Excessive pressure in drain bag. Replace FMS.	350	Advisory xxx: Footswitch failure detected. Check
175-176	Advisory xxx: Infusion pressure sensor calibration error. Remove FMS. If problem persists contact Alcon Technical Services.		footswitch, clean under rear section of treadle and remove debris if present' (Reférence maintenance section of Operator's Manual.) Ensure treadle is not depressed then reset footswitch. If condition persists, contact Alcon Technical Services.
180	Advisory xxx: Invalid FMS ID. Replace FMS.	351	Advisory xxx: Footswitch failure detected. Check
181	Advisory xxx: Excessive Ambient Light. Unable to calibrate FMS ID sensors.	331	and reset footswitch. If condition persists, contact Alcon Technical Services.
182	Advisory xxx: Excessive Ambient Light. Unable to read FMS ID.	352	Advisory xxx: Footswitch failure, replace footswitch.
183	Advisory xxx: Remove MultiPak FMS? See MultiPak Directions-For-Use.	353	Advisory xxx: Footswitch failure detected. Check and reset footswitch. If condition persists, contact Alcon Technical Services.
250	Advisory xxx: Tuning in air.	450	Advisory xxx: Footswitch is depressed. Release
251	Advisory xxx: Insert handpiece.	400	footswitch before pressing Prime FMS, Fill, or Test Handpiece.
252	Advisory xxx: Multiple handpieces detected. Remove a handpiece.	451	Advisory xxx: Can not recognize footswitch.
254	Advisory xxx: Loose tip.		Please check footswitch connection and reset footswitch. If condition persists, contact Alcon Technical Services.
256-270	Advisory xxx: Replace handpiece. If problem persists after restarting system, contact Alcon Technical Services.	460	Advisory xxx: Please install footswitch.
271	Advisory xxx: Two handpieces detected. Remove a handpiece.	461	Advisory xxx: Infiniti® backup power service needed, contact Alcon Technical Services.
272-274	Advisory xxx: Replace handpiece. If problem persists after restarting system, contact Alcon Technical Services.	463	Advisory xxx: Invalid language(s) found during initialization. One or more installed languages may not be available.
276	Advisory xxx: Ultrasound error. Release treadle	464	Advisory xxx: The language specified by system settings is invalid.
	and retry. If problem persists after restarting system, contact Alcon Technical Services.	465	Advisory xxx: The tune sequence was interrupted by removal of the handpiece.
277	Advisory xxx: Handpiece disconnected while applying U/S power. Release treadle then insert and tune handpiece.		Advisory xxx: AquaLase® handpiece test failed. Handpiece tune failed. Check AquaLase® handpiece connection.

Table 5-2 ERROR CODES - Listed in this table are error codes shown on the *Infiniti*® Vision System display panel when the system detects a problem. The error codes are separated between Advisories, Warnings, and Faults.

ADVISORIES

ERROR CODE	MESSAGE DISPLAYED	ERROR CODE	MESSAGE DISPLAYED
467	Advisory xxx: Replace FMS with an AquaLase® FMS to allow tuning of the AquaLase® hand-piece.	570	Advisory xxx: AquaLase® handpiece failed. Replace AquaLase® handpiece.
468	Advisory xxx: The <i>AquaLase</i> ® tune sequence was interrupted by removal of the <i>AquaLase</i> ® container.	571	Advisory xxx: <i>AquaLase</i> ® Error. Release treadle, check fluid container and retry. If problem persists replace <i>AquaLase</i> ® handpiece.
469	Advisory xxx: Doctor data corrupted.	572	Advisory xxx: <i>AquaLase</i> ® handpiece disabled. Retest handpiece.
471	Advisory xxx: Doctor data invalid, U/S Occlusion, Dr. XXXX.	573	Advisory xxx: AquaLase® Error. Release treadle and retry. If problem persists contact Alcon Technical Services.
473	Advisory xxx: Inserted handpiece does not match selected handpiece. Change selected handpiece before proceeding.	574	Advisory xxx: AquaLase® handpiece disabled. Check AquaLase® handpiece connection and retest the handpiece.
474	Advisory xxx: AquaLase® handpiece test failed. Retry test. If problem persists contact Alcon Technical Services.	575	Advisory xxx: Unknown AquaLase handpiece detected.
475	Advisory xxx: CPU Battery should be replaced. Contact Alcon Technical Services. Meanwhile,	580	Advisory xxx: Replace <i>AquaLase</i> ® container.
	you may proceed with surgical cases.	582	Advisory xxx: AquaLase® Error. Release treadle and retry. If problem persists contact
476	Advisory xxx: Invalid console serial number. Contact Alcon Technical Services.	F00	Alcon Technical Services.
478	Advisory xxx: Inserted handpiece does not match selected handpiece. Change selected handpiece before proceeding.	583	Advisory xxx: AquaLase® pressure failure. Check fluid container and retry. If problem persists contact Alcon Technical Services.
550-551	Advisory xxx: AquaLase® handpiece test failed. Retry test. If problem persists contact Alcon	650	Advisory xxx: IV Pole jammed. Check for ex- ternal obstacles. Pole may not have achieved desired height.
552	Technical Services. Advisory xxx: AquaLase® handpiece test failed.	651	Advisory xxx: The IV pole cannot attain the requested height due to the PEL setting.
002	Replace AquaLase® Fluid Container. If problem persists contact Alcon Technical Services.	750	Advisory xxx: Pneumatic pump leakage. If
553	Advisory xxx: AquaLase® handpiece test failed. Check fluid container and retry test. If problem		problem persists, contact Alcon Technical Services.
	persists contact Alcon Technical Services.	751	Advisory xxx: Low pressure. System is charging
554	Advisory xxx: AquaLase® handpiece test failed. Tighten tip and check all fluid connections. If problem persists, replace tip.	752,753	Advisory xxx: Calibration failed. Vitrectomy cut rate will be limited to 800 cpm.
555	Advisory xxx: AquaLase® handpiece test failed. Flush handpiece injection pathway using flush adaptor. If problem persists, replace AquaLase® handpiece and/or fluid container.		
556,558	Advisory xxx: AquaLase® handpiece test failed. Check fluid container and retry test. If problem persists contact Alcon Technical Services.		
559	Advisory xxx: AquaLase® handpiece test failed. Check fluid container and retry test. If problem persists replace AquaLase® handpiece.		
560	Advisory xxx: AquaLase® handpiece test failed. Check <i>AquaLase</i> ® handpiece and retry test. If problem persists replace <i>AquaLase</i> ® handpiece.		

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WARNINGS

ERROR CODE MESSAGE DISPLAYED 100-152 Warning xxx: Fluidics not available. Restart system. If problem persists after restarting system, contact Alcon Technical Services. 200-233 Warning xxx: Ultrasound and Coagulation not available. Contact Alcon Technical Service. 300-331 Warning xxx: Footswitch OK, but not available. Restart system. If problem persists after restarting system, contact Alcon Technical Services. 441 Warning xxx: AC power lost. System is shutting down. 500-544 Warning xxx: AquaLase® not available. If this function is required, restart system. If problem persists after restarting system, contact Alcon Technical Services. 600-635 Warning xxx: IV Pole not available. Restart system. If problem persists after restarting system, contact Alcon Technical Services. Use external IV Pole.

Warning xxx: Vitrectomy and AquaLase® not available. If these functions are required, restart system. If problem persists after restarting system, contact Alcon Technical Services.

FAULTS

ERROR CODE	MESSAGE DISPLAYED
400	System Fault xxx: Please restart system.
401	System Fault xxx: Bus failure.
402	System Fault xxx: 24 V Out of Tolerance.
403	System Fault xxx: Software error.
404	System Fault xxx: Corrupt/Missing File.
405	System Fault xxx: Incompatible Software Version.
406	System Fault xxx: Failed software installation.

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SECTION SIX ACCESSORIES AND PARTS

In this section of the *Infiniti*® Operator's Manual is a list of Alcon-approved accessories and replacement items. Use of non-approved accessories cannot be permitted.

Please contact the Alcon Sales Department for in-service information prior to initial use of handpieces, accessories, or paks.

For additional information, please contact the Alcon Sales Department.

Phone:

(800) 862-5266 or

(817) 293-0450

Ask for Customer Service

Write:

Alcon, Inc.

6201 South Freeway

Fort Worth, TX. 76134-2099

INTERNATIONAL: Please contact your local Alcon Sales Office.

CATALOG NUMBER DESCRIPTION

```
8065741085..... Ultrasound FMS, 30° Round, 0.9 mm ABS® Tip
8065741086.... Ultrasound FMS, 45° Round, 0.9 mm ABS<sup>®</sup> Tip
8065741087..... Ultrasound FMS, 30° Kelman®, 0.9 mm ABS® Tip
8065741088..... Ultrasound FMS, 45° Kelman®, 0.9 mm ABS® Tip
8065741089..... Ultrasound FMS, 30° Round, 1.1 mm ABS® Tip
8065741090..... Ultrasound FMS, 45° Round, 1.1 mm ABS® Tip
8065741091..... Ultrasound FMS, 30° Kelman®, 1.1 mm ABS® Tip
8065741092..... Ultrasound FMS, 45° Kelman<sup>®</sup>, 1.1 mm ABS<sup>®</sup> Tip
8065741093..... Ultrasound FMS, 30° Round, 0.9 mm Flared ABS® Tip
8065741094..... Ultrasound FMS, 45° Round, 0.9 mm Flared ABS® Tip
8065741095..... Ultrasound FMS, 30° Kelman<sup>®</sup>, 0.9 mm Flared ABS<sup>®</sup> Tip
8065741096..... Ultrasound FMS, 45° Kelman<sup>®</sup>, 0.9 mm Flared ABS<sup>®</sup> Tip
8065741097..... Ultrasound FMS, 30° Round, 1.1 mm Flared ABS® Tip
8065741098.... Ultrasound FMS, 45° Round, 1.1 mm Flared ABS® Tip
8065741099..... Ultrasound FMS, 30° Kelman<sup>®</sup>, 1.1 mm Flared ABS<sup>®</sup> Tip
8065741100..... Ultrasound FMS, 45° Kelman<sup>®</sup>, 1.1 mm Flared ABS<sup>®</sup> Tip
8065750266..... Ultrasound FMS, 30° Round, 0.9 mm Mackool** Tip
8065750267..... Ultrasound FMS, 45° Round, 0.9 mm Mackool** Tip
8065750268..... Ultrasound FMS, 30° Kelman®, 0.9 mm Mackool** Tip
8065750269..... Ultrasound FMS, 45° Kelman<sup>®</sup>, 0.9 mm Mackool** Tip
8065750274..... Ultrasound FMS, 30° Round, 1.1 mm Flared Mackool** ABS® Tip
8065750275..... Ultrasound FMS, 45° Round, 1.1 mm Flared Mackool** ABS® Tip
8065750276..... Ultrasound FMS, 30° Kelman®, 1.1 mm Flared Mackool** ABS® Tip
8065750277..... Ultrasound FMS, 45° Kelman<sup>®</sup>, 1.1 mm Flared Mackool** ABS<sup>®</sup> Tip
8065750278..... Ultrasound FMS, 30° Round, 0.9 mm Tapered ABS® Tip
8065750279..... Ultrasound FMS, 45° Round, 0.9 mm Tapered ABS® Tip
8065750280..... Ultrasound FMS, 30° Kelman<sup>®</sup>, 0.9 mm Tapered ABS<sup>®</sup> Tip
8065750281..... Ultrasound FMS, 45° Kelman®, 0.9 mm Tapered ABS® Tip
8065750282..... Ultrasound FMS, 30° Round, 0.9 mm Tip
8065750283..... Ultrasound FMS, 45° Round, 0.9 mm Tip
8065750284..... Ultrasound FMS, 30° Kelman®, 0.9 mm Tip
8065750285..... Ultrasound FMS, 45° Kelman<sup>®</sup>, 0.9 mm Tip
8065750286..... Ultrasound FMS, 30° Round, 1.1 mm Tip
8065750287..... Ultrasound FMS, 45° Round, 1.1 mm Tip
8065750288..... Ultrasound FMS, 30° Kelman®, 1.1 mm Tip
8065750289..... Ultrasound FMS, 45° Kelman<sup>®</sup>, 1.1 mm Tip
8065751035..... Intrepid® Ultrasound FMS, 0.9 mm Ultra Tip
8065751036..... Intrepid® Ultrasound FMS, 1.1 mm Ultra Tip
8065751039..... Intrepid® Ultrasound FMS, 30° Kelman®, 0.9 mm Mini-Flared Tip, 0.9 mm Ultra
8065751040..... Intrepid® Ultrasound FMS, 45° Kelman®, 0.9 mm Mini-Flared Tip, 0.9 mm Ultra
8065750157..... 20 gauge Infiniti® Vitrectomy Pak with Infusion Cannula
8065801351..... Coaxial Anterior Vitrectomy Irrigation Sleeve - Reusable
8065750352.... Coaxial Anterior Vitrectomy Irrigation Sleeve - Single Use
8065751196.....23 gauge Infiniti® UltraVit® Vitrectomy Pak with Infusion Cannula
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6.2 8065751606

CATALOG NUMBER	DESCRIPTION
0065-0796-40	AquaLase® Complete Pak CE
0065-0796-14	. AquaLase® Complete Pak US
8065750846	AquaLase® Kit with Injection Line, 1.1mm Tip
8065750893	AquaLase® Kit with Injection Line, 1.1mm MI Tip
8065750904	AquaLase® Kit with Injection Line, 1.1mm MI Tip, Kelman®
0065-0795-81	AquaLase® Solution CE (90 ml)
8065740842	Small Parts Kit, 0.9 mm <i>MicroSmooth</i> ® High Infusion Sleeve
8065740872	Small Parts Kit, 1.1 mm <i>MicroSmooth</i> ® High Infusion Sleeve
8065750159	Small Parts Kit, 0.9 mm <i>MicroSmooth</i> ®
8065750160	Small Parts Kit, 1.1 mm <i>MicroSmooth</i> ®
8065750517	Small Parts Kit, 0.9 mm <i>MicroSmooth</i> ® Ultra Infusion Sleeve
8065750518	Small Parts Kit, 1.1 mm <i>MicroSmooth</i> ® Ultra Infusion Sleeve
8065750519	Small Parts Kit, 1.1 mm <i>MicroSmooth</i> ® Micro Infusion Sleeve
8065814301	<i>Ultraflow</i> ™ * IA Tip STR
	Ultraflow™ * IA Tip CRVD
	. $.Ultraflow^{TM} * IA 45^{\circ}$
	. $.Ultraflow^{\text{TM}} * \text{IA } 90^{\circ}$
8065814701	. $.Ultraflow^{\text{TM}}*IA 1200$
	. $.Ultraflow^{\text{TM}} * \text{CNL STTL}$
8065814901	
8065-A001-01	$Ultraflow^{\text{TM}}*I/A$ Box
405-184	. $.Ultraflow^{\text{TM}} * \text{Tool}/0\text{-rings}$
ULTRA O-RNG RPL	Replacement O-ring
8065817002	<i>Ultraflow</i> TM * Tip Protector, Standalone
355-1009	I/A Tip 0.5 mm
356-1007	I/A Tip 0.3 mm Small Bore
356-1009	I/A Tip 0.3 mm Small Bore Mod
356-1010	I/A Tip 0.3 mm Bent
	I/A Tip 0.3 mm Bent & Sand Blast
	Silicone I/A Tip, Straight
	Silicone I/A Tip, Bent
	Intrepid® I/A Tip 0.3 mm
8065751013	. Intrepid® I/A Tip 0.3 mm Bent
8065817001	Straight Tip, .3 mm
	45° Bent Tip, .3 mm
8065817301	90° Bent Tip, .3 mm
	Irrigation Only Luer
	Curved Tip, .3 mm
	Threaded Tip - STTL
	<i>Ultraflow</i> ™ * IA Handpiece Comp
8065814201	. $.Ultraflow^{TM} * IA Handpiece Only$

8065751606 6.3

CATALOG NUMBER	DESCRIPTION	
0065-0795-90	.Balanced Salt Solution US (90 ml)	
8065740749	, ,	
	Instrument Sterilization Tray	
000000000000000000000000000000000000000	mistament stermenton Tray	
8065750121	.Handpiece, Infiniti® Ultrasound	
	.Handpiece, <i>Infiniti® NeoSoniX®</i>	
8065750193	-	
	.Handpiece, OZil® Torsional	
8065750184	.Footswitch, <i>Infiniti</i> ®	•
	.Footswitch, Accurus®/Legacy®	
	.Footswitch, Enhanced <i>Infiniti</i> ®	•
	,	
8065750468	.Remote Control, Infiniti®	
	.Transfer Pouch, Remote Control	₹ /
8065740759		
8065128402	.Bipolar Cable, 12 ft. Silicone, IEC-601	
	Bipolar Cable, 12 ft. Disp. Ster IEC-601	
	.Forceps, Curved Jewelers/Iris	
8065129301	_	
	.Forceps, Straight Jewelers/Iris	
	Brush, 18 Gage, Straight	
	Brush, 20 Gage, Straight	
	Brush, 18 Gage, Curved	
	Brush, 18 Gage, Widestroke	
	Brush, 23 Gage, Tapered	
000000,301	Brasii, 23 Gage, Taperea	
8065751606	.Manual, Operator's <i>Infiniti</i> ®	
	.Manual, Service <i>Infiniti</i> ®	
	.Infiniti® Data Card (MMC)	
8065750232	.VideOverlay, <i>Infiniti</i> ®	
	.VideOverlay, High Definition, <i>Infiniti</i> ®	
	.Upgrade Kit, <i>Infiniti</i> ® Wireless VideOverlay	
	.Upgrade Kit, <i>Infiniti</i> ® Wireless Network	
	.Upgrade Kit, <i>Infiniti</i> ® <i>UltraVit</i> ®	
8065750243		

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