UNITY VCS AND CS
USER MANUAL

UNITY VCS
Vitreoretinal
Cataract System

UNITY CS
Cataract
System

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Made in the USA with global materials

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MD

Rx only

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Contents

System Information

This section includes basic information about this manual and the *UNITY*™ Vitreoretinal Cataract System (VCS) and Cataract System (CS). This includes details important to understanding this guide and general safety information.

User Manual Overview

This user manual contains safety, setup, operation, and maintenance information about the *UNITY*™ VCS and CS. It is for licensed ophthalmologists and nurses trained for ophthalmic surgery.To maintain the performance and durability of the system, carry out all adjustment, cleaning, and disinfection procedures specified in this manual.

Terms

The following terms are used in this guide:

- **Console** – Refers to any configuration or model of the *UNITY*™ CS or the *UNITY*™ VCS.
- **Foot controller** – Refers to any compatible foot controller, footswitch, or foot pedal.
- **FMS** – Refers to the Fluidics Management System cassette or cartridge.
- **Image-guided system** – Refers to the *Verion*™ Image-Guided System.
- **Irrigating solution** – Refers to compatible *BSS*™ irrigating solution.
- **Microscope** – Refers to *LuxOR*™ microscopes or microscopes compatible with pairing with the console.
- **System** – Refers to the console, accessories, consumables, and other related devices used to perform functions of the system as intended.
- **Video overlay** – Refers to the *UNITY* Video Overlay.
- **Visualization system** – Refers to the *NGENUITY*™ 3D visualization system or a visualization system compatible with connecting with the console.

Abbreviations and Acronyms

The following abbreviations and acronyms appear in this guide or on the console.

Abbreviation or Acronym	Definition
ABS™	Aspiration bypass system
Ant	Anterior
Ant Vit	Anterior vitrectomy
AS	*Active Sentry*
ASK	Amplitude-shift keying
Asp	Aspiration
BF	Body floating
BLE	Bluetooth Low Energy
BPSK	Binary phase-shift keying
BSS™	Balanced Salt Solution
cc	cubic centimeters
CCK	Complementary code keying
cc/min	Cubic centimeters per minute. A unit of flow.
CDE	Cumulative dissipated energy
CE	A mandatory conformity mark on many products placed on the single market in the European Economic Area (EEA)
CME	Continuing medical education
Coag	Coagulation
cpm	Cuts per minute
DBPSK	Differential phase shift keying
DFU	Directions for use
DQPSK	Differential quadrature phase shift keying
DSP	Disposable
EPI	Epinucleus

Abbreviation or Acronym	Definition
ERP	Effective radiated power
ESD	Electrostatic discharge
FAX	Fluid-air exchange
FLACS	Femtosecond laser-assisted cataract surgery
FMS	Fluidics management system
FP	Foot controller position
Frag	Fragmentation
F/S	Foot controller (as in footswitch)
FSK	Frequency shift keying
GA	Gauge
GFSK	Gaussian frequency shift keying
HF	High frequency
I/A or IA	Irrigation and aspiration
IEC	International Electromechanical Commission
IOL	Intraocular lens
IOP	Intraocular pressure
iP	Intelligent phaco
Irid	Iridectomy
Irr	Irrigation
ISO	International Standards Organization
k	thousand (for example, 10k cuts per miniute = 10,000 cuts per minute)
LIO	Laser indirect ophthalmoscope
ME	Medical equipment
mmHg	Millimeter of Mercury. A unit of vacuum and pressure.
N/A	Not Applicable
NOHD	Nominal ocular hazard distance
OFDM	Orthogonal frequency-division multiplexing
PEL	Patient eye level

Abbreviation or Acronym	Definition
Phaco	Phacoemulsification
psi	Pounds per square inch. A unit of pressure.
QAM	Quadrature modulation
QPSK	Quadrature phase shift keying
Quad	Quadrant
RF	Radio frequency
RFID	Radio frequency identification
sec	Seconds
SI	International System of Units
slpm	Standard Liters per Minute
TS	*Thermal Sentry*
USB	Universal serial bus
UHDVO	*UNITY* High-Definition Video Overlay
V+V	Verion (steps)
VFC	Viscous fluid control
Visco	Viscoelastic
Vit or VIT	Vitrectomy. Extraction of the vitreous from the vitreous cavity.

Symbols

Conformity and Compliance Symbols

Symbol	Description
MD	Medical device
Rx only	Caution: US federal law restricts this device to sale by or on the order of a physician
	WEEE indicates the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.

Safety Symbols

Description	Description
	Consult instructions for use or consult electronic instructions for use
	Refer to instruction manual or booklet
	General warning
	Dangerous voltage
	Hot surface
	Trip hazard or floor-level obstacle
	Do not push when casters are locked
	Type BF applied part
	Protective earth (ground)
	Stacking limit by mass
	Laser beam
	Avoid eye and skin exposure to direct or scattered radiation.
	Magnetic resonance unsafe
	Ultrasound handheld instrument non-continuous use
	Equipotentiality terminal
	Magnetic field

Product Information Symbols

Symbol	Description
 YYYY-MM-DD	Country of manufacture with a date of manufacture
	Manufacturer
	Mass
REF	Catalog number
GTIN	Global trade item number
SN	Serial number
REV	Revision

Front Panel Indicators

Symbol	Description
	Diathermy accessory
	Ultrasound accessory
	Light probe
	Viscous fluid control
	Forceps
	Scissors
	FAX
	Vitrectomy cutter
	Multi-spot laser accessory port

Symbol	Description
	Single-spot laser accessory port (also compatible with *PurePoint* accessories)
	Optical fiber applicator
	6 button, 4 button, or *Centurion*™ foot controller
	*Constellation*™ foot controller
	Console power on or off

Rear Panel Indicators

Symbol	Description
	Active laser room indicator
	External air or nitrogen inlet
	*PurePoint* laser foot controller
	Emergency stop for the laser
	Ethernet
	Power on (laser)
	Power off (laser)
	SuperSpeed USB
	3D visualization system
	Protective filter
	Remote interlock
	Future accessory connection

System Overview

System Description

UNITY™ VCS and CS

The *UNITY*™ VCS is a multifunctional surgical instrument for use in anterior and posterior segment ophthalmic surgeries. The product's capabilities include driving a variety of handpieces that provide the ability to cut vitreous and tissues, emulsify the crystalline lens, illuminate the posterior segment of the eye, and apply diathermy to stop bleeding. Flow-controlled or vacuum-controlled aspiration is used to remove ocular matter from the eye. Pressure-controlled irrigation/infusion capability is provided to replace fluid in the eye, and enters the eye directly through either an infusion cannula or a handpiece. The graphical operator interface is menu-driven. The operator provides inputs using the touchscreen panel, the remote control, and the foot controllers.

The *UNITY* VCS and CS system comes in two configurations: anterior only or *UNITY* CS and combined or *UNITY* VCS.

An optional, fully integrated laser module is available that can be installed in the base of the combined configuration for vitreoretinal surgery. The laser delivers a visible 532-nm green treatment beam designed for ophthalmic use.

Foot Controllers

The *UNITY*™ 4 button and 6 button foot controllers are components that control functional operations of the *UNITY* system console during crystalline lens removal and/or vitreoretinal surgery. The 6-button foot controller has the added capability of controlling the system console during procedures that require the laser console. A laser foot controller also functions to control the *UNITY* system console solely during procedures that require the laser module.

The 4 button and 6 button foot controllers consist of a treadle, left and right horizontal / vertical switches, and a tension adjustment knob. In addition, left and right heel switches are present on the 6 button foot controller.

The laser foot controller has left and right horizontal switches, and a single vertical switch.

Remote Control

The *UNITY* remote control is a battery-operated component that uses Bluetooth radio frequency (RF) to communicate with the *UNITY* system console.

Intended Use

- The *UNITY* VCS (Vitreoretinal Cataract System), consisting of the console and compatible devices, is intended to facilitate management of fluid and gases, as well as removal, grasping, cutting, illumination, and coagulation of ocular materials.
- The *UNITY* CS (Cataract System), consisting of the console and compatible devices, is intended to facilitate management of fluid as well as removal, cutting, and coagulation of ocular materials.

Indications for Use

- The *UNITY* VCS, consisting of the console and compatible devices, is indicated for use during anterior and posterior segment ophthalmic surgery.
- The *UNITY* CS, consisting of the console and compatible devices, is indicated for use during anterior segment ophthalmic surgery.

Target Population

- The *UNITY* VCS is indicated for patients undergoing anterior and posterior segment ophthalmic surgery.
- The *UNITY* CS is indicated for patients undergoing anterior segment ophthalmic surgery.

Intended User

The intended users are ophthalmic surgeons and their operating room staff.

Contraindications

For console configurations that include a laser module, patients with a condition that prevents visualization of target tissue (cloudy cornea, or extreme haze of the aqueous humor of the anterior chamber or vitreous humor) are poor candidates for LIO delivered laser treatment.

Clinical Benefits

- The indirect clinical benefit of the *UNITY* VCS System, consisting of the console and compatible devices, is to aid in the execution of anterior and posterior segment ophthalmic surgery.
- The indirect clinical benefit of the *UNITY* CS System, consisting of the console and compatible devices, is to aid in the execution of anterior segment ophthalmic surgery.

Safety Information

For both VCS and CS models, accessories connected to the console must be certified according to respective IEC standards (for example, IEC 60950-1 or IEC 62368-1 for data processing equipment and IEC 60601-1 for medical equipment). All configurations shall comply with EN 60601-1 (equivalent to IEC 606061-1, as amended), clause 16. Anyone connecting additional equipment or otherwise changing the system configuration other than provided by Alcon is responsible for continued compliance with IEC 60601-1 (as amended), clause 16. If in doubt, contact Alcon Technical Services or a local Alcon representative.

General Warnings and Precautions

The following are general system warnings and precautions applicable to VCS and CS models. This manual includes additional warnings and precautions specific to certain instructions or situations and are stated in relevant sections. If additional information is required, please contact a local Alcon service representative or the Technical Services department.

- **Warning** – A statement written to protect individuals from bodily harm (red border)
- **Precaution** – Action taken in advance to protect against possible danger, failure, or injury: a safeguard.
- **Caution** – A statement written to protect the instrument from damage (black border)
- **Note** – A statement written to bring attention to highlighted information (blue border)

WARNING:

- Do not stand on the base of the console.
- Do not use sterile products if the sterile field is compromised.
- This product can expose you to chemicals including Antimony oxide (Antimony trioxide); Bisphenol A (BPA); 4-vinylcyclohexene; Acrylonitrile; 1,3-butadiene; Styrene; Cumene; Silica, crystalline (airborne particles of respirable size); Beryllium; Carbon black (airborne, unbound particles of respirable size); Gallium arsenide; Glass wool fibers (inhalable and biopersistent); Cobalt metal powder; Arsenic; Tetrabromobisphenol; A C.I. Solvent Yellow 14; Titanium dioxide (airborne, unbound particles of respirable size); Mercury and mercury compounds; a-Methyl styrene (alpha-Methylstyrene); Benzo[a]pyrene; Toluene diisocyanate; 2-Mercaptobenzothiazole; Lithium carbonate; n-Hexane; lead and lead compounds; nickel and nickel compounds; Di-isodecyl phthalate (DIDP); Antimoy Oxide; Glycidyl Methacrylate which are known to the State of California to cause cancer, birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

WARNING:

- Modification of the equipment is not allowed without prior authorization from the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- Do not simultaneously touch any non-medical equipment enclosure (for example, a video overlay) and the patient.
- To avoid the risk of burns or fire, do not use the system near conductive materials. Review electrical cables upon evidence of deterioration.
- When connecting another electrical equipment to the UNITYVCS or UNITYCS equipotentiality terminal, ensure that the configuration complies with clause 16 of IEC 60601-1 (ME systems).
- A qualified technician must check ground continuity and leakage current every 12 months to ensure they are within the limits of the applicable standards (for example, EN 60601-1 or IEC 60601-1). Values must be recorded and, if they are above the limits of the applicable standards or 50% above the initial measurement, do not use the system and call Alcon Technical Services.
- For continued protection against risk of fire, replace only with same type and rating of fuse.
- To avoid risk of electric shock, this equipment must be connected only to a supply mains with protective earth (ground).
- Inadvertent activation of functions that are intended for priming or tuning accessories while the accessory is in the eye can create a hazardous situation that could result in patient injury.
- Never intentionally modify accessories or tips (for example, do not bend, cut, or engrave them) as they could break or malfunction.
- Do not use any of the contents if the sterile package is damaged or the seal is broken in any way.

General Laser Safety Precautions (VCS Models with Optional Laser Only)

This system complies with EN 60825-1 (equivalent to IEC 60825-1) and ANSI Z136.1 standards for laser safety. Corneal burns, inflammation, loss of best-corrected visual acuity, loss of visual field, and transient elevations in intraocular pressure can occur as a result of ophthalmic laser treatment. Unintentional retinal burns can occur if excessive treatment beam power or duration is used.

WARNING: To avoid the risk of fire or explosion, avoid the use of the laser in the presence of flammable anesthetics, oxidizing (such as nitrous oxide, N_2O), or endogenous gases. Also, avoid the use of material that may also be ignited by the high temperatures produced in normal use of the laser equipment (for example, cotton or wool).

The following precautions relate to safe laser setup and use. Refer to IEC 60825-1, ANSI Z136.1, or EN 207 for more information.

- Appoint a laser safety officer to supervise the installation and use of the system.
- Install an indicator light outside the laser room to signify instrument operation.
- Do not direct laser beams toward a door, window, or reflective surface.
- Use non-reflective matte finish wall paint.
- Avoid using carpet or material that generates dust on the floor or walls to minimize grime or dust on the optics or cooling system.
- Ensure there is a minimum of 0.5 m of open space on all sides of the laser.
- To prevent unauthorized use of the laser, remove the key when not in use.
- Post appropriate warning signs at entrances to areas or protective enclosures containing Class 4 lasers.
- Use eye protection with OD 4 or above at 532 nm in all hazard areas. However, for locations complying with EN 207, use eye protection with class D LB6 or above. Eye protection must be resistant to physical damage and photo-bleaching.
- A qualified technician must verify the power plug used is properly grounded.
- Potential hazards may occur when inserting, sharply bending or improperly securing the fiber optics. Not following the recommendations of the manufacturer may lead to damage to the fiber or beam delivery system and/or harm to the patient or laser operator.
- Connect the remote interlock connector to an emergency master disconnect interlock or to a room, door, or fixture interlock.
- Place the laser foot controller, endoprobe, multi-spot, or LIO within 2 m of the console.

Accessory	Beam Divergence (NOHD)
LIO	0.024 radians (20 m)
Endoprobe	0.23 radians (3 m)
Multi-spot	0.19 radians (4 m)

Residual Risk Disclosure

After implementing risk mitigation measures and applying a state-of-the-art process, all residual risks are at an acceptable level. The residual risks are listed below for transparency and to meet Alcon obligations per Medical Device Regulation (MRD) (EU) 2017/245.

Residual risks include abnormal intraocular pressure, burns, edema, electric shock, hemorrhage, ocular inflammation, ischemia, cataract formation (not applicable for cataract removal procedures), microbial ocular infection, accidental exposure/adverse systemic response, device malfunction due to operation of other equipment could lead to patient injury, physical trauma, systemic cross infection, tissue damage, and visual dysfunction.

Serious Incident Reporting

Any serious incident related to the use of the UNITY VCS/CS or their accompanying accessories and consumables should be reported to Alcon Laboratories, Inc.:

By phone: In USA – (800) 757-9780
In EU/International – Contact the local country office or your Alcon distributor.

Website: https://www.alcon.com/contact-us/

Email: qa.complaints@alcon.com

These serious incidents should also be reported to the competent authority for medical devices of your State.

Electromagnetic Compatibility (EMC) Compliance

The system is designed to work in the professional healthcare facility environment. 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 representative.

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

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

WARNING:

- The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by Alcon as replacement parts for internal components, may result in increased emissions, decreased immunity of the system, or improper operation.
- To minimize potential electromagnetic or other interference with other devices, do not use the system adjacent to, or stacked with, other equipment. However, if adjacent to or stacked use is necessary, observe the system to verify normal operation in the configuration in which it will be used.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- MAGNETIC AND ELECTRICAL INTERFERENCE - Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment, magnetic resonance tomography (MRT), nuclear magnetic resonance (NMR), or magnetic resonance imaging (MRI) devices are possible sources of interference as they may emit higher levels of electromagnetic radiation.

Cables Used to Connect System Components

Item	Cable Type	Shield	Length	Ferrite	Connection 1	Connection 2
1	AC cable	No	5 m	No	Console	AC mains
2	UNITY 6 button foot controller cable	Yes	3.7 m	No	Console	UNITY 6 button foot controller
3	Diathermy cable	No	3.6 m	No	Console	Diathermy port
4	UNITY ultrasonic handpiece cable	No	2 m	No	Console	Ultrasonic port
5	Fragmentation handpiece cable	No	2 m	No	Console	Ultrasonic port

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The system is intended for use in the electromagnetic environments specified below. The customer or the user of the system should assure it is used in such an environment.

Emissions Test	Compliance	Emissions Test Compliance Electromagnetic Environment – Guidance
Conducted and radiated RF emissions CISPR 11	Group 1	When coagulation mode is energized, the system will fall into category of Group 2 equipment per CISPR 11 classification. Compliance with Group 2 emission limits are not required. According to IEC 60601-2-2 standard, HF surgical equipment shall comply with the requirements of CISPR 11 Group 1, when it is switched on and in an idle state with the HF output not energized.
Conducted and radiated RF emissions CISPR 11	Class A	The emissions characteristics of the system make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), the system might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The system is intended for use in the electromagnetic environments specified below. The customer or the user of the system should assure it is used in such an environment.

Immunity Test	IEC 60601 Test and Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±15 kV air	None
Electrical fast transient/burst IEC 61000-4-4	±2 kV on power supply lines ±1 kV on input/output lines	Mains power quality should be that of a typical hospital (including ambulatory surgery centers) environment. To avoid premature shutdown due to fast transients, avoid powering the system on the same branch circuit with sources that can generate fast transients (inductive switching; for example, high current motors).
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical hospital (including ambulatory surgery centers) environment.
Voltage dips, short interrupts, and variations on power supply lines IEC 61000-4-11	0% U_T for 0.5 cycle at 8 Φ angles 0% 1 cycle 70% U_T for 25/30 cycles 0% for 250/300 cycles	Mains power quality should be that of a typical hospital (including ambulatory surgery centers) environment. If the use of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply with a minimum rating of 1200 VA.
Power frequency (50/60 Hz) magnetic fields IEC 61000-4-8	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital (including ambulatory surgery centers) environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms at ISM Frequencies	The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

<table>
<tr><th>Immunity Test</th><th>IEC 60601 Test and Compliance Level</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz</td><td>The dwell time should be at least 1 s and should be no less than the response time of the slowest responding function plus the settling time of the immunity test system.</td></tr>
<tr><td>Proximity fields from RF wireless communication equipment
IEC 61000-4-3</td><td><table><tr><th>Frequency (MHz)</th><th>Level (V/M)</th></tr><tr><td>385</td><td>27</td></tr><tr><td>450</td><td>28</td></tr><tr><td>710, 745, 780</td><td>9</td></tr><tr><td>810, 870, 930</td><td>28</td></tr><tr><td>1720, 1845, 1970</td><td>28</td></tr><tr><td>2450</td><td>28</td></tr><tr><td>5240, 5500, 5785</td><td>9</td></tr></table></td><td>The immunity test levels specified in the table were calculated using the following equation:

$E = (6\sqrt{P}) / d$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the Immunity Test Level in V/m. The factor of 6 is a compromise for a range of antenna factors to simplify the test.</td></tr>
<tr><td>Immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz
IEC 61000-4-39</td><td><table><tr><th>Frequency</th><th>Level (A/M)</th></tr><tr><td>30 kHz</td><td>8</td></tr><tr><td>134. kHz</td><td>65</td></tr><tr><td>13.56 MHz</td><td>7.5</td></tr></table></td><td>30 kHz is applicable only to medical equipment and medical systems intended for use in the home healthcare environment.</td></tr>
</table>

NOTE: U_T is the AC mains voltage prior to application of the test level.

Wireless Certification and Compliance Information

Radio Transmitters

The console is a medical device designed for indoor use only. It incorporates short-range frequency radio transmitters for use by the console for communication with system components and the hospital network. These short-range frequency radio transmitters meet EU and AFTA countries requirements. They are also FCC, IC, RED, and Japanese Radio Law compliant.

Transmitter	Frequency or Frequency Band of Transmission and Reception	Type and Frequency Characteristics of the Modulation	Output Power
802.15.4/BLE 5.0 radio module Communication link with foot controller or remote	2.402 GHz to 2.480 GHz	GFSK DBPSK, DQPSK, CCK	8 dBm 6.3 mW (ERP)
Wi-Fi 802.11ac radio module Communication link with hospital network or UHDVO	802.11 b/g/n: 2412 to 2472 MHz 802.11 a/n/ac: • 5180 to 5420 MHz • 5260 to 5320 MHz • 5500 to 5720 MHz • 5745 to 5825 MHz	OFDM: BPSK, QPSK,16-QAM, 64-QAM, 256-QAM	17 dBm 50.1 mW (ERP)
Wireless foot controller battery charger	50 kHz (charging)	N/A	10 W (max)
RFID device	13.56 MHz	ASK	-25.4 dBm 0.003 m/W

USA – Federal Communications Commission (FCC)

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

CAUTION: Change or modifications made to this equipment (including antenna) not expressly approved by Alcon may void the FCC authorization to operate this equipment.

FCC Radiation Exposure Statement

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

Europe – RED Directive 2014/53/EU

This device complies with the essential requirements of the Radio Equipment Directive 2014/53/ EU.

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

Canada – Industry of Canada (IC)

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

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

Exposure of Humans to RF Fields:
This device complies with RF exposure limits for humans as called out in RSS-102.

The antennas used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be located or operating in conjunction with any other antenna or transmitter.

Canada - Industrie du Canada (IC)

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

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

Exposition des personnes aux champs radioélectriques:
Cet appareil est conforme aux limites d'exposition RF pour les êtres humains comme elles le sont notifiées dans la norme RSS-102.

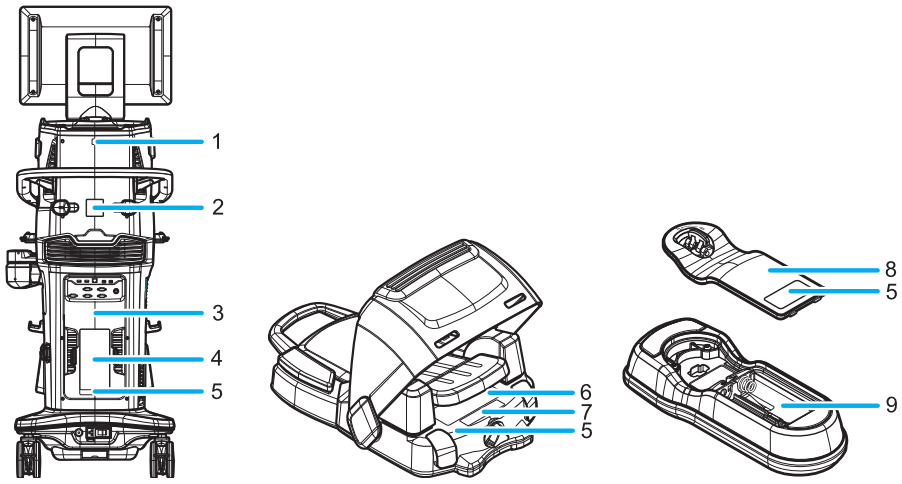
Les antennes utilisées pour ce transmetteur doivent être installées en considérant une distance de séparation de toute personnes d'au moins 20 cm et ne doivent pas être localisées ou utilisées en conflit avec tout autre antenne ou transmetteur.

Wireless Certification

Region	Certification and Compliance (and Label Locations)
United States	FCC ID: VMC-NGPVID (RFID in console) Contains FCC ID: VMCBL654 (BLE/802.15.4 in console and foot controller) Contains FCC ID: SQGBL654 (BLE in remote) Contains FCC ID: SQG-SU60SOMC (Wi-Fi/BLE in console)
Australia	
Canada	IC: 7345A-NGPVID (RFID in console) Contains IC: 7345A-BL654 (BLE/802.15.4 in console and foot controller) Contains IC: 3147A-BL654 (BLE in remote) Contains IC: 3147A-SU60SOMC (Wi-Fi/BLE in console)
Japan	 003-180100  201-180112
Korea	 R-C-LAI-SU60-SOMC R-C-L7C-BL654

Label Locations

Note the following safety and system label locations. The console labels apply to any console unless stated otherwise. Refer to the system for specific information.

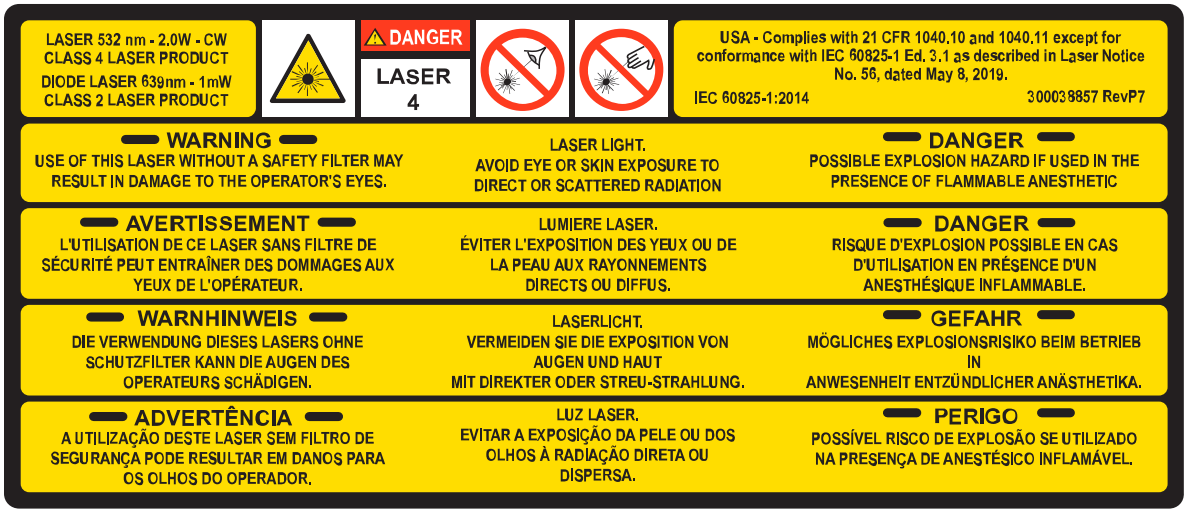


VCS Console (Left), Foot Controller (Middle), and Remote (Right) Labels

1 **Do not push label** – Warns of a potential tip or overbalance hazard if the console is pushed when the casters are locked or the wheels are immobilized.

2 **Console identification label** – Includes product identification and manufacturing information.

3 **Laser label** (VCS models with an optional laser only) – Includes laser class and safety information.



4 **Product label** – Includes basic product details, safety information, and wireless certifications.

5 **Investigational device** and **clinical trial use** labels – Includes statements about limited use.

6 **Foot controller compliance label** – Includes wireless certification and manufacturing information.

7 **Foot controller product label** – Includes product identification information.

8 **Remote product label** – Includes manufacturing, wireless certification, and product identification information.

9 **Abbreviated remote product label** – Includes product identification information.

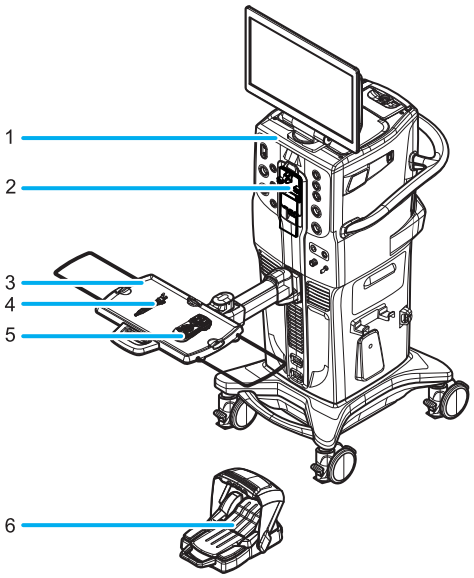
System Features and Compatible Devices

WARNING: The console, accessories, and corresponding Alcon consumables constitute a complete surgical system. Use of consumables other than Alcon consumables may affect system performance and create potential hazards and, if it is determined to have contributed to the malfunction of the system under a service contract, could result in the voidance of the contract and invoicing at prevailing hourly rates.

Contact the Alcon Sales department for in-service information prior to initial use of accessories or packs. Also, contact the Sales department for additional information regarding parts and approved equipment.

Method	USA Sales Department Contact	International Sales Department Contact
Phone	(800) 862-5266 or (817) 293-0450 Ask for customer service	Please contact a local Alcon Sales office.
Write	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134-2099	

Basic System Example



A UNITY VCS with a Large Tray Installed and a 6 button Foot Controller Paired

1 **Console** – Performs general surgical functions and communicates with connected *UNITY* devices (see Console Features).

2 **FMS** – Manages the flow between a fluid or air source, the console, and accessories (see FMS Features).

3 **Tray** – Provides a convenient surface to present tools to the user (see Tray Features).

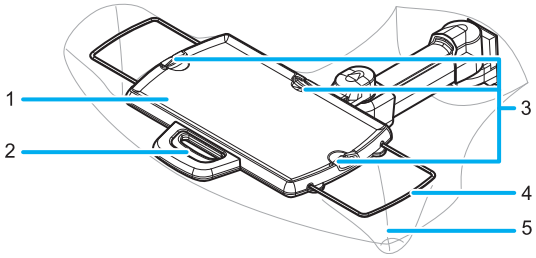
4 **Accessory** – Interacts with the eye (see Accessories).

5 **Remote** – Provides basic console interface navigation and selections (see Remote Features).

6 **Foot controller** – Controls console functions (see Foot Controller Features).

Tray Features

The console supports either a small or large tray.



Tray Features

1 **Surgical tray** – Provides a surface to place instruments.

2 **Handle** – Positions the tray when gripped.

3 **Cable holders (3)** – Secure cables and tubes.

4 **Bail liners (2)** – Create pockets with a drape to hold instruments or other tools.

5 **Cover** – Creates a barrier between items on the tray and the tray surface. The large tray is also compatible with a cover for the small tray, but it has limited coverage.

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Service and Maintenance

This section contains basic preventive maintenance information and troubleshooting ideas. There are no user serviceable components inside the console or foot controller. See Alcon Service for service information.

WARNING: For all people in contact with the console and accessories, practice universal precautions to help prevent exposure to blood-borne pathogens and other potentially infectious materials. If the status of encountered blood or body fluids or tissue is unknown, handle the material in accordance with OSHA or other applicable guidelines as if it is infectious.

Shutdown Procedure

End Case

Upon the completion of the work day, perform the following steps:

1. Clean accessories as instructed by the corresponding DFU.
2. Remove the irrigating solution bag from the bag chamber and set aside.
3. Remove the spike from the irrigating solution bag.
4. Discard the tubing.
5. Close the bag chamber door.
6. Eject the FMS and discard.
7. Turn off the console.

Turn Off the Console

To power down the console, perform the following steps:

1. On the display, select **Menu** > **Shutdown**. Alternatively, press and hold the **Standby** button until the console shuts down.
2. If prompted, select **Confirm**.
3. Press the **Power** switch off.

Cleaning

Wherever possible, use non-flammable agents for cleaning and disinfection.

WARNING: To avoid a risk of fire, allow solvents of adhesives and flammable solutions used for cleaning and disinfecting to evaporate before using the laser equipment.

Clean the Console and Remote

Alcon recommends the following cleaning tips:

- Wipe the console panels with compatible solutions.
- Clean the display with a soft, non-abrasive cloth towel and a mild commercially-available window cleaner. Apply the cleaner to the towel rather than the display.

⚠ CAUTION:

- Do not spray liquid (for example, cleaning solution or water) into console vents.
- Avoid spilling irrigating solution or moisture of any kind around the electrical ports.
- To avoid damage to the remote, do not sterilize it.

Clean the Foot Controller

⚠ CAUTION: Debris, including fluid residue, stuck on the foot controller bottom or under the treadle may cause temporary malfunction of the foot controller.

To clean the foot controller, perform the following steps:

1. Remove any debris stuck under the foot controller or under either end of the treadle.
2. Clean the bottom of the foot controller and under the treadle with water or water with mild soap.

Storage and Transportation

If the system will not be used for an extended period, Alcon recommends the following practices to preserve the backup battery life:

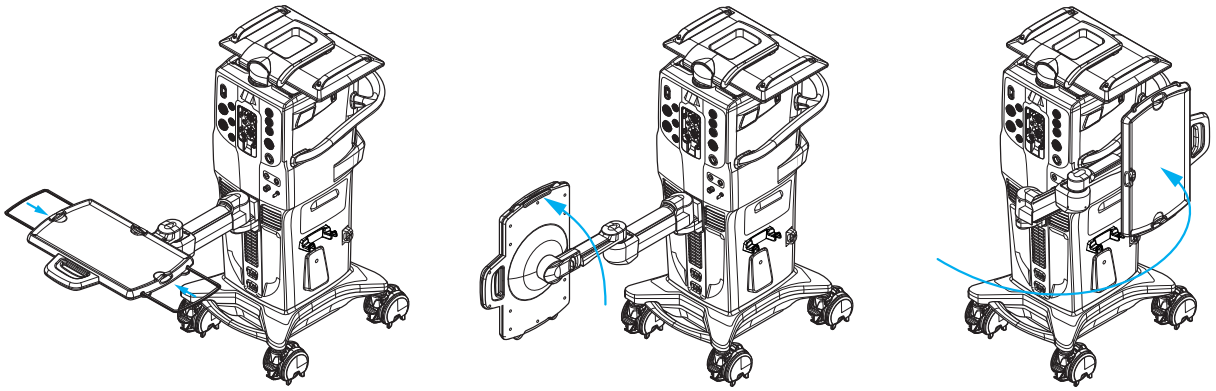
- Leave the console connected to facility power with the main power switch on.
- Turn on the console once week and leave it on at least 7 hours each time.

Display Protection

1. Rotate the display to face the rear.
2. Push the display down until it is level with the top of the console.

Tray Storage

WARNING: Move the console only with the tray in a stowed position.



Steps to Stow the Tray

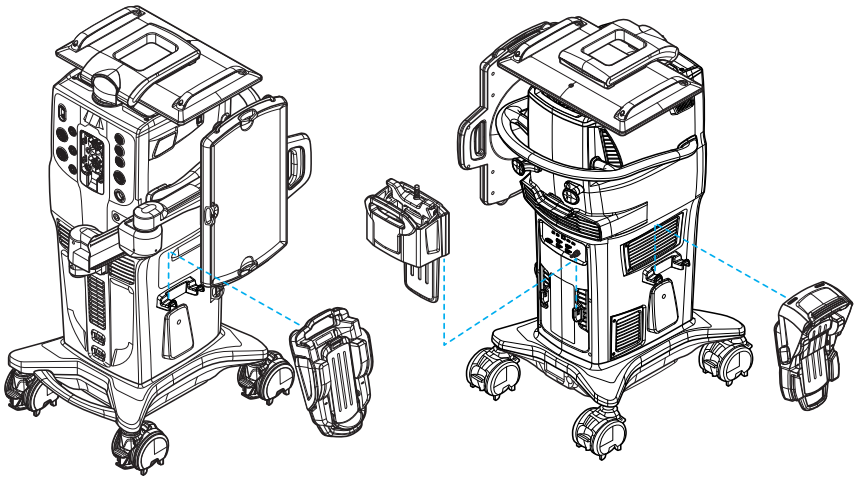
To stow the either tray size, perform the following steps:

1. If necessary, push the metal rims into the tray.
2. Pull the tray lever to tilt the tray to a vertical position.
3. Hold the tray handle to move the tray to either side of the console.

CAUTION: To avoid damaging the tray, do not push or pull the tray without holding the tray handle in.

Foot Controller Hangers

⚠ **CAUTION:** To minimize battery degradation during long-term storage, keep *UNITY* foot controllers at room temperature with low humidity.



3 Stored Foot Controllers

Cable Wraps

Wrap the power cord around the hooks as shown above. The label between the hooks should be visible.

Alcon Service

CLINICAL AND TECHNICAL SERVICES
— SUPPORT LIKE NO OTHER —

For product service, contact Alcon Technical Services or an authorized local service representative. For optimal performance, schedule preventive maintenance for the system and relevant accessories at least once a year. However, systems may require additional service depending on use or other circumstances. Also, verify safety performance at least once a year and ensure ground resistance, leakage current, and dielectric withstand voltage meet appropriate international, national, and local standards.

Before returning systems or accessories, contact Alcon Technical Services or an authorized local service representative. If necessary, follow any provided shipping instructions.

Alcon Technical Services and Clinical Support (US)
Phone: +1 (949) 238-8254
US toll free: +1 (800) 832-7827

Canada phone: +1 (800) 268-4574

Preventive Maintenance for Users or Responsible Organizations

There are no user-serviceable components inside the console or foot controllers. If desired, contact Alcon for a technical description of the system. Upon request, this may include a service manual with additional information to assist service personnel.

WARNING:

- If a deficiency persists, do not use the system and call Alcon Technical Services.
- In addition to the Alcon service recommendations (see Alcon Service), Alcon also recommends a qualified technician perform a safety inspection at least twice a year to help ensure system performance. As part of the inspection, ensure the technician inspects the console skin for cracks, labeling integrity, ground resistance, leakage current, and dielectric withstand voltage.
- A qualified technician must check ground continuity and leakage current every 12 months to ensure they are within the limits of the applicable standards (for example, EN 60601-1 or IEC 60601-1). Values must be recorded and, if they are above the limits of the applicable standards or 50% above the initial measurement, do not use the system and call Alcon Technical Services.
- Inspect all handpiece cables and any cords on a regular basis and replace immediately if damage (for example, exposed wire, nicks in the insulation, deformation, etc.) is observed.
- The VCS console has system back-up battery and foot controller battery. These batteries are not user-replaceable and can only be serviced by a factory-trained service engineer. Access by untrained personnel can lead to injury.