veritas
Vision System



Console dimensions (with display)

Width	61 cm
Depth	61 cm
Height	158 cm
Weight (including IV pole)	84 kg
Power cord length	6.1 m

Electrical specifications

Voltage	100–240 VAC
Frequency	50–60 Hz
Rated power	750 VA
Fuse rating	6.3A, 250V, Bussmann GDA
Enclosure current leakage	<500 uA

Per IEC 60601-1, the VERITAS™ Vision System is a Class 1 device.

VERITAS™ VISION SYSTEM
SPECIFICATIONS

Dual pump system	Flexible switching between peristaltic and venturi mode by operating the side control on the foot pedal
Pack type	**VERITAS™** Advanced Infusion Tubing Pack (VRT-AI)
Foot pedal	VERITAS™ foot pedal—wired or wireless
Phaco tips	Straight, angled (19G, 20G, 21G) Curved (19G, 20G)
Remote	Wireless
Vitrectomy cut rate	50 to 2500 cpm Size: 20G, 23G, or 25G
Monitor/GUI	19" touchscreen
Surgeon customization	100 surgeon capacity
Surgeon programs	20 unique program options per surgeon
Program submodes	11 submode options per program
Submode names	Customizable
IV pole height maximum	106 cm
Vacuum maximum	650mmHg (Peristaltic)/600mmHg (Venturi)
Aspiration maximum	60 cc/min (Peristaltic)
Vacuum ramp	10 to 100 (pump ramp) 1 to 5 (Venturi vac ramp)
Power	0 to 100% (simultaneous transversal and longitudinal)
Preferred default program	Specific or retain current program
Power: continuous setting	Available
Power: burst settings	Single-burst/Multi-burst/Continuous burst
Power: pulse settings	Pulse mode/Short pulse/Long pulse/ Low-power pulse/High-power pulse
Special power mode features	WHITESTAR™ pulsing WHITESTAR™ ICE pulse shaping
Occlusion modes	Regulates vacuum rise time following an occlusion of the phaco tip
Occluded mode	Available via 'Vacuum Threshold'
CASE mode	Available via 'Set mmHg Value'
CASE & Occlusion modes	Available: can work together or independently
Venting	Adjustable
Compliance	In accordance with IEC 60601-1

Reference: VERITAS™ Operator Manual Z370722 Rev B. REF2023CT4038.

†For optimum performance of the system and safety, use only parts recommended by Johnson & Johnson.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE VERITAS™ VISION SYSTEM

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician

INDICATIONS FOR USE / INTENDED USES

The VERITAS™ Vision System is a modular ophthalmic microsurgical system that facilitates anterior segment (i.e., cataract) ophthalmic surgery. The modular design allows the users to configure the system to meet their surgical requirements.

CONTRAINDICATIONS

Any pre-existing patient condition/s that the health care provider determines to be a contraindication to cataract surgery.

UNDESIRABLE SIDE EFFECTS

Complications that may be associated with the VERITAS™ Vision System include

- corneal burn
- infection/inflammation
- corneal edema
- broken capsule

PRECAUTIONS

Once you have set the system up and you have verified that all the functions are operating properly, you are almost ready to use your system.

Read the following safety precautions carefully before using the system in surgery.

- Do not use extension cords with your system
- Do not overload your electrical receptacle (outlet).
- The instrument has ventilation openings at the rear of the console to allow ambient air intake and the release of heat generated during operation. Do not block the openings; as heat build-up can cause system failures which can result in a fire hazard.
- Do not try to move the system cart on deep pile carpets or over objects on the floor, such as cables and power cords.
- Take care not to trip over power and foot pedal cords.
- Do not try to lift the system console.
- Do not place the instrument on uneven or sloped surfaces.
- Only use disposables, accessories, or other surgical instruments designed for this system. For optimum performance of the system and safety, use only parts recommended by JJSV.
- Do not operate the system in a condensing environment (over 95% relative humidity). Take care to protect the instrument from fluid sprays or fluid buildup. To protect the patient from contaminated fluids or handpieces, use only:
  - sterile tubing packs
  - sterile irrigation fluid
  - sterile handpieces
- Wrap the excess power cord neatly around the cord wrap on the back of the console.
- Use caution when you use handpieces with sharp edges or pointed tips.
- Always replace the tubing pack and the balanced salt solution source between cases.
- Use extreme caution when you lower or raise the balanced salt solution source to decrease fluid flow or increase fluid flow, and fluid pressure.
- If you do not properly prime the I/A tubing, errors can occur.
- Care should be taken to avoid abrasion of tissues during phacoemulsification.
- It is very important that the electrical connectors on the handpieces are completely dry before you attach the handpiece to the system receptacles.
- The phaco handpiece is a very delicate instrument and you must handle the handpiece with EXTREME care.
- The ultrasonic titanium phaco tip must never touch any solid material while in use.
- Handpieces can be extremely hot immediately after sterilization. Use care and caution when handling.
- Do not activate the phaco handpiece and vitrectomy cutter with the tip in the air. Exposure of the tip to air drastically reduces the useful life of the handpiece. If you introduce power to the phaco handpiece or vitrector my cutter, the tip must be in a test chamber filled with balanced salt solution, in a container of balanced salt solution, or in the patient's eye.
- Failure to properly attach the tubing to the vacuum source or pressure source can affect the vitrectomy cutter operation.
- You must check the diathermy cable periodically for damage. If the cable shows signs of damage, replace the cable immediately with the same type of cable. Use of other types of cables can affect the diathermy performance.
- During surgery, the diathermy output power must be as low as possible for the intended purpose. JJSV recommends the 30% setting to start.
- You must position the diathermy cable in such a way that the cable avoids contact with the patient or other leads. When you use diathermy, grounded or ungrounded metal parts must not come in contact with the patient.
- For proper operation of the diathermy, replace the handpiece with the same type.
- Do not exceed the maximum weight of two 500 ml balanced salt solution sources on the IV pole bottle holder.
- Do not attempt to carry the foot pedal by the heel when the heel insert is attached. The heel insert could become loose causing the foot pedal to drop.
- Do not place the foot pedal on a wet surface.
- Securely attach plugs, handpiece cables, and other connectors.
- Do not have any other Bluetooth® devices in the same area as the remote and the console (other remote controls, foot pedals, cell phones, or headsets, for example) as the pairing operation will fail. The software can detect a maximum of nine (9) devices.
- Never attempt to straighten a bent phaco ultrasonic tip. This might produce a broken tip when you apply ultrasound.
- Perform functional checks of the system before first use of the day.
- If you do not hear a tone when you press the foot pedal and volume adjustment is unsuccessful, the mode is not functioning properly.
- Only use the JJSV specified replacement battery in the Advanced Linear Pedal to ensure correct system performance.
- This equipment has been tested for radiated RF immunity only at the frequencies and levels listed in the section "Electromagnetic Disturbances" in the Operator's Manual which are the types of emitters expected to be found in the professional healthcare environment. Use of nearby emitters at other frequencies could result in improper operation and may cause the system to enter a safe state as defined in the "Errors" section of the Operator's Manual. It may be necessary to take mitigation measures such as reorienting or relocating the VERITAS™ Vision System or shielding the location.

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- The VERITAS™ Vision System EMISSIONS characteristics 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) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Irrigation solution in a bottle or bag may be used with a VERITAS Pack after a successful Prime/Tune has been completed. Not all bags may successfully complete Prime which may result in treatment delay.

WARNINGS

- All personnel who might operate this equipment must read and understand the instructions in this manual before they use the system. Failure to do so might result in the improper operation of the system. Only a trained licensed physician can use this device.
- Do not modify the VERITAS™ Vision System.
- The system comes equipped with a 3-prong power plug which you must plug into an outlet with a ground receptacle. If the plug does not fit the outlet, contact an electrician.
- For 120V units, grounding reliability can only be achieved when this equipment is connected to a receptacle marked “Hospital Grade” or bearing a green dot.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Ensure the balanced salt solution bottle is at or above the eye level of the patient.
- The surgical staff must monitor the balanced salt solution source height and fluid level at all times. A low irrigation source or empty irrigation source affects the fluid balance and the intraocular pressure (IOP) while aspirating. Low irrigation source height or low or empty irrigation fluid level can result in:
  - Inadvertent chamber shallowing or collapse
  - Aspiration or abrasion of the iris or other tissue
  - An ultrasonic wound heating commonly called wound burn (extreme case)
- Do not attempt to use the system if the system fails to perform properly as stated in this manual.
- Do not use the system in the presence of any of the following as a fire can result:
  - flammable anesthetics
  - other flammable gases
  - flammable fluids
  - flammable objects
  - oxidizing agents
- Ensure the patient does not have a cardiac pacemaker or other active implant as this unit might interfere with any cardiac pacemaker; therefore, obtain qualified advice prior to such use.
- The patient must not come into contact with grounded metal parts or metal parts that have appreciable capacitance to ground. JJSV recommends the use of an antistatic mat for this purpose.
- Use proper handling and disposal methods for biohazards when you dispose of the tubing pack, Mayo tray drape, and monitor drape.
- Ensure the tubing pack drain bag does not over-fill. The maximum capacity of the bag is 600 cc.
- Use caution when you extend, retract, or swivel the Mayo tray articulating arm. Stay clear of the hinged hardware.
- Do not modify the pole height or manually force the pole height because this could cause incorrect indication of irrigation source height and patient injury.
- Please note that when Cont. Irr. Auto-Off is enabled, a significantly large wound leakage or air bubbles in the tubing lines may affect the feature.
- Using the Advanced Infusion Tubing Pack VRT-AI with a bag that is not fully pressurized as the irrigation source could result in a lower irrigation pressure than what is reported by the system. Any time an irrigation solution bag is used or replaced during surgery with the Advanced Infusion feature employed, a period of time is required in order to pressurize the bag, which may be noted by the observation of air bubbles going into the bag. Once the steady stream of air bubbles stops, the bag is fully pressurized and ready for use.
- Operating phacoemulsification without an adequate irrigation flow can result in an elevated temperature of the tip and subsequent damage to the eye tissue or could cause the chamber to collapse
- Place monitoring electrodes or other types of equipment as far from those of the VERITAS™ Vision System as possible. JJSV recommends high current limiting devices for the protection of such systems. Do not use needle monitoring electrodes.
- Keep the diathermy cord away from the patient and other handpieces or leads (for example, monitoring electrodes). Keep unused ACTIVE ELECTRODES away from the patient.
- The output power selected must be as low as possible for the intended purpose.
- This system complies with IEC 60601-1-2 4th edition for Electromagnetic Disturbances. It is still possible that disturbances produced by the operation of this High Frequency (HF) Surgical Equipment may adversely influence the operation of other electronic equipment.
- Do not have skin-to-skin contact on the patient. For example, between the arms and the torso. Insert dry gauze to avoid contact, as appropriate.
  - The unit does not contain any neutral electrode.
  - The diathermy output is bipolar.
  - JJSV recommends that you check the condition of all interconnecting and handpiece cables on a regular basis.
- Risk of burns and fire. Do not use the system near conductive materials such as metal bed parts, inner spring mattresses, or similar items. Replace electrode cables on evidence of deterioration.
- Hazardous electrical output. This equipment is for use only by qualified personnel.
- If there is damage to the cord or the plug, do not use the instrument. A damaged cable can cause an electric shock to the user or a fire hazard to the system. Call JJSV customer service to order a new cord.
- Disconnect the power before you service the equipment.
- Remove the power cord from the power outlet when the equipment is not in use.
- Do not obstruct the power outlet so you can readily remove the power cord.
- To prevent the risk of fire or damage to the instrument, replace the fuses with the exact type and rating (check the voltage sticker on the back panel of the system to confirm your system voltage).
- Not recommended for use in condensing environments. If exposed to a condensing environment, allow the system to equilibrate to typical operating room conditions prior to use. Only use the system within the stated relative humidity conditions.
- You do not need to use a NEUTRAL ELECTRODE with this High Frequency (HF) Surgical Equipment.
- Failure of this High Frequency (HF) Surgical Equipment could result in an unintended increase of output power.
- Do not replace the foot pedal battery while in use with a patient.
- Do not replace the remote control battery while in use with a patient.
- Do not try to replace the batteries for the Advanced Control Pedal. Call your JJSV technical service representative to replace the batteries.

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- Sterility assurance is the responsibility of the user. You must sterilize all non-sterile accessories prior to use.
- Prior to using any invasive portions of the handpiece assembly, examine under the microscope for any obvious damage, oxidation, or the presence of foreign material. You must note any questionable characteristics; use a backup handpiece for surgery. Use of contaminated or damaged system accessories can cause patient injury.
- Do not have the handpiece tip in the eye of the patient when you prime and tune the handpiece.
- Do not use non-JJSV approved products with the VERITAS™ Vision System, as this can affect overall system performance. JJSV cannot be responsible for system surgical performance if you use these products in surgery.
- Use tips and sleeves that are designed to work together. Using improperly matching tip/sleeve combinations can result in insufficient fluid flow.
- Do not use the sleeves beyond their useful life. Using sleeves beyond their useful life can result in insufficient fluid flow or debris in the eye.
- Inspect batteries for damage before installation. Do not install damaged batteries. Installing damaged batteries could result in a fire.
- Avoid balanced salt solution free flow conditions. Balanced salt solution free flow can result in a slip hazard.
- Do not use the ultrasonic tip beyond its specified useful life. Using the ultrasonic tip beyond its specified useful life may result in:
  - exfoliation of the tip leaving debris in the eye
  - reduced cutting capability, which may increase time required for surgery
  - insufficient flow of fluid
- The VERITAS™ Swivel handpiece is an inseparable assembly. The user must not attempt to disassemble the swivel joint.
- If the sterile packaging for a single-use accessory is damaged, notify JJSV. Do not use the accessory as sterility cannot be assured.
- All tubing packs are single-use. Reusing a single-use device can cause bodily fluids from one patient to enter the eye of another patient. This can lead to medical conditions including: Toxic Anterior Segment Syndrome (TASS), Chemosis, Conjunctivitis Microbial, Endophthalmitis, Infectious Keratitis, Anterior Uveitis, and Keratoconjunctivitis.
- Do not charge the Foot Pedal in the patient environment. Do not come in contact with patient when touching the device under charge.
- When using Advanced Infusion, the effective bottle height cannot go below 30cm without re priming and selecting the Advanced Fluidics program.
- This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the VERITAS™ Vision System or shielding the location.
- The VERITAS™ Vision System needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile 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 VERITAS Vision System, including cables specified by JJSV. Otherwise, degradation of the performance of this equipment could result.
- The use of accessories, transducers and cables other than those specified by JJSV, may result in increased electromagnetic EMISSIONS or decreased electromagnetic IMMUNITY of the VERITAS Vision System.
- The USB port should only be used for the data transfer purposes described in this manual. It should not be used to charge devices or connect peripheral devices.
- The VERITAS™ Vision System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the VERITAS™ Vision System should be observed to verify normal operation in the configuration in which it will be used.
- Do not replace the foot pedal battery when the pedal is attached to a power source.
- Electrostatic Discharge (ESD) may disrupt the function and operation of the VERITAS™ Vision System and cause the system to go into a safe state and display an error message. If an error message occurs, follow the on-screen troubleshooting, or refer to the “Troubleshooting” section of the Operator’s manual. If the system enters the safe state, actions described in the “Errors” section of the Operator’s Manual will occur. If the system requires restarting to resolve the error, be sure to remove the handpiece from the eye prior to shutting down the system.
- The VERITAS™ Vision System may be interfered with by other equipment, even if that other equipment complies with regulatory emission requirements such as the International Special Committee on Radio Interference (CISPR).
- Electromagnetic Disturbances from RFID readers are unlikely to affect the VERITAS Vision System; however antennas from RFID readers should be kept more than 2.5 cm (1 inch) from the system.
- Inadvertent activation of functions that are intended for priming or tuning handpieces while the handpiece is in the eye can create a hazardous situation that could result in patient injury.
- Danger of ignition of endogenous gases (e.g., cotton and gauze saturated with oxygen may be ignited by sparks produced during normal use of High Frequency (HF) Surgical Equipment).
- Ensure the maximum capacity of the drain container is not exceeded as this could cause a hazardous situation to the patient.
- The ophthalmic irrigation solution source shall be at or above the patient’s eye level.
- Never intentionally modify handpieces or tips (e.g., do not bend, cut, or engrave them) as they could break or malfunction.
- Use caution when using clamps on a tubing set.
- Use only recommended tubing set(s).
- Do not touch an activated ultrasonic handpiece tip, as injuries could occur.

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VERITAS™ VISION SYSTEM

SPECIFICATIONS

veritas Vision System



23% IMPROVEMENT
vs. OPO73 in post-occlusion surge (IOP change)[1]

ALLOWS 39% HIGHER VACUUM
vs. OPO73 pack at same aspiration flow rate without compromising chamber stability[2]

	 VRT-AI	 OPO73
Reusable/single use	Single use	Single use
Fluidics pump	Dual pump (Peristaltic & Venturi)	Dual pump (Peristaltic & Venturi)
Advanced Tubing System (ATS) Dual durometer	✓ Inner diameter: 0.050”	✗ Inner diameter: 0.056”
Pressurized infusion	✓ Equivalent to 30cm of bottle height	✗
Locking irrigation luer	✓	✗
Improved clog resistance	✓	✗
Superior procedure efficiency	✓	✗
Increased balanced salt solution compatibility	✓	✗

Enhanced for Safety

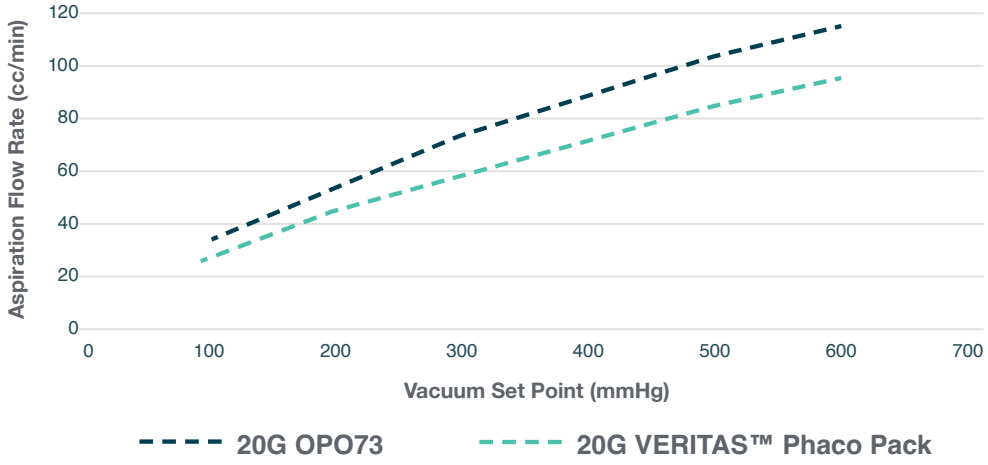
Less surge, more stability

Advanced Tubing System (ATS) provides unsurpassed stability and maneuverability.

Higher active vacuum without compromising chamber stability.

Advanced tubing system (ATS) decreases flow rates even at higher Venturi vacuum levels.

Venturi Flow Rate, 20g, FUSION™ Phaco Pack OPO73 vs. VERITAS™ Phaco Packs[2]



1. Data on File: DOF2021MLT4002 Post-Occlusion Surge Comparison Study
2. Data on File: DOF2021OTH4007 Venturi Flow Comparison Study.

Results from non-clinical study. Designed to evaluate the fluidics performance of OPO73 and VERITAS™ Phaco Packs with 20g tip in Venturi mode in terms of aspiration flows at a full range of vacuum.

For Healthcare Professionals Only. Please reference the Instructions for Use for a complete list of Indications and Important Safety Information and contact our specialists in case of any question.

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