

Viseon, Inc.

Image Control Box Operator's Manual

Safety Information

Indications for Use

The Viseon ICB is an Accessory to the Viseon MaxView® System – Posterior Set or Lateral Set. Refer to the Instructions for Use for the MaxView™ System device being used for the Indications for Use.


Contraindications

The Viseon MaxView System – Posterior Set and Viseon MaxView System – Lateral Set have no known contraindications intrinsic to the device. There are no other known risks associated with the use of the device outside of the standard and expected risks of surgery.


Cautions and Warnings


It is important that the operator read, understand, and comply with all the following safety precautions, markings, labeling, and warnings. Failure to follow these precautions could result in injury to the patient and/or user, as well as damage to the Viseon ICB.

Safety Precautions

	Before using the ICB, inspect the unit for damage or loose components. If the unit is determined to be damaged or has loose components, contact Viseon, Inc. for a replacement unit.
	In the event of suspected damage or failure, DO NOT OPERATE. Return the suspect ICB to Viseon, Inc. and replace with a new unit.
	The ICB must be used with the Display Cable and Power Cable provided. If damaged or lost, contact Viseon, Inc. for a replacement.
	Always place and keep the ICB on a flat level, dry, and secure surface. Avoid placing the ICB on top of other equipment. Do not place any items on top of the ICB.
	The connecting cables may pose a tripping hazard. DO NOT route the cables in a way that someone could trip over the cable.
	During use, always verify that the displayed image orientation is correct before proceeding with the procedure.
	When the ICB is not being actively used, it should always be kept within its protective case.

Warnings

	The ICB must be used with a compatible medical grade display device ("Monitor"). Equipment is intended to be connected to devices and connectors that comply with relevant IEC standards (e.g. IEC 60601 series for Medical Electrical equipment). Additionally, all such device combinations forming a system must comply with IEC 60601-1 (3rd edition), Clause 16 Medical Electrical systems. Any person or organization who has formed such a system is responsible for ensuring the system complies with the requirements according to IEC 60601-1 in Clause 16. If you are not sure, please contact a qualified technician or a local representative.
	The ICB device is rated IPX0, it provides no protection against contact or ingress of fluid. Avoid using the device near any dripping or splashing fluids.
	Do not damage or modify the Power Cable or Connecting Cables. Damage to the cables may cause a fire or shock hazard.
	Proper training of the ICB is required prior to operating this device. Only use the ICB in a manner

	<p>consistent with this Operator's Manual. Any alternative use may result in injury or damage to property.</p>
	<p>Use only components identified in this Operator's Manual or the compatible Viseon MaxView System device Instructions for Use for compatibility. Use of any other systems' components will void all warranties and may result in injury or damage to property.</p>
	<p>There are no user serviceable components inside this device. Do not open the unit. Accessing the ICB internal system will void all warranties and may result in injury or damage to property.</p>
	<p>Do not position the ICB such that it is difficult to unplug any cords from their connections.</p>
	<p>Portable and mobile RF communications equipment may affect the ICB. Follow the separation distance guidelines provided in this document to reduce possibility of interference.</p>
	<p>High frequency surgical equipment (e.g. electrosurgical generators) may interfere with the ICB video transmission. Always separate the ICB and connecting cables from any active electrosurgical generators or its cables.</p>
	<p>The ICB may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as relocating or shielding the device.</p>
	<p>The ICB must be unplugged from wall prior to cleaning.</p>
	<p>No modifications of this equipment are allowed.</p>
	<p>This product is not suitable for use in an oxygen enriched environment or in the presence of flammable anesthetics.</p>