VERIS™
FMS IV / EMS IV Stimulators

Installation & Service Manual

Release D

CE 0413

Electro-Diagnostic Imaging, Inc.
http://www.veris-edi.com

Tel 650-631-0120
Fax 650-631-0122
Email: support@veris-edi.com

Table of Contents

1. Intended Use, Regulatory Information, Warnings and Precautions 3
   1.1. Intended Use 3
   1.2. Contraindications 3
   1.3. Regulatory Information 3
   1.4. Warnings and Precautions 3
2. Labels 5
   2.1. Component Labels 5
   2.2. Shipping Label 5
3. User Profile 6
4. Product Lifetime 6
5. Components of the FMS IV /EMS IV Stimulators 6
6. Theory of Operation 6
7. Specifications 6
8. Installation 8
9. Luminance Calibration 10
10. Grid Calibration 11
11. Preventive Maintenance 12
12. Troubleshooting & Repair 13
13. Parts 14
14. Cables, Schematics & Diagrams 15
15. Software 16

1. Intended Use, Regulatory Information, Warnings and Precautions

1.1. Intended Use

The VERIS system is an electrodiagnostic device used to generate photic signals and to measure and display the electrical signals generated by the retina and the visual nervous system. It displays digitized electroretinogram (ERG) and visual evoked potential (VEP) signals, power spectra and topographic maps. These functions are controlled and interpreted by trained medical professionals. The device is intended for use in the diagnosis and management of diseases affecting the function of the retina and the visual pathway.

1.2. Contraindications

VERIS should not be used unless clinically indicated or in research with an IRB approved protocol.

1.3. Regulatory Information

VERIS Systems are in compliance with:

- FDA - 21 CFR Part 820 - Quality System Regulations
- ISO 13485 - Quality Management Systems - Requirements for regulatory purposes
- ISO 14971 - Medical Devices - Application of Risk Management to Medical Devices
- IEC 60601-1 - Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 - Medical Electrical Equipment - Part 2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic
- VERIS has been tested for radiative emissions and shown to meet the requirements for a Class A medical device.

1.4. Warnings and Precautions

Read this manually carefully before using the VERIS System.

WARNING: To avoid risk of electric shock, this equipment must only be connected to electrical supply mains with protective earth.

WARNING: To avoid risk of explosion, do not operate the isolation power supply in the presence of flammable anesthetics or other flammable gases or liquids.

WARNING: Do not operate the isolation power supply on the floor.

WARNING: Do not connect additional multiple outlet devices or extension cords to the system.

WARNING: Do not connect any device(s) not approved by EDI to the multiple socket outlets of the isolation power supply.

WARNING: Unauthorized modifications to the VERIS hardware and / or software void the warranty and may increase the risk of injury to patient and/or operator.

WARNING: All servicing to be undertaken only by qualified personnel. There are no user serviceable parts inside the unit.

CAUTION: If corneal electrodes are used for data acquisition, follow all instructions provided by the manufacturer and appropriate regulatory agencies for the use, cleaning, disinfection, and maintenance of these electrodes.

CAUTION: Carefully adhere to best medical practices whenever administering medication for mydriasis and/or corneal anesthesia. These include proper instructions to the patient, administration of eye medication, additional care in the event of adverse reactions, and provision of and/or use of dark glasses after testing.

WARNING: Perform system calibrations as described in this manual at intervals of 2-3 months.

WARNING - Some normative sample data as well as some patient data are provided for some of the protocols. They are meant for illustration only. Users are encouraged to collect their own normative data and use VERIS protocols for the statistical analysis.

WARNING - Backup the computer records on a regular basis to prevent the loss of patient data.

WARNING - The VERIS System in its complete configuration has been tested to meet the requirements for hospital use in the United States, Canada and Europe. If the VERIS System is used with customer provided components, testing for safety is the responsibility of the customer.

Do not sit on the cart or table.

CAUTION: Federal law restricts the medical use of this device on the order of a physician or a properly licensed practitioner.

CAUTION: To reduce risk of exposure to airborne pathogens, clean Fresnel lenses, acrylic screens, and painted surfaces of stimulators with a soft cotton cloth and anti-bacterial window cleaning solution or alcohol swabs prior to each use.

WARNING: Clean the outside of the objective lens of the FMS and EMS stimulators ONLY with a high quality lens cleaner and a clean, soft cloth. Antibacterial soft, absorbent micropore cloth may be used with the lens cleaner. Do not, under any circumstances, remove this lens from the stimulator.

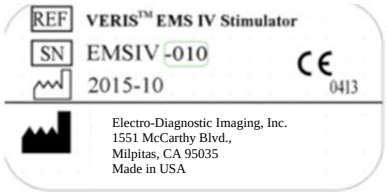
Recording electrodes can transfer pathogens between patients. Disinfect reusable electrodes between patients according to manufacturers instructions.

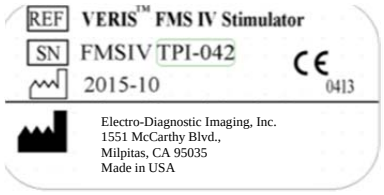
Single use electrodes must be disposed of as biohazardous medical waste.

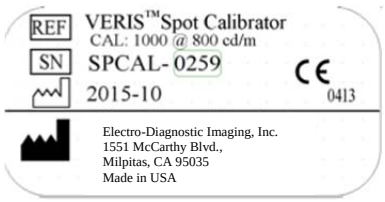
Recycle electronic equipment after end of life according to local laws and regulations

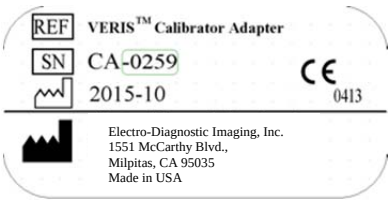
2. Labels

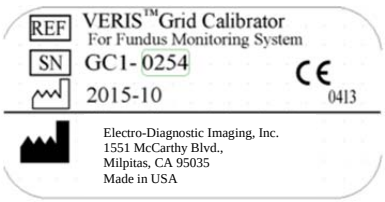
2.1. Component Labels

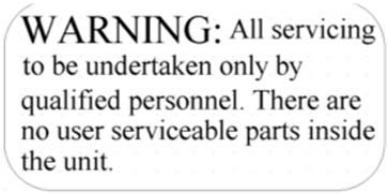




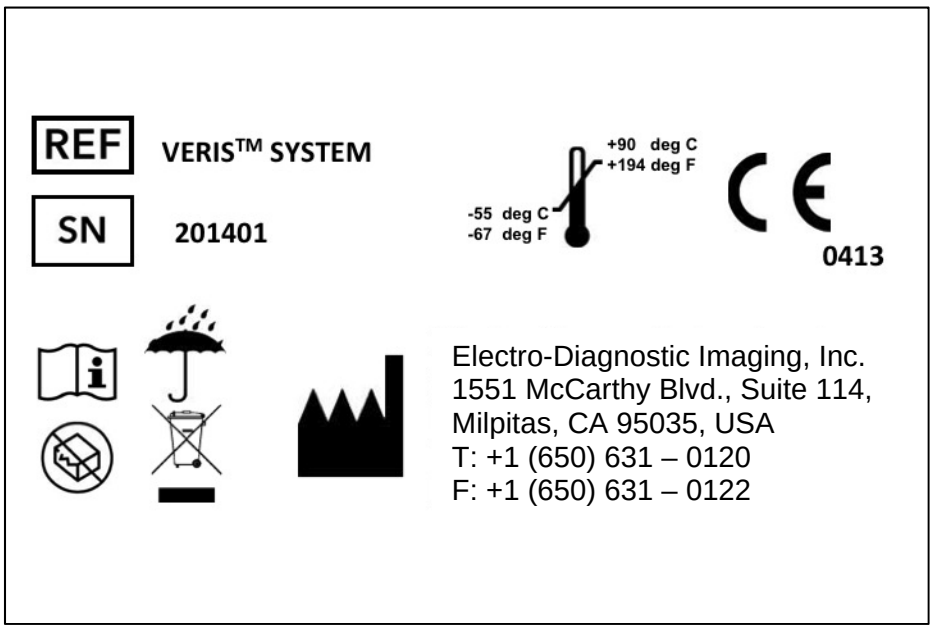








2.2. Shipping Label



3. User Profile

Users of the system include physicians, scientists, and other medical or scientific personnel trained or otherwise experienced in visual electrophysiological testing.

4. Product Lifetime:

The product lifetime is 5 years

5. Components of the FMS IV / EMS IV Stimulators

- FMS IV or EMS IV stimulator unit
- Controller
- Articulating Arm
- Spot Calibrator
- Calibrator Adapter
- Grid Calibrator
- Connecting cables

6. Theory of operation

The FMS and EMS IV stimulators create programmable visual pattern stimulation covering the central 45° of the visual field. Both units incorporate an infra-red (IR) video eye camera for patient alignment to the refraction system of the unit and for monitoring the patient's fixation stability. The FMS IV contains an IR video fundus camera for monitoring fixation position and stability throughout the data collection. Both units provide single knob spherical refractive correction with a range of -20 to +8 diopters.

7. Specifications

Physical

Stimulator unit

- Approx. 18-21” x 7” x 4.25” (46-54 cm x 19cm x 6.7 cm) powder coated upon aluminum housing
- Note: without mounting plate; variable length depends upon focus
- Approx. 8 lbs (3.63 Kg)

Controller

- Approx. 7” x 4.5” x 2” (18cm x 11.5cm x 5cm)

Operating Environment

The FMS IV and EMS IV are designed for use in a typical office, scientific laboratory or hospital environment.

- Maximum Operating Altitude: 10,000 feet (3,048 meters)
- Operating Temperature: 20° to 32° C
- Relative Humidity: 0% to 80% non-condensing
- Atmospheric Pressure: 75-105 kPa
- The maximum combined power drawn from the multiple outlets of the isolation power supply and its internal DC power supplies must not exceed the rating of the Toroid transformer. Any additional devices powered by these outlets become part of the medical equipment and can thus reduce the level of safety of the VERIS system.

Shipping / Storage Specifications

- Shipping Altitude: 35,000 feet (10,668 meters)
- Storage Temperature: -50° to +90° deg C
- Maximum Storage Altitude: 15,000 feet (4,572 meters)
- Relative Humidity: 0% to 90% non-condensing

Power Consumption (at max luminance)

- +12 VDC 1.5 A
- +24 VDC 0.5A

Performance and Operating Specifications

- Internal high-resolution, color, LCOS stimulus display
- 1280 x 1024 pixels at 60 Hz, 75 Hz, or 85 Hz
- 40 microsecond response time
- 24-bit RGB color (8 bits per channel)
- LED life expectancy of 1,000 hours
- Red: 627 nm typical, half-width 20 nm at 350 mA and 25 °C
- Green: 530 nm typical, half-width 30nm at 350 mA and 25 °C
- Blue: 470 nm typical, half-width 20nm at 350 mA and 25 °C
- Approximately 50 degree diameter field of stimulation.
- Greater than 300 cd/m2 maximum luminance.

Infrared Video Eye Monitoring (FMS IV and EMS IV)

- Both use IR LEDs: 850 nm dominant wavelength; half-width 45 nm at ½ intensity
- Eye camera provides magnified IR image of eye for accurate alignment and monitoring during testing.
- Infrared fundus camera provides IR fundus image for accurate fixation monitoring during testing.
- Software provides for capturing and saving single frames of the fundus image. Recorded waveform traces later can be easily superimposed upon saved fundus image images.

Patient Refraction System

- Single-knob correction of spherical refractive errors with automatic compensation for magnification/minification stimulus on the subject's retina
  - Maximum myopic correction: -20 D SPH
  - Maximum hyperopic correction: +8 D SPH
- Stimulator is mounted on an articulated arm for easy positioning (arm included).
- Spot Calibrator mounts on refractor lens for convenient re-calibration using *VERIS* software The Spot Calibrator is included in every Veris™ platform

Fixation monitoring with IR fundus camera (with FMS stimulators only)

- Stimulator incorporates an IR fundus camera and an IR illumination system of the fundus
- Fundus illumination uses IR LEDs at 850 nm dominant wavelength with 45 nm half-width.
- The camera lens has an adjustable aperture.
- A Grid Calibrator is included with every FMS installation. It is a model eye that allows calibration of the stimulus grid shown overlayed over the video fundus image.

8. Installation

Note: Installation and connections of the FMS IV and the EMS IV are the same.

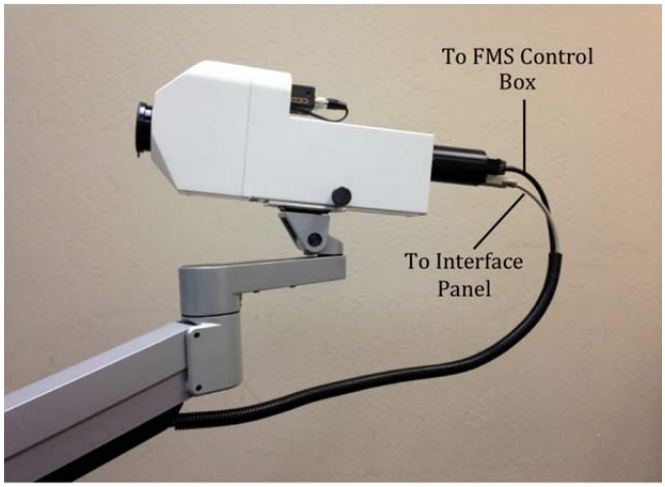
Carefully unpack the FMS IV/EMS shipping carton and the carton containing the light articulated arm. If either box is damaged, notify the carrier and EDI immediately. Check the content of each box against its packing slip when it is opened to account for all items.

Mount the arm on the right front edge of the desktop.

Mount the Control Box to the left of the Arm Mount.

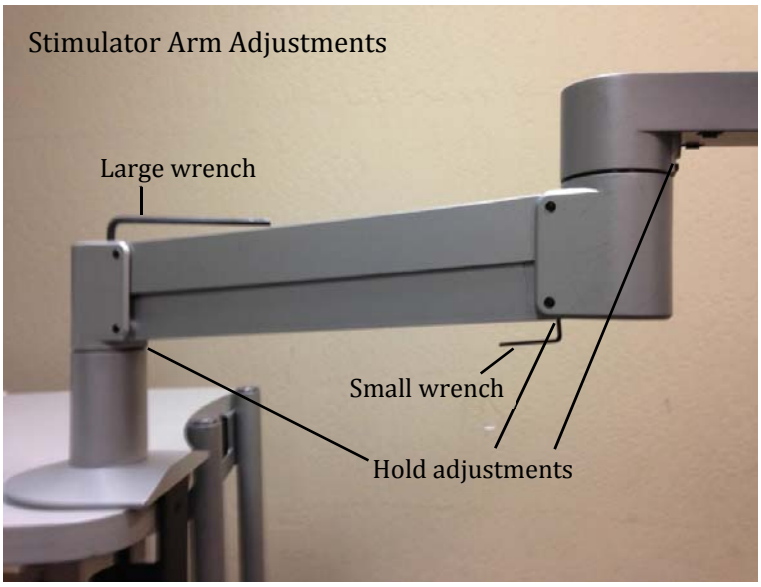
Mount the tilting mechanism with the four small screws that you find in the attached bag. Note the orientation of the plate. The access hole for the adjustment of the focusing break must be toward the back of the unit.

Mount the articulating arm on the side next to the control box. Insert the tilting mechanism of the stimulator unit into the end of the arm.



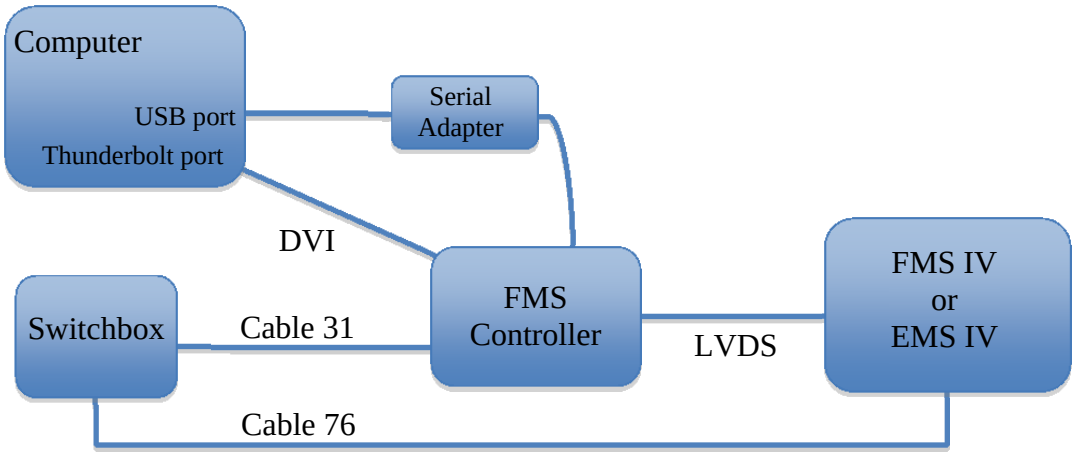
Adjust the articulating arm so that it freely floats the stimulator for easy positioning.

Hold adjustments can be used to prevent unwanted arm movements. Wrenches for the adjustments are included with the arm.



Connect the cables

FMS / EMS IV Block Schematic



IMPORTANT: Observe the keyed orientation of the black LVDS connector to the Controller.

Use the included DVI-to-Thunderbolt adapter to connect the DVI cable to a computer with Thunderbolt ports.

Connect the gray 5-pin Cable 31-02 (blue dot) from the rear of the FMS Control Box to the DIN connector (blue dot) at the upper left corner of the Switchbox labeled "FMS Power Out".

The GearMo serial adapter connects directly to the control box serial port and to the serial port of the Grass 15LT amplifier. **If replacing a previously installed Keyspan Adapter, it will be necessary to install the GearMo driver.**

Connect the VGA connector of the long grey cable (FMSIV-Cable-76) to the matching connector on the back of the black display tube of the FMS IV. The other end is connected to the VGA connector of the switchbox. **Older switchboxes that lack a VGA port require a Cable 76 having a DIN connector and RCA plug in place of one VGA connector. Call EDI for assistance in this situation.**

9. Stimulus Luminance Calibration (FMS IV and EMS IV Stimulators)

Luminance calibration of the EMS IV/ FMS IV microdisplay requires a calibrated Spot Calibrator with Eye Camera Calibrator Adapter (ECCA). These components are provided with every Veris™ platform.

Spot Calibrator (right) with Eye Camera Calibrator Adapter (left)

Spot Calibrator with ECCA attached

Measuring the Calibrator Dark Current

1. Connect the FMS/EMS controller to the existing Veris system.
2. Power up the computer.
3. Turn on the power switch on the Controller.
4. Connect the calibrator's 25-pin connector of the Spot Calibrator to the socket labeled "Auto-calibrator" on the VERIS interface box. A spot calibrator is provided with every Veris™ platform.

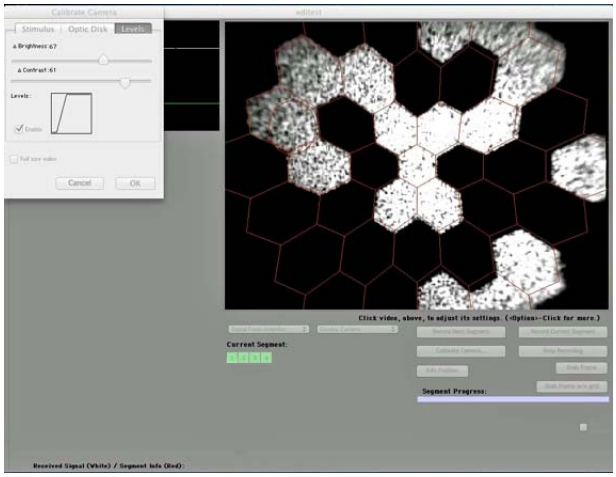
5. Start *VERIS*™, open a protocol that uses the stimulator and select a plot.
6. From Calibration on the menu bar select Calibrator Calibration and make sure Spot Calibrator is Checked
7. Cover the opening of the calibrator to keep the sensor in complete darkness.
8. Click on Read, wait until the the reading is reasonably stable, click stop and accept the reading of the dark current.
9. Slide the calibrator sensor with the Calibrator Adapter (ECCA) attached from the top over the front lens of the stimulator.
10. From Calibration on the menu bar select Autocalibration, press start and wait until the process is finished.
11. The three curves shown must be monotonically increasing toward the right and look similar to those in the figure shown here. If this is verified, you may accept the calibration.

10. Stimulus Grid Calibration (*FMS Stimulators only*)

The retina does not reflect enough light to make it possible to see the stimulus in the IR fundus image**.** To make it possible for the operator to monitor where the subject is fixating on the multifocal stimulus array, Veris™ overlays an outline of the stimulus grid on the fundus image. This grid must be calibrated to match the actual stimulus. This is achieved using a model eye (Grid Calibrator) with a highly reflective fundus using the following procedure:

1. With a test subject folder open, select the protocol containing the words ‘for grid calibration’. from the "FMS Microdisplay" Analysis Settings folder.
2. Open a recording window.
3. Place the Grid Calibrator on the FMS front lens.
4. Turn off IR illumination with the toggle switch at the back of the black microdisplay tube.

5. Select the fundus camera by toggling the up or down arrow keys of the computer keyboard.
6. Double-click on the fundus image in the window to open the camera controls.
7. Adjust the image brightness by means of and contrast controls and by rotating the Grid Calibrator as necessary. Fluctuations of image brightness are normal. If you can still not see the stimulus well enough, you may open the lens aperture. To do so, move the camera back out of the FMS IV housing using the focusing knob until the black aperture lever is accessible.
8. Focus the video image
9. Open the "Stimulus" tab of the camera control window and adjust the size and position of the grid to match the stimulus as closely as possible. (Holding the "*shift*" key down on the keyboard while clicking on the size and position controls produces larger changes.)
10. Click OK to exit from the controls dialog, then exit from the recording window when the grid matches the stimulus as closely as possible. Contact EDI if a satisfactory match cannot be achieved.



11. Reposition the CCD camera aperture to the position you normally use for fundus monitoring and switch the IR fundus illumination back on.

⚠ **This calibration will be correct for any multifocal stimulus array and for any refractive correction.**

⚠ EDI recommends repeating this procedure every 3-4 months or whenever a new version of the software has been installed.

11. Preventive Maintenance

The only areas accessible for field service are external. Internal adjustments of the optics require special tools and must be performed by qualified engineers at the factory.

Do *NOT* open the stimulator housing for any reason. There are no user-serviceable parts inside.

User Maintenance

1. Painted external surfaces of the stimulators may be cleaned with a soft cotton cloth or standard alcohol pads.
2. Avoid touching the large eye lens. Apply lens cover when the instrument is not in use. If necessary, clean lens with eyeglass cleaning materials and soft cotton or micropore cloth.
3. Calibration
   Perform Grid Calibration and Auto-Calibration at periodic intervals of less than three months and after updates to the VERIS software. Instructions are found below and in the *VERIS* User Manuals.
4. *VERIS*™ application software updates are provided from the EDI website free of charge within the first year. Instructions for updating the software are provided in the "Release Notes" file included with the updated software. After one year, an annual service fee is charged. A surcharge may be added and a new key file may be required for major updates. Contact EDI for details.

12. Troubleshooting & Repair

There are no field serviceable parts within any of the *VERIS*™ stimulators. See "Troubleshooting" below in the event of a malfunction. If problem persists, contact EDI.

Do *NOT* open the stimulator housing for any reason. There are no user-serviceable parts inside.

Problem	Diagnostic Test	Finding	Conclusion
Message: VERIS™ does not have a serial port connection to the microdisplay	Make sure microdisplay power is on. Check connections microdisplay control box - Keyspan adapter - USB port of computer. Switch the microdisplay control box OFF, wait, then and ON again. Then run VERIS and enter a recording window. It may be necessary to try twice to enter recording.		If the problem persists, contact EDI
Message: This computer does not have a video monitor for recording	Check Displays preferences. Make sure video mirroring is turned off. Select Detect Displays	The second monitor should show in the Monitors Preferences at resolution 1280 x 1024.	If the problem persists, contact EDI
No video images in recording window; either eye camera or fundus camera	Check the firewire cable at the back of the computer. Make sure it is plugged into the rear firewire port. Check Camera Cable connections to stimulator and switchbox.		If problem persists, contact EDI

13. Parts

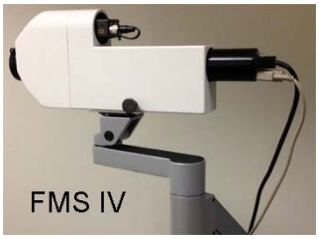
Current (2015 and later)

	ITEM	Model / Part #	Source
	* FMS IV or * EMS IV Stimulator	FMSIV-TPI EMSIV	EDI
1	Tilter Assembly		EDI
1	EMS/FMS Control Box	SA-ContBox-05	Forth Dimension Displays / EDI
1	5-pin DC Power Cable	Cable-31-02	EDI
1	USB/RS232 adapter	USB ADAPTER-02	GearMo
1	Interface Cable	Cable-76-02 or Cable-76-6FT	Cables-to-Go
1	Mini display/DVI adapter	Adapter-03	Apple Computers
1	Stimulator Arm (Light)	IOP7500-500-124	EDI
1	Spot Calibrator	CAL-Spot-01	International Light / EDI
1	Grid Calibrator	CAL-GRID-02	EDI
1	Calibrator Adapter	CA	EDI

Legacy

	ITEM	Model / Part #	Source
1	Camera Interface Cable	Cable-76-01	EDI
1	Keyspan USB adapter	Keyspan Model # USA-28XG	Any Vendor
1	EDI Serial Cable	Cable-34-01	EDI

*** Part pricing varies. Contact EDI for current pricing information.**



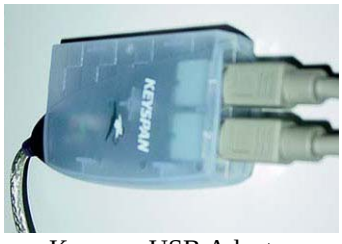
FMS IV on Arm


EMS IV on Arm


EMS/FMS Controller

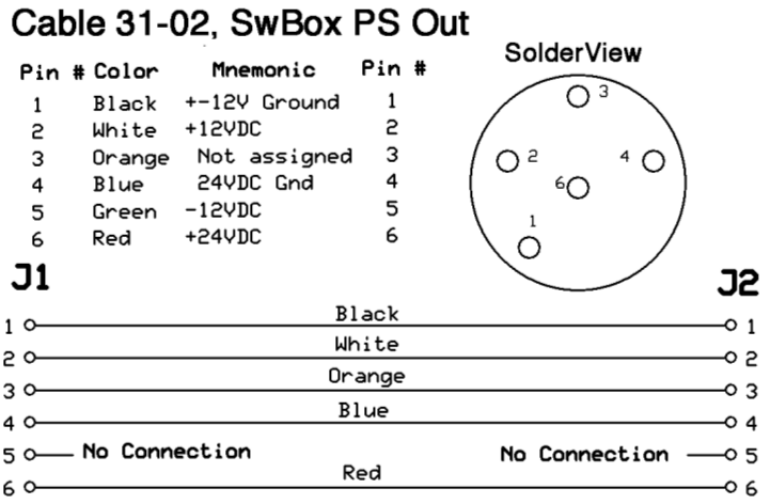

Spot Calibrator with (CA) Adapter


Grid Calibrator

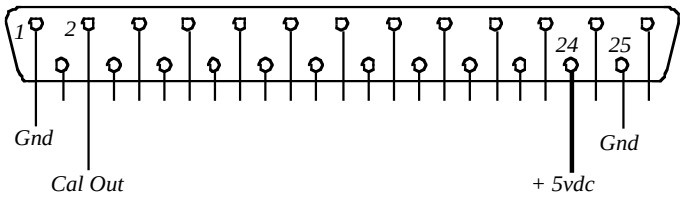


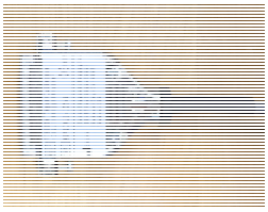
Keyspan USB Adapter (Legacy)

14. Cables, Schematics & Diagrams



Calibrator DB-25 Connector



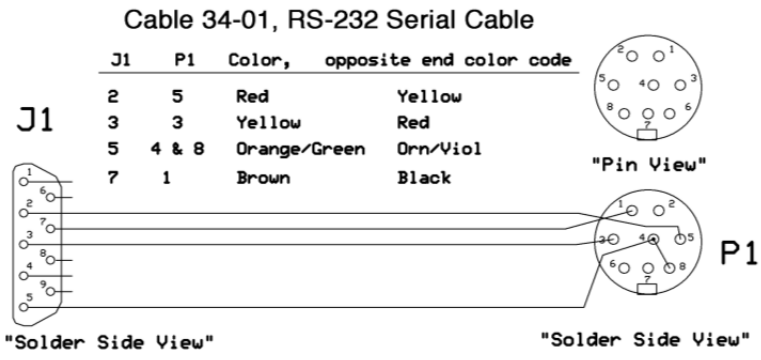


Cable 76-02 and 76-6FT (Standard Male-Male VGA)

Legacy Cables

Cable 76-01 (Camera Interface Cable)

Serial Assembly (Keyspan Adapter and Cable 34-01)



Keyspan USB/Serial Adapter

15. Software

All stimulator functions are controlled by the *VERIS*™ application software.