VERIS™ Fresnel Ganzfeld 1 (FG1)

Installation & Service Manual

Release B

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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 without 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

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 a supply mains with protective earth.

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

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 this device include physicians, scientists, and other medical or scientific personnel trained or otherwise experienced in visual electrophysiological testing.

4. **Product Lifetime**

The device product lifetime is 5 years.

5. **Operating Environment**

- Maximum Operating Altitude - 10,000 feet (3,048 meters)
- Operating Temperature - 20°- 32° C
- Relative Humidity - 0% - 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.

6. **Shipping / Storage Requirements**

- Shipping Altitude - 35,000 feet (10,668 meters)
- Storage Temperature - 5° - 32° deg C
- Maximum Storage Altitude - 15,000 feet (4,572 meters)
- Relative Humidity - 0% - 90% non-condensing

7. **Stimulator Components**

- Ganzfeld Stimulator with removable chin/headrest
- Stimulator controller
- Articulating arm
- Cables for interfacing with the Veris platform

8. **Theory of operation**

The stimulator creates uniform light or flashes covering the visual field of the subject's eyes. The elicited electrophysiological responses are recorded and analyzed by the Veris system to which it is attached. The all software protocols.

9. **Specifications**

**Physical:**

- 10" (25.4 cm) diameter x 4" (10.16 cm) deep
- Approx. 2.2 pounds (1 Kg)

**Power Consumption (at max luminance):**

- +24 / +27 VDC 200 mA
- +12 VDC 150mA
Performance

- All solid-state engineering.
- Background illumination and and flashes are generated by red, amber, green, and blue LEDs with the following emission spectrum:
  - Red: $\lambda_D = 627$ nm, $\Delta\lambda = 20$ nm at 350 mA and 25° C
  - Amber: $\lambda_D = 590$ nm, $\Delta\lambda = 20$ nm at 350mA and 25° C
  - Green: $\lambda_D = 530$ nm, $\Delta\lambda = 30$ nm at 350mA and 25° C
  - Blue: $\lambda_D = 470$ nm, $\Delta\lambda = 20$ nm at 350mA and 25° C
- Fresnel lens provides 36 cm (14 inch) apparent viewing distance and protects internal reflective surface from dust and other potential damage.
- Internal infrared video camera provides continuous monitoring of patient's eyes during recording. The image is shown in the recording window of the econsole and on s small LCD display on the back of the FG1.
- Installed on (included) articulated arm with quick-release mounting for use with infants and reclining or supine patients.

**VERIS™** Science and Pro software provides complete and continuous control of:
- Flash intensity (maximum > 30 cd•sec/m² for 4 msec flash).
- Flash chromaticity.
- Flash duration.
- Background luminance (maximum > 1000 cd/m²).
- Background chromaticity.
- 3 red fixation LEDs for EOG recording.

**VERIS™** software includes fully automated protocols for:
- Conventional electro-oculogram (EOG) with automated analysis and calculation of Arden Ratio and time to peak - (ISCEV 2006 standard).
- Conventional full-field ERG recording (ISCEV 2004 standard: 5 tests).
- Conventional full-field flash VECP (ISCEV 2004 standard).
- M-sequence full-field ERG
10. Installation

1. Attach FG1 controller to cart using pre-drilled holes.

2. Install articulating arm.

3. Attach Ganzfeld mount to arm

4. Insert chin rest into Ganzfeld mount.

5. Pressing mounting locks together with one hand, slide Ganzfeld into mount with the other.

6. Adjust the tilting mechanism with hex wrench.

7. Adjust the articulating arm.

1) Connect the Ganzfeld Controller to the existing Veris system.
2) Power up the computer.
3) Turn on the power switch on the Ganzfeld 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 FG1 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 reading is reasonably stable, click stop and accept the reading.
9) Turn the Ganzfeld to it faces the ceiling and cover its lens with the plastic sheet provided.
10) Remove the shell from the calibrator and insert the sensor into the hole in the plastic sheet.
11) Darken the room as much as possible.
12) From Calibration on the menu bar select Autocalibration, press start and wait until the process is finished.
13) The eight calibration 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.

Testing

- Turn on the Ganzfeld.
- Restart VERIS™.
- Verify proper function FG1 protocols described in the User Manual.
12. Preventive Maintenance

The only areas accessible for field service are external. Internal adjustments 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 may be cleaned with a soft cotton cloth or standard alcohol pads.

2) Avoid touching the acrylic protective lense. If necessary, the it may be cleaned using a soft cotton cloth alcohol pads and eyeglass cleaning liquid.

13. Schematics & Wiring

Cable 88
25 lead Connection from the Interface box Ganzfeld jack to the Controller Box
Pin connections (DB 25):
Cables 30 (36") and 91 (66" option)
DC power cable from Isolation power supply to Controller

<table>
<thead>
<tr>
<th>Pin #</th>
<th>Color</th>
<th>Mnemonic</th>
<th>Pin #</th>
<th>Color</th>
<th>Mnemonic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Black</td>
<td>12V Ground</td>
<td>1</td>
<td>Black</td>
<td>12V Ground</td>
</tr>
<tr>
<td>2</td>
<td>White</td>
<td>+12VDC</td>
<td>2</td>
<td>White</td>
<td>+12VDC</td>
</tr>
<tr>
<td>3</td>
<td>Orange</td>
<td>+5VDC</td>
<td>3</td>
<td>Orange</td>
<td>+5VDC</td>
</tr>
<tr>
<td>4</td>
<td>Blue</td>
<td>24VDC Ground</td>
<td>4</td>
<td>Blue</td>
<td>24VDC Ground</td>
</tr>
<tr>
<td>5</td>
<td>Green</td>
<td>-12VDC</td>
<td>5</td>
<td>Green</td>
<td>-12VDC</td>
</tr>
<tr>
<td>6</td>
<td>Red</td>
<td>+24VDC</td>
<td>6</td>
<td>Red</td>
<td>+24VDC</td>
</tr>
</tbody>
</table>

Cable 90 (F-F DB-15)
(Straight-through connections)

14. Parts Shipped with the FG1 Stimulator

<table>
<thead>
<tr>
<th>Item</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresnel Ganzfeld 1 (FG1)</td>
<td>Electro-Diagnostic Imaging (EDI)</td>
</tr>
<tr>
<td>FG1 Mounting plate with headrest</td>
<td>EDI</td>
</tr>
<tr>
<td>Vinyl Calibration Card</td>
<td>EDI</td>
</tr>
<tr>
<td>Ganzfeld Controller</td>
<td>EDI</td>
</tr>
<tr>
<td>Cable 88 (female DB-25 - female DB-25)</td>
<td>EDI</td>
</tr>
<tr>
<td>Cable 30 (3 ft.) or Cable 91 (5.5 ft) DC power cable</td>
<td>EDI</td>
</tr>
<tr>
<td>Cable 90 (female DB-15 - Male DB-15)</td>
<td>EDI</td>
</tr>
</tbody>
</table>

15. Software

Protocols for the FG1 Ganzfeld and tools to create new protocols are provided in the Veris™ software packages and described in the User Manual.
16. Troubleshooting & Repair

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

Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Diagnostic Test</th>
<th>Finding</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>No video image from Ganzfeld eye camera present in recording window.</td>
<td>Verify that the USB cable from the VERIS Interface is firmly connected to one of the computer's USB ports.</td>
<td>Cable connected. Still no video image.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Turn off power to Ganzfeld, restart the computer and turn Ganzfeld power back on.</td>
<td>Still no video image.</td>
<td></td>
</tr>
<tr>
<td>Background or flash stimuli are too bright, too dim, or the wrong color.</td>
<td>Re-calibrate the Ganzfeld.</td>
<td>Problem persists.</td>
<td>If the problem persists, contact EDI</td>
</tr>
<tr>
<td></td>
<td>With VERIS™ Science, open recording settings file for editing. Use &quot;Colors&quot; controls to test adjustment of background and flash parameters.</td>
<td>No control over background or flash parameters.</td>
<td></td>
</tr>
<tr>
<td>No fixation LED.</td>
<td>With VERIS™ Science, open recording settings file for editing. Adjust Fixation LED intensity in the &quot;Colors&quot; tab.</td>
<td>No control over LED intensity.</td>
<td></td>
</tr>
</tbody>
</table>

Repair

There are no field serviceable parts within the Ganzfeld V2 stimulator. If any problem with the stimulator persists after restarting the stimulator and computer, contact EDI.