

RETeval™ Sensor Strips



Intended Use and Product Description

RETeval sensor strips are skin-contact electrodes intended to be used to measure physiological electric signals with a contact duration of less than 24 hours.

Rx only.

Symbols

Symbol	Description / Function	Symbol	Description / Function
	Manufacturer		Lot number
	Do not reuse		Catalog number
	Council Directive Compliance		Use by date indicated
	Consult instructions for use		Keep dry
	Storage temperature range		

Approvals

This product has been tested for and complies with the requirements of ANSI/AAMI/ISO 10993-1 Biological Evaluation of Medical Devices.

Precautions

- Do not use with patients who are allergic to the sensor strip gel.
- Do not use an electrode if the conductive adhesive is dry and no longer sticky.

- The sensor strips do not require sterilization and are not intended to be sterilized.

Instructions for use

Before electrode application

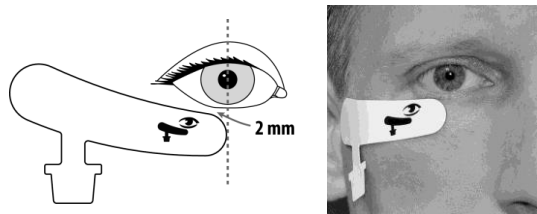
LKC Technologies strongly recommends the use of NuPrep® (sold by LKC, made by Weaver and company, www.doweaver.com), to prepare the patient's skin in the electrode contact area. Use of NuPrep will achieve electrical impedance levels comparable to corneal contact electrodes. Alternately, soap and water, or an alcohol wipe may be used but will result in increased impedance. Use alcohol-based products with caution, as the alcohol fumes may cause irritation to the eye. In all cases using an instrument with a high input impedance will improve results.

Electrode application

The RETeval sensor strips are specific for right and left eyes. Erroneous results will occur if the sensor strips are used with the wrong eye.

The small side of the sensor strip should be placed on the upper portion of the zygomatic process near each eye, with the end of the sensor strip placed under the center of the eye. The side with the connection tab should be located near the temple.

Align the sensor strip such that there is no hair beneath it.



Connection to instrumentation

RETeval device

Use the LKC Sensor strip lead (part number 91-193) to connect the sensor strip to the device.

Other ERG instruments

Use the LKC Sensor strip to DIN cable (part number 91-201) to connect the sensor strip to your non-RETeval ERG instrumentation according to the wiring information provided in the table below.

Sensor Strip electrode position	Cable connector color	Input location on your ERG instrument
Underneath the eye	Red	Positive (+)
Temple	Black	Negative (-)
Middle position	Green	Common/ground/right leg drive. When using two cables to measure the response from both eyes simultaneously, use LKC Vee cable (part number 91-202) to connect both green connectors to the instrument's common/ground/right leg drive position.

Shelf life

For shelf life and storage information, refer to the labeling on the sensor strip box.

Purchasing

Users may purchase the following items by contacting your local distributor.

Part Number	Item
95-068	Sensor strip, quantity 50 pairs
91-193	Sensor strip lead (The cable that connects the RETeval device to a sensor strip.)
91-201	Sensor strip to DIN cable (The cable that connects your non-RETeval ERG device to a sensor strip.)
91-202	Vee cable (A cable that connects 2 male and 1 female safety DIN connectors together, used for testing both eyes simultaneously.)

Thank you for choosing RETeval sensor strips. If you are not completely satisfied or if you have questions or comments, please contact LKC Technologies.

Manufacturer: LKC Technologies, Inc. 2 Professional Drive, Suite 222 Gaithersburg, MD 20879 USA t: 800.638.7055 (USA only) t: +1.301.840.1992 f: +1.301.330.2237 e: sales@lkc.com www.lkc.com	European Representative: Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands Tel: +31 70-345-8570 Fax: +31 70-346-7299 EMERGO EUROPE
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