












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.

Applicable 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		Date of Manufacture
	Medical Device		

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.
- Sensor Strips are not to be reused because (1) they may not stick well upon reuse, causing an excessively high electrode impedance and therefore noisy results, and (2) the biological risk associated with reuse across patients has not been analyzed.

- The operators of the device are intended to be physicians, optometrists, medical technicians, clinical medical assistants, nurses, and other health-care professionals.

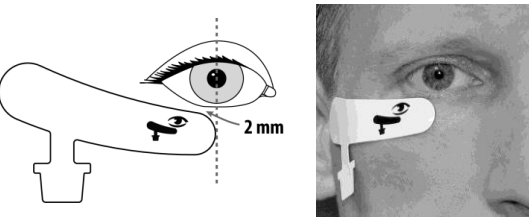
Instructions for use

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 and will improve adhesion on subjects with adhesion issues. Follow with an alcohol wipe if adhesion is problematic. Alternately an alcohol wipe may be used alone but will not reduce the impedance as much as by using NuPrep. 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.



Adhesion enhancement

For most subjects Sensor Strips adhere well, use of NuPrep helps in cases where adhesion is not optimal.

Application of a medical grade adhesive tape is recommended in cases where NuPrep is inadequate.

Connection to instrumentation

RETeval/ device

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

Disposal

Dispose of used Sensor Strips in accordance with local guidelines.

Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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 end color	Input location on your ERG instrument
Under 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. Room temperature storage, e.g., 20 °C, is recommended.

Purchasing

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

Part No.	Item
95-081	Sensor Strip, quantity 25 pairs
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 <div><div>EC</div><div>REP</div><div>EMERGO EUROPE</div></div>
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The RETeval/ Sensor Strips may be covered by U.S. patent 9,510,762; 10,010,261; and foreign counterparts. RETeval/ is a trademark of LKC Technologies, Inc., which has been registered in China, Japan, Mexico, Russian Federation, South Korea, and the United States of America. Copyright © 2022 LKC Technologies, Inc. Document number: 96-025. Issue Date: 2022-08-29