

Small Size Sensor Strips Rx only

Intended Use and Product Description

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

Applicable Symbols

Symbol	Description / Function	Symbol	Description / Function
***	Manufacturer	LOT	Lot number
\otimes	Do not reuse	REF	Catalog number
CE	Council Directive Compliance	X	Use by date indicated
Ĩ	Consult instructions for use	Í	Keep dry
	Storage temperature range	Ł	Date of Manufacture
MD	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 healthcare 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. 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.

Adhesion enhancement

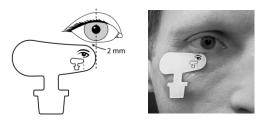
For most subjects Sensor Strips adhere well, use of NuPrep helps in cases where adhesion is not optimal. Application of a medical grade adhesive tape is recommended in cases where NuPrep is inadequate.

Electrode application

The **RET**eval 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 eve. 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 Small Sensor Strip lead (part number 91-235) to connect both Small Sensor Strips 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 two LKC Sensor Strip to DIN cables (part number 91-201) to connect the Small Sensor Strips to your non-**RET**eval 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 right eye	Red	Positive (+) when measuring the right eye Negative (-) when measuring the left eye
Under the left eye	Black	Positive (+) when measuring the left eye Negative (-) when measuring the right eye
Temple (both eyes)	Green	Common/ground/right leg drive. (Connect both)

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 vour local distributor.

Part No.	Item
95-090	Small Sensor Strips, quantity 50 pairs
91-235	Sensor Strip lead (Connects the RET eval device to a pair of Small Sensor Strips.)
91-201	Sensor Strip to DIN cable (The cable that connects your non- RET <i>eva</i> / ERG device to a sensor strip.)

Thank you for choosing **RET**eval Sensor Strips. If you are not completely satisfied or if you have questions or comments, please contact LKC Technologies.

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The **RET**eval Sensor Strips may be covered by U.S. patent 9,510,762; 10,010,261; and foreign counterparts. **RET***eva*/ 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.

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