

ERG Thread



STERILE R REF:ET-01

INSTRUCTION MANUAL

EN DO NOT USE THE ELECTRODE IF THE PACKAGING IS DAMAGED. USE THE ELECTRODE ONLY FOR CLINICAL ELECTRORETINOGRAPHY.

Human use of the Erg-Thread requires equipment that complies with all applicable medical device safety standards, including IEC 60601 Series.

(please see the connection scheme) *

DEVICE DESCRIPTION

The ERG-Thread is a corneal electrode used to record the electroretinogram (ERG), produced by light stimulation of the retina, suitable for human application.

PATIENT POPULATION

Patients requiring an ERG testing.

OPERATING ENVIRONMENT

Ophthalmic hospitals and clinics.

INTENDED USE

The ERG-Thread is used to support diagnostic systems for anomalies of the eye by transmitting the retinal electrical signal. It is indicated in various clinical situations such as the assessment of retinal functions and neurological disorders. It can be used for assessment of either fERG, mERG or PERG.

CONTRAINDICATIONS

The ERG-Thread is not indicated for use on children or adults with cases of trauma or disease of the anterior segment of the eye. In the case of ocular and corneal pathologies, its use requires the consent of an ophthalmologist.

WARNINGS AND PRECAUTIONS

For small children, due to the risk of irritation of the cornea, it should be ensured that they are kept in a stable position for the duration of the test. Eyelid retractor may be used if required.

The manipulation of the ERG-Thread requires the respect of the rules of the art, in particular the cleanliness in the handling of this sterile object and the unique use.

Mydriatic drops could be used to dilate the pupils for better light response of the eye to the stimuli.

This electrode should be placed and removed gently. If pain occurs or persists a few hours after the handling, ophthalmological control is considered necessary.

Redness and mild irritation of the eye, without exacerbation of the condition, is possible after performing the procedure.

It is suitable to keep the patient in supine position during the test.

A topical cornea anesthesia is recommended prior testing, but general anesthesia should be avoided, when possible, because it could have an impact on the ERG recordings.

The ERG-Thread is not intended for multiple use. If re-used, an infection of the cornea can occur, and the measuring results are no longer guaranteed.

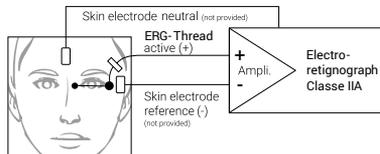
The ERG-Thread is not indicated to be used more than one hour.

Feeling of discomfort could be witnessed during the test.

POTENTIAL SIDE EFFECTS

To date, no undesirable side effects have been observed. However, it may be that a slight unease is experienced during the procedure and the product triggers a slight reddening of the eye. In the case of a persisting impairment, an ophthalmologic control is necessary.

CONNECTION SCHEME



PROCEDURE

Installing the Electrode:

The electrode can be easily inserted into the patient's eye if you follow these instructions:

- 1 Open the package
- 2 If necessary, a topical cornea anesthesia can be applied
- 3 Remove the two sticky patches and affix the end patch containing the connection wire onto the temporal side of the eye. Drape the connection wire over the patient's ear
- 4 Ask the patient to look up and slightly pull down their lower eyelid.
- 5 Drape the fiber over the eye just above the lid, making sure as much of the fiber as possible is in contact with the eye.
- 6 Release the eyelid. The fiber should now be either slightly behind the lid or just at the top of the lower lid in contact with the eye. You may need to perform this step again until the fiber sits correctly
- 7 Stick the other sticky pad onto the nose near the eye.
- 8 Check that the fiber is not too taut. You might ask the patient if the electrode is comfortable (after a few minutes they will hardly notice its presence). If in doubt move the external sticky pad slightly nearer to the eye to reduce tension
- 9 Finally plug the connection wire into the montage.

For any questions, suggestions or experiences concerning ERG-Thread electrode please get in touch with Fabrinal.

fabrinal
EYE CARE

+41 32 968 09 08, info@fabrinal.ch, fabrinal.com



FABRINAL SA, Rue de la Tuilerie 42
CH-2300 La Chaux-de-Fonds, Switzerland

EDITION D12/19