

LKC RETeval Cleaning and Disinfection

The following is the FDA cleared cleaning procedure and should be followed.

Cleaning and disinfecting the RETeval exterior

Cleaning of the patient contacting parts of the device (eyecup and Sensor Strip lead) is recommended between patient uses. The RETeval device is chemically compatible to **wipes containing 70% isopropyl alcohol** and with **wipes containing alkyl dimethyl benzyl ammonium chloride**. The use of other wipes may damage the device.

1. Remove all visible soil by wiping all exterior surfaces with a compatible wipe. Ensure that all visible contamination has been removed.
2. Disinfect using a germicidal wipe labeled suitable for use on healthcare equipment and capable of low or intermediate level disinfection, following the procedures and contact time recommended by the germicidal wipe manufacturer.
3. Inspect for any visible damage prior to use. Discontinue use if any abnormalities are found. Replacement eyecups and Sensor Strip leads are available via the LKC web site (Sales@lkc.com).
4. Other liquid cleaners and hand sanitizers should NOT be used as they may damage the surfaces or interfere with the joy stick operation.

Cleaning the ganzfeld bowl

The white interior sphere that the patient looks into (the ganzfeld), should be cleaned when there is visible dust inside or when the device fails to calibrate at the start of a test. The ganzfeld can be cleaned with a compressed gas air duster to remove dust. A damp cloth moistened with water or **isopropyl alcohol wipes** may be used if compressed gas doesn't work. Liquid cleaners or hand sanitizers should NOT be used as they may damage the LED lights and camera inside the ganzfeld bowl.

Sterilization

Neither the device nor the Sensor Strips require sterilization or are intended to be sterilized

Please be aware of the following warnings and cautions which are required by the FDA regulators relative to these cleaning and disinfecting procedures.



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WARNING: Consult the cleaning agent and germicidal cleaner agent manufacturer instructions for their proper use and germicidal efficacy prior to their use.

CAUTION: Do not submerge the device in liquid or allow liquid to enter the interior of the device as this could damage the electronics. Do not use automatic cleansing machines or sterilization.

CAUTION: Follow these instructions and only use the cleaning or germicidal cleaner agent types listed or damage may occur.