



The difference between good electrodes and bad electrodes is in the amount of noise they generate, which is clearly visible to the technician performing the study. They also

differ in their construction, meaning that good quality electrodes will last longer in use.

The electrode is a negligible part of the EEG system. There are voluntary standards for skin contact electrodes by the AAMI, but these apply to ECG electrodes, not to EEG.

C. Environmental impact

There are no Environmental issues of any kind relating to EEG electrodes.

D. Economic impact

Eliminating the need to approve EEG electrodes by 510K will lower the regulatory burden on electrodes manufacturers, which will allow them to lower the cost of these products on the market, and allow more people to purchase higher quality products.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

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