VolksEEG Specifications

# Anesthesia Research Model

* 8 leads
* Amenable to approval by investigational review boards (IRBs)

## Performance

In general, the device will conform to *IEC 60601-2-26: Particular requirements for the basic safety and essential performance of electroencephalographs*. The standard defines minimum performance and testing:

|  |  |
| --- | --- |
| Requirement | Subclause |
| Accuracy of amplitude and rate of variation  Input dynamic range and differential offset voltage  Input noise  Frequency response  Common mode rejection  Indication of invalid data | 201.12.1.102  201.12.1.103  201.12.1.104  201.12.1.105  201.12.1.106  201.12.4.101 |

<<We should add some actual values from the standard>>

Note: we generally assume that the ADS1299 IC will do virtually all of the “heavy lifting” in meeting these. But we should review, and test per the standard’s test procedures.

## Safety

The system will conform with all mandatory electrical safety clauses in *IEC 60601-2-26*, and in linked standards (e.g., *IE60601-1*). It may conform to optional clauses e.g., protection against defibrillation.

## Other regulatory

The system should conform to the following standards for electromagnetic compatibility (EMC), including emissions and immunity:

* *IEC 60601-1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
* FCC standards for intentional and non-intentional radiators. The former is necessary to accommodate Bluetooth, and will likely be met by using a pre-certified module.

## Power

The system may be powered by:

* USB (micro B connector, either a USB power supply or data connection.
* Inbuilt rechargeable battery, UL-approved, that can power the system for XXX hours when fully charged

## Communications

## Physical

The device should:

* be splash-proof (IPX-4)
* not have sharp corners