

# Use of ECG Quality Metrics in Clinical Trials

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Management of large number of digital electrocardiograms (ECGs) is today a common practice in both clinical and research practice. More specifically, the need of robust quality metrics that can be useful to easily identify and classify subsets of ECGs (for example with high content of noise) has recently received growing interest and attention. We present a software package designed with the purpose to provide a viable mean to manage and automatically classify large amount of ECGs on the basis of built-in quantitative metrics, grouped into five categories:

Noise content (All frequencies, low-frequency (LF) and high-frequency (HF)) Interval annotations, based on an embedded automated algorithm (QT, PR, QRS and HR), Amplitude annotations (for example R or T wave amplitudes), Repolarization Regularity (for example, indexes of morphology of the T wave), Heart Rhythm Regularity (for example the percent of abnormal non-sinus cardiac beat contained in the ECG).

One or more combined metrics are finally used to generate ECGs subsets using, for each of the considered metric, one or more thresholds (for example, using heart rate as the single classifier, we could generate three subsets, one with the ECGs with  $HR < 40$ , a second one with the ECGs between 40 and 100, and the last one with the ECGs with  $HR > 100$ ). The number of ECG subsets, as well as the thresholds to use are parameters of the system. For the metric lacking a reference values (for example for the noise scores), the distribution for the metric derived from a database of approximately 300.000 digital ECGs clinical trials is provided. Quantitative examples of the usage of ECG classifier will be provided. The use of this tool can largely improve the quality of recorded ECG in both clinical trials and common clinical ECG practice.