Quality Assurance in Biosignal Processing – Procedures and Recommendations for Evaluation for Electrocardiological Analysis Systems

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Abstract

Following a European R & D Project for conformance Testing a Pilot Test Center for Computer assisted Electrocardiography has been established at Medical School Hannover Germany. Since 1993 many manufacturers have contacted our test center and provided new ECG devices (ECG amplifiers or computer ECG systems) for testing. The layout of the test system is described as well as new test tools, e.g., artificial calibration signals, annotated real ECGs and the test procedures. Testing results are presented for devices of nine manufacturers. Our experience from the tests performed (in part jointly with the manufactures) and from devices on the market prove that the new test tools and the new procedures developed during the CTS project are extremely valuable in promoting the accuracy of signal reproduction in electrocardiographs and the measurements of computerized ECG system.

1. Introduction

Three categories of Medico Technical Support can be identified:

1. ***Tools***, which enhance and expand the manual capability of physicians, including, for example, the scalpel of the surgeon, the hammer of the neurologist, the dentist's drill or even the lithotriptor

2. ***Instruments***, which enhance the senses, for instance, stethoscopes and microscopes. Other types of Instruments extend the perception space, e.g., the x-ray apparatus, electroencephalographs, electrocardiographs and others.

3. ***Systems*** consisting of an instrument and a computer for processing of signals picked up by the instrument. Processing may include feature extraction as well as diagnostic classification. These systems combine signals, human experience and decision support. They enter the decision domain and may enhance the physicians reasoning and decision making.

Figure 1 illustrates the evolution of Medico Technical Equipment in terms of categories and domains. Tools are effective in the operational domain, instruments are related to the information domain and systems, as defined before, are associated with the classification and decision making domain.

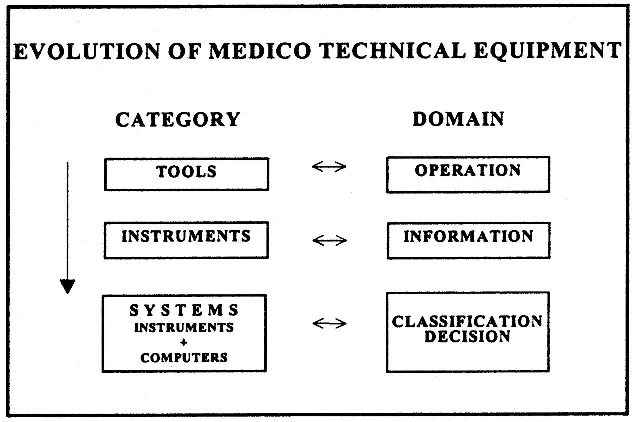

Figure 1. A meta view on the evolution of medico technical equipment

Technical as well as legal aspects make quality assurance for systems as defined above mandatory! Respectively, it is recommended within the essential requirements of the European Medical Devices Directive that "*devices with a measuring function must have an appropriate measurement accuracy*".

2. Methods

Within the European project "Conformance Testing Services" two pilot test centers for computer-assisted Electrocardiography have been established, one in Leuven, Belgium, and the other at Medical School Hannover (Biosignal Processing), Germany.
Fundamental problems in testing the performance of Biosignal Analysis systems are:

a. The truth of the analysed signal is unknown.
b. Usually no analytical mathematical signal description can be given.
c. Biosignals are, if at all, only quasi stationary.
d. Measurements of many signal parameters refer to human expertise and arbitrariness.
e. Processing of biosignals contains very often non-linear procedures.

f. Application of simple standard test signals (like Dirac Pulse or Step Functions), known from linear systems analysis, is of limited use.

In view of the extensive experience collected during the European project "Common Standards for Quantitative Electrocardiography" [1] new test procedures and a specific test system have been developed and applied during the past years.

We report here about the test system developed, the testing services provided and results obtained during the testing activities.

2.1. The CTS Test System

After reviewing recommendations and the standards in force at this time [2...5] it was realized that new requirements, new test procedures and extended test systems needed to be developed [6]. Figure 2 depicts the CTS Testing System that evolved from the CTS-ECG project.

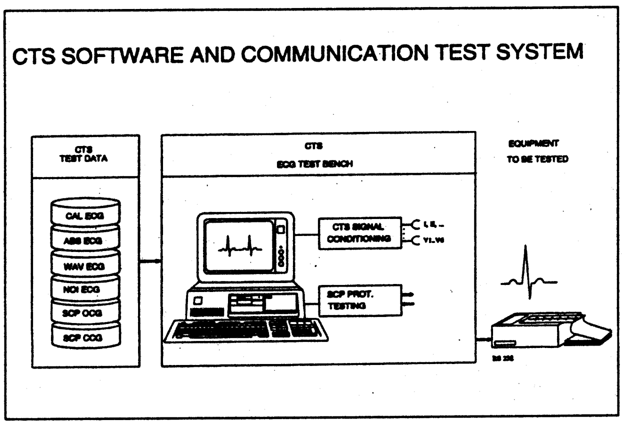

Figure 2. CTS Test System with the CTS test signal data base.

Safety requirements, electro-magnetic compatibility, and many other hardware characteristics and properties could and are being tested by officially accredited testing and approval institutions (e.g., in Germany TÜV, in USA FDA). The incorporation of microprocessors and of signal processing into electrocardiographs required the extension of performance specifications and of testing procedures. It turned out during the project that in particular a system providing different sets of testing data with analytically specified properties and "real" biosignals with human expert annotation would allow best to test the performance of computer based electrocardiographs.

The CTS Test System contains therefore a set of signal forms which are digitally defined sample by sample in their shape and amplitude. This is the set of "CAL ECGs" which can be used to analyze the calibration of amplifier channels. There are furthermore three "Normal-ECG" like signals (ABS ECGs), and there are 100 biological ECGs from the CSE Multi-Lead Atlas with expert annotation of wave form on-sets and off-sets. There are also ECG-like wave forms where defined levels of noise can be added (NOI ECGs) and there are ECGs specified within the Standard Communications Protocol SCP (European Pre-Standard ENV 1064 [7]). All these signals can be digital to analogue converted and then - by means of a signal conditioning box - scaled to the typical ECG amplitude levels as they are obtained from patients during clinical ECG recording. The CAL ECGs, ABS ECGs, and Noise Signals are documented within the IEC CTS Atlas and are part of the new IEC Standard for Electrocardiographs [8].

2.2. The testing procedure

The CTS Testing System allows to test, e.g., simply the signal reproduction of an ECG acquisition and recording system but also the testing of a computer-based Electrocardiograph which provides ECG measurements. Any System to be tested will be connected after a warm-up period to the CTS System and then successively the different signals are fed into the lead cables of the device under test.

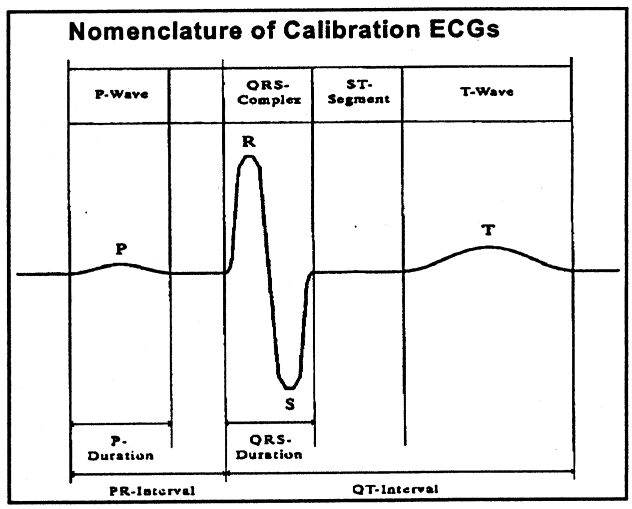

Figure 3. Shape and nomenclature of the so called CAL ECGs

Figure 3 depicts the typical shape of a "CAL-ECG" signal. Characteristic is that the "peak of the R-Wave and the S-Wave are flat for a duration of eight ms. This allows also systems with sampling rates down to approximately 125 S/s to pick up the peak amplitude. Of this shape six signal forms with peak amplitudes between 0.5 mV and 5.0 mV are used to test calibration and linearity of the equipment under test.

Figure 4 depicts CTS signals which are specifically designed for testing the ST-T reproduction of an ECG amplifier.

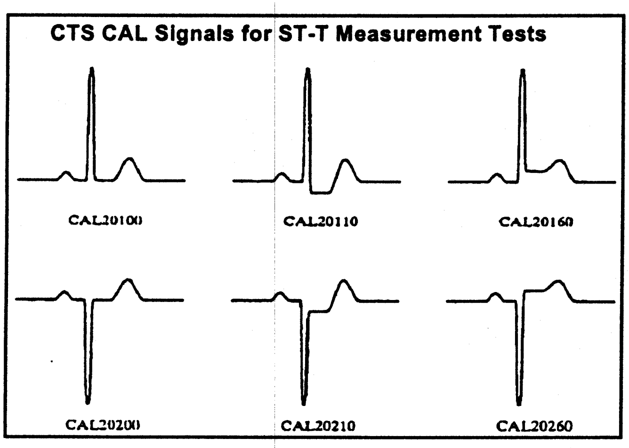

Figure 4. CAL ECG signals with specifically designed ST shape including depression and elevation.

These signals may be used as an alternative test to the low frequency cut-off test (0.05 Hz/3.2 s decay). Note, that the effect of the positive/negative pulse before the "ST-segment" is to be considered at test evaluation.

3. Testing results

Within this section some of the observations made during testing ECG devices from eight manufactures are presented.

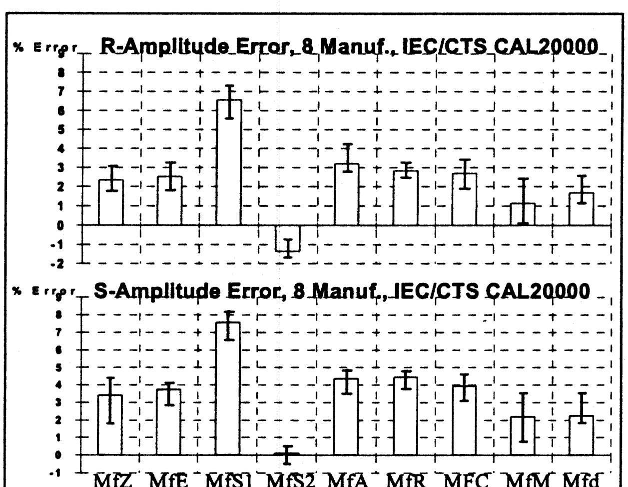

Figure 5. Amplitude (calibration) errors for "R" and "S" waves at 2.0 mV for eight ECG devices of manufacturers Mxy.

Figure 5 depicts the calibration error observed in eight devices from eight manufacturers. The columns show the error in percent as mean value with their range for the leads I...AVF, V1...V6 when the calibration signal with CAL 20000 (2.0 mV) was fed into the devices. The third column exceeded the typical errors of three to five percent markedly. Based on this result the manufacturer has modified the amplifier, and as shown in column four, successfully reduced the amplitude errors.

While these linear distortions are normally not difficult to handle, errors introduced by filters are more serious.

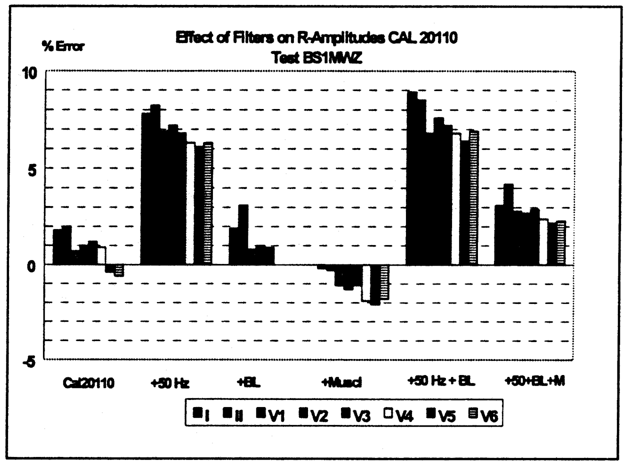

Figure 6. Increased R amplitude error if 50 Hz LF filter is switched on.

Figure 6 depicts the effect of filters on R amplitudes of calibration signal CAL 20110 (see Figure 4). The Amplitude errors exhibited on the Standard CAL Signals were without filters far below five percent, however, when a line frequency notch filter was introduced peak amplitudes were markedly increased by up to nine percent for the R-Wave. The baseline drift filter (BL) has practically no effect and the muscle tremor noise filter (Musc) reduces R amplitudes slightly. The effect of the LF filter is the same if the BL filter is additionally "on" and the LF error effect is partly compensated if all three filters are "on". There are devices where switching on a frequency notch filter has even worse effects.

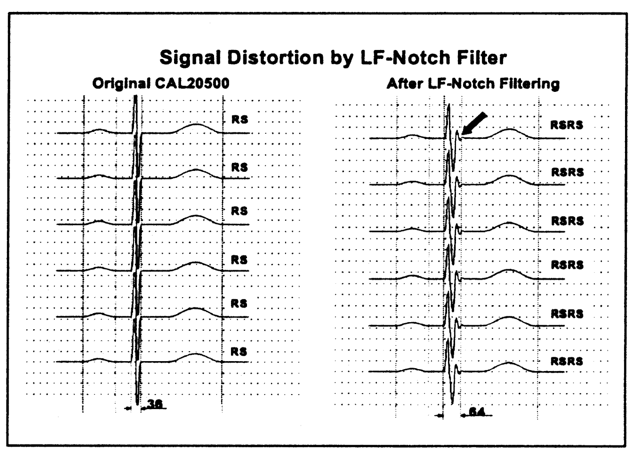

Figure 7. Filter ringing of a line-frequency notch filter.

The pediatric ECG like signal CAL 20500 with only 2 mV R/S amplitude but a short QRS duration of 38 ms has been fed into one of the tested systems. The output signal showed a widening of QRS duration from 36 ms to 64 ms and artificial r, s waves (~ 300/150 μV) from filter ringing.

The results shown so far were observed on devices which were brought to our laboratory before they were marketed. The next figure shows an example print-out of a device which has been sold many times before it came by chance to our laboratory for testing.

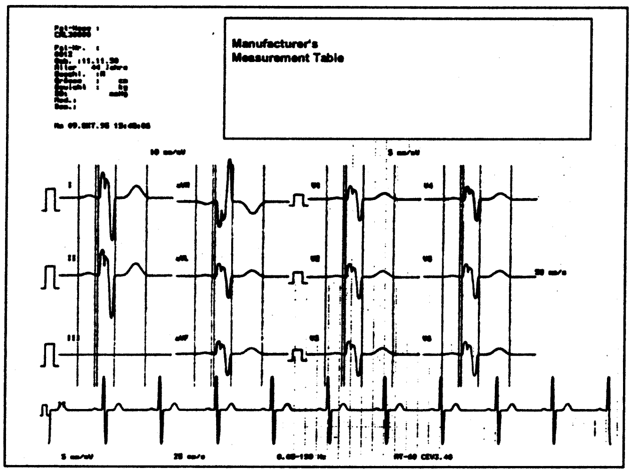

Figure 8. Reproduction of the CAL 30000 signal in a marketed electrocardiograph

This CAL 30000 is a signal with +/- 3 mV in amplitude and a regular QRS duration of ~ 100 ms. As can be seen in this signal the positive deflections are completely distorted (on the bottom line there is the correct signal form for one signal channel given). The result of processing this signal is shown in the upper tracing and it can be seen that the symmetric QRS complex is completely distorted. Obviously these distortions result from processing problems possibly due to programming errors. (To our knowledge the manufacturer has meanwhile corrected the program). It is true that the CAL ECG signals do not completely resemble with biological ECGs. But neither the amplitudes nor the slew rates exceed values that can be found in real ECGs. And such a result does not prove, that this electrocardiograph principally is a bad one. However, in view of the fact that for biosignals the truth is never known, this example shows that careful and extensive testing of medical devices which process biosignals and provide measurements should be mandatory.

4. Summary and conclusions

Extensive studies, like the European project Common Standards for Quantitative Electrocardiography have been carried out to analyze the problems of measurement and classification of electrocardiograms. Many of the lessons learned during these projects and many of the results obtained can be principally applied to the analysis and to performance testing of other biosignal processing systems:

1. The "truth" of such signals is not known.
2. Any definition of characteristic points or features are therefore subject to arbitrariness as well as inter- and intra observer variability.
3. Quality assurance of feature extraction processes and quantitative analysis of biosignals requires therefore: (a) Establishment of artificial biosignal-like wave forms which are sample by sample defined in shape and amplitude in order to make possible system testing on an "absolute" basis. (b) Biological data sets with human expert consensus annotation.
4. The system and the testing results presented in this paper show that performance analysis and quality assurance is an interactive process between scientists, end-users, and manufacturers. The new testing procedures resulted in improved devices. These will provide more accurate ECG analysis results which are necessary for the future serial comparison processes.

References

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