IEC 60601-2-25:2011 CSE database testing notes

The standard IEC 60601-2-25:2011 includes tests to verify the accuracy of interval and duration measurements, such as QRS duration or the P-Q interval.

These tests are separated into the artificial waveforms (the CTS database) and the biological waveforms (the CSE database). The CSE database is available on CD-ROM and must be purchased from the INSERM (price $1500, contact Paul Rubel, prubel.lyon@gmail.com)[1].

In principle, the database tests required by IEC 60601-2-25:2011 should be simple: play the waveform (in digital or analogue form), compare the data from the equipment under test to the reference data. In practice, there are some considerations and complications. This document covers some of the issues associated with the CSE database.

First, it should be confirmed that the equipment under test actually measures and displays *global* intervals, rather than intervals for a specific lead. As stated in Annex FF.2 of the standard:

> "The global duration of P, QRS and T are physiologically defined by the earliest onset in one LEAD and the latest offset in any other LEAD (wave onset and offset do not necessarily appear at the same time in all LEADS because the activation wavefronts propagate differently)."

Global intervals can be significantly different to lead intervals. This becomes evident from the first record of the database (#001), where the reference for the QRS duration is 127ms, while the QRS on LEAD I is visibly around 100ms. The following image is from the original "CSE Multilead ATLAS" analysis for recording #001 shows why: the QRS onset for Lead III (identified with the line and sample number 139) starts much earlier than for Lead I.

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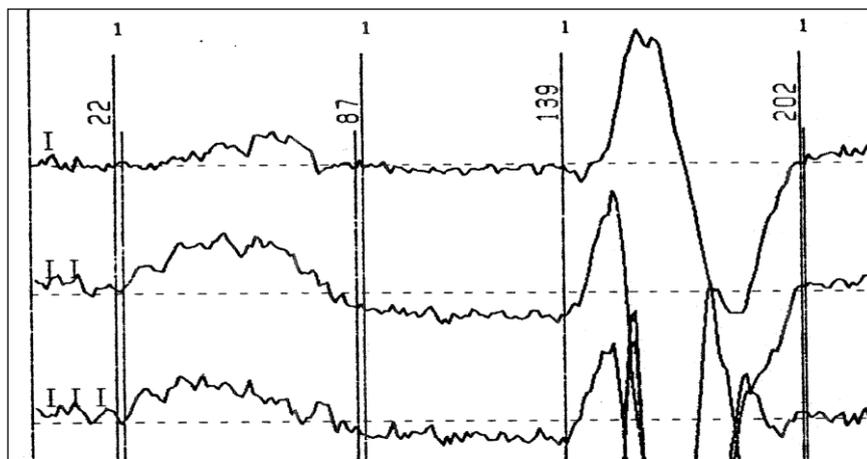
[1] The CSE database MA1 series are embedded in the MEDTEQ/Whaleteq MECG software, and can be played directly without purchasing the CD-ROM. However the CD-ROM is required to access the official reference values.

If the equipment under test does not display global intervals, it is not required to test using the CSE database to comply with IEC 60601-2-25.

The next aspect to be considered is whether to use waveforms from the MO1 or MA1 series.

The MO1 series is the original recording, and contains 10s with multiple heart beats. Each heart beat is slightly different, and the reference values are taken only for a specific heart beat (generally the 3rd or 4th beat in the recording). The beat used for analysis can be found from the sample number in the file "MRESULT.xls" on the CD-ROM[2]. The MO1 recordings are intended for manufacturers using the software (digital) route for testing their measurement algorithms. Many ECGs perform the analysis by averaging the results from several beats, raising a potential conflict with the standard since the reference values are for a single beat only. It is likely that the beat to beat variations are small and statistically insignificant in the overall analysis, as the limits in the standard are generous. However manufacturers investigating differences in their results and the reference values may want to check other beats in the recording.

The MO1 files can played in analogue form but there are two disadvantages: one is to align the equipment under test with the reference beat, the second is looping discontinuities. For example Record 001 stops in the middle of a T-wave, and Lead V1 has a large baseline drift. If the files are looped there will be a large transient and the potential for two beats to appear together; the ECG under test will have trouble to clear the transient events while attempting to analyze the waveforms. If the files are not looped, the ECG under test may still have trouble: many devices take around 5s to adjust to a new recording, by which time the reference beat has already passed.

The MA1 series overcomes these problems by isolating the selected beat in the MO1 recording, slightly modifying the end to avoid transients, and then stitching the beats together to make a continuous recording of 10 beats. The following image superimposes the MA1 series (red) on top of the MO1 series (purple) for the 4th beat on Lead I. The images are identical except for a slight adjustment at the end of the beat to avoid the transient between beats:

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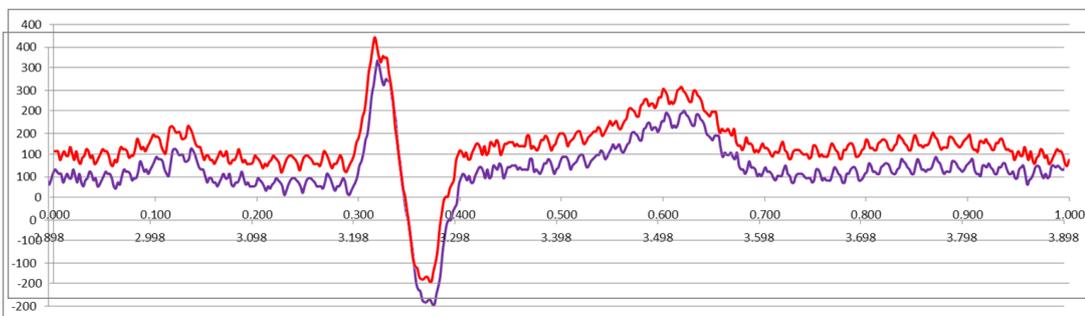
[2] For record #001, the sample range in MRECORD.xls covers two beats (3rd and 4th). The correct beat is the 4th beat, as shown in the original ATLAS records, and corresponds to the selected beat for MA1 use.

The MA1 series is suitable for analogue and digital analysis. Unlike MO1 files which are fixed at 10.0s, the MA1 files contain 10 whole heart beats, so the length of the file varies depending on the heart rate. For example, record # 001 has a heart rate around 63bpm, so the file is 9.5s long. Record 053 is faster at 99bpm, so the file is only 6s long. As the file contains whole heart beats, the file can be looped to allow continuous play without limit. There is no need to synchronize the ECG under test, since every beat is the same and the beat is always the reference beat.

The only drawback of the MA1 series is the effect of noise, clearly visible in the above original recording. In a real recording, the noise would be different for each beat, and helps to cancel out errors if averaging is used. For manual analysis (human), the noise is less of a concern as we can visually inspect all leads simultaneously, from this we can generally figure out the global onset even in the presence of noise. Software usually looks at each lead individually and can be easily tricked by the noise. This is one reason why ECGs often average over several beats. Such averaging may not be effective for the MA1 series since the noise on every beat is the same.

Finally, it should be noted that the CSE database contains a large volume of information much of which is irrelevant for testing to IEC 60601-2-25. Sorting through this information can be difficult. Some manufacturers and test labs, for example, have been confused by the file "MRESULTS.xls" and attempted to use the reference data directly.

In actual case, file "MRESULTS.xls" does not contain the final reference values used in IEC tests. They can be calculated from the raw values (by selective averaging), but to avoid errors it is best to use the official data directly.

Most recent versions of the CD-ROM should contain a summary of the official reference values in three files (all files have the same data, just difference file format):

> IEC Biological ECGs reference values.pdf
> IEC Biological ECGs reference values.doc
> CSE_Multilead_Library_Interval_Measurements_Reference_Values.xls

If these files were not provided in the CD-ROM, contact Paul Rubel (prubel.lyon@gmail.com).

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