MECG Range

The MECG is designed around the high accuracy and test signals used in IEC 60601-2-25, with 14-bit simulation down to 2.5 uV/LSB over a range of $\pm 5 \text{mV}$ and up to 8 channels at 1kHz, with an overall accuracy of $\pm 5 \text{\mu V}^1$.

Users intending to test with PhysioNet databases will find that some waveforms exceed ±5mV. Most of these appear to be noise events associated with poor electrode contact or even fully detached electrodes, with the waveform having no diagnostic information. In many cases, the noise appears on a secondary lead which has obviously detached or degraded during the recording, with the main lead still capable of providing useful diagnostic information.

When importing from a database, the MECG software will make some attempts to shift the waveform baseline to fit within ±5mV. Otherwise, the software will provide a warning and clip values that are out of range.

If the warning message is provided, users should review the section of the waveform that exceed the range and determine if they have any significant impact on the test result. If they do, users can select to:

- pre-process the waveform (e.g. remove baseline drift using a pre-processing high pass filter with a cut off selected to be unlikely to affect the EUT software algorithm)
- use digital testing only for those waveforms, not analogue simulation
- request a wide range MECG

Special versions of the MECG can be made with a wide range such as ± 7.5 mV or ± 10 mV. Users should be aware that increasing the range also reduces the overall accuracy of the system. For a system with ± 10 mV range, the simulation accuracy will be ± 10 µV. Depending on the application, this relaxed accuracy may be acceptable. These special versions require hardware changes, and therefore must be specified at the time of ordering.

Even with expanded ranges, users should be aware that it may be impractical to cover all waveforms in the PhysioNet databases, as some noise can be very large. For example, the NST database includes waveforms with noise up to 36mVpeak. An MECG system with $\pm 40\text{mV}$ can be ordered on request, but the simulator resolution of $\pm 20\mu\text{V}$ may adversely influence EUT interpretations.



It should be noted that the NST database is not an actual recording, rather it is a composite of a real recording together with added artificial noise. The annotations are taken from the original (clean) ECG, not from the composite record. It is not expected nor required that an ECG will accurately interpret waveforms when such heavy noise is present.

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 $^{^{1}}$ All range and accuracy references above are for the LA, LL simulation as associated with Lead I, II and III. For chest leads (V1 to V6), simulation range and accuracy is 1.67 times to account for electronic reverse Wilson compensation. The basic range of a chest lead is ± 8.67 mV, and $\pm 8\mu$ V accuracy.