ΕΝΤΥΠΟ 1

Standards and Technology

IEC 60601-2-25:2011 - Analysis of Changes

At the end of 2011, **IEC 60601-2-25** and **IEC 60601-2-51** were combined and re-published as **IEC 60601-2-25:2011 (Edition 2.0)**.

The standard has of course been updated to fit with IEC 60601-1:2005 (the 3rd edition). Also, similar to IEC 60601-2-27, the opportunity has been taken to correct some of the errors in requirements and test methods for performance tests that existed in the previous edition. However, compared to the update of IEC 60601-2-27, the changes are far more extensive making it difficult to apply the new standard in a gap analysis approach. Experience also indicates that historical data for existing equipment if often of limited quality, so it may anyhow be an excellent opportunity to do a full re-test against the new standard.

Despite the updated tests, it seems that significant errors still persist, which is to be expected given the number of complexity of the tests.

The table provides an overview of corrections, changes and problems found to date in the new standard. This table was compiled during the test of a sample against the new standard, using WhaleTeq's SECG, MECG and CMRR boxes which were found to be suitable for the new standard.

One major change worth noting is that requirements for ECG *interpretation* (the old clause 50.102 in IEC 60601-2-51) have been completely removed from the standard. There is no explanation for this, however the change is of interest for the CB scheme since it is now possible to objectively test compliance with all performance tests.

Table: List of changes, corrections and problems in IEC 60601-2-25:2011
(Compared to IEC 60601-2-25:1993/A1:1999 + IEC 60601-2-51:2003)

Clause	Subject	Type	Content
201.1.1	Scope	Change	The scope statement has been reworded, so for unusual cases it should be checked carefully. There has been a common mistake that IEC 60601-2-25/IEC 60601-2-51 should not be applied to patient monitors, and a similar mistake can also expected for this edition. However, the correct interpretation has always been that if the patient monitor provides an ECG record *intended for diagnostic purposes*, then diagnostic standard should also be applied. This would then depend on the intended purpose statement (and contraindications) associated with the patient monitor. However, manufacturers of patient monitors with 12 lead ECG options, with measurements of amplitudes, durations and intervals or automated interpretations might find it difficult to justify a claim of not being for diagnostic purpose.
201.5.4	Component values	Change	For test circuits, resistors are now required to be +/-1% (previously 2%)
201.6.2	Classification	New	The ECG applied part must now by Type CF (previously there was no restriction).
201.7.4.101	Detachable lead wires	Change	Detachable lead wires must be marked at both ends (identifier and/or colour)
201.7.9.2.101	Instructions for use	Change	Requirements for the operation manual have been substantially modified in the new standard (see standard for details). Note: it seems that HF surgery got mentioned twice in item 6) and 12), possibly as a result of combining two standards (IEC 60601-2-25 and IEC 60601-2-51)

201.12.4.101	Indication of inoperable ECG	Problem	The standard indicates that the test should be performed with 1V steps, up to 5V. However, the point of saturation normally occurs well below 1V (experience indicates this is from 400 - 950mV). This means it is possible to pass the test, without passing the requirement. The standard should instead require the dc voltage to be increased in steps of 5 or 10mV to ensure that the indication of saturation is provided *before* the signal amplitude starts to reduce.
201.12.4 102.3.2	Test of network	Change	The previous test (application of 2mV and 6mV waveforms to various leads) is now replaced with the CAL and ANE waveform, with a limit of 10%
		Problem	The above change has interesting points. The first is that one might ask why the test is needed, since the CAL and ANE waveforms have already been tested under 201.12.1.101 (automated amplitude measurements). However, Clause 201.12.1.101 can be done by digital analysis, whereas this test is for the full system including the ECG's hardware. Also, not all ECGs measure all amplitudes. It therefore requires the ability to generate CAL and ANE test signals by analogue (with laboratory 1% accuracy) which many laboratories may not have. That said, the test really does not really seem to test the networks correctly. As in the old standard, the networks are best tested by providing a signal to one lead electrode only, whereas the CAL/ANE waveforms provide the same signal to all leads simultaneously, except RA which is grounded. Although some analysis is required it seems clear that at least part of the lead network cannot be tested by the CAL/ANE waveforms. Finally, one might ask why there is a 10% limit for the test method, while the requirement statement says 5%. The reason could be that the basic measurement function is 5%, while

			the lead networks add another 5%, thus providing an overall 10% error. This is a clear relaxation on the previous edition, which seems unnecessary given that modern electronics (and software) easily handles both the measurement and network well below the 5% in the old standard.
201.12.4.103	Input Impedance	Correction	The previous version of the standard had an allowable limit of 18% (for reduction with 620k in series), but Table 113 incorrectly had an effective 6% limit. The 6% limit could be met at 0.67Hz, but most ECGs failed at 40Hz (the input impedance changes with frequency). The new standard now corrected this to a limit of 20%, aligned with IEC 60601-2-27. The requirement to test with a common mode 300mV to RL has been removed.
201.12.4.104	Required GAIN	Change/ Problem	The previous standard included a test of a 1mV step to verify the sensitivity (mm/mV), with a limit of 5%. This test and the limit are now removed, which means there is no objective measurement to verify that a 1mV step corresponds to 10mm on the ECG record. This may or may not be deliberate: it opens the possibility that manufacturers may use a gain of "10mm/mV" in a nominal sense only, with the actual printed record being scaled to fit the report or screen. The classic 5mm pink background grid also then also scaled to give the appearance of 10mm/mV, even though the true measurement reveals strange values such as 7mm/mV (on a small screen) or 13mm/mV (on a printed record). Using the definition, "GAIN" is the "ratio of the amplitude of the output signal to the amplitude of the input signal". The text in 201.12.4.104 refers to the amplitude on the *ECG record*. Putting these together, it seems the literal interpretation is that 1mV input should be

			lead electrodes should be connected and also which leads to inspect for crosstalk. The test is the same as in IEC 60601-2-27:2011.
		Problem	In step c) of the compliance test, the standard says to inspect Leads I, II and III, but this appears to be a "cut and paste" typographical mistake. The correct lead is only Lead I (Leads II, III will have a large signal not related to crosstalk). Similarly, in step d) this should be only Lead III. Steps e), f) and g) are all correct.
201.12.4.107.1.1	High frequency response	Change	For frequency response, previously all tests A to E were applied, in the new standard only tests (A and E) or (A, B, C and D) are required. Also the limit for test E has been slightly reduced (made stricter) from -12% to -10%.
201.12.4.107.1.2	Low frequency response	Change	The allowable slope has been changed from 250uV/s to 300uV/s, perhaps in recognition that a single pole 0.05Hz high pass filter (typically used in many ECGs) could not pass the 250uV/s limit. Theoretical simulations showed that 0.05Hz single pole filter produces a slope of 286uV/s.
		Problem	Minor mistake in the standard: the requirement statement does not include the limit for the slope of 300uV/s. This is however included in the compliance statement.
201.12.4.107.2	Linearity and dynamic range	Change / problem	The previous test method used a 1mVpp signal, but required the minimum gain. For an ECG with typical minimum gain of 2.5mm/mV, this meant that the test signal was only 2.5mm, which then conflicted with the diagram. The new standard corrected this, but made the slight mistake of saying "10mV" rather than "10mm". But the test only makes sense if 10mm is used.

201.12.4.108.3.1	Time and event markers	Change / problem	It appears as if the authors of the standard were getting a bit tired by this stage. Both editions of the standard fail to provide a test method, and it is not really clear what to do. The compliance statement is effectively "X shall be accurate to within 2% of X", which makes no sense. In the latest edition, things have got worse, with the reference to test conditions referring to a clause that has no test conditions (201.12.4.107.3). In practice one would expect the time markers to be accurate to within 2% compared to either a reference signal (e.g. 1Hz for time makers of 1s), and/or against the printed grid. Of course, all of this really has not much impact in the digital world with crystal accuracy of 50ppm (software bugs notwithstanding).
201.12.4.109	Pacemaker tests	Change	The previous pacemaker tests (51.109.1 and 51.109.2) have been combined and extensively reworked: • The requirement statement has been changed to include pacing pulses of 2mV to 250mV and durations 0.5 to 2.0ms • The test circuit for pacemaker has been defined • The point of measurement of amplitude after the pulse is changed from 50ms to 120ms (3mm) • The test with the triangle pulse (or CAL ECGs) is removed • The test method now includes a calibration step (item e)) to ensure the 2mV pulse is