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)

201.8.8.5	Defibrillator proof tests	Change	Due to the size of the clause, it is difficult to fully detect all changes. However, at least the following changes have been found: • The test combinations (Table 201.103) now includes 12 lead ECGs (i.e. C1 ~ C6 should also be tested) • The energy reduction test is now included (previously not required for diagnostic ECGs) • The test with ECG electrodes is now removed The energy reduction test is a major change: many diagnostic ECGs have no series resistors which help to limit noise, improve CMRR. To pass the energy reduction test, ECG lead wires should have at least 1k resistors and preferably 10k (as discussed in the technical article on Defibrillator Tests). With this series resistance, the impact of the ECG gel electrodes is reduced, and perhaps this is the reason for making the test with electrodes obsolete. The test result anyhow depended on the type of ECG electrodes, which is often outside the control of the manufacturer, making the test somewhat unrepresentative of the real world.
201.12.1.101	Automated interpretation	Change	Automated interpretation is now removed from the standard. Note that it is still expected to be covered by regulatory requirements, such as Annex X of the MDD.
201.12.1.101.1.2	Automated amplitude measurements	Correction	The limits stated in the requirements have now been corrected to match the test method (5% or 40uV). The reference values for CAL and ANE waveforms have now been included in the standard (Annex HH). The previous edition stated that these values were there, but they were missing.
		Problem	In the Annex HH reference data, the polarity of some S segment values is wrong (CAL 20500, aVL, aVF , and V3 for all of the ANE waveforms). There may be other errors that get revealed with time.

201.12.1.101.3	Automated interval measurements (CAL/ANE)	Problem	The requirement statement refers to global measurements (with 17 waveforms, up to 119 measurements), however the compliance statement refers to measurements from each lead (for a 12 lead ECG, up to 1428 measurements if all durations/intervals are measured). Not all ECGs provide global measurements, so this really should be clarified. Because of this it is also unclear about the removal of 4 outliers "for each measurement". If global measurements are used, this would imply that 4 out of the 17 measurements can be removed from the statistical analysis (which seems a lot). However, if lead measurements are used, this implies 4 out of 204 measurements, which is more reasonable.
201.12.4	General test circuit	Correction/ Change	The test circuit is now correctly and harmonized with IEC 60601-2-27:2011, IEC 60601-2-47 and also ANSI/AAMI EC 13. Previously the 300mVdc offset was placed in parallel with the test signal which meant the impedance of the dc supply appeared in parallel with the 100Ω resistor and reduced the test signal. The dc offset is now placed in series where this problem does not occur. However, it is noted that for one test the 300mV DC offset is still required to be applied "common mode" using the old circuit. Also, in the old standard the resistance between RL/N to the test circuit was 100Ω, whereas now it is a 51kΩ//47nF. A conservative interpretation is that all tests should be repeated with the new circuit, given the significant change (although experience indicates the results don't change).

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

			10mm on the ECG record. Also several tests provide the allowable limits in mm (e.g. CMRR test limit is 10mm), if the outputs are scaled this would make little sense. But in the absence of any criteria (limit), it is all a bit vague. If scaling is allowed, it should be clearly stated, and limited to a suitable range otherwise it can get confusing (e.g. at "10mm/mV", a 1mV indication should be in the range of 8-14mm. The scaling and reference grid should be accurate to within 5%, although in the digital world, this may be not necessary to test beyond a spot check to detect software bugs. Finally all limits in the standard should be converted to mV or uV as appropriate.
201.12.4.105.1	CMRR	Change	The test is the same except that the DC offset is now included in the CMRR test box, and the RL/N lead electrode is no longer required to be switched (test is harmonized with IEC 60601-2-27). Previously, the standard indicated that the dc offset is not required, because it has been tested elsewhere.
201.12.4.105.3	Filter affecting clinical interpretation	New	The standard now requires the ECG report to include an "indication" that the clinical interpretation may be affected by filter settings (if applicable). However, there is no clear statement about what is an acceptable "indication". It could mean text such as "Warning the interpretation: might not be valid due to the use of filters"; on the other hand it could mean just making sure that the filters used are clearly shown on the record, perhaps adjacent to the interpretation (allowing the user to make their own conclusion). What makes the issue more confusing is that some manufacturers might apply the filters only to the printed waveforms, while the interpretation is still performed on the unfiltered data (to ensure that the filters don't mess up to the interpretation), or worse, some kind of

			mixed situation (e.g. only mains hum filter is allowed for interpretation).
201.12.4.105.3	Notch filter effect (on ANE20000)	Change	The allowable limit for ringing in the ST segment has now been increased from 25uV to 50uV. Test experience indicates that the impact of notch filters for the waveform ANE 20000 on Leads I, II and III, aVR, aVL, aVF is minimal. However, the very large S amplitude on Leads V2 (1.93mV) and V3 (1.2mV) can cause a large amount of ringing in the ST segment, which is probably the reason for the change in limit. It is possible that previous tests have been limited to inspection of Lead II with the assumption that the ANE20000 waveform is the same for all leads (a mistake which the author has made in the past). In fact, the test should be done with a full 12 lead ECG simulator, with each lead inspected one by one. If the notch filter is applied in hardware (in part or full), the test should be done in analogue form.
201.12.4.106	Baseline, general	Change	Many of the baseline tests have now been removed, such as temperature drift, stability, writing speed and trace width, presumably because in the modern electronic / digital world these are not worth the effort to test. Most ECGs use a high pass filter and digital sampling, which means there is no real possibility for baseline drift.
201.12.4.106.2	Channel crosstalk	Change	The previous edition mixed up leads and lead electrodes (for example, putting a signal on RA/R results in a signal on Leads I, II, aVx, and Vx) so the criteria never made any sense. In practice the test needed to be adapted. Fortunately, this test has now been corrected and updated to give clear direction on where

			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

			accurate • There is now no requirement to declare the impact of filters • (B**ig point**) the test is now clearly required for all electrodes, tested one by one as per Table 201.108
		Problem	Although the requirement statement refers to 0.1ms, there is no test for this. Also, the status of filters is not clear. Most ECGs use hardware or software "blanking" when a pacing pulse is detected, leaving a clean ECG signal for further processing including filters. This means that the filter setting has no impact on how the ECG responds. However, some manufacturers don't use this method, allowing the display to be heavily distorted with the pulse, with the distortion varying greatly depending on the filters used. Ideally, the standard should encourage the former approach, but at least if heavy distortion can occur for some filter settings, this should be declared.

(This application note is copied with permission from MEDTEQ)