Standards and Technology

IEC 60601-2-27:2011 Changes

In 2011, IEC 60601-2-27 was updated to fit with the 3rd edition (IEC 60601-1:2005). Most of the performance tests are the same, but the opportunity has been taken to tweak some tests and correct some of the errors in the old standard. The following table provides an overview of significant changes, based on a document review only. It is expected that after practical experience provide more detail on the changes can be provided.

Clause	Change compared to IEC 60601-2-27:2005
201.5.4	Resistors in the test networks and defibrillator tester set ups should be ±1% unless otherwise specified (previously ±2%) *Note: the WhaleTeq SECG4.0 system uses 0.5% resistors for the 51k and 620k resistors, and the precision divider (100k/100R) uses on 0.05% resistors.*
201.7.2.4.101	New requirement: both ends of detachable lead wires shall use the same identifiers (e.g. color code).
201.7.9.2.9.101	Instructions for use: significant new requirements and rewording, each item should be re-verified for compliance.
201.11.8.101	Depletion of battery test: - Technical alarm 5min before shutdown - Shutdown in a safe manner

201.12.1.101	Essential performance tests, general: 51kΩ/47nF not required except for Neutral electrode (previously, required for each electrode). Some test method "errors" have been corrected: - Accuracy of signal reproduction: test starts at 100% and reduces to 10%, rather than starting at 10% and increasing to 10%; - Input dynamic range: input signal can be adjusted to 80% of full scale, rather than adjusting the sensitivity; - Multichannel cross talk: actual test signal connections and leads to be inspected are fully defined.
201.12.1.101.8	Frequency response test: Mains (ac) filter should be off for the test.
201.12.1.101.4	Input noise test (30µVpp): 10 tests of 10s required, at least 9 must pass (previously only one test required).
201.12.1.101.9	Gain indicator New test to verify the accuracy of the gain indicator (input 1mV signal input and verify same as the gain indicator).
201.12.1.101.10	CMRR test: Must be performed at both 50Hz and 60Hz
201.12.1.101.12	Pacemaker indication tests: Need to perform with all modes / filter settings
201.12.1.101.13	Pacemaker rejection (rate accuracy): If pulse rejection disabled, indication is required
	Pacemaker tests: the test circuit has been defined (Figure 201.114). *Note: this circuit is already implemented in WhaleTeq SECG4.0 equipment.*

201.12.1.101.14	Synchronizing pulse for cardioversion (<35ms delay to SIP/SOP) Test more detailed (more test conditions)
201.12.1.101.15	Heart rate accuracy: New test @ 0.15mV (70-120ms), and also with QRS of 1mV 10ms, both cases no heart rate shall be indicated. *Note: the most recent software for WhaleTeq SECG4.0 includes this function*
201.12.4.101.1	Indications on display: - Filter settings - Selected leads - Gain indicator - Sweep speed
201.15.4.4.101	Indication of battery operation and status required
208	Alarms: - Greatly modified, needs full re-check - IEC 60601-1-8 needs to be applied in full - Distributed alarm systems: disconnection should o Make technical alarm at both sides o Turn on audible alarms in the patient monitor

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