5.2.6.3 Amplitude calibration

Compliance with amplitude calibration requirements is made by inspection.

5.2.7 Accuracy of input signal reproduction

5.2.7.1 System noise

a) Insert in series with each patient electrode connection a 51 KΩ resistor in parallel with a 47 nF capacitor, as shown in figure 5, and then connect together all patient electrode connections, including the reference connection. Do not connect the input signal generator and the 100 pF capacitor for this test. At the highest gain possible, record for 2 min.

b) Ignore the first 10 s and the last 10 s of the recording. Divide the remaining 100 s into 10 intervals of 10 s each, then check the output for noise levels in each interval. The p-v noise level shall be within the limit for at least nine of the ten intervals.

5.2.7.2 Multichannel crosstalk

a) Connect the recorder to the test circuit of figure 3 with switches S1 and S2 closed, S5 open, S3 in position A, and the positive patient electrode connections for each channel joined to P1. The reference patient electrode connections for each channel are joined via P2 to the reference leadwire through a parallel combination of a 51 KΩ resistor and a 47 nF capacitor.

b) Adjust the signal generator to produce a 2.0 mV p-v 30 Hz triangular wave between P1 and P2. Record at least 10 s of signal.

c) Reconnect all but one of the positive electrodes from P1 to P2. Record at least 10 s of signal.

d) Repeat step (c) with a different positive electrode connection joined to P1 for each 10 s recording for as many channels as can be recorded. Only one positive electrode connection is joined to P1 at a time.

e) Outputs of playback signals at standard gain and speed shall be less than 1.0 mm during the 10 s periods when corresponding positive electrode connections are joined to P2.

5.2.7.3 Frequency response

a) With the recorder connected to the test circuit as in 5.2.7.2 (figure 3), record a 1 mV p-v sinusoidal signal at 0.67 Hz for at least 5 s.

b) Repeat step (a) at 1 Hz, 2 Hz, 5 Hz, 10 Hz, 20 Hz, and 40 Hz (30 Hz for Type 3 devices).

c) Record a 1 Hz train of 1.5 mV triangular pulses with a base width of 200 ms for at least 5 s.

d) Now adjust the base width of the 1.5 mV triangular wave to 40 ms (20 ms for devices meeting special infant requirements). Record for 2 min (30 s for Type 3 devices) while slowly changing the repetition rate from 60 per min to 70 per min. This procedure will ensure that the full range of amplitude variability, which results from sample points missing the peak of the triangular waveform, will be obtained.

e) Record at least 20 s of zero volt baseline and then a single 3 mV, 100 ms (1.5 mV, 200 ms for Type 3 devices) rectangular pulse. Twenty seconds is about six time constants for 0.05 Hz and is required to isolate the response of the rectangular pulse from other signals in the recording. (For devices in which the low frequency is altered following detection of a pacer pulse, the rectangular pulse may need to be low pass filtered slightly or its rise time increased so that the device's pacer detector is not triggered.)

f) Playback signals at standard gain (10 mm/mV) and speed (25 mm/s).

g) Using the 5 Hz p-v playback amplitude as the reference, verify that the p-v response of each of the 0.67 Hz, 1 Hz, 2 Hz, 10 Hz, and 20 Hz test frequencies is within the 70% to 115% limits.

h) Either test (1) or test (2) shall pass:

   1) Test (g) is repeated using the 40 Hz test frequency (30 Hz for Type 3 devices);

   2) Measure output amplitudes of step (d) from the peak of the triangle to the baseline point defined as the average level of a 100 ms region halfway in time between triangles. Locate the lowest amplitude 20 ms triangle wave and confirm that it is no less than 60% of the peak amplitude of the 200 ms triangles.

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i) Verify that the output baseline following the pulse of step (e) above is displaced no more than 0.1 mV (1.0 mV if 4.2.7.3 (d) applies) from the baseline preceding the pulse. Verify also that the slope of the response outside the region of the pulse does not exceed 0.30 mV/s (2.0 mV/s if 4.2.7.3 (d) applies).

5.2.7.4 Hysteresis and minimum feature size

a) Record a + 1.5 mV pulse having a step leading edge and an exponential trailing edge with a time constant between 50 ms and 100 ms. Three seconds later, record a similar pulse of opposite polarity.

b) Record a 10 Hz, 50 μV p-v sinusoidal signal for at least 5 s.

c) Set the systems to standard gain (10 mm/mV) and speed (25 mm/s) and confirm that 2 s after each pulse the output trace has returned to within ± 50 μV of the initial baseline.

d) Confirm that a deflection corresponding to the 10 Hz signal is visible.

5.2.7.5 Overall system error

a) Adjust the signal generator of figure 3, with switches S1 and S2 closed, S5 open and S3 in position A, to obtain a 2 Hz, 4 mV p-v triangle wave between P3 and P4 (3 mV p-v for Type 3 devices). Record at least 5 s of this signal in all channels.

b) For Type 1 and Type 2 devices, apply the test waveform of figure 7 to the recorder leads. Record 5 s of signal in all channels for the appropriate combinations of the following waveform parameters:

System labeled for infant use	Other systems
1) a = 0.5 mV and 3.0 mV	a = 0.5 mV and 3.0 mV
2) d = 40 ms and 120 ms	d = 70 ms and 120 ms
3) heart rate = 30 bpm and 250 bpm	(heart rate = 30 bpm and 250 bpm)

c) At standard gain (10 mm/mV) and speed (25 mm/s) confirm that the playback output signal amplitude from step (a) is within 20% of 4 mV (3 mV for Type 3 devices).

d) For Type 1 and Type 2 devices, verify that the reproduced test waveform amplitudes from step (b) are indicated to be within 20% or 100 μV (whichever is greater) of the corresponding inputs.

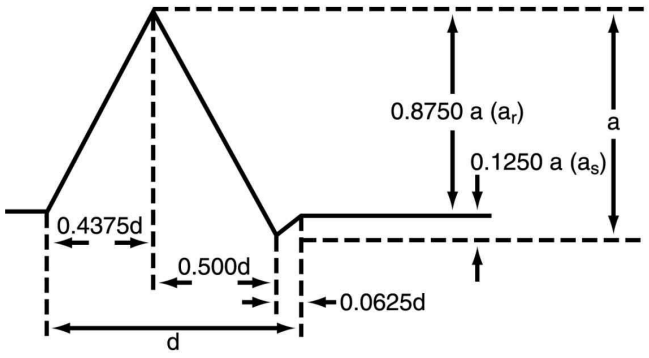


**Figure 7—Test signal simulating the QRS complex of the ECG—
QRS amplitude is noted by "a"; "ar" is 0.8750a, and "as" is 0.1250a**

5.2.7.6 Special considerations for high speed superimposition display

Compliance with the standard is established by inspection.

5.2.7.7 Baseline stability

a) Insert in series with each patient electrode connection a 25 KΩ resistor. Connect all patient electrode connections of the recorder together, including the right leg connection. Record for 24 h. For Type 3 devices, the recording period shall be reduced to match the maximum memory available and the actual usage conditions.

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b) With the sensitivity set to maximum, verify that the baseline drift in the output hard copy does not exceed 600 μV in any 60 s period, or 1 mV at any time.

5.2.7.8 Pacemaker pulse tolerance and display capability

Compliance can be determined by the following procedure.

a) Connect the device to the circuit of figure 8, with the positive patient electrode connection for each channel connected to P1 and the negative electrode connection for each channel, as well as the reference electrode connection, if present, connected to P2.

b) Check that the 10 ± 1 Hz sine wave generator provides a 1.0 ± 0.1 mV p-v signal across the 100 ohm resistor and that the pulse generator adds 250 ± 25 mV p-v, 2.0 ± 0.2 ms pulses with rise times no greater than 100 μs. The frequency of the pulses shall be 100 ± 10 pulses per minute. The frequencies of the two generators shall not be synchronous.

c) Record at least 10 s of this combined test waveform.

d) For each channel, reverse the positive and negative patient electrodes of step (a) and record at least 10 s of the test waveform.

e) Disconnect the sine wave generator (or reduce its output to 0.0 V). Adjust the pulse generator to produce a pulse across the 100 ohm resistor with an amplitude of 2.0 ± 0.2 mV and a width of 100 ± 10 ms. Record at least 10 s of this test waveform.

f) Reduce the pulse width to 0.5 ± 0.05 ms, and record at least 10 s of this test waveform.

g) For each channel, reverse the positive and negative patient electrodes of step (d) and record at least 10 s of the test waveform.

h) Confirm on playback at 10 mm/mV that for all pulses recorded in steps (c) and (d), the height of the second sine wave peak after the pulse differs by less than 1.0 mm from the height of the sine wave peak immediately preceding the pulse.

i) For the pulses recorded in steps (f) and (g), verify on playback at 10 mm/mV that the presence of each pulse is clearly indicated and that the indication is at least as large as 10% of the reference pulses recorded in step (e).

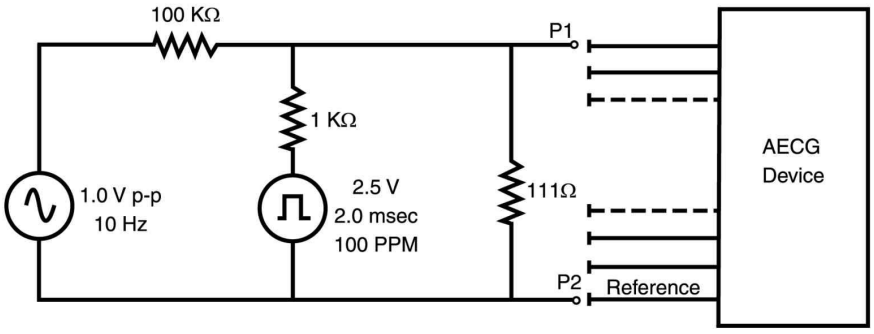


Figure 8—Test circuit for pacemaker pulse tolerance and display

5.2.7.9 Special infant requirements

Devices intended for use in infants (weight ≤ 10 kg) are to be tested as in 5.2.7.3 with the addition of a test at the power line frequency (50 Hz or 60 Hz). In step (h) of that procedure, however, the lowest amplitude 20 ms triangle shall be no less than 80% of the 200 ms triangles.

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5.2.7.10 Patient event marks

For Type 1 and Type 2 devices, press the patient marker once per h during the procedure, and verify that the device reports the time for each event within ± 3 s of the actual time that the patient marker was activated.

5.2.8 Time base selection, accuracy, and stability

Throughout all of these tests, a “CAL test signal” refers to a 100 ms wide, 1 mV high, 60 ppm signal generated by a test box or the recording device itself. Setting a recorder in “CAL MODE” means feeding the CAL test signal to all of its recording channels or activating the internal CAL circuit to produce the same effect. The basic time accuracy for this “CAL test signal” shall be ± 1%.

5.2.8.1 Timing accuracy

Set the recorder under test in the “CAL MODE” (or use an ECG simulator) for 24 h. At exactly 1 h, 8 h, and 23 h into the test, insert an event mark on the recording. With the scanning device, generate a full-disclosure, 24 h report of the recorded test signal. By inspection of the report, verify that each event mark’s actual time of day is within 60 s of the end of the 1st hour, 8th hour, and 23rd hour of the scan.

5.2.8.2 Hard copy time base

Print a 10 s strip of CAL pulses at 25 mm/s. Verify that the width of every CAL pulse is 100 ms ± 10 ms by observation. Verify the cumulative error over 7 s, by measuring the time difference between the leading edge of the 8th and first CAL pulses on the paper grid. This should be from 166.25 to 183.75 mm.

5.2.8.3 Hard copy grid standard

Grid rulings shall be verified by inspection using an optical magnifier with a scale resolution of at least 0.05 mm. Measurements of the spacing of each ruling shall be made on a representative 7 s segment of ECG printout with a time axis scale of 25 mm/s and voltage scale of 10 mm/mV. Three distinct locations within the printout shall be measured: the upper left corner, the middle, and the lower right corner. At each location, the spacing between every 10th ruling within a 2 cm-by-2 cm square shall be verified to be within ± 2% tolerance.

If grid rulings are provided with scaling factors different than those specified above, then an optical measurement of the grid spacing shall be made in a similar manner with a measuring device capable of resolving their accuracy to within a ± 2% tolerance.

5.2.8.4 Full disclosure (miniature displays)

Visually check that all of the information specified in 4.2.8.4 is available on each full-disclosure hard copy page.

5.2.8.5 Gain settings and switching

Verify that the system under test has at least the following scale factors for printout:

20 mm/mV, 10 mm/mV, and 5 mm/mV.

Additional scale factors (typically 40 mm/mV and 2.5 mm/mV) may be provided.

Verify that the system printing device will clearly label the scale factor selected in the report output. If the system allows for uncalibrated printouts due to failure of the automatic gain circuit or operator device, verify that the printout clearly states that the ECG tracings are not calibrated.

5.2.9 Temporal alignment

Connect the recorder to the test circuit shown in figure 3. Switches S1 and S2 should be closed, S3 should be in position A, and S5 should be open. For all channels of recorders with multiple bipolar leads, connect all positive lead connections to point P1 and all negative lead connections to point P2. The signal source is adjusted to provide a rectangular pulse stream with an amplitude of 1.0 mV (peak) ± 0.05 mV across P1 and P2. The pulses are to be 200 ms in duration with a rise-and-fall time of less than 1.0 ms. The pulse repetition rate shall be 1 pulse per s.

If the recorder and/or scanning device have switchable amplifier filters, they should be adjusted such that all channels have the same frequency response.

Record at least 1 h of pulses on all of the channels of the recorder. Play the recorded signal back on the system and print out or display the signal for each channel at a resolution of 25 mm/s and 10 mm/mV. Verify that the skew of the rising and falling edges of the signal between each of the channels is less than 20 ms (0.5 mm). This measurement shall be made at three distinct points in the 1 h recorded signal. Repeat this test for all playback speeds available in the scanning device.

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Verify that a warning is printed/displayed by the scanning device if the measure skew exceeds 0.5 mm (e.g., if the recorder and/or scanning device has switchable amplifier filters).

5.2.10 Electromagnetic compatibility

AECG patient recorders are patient-coupled devices. The configuration and termination of the patient cables and electrodes markedly affect electromagnetic emissions and immunity. Instrument test configurations should be determined by the manufacturer. However, it is recommended that the instrument be tested in a sufficient variety of configurations and operating states that might be used in normal operation, so that the worst case may be determined. The ECG cables should be tested in both an unterminated and a patient-simulated (51 KΩ in parallel with 47 nF) terminated mode. The test methods and instruments for verifying the electromagnetic compatibility requirements of 4.2.10 are extremely complex and detailed. It is not practical to include these in sufficient detail in this standard. Rather, the responsible person needs to study and follow the detailed instructions and procedures found in the reference documents: EN 61000-4 series (2, 3, 4, 5, 6, 8, 11) and International Special Committee on Radio Interference (CISPR) 11 and 16.

5.2.10.1 Electromagnetic emissions

5.2.10.1.1 Radiated and conducted electromagnetic emissions

The instrument shall be tested with ECG cables (leads) attached and either unterminated or terminated in a load simulating the patient (51 KΩ in parallel with 47 nF.)

5.2.10.2 Electromagnetic immunity

5.2.10.2.1 Immunity to radiated electromagnetic fields

The ECG cables are terminated in a simulated patient load (51 KΩ in parallel with 47 nF). The instrument is tested with all of its faces sequentially exposed to the RF field.

5.2.10.2.2 Immunity to conducted RF interference

A. *For AECG systems in which the ambulatory portion cannot be simultaneously connected to a line powered portion and to the patient*: Tests shall be done with the interfering signal injected (in common mode fashion) into the ECG cable while that cable is terminated in a load simulating the electrodes (51 KΩ in parallel with 47 nF) and the ambulatory portion is wrapped in foil, with the latter being connected to earth ground by the “artificial hand” described in EN 61000-4-6. Separate tests shall also be done on the line-powered portion (if it exists) with the interfering signal injected into the line cord. If the instrument fails the 100 μV specification (section 4.2.7.1), the actual performance of the instrument to this test shall be specified in the instrument’s manual/specifications.

B. *For AECG systems in which the ambulatory portion can be simultaneously connected to a line powered portion and to the patient:* Tests shall be done with the interfering signal injected (in common mode fashion) into the ECG cable while that cable is terminated in a load simulating the electrodes (51 KΩ in parallel with 47 nF) and the ambulatory portion is connected to the line powered portion with no interfering signal injected into the line cord. Separate tests shall also be done with the interfacing signals injected into the line cord while the ECG cable is terminated (51 KΩ in parallel with 47 nF) and the cable’s shield tied to earth through the “artificial hand” described in EN 61000-4-6. Both sets of tests in this paragraph are to be done with the two portions connected.

5.2.10.2.3 Immunity to magnetic fields

NOTE—Test methods and procedures are specified or referenced in 4.2.10.2.3.

5.2.10.2.4 Immunity to electrostatic discharge

NOTES—

1. Test methods and procedures are specified or referenced in 4.2.10.2.4.

2. If the loops formed by the unterminated ECG cable (leads) are not small, the instrument could fail its ECG noise specifications.

5.2.10.2.5 Power line transients

NOTE—Test methods and procedures are specified or referenced in 4.2.10.2.5.

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5.2.11 Auxiliary output

5.2.11.1 Shorted auxiliary output

If the reproducer is provided with an auxiliary output, this output shall be short-circuited for at least 1 min, with the reproducer in the normal playback mode but the chart recorder not activated. Upon removal of the short circuit, the reproducer shall meet all of the requirements of this standard.

5.2.11.2 Effect on risk current

With the auxiliary device connected as specified by the manufacturer or simulated by a resistor equivalent to the drive capability specified for the auxiliary device, all risk currents shall fall within the limits specified in 4.2.4. See ANSI/AAMI ES1:1993 which describes a test method.

5.2.12 Monitoring time and battery capacity

Compliance with the requirements of 4.2.12 can be determined by the following procedure.

a) Fully charge the battery in the device under test according to the manufacturer's instructions. Nonrechargeable batteries should be replaced with new, undepleted ones according to the manufacturer's instructions.

b) Place the device under test in an environmental chamber adjusted for the lowest operating temperature specified in 4.2.1. Maintain this operating temperature for 4 h, and then vary the temperature during the remainder of the procedure.

c) Operate the device under test for the entire monitoring period as specified by the manufacturer, recording test signals as indicated in 5.2.6.1, 5.2.6.2, and 5.2.8.1 at least once per h.

d) At the end of the test, record crosstalk test signals as indicated in 5.2.7.2.

e) Wait 72 h (24 h for Type 3) and then play back the recording on a reproducer approved by the manufacturer, and record the test signal output on hard copy. Verify that the reproduced signals meet the requirements of 5.2.6.1, 5.2.6.2, 5.2.7.2, and 5.2.8.1.

5.2.13 Special requirements for intermittent event recorders

5.2.13.1 Data retention

Compliance with 4.2.13.1 can be determined by the following procedure.

a) Fully charge the battery in the device under test according to the manufacturer's instructions. Nonrechargeable batteries should be replaced with new, undepleted ones according to the manufacturer's instructions.

b) Place the device under test in an environmental chamber adjusted for the lowest operating temperature specified in 4.2.1.1, ± 2º C. Maintain operating temperature with that tolerance for the duration of the recording test.

c) Connect the device under test such that it is ready to record test signals as indicated in 5.2.6.1, 5.2.6.2, and 5.2.8.1 whenever the trigger becomes activated.

d) Operate the device under test in the ready mode for the minimum operating period specified by the manufacturer (see NOTE below). Do not activate the trigger.

e) At the end of the minimum specified operating period, record test signals as indicated in 5.2.6.1, 5.2.6.2, and 5.2.8.1 and record crosstalk test signals as indicated in 5.2.7.2.

f) Put the device under test into memory hold mode for a period of 24 h.

g) Play back the recording on a reproducer approved by the manufacturer and record the test signal output on hard copy. Verify that the reproduced signals meet the requirements of 5.2.6.1, 5.2.6.2, 5.2.8.1, and 5.2.7.2.

NOTE—If the specified operating period is longer than 2 weeks, the manufacturer may substitute batteries depleted to a capacity equivalent to worst-case device operation for the entire minimum specified operating period in order to avoid extended delays. Any device passing depleted battery testing shall be considered to have satisfied the intent of this standard. If depleted battery substitution is used, however, the manufacturer shall conduct a full operating period test according to the provisions of this standard using fresh, undepleted batteries without substitution. After twice the specified minimum operating period from the date of the

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substituted abbreviated test, the manufacturer shall have test data retained on file showing successful completion of a full operating period test in compliance with the requirements of 4.2.13.1.

5.2.13.2 ECG recording intervals

Compliance with the requirements of 4.2.13.2 can be determined by inspection.

5.2.14 Automated analysis

The requirement that evaluations be reproducible (4.2.14) implies that evaluations shall be performed without human intervention.

Use of standard databases:

Each record shall be supplied to the device continuously from the beginning to the end (i.e. without rewinding or "fast forwarding"). This requirement applies only to the manner in which the evaluator presents ECG samples to the device under test and in no way is to be construed as a restriction on the manner in which the device performs its analysis.

If the digitized ECG signals from the database records are preprocessed in any way before they are presented as input to the device under test, the preprocessing shall be disclosed in sufficient detail to permit a third party to reproduce the test. Preprocessing includes, but is not limited to:

a) resampling (i.e. conversion to a sampling rate different from that used in the standard database files);

b) reformatting (i.e. conversion of byte order, sample precision, or numeric coding);

c) rescaling (altering the signal amplitude, i.e. changing the gain);

d) filtering performed by software or hardware not employed in the normal operating mode of the device under test; and

e) conversion from digital to analog signals.

If the evaluation of the device under test is performed using signals converted into analog form and supplied to the normal analog inputs of the device, the device's automatic gain control (AGC) will be allowed to adjust the gain automatically. If the evaluation is performed using digital data and the AGC is not digital but part of the analog front end of the device, the device may simulate its AGC capabilities by an alternative method. This alternative method allows the "test mode" that generates the "test annotations" to emit an announcement that a "gain adjustment" would be required prior to proceeding with analyzing the ECG for each patient record. This announcement should instruct the evaluator to adjust the gain of the ECG for either one or both of the ECG channels. The evaluator shall then run the 'xform' (or equivalent) program to adjust the ECG's gain based on the instructions provided by the program. This process shall be repeated until "no gain change" is announced and the device under test shall then automatically proceed with the ECG analysis.

Beat-by-beat comparisons, following the protocol described in 5.2.14.3, shall be used to derive QRS Se, QRS +P, rms RR interval error, VEB Se, VEB +P, and (where applicable) SVEB Se and SVEB +P. Run-by-run comparisons, following the protocol described in 5.2.14.4, shall be used to derive VE couplet Se and +P, VE short run Se and +P, VE long run Se and +P, and (where applicable) SVE couplet Se and +P, SVE short run Se and +P, and SVE long run Se and +P. The protocol described in 5.2.14.5 shall be used to derive VF and AF episode Se and +P, and VF and AF duration Se and +P, where applicable. ST comparisons, following the protocol described in 5.2.14.6, shall be used (where applicable) to derive the data necessary to satisfy the reporting requirements of 4.2.14.3.1.

Use of annotation files:

The test protocols described in 5.2.14.3 through 5.2.14.6 require that, for each record, the output of the device has been recorded in an annotation file (the "test annotation file") in the same format as the reference annotation file for that record. The device need not produce this file directly. Any automated procedure for doing so is acceptable as long as it is disclosed. The programs 'bxb,' 'rxr,' 'epic,' and 'mxm,' (either the versions supplied on the MIT-BIH Arrhythmia Database CD-ROM, or any later versions released by MIT) shall be used to perform the comparisons between the test annotation files and the reference annotation files as described in 5.2.14.3 through 5.2.14.6. The reference annotation files distributed with the databases and used as input to these programs may not be altered in any way, except that (where applicable) corrected reference annotation files obtained from the database suppliers may be substituted for those originally distributed with the databases.

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Within annotation files, beat labels are defined as follows:

N = any beat that does not fall into the S, V, F, or Q categories described below (a normal beat or a bundle branch block beat)

S = a supraventricular ectopic beat (SVEB): an atrial or nodal (junctional) premature or escape beat, or an aberrated atrial premature beat

V = a ventricular ectopic beat (VEB): a ventricular premature beat, an (R-on-T) ventricular premature beat, or a ventricular escape beat

F = a fusion of a ventricular and a normal beat

Q = a paced beat, a fusion of a paced and a normal beat, or a beat that cannot be classified

Other labels are needed to facilitate the beat-by-beat comparison process defined in 5.2.14.3:

U = a label that marks a segment of unreadable data

U labels appear in the databases where beats cannot be located because of excessive noise or signal loss in both signals. In the MIT and ESC databases, a pair of U labels marks the beginning and end of each unreadable segment. In the AHA database, a single U label marks the (approximate) center of each unreadable segment, which is assumed for testing purposes to begin 150 ms after the previous beat label and to end 150 ms before the following beat label. In order to mark segments during which a device's analysis is suspended (shut down) because of excessive noise or signal loss, or for any other reason, devices may also generate U labels. Beat labels are never paired with U labels during beat-by-beat comparisons.

Extra beats are sometimes detected (false positive QRSs), and true beats are sometimes missed (false negative QRSs). In order to perform beat-by-beat comparisons, pseudobeat labels are added to those in the reference and test annotation files to preserve a one-to-one correspondence between beat labels. They represent the absence of a beat label. There are two types:

X = a pseudobeat label generated during a segment marked as unreadable

O = a pseudobeat label generated at any other time

In beat-by-beat comparisons, all beat labels are paired up. If either the reference or the test annotation file contains an extra beat label that has no match in the other file, the appropriate O or X label is paired with the extra label. This corresponds to a QRS detection error—either a false detection (if the extra label is in the test annotation file) or a missed beat (if it is in the reference annotation file). All such beat label pairs are counted, including those that involve O or X labels. O and X labels are not used in run-by-run comparisons (5.2.14.4), or for ventricular flutter or fibrillation (VF), atrial flutter or fibrillation (AF), or ST comparisons (5.2.14.5 and 5.2.14.6), as it is not necessary in these instances to pair individual beat labels.

Rhythm labels mark segments of ventricular flutter or fibrillation VF in the AHA and MIT databases:

[= beginning of VF

] = end of VF

Beat labeling is discontinued between "[" and "]" labels. VF segments are excluded from beat-by-beat comparisons. Additional rhythm labels mark changes in rhythm in the MIT and ESC databases. Those that mark segments of atrial flutter or fibrillation AF (see the documentation that accompanies each database) are used for evaluation of AF detection; others are ignored. Beat labels are never paired with rhythm labels.

Beat-by-beat comparison:

During a beat-by-beat comparison, reference beat labels and device beat labels are matched up in pairs. To be considered a match, the absolute value of the difference between the device's estimate of the time of occurrence of a beat and the time as recorded in the reference annotation file shall not exceed 150 ms. If matching does not occur within this window, the candidate beat is considered to have been missed or to be an extra detection. The end product of a beat-by-beat comparison is a matrix in which each element is a correct count of the number of beat label pairs of the appropriate type:

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Reference label	Algorithm label							
		n	s	V	f	q	o	x
	N	Nn	Ns	Nv	Nf	Nq	No	Nx
	S	Sn	Ss	Sv	Sf	Sq	So	Sx
	V	Vn	Vs	Vv	Vf	Vq	Vo	Vx
	F	Fn	Fs	Fv	Ff	Fq	Fo	Fx
	Q	Qn	Qs	Qv	Qf	Qq	Qo	Qx
	O	On	Os	Ov	Of	Oq		
	X	Xn	Xs	Xv	Xf	Xq		

Method for beat-by-beat comparison:

a) Set the variable T to the time of the first reference beat label after the end of the learning period, and set the variable t to the time of the first test beat label after the end of the learning period (see NOTE below). Set all elements of the matrix to zero.

NOTE—If T is within 150 ms of the beginning of the test period, it is possible that a matching test beat label may be placed before the beginning of the test period. If this occurs, it is counted as a match [t is set to the time of the matching test beat label before going on to step (b)]. Conversely, if t is within 150 ms of the beginning of the test period and there is no matching reference beat label after the beginning of the test period, the test annotation at t is not counted [t is set to the time of the next test beat label before going on to step (b)].

b) One of the following cases shall apply:

1) If t precedes T, set t' to the time of the next test beat label (or to a time beyond the end of the record if there are no more test beat labels). There are now two possibilities:

i) If T is closer to t than to t' and t is within 150 ms (the match window) of T, the beat labels at T and t are paired. The variable T is reset to the time of the next reference beat label.

ii) Otherwise, the test beat label at t is an extra detection. The extra label is paired with an O or X "pseudobeat" label. The variable t is reset to the value of t'.

2) If t does not precede T, set T' to the time of the next reference beat label (or to a time beyond the end of the record if there are no more reference beat labels). There are again two possibilities:

i) If t is closer to T than to T' and t is within 150 ms of T, the beat labels at T and t are paired. The variable t is reset to the time of the next test beat label.

ii) Otherwise, the device has missed the beat at T. The extra reference beat label is paired with an O or X "pseudobeat" label. The variable T is reset to the value of T'.

c) The matrix element corresponding to the beat label pair that was generated in step (b) is incremented.

d) Steps (b) and (c) are repeated until both t and T are set to times beyond the end of the record.

During the derivation of the matrix, the procedure shall keep track of segments that have been marked as unreadable or as VF in either the reference or the test annotation file. During unreadable segments, pseudobeat labels are X; at all other times, pseudobeat labels are O. Test beat labels generated during true VF segments are not counted for these purposes. Reference beat labels present during device-marked VF segments are paired with O pseudo-beat labels and counted like all other missed beats. In principle, an unreadable segment or a VF segment may begin during the learning period; this possibility shall be taken into account by software designed to perform beat-by-beat comparisons.

Run-by-run comparison:

Run-by-run comparisons are used to measure a device's ability to detect runs of consecutive ectopic beats. For each type of ectopic beat (VEB and SVEB), two run-by-run comparisons are required, one for sensitivity and another for positive predictivity. The end product of a run-by-run comparison is a pair of matrices in which each element is a correct count of the number of run pairs of the appropriate type:

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Reference run length	Algorithm run length							
		0	1	2	3	4	5	>5
	0		S01	S02	S03	S04	S05	S06
	1	S10	S11	S12	S13	S14	S15	S16
	2	S20	S21	S22	S23	S24	S25	S26
	3	S30	S31	S32	S33	S34	S35	S36
	4	S40	S41	S42	S43	S44	S45	S46
	5	S50	S51	S52	S53	S54	S55	S56
	>5	S60	S61	S62	S63	S64	S65	S66

(Run sensitivity summary matrix)

Reference run length	Algorithm run length							
		0	1	2	3	4	5	>5
	0		P01	P02	P03	P04	P05	P06
	1	P10	P11	P12	P13	P14	P15	P16
	2	P20	P21	P22	P23	P24	P25	P26
	3	P30	P31	P32	P33	P34	P35	P36
	4	P40	P41	P42	P43	P44	P45	P46
	5	P50	P51	P52	P53	P54	P55	P56
	>5	P60	P61	P62	P63	P64	P65	P66

(Run positive predictivity summary matrix)

NOTE—Each entry corresponds to a combination of reference run length and algorithm run length. All run lengths greater than 5 are condensed into the last column (row). Each element is named according to the matrix to which it belongs (S or P) followed by two subscripted numerals corresponding to the reference and algorithm run lengths.

Definitions:

In the rest of this section, the general term “VE run” refers to a sequence of consecutive V or F labels (which may be mixed in any order) delineated by surrounding N, S, or Q labels (or by the beginning or end of the test period or of an unreadable segment). Similarly, the term “SVE run” refers to a sequence of consecutive S labels delineated by surrounding N, V, F, or Q labels (or by the beginning or end of the test period or of an unreadable segment). The following terms and abbreviations are used to denote runs of specific lengths:

Couplet (C) = a run of two beats;
Short run (S) = a run of three, four, or five beats;
Long run (L) = a run of six or more beats.

A segment of ventricular fibrillation or flutter marked by “[” and “]” labels is considered to be equivalent to a VE long run for the purposes of this section; any adjacent V or F labels are considered to be part of the same run. Similarly, a segment of atrial fibrillation or flutter marked by rhythm labels is considered to be equivalent to an SVE long run, and any adjacent S labels are considered to be part of the same run.

Run sensitivity summary matrix:

This paragraph describes how to derive the VE run sensitivity summary matrix.

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a) The reference annotation file defines the location of all runs. For each true run, a match window is defined, beginning 150 ms before the time of the first beat label of the true run and ending 150 ms after the time of the last beat label of the true run.

b) For each true run, the true run length is the number of consecutive V or F reference beat labels within the match window.

c) For each true run, the test run length is the number of consecutive V or F test beat labels within the match window. If more than one detected run occurs during a single true run, the test run length is determined by the longest detected run within the match window. If there are no V or F test beat labels during a true run, the test run length is zero.

d) Each possible combination of true run length and test run length corresponds to a cell in the run sensitivity summary matrix. For each true run, the count in the appropriate cell is incremented.

To derive the SVE run sensitivity summary matrix, follow the same procedure, replacing each “V” or “F” with “S” in the description above.

Run positive predictivity summary matrix:

This paragraph describes how to derive the VE run positive predictivity summary matrix.

a) The test annotation file defines the location of all runs. For each test run, a match window is defined, beginning 150 ms before the time of the first beat label of each test run and ending 150 ms after the time of the last beat label of the test run.

b) For each test run, the test run length is the number of consecutive V or F test beat labels within the match window.

c) For each test run, the true run length is the number of consecutive V or F reference beat labels within the match window. If more than one true run occurs during a single test run, the true run length is determined by the longest true run during the match window. If there are no V or F reference beat labels during a test run, the true run length is zero.

d) Each possible combination of true run length and test run length corresponds to a cell in the run positive predictivity summary matrix. For each true run, the count in the appropriate cell is incremented.

To derive the SVE run positive predictivity summary matrix, follow the same procedure, replacing each “V or F” with “S” in the description above.

VF and AF comparisons:

For devices that are claimed to detect VF, a VF comparison shall be performed. This test requires the production of an annotation file based on the device’s outputs, containing (at a minimum) the times when the device has determined that episodes of VF have begun or ended. Overlap exists during any interval in which both the reference and algorithm annotations indicate that VF is in progress. Each reference episode for which overlap exists is counted as a true positive for purposes of determining VF episode sensitivity; any other reference episodes are counted as false negatives. Similarly, each algorithm-marked episode for which overlap exists is counted as a true positive for purposes of determining VF episode positive predictivity; any other algorithm-marked episodes are counted as false positives.

Measurement of VF duration sensitivity and positive predictivity requires determination of the total duration of reference and algorithm-marked VF and of the total duration of periods of overlap as defined above.

For devices that are claimed to detect AF, an AF comparison shall be performed. This test is performed in the same manner as the VF comparison (described above) with the substitution of “AF” for each occurrence of “VF.” Segments labeled as atrial flutter in the reference annotation files shall be excluded from this comparison.

ST comparison:

For devices that measure the ST segment or detect ST changes, an ST comparison shall be performed. This test requires the production of an annotation file based on the device’s outputs, containing (at a minimum) numerical measurements of ST level attached to each beat label, and ST episode annotations (if the device attempts to detect ST episodes). The device need not produce this annotation file directly; any automated procedure for doing so is acceptable if disclosed. The device’s ST episode annotations shall indicate the times of the beginning, the extremum, and the end of each ST episode, following the scheme used for the (ESC DB) reference annotations.

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ST deviation errors are measured by comparing each reference ST deviation measurement with the device's measurement on the same signal and nearest the time of the reference measurement.

Episode-by-episode comparisons similar to run-by-run comparisons are needed in order to derive ischemic ST episode sensitivity and positive predictivity. Overlap exists during any interval in which both the reference and algorithm annotations indicate that an ischemic ST episode is in progress. Episodes match for purposes of measuring sensitivity when the period of overlap includes either the reference-marked extremum or at least 50% of the length of the reference-marked episode. Episodes match for purposes of measuring positive predictivity when the period of overlap includes either the algorithm-marked extremum or at least 50% of the length of the algorithm-marked episode.

For devices that detect ST changes based on more than one signal simultaneously, the definition of a reference-marked ischemic ST episode shall be modified so that such an episode is considered to be in progress if any signal has been annotated as having an ischemic ST episode in progress. In this case, episodes match for purposes of measuring sensitivity when the period of overlap includes the reference-marked extremum in any signal, or 50% of the length of the reference-marked episode.

Measurement of ischemic ST duration sensitivity and positive predictivity requires determination of the total duration of reference- and algorithm-marked ischemic ST episodes and of the total duration of periods of overlap as defined above.

5.2.15 Minimum requirements for clinical report

Compliance with these requirements is made by inspection.

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Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Introduction

A.1.1 General

So-called “ambulatory ECG monitoring” is not typically real-time monitoring like that required for the intensive care of critically ill patients. Nevertheless, ambulatory ECGs (AECGs) have proven useful for several purposes (see Knoebel *et al*., 1989), viz.:

a) evaluation of symptoms that may be caused by cardiac arrhythmias and/or conduction disturbances;

b) evaluation of symptoms that may be due to myocardial ischemia;

c) detection of ECG events that alter prognosis in certain forms of heart disease;

d) detection and analysis of pacemaker function and failure;

e) determination of cardiac response to lifestyle events;

f) evaluation of therapeutic interventions;

g) investigations in epidemiology and clinical trials.

AECG systems may be capable of serving most but not necessarily all of the above purposes. The recommended uses of each system, however, should be disclosed in the product literature.

Typically, 24 h or more of AECG data (2 or 3 channels) are recorded on analog or digital media. The recording is then processed according to several different techniques that involve varying degrees of human interpretation. Superimposition scanning, in which the reader uses a high-speed scanning machine, represents one method of processing that has been used for over 20 years. More recently, the so-called “full disclosure” approach to processing produces a condensed hard copy of the whole 24 h of AECG data, which shall be carefully scanned in its entirety by the human reader. Computer-assisted scanning combined with appropriate editing by a well-trained human reader can produce very detailed and accurate diagnosis of even complex arrhythmias if the system permits rapid review of large epochs of data.

A fourth approach is complete automation of the processing with a computer program to analyze ECG features such as disturbances in rhythm, that until recently, have been the main focus of AECGs. The computer program may produce an “interpretation” of the data and present a summary of the results; such systems may require little or no human editing but may, nevertheless, need a skilled review to produce an accurate report.

The technique of so-called “real-time arrhythmia analysis” takes this approach to the patient by miniaturizing the computer and integrating it with the ECG recorder. The computer has algorithms designed to label all QRS complexes and store summary data. Also, some systems have algorithms to select and store samples of rhythm with or without changes for later recall and display.

This standard covers all AECG devices, with or without the capability for ECG waveform display and with or without computer processing. The standard does not require the provision of these features, but instead defines the performance criteria for ECG waveform display and computer processing when an AECG system is so equipped.

This annex provides the rationale for the initiation of a standards development effort on AECG systems, as well as the rationale for each of the standard’s provisions.

A.1.2 Types of devices

There are several approaches to ambulatory monitoring that serve different clinical objectives. This standard separates types of devices according to their approaches to recording, analysis, and display of the AECG signal. Type 1 devices continuously record the signal. Type 2 devices continuously analyze the AECG signal and record only selected epochs. Type 3 devices only record or transmit AECG signals when activated, i.e. via a push button operated by the patient. Requirements and testing methods are tailored for each device type.

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The approach to AECG monitoring may depend upon symptom frequency. Symptoms occurring often enough to be revealed in a monitoring period of 24 h may require a fidelity of recording approximately equivalent to that of a bedside monitor; the differential diagnosis of arrhythmogenesis (e.g., separating atrial from nodal beats) may require analysis of the P wave and/or QRS morphology. Type 1 and Type 2 devices are aimed at such applications and have fidelity requirements designed for that purpose.

When symptoms are less frequent so that the events indicative of a cardiac risk may not be captured in only 24 h of AECG, then the overriding clinical need is to distinguish cardiac vs. noncardiac causes for the symptoms, i.e. to correlate symptoms with disturbances in rhythm. Hence, the AECG monitor shall stand by until symptoms occur, which is the aim of the Type 3 devices. To be worn, they shall be lightweight and small; to stand by for long durations, they shall consume very little power. To achieve these design specifications, it is necessary to reduce the signal fidelity somewhat, however, not beyond that required for detection of episodes of significant rhythm disturbances such as tachy- or brady-arrhythmia, asystole, or flutter/fibrillation.

A.2 Need for the standard

AECG monitoring was first invented and developed by Norman J. Holter in 1956 (Holter 1957, 1961). Subsequently, AECGs were increasingly used in the 1960–1975 period for clinical investigations by the larger medical centers. Since then, advances in technology, especially in microcomputers, have allowed the use of AECGs to spread ever wider throughout the medical community so that they are rapidly becoming commonplace in the offices of private practitioners. For this reason, the AHA and the ACC conjointly published a precise statement of those clinical contexts in which the use of AECGs is appropriate (Knoebel *et al*., 1989). Furthermore, the AHA has published "recommendations for standards of instrumentation and practice in the use of ambulatory electrocardiography" (Sheffield *et al*., 1985). A more recent AHA publication of some relevance is on "instrumentation and practice standards for electrocardiographic monitoring in special care units" (Mirvis *et al*., 1989).

In 1974, the Food and Drug Administration (FDA) established classification panels to serve as advisory committees to the agency in determining how best to regulate cardiovascular and other medical devices—by general controls (Class I), performance standards (Class II), or premarket approval (Class III). This action was taken in anticipation of the passage of the Medical Device Amendments to the U.S. Food, Drug, and Cosmetic Act (enacted 28 May 1976).

Based on the preliminary recommendations of the Cardiovascular Device Classification Panel, the FDA initiated a contract with the Division of the University of Utah Research Institute (UBTL) to conduct a literature review and "Phase I" study and to develop what was anticipated to be a regulatory standard for electrocardiographic devices. Subsequently, UBTL and the FDA have published a series of reports reflecting UBTL's initial recommendations for addressing potential risks associated with electrocardiographic devices through the establishment of device safety and performance standards. In 1978–1979, at the request of the FDA, AAMI began to develop such voluntary standards for diagnostic ECGs and cardiac monitors; consideration of ambulatory ECGs was deferred until a later time.

In the 9 March 1979 *Federal Register*, the FDA proposed regulations that would classify electrocardiographic devices in the Class II regulatory category (performance standards). This proposed regulation was based on the final recommendations of the FDA's Cardiovascular Device, Anesthesiology Device, and General and Plastic Surgery Device Classification Panels. The following excerpt from the proposed rule summarizes the basis for the Panels' recommendations:

> The Panels recommend that establishing a performance standard for this device be high priority . . . that electrocardiographs be classified into Class II because this electrically powered device is neither life supporting nor life sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of the electrical activity of the heart, the resulting misdiagnosis could have a significant negative effect on the patient's health. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of the electrical activity of the heart, should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of the device.

These recommendations of the FDA's 1979 proposed regulations that were directed at that time toward diagnostic ECGs and cardiac monitors apply equally well to ambulatory ECGs today. In undertaking the development of a voluntary standard, the AAMI ECG Committee and its Subcommittee on Ambulatory ECGs considered the need for the standard to be well established, given these recommendations, the recommendations of the AHA and the ACC, and the relevant medical literature.

Whether an AECG is used in a clinical or research context, the outcome is critically dependent upon the quality and completeness of the data. With respect to device efficacy, this standard primarily attempts to address the clinical risks associated with misdiagnosis of a patient's condition due to faulty measurement and display of

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electrocardiographic data. This is accomplished by performance requirements for such parameters as display accuracy in amplitude and time, allowable noise, linearity, calibration accuracy, and controls and markings necessary to minimize operator error.

A.3 Definitions

No rationale is provided for clause 3.

A.4 Requirements

This section contains the rationale for each of the requirements of section 4. The paragraph numbers below correspond (except for the letter prefix) to those of section 4.

A.4.1 Device labeling

The requirements of 4.1 supplement those mandated for all medical devices by federal labeling regulations (*Code of Federal Regulations*, Title 21, Chapter 1, Subchapter H, Part 801). The additional labeling requirements provided by this standard address specialized information needed by the device user to operate ambulatory ECG devices safely and effectively.

A.4.1.1 Device markings

The requirements of 4.1.1.1 through 4.1.1.4 are intended to ensure that sufficient information is provided for device identification and traceability, that controls and switches are adequately labeled, and that the shock hazard to maintenance personnel is minimized. Reproducible performance by operating personnel is facilitated by standardized electrode connection nomenclature and colors (4.1.1.5).

A.4.1.2 Operator's manual

Certain minimum information should be included in the operator's manual supplied with the device in order to ensure that the user will be thoroughly familiar with the capabilities and functions of the device.

A.4.1.2.1 Disclosure of cautionary information/performance characteristics

a) *Cautionary information:* For operator and patient safety, cautionary information concerning potential hazards shall be provided. It is also important that the device user be informed if electromagnetic interference and/or power overload can damage the device, so that appropriate precautions can be taken.

b) *Battery-powered devices:* Information concerning device operating time and battery charge time shall be provided so that the user can effectively operate the device and rely on its performance.

c) *Accuracy of input signal reproduction:* Ambulatory monitoring technology continues to move towards ever-increasing use of digital technology. The older, purely analog technologies generally exhibited a monotonic response to out-of-band signals and thus remained essentially unperturbed by them. Digital products, however, should contend with the nonlinear phenomenon of aliasing—whereby out-of-band signals can fold back down into the pass band and produce spurious outputs. It is therefore necessary to scrutinize the response of devices between their specified upper cutoff frequency and a designated maximum test frequency. This was chosen as 10 MHz, because it is high enough to greatly exceed any reasonable ambulatory device sampling frequency and yet low enough to avoid radio frequency behavior and the concomitant need for constant impedance transmission lines during testing.

A.4.1.2.2 Applications notes

Disclosure of the operational procedures, input conditions, and recommended electrodes helps ensure that the device and electrodes are properly used and that a reasonably accurate and noise-free ECG signal will be obtained.

A.4.1.3 Physician's guide

The physician's guide is required to ensure that the physician makes effective use of AECG as recommended by AHA (Knoebel *et al*., 1989).

A.4.1.4 Service manual

The information specified in 4.1.4 enables personnel to accomplish reasonable field repair.

A.4.1.5 Summary

No rationale is provided for this section.

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A.4.2 Performance requirements

This specification was designed with certain minimum equipment in mind. The minimum equipment that would be utilized for the stationary equipment was a PC (or equivalent) and a printer that could print 150 dots per inch or more. The portable equipment (minimally) should store ECG data that would eventually be digitized at 120 samples per s (or greater) with an 8 bit (or larger) analog to digital converter (ADC). Table A.1 assumes a 5 cm grid and an 8 bit ADC (which generates approximately 5 ADC values per mm).

Table A.1—Values for each of the three gains

Gain	p-v volt	mm/mV	mV/mm	µV/mm	µV/ADC
1/2x	10 mV	5 mm	0.20 mV	200 µV	39.2 µV
1x	5 mV	10 mm	0.10 mV	100 µV	19.6 µV
2x	2.5 mV	20 mm	0.05 mV	50 µV	9.8 µV

A.4.2.1 Operating conditions

Due to its portable nature, ambulatory monitoring equipment can be subjected to a very wide range of environments. The requirements of 4.2.1 were chosen to insure reliable performance of the equipment in that wide environmental range, taking into account limitations of current technology.

A.4.2.1.1 Stationary equipment

It is assumed that playback, analysis, or other ac line-connected equipment is to be installed and operated in a hospital or office setting. The specified operating ranges encompass the conditions likely to be encountered by a device in such an environment. Many items of stationary equipment are mass-produced primarily for nonmedical use and are regulated by appropriate standards accepted by the manufacturers of AECG systems.

A.4.2.1.2 Portable equipment

Patient-worn recording or monitoring equipment could be subjected to environmental conditions that, for limited periods, can be much more severe than those normally encountered by electronic equipment in an office setting. The specified range of conditions does not encompass all conditions possible in such an uncontrolled environment; however, the range is felt to reflect those conditions that a patient will tolerate. Conditions beyond these limits will generally cause the patient to feel great discomfort and to alter the environment in which the equipment is operating.

Specified temperature ranges cover the expected extremes (e.g., from a device worn under a coat on a cold winter's day to a summer day in the desert). Vibration standards reflect those that might be typically seen while driving a car or operating other machinery. Operating shock requirements account for banging and jarring expected to be encountered in everyday life. Non-operating shock requirements should help preclude damage to the equipment if it is accidentally bumped from a table-top or desk onto the floor.

A.4.2.2 Lead definition

A.4.2.2.1 Number of leads

The requirement for a minimum of two channels is taken from AHA recommendations. It is thought that this requirement provides redundancy and a record of at least one channel in the event of a single channel malfunction. It also permits improved detection of P-wave and ST-segment shifts that may be best detected along different lead axes. Dual channel recording also permits better assessment of QRST changes that result from body position shifts, permits detection of QRS axis shifts due to transient intraventricular conduction defects, and permits distinction between ventricular ectopic and supraventricular aberrant complexes by viewing the QRS complex in more than one plane.

More ECG channels (beyond two) can in certain clinical situations yield additional clinical information.

A.4.2.2.2 Verification of electrode placement

An erroneous or defective lead attachment can render an ambulatory ECG monitoring procedure useless. Even if performed correctly, the electrode placement might not produce the desired waveforms or results due to the large number of variables involved. The requirement for the capability to verify the hookup greatly increases the chances for a successful procedure.

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A.4.2.2.3 Safe electrode lead wire connectors

Several incidents, some fatal, have been reported in recent years, arising from electrode lead wires attached to the patient having exposed male pins at the other end that may come into contact with a power source or may inadvertently be inserted into an inappropriate outlet or a detachable power cord. To ensure patient safety, the lead wire connector pins must not be permitted to contact a possibly hazardous potential, or a conductive surface that may be at ground potential, thereby compromising patient insulation. This can be achieved by recessing the pins inside a surrounding insulating shield, though the standard does not impose a specific design, which might limit innovation.

A.4.2.3 ECG input channels

A.4.2.3.1 Input dynamic range

AECG interpretations do not ordinarily involve analysis of the QRS in fine morphological detail; hence, a ± 5 mV input dynamic range and slew capability of 125 mV/s are quite sufficient. While less than the 320 mV/s slew rate specified for diagnostic ECGs and cardiac monitors, this AECG requirement does exceed the 75 mV/s recommended by the 1985 AHA Report (Sheffield *et al*. 1985).

The maximum rate of change of a sine wave equals the p-v amplitude times the frequency times Pi. A 10 mV p-v 4 Hz sine wave has a maximum rate of change of 125.66 mV/s; a 4 mV 7.5 Hz sine wave has a maximum rate of change of 94.24 mV/s. The “smooth tops” of the sine wave guarantee that no losses will be due to digital sampling and that no saturations should occur due to overshoots. Some devices may switch to special modes of operation when presented with a “nonphysiologic” continuous large sine wave signal. Use of isolated cycles as shown in figure 4 that mimic a large RS pattern at 60 “beats”/min may obviate the need to switch to a special mode of operation.

It is essential that AECG recording devices perform adequately in the presence of substantial dc offset voltages. This requirement originally arose from the need to deal with large electrode polarization voltages. The specification of ± 300 mV offset tolerance is in harmony with AHA and IEC recommendations as well as the 2.1 and 2.2 normative references.

When used in the normal mode, a ±5 mV range is beyond the capability of many, if not all, analog recorder systems on the market at this time (Shook, *et al*., 1987). Some recorders include a gain reduction switch that can double the dynamic range. This option, however, reduces the resolution of stored data and decreases the signal-to-noise ratio. There is often some risk that the recorder switch setting will not be correctly indicated to the reviewing station, with the consequence that overall system gain could be in error by a factor of two. Many times, the switch is simply not used. Because so little clinical importance is attached to the actual height of a QRS when it already exceeds ±3 mV, and because the reconstruction of small P waves and other details near the baseline is of much greater clinical importance, it is recognized that analog recorders with + 3 mV range are acceptable.

The dynamic range, slew rate capability, and offset voltage tolerances are all reduced for Type 3 devices. Multi-day surveillance and patient compliance require small size but long battery life in these devices. The relaxed requirements allow reduced circuitry and lower power drain. Built-in (matched) electrodes and modern electrode design can control offset voltages so the ± 150 mV offset tolerance is adequate. The use of a ± 2 mV p-v test signal is consistent with the limitation of the 8 bit analog to digital conversion techniques typically used in Type 3 devices.

A.4.2.3.2 Input impedance

The input impedance is primarily set by effective skin-to-electrode impedance levels over the frequency range of the ECG signal. If conventional ECG electrodes are to be used, measuring systems should have sufficiently high input impedance that practically all subjects will be measured without significant errors.

Input impedance requirements for AECGs are the same as those in ANSI/AAMI EC11—1991 and ANSI/AAMI EC13—1992, which rely upon several studies (Almasi, 1970; Berson, 1968; and Spach, 1966). Industry has been able to meet these requirements for many years. Although continued development of pregelled electrodes has resulted in even lower average impedance levels, the cited studies are still relevant for worst-case limits, as use of older style electrodes persists. The use of modern reduced impedance electrodes will decrease further the small number of subjects whose excessive electrode-to-skin impedance causes measurement error.

Skin-to-electrode impedance decreases with increasing frequency and with time after electrode application. The test method simulates the frequency-dependent drop in impedance by means of a 4.7 nF capacitor connected in parallel with a 0.62 MΩ resistor. At 10 Hz, the impedance of this combination is 609.862 KΩ. Hence, a device whose 10 Hz single-ended input impedance magnitude is 2.44 MΩ or greater will pass this test.

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A.4.2.3.3 Direct currents in patient electrode connections

This requirement is essentially the same as in ANSI/AAMI EC11—1991. Excess dc currents cause electrode polarization effects in patient electrode connections. If high enough, they can themselves pose risks to the patient. Limits of 0.1 μA in amplifier input connections and 1.0 μA in all other leads were established several years ago (see IEC 60601-2-25 and Schoenberg, 1979).

A.4.2.3.4 Common mode rejection

The particular method of specifying and measuring common mode rejection (CMR) chosen for this standard produces a worse than normal configuration of capacitance to ground in relation to capacitance to patient from the AECG monitor. The CMR requirement of 60 dB at line frequency is fairly conservative. In actual use where the dominant capacitance is that between the AECG monitor and the patient, significantly higher CMR performance can be expected. The line frequency harmonic measurements are included because of power line waveform distortion that can occur because of discontinuous loads from items such as SCR controllers and electronic equipment power supplies with capacitor input filters.

The AECG monitor is encapsulated in earth-grounded foil in order to define and stabilize the capacitance of the AECG monitor to earth ground. The input test components and the patient cable are guarded by the driven shield that eliminates the effect of stray capacitance to earth ground from those components. Furthermore, the entire test setup is enclosed in an earth-referenced shield in order to stabilize the Cx stray capacitance.

The only remaining variable that will influence the test is the physical design of the particular AECG monitor, which fixes the size of the AECG monitor and also sets the spacing between the internal circuitry and the external foil wrap (i.e. the thickness of the insulated case). The higher the resulting capacitance of the AECG monitor to the foil wrap, the greater the difficulty in meeting the requirements set forth with this particular test methodology. On the other hand, the guarding of the input test components and patient cable reduces the difficulty in meeting this performance specification.

A.4.2.4 Risk currents

The rationale for protecting the patient from hazardous electrical shock is well covered in other documents. This has not been an issue in the past, as no electrical connection exists between the analog tape recorder and the playback scanner.

Evolving forms of digital recorders routinely, however, connect to a line-powered device for setup control, data transfer, and/or results printing. These line-powered computers and printers come from the commercial market where power isolation is not required. Therefore, these systems should provide hazard protection to the patient.

The requirement is further extended to those devices that do not physically preclude simultaneous connection to the patient and line because if the capability exists, it will happen.

A.4.2.5 Overload protection

A.4.2.5.1 AC voltage

The recommendations of the draft International Electrotechnical Commission (IEC) standard for electrocardiographs were adopted. The 1 volt p-v differential signal represents a noise level approximately 100 times the maximum signal. The need for such a test derives from the possibility that the AECG recorder input leads may inadvertently be exposed to power line currents from other devices.

A.4.2.5.2 Defibrillator energy shunting

If a patient wearing an AECG recorder needs to be defibrillated, it is recommended that the AECG electrodes be removed before the defibrillator is used. If the operator fails to remove the AECG electrodes and proceeds to defibrillate the patient, however, the AECG recorder and its electrodes should be so designed that defibrillation is not impaired by the presence of the AECG.

The American National Standard, *Cardiac Defibrillator Devices* (ANSI/AAMI DF2) specifies a maximum selectable deliverable energy in the range of 250 to 360 joules (J). The energy and voltages that the AECG recorder sees as a result of a defibrillator discharge are dependent on the relative resistances of the human torso for the defibrillation path and the AECG recording paths, the placement of the defibrillator paddles relative to the AECG electrodes, the skin-to-electrode resistances, and the effective impedance of the AECG recorder. The equivalent circuit is shown in figure 6 where the defibrillator is simulated by a capacitor (C) charged to a voltage (V), and the stored energy (E) is given by $E = 1/2\ CV^2$.

For example, a capacitor of 32 μF charged to 5000 V will have a total stored energy of 400 J. This value has been proposed by the IEC as a worst-case value for purposes of defining a defibrillator overload circuit. Using a total

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series resistance of 11 ohms (as indicated in figure 6), 360 J will be delivered into the test load, which corresponds to the maximum allowed by the defibrillator standard.

The human torso and defibrillator paddle/skin resistance, under high energy discharge, varies over a wide range, with a mean of 67 ohms and standard deviation of 36 ohms (i.e. mean ± 1 std = 103 ohms) according to a recent study by Kerber, *et al*. The 100 ohm resistance specified in this standard fairly represents the worst-case voltage and power duration to which the AECG recorder would be exposed. The skin-to-skin electrode impedance (Rs) and the internal net impedance of the AECG recorder under defibrillator overload (R1) are highly variable.

The AECG recorder should not significantly shunt defibrillation currents from the patient. An excessive shunt may result in reduced efficacy of defibrillation, in burning of the patient at the electrode sites, and in reduced likelihood that the electrodes will continue sensing the ECG accurately. These problems are minimized by allowing the AECG recorder to absorb no more than 10% of the energy intended for delivery to the patient.

A.4.2.6 Gain control, accuracy, and stability

A.4.2.6.1 Gain accuracy

The reference gain setting of 10 mm/mV reflects a well-established convention (see EC11 and EC13 and the AHA Recommendation [Sheffield, 1985]). Additional settings of 5 mm/mV and 20 mm/mV are required in EC11 and the 1985 AHA Recommendation, but not in EC13, and are not needed to guarantee safety and efficacy. The system output at all available gain settings, however, should be guaranteed to be reasonably close to that of an “ideal” system.

A.4.2.6.2 Gain stability

In order to guarantee consistent interpretation, gain stability is especially important in ambulatory monitoring equipment where the typical monitoring period is 24 h or more. Changes in the ECG signal that do not stem from physiological or pathophysiological changes should be minimized. The limits specified here represent a consensus on achievable levels established in practice.

A.4.2.6.3 Amplitude calibration

The standardizing voltage ensures the ability of an analog tape system to reproduce a signal relative to an absolute reference. This ability is critical to the accurate measurement of ST segment levels, where a 1 millivolt shift can indicate the difference between normal and ischemic repolarization. ST segment analysis has been a major application of visual superposition systems and is becoming increasingly implemented in more automated digital AECG systems.

Analog media are inherently more susceptible to gain variances than digital media. Thus, analog systems employing removable media conventionally use calibration pulses to adjust playback amplifier gain, thereby assuring needed overall system gain accuracy. The limit of 5% error represents a reasonable standard for performance.

A.4.2.7 Accuracy of input signal reproduction

A.4.2.7.1 System noise

Noise in electrocardiographic records is one of the most persistent detriments to a clean, diagnosable signal. This problem, however, can generally be traced to external interferences (EMI), patient movement (myographic signals), or poor technique in electrode application or routing of cables. Most manufacturers provide guidelines for correct techniques in measuring ECG. Shielded cables, as well as high-input impedance and common mode rejection alleviate some of the noise problems. The “driven right leg,” which helps cancel the common mode noise from the signal sensed at the electrodes, further reduces the noise.

Compared to the 1994 edition of this standard, this test method was changed to harmonize with the most recent draft of IEC 60601-2-47. The allowable noise level is established in harmony with the 1994 edition of this standard by observing that a 25 µVrms level measured from a Gaussian distributed random noise signal equates to a p-v measure of 100 µV. Plus and minus 1.96 standard deviations contains 95% of the distribution.

A.4.2.7.2 Multichannel crosstalk

The maximum level of crosstalk is determined by the requirements of accurate diagnosis and the incremental costs of noise suppression. This specification is based on EC11:1991. The level specified is quite sufficient for diagnostic purposes and is economically feasible in practice.

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A.4.2.7.3 Frequency response

Complete specification of frequency response should address phase distortion, which is most critical for low-frequency response. The impulse response requirement tests this capability with a relatively easy-to-apply procedure. Tests at higher frequencies are not proposed, because measuring phase shift for frequencies above 25 Hz would be difficult at best at the required time base of 25 mm/s; at 40 Hz, an accurate measure would require a time base of 400 mm/s.

Historically, the phase response of a 1 pole 0.05 Hz high pass filter has been considered acceptable. The baseline offset allowed following the impulse represents the droop that can be expected from a 0.05 Hz filter. The slope requirement of 0.30 mV/s translates at standard gain and speed to a change of 0.3 mm across a typical ST interval of 100 ms and would not be clinically significant, particularly as a typical QRS complex has an impulse value closer to 0.1 mV/s (cf. 0.3 mV/s).

The high-frequency response limit of 40 Hz for Type 1 and Type 2 devices is based on two considerations. First, the primary purpose of the ambulatory ECG (which is [a] to identify rhythms and [b] to reveal displacements of the ST segment necessary to identify ischemic episodes) can be adequately accomplished without a higher frequency response. Second, the persistent problem of high-frequency noise from power line frequencies and from muscle artifact can be reduced with a 40 Hz bandwidth. The high-frequency response limit of 30 Hz for Type 3 devices is consistent with the primary purpose of event monitoring to capture infrequent episodes of arrhythmia. For Type 3 devices, an extended bandwidth provides little (if any) increase in pertinent information, at the expense of complexity and battery life.

This standard proposes test methods to evaluate both the frequency response and the ability of the ambulatory ECG device to deal with ECG-like signals such as a triangular wave simulating the R wave. Allowing a 40% reduction in the peak value of the triangular input signal corresponds to the expected reduction due to a digital sampling system that stores one 24 h channel in about 10 million samples. The impulse response test is also employed to simulate R wave and to readily observe whether the monitor produces baseline changes following the impulse that, with real ECG input signal, might result in artifactual displacements of the ST segment and lead to false interpretations regarding the presence of ischemia.

The low-frequency response of 0.67 Hz is based upon heart rate data from the Framingham Heart Study and Simonson's studies. These studies indicate that 44 bpm encompass more than 99% of adult heart rates with intra-individual RR interval variation of less than 126 ms. Thus, a lower bound of 40 bpm (0.67 Hz) exists for 99% of adults, 90% of the time. Bailey *et al*. used these data to justify the 0.67 Hz low-frequency bound in the 1990 AHA recommendations.

A.4.2.7.4 Hysteresis and minimum feature size

Hysteresis is a phenomenon that occurs in most amplifying systems. It is usually more significant in systems having mechanical components. For ECG instruments in which resolution of 50 μV is expected, the error caused by hysteresis shall not exceed the resolution. Well-designed instruments can achieve this level of performance. Responses to small 30 μV signals increase the likelihood that low-amplitude P waves, often diagnostically important, can be discerned.

A.4.2.7.5 Overall system error

Because the overall system error represents the accumulation of all noises and inaccuracies in the system, a constraint of 20% actually requires many individual parts of the instrument to be fairly accurate and noise-free.

A.4.2.7.6 Special considerations for high-speed superimposition display

Visual Superimposition Scanning (VSS) can be utilized in at least two different ways. It can be used to review a contiguous sequence of QRS complexes (from a few minutes to many h) to search manually for arrhythmias (especially atrial arrhythmias) either not detected or not correctly identified by the automated analysis. It can also be used to identify displacements of ST segments (Holter, 1957). Additionally, it can be used to verify that all members of a select data subset, obtained during automated analysis of the data, are authentic members of this subset. A common example of such usage is VSS of members of a QRS form family.

a) Frequently, two different channels are needed to discriminate between normal and abnormal beats. A major benefit of VSS display is the ability to survey atrial and atrial ventricular activity. As the vectors of atrial depolarization are directed differently from those of ventricular depolarization, two channels become necessary to capture both atrial and ventricular activities. Furthermore, displacements of ST segments may be apparent in only one of the two leads.

b) Due to the variation in sizes of CRT displays that are commonly available and the ease of interchanging one CRT for another, it is not practical to require that a standard size signal be displayed on all displays.

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c) While systems may allow scanning speeds below 60 times real time, for normal usage it is believed to be too slow and cumbersome and is not recommended. Speeds greater than 240 times real time are not recommended for manual arrhythmia searches due to the short time the data are displayed; however, speeds greater than 240 times real time are very useful in verification of the members of a specific subset.

d) The need to observe the usually fine details of atrial activity requires signal quality to be as good as elsewhere in the system.

e) Periods of artifact and abnormal events are frequently correlated. as both are elicited during patient activity.

A.4.2.7.7 Baseline stability

The 10 μV/s requirement essentially allows less than 100 μV drift in a typical 10 s strip output. Such a drift would not produce any misinterpretation of the ECG due to measurement errors. A 60 s period is considered to represent a typical duration of a single ECG line across a full disclosure printout where drift of subsequent lines over each other can make interpretation difficult. The total drift rate of 1 mV ensures that the baseline will remain fairly close to the center of the output display over long periods of time without constant operator adjustment.

Due to the short and discontinuous recording periods of Type 3 devices, long-term baseline stability is not an issue.

A.4.2.7.8 Pacemaker pulse tolerance and display capability

Patients having high amplitude pacemaker pulse amplitudes at the body surface are prevalent in the population receiving AECGs for diagnostic purposes. For this reason, the ECG recorded by AECG devices, other than those whose manufacturers state that they are not inherently suitable for use with patients having implanted pacemakers, should not be unduly distorted by the presence of the pacemaker pulse signal.

Although pacemaker pulse amplitudes (on the skin surface) as great as 700 mV have been reported, the flexibility of electrode placement in AECG recording allows clinically relevant ECG signals to be obtained while avoiding pacemaker pulse amplitudes greater than 250 mV.

For an AECG device to be suitable for use in analyzing pacemaker function, it must be capable of displaying an indication of the occurrence of each pacemaker pulse. These pulses can range in amplitude from the large pulses (as large as 700 mV as noted above) characteristic of unipolar pacemakers to the low amplitude pulses characteristic of bipolar pacemakers. As far as the capability to display an indication of the pacemaker pulse is concerned, the challenge is not with the high amplitude pulses, but with the very small pulses. It is generally agreed that the ability to display an indication of a pacemaker pulse having an energy content as low as a pulse 2 mV in amplitude and only 0.5 ms wide shows a sufficient sensitivity for the purpose of analyzing pacemaker function.

A.4.2.7.9 Special infant requirements

For infants weighing less than 10 Kg (22 lb), i.e. neonates and small infants, the higher frequencies in the ECG signal resulting from high, narrow QRS waveforms and higher average heart rates require a higher frequency response as specified in 4.2.7.9.

A.4.2.7.10 Patient event marks

No additional rationale is provided for this subclause.

A.4.2.8 Time base selection, accuracy, and stability

A.4.2.8.1 Timing accuracy

The correlation of the occurrence time of an external event (e.g., drug administration, presence of symptoms, physical activity) and the patient's ECG complexes is essential to clinical interpretation. As the recorded ECG is reviewed retrospectively, the recording device and system should provide a mechanism for accurately indicating the actual occurrence time along with the ECG signals on both the display and printout.

Independent indication of the time of day and time markers is necessary (rather than extrapolating this information from the ECG time base), given the length of time the ECG is recorded. Time marker ouput to displays and printouts should be sufficiently frequent to facilitate review of the ECG.

The cumulative accuracy requirement of ± 60 s over 24 h ensures that the difference between the actual occurrence time and the recorded occurrence time is sufficiently small to allow clinical correlation and interpretation of the concomitant ECG complexes. Greater long-term accuracy is desirable and is attainable with crystal-controlled timebases.

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A.4.2.8.2 Hard copy time base

The accuracy of the time base is important in establishing many diagnostic parameters related to time, such as PR, QRS, QT, and RR intervals. It seems reasonable to require that instrument-induced errors be kept below 5% for critical time interval measurements within a single cardiac cycle. Errors greater than this can lead to false clinical interpretations, such as presence of a conduction defect for long QRS duration. On the other hand, longer time intervals such as RR or QT intervals may not require this accuracy. A time base error of ± 5% (or ± 10 ms, whichever is greater) is intended to limit measurement inaccuracies. This error value corresponds to a displayed error of ± 0.25 mm (at a scale of 25 mm/s). This value should be sufficient for short interval measurements such as QRS interval.

Greater accuracy is desirable but would be very difficult to measure and to maintain over all environmental conditions.

A.4.2.8.3 Hard copy grid standard

A rectilinear coordinate grid with a time axis of 25 mm/s and a voltage axis of 10 mm/mV has been traditional in electrocardiography. Accentuation of every fifth ruling simplifies time and voltage measurements. The grid pattern can be preprinted on the output paper or it may be printed by the same printing mechanism used to print the ECG (e.g., a laser printer).

The specification of a maximum ± 2% error provides sufficient accuracy for clinical measurements and is attainable. Changes in humidity will result in expansion and contraction of the paper fibers. Both measurement error and humidity are accounted for in the tolerance specification of ± 2%.

A.4.2.8.4 Full disclosure (miniature displays)

A full-disclosure display of the entire ECG record provides the physician with a means to scan the entire record as an aid in the physician's evaluation. The minimum scale factors of 2.5 mm/s and 1 mm/mV reduce the printout record size while providing a clinically useful display of the ECG. Indications of the actual time of day, of the patient identity, and of any lapses in the ECG signal acquisition are necessary to form a complete account of the procedure. As patient event indications may provide clinical information, it is desirable that these also be indicated on the full-disclosure report.

A.4.2.8.5 Gain settings and switching

Variations in the recorded amplitude of a patient's ECG (due to physiological factors or lead placement) warrant the selection of different scale factors. A nominal scaling factor of 10 mm/mV traditionally has been used. The additional gain settings of 5 mm/mV and 20 mm/mV conform to both IEC and AHA recommendations. Other gain settings (e.g., 40 mm/mV and 2.5 mm/mV) may be provided at the option of the manufacturer. Continuous gain control is generally not desirable.

Inclusion of the ECG calibration pulse in the display provides the operator with a means of verification of the reproduced ECG amplitude.

A.4.2.9 Temporal alignment

Clinical evaluation of the ECG record requires viewing the ECG complex in different planes. Certain features, such as pacemaker pulses, are sometimes only discernible in one plane. Concurrent analysis of two (or more) ECG channels requires that the channel-to-channel skew be sufficiently small so as not to influence the clinical interpretation of the ECG. The skew error of ± 0.5 mm corresponds to a maximum temporal skew of ± 20 ms (at a scale of 25 mm/s). This tolerance accounts for practical measurement errors and also for variations in the recording and playback devices due to alignment of magnetic recording heads, due to tape tracking, and/or due to analog-to-digital conversion skew.

A.4.2.10 Electromagnetic compatibility

With the proliferation of digital and computer-based instruments operating in close proximity in the hospital, there are instances where one instrument emits radiation that interferes with the performance of another instrument. Also, an AECG patient recorder is expected to perform well in a variety of locations and environments and may be exposed to strong external electromagnetic (EM) fields. For these reasons, it is imperative to address the problem of electromagnetic compatibility (EMC) in ample detail so that compliance with EMC emission and immunity standards will minimize detrimental interference between instruments and will minimize the occurrence of incidents in which a particularly severe EM environment degrades instrument performance.

This standard addresses complementary issues:

a) emission, i.e. the intensity and characteristics of EM radiation emitted or conducted by the operating device; and

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b) immunity, i.e. the ability of the instrument to perform satisfactorily while exposed to external EM radiation.

A.4.2.10.1 Electromagnetic emissions

This standard sets maximum levels for EM emissions and defines the levels of external radiation that the instrument shall tolerate while still performing satisfactorily. The characterization of the external EM environment, and particularly the frequency ranges over which immunity is tested, is based on the IEC 60601-1-2 standard, the EN 61000-4 series, and the CISPR 11, which are accepted generally for EMC purposes and are referenced in section 2 of this standard.

The IEC Collateral Standard 60601-1-2 on EMC in medical devices recognizes that measurement and control of EMC is much more difficult for patient-coupled devices where the patient cables act as antennae for both emission and reception of EM signals, with an antenna gain that depends upon the layout of the cables. Therefore, the general standard makes allowance for this situation by providing limited exemptions from the immunity requirements on the condition that the reduced immunity levels be measured and disclosed. This clause of the general EMC standard has been specifically extended to the present AECG standard.

Tests for magnetic emissions are intentionally omitted from this standard. Magnetic emission requirements were felt by the committee to be most appropriately applied only to the ambulatory portion, if at all, and dc or low frequency fields from speakers and recording heads were specifically exempted. Any magnetic field leakage from recording heads should be limited by magnetic shielding of those heads. If their shielding is inadequate, the ambulatory portion will fail its noise specification during magnetic susceptibility testing. Furthermore, magnetic fields likely emitted by the ambulatory portion were felt to be far too weak to activate the “magnet mode” of an implanted pacemaker. Stationary equipment is likely to have the stronger magnetic emissions of the various AECG system portions due to a 50/60 Hz power transformer, magnetically deflected CRT display, etc. However, stationary equipment can reasonably be located away from susceptible devices and is furthermore not allowed to corrupt itself.

When addressing the general problem of EM immunity, it is important to specify the intensity of external EM fields that are tolerated by the instrument or that produce specified degrees of degradation. This can be done reasonably well for electrical circuitry and displays. The main function of an AECG recorder, however, is to record several channels of ECG and, in some cases, also to analyze the ECG in order to detect disturbances in rhythm or displacements of the ST segment. Strong external EM fields or electrostatic discharges can inject noise and artifacts into the ECG record, resulting in erroneous analyses. Therefore the requirements for EM immunity shall consider not only electrical circuitry but also ECG recording distortion and ECG analysis accuracy. Unfortunately, an endless variety of external EM fields may be encountered that inject noise and artifacts into the ECG record; hence, it may not be possible to correlate ECG analysis immunity with defined levels of EM fields. So the degree of distortion of the ECG record and degradation of analysis produced by various EM fields cannot be directly determined at this time. Important inferences, however, can be made from 4.2.14 and 5.2.14, which treat computer-aided ECG analysis and specify tests with databases (such as the special MIT-NST database) that contain progressively higher levels of noise in the ECG records and allow noise-induced degradation of the ECG analysis to be measured and reported.

A.4.2.10.2 Electromagnetic immunity

There has been some degree of iteration in settling on the range of test frequencies to be used by the referenced standards. A compromise was reached whereby the lower frequencies of RF susceptibility are checked by conducting the RF into the device on its cables (arguably the most common coupling method in actual situations for these frequencies), while the higher frequency susceptibilities are tested by radiated RF.

In the interest of minimizing the time and expense of EMC testing, it is considered practical to do all RF susceptibility testing using a single modulation frequency (such as 2 Hz or 10 Hz) that falls within the passband of the ECG channel. This single modulation frequency should suffice to show any susceptibilities.

Patient data being transferred to and/or stored in stationary equipment are subject to possible loss or corruption during transients, surges, or dips in the line voltage that operates the stationary equipment. It is desirable to prevent such data loss or corruption by the design of the stationary equipment, if such corruption places the patient at risk.

Until recently, “off-the-shelf” information technology equipment, such as personal computers, have not been required to meet power line immunity requirements like transients, surges, and sags. When the stationary equipment is used for medical purposes or as part of a medical system, however, it falls under the Medical Device Directive, even if it is off-the-shelf equipment.

The IEC 950 reference in 4.2.1.1 is limited to safety requirements only. Inclusion of EN 50082-1:1997 establishes the line immunity compliance requirements for products that have no dedicated product or dedicated product-family immunity standards. Parts A and B of ANSI/AAMI EC38, subclause 4.2.10.2.5, correspond directly to table entries 4.2 and 4.3 respectively of EN 50082-1:1997. Part C of this ANSI/AAMI EC38, subclause 4.2.10.2.5, requires the AECG manufacturer to disclose performance behavior for the disturbances for which EN 50082-1:1997, table entries

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4.3 and 4.4, list specific compliance requirements. Note that EN 50082-1:1992 (its previous edition) has a counterpart for part A of ANSI/AAMI EC38, subclause 4.2.10.2.5, but not for parts B and C, so the date is significant.

The committee recognizes that large numbers of existing AECG systems are currently in use that do not meet the requirements of this section. It was felt that allowing off-the-shelf personal computers that possessed a CE mark would be a reasonable compromise. New PC designs (after January 1998) are required to pass the relevant portions of EN 50082-1:1997 prior to obtaining the CE mark. It was also noted that the PC industry was changing so rapidly that, by the time this document became a standard, it would be unlikely that newly designed PCs would not pass the tests of EN 50082-1:1997.

Regarding the choice of magnetic field strength to be tolerated, the committees for the referenced standards debated whether Level 2 at 3 V/M or Level 3 at 10 V/M should be the requirement. (A draft of IEC 60601-2-47 considered making the requirement as high as 80 V/M.) Listed in EN 61000-4-8 are survey field strength measurements in various environments. For example, at 0.3 M distances, 95% of fields in the home are under 10 V/M. In the home, however, separation distances may well be less than 0.3 M. Major portions of acquired data can be corrupted by magnetic fields without the technician realizing it at the time, so requiring Level 3 magnetic immunity (though not harmonized with IEC 60601-1-2) seems a reasonable compromise. It seems inappropriate to burden all AECG manufacturers with the design task of meeting higher than Level 3 (and to burden patients with the passed-along costs) for such special conditions. Devices should carry instructions that warn of signal impairment when used in power substations and near power distribution equipment in industrial plants where field strengths may be excessive.

A.4.2.11 Auxiliary output

In general, the type of device connected dictates the auxiliary output requirements. While it is not necessary to enumerate detailed requirements for auxiliary output, safety and efficacy require that a short-circuited output not damage the instrument and that risk currents are acceptable when auxiliary devices are properly connected.

A.4.2.12 Monitoring time and battery capacity

The minimal time for AECG recording varies with the indication for the test. Events that occur frequently could be detected with short recording periods, whereas those that occur less frequently or rarely may require prolonged recording. For most clinical uses, a minimum recording period of 24 consecutive hours is recommended. This time span permits detection of most episodes of intermittent arrhythmias during waking and sleeping phases with recognition of temporal variability in frequency while providing adequate leeway for intermittent recorder malfunction.

Symptoms of battery depletion in a recorder may vary depending on the recording media employed. Gain reduction is a common symptom in analog tape recorders. In nonvolatile memory recorders, battery failure will appear as an out-of-tolerance power supply and may have unpredictable consequences. In moving media recorders, battery failure will appear as a slowing of the drive motor. When processed in reproducers without servo locks, this can appear as a contraction of the time scale, i.e. a rate speed-up, which can appear earlier and be more serious than a loss of gain. At a minimum, gain should remain within useable limits, and reproduced rates should remain within useable limits.

A.4.2.13 Special requirements for intermittent event recorders (patient- or event-activated)

An intermittent event recorder is expected to contain less recording memory than a continuous event recorder. Unless all available recording memory is filled, an intermittent event recorder should be functional throughout the entire minimum operating period as specified by the manufacturer. Ideally, a looping memory recorder should employ sufficient running memory to capture the onset of cardiac events prior to the occurrence of symptoms. If non-looping recorders are activated only after symptoms appear, the onset of cardiac events cannot be captured. There is no general consensus on the minimum required length of pre- and post-trigger event storage (windows). Disclosure of window characteristics will allow comparisons between different devices.

Each intermittent event recorder has a specified minimum operating period, the length of which is a major feature characterizing that device. Longer operating periods offer distinct clinical advantages. Testing this period requires operation of the recorder for the entire specified duration. As operating periods often exceed 6 months, a full running test of that period will impose a significant delay. As the purpose of this standard is not to exacerbate testing difficulties in the introduction of clinical improvements, an alternative test is offered when the specified operating period exceeds 2 weeks. Manufacturers may substitute worst-case depleted batteries for new fully charged ones, provided that they later back up that substitution by a full operating period test using fresh and undepleted batteries and that they retain the test data on file.

A.4.2.14 Automated analysis

A credible evaluation shall be reproducible. For this reason, evaluations of these devices shall be performed without human intervention, i.e. a strictly reproducible “hands-off” evaluation is required. (With human intervention allowed,

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perfect results are achievable in principle for any device that provides “full-disclosure” output. Thus, evaluations that allow human intervention measure only the persistence and expertise of the operator and are of no value in assessing the performance of the device. For this reason, such evaluations are neither required nor encouraged.)

AECG systems are often designed to provide optimal performance when used with a skilled technician who interacts with the program. Specifications for complete evaluation techniques for AECG scanning systems are outside the scope of this document.

Full disclosure of the procedure for generating annotation files enables an independent (third-party) evaluator to use the procedure, thereby permitting verification of test results when the same test data are used. It also permits the use of additional test data of the evaluator’s choice as such data become available.

The evaluation methodology of 5.2.14 requires the combination of the device with its interface. In principle, the interface might include significant analytical components when processing the outputs of the device, thereby “improving” its apparent performance. Full disclosure will provide a disincentive for having the interface do anything other than straightforward translations of the device’s normal outputs into standard annotation files.

A.4.2.14.1 Use of standard databases

As performance is highly dependent on the characteristics of the particular ECGs that are analyzed, evaluations shall be performed using standard recordings so that the results will have value for purposes of comparison among devices or against a performance standard.

The exclusion of records with paced beats is permitted only for devices that are not designed to analyze paced analog ECG recordings made without pacer artifact detection or enhancement on the grounds that the original analog tapes do not reproduce pacemaker artifacts with sufficient fidelity to permit use of common techniques for recognition of these artifacts in “live” signals. The digital databases reproduce the analog tapes with sufficient fidelity, however, to permit use of techniques used for recognition of pacemaker artifacts by devices designed to analyze analog AECG tapes.

Most devices need a certain amount of time to learn the underlying rhythm. For this reason, a 5 min learning period is allocated at the beginning of each record and is excluded from calculated performance statistics. If the long version of the AHA DB (containing 2.5 h of non-annotated signals per record immediately preceding the 30 min test periods) is used, only the final 35 min of each record (equivalent to the standard version) may be presented to the device under test.

Type 3 devices, which may include event recorders, are usually within reach of the patient but do not actively monitor for extended periods of time. Such devices do not have a minimum monitoring time.

Well-defined QRS complexes necessary for a beat-by-beat comparison are not present during VF segments, which are marked by rhythm labels in the reference annotation files and excluded from beat-by-beat comparisons. On the other hand, these segments are included in tests of consecutive VEB and SVEB detection and VF detection.

A.4.2.14.2 Testing requirements

The incidence and variety of arrhythmias and ectopic beats in the 90 records of the ESC DB are insufficient to allow that database to serve as a substitute for the AHA and MIT databases for the purposes of assessing QRS detection and classification performance. An evaluation using the 90 records of the ESC DB and the same beat-by-beat and run-by-run comparison protocols, however, may supplement the required AHA and MIT database evaluation. Such a test may be particularly useful for assessing the robustness of QRS detection and classification performance in the presence of ST-segment and T-wave changes.

The incidence and variety of VF in the AHA and MIT databases are not sufficient to allow those databases to serve as substitutes for the CU DB for the purposes of 5.2.14.5. An evaluation of VF detection using the 80 records of the AHA DB and the 48 records of the MIT DB should supplement the required CU DB evaluation, however, as the CU DB does not contain a sufficient sample of signals likely to provoke false VF detections.

A.4.2.14.3 Requirements for the system evaluation report

There are four possible outcomes of an experiment in which a detector is presented with an input that is either an event or a nonevent. A correctly detected event is called a true positive (TP); an erroneously rejected (missed) event is called a false negative (FN); an erroneously detected nonevent is called a false positive (FP); and a correctly rejected nonevent is called a true negative (TN). In many detection problems, nonevents cannot be counted, so that the number of true negatives is undefined. In such problems, the commonly used detector performance measures are sensitivity (Se, the fraction of events that are detected) and positive predictivity (+P, the fraction of detections that are events):

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$$Se = \frac{TP}{TP + FN} + P = \frac{TP}{TP + FP}$$

It is useful, particularly when the total number of events is small, to define aggregate statistics, which describe the performance of a detector on an entire database as a whole. Two types of aggregate statistics are commonly used: gross statistics, in which each event or detection is given equal weight, and average statistics, in which each record (subject) is given equal weight. If the incidences of events and detections were equal in all subjects, these statistics would be equivalent.

When considering detection statistics for persistent events (such as episodes of fibrillation or ischemic ST), it is of interest to know how many episodes are detected as well as the total duration of the detected episodes. Episode statistics give equal weight to each episode, irrespective of length. Duration statistics give weight to each episode or detection in proportion to its duration.

Thus, episode statistics for persistent events are very roughly analogous to average statistics for discrete events, and duration statistics are similarly analogous to gross statistics.

QRS sensitivity and positive predictivity: The results of beat-by-beat comparisons can be used to derive QRS sensitivity and positive predictivity:

$$\begin{aligned} QTP = {} & Nn + Ns + Nv + Nf + Nq + \\ & Sn + Ss + Sv + Sf + Sq + \\ & Vn + Vs + Vv + Vf + Vq + \\ & Fn + Fs + Fv + Ff + Fq + \\ & Qn + Qs + Qv + Qf + Qq \end{aligned}$$

$$\begin{aligned} QFN = {} & No + Nx + \\ & So + Sx + \\ & Vo + Vx + \\ & Fo + Fx \\ & Qo + Qx \end{aligned}$$

$$\begin{aligned} QFP = {} & On + Os + Ov + Of + Oq + \\ & Xn + Xs + Xv + Qf + Xq \end{aligned}$$

$$QRS\ Se = \frac{QTP}{QTP + QFN} \qquad QRS + P = \frac{QTP}{QTP + QFP}$$

VEB and SVEB sensitivity and positive predictivity: The results of beat-by-beat comparisons can be used to derive VEB sensitivity and positive predictivity:

$$VTP = Vv \qquad VFN = Vn + Vs + Vf + Vq + Vo + Vx$$

$$VFP = Nv + Sv + Ov + Xv$$

$$VEB\ Se = \frac{VTP}{VTP + VFN} \qquad VEB + P = \frac{VTP}{VTP + VFP}$$

Note that VTP and VFP do not include Fv or Qv; thus, a detector is neither penalized nor rewarded for its treatment of ventricular fusion beats and ambiguous beats.

SVEB sensitivity and positive predictivity are similarly defined:

$$SVTP = Ss \qquad SVFN = Sn + Sv + Sf + Sq + So + Sx$$

$$SVFP = Ns + Vs + Fs + Os + Xs$$

$$SVEB\ Se = \frac{SVTP}{SVTP + SVFN} \qquad SVEB + P = \frac{SVTP}{SVTP + SVFP}$$

Again, note that Qs is excluded from SVTP and SVFP, so that a detector's treatment of ambiguous beats does not influence its measured SVEB detection performance.

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Couplet and run sensitivity and positive predictivity: The results of run-by-run comparisons can be used to derive VE couplet and run sensitivity and positive predictivity:

$$CTPs = S22 + S23 + S24 + S25 + S26 \qquad CFN = S20 + S21$$
$$CTPp = P22 + P32 + P42 + P52 + P62 \qquad CFP = P02 + P12$$

$$\text{VE Couplet Se} = \frac{CTPs}{CTPs + CFN} \qquad \text{VE Couplet} + P + \frac{CTPp}{CTPp + CFP}$$

$$STPs = S33 + S34 + S35 + S36 + S43 + S44 + S45 + S46 + S53 + S54 + S55 + S56$$

$$SFN = S30 + S31 + S32 + S40 + S41 + S42 + S50 + S51 + S52$$

$$STPp = P33 + P43 + P53 + P63 + P34 + P44 + P54 + P64 + P35 + P45 + P55 + P65$$

$$SFP = P03 + P13 + P23 + P04 + P14 + P24 + P05 + P15 + P25$$

$$\text{VE Short Run Se} = \frac{STPs}{STPs + SFN} \qquad \text{VE Short Run} + P = \frac{STPp}{STPp + SFP}$$

$$LTPs = S66 \qquad LFN = S60 + S61 + S62 + S63 + S64 + S65$$
$$LTPp = P66 \qquad LFP = P06 + P16 + P26 + P36 + P46 + P56$$

$$\text{VE Long Run Se} = \frac{LTPs}{LTPs + LFN} \qquad \text{VE Long Run} + P = \frac{LTPp}{LTPp + LFP}$$

SVE couplet and run statistics are similarly derived.

VF and AF detection:

From the counts of true positives, false negatives, and false positives derived according to the methods of section 5.2.14.5, VF and AF episode sensitivity and positive predictivity are derived in the usual way.

The VF duration sensitivity and positive predictivity are calculated as:

$$\text{VF duration Se} = \frac{\text{duration of overlap}}{\text{duration of reference-annotated VF}}$$

$$\text{VF duration} + P = \frac{\text{duration of overlap}}{\text{duration of algorithm-annotated VF}}$$

The AF duration sensitivity and positive predictivity are calculated in a similar way.

ST segment measurement and ischemic ST detection:

Although the device's measurements may not necessarily be updated beat-by-beat, the requirement for an annotation file containing beat-by-beat measurements facilitates comparisons of measurements at arbitrary times, as required by the first part of the evaluation protocol described in 5.2.14.6.

Detection of ischemic ST changes is complicated by the presence of nonischemic ST deviations, often caused by position-related changes in the cardiac electrical axis. These axis shifts may cause significant shifts in the ST level, hence false detections of ischemic ST changes.

Although differentiating between ischemic and nonischemic ST changes is not an easy task for either human experts or automated analyzers, the clinical importance of making such distinctions is so great that the effort should be made. Because non-ischemic ST changes have been differentiated from ischemic ST episodes in the reference annotation files of the ESC DB, it is possible to define performance measures for detection of ischemic ST episodes; these are emphasized in this protocol over less stringent and less clinically relevant tests of an analyzer's ability to detect ST changes without making this important distinction.

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Considering the difficulty of accurate automated analysis, however, it should be permissible for the system to suggest physician validation by printing statements such as “ST segment change—consider ischemia” or “ST segment change—probably nonischemic.”

ST deviation measurement:

The purpose of the episode-by-episode report is to permit an independent reviewer to identify the types of waveforms that may cause difficulty for a given ST deviation measurement algorithm. The purpose of the scatter plot is to summarize the contents of the episode-by-episode report in a manner that allows rapid visual assessment of any systematic measurement bias, nonlinearity, or domain of unreliable performance that may be exhibited by an ST deviation measurement algorithm.

Summary statistics such as correlation coefficient or rms error may be ill-suited to the task of describing the accuracy of ST deviation measurements, as they are highly sensitive to outliers and do not distinguish between systematic errors (resulting from bias or nonlinearity) and nonsystematic errors (resulting from poor noise tolerance or unreliable measurement techniques). A slightly better statistic (because it is robust in the presence of outliers) may be a confidence limit estimate (for example, the value of error which 95% of the measurements do not exceed). The percentage of discrepant ST measurements specified in 4.2.14.3.1 is another example of a robust estimator. This statistic is defined as:

$$\text{Discrepant ST measurement percentage} = 100 \times \frac{\text{number of discrepant measurements}}{\text{number of reference measurements}}$$

where the numerator is the number of ST deviation measurements made by the device that differ from the corresponding reference ST deviation measurement by more than 100 microvolts, and the denominator is the total number of reference ST deviation measurements in the database used for testing (368 in the ESC DB). It may be useful to partition the data (considering ST depression and elevation separately, or even considering “moderate” and “severe” ranges of each).

Ischemic ST episode detection:

As there is considerable uncertainty with respect to the exact locations of the beginnings and ends of ST episodes, performance measures should be designed to be relatively insensitive to small discrepancies in the times indicated by the reference annotators and by the device for these events. It is nevertheless important to be able to estimate (a) the likelihood that an ST episode will be detected and (b) the likelihood that a given detection is actually an ST episode. It may be argued that some episodes (those with greater extreme deviations or those that are lengthy) are more important than others are, but this protocol does not address such concerns. In principle, the basis for calculating the statistics described above could be data stratified by extreme deviation, length, or any other metric of clinical significance, but (given the small number of episodes) the reliability of the statistics thereby obtained would be highly questionable. For these reasons, the discussion below proceeds from the assumption that all annotated ST episodes are equally important.

Ischemic ST episode sensitivity and positive predictivity are derived from the numbers of matching episodes and the total numbers of reference and algorithm-marked episodes as obtained using the methods of 5.2.14.6.

An important clinical index of ischemia is the total duration of all ischemic ST episodes within the monitoring period, often expressed as the percentage of the time during which ischemic ST occurred. As estimates of the accuracy with which an ST analyzer can measure this index, the ischemic ST duration sensitivity and positive predictivity are calculated as:

$$\text{Ischemic ST Duration Se} = \frac{\text{duration of overlap}}{\text{duration of reference} - \text{annotated ischemic ST}}$$

$$\text{Ischemic ST Duration} + \text{P} = \frac{\text{duration of overlap}}{\text{duration of algorithm} - \text{annotated ischemic ST}}$$

A.4.2.14.4 Reporting requirements

Although the MIT DB has been available since 1980 and the AHA DB since 1982, it remains a difficult task to determine minimal acceptable levels of performance for ambulatory ECG analyzers. Users should understand clearly

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that diagnostic outputs of these devices cannot be accepted uncritically. Given that review is necessary in any case, what constitutes “acceptable” performance depends to a significant extent on how much effort the user is willing to devote to assessing the accuracy of a device’s output. (The effort required of the user will, in turn, depend on the quality of the review and editing facilities provided by the device, if any.)

Performance is often characterized in terms of aggregate statistics, which provide a convenient summarization of device performance on many records. To extrapolate from an aggregate statistic to a prediction of real-world performance is difficult, because the selection criteria used by database developers vary, as do subject populations among clinical practices. It might be expected that average statistics, in which each record is equally weighted, would be better predictors of real-world performance than would gross statistics. The record-by-record statistics on which average statistics are based are often unreliable, however, as the number of events in each record may be small. As a result, average statistics can be extraordinarily sensitive to single errors and are usually less robust estimators of performance than are the gross statistics, which are based on larger numbers of events. For this reason, most of the reporting requirements are specified as gross statistics, and reporting requirements for statistics such as average VEB positive predictivity have been omitted intentionally.

The distribution of record-by-record statistics is a somewhat better basis for predicting real-world performance to the extent that the records studied are representative of the subject population in clinical practice. These distributions are rarely normal (Gaussian), however, and classical parametric models (e.g., measures such as sample variance) are inadequate for characterizing or comparing them. Bootstrap estimation is a nonparametric method for determining confidence limits on performance that has been applied to this problem and may also be useful in comparing the robustness of different statistics.

Other aspects of performance:

Several issues cannot be addressed adequately using existing testing methodology. Automated P-wave detection, though desirable, is beyond the current state-of-the-art for ECG analyzers that rely on body surface leads alone. The MIT DB includes five records with annotated nonconducted P-waves; no other P-wave annotations are present in any of the available databases. Similarly, T-wave annotations are wholly absent, except for annotations that indicate possibly significant changes in T-wave morphology in the ESC DB. Conduction disturbances exist and are annotated in nine records of the MIT DB and in two records of the European ST-T database, but it is not clear how accuracy in analysis of conduction disturbances can be measured with confidence, given a sample of this size. Similar concerns arise with respect to junctional rhythms (annotated in three MIT DB records) and SVTA (annotated in seven MIT DB records and three ESC DB records). A major concern is evaluation of arrhythmia detectors in the context of paced beats and the corollary issue of evaluation of pacer function analysis algorithms and pacer malfunction detectors. A modern database of high fidelity pacer recordings, including examples of pacer malfunction, is needed in order to address this issue.

A.4.2.15 Minimum reporting requirements

It is important to flag episodes of tachycardia, bradycardia, ectopy, and ST segment shifts and to bring these episodes to the attention of the physician taking care of the patient in order that the goals and objectives listed in A.1 are served.

Because long-distance athletes (runners, swimmers, bikers) may often have resting rates below 50 bpm, it is important to have the capability for user-selected parameters, so that cardiac pathology is not falsely diagnosed in such cases.

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Annex B
(Informative)

References

ALBRECHT, P, *et al*. Use of the 'bootstrap' to assess the robustness of the performance statistics of an arrhythmia detector. *Journal of Ambulatory Monitoring* 1(2): 171-176, 1988.

ALMASI, JJ and SCHMITT, OH. Systematic and random variations of ECG electrode system impedance. *Ann NY Acad Sci*, 1970, vol. 170, p. 509.

ALMASI, JJ and SCHMITT, OH. Electrode impedance and voltage offset as they affect efficiency and accuracy of VCG and ECG measurement. In *Proceedings of the XIth International Vectocardiography Symposium*. New York: North-Holland Publishing Co., 1970.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Testing and reporting results of cardiac rhythm and ST segment measurement algorithms*. AAMI EC57:1998. Arlington (Vir.): AAMI, 1998.

BAILEY, JJ, *et al*. Recommendations for standardization and specifications in automated electrocardiography: Bandwidth and digital signal processing. (AHA special report by an ad hoc writing group of the Committee on Electrocardiography and Cardiac Electrophysiology of the Council on Clinical Cardiology.) *Circulation*, 1990, vol. 81, p. 730.

BERSON, AS and PIPBERGER, HV. Skin-electrode impedance problems in electrocardiography. *Amer Heart J*, 1968, vol. 76, p. 519.

DEEDWANIA, P, *et al*. Ambulatory ECG monitoring for the detection of ischemic events and ventricular arrhythmia: Differential utility of event recording versus conventional monitoring systems. *JACC*, 1988, vol. 11, p. 67A.

EFRON, B. Bootstrap methods: another look at the jackknife. *Annals of Statistics*, 1979, vol. 7, pp. 1–26.

GARRISON, RJ and LEVY, D. Personal communication. Framingham Heart Study.

HOLTER, NJ. Radioelectrocardiography: A new technique for cardiovascular studies. *Ann NY Acad Sci*, 1957, vol. 65, pp. 913–923.

HOLTER, NJ. New method for heart studies. *Science*, 1961, vol. 134, pp. 1214–1220.

JAGER, F, *et al*. Analysis of transient ST changes during ambulatory monitoring. *Computers in Cardiology*, IEEE Computer Society Press: Los Alamitos, CA, 1992, pp. 453–456.

JAGER, F, *et al*. Analysis of transient ST changes during ambulatory monitoring using the Karhunen–Loeve transform. *Computers in Cardiology*, IEEE Computer Society Press: Los Alamitos, CA, 1992, pp. 691–694.

JAGER, F, *et al*. Performance measures for algorithms to detect transient ischemic ST segment changes. *Computers in Cardiology*, IEEE Computer Society Press: Los Alamitos, CA, 1991, pp. 369–372.

KNOEBEL, SB, *et al*. (American College of Cardiology Subcommittee); and FISCH, C, *et al*. (American Heart Association Task Force). Guidelines for ambulatory electrocardiography. Special report of joint ACC/AHA task force. *Circulation*, 1989, vol. 79, pp. 206–215.

MALIK, M, *et al*. Heart rate variability, standards of measurement, physiological interpretation, and clinical use. (Task force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology.) *Circulation*, 1996; 93:1043–1065.

MERRI, M, *et al*. Sampling frequency of the electrocardiogram for spectral analysis of the heart rate variability. *IEEE Trans Biomed Eng*, 1990, vol. 17, pp. 99–106.

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MIRVIS, DM, *et al*. Instrumentation and practice standards for electrocardiographic monitoring in special care units. (AHA special report by a task force of the Council on Clinical Cardiology.) *Circulation*, 1989, vol. 79, pp. 464–471.

NEARING, BD, *et al*. Frequency response characteristics required for detection of T-wave alternans during ambulatory ECG monitoring. Annals of Noninvasive Electrocardiology, 1996, vol. 1, N. 2, Part 1, pp. 103–112.

SCHOENBERG, AA, *et al*. The development of test methods for disposable ECG electrodes. Final Report. UBTL TR 1605-005, FDA Contract No. 223-74-5253. Salt Lake City: UBTL, April 1979.

SHEFFIELD, LT, *et al*. Recommendations for standards of instrumentation and practice in the use of ambulatory electrocardiography. (AHA special report from the task force of the Committee on Electrocardiography and Cardiac Electrophysiology of the Council on Clinical Cardiology.) *Circulation*, 1985, vol. 71, pp. 626A–636A.

SHOOK, *et al*. Comparison of amplitude modulated (direct) and frequency-modulated ambulatory techniques for recording ischemic electrocardiographic changes. Am J Cardiol, 1987; 60:895–900.

SIMONSON, E. Differentiation between normal and abnormal in electrocardiography. St. Louis: C. V. Mosby Co., 1961, p. 158.

SIMONSON, E, *et al*. Variability of the electrocardiogram in normal young men. *Am Heart*, 1949, vol. 38, p. 407.

SPACH, MS, *et al*. Skin electrode impedance and its effect on recording cardiac potentials. *Circulation*, 1966, vol. 34, p. 694.

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