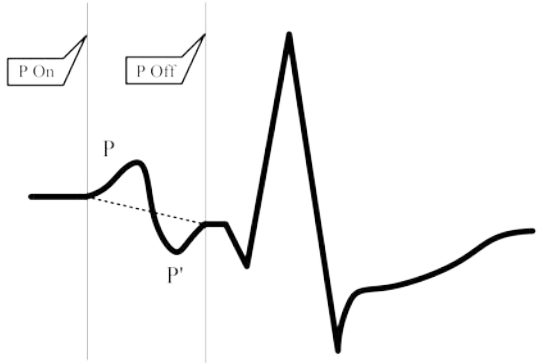
Appendix D Measurement, Diagnosis, Analysis and Assessment of ECG Machine

D.1 Methods to determine the amplitude of P, QRS, ST and T wave

(1) P wave amplitude

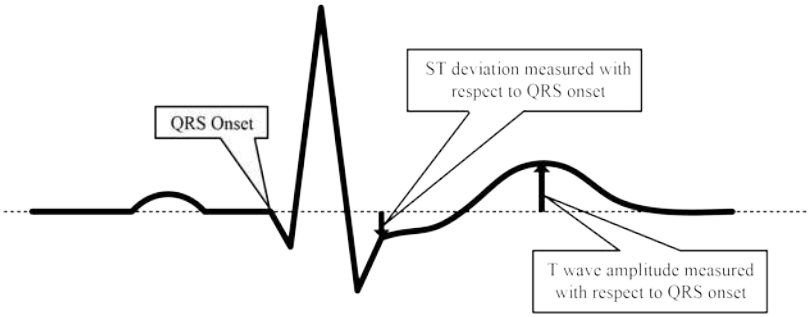


P On is the starting position of P wave, P Off is the ending position of P wave, and dashed line is the reference baseline

To measure P wave amplitude: the line from the starting point to the ending point of P wave is the reference baseline, as shown in above figure. The positive amplitude is from the reference baseline to top edge of P wave; the negative amplitude is from the reference baseline to bottom edge of P wave.

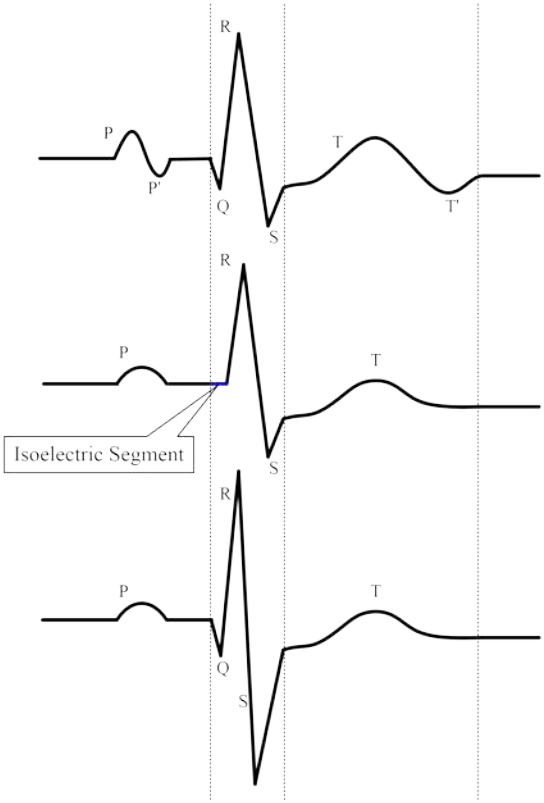
(2) QRS complex, ST segment and T wave amplitude

When measuring QRS complex, ST segment and T wave amplitude, the horizontal line of QRS complex beginning part is used as the reference baseline, as shown below:



The measurement of QRS complex, ST segment and T wave amplitude uses the horizontal line of QRS complex beginning part as the reference baseline QRS Onset is the starting position of QRS wave

D.2 Processing method of isoelectric segment in QRS complex



Isoelectric segment between dash lines are in QRS complex

As shown above, the isoelectric segment beginning from the starting position of QRS complex is processed as a part of QRS complex, but doesn't belong to the meaningful wave later (waveform area is larger than 160 $\mu V \cdot ms$)

D.3 Low incidence heart disease not included in testing and diagnosis database

Test with CSE database, but this database doesn't have sufficient number of acute myocardial infarction and myocardial ischemia ECG.

D.4 ECG diagnosis categories and the number of ECG test of each category

The accuracy of disease diagnosis and non-ECG means used to verify the effectiveness of heart disease diagnosis, as well as the patients statistics data (e.g. age, gender, race) of each group.

Test with CSE database, The following Table lists disease diagnostic categories, the number of ECG testing of each category and the accuracy of disease diagnosis.

CSE database sample properties are as follows:

Total number of samples: 1220 (male: 831, female: 389)

Race: White

Age: 52±13

Type of disease	ECG test number	Sensitivity (%)	Specificity (%)	Positive predictive value (%)
Normal	382	92.7	73.9	61.8
Left ventricular hypertrophy	183	60.1	97.0	77.7
Right ventricular hypertrophy	55	32.7	99.9	92.3
Biventricular hypertrophy	53	26.4	99.9	93.3
Anterior wall myocardial infarction	170	80.6	97.7	85.1
Inferior wall myocardial infarction	273	67.0	97.8	89.7
Composite myocardial infarction	73	64.7	99.7	94.0
Hypertrophy and myocardial infarction	31	46.8	100.0	100.0

D.5 The smallest waveform identified by the device and the stability of measurement when noise exists

If the area of certain waveform is greater than or equal to 160 $\mu V \cdot ms$, it is considered as meaningful wave, otherwise it is meaningless. Recognizing meaningful waveforms in area method can effectively reduce the noise. The stability of the measurement when noise exists is shown below

Overall measurement parameter	**Type of added noise**	**Mean difference (ms)**	**Variance (ms)**
P time limit	High frequency	-0.1	0.64
	Power frequency	0.25	1.5
	Low frequency	-2.3	3.8
PR interval	High frequency	1.6	2.4
	Power frequency	-0.1	1.5
	Low frequency	0.38	9.5
QRS time limit	High frequency	0.75	4.0
	Power frequency	-1.1	1.7
	Low frequency	0.3	4.4
QT interval	High frequency	-1.6	3.6
	Power frequency	-0.5	1.2
	Low frequency	4.9	5.6

D.6 Low incidence cardiac rhythm not included in the ECG rhythm test database

The low incidence cardiac rhythms not included in the test database:

1. Grade II conduction block;
2. Grade III conduction block.

D.7 ECG rhythm diagnosis categories and ECG test number of each category

Accuracy of rhythm diagnosis and the patient statistics data (e.g. age, gender, race) of each group

The following table gives the rhythm categories, ECG test number of each category and accuracy of disease diagnosis.

The test database sample properties are as follows:

Total number of sample: 4500 (male: 2847, female: 1653)

Race: Yellow

Age: 48±12

Rhythm type	ECG test number	Sensitivity (%)	Specificity (%)	Positive predictive value (%)
Sinus rhythm	3656	98.0	91.1	97.9
Premature ventricular contractions	351	87.2	98.9	81.2
Supraventricular premature beats	247	68.8	99.6	89.9
Atrial fibrillation	192	89.6	98.7	91.0
Atrial flutter	49	65.3	99.9	88.9
Pacemaker rhythm	5	100.0	100.0	100.0

D.8 Sensitivity regularly test instructions

Inspect ECGs: EGC-1C

Inspection methods:

(1) Make ECG machine set in lead I, the sensitivity is set as 10 mm/mV., EGC-1C transmits the U_{in} as 1 mV, frequency 10 Hz sine wave signal to the ECG machine.

(2) Test the waveform amplitude h_m on the Inspected ECG machine. Calculate the corresponding to deviations of the sensitivity according to the following formula, should meet the maximum allowable relative deviation of ± 5 %.

$$\delta_S = \frac{S_m - S_n}{S_n} \times 100\%$$

The formula: S_n - nominal value of Sensitivity;

S_m-test value of sensitivity;

h_m-the waveform amplitude of sensitivity;

U_{in}-input signal amplitude if the inspected ECG machine

(3) Make ECG machine set in lead I, the sensitivity is set as 20 mm/mV. EGC-1C transmits the Uin as 0.5 mV, frequency 10 Hz sine wave signal to the ECG machine. Using the same method to test the relative deviation of 20 mm/mV sensitivity.

(4) Make ECG machine set in lead I, the sensitivity is set as 5 mm/mV. EGC-1C transmits the Uin as 2 mV, frequency 10 Hz sine wave signal to the ECG machine. Using the same method to test the relative deviation of 5 mm/mV sensitivity.

(5) Make ECG machine set in lead I, the sensitivity is set as 2.5mm/mV. EGC-1C transmits the Uin as 4 mV, frequency 10 Hz sine wave signal to the ECG machine. Using the same method to test the relative deviation of 2.5 mm/mV sensitivity.

(6) According to the 1 and 2 steps to change the leads of the ECG machine, and make the ECG-1C's output signals connected to corresponding lead of the ECG machine, to complete all channel’s inspect, and then select the largest relative deviation from the test results for each test point, as the result of the inspection.

D.9 Distortion test

The function of ECG machine will not be affected adversely by the running of the pacemaker, which can be verified in the following way:

a) Superimpose the pulse wave of 200 mV peak, rise time less than 100 μs, 1ms pulse width, and 100 beats / min repetition rate with the sine wave signal of 1mV peak-valley value and 40 Hz frequency, and input to the ECG machine (set to standard sensitivity). The time required to restore the sine wave signals recorded by the ECG machine to 70 % of the initial value (when peak-valley value is 1mV and gain is 10 mm/mV, the initial value should be 10 mm) shouldn't exceed 50 ms; in the above test, the maximum baseline drift accumulated in 10 s doesn't exceed 10 mm; both with and without pulse, the amplitude difference recorded by sine wave signals (after waveform is stable) isn't greater than ±1 mm.

b) The filter of ECG machine must be opened for distortion tests.

c) The ECG machine can pass one of the following two tests:

- String the pacemaker pulse wave of 200 mV peak, rise time less than 100 μs, 1ms pulse width, and 120 pulses / min repetition rate together with the symmetrical triangular wave of 2 mV amplitude and 100 ms duration. The starting time of pulse wave should be 40 ms earlier (or later) than the starting time of triangular wave, input such a signal to the ECG machine, record in the standard sensitivity, the triangular wave is clearly visible on the ECG machine records, the difference between recorded amplitude and the original amplitude

(the original amplitude of the waveform with 2 mV amplitude should be 20 mm under 10 mm/mV gain) does not exceed 20 %, and the location of the pacemaker pulse can be clearly identified in the ECG machine records.

- String the pacemaker pulse wave of 200 mV peak, rise time less than 100 μs, 1ms pulse width, and 120 pulses / min repetition rate together with the ECG calibration signal CAL20000, and input to the ECG machine. The QRS curve of calibration signal can be clearly identified on ECG machine records, the difference between the recorded amplitude and the original amplitude of QRS curve does not exceed 20%, and the location of the pacemaker pulse can be clearly identified in the ECG machine records.

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