

Biomedical Instrumentation

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Biopotential Amplifiers

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Rough sketch of the dipole field of the heart when the R wave is maximal. The dipole consists of the points of equal positive and negative charge separated from one another and denoted by the dipole moment vector M .

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$v_{a1} = \mathbf{M} \cdot \mathbf{a}_1$ or $v_{a1} = |\mathbf{M}| \cos \theta$

Relationships between the two lead vectors a_1 and a_2 and the cardiac vector M . The component of M in the direction of a_1 is given by the dot product of these two vectors and denoted on the figure by v_{a1} . Lead vector a_2 is perpendicular to the cardiac vector, so no voltage component is seen in this lead.

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Cardiologists use a standard notation such that the direction of the lead vector for lead I is 0° ; that of lead II is 60° ; and that of lead III is 120° . An example of a cardiac vector at 30° with its scalar components seen for each lead is shown.

$\mathbf{I} - \mathbf{II} + \mathbf{III} = 0$

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(a) aVR (b) VR (c) Simplified circuit of (a)

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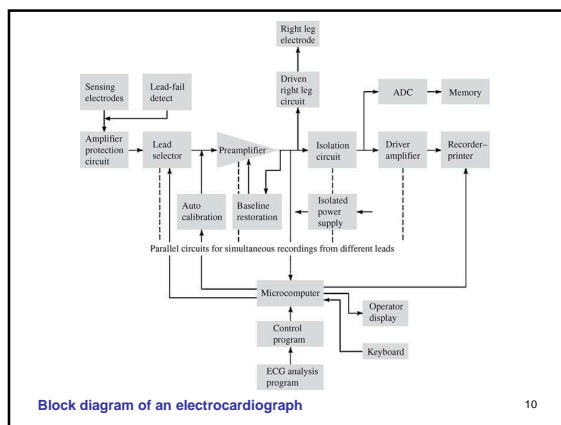
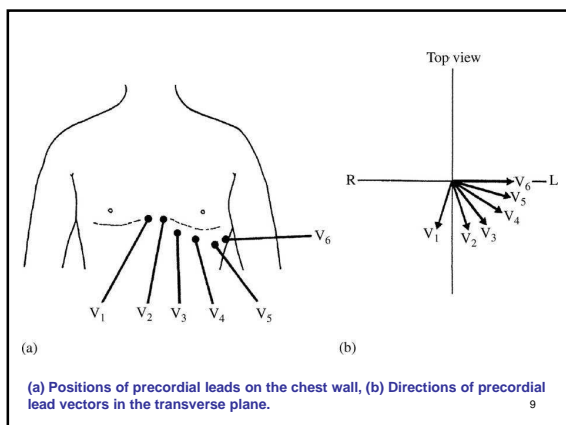
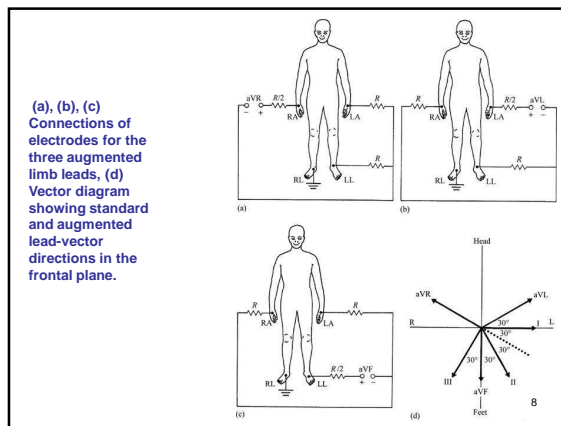
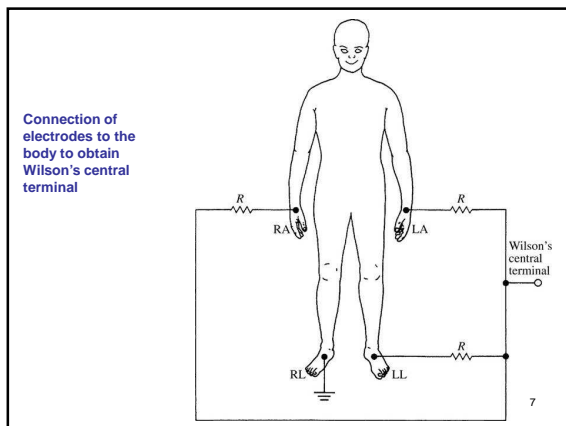


Table 6.1 Summary of Performance Requirements for Electrocardiographs (Anonymous, 1991)

| Section | Requirement Description | Min/max | Units | Min/Max Value |
|---------|---|---------|-------|---|
| 3.2.1 | Operating conditions: | | | |
| | Line voltage | Range | V rms | 104 to 1127 |
| | Frequency | Range | Hz | 60 ± 1 |
| | Temperature | Range | °C | 25 ± 10 |
| | Relative humidity | Range | % | 50 ± 20 |
| | Atmospheric pressure | Range | Pa | 7 × 10 ⁴ to 10.6 × 10 ⁴ |
| 3.2.2 | Lead definition (number of leads): | NA | NA | Table 3 |
| | Single-channel | Min | NA | 7 |
| | Three-channel | Min | NA | 12 |
| 3.2.3 | Input Dynamic Range: | | | |
| | Range of linear operations of input signal | Min | mV | ±5 |
| | Slew rate change | Max | mV/s | 320 |
| | DC offset voltage range | Min | mV | ±300 |
| | Allowed variation of amplitude with dc offset | Max | % | ±5 |
| 3.2.4 | Gain control, accuracy, and stability: | | | |

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| | | | | |
|---|-------------------------------------|-------|-----------|-----------|
| Gain selections | Min | mm/mV | 20, 10, 5 | |
| | Max | % | 5 | |
| Gain error | NA | NA | NA | |
| Manual override of automatic gain control | NA | NA | NA | |
| Gain change rate/min | Max | %/min | ±0.33 | |
| Total gain change/h | Max | % | ±3 | |
| 3.2.5 Time base selection and accuracy: | | | | |
| | Time base selections | Min | mm/s | 25, 50 |
| Time base error | Max | % | ±5 | |
| 3.2.6 Output display: | General | NA | NA | per 3.2.3 |
| | Width of display | Min | mm | 40 |
| | Trace visibility (writing rates) | Max | mm/s | 1600 |
| | Trace width (permanent record only) | Max | mm | 1 |
| 3.2.7 | Departure from time axis alignment | Max | mm | 0.5 |
| | | Max | ms | 10 |
| | Preruled paper division | Min | div/cm | 10 |
| | Error of rulings | Max | % | ±2 |
| | Time marker error | Max | % | ±2 |
| Accuracy of input signal reproduction: | | | | |
| Overall error for signals | Max | % | ±5 | |
| Up to ±5 mV and 125 mV/s | Max | µV | ±40 | |

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Table 6.1 (Continued)

| Section | Requirement Description | Min/max | Units | Min/Max Value |
|---------|--|---------|---------|---------------|
| | Upper cut-off frequency (3 dB) | Min | Hz | 150 |
| | Response to 20 ms, 1.5 mV triangular input | Min | mm | 13.5 |
| | Response after 3 mV, 100 ms impulse | Max | mV | 0.1 |
| | Error in lead weighting factors | Max | mV/s | 0.30 |
| | Hysteresis after 15 mm deflection from baseline | Max | % | 5 |
| 3.2.8 | Standardizing voltage: | | | |
| | Nominal value | N/A | mV | 1.0 |
| | Rise time | Max | ms | 1 |
| | Decay time | Min | s | 100 |
| | Amplitude error | Max | % | ±5 |
| 3.2.9 | Input impedance at 10 Hz (each lead) | Min | megohms | 2.5 |
| 3.2.10 | DC current (any input lead) | Max | µA | 0.1 |
| | DC current (any patient electrode) | Max | µA | 1.0 |
| 3.2.11 | Common-Mode Rejection: Allowable noise with 20 V, 60 Hz Max and ±300 mV dc and 51 kΩ | | mm | 10 |

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| | | | | |
|--------|--|-----|------|------|
| | Imbalance | Max | mV | 1 |
| 3.2.12 | System noise: | | | |
| | RTI, p-p | Max | µV | 30 |
| | Multichannel crosstalk | Max | % | 2 |
| 3.2.13 | Baseline control and stability: | | | |
| | Return time after reset | Max | s | 3 |
| | Return time after lead switch | Max | s | 1 |
| | Baseline stability: | | | |
| | Baseline drift rate RTI | Max | µV/s | 10 |
| | Total baseline drift RTI (2 min period) | Max | µV | 500 |
| 3.2.14 | Overload protection: | | | |
| | No damage from differential voltage, 60 Hz, 1 Vp-p, 10 s application | Min | V | 1 |
| | No damage from simulated defibrillator discharges: | | | |
| | Overvoltage | N/A | V | 5000 |
| | Energy | N/A | J | 360 |
| | Recovery time | Max | s | 8 |
| | Energy reduction by defibrillator shunting | Max | % | 10 |
| | Transfer of charge through defibrillator chassis | Max | µC | 100 |

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Table 6.1 (Continued)

| Section | Requirement Description | Min/max | Units | Min/Max Value |
|---------|--|----------------------------------|------------|---------------|
| | ECG display in presence of pacemaker pulses: | | | |
| | Amplitude | Range | mV | 2 to 250 |
| | Pulse duration | Range | ms | 0.1 to 2.0 |
| | Rise time | Max | µs | 100 |
| | Frequency | Max | pulses/min | 100 |
| 3.2.15 | Risk current (isolated patient connection) | Max | µA | 10 |
| | | As per applicable document 2.11 | | |
| 3.2.16 | Auxiliary output (if provided): | | | |
| | No damage from short circuit risk | Max | µA | 10 |
| | Current (isolated patient connection) | As per applicable document 2.1.1 | | |

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