

Framingham Heart Study

Manual of Procedures

MOP-version 1.0

August 22, 2018

Research Examination Center

Generation 3, Omni 2, NOS Cohorts Examination 3

Section #7 Physician Administered Medical History and Blood Pressure

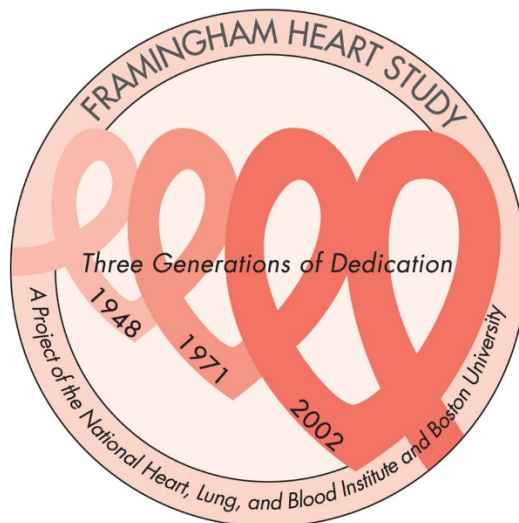


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1.0 Seated Blood Pressure

A. Equipment:

1. One standard Litman stethoscope tubing and earpieces with bell: Classic II 3M
2. One standard mercury column sphygmomanometer: Baumanometer (clinic)
3. Aneroid sphygmomanometer (offsite)
4. BP cuffs in four sizes (all Latex free)
 - Thigh adult cuff
 - Large adult cuff
 - Regular adult cuff
 - Pediatric cuff

B. Blood Pressure Cuff Placement:

1. Bare participant's left arm to above the point of the shoulder.
2. Determine correct cuff size using guidelines inside the cuff.
3. Palpate the brachial artery.
4. With participant seated, place the appropriate cuff around the upper left arm. The midpoint of the length of the bladder should lie over the brachial artery. Each cuff has an artery marker. The mid-height of the cuff should be at heart level.
5. Place the lower edge of the cuff, with its tubing connections, about one inch (1") above the natural crease across the inner aspect of the elbow.
6. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward.
7. If the subject has had a left-sided mastectomy, the right arm may be used for blood pressure measurement. If right arm is used, note it on the form.

C. Determination of Maximal Inflation Level

For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.

1. Attach the cuff tubing to the sphygmomanometer.
2. Palpate the radial pulse.
3. Inflate the cuff rapidly until the radial pulse is no longer felt (palpated systolic pressure) by inflating rapidly to 70 mmHg, then inflating by 10mmHg increments.
4. Deflate the cuff quickly and completely.
5. The maximal inflation level is 30 mmHg **above** the palpated systolic pressure.

D. Guidelines for Accurate Blood Pressure Readings:

1. The participant should be in a seated position for at least 5 minutes before the blood pressure is measured with both feet remaining flat on the floor.
2. All readings are made to the nearest even digit.
3. Any reading which appears to fall exactly between marking on the mercury column should be read to the next higher marking (i.e. 2, 4, 6, 8, or 0).
4. All readings are made to the top of the meniscus, the rounded surface of the mercury column.
5. When the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer.

E. Blood Pressure Readings:

1. Following any previous inflation, wait at least 30 seconds after the cuff has completely deflated.
2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth continuous rate to the maximal inflation level (30 mmHg above palpated systolic pressure).
3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.
4. Open the thumb valve slightly. Allow the cuff to deflate, maintaining a constant rate of deflation at approximately 2 mmHg per second.
5. Using the bell of the stethoscope, listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the FIRST regular sound is heard), until 10 mmHg BELOW the level of the diastolic reading (that is, 10 mmHg below the level at which the LAST regular sound is heard).
6. Deflate the cuff fully by opening the thumb valve.
7. Remove the stethoscope. Neatly enter systolic and diastolic readings in the spaces provided on the form.

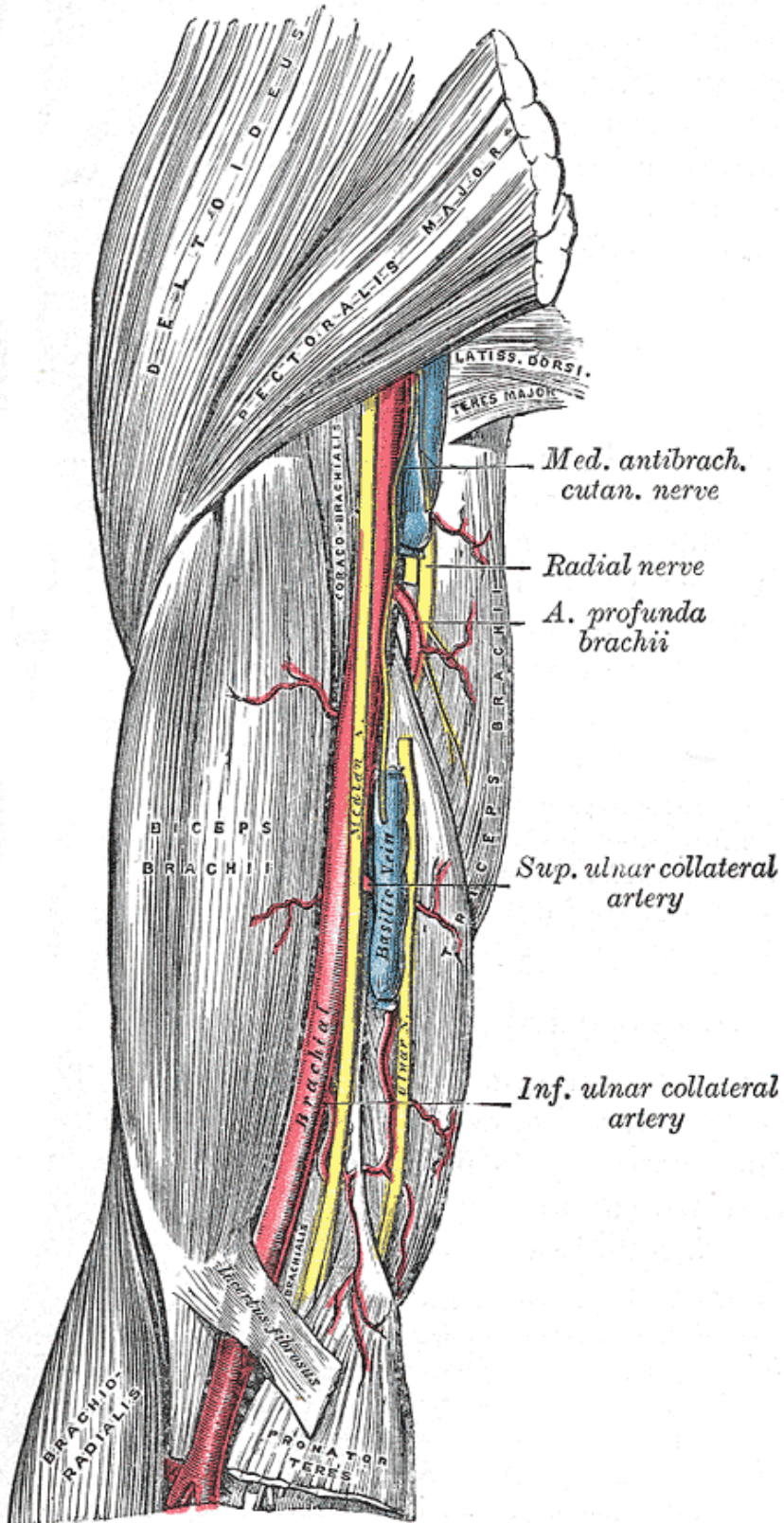
2.0 Blood Pressure Equipment

1. Portable standard mercury column sphygmomanometer:
Baumanometer, 300 model; Catalogue #0661-0320
W.A. Baum Co., Inc.
620 Oak Street
Copaigue, NY 11726-3292
(631) 226-3940
Fax (631) 226-3969
<http://www.wabaum.com>
Tech: Larry DiPippo
603-401-1483

2. Bauman latex free blood pressure cuffs in four sizes: regular adult, large adult, pediatric, thigh. (Ordered through AllHealth)

3. Litman stethoscope tubing and earpieces with bell: Classic II

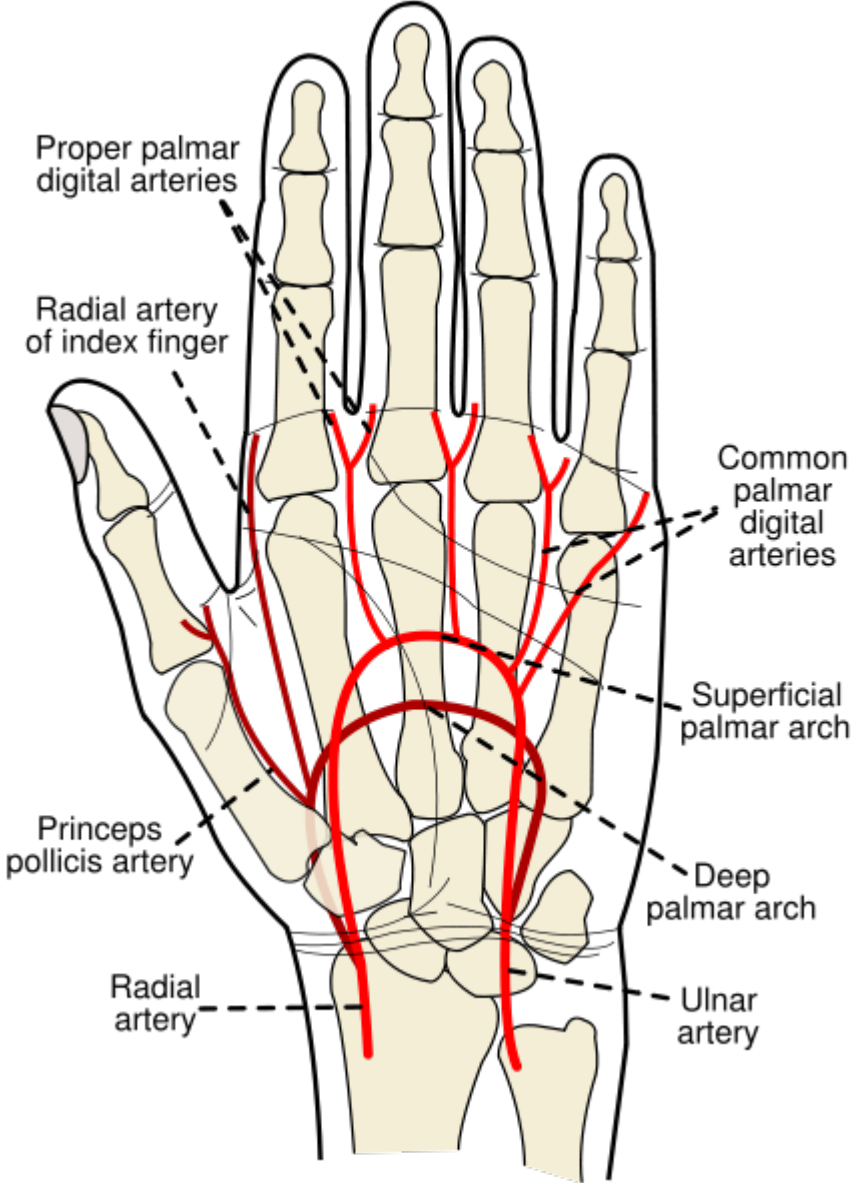
3.0 Arteries Diagrams



Brachial Artery:

Located between the biceps and triceps, on the medial side of the elbow.

Radial Artery: Located on the thumb side of the wrist.



4.0 Training and Certification of Staff

New Staff

- Given Protocol to read, understand, ask questions to Supervisor
- Protocol is demonstrated by Supervisor
- New Staff observes other Techs performing Protocol
- New Staff practices Protocol on staff and volunteers
- New Staff performs Protocol on participant with Supervisor or Certified Tech observing
- When Supervisor feels New Staff is proficient in Protocol, Supervisor will certify New Staff
- Certified New Staff will perform Protocol on own
- Certification date is noted in Certification Log

Recertification of Staff

- Occurs when there is a major deviation on Supervisor Observations or a new study with a new protocol is introduced into the exam
- Protocol is demonstrated by Supervisor
- Staff observes other Techs performing Protocol
- When Supervisor feels Staff is proficient in Protocol, Supervisor will recertify Staff
- Recertification date is noted in Certification Log

5.0 Criteria for Events

1. Cardiovascular Disease

Cardiovascular disease is considered to have developed if there was a definite manifestation of coronary heart disease, intermittent claudication, congestive heart failure, or stroke or transient ischemic attack in the absence of a previous manifestation of any of these diseases. Criteria for all these events are given below. A person having more than one cardiovascular manifestation within the follow-up period is counted as an incident case only at the time of the first event.

2. Coronary Heart Disease

Subjects are diagnosed as having developed coronary heart disease (CHD) if upon review of the case a panel of three investigators (the Framingham Endpoint Review Committee) agrees on one of the following definite manifestations of CHD: myocardial infarction, coronary insufficiency, angina pectoris, sudden death from CHD, non-sudden death from CHD. Persons with pre-existing CHD at Exam 1 are excluded from the population at risk of developing CHD but may be eligible for studies of prevalent CHD. Pre-existing CHD at Exam 1 is identified by any one of the following diagnoses at Exam 1: definite angina pectoris, definite history of myocardial infarction, definite myocardial infarction by electrocardiogram, doubtful myocardial infarction by electrocardiogram, definite coronary insufficiency by electrocardiogram and history.

The various manifestations of CHD are these:

Angina Pectoris

Brief recurrent chest discomfort of up to 15 minutes duration, precipitated by exertion or emotion and relieved by rest or by nitroglycerine is regarded as angina pectoris (AP) if two physicians interviewing the subject at a Framingham clinic visit or the Framingham Endpoint Review Committee, upon review of medical records, agree that this condition was definitely present. This diagnosis is based solely on evaluation of subjective manifestations. Abnormality of the resting or exercise electrocardiogram is not required for this diagnosis.

Myocardial Infarction

Recent or acute myocardial infarction (MI) is designated when there were at least two of three findings:

- 1) symptoms indicative of ischemia;
- 2) changes in biomarkers of myocardial necrosis;

- 3) serial changes in the electrocardiograms indicating the evolution of an infarction, including the loss of initial QRS potentials (that is, development of “pathologic” Q-waves of 0.04 second duration or greater).

An old or remote myocardial infarction is considered to be present when the electrocardiogram shows a stable pattern including a pathologic Q-wave of 0.04 second or greater or loss of initial QRS potential R-wave in those leads in which this would not be expected to occur. Also, an interim unrecognized MI is indicated when changes from a previous tracing show development of loss of R-wave potential or appearance of pathologic Q-waves not otherwise explained, in persons in whom neither the patient nor his physician considered the possibility of MI. If the patient was asymptomatic for chest pain or upper abdominal pain during the interval at which the unrecognized MI occurred, the event is classified as silent, unrecognized. More weight is given to this finding if a T-wave abnormality is also associated with Q-wave abnormality.

An autopsy report showing an acute, new, or recent infarction of the myocardium is accepted as evidence of an incident myocardial infarction. Because it is not possible to date an old infarction found on autopsy, such evidence is not used in the clinical diagnosis of a new event, unless there was an interim clinical event suspected of being an infarction.

Coronary Insufficiency

The coronary insufficiency syndrome is designated when a history of prolonged ischemic chest pain (> 15 minutes duration) was accompanied by transient ischemic S-T segment and T-wave abnormality in the electrocardiographic tracing but not accompanied by development of Q-wave abnormality or by serum enzyme changes characteristic of myocardial necrosis.

Coronary Heart Disease Death

Death from coronary heart disease is diagnosed as either sudden or nonsudden. For a detailed description of these diagnoses, see 6 below.

3. Stroke

The diagnosis of cerebrovascular disease is based on the occurrence of a clinically evident stroke documented by clinical records reviewed by at least two neurologists. Stroke is defined as the sudden or rapid onset of a focal neurologic deficit persisting for greater than 24 hours. Stroke is further categorized into infarction or hemorrhage.

Hemorrhagic Stroke

The diagnosis of subarachnoid hemorrhage is based on a history suggestive of this process such as abrupt onset headache, with or without change in the level of

consciousness, and signs of meningeal irritation with or without other localizing neurological deficits. Intracerebral hemorrhage is diagnosed clinically by the occurrence of abrupt focal neurologic deficit, often with altered level of consciousness and symptoms of increased intracranial pressure. Hemorrhages are confirmed by imaging.

Ischemic Stroke

A diagnosis of cerebral embolism is made when an established source for embolus including atrial fibrillation, rheumatic heart disease with mitral stenosis, recent myocardial infarction, bacterial endocarditis or other known source is determined. A clinical course consistent with embolic infarction or evidence of other systemic embolism may be present. Symptoms are usually rapid with maximal severity at onset.

Antherothrombotic brain infarction is defined as the sudden onset of a focal neurologic deficit lasting longer than 24 hours, in the absence of:

- 1) known source of embolism (atrial fibrillation, rheumatic heart disease with mitral stenosis, myocardial infarction within preceding six months, bacterial endocarditis);
- 2) intracranial hemorrhage (intracerebral or subarachnoid);
- 3) known hypercoagulable states;
- 4) other disease processes causing focal neurologic deficits (brain tumor, subdural hematoma, hypoglycemia).

Confirmatory imaging supports the diagnosis.

Silent stroke may be documented at the stroke review sessions when a stroke event is determined and an incidental infarct is seen on brain imaging in the absence of a reported clinical event.

Transient ischemic attack

A transient ischemic attack is defined as a focal neurologic deficit of sudden or rapid onset that fully resolves in less than 24 hours.

Stroke Death

Death attributed to stroke is designated when a documented focal neurologic deficit of greater than 24 hours duration preceded death and was responsible for the fatality.

4. Intermittent claudication

Minimum criteria for the subjective diagnosis of intermittent claudication consists of a cramping discomfort in the calf clearly provoked by walking some distance with the pain appearing sooner when walking quickly or uphill and being relieved within a few minutes by rest. This diagnosis is designated if two physicians at a Framingham clinic visit or the Framingham Endpoint Review Committee, upon review of medical records,

agree that this condition is definitely present. A diagnosis of intermittent claudication is based solely on evaluation of subjective manifestations.

5. Congestive heart failure

A definite diagnosis of congestive heart failure requires that a minimum of two major or one major and two minor criteria be present concurrently. The presence of other conditions capable of producing the symptoms and signs are considered in evaluating the findings.

Major Criteria:

- 1) Paroxysmal nocturnal dyspnea or orthopnea;
- 2) Distended neck veins (in other than the supine position);
- 3) Rales;
- 4) Increasing heart size by x-ray;
- 5) Acute pulmonary edema on chest x-ray;
- 6) Ventricular S(3) gallop;
- 7) Increased venous pressure > 16 cm H₂O;
- 8) Hepatojugular reflux;
- 9) Pulmonary edema, visceral congestion, cardiomegaly shown on autopsy;
- 10) Weight loss on CHF Rx: 10 lbs./5days.

Minor criteria:

- 1) Bilateral ankle edema;
- 2) Night cough;
- 3) Dyspnea on ordinary exertion;
- 4) Hepatomegaly;
- 5) Pleural effusion by x-ray;
- 6) Decrease in vital capacity by one-third from maximum record;
- 7) Tachycardia (120 beats per minute or more);
- 8) Pulmonary vascular engorgement on chest x-ray.

6. Coronary heart disease death

Death from coronary heart disease is diagnosed as either sudden or nonsudden.

Nonsudden death from CHD

If the terminal episode lasted longer than one hour, if the available information implies that the cause of death was probably CHD, and if no other cause can be ascribed, this is called nonsudden death from CHD. In making this diagnosis, the review panel uses prior clinical information as well as information concerning the final illness.

Sudden death from coronary heart disease

If a subject, apparently well, was observed to have died within a few minutes (operationally documented as under one hour) from onset of symptoms and if the cause of death cannot reasonably be attributed on the basis of the full clinical information and the information concerning death to some potentially lethal disease other than coronary heart disease, this is called sudden death and is attributed to coronary heart disease.

7. Cardiovascular disease death

This cause of death is designated when any disease of the heart or blood vessels is considered responsible.

8. All-cause mortality

The fact of death is supported by a death certificate. Additional information is obtained from records supplied by hospital, attending physician, pathologist, medical examiner, or family. The Framingham Endpoint Review Committee reviews all evidence to arrive at the cause of death.

6.0 MD BP Certification

MD BP CERTIFICATION

MD	Certification Date		Certified by	Recertification Date		Recert by

X = not at center anymore

7.0 Criteria for Events

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Minor criteria:

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8. All-cause mortality

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8.0 ECG coding for Gen 3/Omni 2/New Offspring Spouse Exam 3

General Comments

The computerized ECGs include measurement of rate, intervals and axis and will be directly transmitted to the MUSE.

Be sure to always look at the last ECG for changes.

Please code the **predominant Rhythm**.

AV BLOCK

1st degree when PR duration is .20 seconds or greater (measured in lead II).

2nd degree when some P waves are not conducted. This comes in two forms a) Mobitz I. When progressive PR prolongation precedes the dropped P wave and b) Mobitz II when QRS complexes are dropped without prior PR prolongation. AV dissociation occurs when P waves and QRS complexes march out independent of each other.

Ventricular Conduction Abnormalities

IV Block

This refers to right and left bundle branch block. Note that the code 1 is used for incomplete BBB and 2 is for complete BBB. For complete BBB the QRS interval should be .120 sec or greater. When the QRS is prolonged, but the pattern is not that of right or left BBB, the indeterminate IV block is coded as follows: 1=QRS .120 sec or greater, 2=QRS of .110 or .100 sec. Remember that the measurements of QRS duration are those made by the examining physician and not by the computer. An RSR' pattern in the absence of QRS prolongation should be coded as normal. When an RSR' pattern occurs with a QRS duration of .090 sec or greater it represents incomplete RBBB.

Hemiblock

1=left anterior. This is present when the QRS axis is -30 or less and small q wave is present in lead I.

2=left posterior. QRS axis is >90 and small q is present in AVF, in absence of evidence of right ventricular hypertrophy.

WPW

A short PR interval is present (typically .12 seconds or less) and a slurred upstroke of the QRS is present (so called delta wave). When these features are both fulfilled, WPW is present. When

the PR is .12 or less and a delta wave is possibly present, or when a delta wave is present but the PR is marginally short .13 to .14 seconds, WPW is “maybe” present.

ARRHYTHMIAS

The presence of rhythm disturbances should be made on the basis of examination of the ½ speed rhythm strip which accompanies each ECG. This represents a simultaneous 3 lead recording of the entire 12-lead ECG.

MYOCARDIAL INFARCTION

This is determined on the basis of the appearance of wide (.04 seconds) or deep (1/4 the height of the R wave) q waves. All tracings should be compared to the prior exam ECG which is always provided. The appearance of new, but small q waves should also be regarded as suggestive of MI. Loss of R waves in leads where they were previously present (see prior exam’s ECG) should also raise suspicion of MI. A posterior MI is present when R > S in V1, R is .04 seconds in duration, and an upright T wave is recorded in that lead. When criteria are largely, but incompletely fulfilled be sure to code this item as maybe!

ATRIAL ENLARGEMENT

Left Atrial Enlargement: Morris P wave: The terminal portion of the P wave in lead V1 is inverted and measures at least 1mm by 1mm (at normal standardization).

Right Atrial Enlargement: The P wave in inferior leads is peaked with a height of 2.5 mm.

RIGHT VENTRICULAR HYPERTROPHY Definite RVH is present when increased R wave voltage is present in V1 and increase S wave voltage is present in V5 in the absence of RBBB. The sum of RV1 + SV5 should be at least 10.5mm.

LEFT VENTRICULAR HYPERTROPHY

LVH with strain is present when increased voltage is present together with a strain pattern, i.e. downsloping ST.

LVH with mild S-T abnormality is present when voltage criteria are fulfilled but only mild ST-T abnormalities (flattening) are noted.

LVH by voltage only is present when voltage criteria are met without ST abnormality.

When complete BBB is present or the tracing is fully paced, LVH should be coded as unknown.

Voltage criteria for LVH:

R > 20mm in any limb lead

R > 11mm in AVL

R in lead I plus S in lead III ≥ 25mm

R in V5 or V6; S in V1 or V2:

$R \geq 25\text{mm}$

$S \geq 25\text{mm}$

$R \text{ or } S \geq 30\text{mm}$

$R + S \geq 35\text{mm}$