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SEMIP

Smart ECG Measurement and Interpretation Programs

Version 1.5

User Manual

CE 0123

About this Manual

P/N: 01.54.001702

MPN: 01.54.001702015

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User’ s operation failing to comply with this manual may result in malfunction or accident for which the manufacturer cannot be held liable.

The manufacturer holds the rights to modify, update, and ultimately explain this manual.

Responsibility of the Manufacturer

The manufacturer only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by the manufacturer, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

Table of Contents

Chapter 1 Introduction

SEMIP is designed to assist the physician in reading and evaluating an ECG printout. It was developed in cooperation with leading cardiologists. It is installed in the electrocardiographs, ECG workstations, and data management software, and is applied to measure and diagnose the 3-, 9-, 12-, 15- or 18-lead ECG printout.

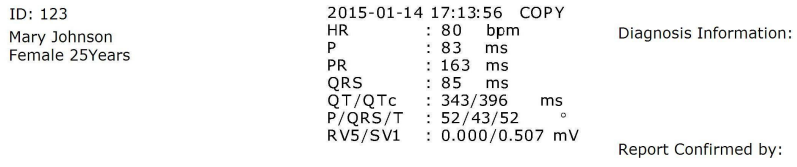
Since SEMIP is a smart analysis system constructed based on clinical diagnosis criteria. It is limited and not completely infallible. Therefore, the results given by SEMIP are offered to clinicians on an advisory basis only and always need the physician’s confirmation.

This manual illustrates the features and classification of the criteria which are applied in generating measurements and diagnosis of the manafacturer's electrocardiographs, ECG workstations, and DMS. Before using SEMIP, please read through this manual carefully.

NOTE: The results given by SEMIP are offered to clinicians on an advisory basis only. They do not replace a detailed report by the physician. The comprehensive clinical diagnosis of a patient is the physician’s responsibility and privilege.

Chapter 2 Definition of Terms

In the auto mode, when ECG data is sampled by Smart ECG series electrocardiograph and PC ECG with the Smart ECG Measurement and Interpretation Programs (SEMIP), the program measures the ECG data and interprets it. The following figure shows the auto measurement and interpretation information.



The following pages define what the measurements and interpretation are, and how they are derived.

2.1 Patient Information

Patient information includes the patient ID, name, gender, age, BP, weight, height, etc. For details about how set these parameters, please refer to related user manuals.

NOTE:

1. The age and gender affects the automatic analysis result.
2. If not set, the system automatically takes 35 Years for Age and Male for Gender by default.
3. To obtain a more accurate analysis result, please input the age and gender.

2.2 Heart Rate (HR)

Average heart rate (HR) is calculated on the basis of the entire 10-second recording

and the unit is bpm (beats per minute).

2.3 Global Intervals and Amplitude

Parameter	Description	Measurement unit
PP int	Mean of PP interval within 10 seconds	mS
RR int	Average time interval between two consecutive QRS complex	mS
P Dur	P wave duration: mean of duration of P-wave from several of all selected dominant beats	mS
PR int	P-R interval: mean of P-R interval from several of all selected dominant beats	mS
QRS Dur	QRS complex duration: mean of duration of QRS complexes from several of all selected dominant beats	mS
QT int	Q-T interval: mean of Q-T interval from several of all selected dominant beats	mS

QTc int	Normalized QT interval. As the QT interval is dependent on the heart rate it is often converted to the normalized QTc interval i.e. the QT interval that the patient would show at a heart rate of 60 BPM. The conversion is according to Bazett formula: $QTcBz = QT * \sqrt{1000/RR}$	mS
QTcBz	QTc interval (Bazett): $QTcBz = QT * \sqrt{1000/RR}$	mS
QTcFd	QTc interval (Fridericia): $QTcFd = QT * \sqrt[3]{1000/RR}$	mS
QTcFm	QTc interval (Framingham): $QTcFm = QT + 0.154 * (1000 - RR)$	mS
QTcQRS	QTc interval based on the QRS complex duration $QTcQRS = QT - 155 * (60/HR - 1) - 0.93 * (QRS - 139) + k$ k = -22ms (male) or -34ms (female)	mS
QTcHd	QTc interval (Hodges): $QTcHd = QT + 1.75 * (HR - 60)$	mS

RV5 amp	The maximum of amplitude of R or R' wave of one selected dominant beat from lead V5	mV
SV1 amp	The maximum of amplitude of S or S' wave of one selected dominant beat from lead V1	mV
RV6 amp	The maximum of amplitude of R or R' wave of one selected dominant beat from lead V6	mV
SV2 amp	The maximum of amplitude of S or S' wave of one selected dominant beat from lead V2	mV
RV5+SV1 amp	Sum of RV5 and SV1	mV

2.4 Electrical Axes

The Smart ECG Measurement and Interpretation Programs (SEMIP) calculate the axes on the basis of the maximum deflection of the relevant waves of leads I and II and III.

The electrical axes of the heart are determined separately for the P, QRS, and T waves.

The following formulas are used for the calculation:

$$\text{axis a} = \begin{cases} 90 & (I = 0,\ III > 0) \\ -90 & (I = 0,\ III < 0) \\ tg^{-1}\left(\dfrac{\sqrt{3}(I + 2III)}{3I}\right) * \dfrac{180}{\pi} & (I > 0) \\ 180 + tg^{-1}\left(\dfrac{\sqrt{3}(I + 2III)}{3I}\right) * \dfrac{180}{\pi} & (I < 0) \end{cases}$$

$$I, II, III = Qa + Ra + Sa + R'a + S'a$$

2.5 Interpretation on ECGs

Interpretation on ECGs is diagnosis result from SEMIP, whose code is defined by SEMIP (see 5.4).

Chapter 3 Measurements

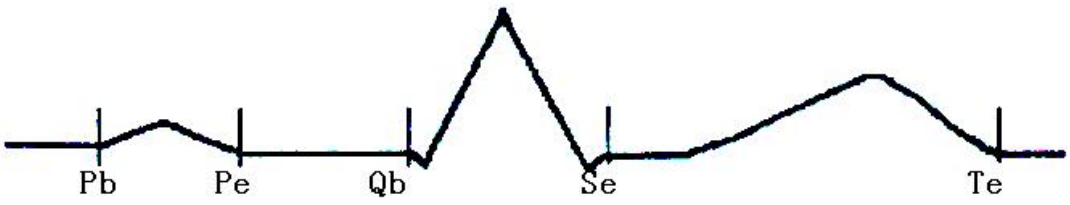
One predominant beat is selected from each of n-lead waveforms. The n predominant beats are used by SEMIP to locate the waveform boundaries (the onsets and ends of the P, QRS, T waves) in multilead ECG signals and measure features of clinical importance (such as the amplitude and the duration of the Q, R, S, R' and S' waves, the ST segment, the QT interval, the PR interval).

3.1 Waveform Boundaries

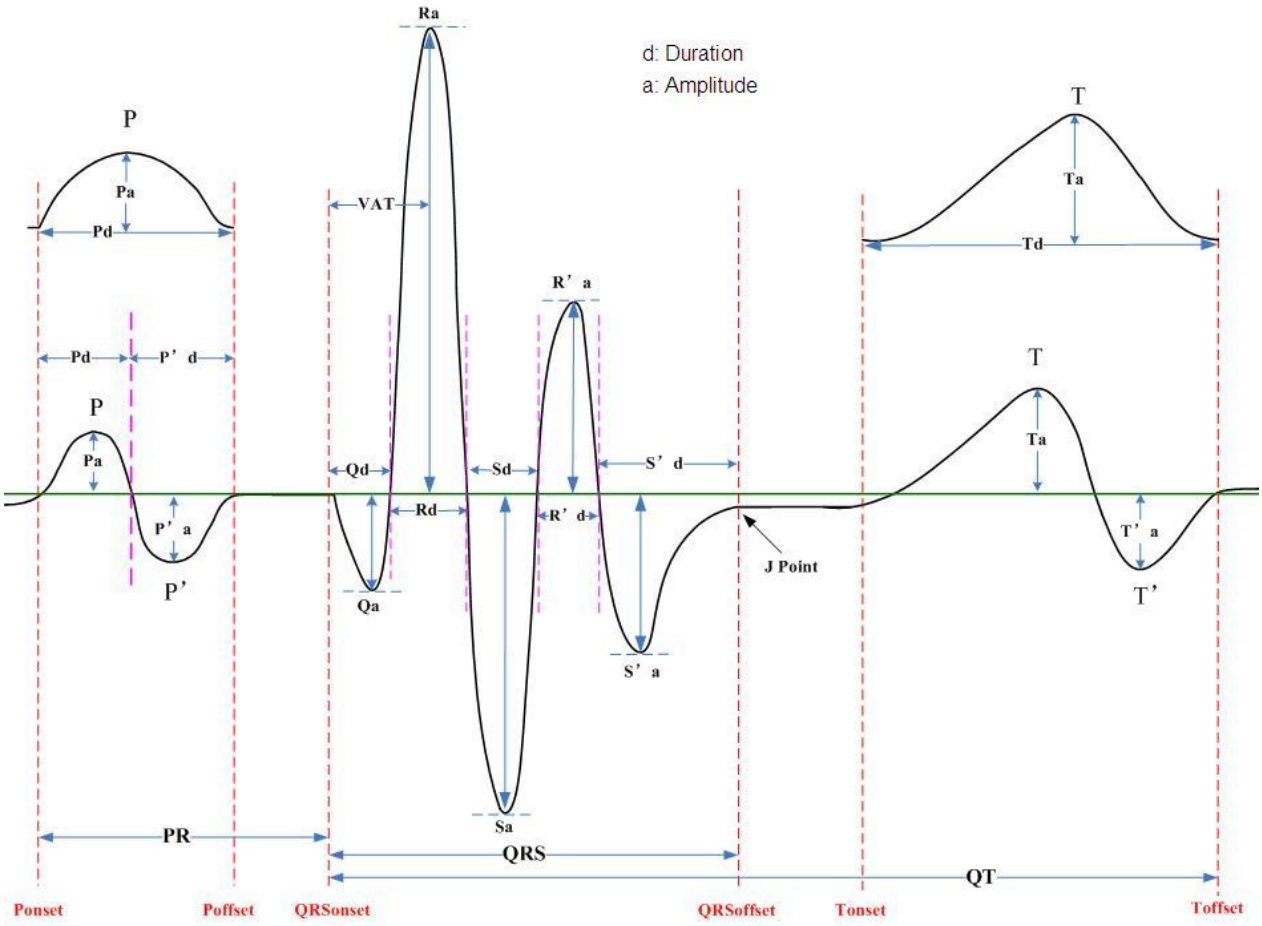
We adopt some scientific methods to determine the onset and end of multilead waves as follows:

Firstly, we detect and obtain, for each waveform boundary WB (including P end (Pe), P onset (Pb), QRS onset (QRSb), QRS end (QRSe), T end (Te)), a set of waveform boundary positions WB$j(i)$ belonging to beat i of lead j (j can take values from 1 to n (n leads), except for values corresponding to the leads where no detection was made). The next step is the selection, from these WB$j(i)$ positions, of one WB(i) that will be considered as the real onset or end of the waveform at the ith beat. Electrophysiologically, if all WB$j(i)$ were correctly detected, we should select the earliest WB$j(i)$ (j=1,2,…,n) for the waveform onset and the latest for the waveform end, in order to recover the boundary from that lead where the electrical activity of the heart has the longest temporal projection. However, due to noise or errors, misestimations could occur in the determination of some WB$j(i)$, which may lead to

an erroneous final WB(*i*) position. To reduce the risk of this occurrence, we apply the following mulitilead wave boundary detection rule for each *i*th beat: We calculate the mean and the standard deviation of WB*j*(*i*) (*j*=1,2,⋯.,n), and we search the minimum time position (for onsets) or maximum time position (for ends) of WB*j*(*i*) (*j*=1,2,⋯.,n). If the difference between the minimum or maximum WB*j*(*i*) position and the mean is bigger than three times the standard deviation, the minimum or maximum WB*j*(*i*) point is rejected as a possible noisy detection. After that, we take the wave onsets (ends) as the minimum (maximum) of the remaining WB*j*(*i*) positions, obtaining the final WB(*i*).



3.2 Measurements of One Beat



NOTE: STj=Se

ST1=STj + QT/10

ST2=ST1 + QT/10

ST3=ST2 + QT/10

Parameter	Description	Measurement unit
Pa	Amplitude of the P wave	mV
P' a	Amplitude of the P' wave (in case of biphasic P wave)	mV
Qa	Amplitude of the Q wave	mV

Ra	Amplitude of the R wave	mV
Sa	Amplitude of the S wave	mV
R’a	Amplitude of the R’ wave	mV
S’a	Amplitude of the S’ wave	mV
STj	Elevation or depression at the onset (J point) of the ST segment	mV
ST1	Elevation or depression of the ST segment QT/10 ms after the end of the QRS complex (J point)	mV
ST2	Elevation or depression of the ST segment QT/5 ms after the end of the QRS complex (J point)	mV
ST3	Elevation or depression of the ST segment (3*QT/10) ms after the end of the QRS complex (J point)	mV
ST20	Elevation or depression of the ST segment 20 ms after the end of the QRS complex (J point)	mV
ST40	Elevation or depression of the ST segment 40 ms after the end of the QRS complex (J point)	mV
ST60	Elevation or depression of the ST segment 60 ms after the end of the QRS complex (J point)	mV
ST80	Elevation or depression of the ST segment 80 ms after the end of the QRS complex (J point)	mV
Ta	Amplitude of the T wave	mV
T’a	Amplitude of the T’ wave (in case of biphasic T wave)	mV

Pd	Duration of P wave	mS
PR	Interval from the onset of the P wave to the onset of the QRS complex	mS
QRS	Duration of QRS complex	mS
QT	Interval from the onset of the QRS complex to the end of the T wave	mS

The amplitude values for the P-, QRS-, ST-, and T-waves are determined as follows:

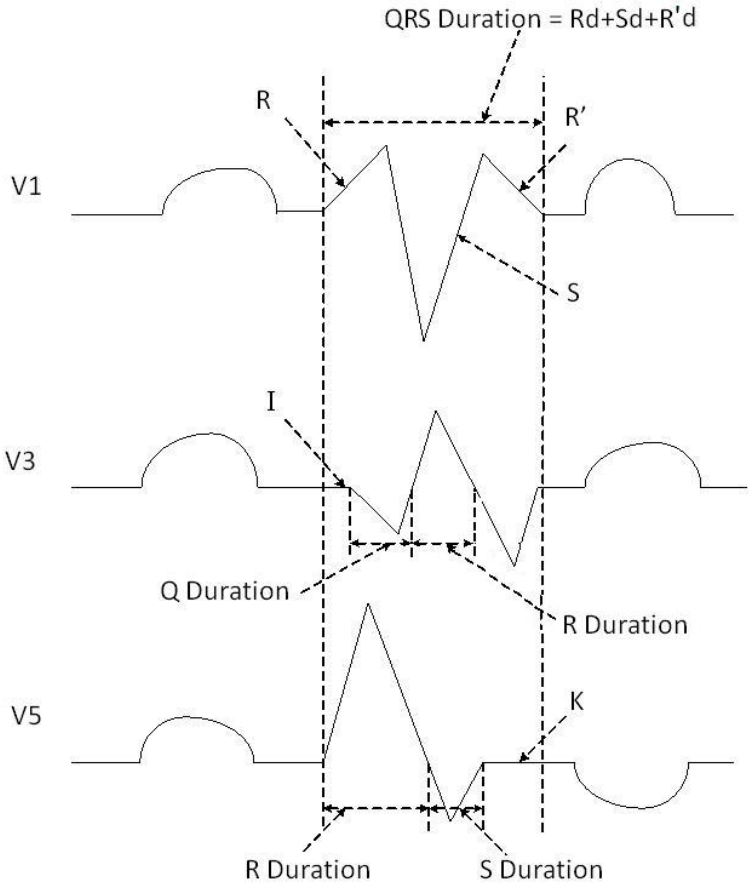
At first, isoelectric segments of one beat are acquired according to 2.3.The mean amplitude value of isoelectric segments is defined as fiducial value. The fiducial value subtracted from the amplitude value of P (QRS, T) wave peak gives the amplitude value of the P (QRS, T) wave. The P (QRS, T) wave peak is the point whose amplitude value is the maximum of P (QRS, T) wave relative to fiducial value. The fiducial value subtracted from the amplitude value of ST point gives the amplitude value of ST wave. Take STj for example, its ST point is the end of the QRS complex (J point), and the fiducial value subtracted from the amplitude value of J point gives its amplitude value.

3.3 Wave Form Durations and Isoelectric Segments

Between the global onset and offset of the QRS-complex, signal parts with a duration of more than 6 ms and amplitude not exceeding 20 uV for at least three samples should be defined as isoelectric segments – I before the global QRS-ONSET and K after the global QRS-OFFSET.

Because the duration of the Q-, R- or S-wave of all leads is respectively detected by SEMIP, isoelectric parts (I-waves) after global QRS-ONSET or before global

QRS-OFFSET (K-wave) are excluded in the measurement duration of the respective adjacent waveform.



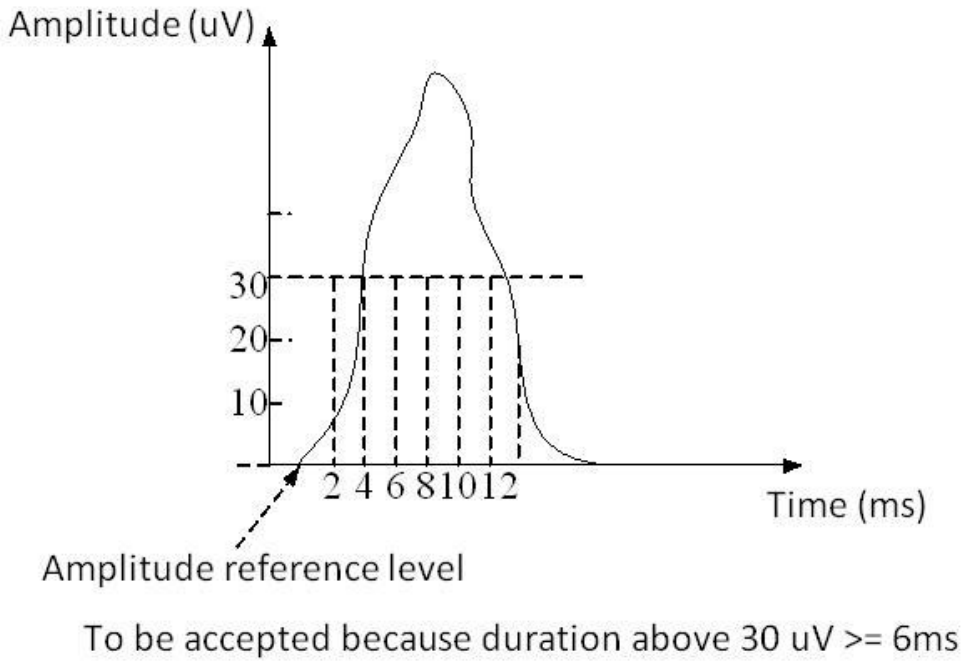
3.4 Acceptance of Minimum Waves

The labeling of the QRS waveforms depends on definition (since Einthoven) on the first detected wave. A tiny positive wave at QRS beginning is called r or R and may mask a true, following Q wave. Therefore the acceptance criteria of initial waveforms should be clearly defined and standardized.

The following rule for acceptance of minimum waves is used by SEMIP;

a) the signal part under consideration shows clearly two opposite slopes with at least one turning point in between;

b) the signal part under consideration deviates at least 30 uV from the reference level for a duration of at least 6 mS.



Chapter 4 Statements of Intended Use of SEMIP

4.1 Diagnostic Application

SEMIP is intended to provide an interpretation of the resting 12/15/18-lead ECG in hospital, general physician’ s office, ambulance. It is capable of diagnosing all commonly recognized ECG abnormalities such as myocardial infarction (MI), ventricular hypertrophy, abnormal ST-T changes and common abnormalities of rhythm. Conduction defects and other abnormalities such as prolonged QT interval are also reported. The software is not designed for interpretation of exercise electrocardiograms. The software has been widely used in clinical trials; hence it has wide exposure to recording of electrocardiograms in all commonly required situations.

4.2 Intended Population

SEMIP is intended to be used on adult and pediatric patients and is offered to clinicians on an advisory basis only.

4.3 Intended Location

SEMIP is intended to be used in hospital or in general physician’ s office, or in ambulance. It is able to accept details of the patient’ s name, age, sex, and automatically invokes the appropriate criteria and routines such as special logic for acute cardiac ischemia when necessary.

4.4 Diagnostic Accuracy

Emphasis of the accuracy of SEMIP is as follows:

- High-specificity and high-sensitivity program for low-risk patients;
- High positive predictive and high-sensitivity program for detecting sinus rhythm;
- High positive predictive and high-sensitivity program for detecting paced rhythms;
- High-specificity program for detecting right bundle branch block;
- High-specificity and high-sensitivity and high positive predictive value program for detecting tachycardia or bradycardia.
- High-specificity and high-sensitivity program for detecting ST-T Abnormality.

Chapter 5 Interpretation Statements

NOTE: Statement of Confidence

SEMIP is designed to assist the physician in reading and evaluating an ECG printout. It was developed in cooperation with leading cardiologists. However, no program is completely infallible, and interpretative standards and criteria can and do vary between cardiologists and programs. Never rely solely on the statements given with any computerized interpretation program; a machine cannot deliver a complete diagnosis on the basis of the ECG alone without a considerable amount of additional information. Always obtain physician’s confirmation.

The statements given with this or any interpretation program do not replace a detailed report by the physician. The comprehensive clinical diagnosis of a patient is the physician’s responsibility and privilege.

5.1 Diagnosis Information

Diagnosis information is composed of three-bite or four-bite digital and description of disease.

Classification			Type
1	□	□	Otherwise
2	□	□	Electrical Axes Deviation
3	□	□	Ventricular Hypertrophy and Atrial Enlargement

4	☐	☐	AV Block
5	☐	☐	Ventricular Conduction Block
6	☐	☐	ST-T Morphology Statements
7	☐	☐	Myocardial Infarction
8	☐	☐	Arrhythmias

Skip other types if test of Artificial Pacemaker Rhythm is passed.

5.2 Generation of Interpretation Statements

Interpretations are divided into several categories, including, for example: hypertrophy, infarcts, ischemia, axis deviation, conduction defects, and others.

Each category is represented on the ECG report by a single statement if any criteria are met in the category. This statement is the last one encountered whose medical criteria were true based on the measurements, earlier decisions, and entered patient demographic information such as age or gender. In each diagnostic category, more clinically significant findings override more benign ones.

5.3 Datum Value

Datum value used for classification of diagnosis information is based on age and gender according to two methods as follows:

(1) a (b1,b2) c d

a	Age of the male or the female not less than 19 years old

b1	Age of the male between 12 years old and 18 years old
b2	Age of the female between 12 years old and 18 years old
c	Age of the male or the female between 3 years old and 11 years old
d	Age of the male or the female not more than 2 years old

(2) a (b) c

a	Age of the male or the female not less than 19 years old
b	Age of the male or the female between 12 years old and 18 years old
c	Age of the male or the female not more than 11 years old

NOTE: Default of age is 35 years old. Default of gender is male.

5.4 Diagnosis Information Classification System

Otherwise（1□□）

Skip 1□□ if test of WPW or CLBBB is passed.

/	Normal ECG
111	Poor-quality Data
112	Reversal of Left and Right Arm Electrodes?
113	Lead Off
115	Reversal of Right Arm and Left Leg Electrodes?
121	Counter Clock Wise Rotation
122	Clock Wise Rotation
131	Low Voltage (Limb Leads)
132	Low Voltage (Chest Leads)
133	Low Voltage
141	Prolonged QT Interval
142	Short QT Interval
151	Dextrocardia (Re-examination)?

Electrical Axes Deviation（2□□）

Skip 2□□ if test of WPW, CLBBB or Low Voltage is passed.

201	Indeterminate Axis
202	Slight Left Axis Deviation
203	Right Axis Deviation

204	Marked Right Axis Deviation
205	Left Axis Deviation
206	S1-S2-S3 Pattern

Ventricular Hypertrophy and Atrial Enlargement（3□□）

Skip 3□□ if test of WPW or CLBBB is passed.

Statement is made by point scoring technique.

Classification of Ventricular Hypertrophy and Atrial Enlargement

301	High Voltage (Left Ventricle)
302	Positive T Wave in V1
303	Suspect Right Ventricular Hypertrophy
304	Suspect Left Ventricular Hypertrophy
305	Left Ventricular Hypertrophy (Probably Normal for this Age)
306	Right Ventricular Hypertrophy
307	Left Atrial Enlargement
308	Right Atrial Enlargement
309	Right Ventricular Hypertrophy(Pulmonary Disease?)
310	Biatrial Enlargement
314	Biventricular Hypertrophy
315	Left Ventricular Hypertrophy
316	Enlarged PtfV1

317	Prolonged P-wave

AV Block（4□□）

401	Short PR Interval
402	Ventricular preexcitation type A
403	Ventricular preexcitation type B
404	Ventricular preexcitation type unkown
405	Ventricular preexcitation
410	First-degree Atrioventricular Block
412	Second-degree Atrioventricular Block (Wenckebach type)
413	Second-degree Atrioventricular Block (Mobitz type II)
414	2:1 Atrioventricular Block
415	Third-degree Atrioventricular Block
420	Uncertain-Pulse
421	Atrial-paced Rhythm on Demand
422	Atrial-paced Rhythm
423	Atrial-paced Complexes
424	Atrial-sensed Ventricular-paced Rhythm on Demand
425	Atrial-sensed Ventricular-paced Rhythm
426	Atrial-sensed Ventricular-paced Complexes
427	Ventricular-paced Rhythm on Demand

428	Ventricular-paced Rhythm
429	Ventricular-paced Complexes
430	AV Dual-paced Rhythm on Demand
431	AV Sequential-paced Rhythm
432	AV Dual-paced Complexes
433	AV Sequential-paced Rhythm on Demand
434	AV Sequential-paced Complexes
435	Biventricular-paced Rhythm on Demand
436	Biventricular-paced Rhythm
437	Three-chamber pacing ECG

Ventricular Conduction Block（5□□）

Skip 5□□ if test of WPW is passed.

500	RSR' Pattern
501	Incomplete Right Bundle Branch Block
502	Nonspecific Intraventricular Conduction Block
504	Complete Right Bundle Branch Block
505	Complete Left Bundle Branch Block
506	Incomplete Left Bundle Branch Block
510	Suspect Left Anterior Fascicular Block
511	Left Anterior Fascicular Block
512	Left Posterior Fascicular Block

513	Suspect Left Posterior Fascicular Block
514	Septal Fascicular Block
541	Peri-Infarction Block

ST-T Morphology Statements（6□□ or 6□□□）

Skip 6□□ or 6□□□if test of WPW or CLBBB is passed.

Skip V1~V4 ST abnormal when age of patient is under five years old if test of CRBBB or IRBBB or IVCD or Atrial Fibrillation passed.

Skip V1~V3 ST abnormal when age of patient is under 18 years old.

Skip V1~V3 T wave abnormal when age of the male is under 18 years old or age of the female is under 30 years old.

Skip V1~V2 T wave abnormal when age of the female is over thirty years old.

601	Flat T Wave
611	Low T Wave
621	Inverted T Wave
622	Deep Negative T Wave
623	Giant Negative T Wave
631	Biphasic T Wave
641	Poor T Progression
651	Peaked T wave
661	Slight ST Depression

662	Middle ST Depression
663	Marked ST Depression
671	Slight ST Elevation
672	Middle ST Elevation
673	Marked ST Elevation
642	Possible anteroseptal subendocardial injury
643	Anteroseptal subendocardial injury
644	Possible anterolateral subendocardial injury
645	Anterolateral subendocardial injury
646	Possible septal subendocardial injury
647	Septal subendocardial injury
648	Possible lateral subendocardial injury
649	Lateral subendocardial injury
6491	Possible inferior subendocardial injury
6492	Inferior subendocardial injury
650	T wave abnormality, possible anterior ischemia
652	T wave abnormality, consistent with anterior ischemia
653	T wave abnormality, possible anterolateral ischemia
654	T wave abnormality, possible anterolateral ischemia or digitalis effect

655	T wave abnormality, consistent with anterolateral ischemia
656	T wave abnormality, possible lateral ischemia
657	T wave abnormality, possible lateral ischemia or digitalis effect
658	T wave abnormality, consistent with lateral ischemia
659	T wave abnormality, possible inferior ischemia
6591	T wave abnormality, possible inferior ischemia or digitalis effect
6592	T wave abnormality, consistent with inferior ischemia
680	Nonspecific T Wave Abnormality
681	Negative T Wave
682	T Wave Abnormality
683	ST Depression
684	ST Elevation
685	Slightly Abnormal ST-T
686	Abnormal ST-T
687	Marked Abnormal ST-T
688	Subsequent T Wave Abnormality
689	Subsequent ST-T Abnormality
690	Brugada wave
691	Nonspecific ST Elevation

692	ST elevation, consistent with subendocardial injury, pericarditis, or early repolarization
693	Nonspecific ST-T wave abnormality
694	Nonspecific ST-T wave abnormality, probably digitalis effect
695	Tall T waves, possible hyperkalemia
696	Nonspecific T wave abnormality
697	Nonspecific T wave abnormality, probably digitalis effect
698	Nonspecific ST elevation

Myocardial Infarction（7□□ or 7□□□）

Skip 7□□ or 7□□□ if test of WPW or CLBBB is passed.

Scoring Table of Myocardial Infarction

Position / Condition		Anterior			Lateral			Inferior		
		V2	V3	V4	I	V5	V6	II	III	aVF
Q wave abnormal										
|Qa|≥0.074mV &&|Qa|/Ra≥1/4	|Qa|/Ra≥1/3 && Qd≥36(34)32mS	3	3	3	3	3	3	3	2	3
	|Qa|/Ra≥1/3 && Qd≥28(26)24mS	2	2	2	2	2	2	2	1	2

	|Qa|/Ra≥1/3 && Qd≥24(22)20mS	1	1	1	1	1	1	1	0	1
T wave abnormal										
	Three leads Ta<-0.1mV	3			3			3		
	Two leads Ta<-0.1mV	2			2			2		
	One leads Ta<-0.1mV	1			1			1		

Classification of Myocardial Infarction Level

	Point	Level	Description
Q wave abnormal	≥6	1	Consistent
	≥4	2	Possible
	≥2	3	Suspect
Q wave abnormal and T wave abnormal	≥8	1	Consistent
	≥6	2	Possible
	≥4	3	Suspect

Classification of Myocardial Infarction Position

Anterior	V1, V2, V3, V4
Lateral	I, V5, V6, aVL
Inferior	II, III, aVF

Anterolateral	test Lateral Myocardial Infarction and test Anterior Myocardial Infarction all passed.
Posterior	ST depression with wide and tall R wave in leads V1 and V2

Classification of Myocardial Infarction Age

Acute	Q wave normal, ST segment elevation
Recent	Q wave abnormal, ST segment elevation
Old /Age undetermined	No ST segment elevation, Myocardial Infarction is present

NOTE:

① Skip classification of Inferior Myocardial Infarction when QRS amplitudes of all leads II, III, aVF are less than 0.5 mV.

② If test of myocardial infarction is passed, and the age of patient is under 18 years old, diagnosis information is print out as 711 (Abnormal Q).

③ Please check whether the classification of Myocardial Infarction is true because small r wave is misidentified.

Classification of Myocardial Infarction

701	Poor r Wave Progression
711	Abnormal Q Wave

712	Abnormal q Wave
713	Abnormal q and Q Wave
714	Deepened Q Wave
715	QS Wave in lead V1
720	Hypertrophic Cardiomyopathy
721	Subendocardial Myocardial Infarction
731	Suspect Anterior Myocardial Infarction?
7311	Suspect Anterior Infarction? (Possible Old)
741	Possible Anterior Myocardial Infarction
7411	Possible Anterior Infarction（Possible Recent）
7412	Possible Anterior Infarction（Possible Acute）
7413	Possible Anterior Infarction（Possible Old）
751	Anterior Myocardial Infarction
761	Evolution Period of Acute Anterior Myocardial Infarction
771	Acute Anterior Myocardial Infarction
781	Extensive Anterior Myocardial Infarction
791	Possible Extensive Myocardial Anterior Infarction
734	Suspect Anteroseptal Myocardial Infarction?
7341	Suspect Anteroseptal Infarction ?（Possible Old）
744	Possible Anteroseptal Myocardial Infarction
7441	Possible Anteroseptal Infarction（Possible Recent）

7442	Possible Anteroseptal Infarction（Possible Acute）
7443	Possible Anteroseptal Infarction（Possible Old）
754	Anteroseptal Myocardial Infarction
764	Evolution Period of Acute Anteroseptal Myocardial Infarction
774	Acute Anteroseptal Myocardial Infarction
732	Suspect High Lateral Myocardial Infarction?
7321	Suspect Lateral Infarction? （Possible Old）
742	Possible High Lateral Myocardial Infarction
7421	Possible Lateral Infarction（Possible Recent）
7422	Possible Lateral Infarction（Possible Acute）
7423	Possible Lateral Infarction（Possible Old）
752	High Lateral Myocardial Infarction
762	Evolution Period of Acute High Lateral Myocardial Infarction
772	Acute High Lateral Myocardial Infarction
733	Suspect Inferior Myocardial Infarction?
7331	Suspect Inferior Infarction?（Possible Old）
743	Possible Inferior Myocardial Infarction
7431	Possible Inferior Infarction（Possible Recent）
7432	Possible Inferior Infarction（Possible Acute）
7433	Possible Inferior Infarction（Possible Old）

753	Inferior Myocardial Infarction
763	Evolution Period of Acute Inferior Myocardial Infarction
773	Acute Inferior Myocardial Infarction
735	Suspect Posterior Myocardial Infarction
745	Possible Posterior Myocardial Infarction
755	Posterior Myocardial Infarction
736	Suspect AnteroLateral Myocardial Infarction
7361	Suspect AnteroLateral Infarction （Possible Old）
7362	Suspect AnteroLateral Infarction （Possible Acute）
7363	Suspect AnteroLateral Infarction （Possible Recent）
746	Possible AnteroLateral Myocardial Infarction
7461	Possible AnteroLateral Infarction（Possible Recent）
7462	Possible AnteroLateral Infarction（Possible Acute）
7463	Possible AnteroLateral Infarction（Possible Old）
756	AnteroLateral Myocardial Infarction
7561	AnteroLateral Infarction（Possible Recent）
7562	AnteroLateral Infarction（Possible Acute）
7563	AnteroLateral Infarction（Possible Old）
766	Evolution Period of Acute Anterolatera Myocardial Infarction
776	Acute Anterolateral Myocardial Infarction

737	Suspect Inferolateral Myocardial Infarction?
7371	Suspect Inferolateral Infarction（Possible Recent）
7372	Suspect Inferolateral Infarction（Possible Acute）
7373	Suspect Inferolateral Infarction（Possible Old）
747	Possible Inferolateral Myocardial Infarction
7471	Possible Inferolateral Infarction（Possible Recent）
7472	Possible Inferolateral Infarction（Possible Acute）
7473	Possible Inferolateral Infarction（Possible Old）
757	Inferolateral Myocardial Infarction
7571	Inferolateral Infarction（Possible Recent）
7572	Inferolateral Infarction（Possible Acute）
7573	Inferolateral Infarction（Possible Old）
738	Suspect Right Ventricular Myocardia Infarction
748	Possible Right Ventricular Myocardia Infarction
758	Right Ventricular Myocardia Infarction
792	Occlusion of the First Septal Branch of LACA
793	Occlusion of the Left Anterior Descending Coronary Artery(LACA)
794	Occlusion of the Left Main Coronary Artery Stenosis
795	Occlusion of the Right Coronary Artery(RCA)
796	Occlusion of Ostium Right Coronary Artery
797	Occlusion of the Left Circumflex Coronary Artery(LCx)

Arrhythmias（8□□）

800	Sinus Rhythm
801	Coronary Sinus Rhythm
802	Suspect Left Atrial Rhythm?
803	Junctional Escape Rhythm
804	Atrioventricular Dissociation
805	Asystole
806	Ventricular Fibrillation
810	Marked Sinus Bradycardia
811	Sinus Bradycardia
812	Sinus Tachycardia
813	Nonsinus Tachycardia
814	Nonsinus Bradycardia
816	Marked Nonsinus Bradycardia
817	Junctional Bradycardia
821	Sinus Arrhythmia
822	Sinus Bradycardia with Sinus Arrhythmia
823	Sinus Tachycardia with Sinus Arrhythmia
831	Junctional Escape Beat
841	Premature Atrial Contraction
845	Frequent Premature Atrial Contraction
847	Premature Atrial Contraction Bigeminy

843	Premature Atrial Contraction Trigeminy
842	Premature Ventricular Contraction
846	Frequent Premature Ventricular Contraction
848	Premature Ventricular Contraction Bigeminy
844	Premature Ventricular Contraction Trigeminy
851	Sino-Atrial Block
852	Blocked Premature Atrial Contraction
853	Pair Premature Atrial Contraction
854	Pair Premature Ventricular Contraction
861	Supraventricular Tachycardia
862	Runs of Premature Atrial Contraction
863	Ventricular Tachycardia
864	Runs of Premature Ventricular Contraction
865	Ventricular Escape Beat
866	Idioventricular Rhythm
871	Atrial Fibrillation
872	Atrial Flutter
874	Atrial fibrillation with rapid ventricular response
875	Atrial fibrillation with slow ventricular response
876	Atrial flutter with aberrant conduct or premature ventricular complexes

877	Atrial fibrillation with aberrant conduct, or premature ventricular complexes
878	Atrial fibrillation with rapid ventricular response with aberrant conduct or premature ventricular complexes
879	Atrial fibrillation with slow ventricular response with aberrant conduct, or premature ventricular complexes
881	Undefined Arrhythmia
882	Atrial rhythm
883	Atrial tachycardia
890	Marked rhythm irregularity, possible non-conducted PAC,SA block, AV block or sinus pause
891	Undetermined regular rhythm
892	Undetermined rhythm
893	Undetermined regular rhythm（tachycardia）
894	Undetermined rhythm（tachycardia）
895	Undetermined regular rhythm（bradycardia）
896	Undetermined rhythm（bradycardia）

Chapter 6 Accuracy of Automated Measurements and Interpretation

6.1 Accuracy of Automated Measurements on ECGs

The accuracy of automated measurements for SEMIP is tested according to the standard IEC60601-2-25. The details of ECGs mentioned bellow can be indexed in the standard, such as Table GG1, GG2, which shall not be listed in this manual.

6.1.1 Accuracy of Amplitude Measurements

SEMIP provides automated measurements on ECGs, whose accuracy has met the requirements as stated at 201.12.1.101.2 in the international standard IEC 60601-2-25.

Test set:

- 16 calibration and analytic ECGs (Table GG.1).

Method:

- Analyze the test ECGs with SEMIP.
- Calculate the SEMIP P, Q, R, S, ST and T wave amplitudes errors for each ECG against the reference measurements.
- The test limits are:
  - Less than 5% deviation from the reference or +/- 40uV (whichever is greater) when the amplitude is greater than 500 uV.
  - Less than +/- 25uV deviation from the reference when the amplitude is 500uV or less.

- Calculate the mean error and the standard deviation of the amplitude errors.
- Exclude the two biggest differences in the amplitude measurements.

Test result: PASS.

6.1.2 Accuracy of Absolute Interval and Wave Duration Measurements

SEMIP provides automated measurements on ECGs, whose accuracy has met the requirements as stated at 201.12.1.101.3.1 in the international standard IEC 60601-2-25.

Test set:

- 16 calibration and analytic ECGs (Table GG.1).

Method:

- Analyze the test ECGs with SEMIP.
- Calculate the global measurements (P-duration, PR-interval, QRS-duration, QT-interval) and individual lead measurements (Q-duration, R-duration, S-duration) errors for each ECG against the reference measurements.
- Calculate the mean difference and the standard deviation of the interval and duration errors.
- Remove the four largest deviations from the mean (outliers) for each measurement.

Test result: PASS. All interval/duration measurement error statistics fall within the test limits.

The mean differences and standard deviations of intervals and durations for calibration and analytical ECGs are computed and should not exceed the tolerances

given in Table 6-1-1 (in the international standard IEC 60601-2-25). The mean differences and standard deviations are given in Table 6-1-2.

Table 6-1-1 Acceptable mean differences and standard deviations for global intervals and Q-, R-, S-durations on calibration and analytical ECGs

Measurement	Acceptable mean difference (ms)	Acceptable standard deviation (ms)
P-duration	±10	8
PR-interval	±10	8
QRS-duration	±6	5
QT-interval	±12	10
Q-duration	±6	5
R-duration	±6	5
S-duration	±6	5

Table 6-1-2 Mean differences and standard deviations for intervals and durations for calibration and analytical ECGs measured by SEMIP V2.1

Measurement	Mean difference (ms)	Standard deviation (ms)
P-duration	-9.33	2.19
PR-interval	-3.83	1.99
QRS-duration	-2.25	1.42

QT-interval	-3.67	2.64
Q-duration	0	0.26
R-duration	-0.02	2.83
S-duration	-0.2	1.52

6.1.3 Accuracy of Interval Measurements on Biological ECGs

SEMIP provides automated measurements on ECGs, whose accuracy has met the requirements as stated at 201.12.1.101.3.2 in the international standard IEC 60601-2-25.

Test set:

- 100 biological ECGs from the CSE “MO” series. (Table GG.2).

Method:

- Analyze the test ECGs with SEMIP.
- Calculate interval and wave duration errors by comparing the SEMIP global P duration, PR interval, QRS duration and QT interval measurements to the reference global measurements.
- Calculate the mean difference and the standard deviation of the interval/duration errors across the entire test set.
- From the differences, remove the eight largest deviations from the mean (outliers) for each measurement.

Test result: PASS. All global interval/duration error statistics fall within the test limits. The mean differences and standard deviations of global durations and intervals for biological ECGs (from CSE database) are computed and should not exceed the

tolerances given in Table 6-1-3 (in the international standard IEC 60601-2-25). The mean differences and standard deviations for global durations and intervals for biological ECGs (from CSE database) measured by SEMIP are given in Table 6-1-4.

Table 6-1-3 Acceptable mean differences and standard deviations for global durations and intervals for biological ECGs

Measurement	Acceptable mean difference (ms)	Acceptable standard deviation (ms)
P-duration	±10	15
PR-interval	±10	10
QRS-duration	±10	10
QT-interval	±25	30

Table 6-1-4 Mean differences and standard deviations for global durations and intervals for biological ECGs measured by SEMIP V2.1

Measurement	Mean difference (ms)	Standard deviation (ms)
P-duration	-0.76	5.43
PR-interval	1.58	3.82
QRS-duration	-0.86	5.1
QT-interval	-3.14	8.59

6.2 Accuracy of Automated ECG Interpretation

6.2.1 Definition of Accuracy Measures for Automated ECG Interpretation

Four key accuracy measures are explained below.

It is assumed that the true diagnosis for a PATIENT is known (“truth”). The ECG interpretation (classification) is called “Test” . The following designations are applied to characterize the performance of a test (respectively of an ECG interpretation system), see Table 6-2-1:

a) a “Normal” correctly classified as “Normal” is called “True normal” (TN);

b) a “Normal” incorrectly classified as “Pathologic” is called “False pathologic” (FP);

c) a “Pathologic” incorrectly classified as “Normal” is called “False normal” (FN);

d) a “Pathologic” correctly classified as “Pathologic” is called “True pathologic” (TP).

Table 6-2-1 Tabulation of test results

Reference	Test	
	“Normal”	“Pathologic”
“Normal”	TN	FP
“Pathologic”	FN	TP

The following equations are calculated from a two (or multi-) category test:

a) *Sensitivity*: probability that a “True pathologic” would be classified as a

"Pathologic".

$$Sensitivity = \frac{TP}{TP + FN} \times 100\%$$

b) *Specificity*: probability that a "True normal" would be classified as "Normal".

$$Specificity = \frac{TN}{TN + FP} \times 100\%$$

c) *Positive predictive value (P^+)*: probability that a classified "Pathologic" is a "True pathologic".

$$P^+ = \frac{TP}{TP + FP} \times 100\%$$

6.2.2 Contour Diagnostic ECG Database

In order to test of accuracy of morphology diagnostic and rhythm interpretative statements, we collected a large of ECGs data in different ways. 9016 adult ECGs and 1738 pediatric ECGs were used to test SEMIP.

The adult diagnostic ECG database contains 7386 ECGs with sinus rhythm, 1319 ECGs with atrial fibrillation, 885 ECGs with Premature Ventricular Contraction, 51 ECGs with Atrial Rhythm, etc.

The pediatric diagnostic ECG database most are composed ECGs with sinus rhythm. There were 1721 ECGs with sinus rhythm.

6.2.3 Disclosure of Group Statistics of Patient Demographics

The patients whose ECGs are tested random have different age and diverse gender. The group statistics of patient demographics are showed in table 6-2-2 and 6-2-3.

Table 6-2-2 group statistics of adult patient demographics

Patient Demographics	Number of	Percentages

		subjects	%
Gender	Male	4619	51.23
	Female	4396	48.76
	Unknown	1	0.01
Age	Not less than 18 years old And Not more than 59 years old	4869	54.00
	Not less than 60 years old And Not more than 79 years old	3281	36.39
	More than 80 years old	866	9.61

Table 6-2-3 group statistics of pediatric patient demographics

Pediatric Patient Demographics		Number of subjects	Percentages %
Gender	Male	1017	58.52
	Female	719	41.37
	Unknown	2	0.12
Age	Less than 1 year old	189	10.87
	Not less than 1 year old	1234	71.00

	And Not more than 7 years old		
	Not less than 8 years old And Not more than 17 years old	315	18.12

6.2.4 Disclosure of Accuracy Measures for Diagnostic Interpretative Statements

The accuracy measures for the adult diagnostic interpretative statements whose interpretation are showed in table 6-2-4, which includes sensitivity, specificity, and positive predictive value for all the major diagnostic interpretative statements, and those of pediatric database are showed in table 6-2-5.

6.2.4.1 Accuracy of Interpretation for Adult ECG Database

Table 6-2-4 Accuracy of interpretation for ECG database, adult contour diagnoses

Diagnostic Category	Number of ECGs Tested	Sensitivity %	Specificity %	Positive predictive value %
NORMAL	1214	65.98	98.27	85.58
Low Voltage	228	84.65	99.21	73.66
Anterior Myocardial Infarction	230	85.22	99.29	75.97
Inferior Myocardial Infarction	306	86.93	98.67	69.63
Anteroseptal Myocardial Infarction	307	86.64	99.13	77.78
Left Ventricular Hypertrophy	786	93.64	98.23	83.45
Right Ventricular Hypertrophy	127	56.69	99.56	64.86
Left Atrial Enlargement	145	48.28	99.53	62.5

Right Atrial Enlargement	48	87.5	99.54	50.6
Pre-excitation Syndrome	199	88.44	99.85	93.12
Right Bundle Branch Block	1562	89.63	99.06	95.24
Left Bundle Branch Block	204	93.63	99.83	92.72
Left Anterior Hemi Block	354	84.46	99	77.46

6.2.4.2 Accuracy of Interpretation for Pediatric ECG Database

Table 6-2-5 Accuracy of interpretation for ECG database, pediatric contour diagnoses

Diagnostic Category	Number of ECGs Tested	Sensitivity %	Specificity %	Positive predictive value %
Normal	693	63.2	96.46	92.21
Pre-excitation Syndrome	12	75	99.94	90
Right Bundle Branch Block	60	70	99.46	82.35

6.2.5 Disclosure of Accuracy Measures for Rhythm Interpretative Statements

6.2.5.1 Accuracy of Rhythm Interpretation, Adult ECG Database

Table 6-2-6 Accuracy measures for adult rhythm interpretative statements

Diagnostic Category	Number of ECGs Tested	Sensitivity %	Specificity %	Positive predictive value %
Sinus Rhythm (Including SA, ST, and SB)	7386	97.93	90.55	97.92
Sinus Arrhythmia	561	90.73	94.12	50.6
Sinus Tachycardia	415	93.73	98.74	78.27
Sinus Bradycardia	601	94.01	98.05	77.5
Atrial Fibrillation	1319	92.34	99.16	94.93
PaceMaker	210	97.62	99.98	99.03
Premature Atrial Contraction	534	75.28	99.15	84.81
Premature Ventricular Contraction	885	89.04	99.13	91.73

Atrial Rhythm (Coronary Sinus Rhythm, Left Atrial Rhythm)	51	82.35	99.41	44.21
First-degree AV Block	382	93.19	98.34	71.34
Second-degree AV Block	27	66.67	99.84	56.25
Third-degree AV Block	25	76	99.9	67.86

6.2.5.2 Accuracy of Rhythm Interpretation, Pediatric ECG Database

Table 6-2-7 Accuracy measures for pediatric rhythm interpretative statements

Diagnostic Category	Number of ECGs Tested	Sensitivity %	Specificity %	Positive predictive value %
Sinus Rhythm	1721	98.26	47.06	99.47
Sinus Arrhythmia	323	92.26	88.76	65.21
Sinus Tachycardia	555	93.69	94.25	88.44
Sinus Bradycardia	33	75.76	99.35	69.44
Premature Atrial Contraction	32	68.75	99.18	61.11
Premature Ventricular Contraction	57	80.7	98.57	65.71

6.2.6 Cardiac Abnormalities with No Statistics

- SEMIP will interpret more cardiac abnormalities in the intended population. Several cardiac abnormalities with no statistics of Sensitivity, Specificity and PPV occurred in the adult ECG database with a frequency < 15 samples or the Pediatric ECG database with a frequency < 10 samples. The following categories of abnormalities not covered by the test databases above are:
- Adult contour analysis

- Early repolarization, pericarditis, dextrocardia, electrolyte and QT disturbances, left posterior fascicular block, Brugada wave

- Pediatric contour analysis
  - Atrial enlargement, left bundle branch block, fascicular block, intraventricular conduction delay

6.2.7 Cardiac Rhythms with No Statistics

- The SEMIP will interpret more cardiac rhythms in the intended population. Several cardiac rhythms with no statistics of Sensitivity, Specificity and PPV occurred in the adult ECG database with a frequency < 15 samples or the Pediatric ECG database with a frequency < 10 samples. The following categories of rhythms not covered by the test databases above are:

- Adult rhythm analysis
  - Rhythms of junctional focus, atrial tachycardia, ventricular tachycardia , non-sinus supraventricular tachycardia

- Pediatric rhythm analysis
  - Rhythms of junctional focus, atrial rhythm, ventricular rhythm, nonsinus tachycardia, nonsinus bradycardia, paced rhythm.

6.3 CSE evaluation for SEMIP interpretation

6.3.1 CSE (Common Standards for Quantitative Electrocardiography) diagnostic database

The CSE database consisted of 1220 ECGs recorded from individuals living in several European

countries. It included recordings from 831 men and 389 women, mean age 52 ± 13 years. The cohort consisted entirely of European subjects and the racial distribution was never determined. The study population included 286 individuals who were apparently healthy and 96 patients referred for cardiological investigation but found to have no cardiac abnormality, who together made up a group of 382 controls. The remaining 838 subjects had known clinical conditions, e.g. myocardial infarction, valvular heart disease. Patients were therefore classified as having ventricular hypertrophy, myocardial infarction or "no structural abnormality" on the basis of clinical information. Three cardiologists from different European countries reviewed the clinical data and agreed on the clinical classification.

There was a second classification produced by a set of 8 cardiologists, who each interpreted the 1220 ECGs. Their interpretations were combined to produce a so-called "cardiologist interpretation" or "combined referee" with respect to which programs, and the individual cardiologists themselves, were also evaluated.

This database remains the only truly independent database with "secret" classifications for individual cases.

6.3.2 CSE evaluation

Tables 6-3-1 – 6-3-3, which follow this section, provide the results of analyzing the 1220 ECGs in the Common Standards for Quantitative Electrocardiography (CSE) database using SEMIP. The analysis was undertaken in November 2015 by Prof Rubel's lab. The following is a brief explanation of the study and the outputs.

The CSE database was constructed by acquiring ECGs from 1220 individuals (831 men, 389 women, mean age 52 ± 13 years). The ECGs were acquired in five different European centers

using a variety of equipment but signals were sampled at 500 samples/sec and all leads were recorded simultaneously. Individual centers in the study processed the ECGs in their own local laboratory and submitted the interpretations, mapped to an agreed scheme, e.g. LVH was 21A, to a central lab in Leuven, Belgium where data on sensitivity etc. were calculated. In other words, the true classification of the cases was known only to the core lab, and in practical terms this meant that the classifications were effectively stored inside software used to determine the accuracy of individual programs. This is still the case today, but following the untimely death of Professor Jos Willems who directed the lab in Leuven, the responsibility for maintaining the secrecy of the classifications and for providing further assessments of accuracy of software has transferred to the lab of Professor Paul Rubel, based in Lyon, France.

The composition of the study population included 286 individuals who were apparently healthy and 96 patients referred for cardiological investigation but found to have no cardiac abnormality, who together made up a group of 382 controls. The remaining 838 subjects had known clinical conditions, e.g. myocardial infarction, valvular heart disease. Patients were therefore classified as having ventricular hypertrophy, myocardial infarction or "no structural abnormality" on the basis of clinical information. This could have included echocardiographic data, cardiac enzyme data and in some cases, a knowledge of intra cardiac pressures determined at cardiac catheterisation. Three cardiologists from different European countries reviewed the clinical data and agreed on the classification. The first set of results is based on this information.

It is also important to understand that ST-T abnormalities in isolation were mapped to NORMAL (or more strictly NO STRUCTURAL ABNORMALITY). Thus if a patient had an inferior myocardial infarction, and a program reported ST-T abnormalities suggestive of myocardial ischaemia, the

corresponding ECG would be regarded as false negative and placed in the normal/inferior MI box i.e. in the computer report of normal column in the row entry for inferior MI, where the percentage is 22.5%.

Some patients had multiple abnormalities such as left ventricular hypertrophy and inferior myocardial infarction. A complicated scoring system allowed for such combinations to be considered and some of the outputs therefore state that there was "additional mixing" in the CSE test centre. In general terms, this mixing gave credit for both abnormalities in such a patient being reported by a program. Thus, the use of mixing leads to an enhanced result or total accuracy.

Separately from this form of classification, which was not always acceptable to members of the CSE Working Group, was another classification produced by a set of 8 cardiologists. In turn, the accuracy of the cardiologists was assessed against the clinical data but, on the other hand, their interpretations were combined to produce a so-called "cardiologist interpretation" or “referee consensus” with respect to which programs were also evaluated. There was not much in the way of detail from this aspect of the CSE study presented in the original paper [1] in 1991 although outcomes were lodged separately with the publisher.

As might be expected, a completely different set of results is obtained when the cardiologist is used as the gold standard. Consider the following example by way of explanation.

A patient may well have LVH by echo but a normal ECG. With respect to the clinical database, a program reporting a normal ECG in this patient would be regarded as providing a false negative result. On the other hand, the cardiologists' combined opinion in this case would also be a normal ECG, similar to the computer. In this case, the program would be regarded as providing

the correct interpretation. Thus, the same ECG may be correct with respect to one gold standard an incorrect with respect to another.

In general terms, it can be seen that the program has a much higher agreement with cardiologists than with the clinical data. Part of the answer lies in the previous paragraph, e.g. 73.6% correct diagnoses of IMI v. the clinical data and 85.6% v. the cardiologists. Note also that in the group of 382 controls, the SEMIP agreed in 92.02% of cases with the cardiologists.

6.3.3 Definitions

TRUE POSITIVE (TP) = A correct report of an abnormality being present

TRUE NEGATIVE (TN) = A correct report of an abnormality being absent

FALSE POSITIVE (FP) = An incorrect report of an abnormality being present

FALSE NEGATIVE (FN) = An incorrect report of an abnormality being absent

SENSITIVITY (SENS) = $\frac{TP}{(TP + FN)}$

SPECIFICITY (SPEC) = $\frac{TN}{(TN + FP)}$

POSITIVE PREDICTIVE VALUE (PPV) = $\frac{TP}{(TP + FP)}$

NEGATIVE PREDICTIVE VALUE (NPV) = $\frac{TN}{(TN + FN)}$

PREVALENCE (PREV) = $\frac{\text{Number of occurrences of an abnormality}}{\text{Total number of cases in the database}}$

TOTAL ACCURACY = $\frac{\text{Total number of cases correctly classified}}{1220}$

6.3.4 CSE Abbreviations

NL = Normal

LVH	=	Left ventricular hypertrophy
RVH	=	Right ventricular hypertrophy
BVH	=	Right and left ventricular hypertrophy
MI	=	Myocardial infarction
AMI	=	Anterior myocardial infarction
IMI	=	Inferior myocardial infarction
MIX	=	Anterior and inferior myocardial infarction
VH+MI	=	Ventricular hypertrophy and myocardial infarction
OTHER	=	Cardiologist defined abnormality excluding above definitions

6.3.5 Results

Table 6-3-1 Results from an analysis of the CSE database in November 2015. In this case, the gold standard ("truth") was derived from the clinical data.

DIAGNOSTIC CATEGORY	SENSITIVITY (%)	SPECIFICITY (%)	PPV (%)	PREV
NL	91.1	75.8 [2]	63.2 [2]	382/1220
LVH	47.8	97.9	79.9	183/1220
RVH	43.6	99.1	68.6	55/1220
BVH	45.8	100.0	100.0	53/1220
AMI	75	97.9	85.3	170/1220
IMI	73.6	95.4	82.2	273/1220
MIX	54.5	99.4	85	73/1220
VH+MI	45.2	100	100.0	31/1220

Total Accuracy: 71.0% Partially correct: 71.0% (both on 1220 cases)

[1] The CSE database does not allow a meaningful interpretation of statistics on statements involving "possible" and "probable" qualifiers. They are taken into account in determining the sensitivity etc of the various diagnoses as the statement with the highest likelihood, where definite > probable > possible, is given most weight in handling a specific interpretation.

[2] Specificity and positive predictive value for 'NORMAL' should be interpreted carefully. A

report of 'NORMAL' in a case of 'MYOCARDIAL INFARCTION' or 'hypertrophy' contributes to decreased specificity for 'NORMAL' (even though the ECG may appear 'NORMAL'). In the CSE study, an ECG report stating only 'MYOCARDIAL ISCHEMIA' was mapped to 'NORMAL' even if the true answer was 'INFARCTION', thereby also contributing to decreased specificity for 'NORMAL'.

Table 6-3-2 Results from an analysis of the CSE database in November 2015. In this case, the gold standard ("truth") was derived from the clinical data. In this table, there is a more detailed breakdown of the reports, e.g. 2.6% of ECGs from individuals regarded as normal were reported by the program as LVH. On the other hand, 31.1% of ECGs from patients with clinical evidence of LVH were reported as normal.

PROG / TRUTH	NORM	LVH	RVH	BVH	AMI	IMI	MIX	VH+MI	OTHER	TOTAL	PREV
NL	**91.1**	2.6	0.0	0.0	2.1	3.4	0.8	0.0	0.0	100	382/1220
LVH	31.1	**47.8**	4.4	0.0	4.6	9.3	2.2	0.0	0.5	100	183/1220
RVH	40.9	1.8	**43.6**	0.0	1.8	4.5	0.0	0.0	7.3	100	55/1220
BVH	17.0	0.0	0.0	**45.8**	4.7	6.6	0.0	0.0	25.9	100	53/1220
AMI	17.9	1.5	0.6	0.0	**75.0**	4.4	0.0	0.0	0.6	100	170/1220
IMI	22.5	2.2	0.5	0.0	0.7	**73.6**	0.0	0.0	0.4	100	273/1220
MIX	16.4	3.4	0.7	0.0	0.0	0.0	**54.5**	0.0	25.0	100	73/1220
VH+MI	33.9	0.0	0.0	0.0	0.0	0.0	0.0	**45.2**	21.0	100	31/1220

Total Accuracy: 71.0% Partially correct: 71.0% (both on 1220 cases)

Table 6-3-3 Distributions of the CSE November 2015 computer interpretations with respect to the consensus opinion of the 8 cardiologists. Prevalence totals change compared to Tables 1 and 2 because the gold standard has changed.

PROG REF	NL	LVH	RVH	BVH	AMI	IMI	MIX	VH+MI	OTHER	TOTAL	PREV
NL	88.2	2.0	1.7	0.8	1.6	4.5	0.4	0.0	0.9	100.0	503/1220
LVH	21.5	62.3	4.2	0.0	3.1	6.2	1.7	0.0	1.0	100.0	144.5/1220
RVH	38.3	0.0	48.3	0.0	6.7	0.0	0.0	0.0	6.7	100.0	30/1220
BVH	10.3	5.2	8.6	63.8	0.0	3.4	0.0	0.0	8.6	100.0	29/1220
AMI	11.6	0.9	0.0	0.3	80.5	3.5	1.9	0.0	1.3	100.0	159/1220
IMI	10.1	2.2	0.9	0.0	0.4	85.6	0.4	0.0	0.4	100.0	228.5/1220
MIX	13.9	1.4	2.1	0.0	4.2	7.6	61.1	0.0	9.7	100.0	72/1220
VH+MI	22.7	2.3	0.0	0.0	2.3	6.8	0.0	61.4	4.5	100.0	22/1220
OTHER	17.1	0.0	0.0	12.5	1.6	6.3	3.1	1.6	57.8	100.0	32/1220
TOTAL	45.2	9.0	2.9	2.2	12.1	19.8	4.4	1.1	3.3	100.0	1220

Total agreement: 77.66%

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