Karlstad 2008-02-14

Till ansvariga personer inom området Eletrokardiografi.

Information gällande automatisk tolkning för Schiller Cardiovit AT-102

Vi har haft ett ärende angående den automatiska tolkningen i EKG-utrustningen Schiller Cardiovit AT-102 som inte tolkade 100 % korrekt. Vi vill därför ge er mer information om den automatiska tolkningsmjukvaran i utrustningen för att på så sätt förebygga att fler sådana ärenden uppstår.

Bifogat finner ni foldern "Statement of accuracy for analysing ECG unit". I denna folder hittar ni en hel del information om dels begränsningar i automatisk tolkning och dels en beskrivning av de tester och valideringar som tolkningsmjukvaran har genomgått.

Har ni ytterligare frågor var vänlig att kontakta din Aiolos-representant:

Aiolos Medical AB
Fjärrviksvägen 4
653 50 Karlstad
Telefon: 054-53 48 05
Fax: 054-53 47 87
Mail: air@aiolos.se

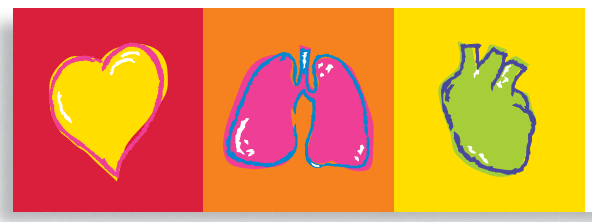
Med vänliga hälsningar
Aiolos Medical AB

Tim Hagström
Teknisk Chef

ECG Measurement and Interpretation

Statement of accuracy for analysing ECG units

Physicians Guide



The Art of Diagnostics

SCHILLER

www.schiller.ch

Art. no.: 2.530036 rev.: a

Sales and Service Information

The SCHILLER sales and service centre network is world-wide. For the address of your local distributor, contact your nearest SCHILLER subsidiary. In case of difficulty a complete list of all distributors and subsidiaries is provided on our internet site:

Address Headquarters

SCHILLER AG
Altgasse 68
CH-6341 Baar
Switzerland

Tel: +41 (0) 41 766 42 42
Fax: +41 (0) 41 761 08 80
E-Mail: sales@schiller.ch
www.schiller.ch

Article No: 2.530036 rev.: a
Issue date: 22.11.05

The Art of Diagnostics

SCHILLER
www.schiller.ch

Contents

Art. no.: 2.530036 rev.: a

Art. no.: 2.530036 rev.: a

1 Statement of Accuracy

This appendix is provided for all SCHILLER interpretive units to give support data for the physician for verification of the interpretation program. Also provided is specific information about the program and about computer interpretation programs in general.

The interpretation statements provided by the program, and the criteria used for the statements, are given in **ECG Measurement and Interpretation physicians guide (SCHILLER article number 2.510179)**. This is provided with every SCHILLER interpretive unit.

1.1 Limitations of Computer Interpretation

The SCHILLER ECG Interpretation program is designed to assist the physician in reading and evaluating an ECG printout. It was developed in cooperation with leading cardiologists and evolved over many years; extensive checking has been carried out using, among others, the CSE diagnostic data base (Common Standards for Quantitative Electrocardiology (concerted action Project II.1.1.2). 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 computerised 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.

The numerical and graphical results and any interpretation given must be examined with respect to the overall clinical condition of the patient and the general recorded data quality.

The ECG evaluation should always be systematic and conducted in a predetermined order. Before each ECG evaluation, verification that the recording was carried out correctly must be made. It should also be determined whether the patient received any heart-active medication (digitalis, beta-blockers, anti-arrhythmics, diuretics etc.) before the recording that could affect the recording. Always examine the ECG first, then read the interpretation statements. A computerised ECG analysis is not a substitute for over-reading by a qualified physician. Erroneous interpretations can occur.

Just as cardiologists may differ on interpretation, some disagreement between the computer report and the cardiologist may occur.

The ECG computer interprets the ECG in an isolated way. Therefore two recordings taken from the same patient within a brief period of time may show different interpretations. This situation is due to the ' borderline' effect in which one ECG barely fulfils a certain criteria, whilst in another recording this criteria is just missed (e.g the QRS duration in bundle branch block).

Art. no.: 2.530036 rev.: a

1.2 Interpretation Criteria

The interpretation criteria used by the SCHILLER program are identical to those utilized by electrocardiologists for several years. For the most part, decision tree algorithms lead to specific interpretations. For statements with varying degrees of certainty, a scoring scheme is adopted. This means that different ECG features contribute to a total score. A low score gives a lower probability to a statement than a measurement with a higher score.

The levels of confidence, the scoring scheme and the statements are provided in the SCHILLER book **ECG Measurement and Interpretation Program Physicians Guide** (also see para. 1.12 Diagnostic Interpretive Statements, page 10).

1.3 Development Process

Classical textbook criteria are sometimes rather imprecise and sometimes contradictory or incomplete. Therefore improvement of the criteria is always possible and necessary.

To do this in a systematic way, SCHILLER utilises several sets of ECG data stored on computer. The availability of this data allows for validation of the interpretation software. More than 50,000 ECGs were used for program development, while ca. 3,000 ECGs, validated by expert cardiologists, were used to measure program performance.

Art. no.: 2.530036 rev.: a

1.4 Interpretative Accuracy

The interpretive accuracy of the SCHILLER ECG interpretation program is demonstrated on the following database. This data was obtained on a test set of 618 ECG recordings. This particular test set consists of 3 groups of different patient population.

All ECGs were reviewed by different expert cardiologists. The figures show the agreement between the computer interpretation and these experts:

Group 1	• Number of patients	→ 242
	• Male	→ 139
	• Female	→ 104
	• Age range	→ 24-93 (mean 56 ±11)
	• Validated at:	→ University Hospital, Basel, Switzerland (cardiology department)
Group 2	• Number of patients	→ 126
	• Male	→ 126
	• Female	→ 0
	• Age range	→ 18-22 (mean 20 ± 1)
	• Validated at:	→ Swiss Military Service, Cantonal Hospital, Lucerne, Switzerland (cardiology department)
Group 3	• Number of patients	→ 250
	• Recorded / Validated	→ CSE Study (common standards for quantitative electrocardiology)
	• Validated at	→ University Hospital, Zurich, Switzerland, → Central Hospital, Karlstad, Sweden → University Hospital, Basel, Switzerland

Total number of validated ECGs: 618

Total number in agreement: 617

1.5 Study for the Identification of Acute Myocardial Infarction

A Study population of 448 patients (288 male, 160 female) suspected of acute myocardial infarction with onset of pain < 6 hours were screened as part of the PREMISE project (Prehospital Myocardial Infarction Treatment by Streptokinase), initiated in June 1992 and still ongoing at the department of Cardiology, District hospital Midden, Twente, Netherlands. Leader Dr. JJJ Bucx. The measurements were carried out using the SCHILLER Cardiovit AT-3 and the CK levels determined and monitored.

For an overview of these results see para. 2.5.1 Acute Myocardial Infarction Results, page 19.

Art. no.: 2.530036 rev.: a

1.6 Test Results

It is understood that good agreement is possible only for statements where cardiologists agree on the criteria.

Furthermore, it must be stated that the level of sensitivity and specificity may show lower figures if the reference is not an ECG based opinion of an expert cardiologist but an ECG independent diagnostic result such as ECHO-cardiographic measurements (i.e. left ventricular hypertrophy or myocardial infarction)

Such figures, however, simply reflect the limits of electrocardiology, while our aim is to demonstrate the adequacy of computer interpretation.

The interpretive accuracy of the SCHILLER interpretive program is demonstrated in the following paragraphs.

1.7 Measuring Wave Amplitudes

- International Standard IEC 60601-2-51 First edition 2003-02, (50.101.2).
- SCHILLER ECG measurement and Interpretation Program Physicians Guide (Page 13).

1.7.1 Signal Acquisition

SCHILLER ECG units acquire all 12 (15) leads simultaneously. A full recording of 10 seconds on all leads is retained in memory for processing and report printing.

1.7.2 Pattern Recognition

Within the average beat, the program detects beginning and end of the QRS complex, searches for the P wave and its onset and offset, and finally determines the end of the T wave. It is evident that there is only one (global), onset and offset for these waves in all 12 (15) leads and it is the earliest and the latest electrical activity in any lead.

1.7.3 Measurements

Intervals are calculated based on the wave onset and offset. Next, the individual time duration and amplitudes in all leads are determined in addition to the electrical axes in the frontal plane for all waves.

The way that the wave amplitudes are measured are detailed in the ECG Measurement and Interpretation Program Physicians Guide page 7 et seq.

(Also see para. 2.3 Amplitude Measurement Calibration, page 17).

1.8 Isoelectric Segments within the ECG

International Standard IEC 60601-2-51 First edition 2003-02, (50.101.3) and (50.101.4).

Isoelectric segments are excluded from the corresponding lead arc duration measurements (Q, R, S waves). Isoelectric parts (I-wave) are also excluded in the duration measurement of the respective adjacent waveform.

Art. no.: 2.530036 rev.: a

1.9 Minimum Wave Acceptance

The criteria applied in the equipment for acceptance of minimum waveforms is as follows:

- Amplitude ≥ 20 µVolts
- Duration ≥ 6 ms

The disclosed changes in measurements caused by noise on ECGs is as follows:

Global Measurement	Type of added noise	Mean (ms)	Standard Dev. (ms)
P duration	High Frequency	8.9	6.3
P duration	Mains Frequency 50Hz	-2.7	3.4
P duration	Mains Frequency 60Hz	-3.7	9.5
P duration	Base Line	-1.1	17.5
QRS duration	High Frequency	6.6	8.9
QRS duration	Mains Frequency 50Hz	-0.2	1.5
QRS duration	Mains Frequency 60Hz	-0.1	2.2
QRS duration	Base Line	0.0	1.5
QT Interval	High Frequency	8.1	10.1
QT Interval	Line Frequency	0.6	1.4
QT Interval	Base Line	0.1	2.3
QT Interval	Base Line	-0.4	2.2

1.10 Intended Use

International Standard IEC 60601-2-51 First edition 2003-02, (50.102.2).

- ▲ SCHILLER ECG units are designed for the recording, analysis and evaluation of ECG Recordings. Recordings can be used as a diagnostic aid for heart function and heart conditions and can be used for all patients of both sexes, all races, and all ages.
- ▲ The diagnostic applications for which the results are intended is in the diagnosis of cardiac abnormalities in the general population, detecting acute myocardial ischemia, and infarction in chest pain patients, etc.
- ▲ Intended for use in hospitals, cardiological units, out-patient clinical units, and general physicians offices.
- ▲ Low sensitivity settings will suppress certain non-specific ECG diagnoses; this can be used for screening high-specificity program intended for low-risk patients. The high sensitivity setting is used for detecting cardiac abnormalities in all and high risk patients.
- ▲ There is no danger for patients with pacemaker.
- ▲ The unit must be operated in accordance with the specified technical data.

Art. no.: 2.530036 rev.: a

1.11 Accuracy Measures for Diagnostic Statements

International Standard IEC 60601-2-51 First edition 2003-02, (50.102.3.1).

The ECGs of normals had the diagnosis verified by standard clinical methods to establish the absence of disease, particularly heart disease. These methods include:

- normal physical examination
- absence of cardiac symptoms
- absence of history of any known disease with a known influence on cardiac function or morphology.

The ECGs of heart disease patients used for validation of the database contour for testing the accuracy of the interpretation has also had the diagnosis verified by a confirmatory non-ECG means as follows:

- Ultrasound
- SPECT
- Szintignaphy
- Coronary angiography
- Determination of CPK and myoglobin
- etc.

The number of ECGs tested in each diagnostic category, group statistics (mean standard deviation, percentages, etc.) of patient demographics such as age, gender, and race, etc. are given in the following result tables.

1.12 Diagnostic Interpretive Statements

- International Standard IEC 60601-2-51 First edition 2003-02, (50.102.3).
- SCHILLER ECG measurement and Interpretation Program Physicians Guide (Page 16 and 17).

The following accuracy measures for the diagnostic interpretative statements are included:

- sensitivity, specificity, and positive predictive value for all the major diagnostic interpretative statements.
- sensitivity, specificity and positive predictive values for more detailed diagnostic interpretative statements.

Art. no.: 2.530036 rev.: a

For the purpose of this document, four key accuracy measures are explained following.

The true diagnosis for a patient is known (**truth**). The ECG interpretation (classification) is called **Test**. The following designations are applied to characterise the performance of a test (respectively of an ECG interpretation system).

- a **Normal** correctly classified as **Normal** is called **True normal (TN)**
- a **Normal** incorrectly classified as **Pathologic** is called **False pathologic (FP)**
- a **Pathologic** incorrectly classified as **Normal** is called **False normal (FN)**
- a **Pathologic** correctly classified as **Pathologic** is called **True pathologic (TP)**

Reference	**Test**	
	Normal	Pathologic
Normal	TN	FP
Pathologic	FN	TP

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

Sensitivity

Probability that a **True pathologic** would be classified as a **Pathologic**.

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

Specificity

Probability that a **True normal** would be classified as **Normal**.

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

Positive predictive value

Probability that a classified **Pathologic** is classified a **True pathologic**.

$$\text{Positive Predicted Value} = \frac{TP}{TP + FP} \times 100\%$$

- The term **Sensitivity** here and in related requirements, stands for ECG interpretation sensitivity.
- Note that the explanation above can be made general by substituting **Negative** for **Normal** and **Positive** for **Pathologic**.

Art. no.: 2.530036 rev.: a

2 Test Results

2.1 Test Data Base Comparison

2.1.1 Summary of the Test Data Base Comparison

The following results were obtained:

Statement	True positive	False Positive	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)
Rhythm Statements					
Sinus Rhythm	1677	0	99	100	100
Abnormal Rhythm	54/54	5	100	99	92
Premature atrial contraction	28/28	3	100	99	90
Premature ventricular contraction	29/32	0	91	100	100
Atrial fibrillation	138	14	98	99	90
Conduction Defects					
Right bundle branch block (RBBB)	33/37	0	92	100	100
Left bundle branch block (RBBB)	29/30	0	97	100	100
Infarction					
anterior	105/109	4	97	100	97
inferior	63/66	13	95	98	83
Hypertrophy					
Left ventricular hypertrophy (LVH)	42/43	1	98	100	98
Overall Performance	393/400	14	98	94	97

Art. no.: 2.530036 rev.: a

2.1.2 Test Data Base Comparison - Detailed

Diagnosis	Sub Category	True Neg.	False Neg.	True Pos.	False Pos.	Sens. (%)	Spec. (%)	P.Red. (%)	N.p.v (%)	Prev.
Rhythm										
Supraventricular	Extra systole	587	0	28	0	100	99.5	90.3	100	0.045
	Bigeminy	616	0	28	3	100	100	100	100	0.003
	Trigeminy	-	-	-	-	-	-	-	0	-
	Atr. escape beats	-	-	-	-					0
Ventricular	Extra systole	586	3	29	0	90.6	100	100	99.4	0.052
	Bigeminy	617	0	1	0	100	100	100	100	0.002
Ventricular escape beats		614	0	4	0	100	100	100	100	0.006
Aberr. ventr. cond		-	-	-	-					0
Sinus Rhythm		126	5	487	0	99	100	100	96.2	0.746
Sinus arrhythmia		594	0	23	1	100	100	99.8	95.8	0.037
Sinus Bradycardia		599	0	19	0	100	100	100	100	0.031
Sinus Tachycardia		588	0	30	0	100	100	100	100	0.049
Rhythm 2										
Supraventricular Tachycardia		617	0	1	0	100	100	100	100	0.002
Nodal rhythm		617	0	1	0	100	100	100	100	0.002
Reg. rh. no P found		617	0	0	1	100	99.8	0	100	0.002
idioventr. rhythm		-	-	-	-	-	-	-	-	0
Ventricular Tachycardia		-	-	-	-	-	-	-	-	0
Atr. fib / flutter		583	1	31	3	97	99.7	94.1	99.6	0.053
Atr. fib / rapid evnt. resp.		602	0	13	3	100	99.5	81.2	100	0.021
Pacemaker		613	0	11	1	100	99.8	80	100	0.006
Electrical Axis										
Abn. left axis dev.		545	0	73	0	100	100	100	100	0.118
Leftward axis		535	0	83	0	100	100	100	100	0.134
Rightward axis		604	0	14	0	100	100	100	100	0.023
Abn. right axis dev.		606	0	12	0	100	100	100	100	0.019
Abn. right sup. axis dev.		609	0	9	0	100	100	100	100	0.015
Indetern. axis		608	0	10	0	100	100	100	100	0.016
Atrial Activity										
Left atrial abn.		591	3	24	0	89	100	100	99.5	0.044
Poss. left atrial enlargement		605	0	10	3	100	99.5	76.9	100	0.016
Right atrial enlargement		611	0	7	0	100	100	100	100	0.011
Biatrial enlargement		617	0	1	0	100	100	100	100	0.002
Prolonged PR		590	1	25	2	96.2	99.7	92.6	99.8	0.042
ECG Voltages										
Low limb lead voltage		592	0	26	0	100	100	100	100	0.042
Low Voltage		-	-	-	-					0

Art. no.: 2.530036 rev.: a

Diagnosis	Sub Category	True Neg.	False Neg.	True Pos.	False Pos.	Sens. (%)	Spec. (%)	P.Red. (%)	N.p.v (%)	Prev.
Blocks										
RBBB		582	3	33	0	92	100	100	99.5	0.058
Incomplete RBBB		589	4	25	0	86.2	100	100	99.3	0.047
LBBB		589	1	28	0	96.6	100	100	99.8	0.047
Incomplete LBBB		616	0	2	0	100	100	100	100	0.003
Non specific AV Block		595	0	20	3	100	99.5	87	100	0.032
LAFB		612	1	26	0	96.3	100	100	99.8	0.044
LPFB		612	1	5	0	83.3	100	100	99.8	0.070
Bifasc. Block		604	1	13	0	92.9	100	100	99.8	0.023
QRS Abnormalities										
anteroseptal		606	1	10	1	91	99.8	91	98.8	0.018
anterolateral		615	0	3	0	100	100	100	100	0.005
lateral		611	0	7	0	100	100	100	100	0.008
inferior		611	0	7	1	100	100	100	100	0.011
Myocardial Infarctions										
septal		617	0	1	0	100	100	100	100	0.002
anteroseptal		580	2	36	0	94.7	100	100	99.7	0.060
anterior		599	0	19	0	100	100	100	100	0.030
anterolateral		611	0	6	1	100	99.8	85.7	100	0.010
lateral		610	0	8	0	100	100	100	100	0.013
high lateral		612	0	5	1	100	99.8	83.3	100	0.008
inferolateral		617	0	1	0	100	100	100	100	0.002
inferior		539	3	62	13	95.4	97.6	82.7	99.4	0.105
ST-T Morphology										
ST abn., ant. sept.		618	-	-	-	-	-			0
ST abn., ant.		612	1	5	0	83	100	100	99.8	0.010
ST abn., ant. lat.		618	-	-	-	-				0
ST abn., lat		617	0	1	0	100	100	100	100	0.002
ST abn., inf.		616	0	2	0	100	100	100	100	0.003
Non specific ST depression		616	0	2	0	100	100	100	100	0.003
ST-T abn., ant. sept ischemia or strain		616	-	-	-					0
ST-T abn., ant. ischemia or strain		608	0	10	0	100	100	100	100	0.016
ST-T abn., ant. lat. ischemia or strain		597	0	21	0	100	100	100	100	0.034
ST-T abn., lat ischemia or strain		599	0	19	0	100	100	100	100	0.030
ST-T abn., inf. ischemia or strain		598	0	20	0	100	100	100	100	0.032
ST-T abn., recent myo/peric. damage		614	0	4	0	100	100	100	100	0.006

Art. no.: 2.530036 rev.: a

Diagnosis	Sub Category	True Neg.	False Neg.	True Pos.	False Pos.	Sens. (%)	Spec. (%)	P.Red. (%)	N.p.v (%)	Prev.
ST-T Morphology 2; QT Interval										
Non Specific ST abn., elevation		617	1	0	0	0	100	100	0	0.002
T abnorm., ant. sept.		617	0	1	0	100	100	100	100	0.002
T abnorm., ant.		601	0	17	0	100	100	100	100	0.028
T abnorm., ant. lat.		616	0	2	0	100	100	100	100	0.003
T abnorm., lat.		590	0	24	4	100	99.3	85.7	100	0.039
T abnorm., inf.		608	1	9	0	90	100	100	99.8	0.016
Non specific T Abnormality		594	2	22	0	92	100	100	99.7	0.039
Prolonged QT		603	0	15	0	100	100	100	100	0.024
Hypertrophy										
LVH	definitive	606	0	12	0	100	100	100	100	0.020
	consider	599	0	18	1	100	100	100	100	0.003
	ampl. criteria	616	0	2	0	100	100	100	100	0.003
	mod. am-pl.criteria	617	1	10	0	91	100	100	99.8	0.016
RVH	definitive	-	-	-	-					0
	consider	611	2	5	0	71	100	100	99.7	0.008
Miscellaneous Statements										
S1S2S3 pattern		618	-	-	-	-	-	-	-	0
WPW type A		616	0	2	0	100	100	100	100	0.003
WPW type B consider		616	0	2	0	100	100	100	100	0.003
RS trans. zone in V to the right		612	0	6	0	100	100	100	100	0.010
RS trans. zone in V to the left		613	0	5	0	100	100	100	100	0.008
poss. reversal of arm leads		617	0	1	0	100	100	100	100	0.002
abnormal ECG		204	7	393	14	98.25	93.58	96.68	0.6472	

Art. no.: 2.530036 rev.: a

2.2 Database

International Standard IEC 60601-2-51 First edition 2003-02, (50.102.4.1 and 50.102.1.2).

The electrocardiograms for testing the accuracy of rhythm statements were representative of the target population. The database contained:

- 1692 ECGs with sinus rhythms (normal sinus rhythm, sinus bradycardia, sinus tachycardia).
- 138 ECGs with atrial fibrillation.

ECGs of other major rhythm categories (e.g. atrial flutter, atrial tachycardia, paced rhythms, junctional rhythms, ventricular rhythms, etc.) were also included in this database. Similarly, degree atrio-ventricular (AV) block, second degree AV blocks, AV dissociation, premature atrial complexes, etc.), were also included.

The true rhythm of these ECGs (gold standard used to compare the accuracy of the analysing electrocardiograph) was confirmed by at least two trained cardiologists specialised in rhythm disorders after carefully reviewing rhythm from an ECG plot of at least two simultaneously plotted LEADS showing the atrial activity (e.g.: LEAD II and LEAD V1) for at least 10 s.

International Standard IEC 60601-2-51 First edition 2003-02, (50.102.4.2)

Full results the tests taken are available on request. (Also see para. 2.5.1 Acute Myocardial Infarction Results, page 19, and see para. 1.12 Diagnostic Interpretive Statements, page 10).

Art. no.: 2.530036 rev.: a

2.3 Amplitude Measurement Calibration

- International Standard IEC 60601-2-51 First edition 2003-02, (51.103.2)
- Details of the CTS test atlas are given in International Standard IEC 60601-2-51 First edition 2003-02, (Annex II).

The amplitude must be checked and calibrated against a reference value every two years. The factory reference calibration table is given in the test results (see para. 2.5.3 Reference and Actual Measured Value, page 22).

Amplitude measurements

Amplitude measurements given for P, Q, R, S, ST and T must not deviate from the reference values by more than ±25 µV for amplitudes 500 µV or by more than 5 % for amplitudes >500 µV.

The calibration and analytical ECGs listed in IEC 60601-2-51 Table HH.1 of Annex HH must be fed into the electrocardiograph and recorded for at least 10s. The differences between the amplitude measurements and the reference values for LEADS I, II, V1, ..., V6 are to be determined for all P-, Q-,R-, S-, ST- and T-waveforms.

The difference for each amplitude measurement must not deviate from the reference value by more than ±25 µV for reference values 500 µV, or by more than 5 % or ±40 µV for reference values >500 µV.

The minimum time that the unit is guaranteed to perform according to the interpretation statements and measurement results is 2 years.

International Standard IEC 60601-2-51 First edition 2003-02, (50.102.4.2)

Art. no.: 2.530036 rev.: a

2.4 Pacemaker Signal Distortion

International Standard IEC 60601-2-51 First edition 2003-02, (51.109.1).

The function of SCHILLER devices is not adversely affected by the operation of a pacemaker.

Compliance has been proved as follows:

A pulse of amplitude 200 mV peak with a rise time less than 100 µs and a duration of 1 ms at a repetition rate of 100 pulses/minute summed with a 1 mV peak to valley 40 Hz sinusoidal signal were applied to the input of the unit. The time required for the sinusoidal signal on the ECG record to recover to 70 % of its initial value (1 mV peak to valley) did not exceed 50 ms. During the test the maximum cumulative shift of the base line did not exceed 10 mm in a period of 10 s. The peak to valley amplitude of the test sinusoidal signal measured on the ECG record in the presence of pulses does did not differ more than 1 mm (10 %) from the original test sinusoidal signal measured in the absence of pulses.

To pass the test the filter setting was set to **Normal sensitivity**.

	Original test sinusoidal waveform	ECG record in the presence of pulses
Amplitude	200 mV	200mV
Duration	1 ms	1 ms
Baseline shift	1 mm	1.2 mm

International Standard IEC 60601-2-51 First edition 2003-02, (50.102.4.2)

The minimum time that the unit is guaranteed to perform according to the aforementioned interpretation statements and measurement results is 2 years.

Art. no.: 2.530036 rev.: a

2.5 Result Tables

Full results tables are available on request. The following tables give a summary of the results and other data.

2.5.1 Acute Myocardial Infarction Results

Of the 448 patients (228 male, 160 female), 94 had an acute Myocardial infarction as defined by CK levels.

	Not acute MI by CK levels	Acute MI by CK levels
Not acute MI ECG	352	31
Acute MI ECG	2	63
Sensitivity	0.67	
Specificity	0.99	
Positive predict. value	0.97	
Negative predict. value	0.92	

For the Chi square test for confidence limits the resulting confidence limit is <0.01.

Of the two patients with false positive results, one suffered from hyperkalemia, the other had a pacemaker.

Art. no.: 2.530036 rev.: a

2.5.2 SCHILLER Program Performance

Schiller versus Combined Referees

The following tables gives the agreement on 1220 cases (CSE) by the SCHILLER program versus the combined referees (cardiologists) in percent (%).

Program	normal	LVH	RVH	BVH	AMI	IMI	MIX	VH+MI	other	TOTAL
Referee										
normal	89.3	1.6	1.5	0.7	1.6	3.4	0.2	0	1.7	100.0
LVH	18.7	66.1	0	3.5	2.4	6.2	2.4	0	0.7	100.0
RVH	26.7	0	56.7	3.5	3.3	0	1.7	0	8.3	100.0
BVH	10.3	3.4	1.7	70.7	3.4	0	1.7	0	8.6	100.0
AMI	5.0	5.0	0	0.9	78.6	0.6	9.4	0	0.3	100.0
IMI	7.9	1.3	0.2	0.2	0.4	88.2	1.8	0	0	100.0
MIX	3.5	3.1	0	0	3.5	3.5	78.5	0	6.3	100.0
VH+MI	15.9	2.3	0	0	2,3	2,3	4.5	65.9	6.8	100.0
other	3.1	4.7	0	1.6	4.7	0	1.6	7.8	76.6	100.0
TOTAL	42.6	9.8	2.1	2.7	11.8	19.1	6.8	1.4	3.7	100.0

Condition	Sensitivity	Positive Predictive value	Negative Predictive value
normal	92.4	98.4	22.2
LVH	66.4	93.1	55.3
RVH	45.2	78.1	61.1
BVH	72.3	81.0	79.7
AMI	90.6	97.8	61.0
IMI	88.0	93.9	64.7
MIX	77.9	95.7	53.7
VH+MI	75.7	93.3	71.9
HYP	675.6	79.5	71.4
MI	89.2	96.4	61.5
Abnormal	80.3	93.9	62

Total agreement: 80.29% on 1220 cases.

Art. no.: 2.530036 rev.: a

Schiller versus Truth (Gold Standard)

The following tables give SCHILLER program versus 'truth' (diagnostic results based on golden standards) in percent (%).

Program	normal	LVH	RVH	BVH	AMI	IMI	MIX	VH+MI	other	TOTAL
Truth										
normal	90.6	2.1	0.8	1.0	2.1	2.5	0	0	0.8	100.0
LVH	32.8	48.6	0	0.5	6.8	7.4	1.6	0	2.2	100.0
RVH	43.6	5.5	29.1	12.7	5.5	1.8	0	0	1.8	100.0
BVH	20.8	0	0	39.2	11.3	0.9	0	0	27.8	100.0
AMI	11.8	3.8	9	9	79.4	4.4	0	0	0.6	100.0
IMI	20.1	1.6	0.9	0.4	2.5	73.4	0	0	1.1	100.0
MIX	6.8	4.8	1.4	0	0	0	59.6	0	27.4	100.0
VH+MI	22.6	0	0	0	0	0	0	48.45	29.0	100.0

Condition	Sensitivity	Positive Predictive value	Negative Predictive value
normal	90.6	65.5	94.8
LVH	48.6	77.7	91.5
RVH	29.1	71.6	96.7
BVH	39.2	61.5	97.3
AMI	79.4	78.8	96.7
IMI	73.4	86.0	92.6
MIX	59.6	93.5	97.5
VH+MI	48.4	100.0	98.7
HYP	47.0	80.2	86.6
MI	74.6	87.7	81.6

Total accuracy: 70.9% on 1220 cases; accuracy for 1063 cases only (without MIX, VH+MI, BVH): 74%

Art. no.: 2.530036 rev.: a

2.5.3 Reference and Actual Measured Value

Confidence was established by using all the calibration waveforms in International Standard IEC 60601-2-51 First edition 2003-02. The following is a sample result measured using reference wave CAL20160:

	Reference Value (CAL20160)						Measured Value					
Global Interval (ms)												
P duration	116						118					
QRS duration	56						60					
Heart rate	60						60					
P-Q (P-R) interval	178						180					
Q-T Interval	354						352					
Abtastrate	500											
	I	**II**	**III**	**aVR**	**aVL**	**aVF**	**I**	**II**	**III**	**aVR**	**aVL**	**aVF**
Time Duration (ms) / Amplitude (µVolts)												
P1 Duration	116	116	0	116	112	112	116	116	0	116	112	112
P1 Amplitude	150	150	0	-150	75	75	150	150	0	-150	80	80
P2 Duration	0	0	0	0	0	0	0	0	0	0	0	0
P2 Amplitude	0	0	0	0	0	0	0	0	0	0	0	0
Q Duration	0	0	0	56	0	0	0	0	0	60	0	0
Q Amplitude	0	0	0	-2000	0	0	0	0	0	-2030	0	0
R Duration	56	56	0	-	56	56	58	58	0	-	56	56
R Amplitude	2000	2000	0	0	1000	1000	2030	2030	0	0	1020	1020
S Duration	0	0	0	0	0	0	0	0	0	0	0	0
S Amplitude	0	0	0	0	0	0	0	0	0	0	0	0
QRS Duration	56	56	0	56	56	56	60	60	0	60	60	60
ST-T-Measured value, J-Point = QRS End												
ST-20-Amplitude	200	200	0	-200	100	100	180	180	0	-180	90	90
ST-40-Amplitude	200	200	0	-200	100	100	180	180	0	-180	90	90
ST-60-Amplitude	200	200	0	-200	100	100	180	180	0	-180	90	90
ST-80-Amplitude	200	200	0	-200	100	100	180	180	0	-180	90	90
T-Amplitude	400	400	0	-400	200	200	380	360	0	-380	190	190

Art. no.: 2.530036 rev.: a

	Reference Value (CAL20160)						Measured Value					
	V1	V2	V3	V4	V5	V6	V1	V2	V3	V4	V5	V6
Time Duration (ms) / Amplitude (µVolts)												
P1 Duration	116	116	116	116	116	116	116	116	116	116	116	116
P1 Amplitude	150	150	150	150	150	150	150	150	150	150	150	150
P2 Duration	0	0	0	0	0	0	0	0	0	0	0	0
P2 Amplitude	0	0	0	0	0	0	0	0	0	0	0	0
Q Duration	0	0	0	0	0	0	0	0	0	0	0	0
Q Amplitude	0	0	0	0	0	0	0	0	0	0	0	0
R Duration	56	56	56	56	56	56	58	58	58	58	58	58
R Amplitude	2000	2000	2000	2000	2000	2000	2030	2040	2050	2050	2050	2070
S Duration	0	0	0	0	0	0	0	0	0	0	0	0
S Amplitude	0	0	0	0	0	0	-0	0	0	0	0	0
QRS Duration	56	56	56	56	56	56	60	60	60	60	60	60
ST-T-Measured value, J-Point = QRS End												
ST-20-Amplitude	200	200	200	200	200	200	180	180	180	180	180	190
ST-40-Amplitude	200	200	200	200	200	200	180	180	180	180	180	190
ST-60-Amplitude	200	200	200	200	200	200	180	180	180	180	180	190
ST-80-Amplitude	200	200	200	200	200	200	180	180	180	180	180	190
T-Amplitude	400	400	400	400	400	400	380	380	380	380	390	390

Art. no.: 2.530036 rev.: a

Art. no.: 2.530036 rev.: a