

# 2004 Report of portable electrocardiograph clinical evaluation (Kyoto Senbai Hospital)

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## 【Purpose】

1. To evaluate the accuracy and usefulness of the portable electrocardiograph HCG-801WS waveforms from the following point of views.
  - Are waveforms of the HCG-801 WS identical to those of the 12-lead electrocardiogram?
  - Do waveforms measured in an expected condition (daily activity) have sufficient accuracy for screening?
  - Do the messages properly indicate analysis results of electrocardiograph waveforms?
2. To evaluate the safety of the portable electrocardiograph HCG-801WS from a point of view of biocompatibility.

## 【Conclusion】

### 1 .Usefulness

Usefulness was found in both the accuracy of waveforms and the accuracy of messages.

Evaluative criterion		Sensitivity	Specificity	Number of subjects	Number of data
Waveform	Reference concordance rates (*)	88%	100%	32	32
	Readable rates	100%	75%	24	452
Message	Concordance rates	85%	92%	56	616

\* Reference concordance rates are based on data obtained in the V4 region.

- Reference concordance rates of waveforms (comparison with the 12-lead)
  - When measured in the V4 region, amplitudes R and T of the 12-lead had high correlations with those of the WS waveforms.
  - When measured in the V5 region, amplitude R of the WS waveforms was smaller and amplitude T of the WS waveforms was larger than those of the 12-lead.
  - By physician 's inspection, data obtained in the V4 or lower V4 region had high concordance rates of more than 90%. Data obtained in the other regions (V5, V2, I) also had concordance rates of more than 80%.

- Readable rates of waveforms (data accuracy when measured during daily activity)  
 Among 452 measurements, about 95% were analyzable. On almost all subjects, more than 90% of the measurements were readable.  
 Specificity was 75% with 18 true negative data and 6 false positive data. 25% included the cases of unsuccessful measurement and analysis failure of data due to many noises. This will not affect the usefulness as a screening device.
- Message concordance rates  
 The concordance rate between waveforms and messages was about 89%. The main factor of the discordance was "false positive" findings of ventricular premature conduction and premature atrial contraction resulting from the disturbance of heart pulses and rhythm. As a single artifact (ex. twitching of a body) can make noise judgment difficult, leading to "false positive" findings, patients should be advised to pay attention to their posture during the measurement or restart the measurement.

## 2.Safety

Although the electrodes use stainless which has biocompatibility, allergic reactions or side effects to the electrodes did not occur, indicating the safety during the clinical evaluation.

### 【Method】

Measurements were performed by the WS in the hospital (hereto after measurement in the hospital) and in daily activities - with the WS brought home - (hereto after measurement at home). The results were compared to the measurements obtained by the 12-lead based on the protocols below.

#### Measurement in the hospital

Subjects 32 patients who regularly visit the Kyoto Senbai Hospital (12 males, 20 females, age: 48-90)

Period of measurement : 17.May.2004 - 31.May.2004

Region of interest :

WS (1-lead) .. five positions (Right hand - V4, Right hand - V5, Right hand - V2, Right hand - Lower V5, Right hand - Left hand)

12-lead electrocardiograph (12-lead) .. references

Measurement procedure :

The measurement was performed simultaneously by the 12-lead electrocardiograph and the WS at a resting state.

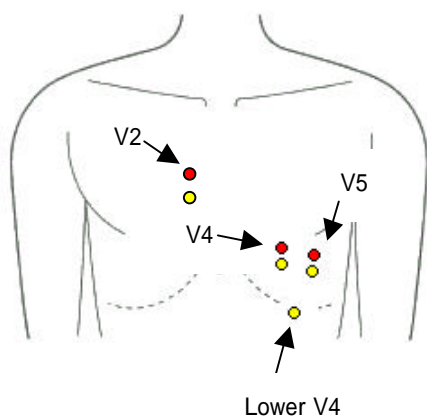
The 12-lead electrocardiogram was taken at a sitting position in normal style.

With the WS measurement, subjects placed the prototype on the regions of the chest and the left hand with their right hand.

### Order of the measurement

	Condition	Time
	Attaching 12-lead electrodes	2 minutes
	Sitting, resting position	4 minutes (including the time to change electrodes)
1	·12-lead + prototype in the lower V5 region	45 seconds
2	·12-lead + prototype in the V4 region	45 seconds
3	·12-lead + prototype in the V5 region	45 seconds
4	·12-lead + prototype in the V2 region	45 seconds
5	·12-lead + prototype in the left hand	45 seconds
	Total	about 10 minutes

### Comparison of the 12-lead and 1-lead



V4,V5,V2 •• References of the 12-lead  
 Lower V4 (L-V4) •• Intercostal directly below the V4 position

- Positions of 12-lead reference electrodes
- Positions of 1-lead electrodes

Note Measurement with the 12-lead (V4 prototype) was performed with the prototype placed directly below the V4 lead.

Measurements with the 12-lead (V5 prototype, V2 prototype) were also performed with the prototype placed below the V5 and the V2 positions.

## Measurement at home

Subjects 25 Kyoto Senbai Hospital staff members and patients (7 males, 18 females)

Period of measurement : 25.May.2004 - 7.Sep.2004

Region of interest :

WS (1-lead) ··Right hand - V4

Measurement procedure :

Measurements were performed in the right hand - V4 position with the WS.

We taught patients how to perform measurements, and they brought the WS home.

Patients were told to perform measurements once each in the morning and the evening and when they felt palpitation or chest pain. Measurements beside these could be taken voluntarily.

Patients recorded the status and appearances during the measurement on the notebook.

The study period was 4-9 days.

## Evaluation methods

### Measurement in the hospital

- Compare waveforms of the reference (12-lead electrocardiogram) and the WS in each region of interest to calculate reference concordance rates.
- Review correlations of concordance rates in amplitude R, amplitude T, and QRS width. Physicians determine identity between waveforms of the 12-lead and the WS.
- Physicians inspect validity of displayed messages (not including right hand - V2, right hand - left hand lead) and waveforms of the WS to calculate concordance rates.

### Measurement at home

- Determine if recorded waveforms are readable to calculate readable rates
- Judge will be made based on the readable levels set by physicians.
- Physicians inspect validity of displayed messages and waveforms of the WS to calculate concordance rates.
- Measurement statuses on the records should be referred to.

Calculation method of sensitivity/specificity

As for readable rates/concordance rates, sensitivity and specificity were calculated using the following formula. The number of a-d data are listed on the quartile table below.

$$\text{Sensitivity} = a / ( a + c )$$

$$\text{Specificity} = d / ( b + d )$$

Quartile table

		A	
		A-1	A-2
B	B-1	a	b
	B-2	c	d

\*a, b, c, and d indicate the number of measurements for true positive, false positive, false negative, and true negative, respectively.

For each item of the quartile table, refer to the table below.

	A	A-1	A-2
Reference concordance rate	12-lead	Abnormal	Normal
Readable rate	Physician 's inspection	Readable	Unreadable
Message concordance rate	Physician 's inspection	Abnormal	Normal

	B	B-1	B-2
Reference concordance rate	WS	Abnormal	Normal
Readable rate	WS	Analyzable	Unanalyzable
Message concordance rate	Algorithm	Abnormal	Normal

## Results】

### Result 1 Measurement in the hospital (comparison with 12-lead electrocardiographs)

The following analysis was performed on 32 examples.

Amplitude R, amplitude T, QRS width of the 12-lead and the WS were measured in the V2, V4, and V5 regions to observe correlations.

#### Amplitude R

Here are correlations between amplitude R data of the 12-lead and those of the WS in the V2, V4, and V5 region.

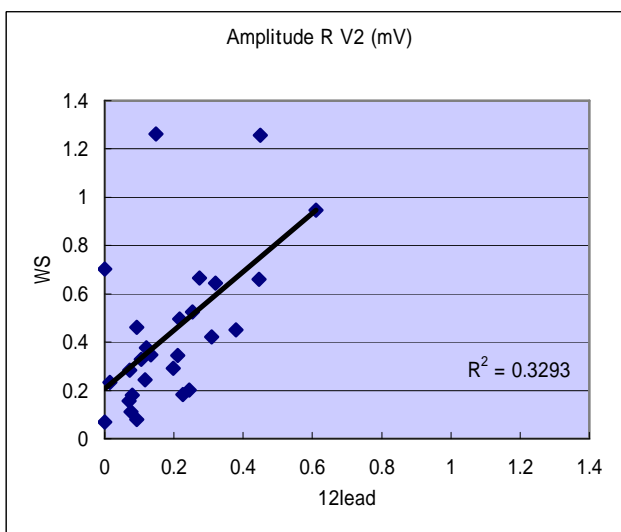


Fig.1-1 Amplitude R in the V2 region

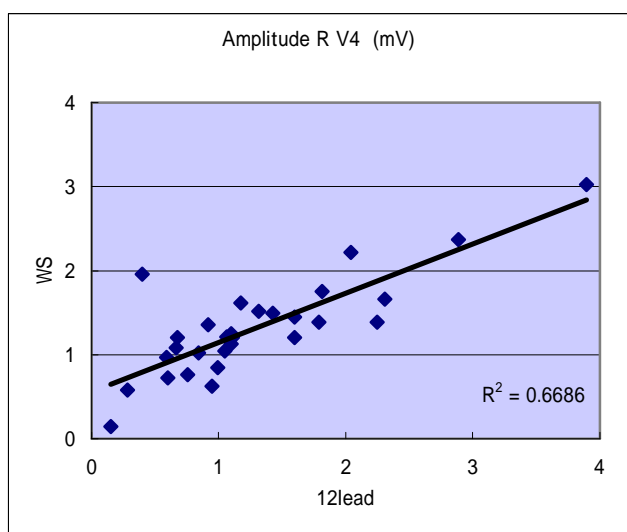


Fig.1-2 Amplitude R in the V4 region

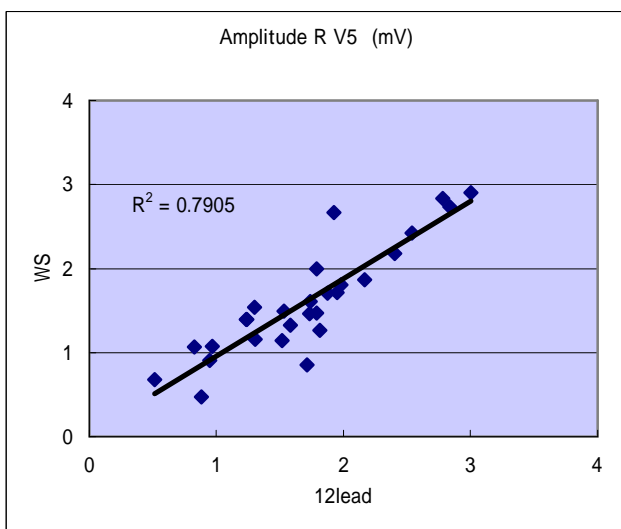


Fig.1-3 Amplitude R in the V5 region

Average amplitude R widths are shown here.

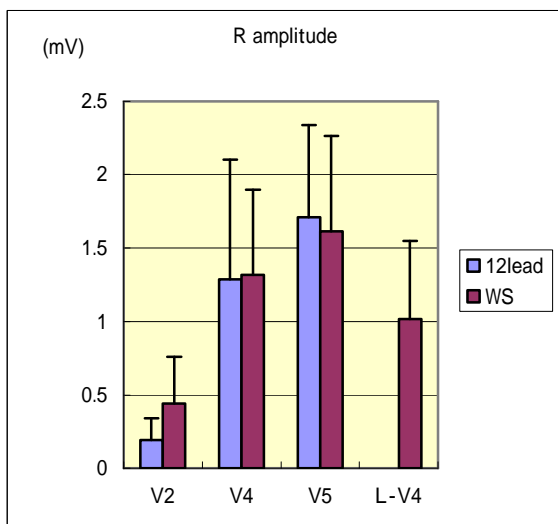


Fig.1-4 Average amplitude R widths and standard deviations in each region

Correlations are high in the V4, V5 region, and low in the V2 region. On average, amplitude R data of the WS are significantly higher.

In the V5 region, amplitude R data of the 12-lead are significantly higher than those of the WS ( $p < 0.05$ ).

#### Amplitude T

Here are correlations between amplitude T data of the 12-lead and those of the WS in the V2, V4, and V5 region.

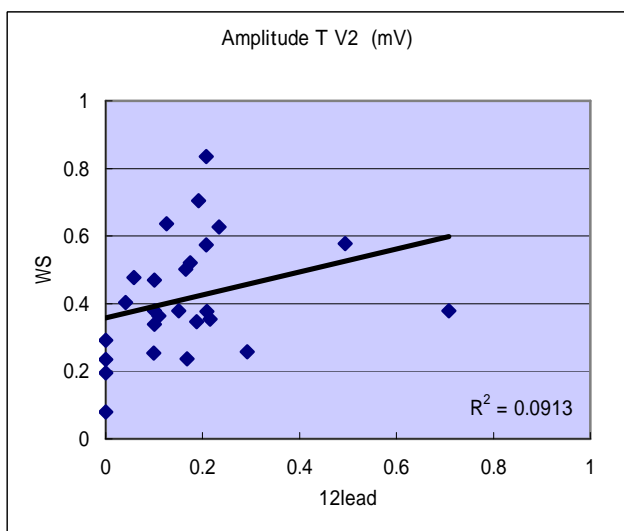


Fig.1-5 Amplitude T in the V2 region

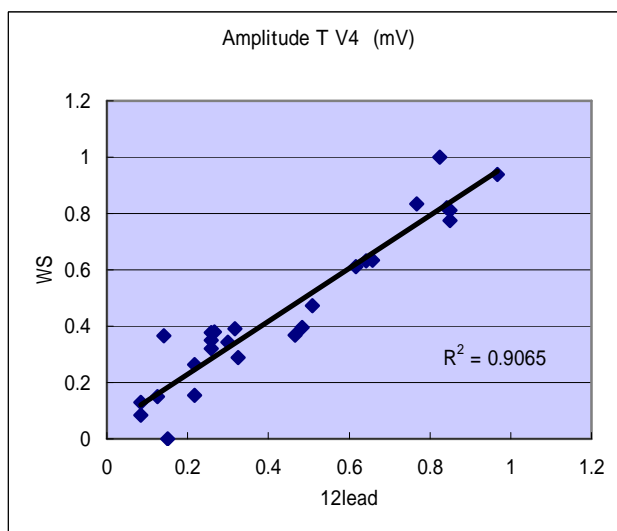


Fig.1-6 Amplitude T in the V4 region

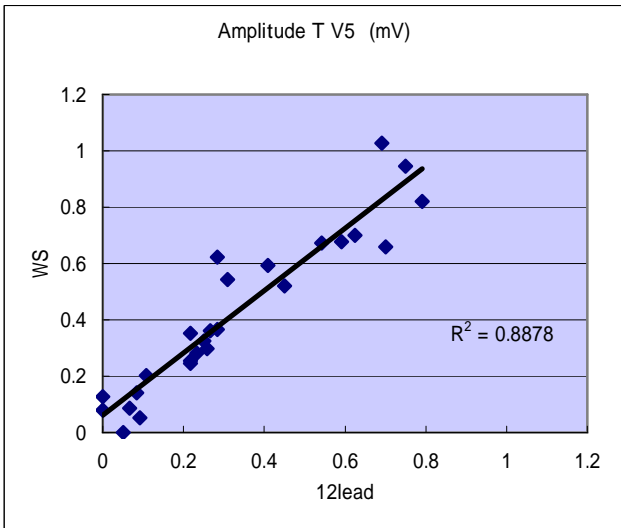


Fig.1-7 Amplitude T in the V5 region

Average T amplitude widths are indicated here.

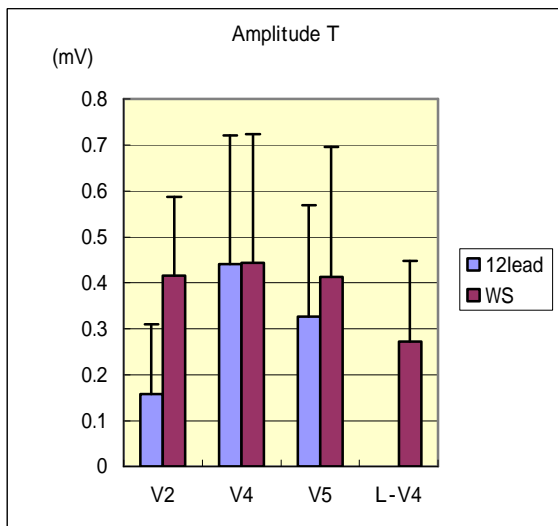


Fig.1-8 Average amplitude T widths and standard deviations in each region

Amplitude T data of the WS had high correlations with the 12-lead in the V4 and V5 region, and had low correlation in the V2 region.

In the V5 region, amplitude T data of the WS are significantly higher than those of the 12-lead ( $p < 0.001$ ).

### QRS width

Here are correlations between QRS width data of the 12-lead and those of the WS in the V2, V4, and V5 region.

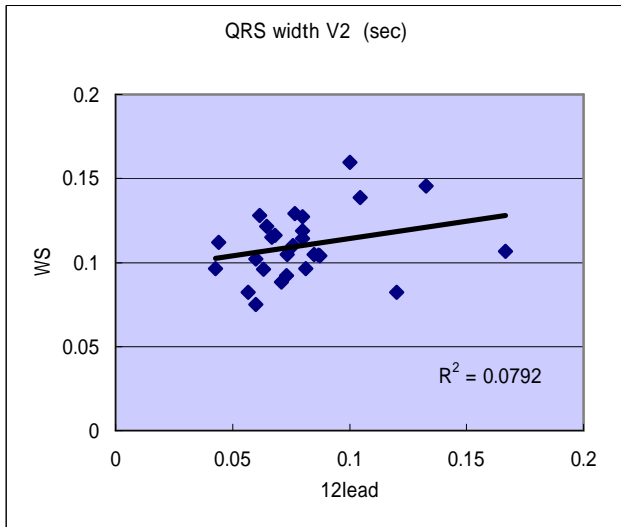


Fig.1-9 QRS width in the V2 region

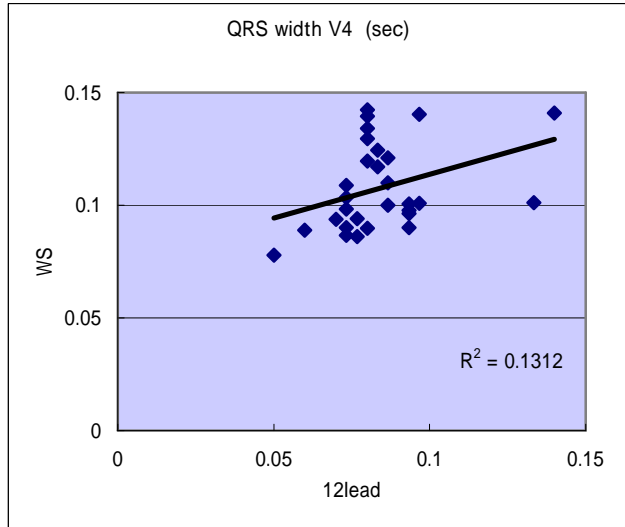


Fig.1-10 QRS width in the V4 region

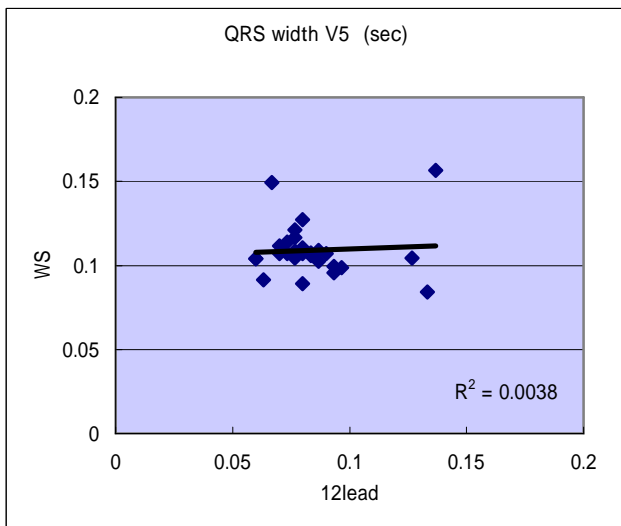


Fig.1-11 QRS width in the V5 region

Average QRS widths are shown here.

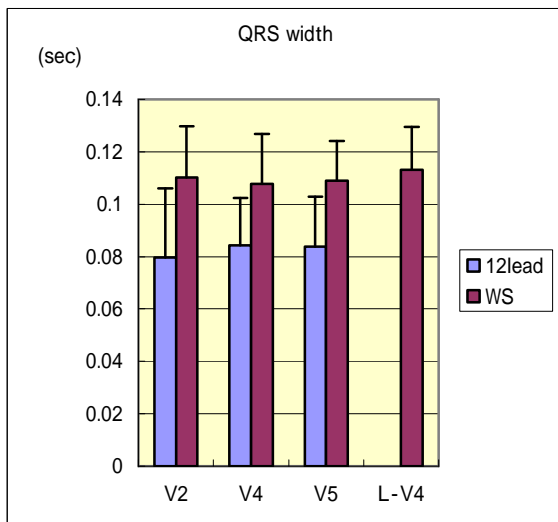


Fig.1-12 Average QRS widths and standard deviations in each region

The WS had low correlations with the 12-lead in the V2, V4, and V5 region. In the V2, V4, and V5 region, QRS width data of the WS are significantly higher than those of the 12-lead (ps<0.001).

### Findings

Concordance rates with the 12-lead were calculated in each region based on physician 's inspection.

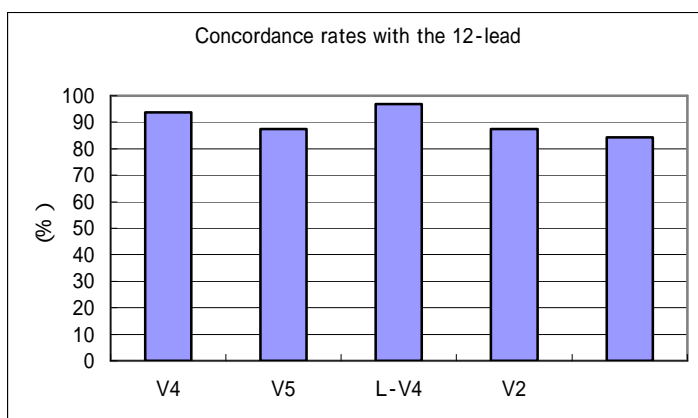


Fig.1-13 Concordance rates with the 12-lead in each measurement region by physician 's inspection.

### Summary of result 1

- Amplitude R/T data of the 12-lead had high correlations with those data of the WS in the V4, V5 regions (Fig. 1-2, Fig. 1-3, Fig. 1-6, Fig. 1-7).
- Amplitude R/T data of the 12-lead and the WS were identical in the V4 region (Fig. 1-2, Fig. 1-4, Fig. 1-6, Fig. 1-8).
- Measured in the V5 region, amplitude R was higher in the WS than in the 12-lead, and amplitude T was higher in the WS than in the 12-lead (Fig. 1-4, Fig. 1-8).

- QRS were wider in the WS, and had no correlation with QRS width data in the 12-lead (Fig. 1-9 - Fig. 1-12).
- Amplitude R, amplitude T, QRS width data of the 12-lead had low correlations with those data of the WS in the V2 region. The measurement positions of the 12-lead and the WS were 1 cm apart, and this made the difference in measurement results (Fig. 1-1, Fig. 1-5, Fig. 1-9).
- Physician 's inspection found high concordance rates of 95% or more in the V4 and lower V4 region, and also high rates of 80% or more in the other regions (Fig. 1-13).

Result 2 Results of measurement at home (analysis results of 24 subjects and 452 measurements)

The figure below indicates analyzable rates of 452 waveform measurements by algorithm/physician 's inspection.

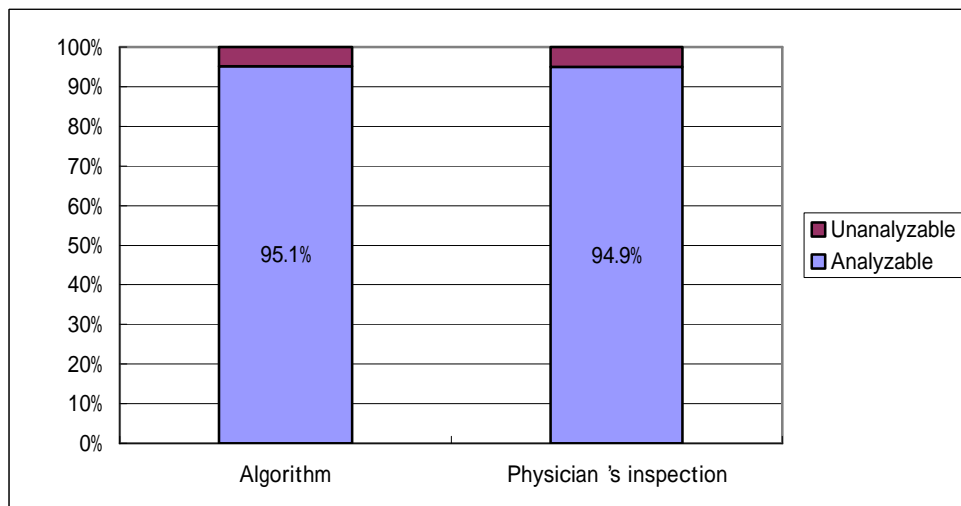


Fig.2-1 Analyzable rates by algorithm and physician 's inspection

The following table indicates a distribution of the subjects based on the analyzable rate.

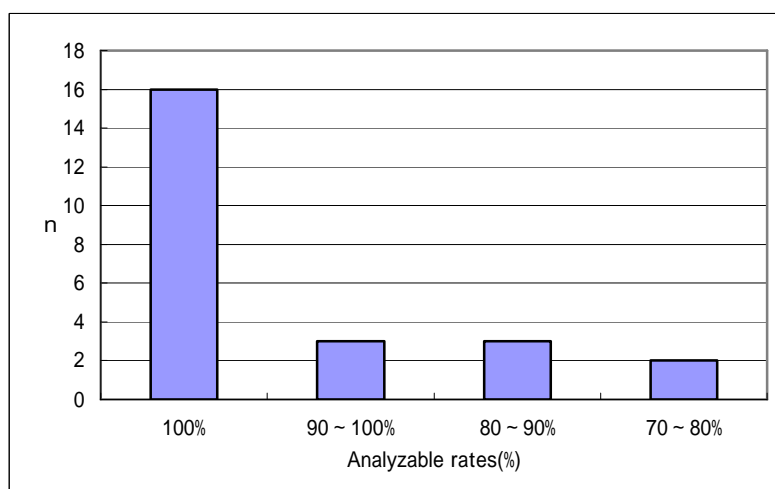


Fig.2-2 Distribution of analyzable rates

Measurement statuses of 5 subjects with many unanalyzable measurements on the records are listed here.

Two subjects were aware of their mistakes during the measurement. Ex. their fingers were separated from electrodes.

D17: Measurement after eating observed many unanalyzable measurements. In all data R waves were relatively low, 0.7-0.8 mV. Unanalyzable data had many EMG noises.

D19: Many measurements taken just before sleeping were unanalyzable. Input signals were cut off during the measurement.

D21: It is highly possible that electrodes not attached directly to the skin created many unanalyzable measurements.

#### Summary of result 2

- About 95% of the measurements were analyzable by either algorithm or physician 's inspection (Fig. 2-1).
- Patients with many unanalyzable measurements used a few specific measurement methods in common situations (Fig. 2-2).

#### Result 3 Message concordance rates

Physicians inspected to check the identity between waveforms and event results. We named the case in which event results were not detected but the waveforms could be recognized "false negative " finding. We named the case in which event results were detected but the waveforms could not be recognized "false positive " finding. For the analysis, we used 616 measurements obtained in the hospital and at home.

#### Data confirmation

Before the calculation of concordance rates, physicians inspected collected data to determine the data composition (ratio of normal waveforms and others). About half of the measurements had some type of abnormal waves. Therefore, the data composition proved to be appropriate.

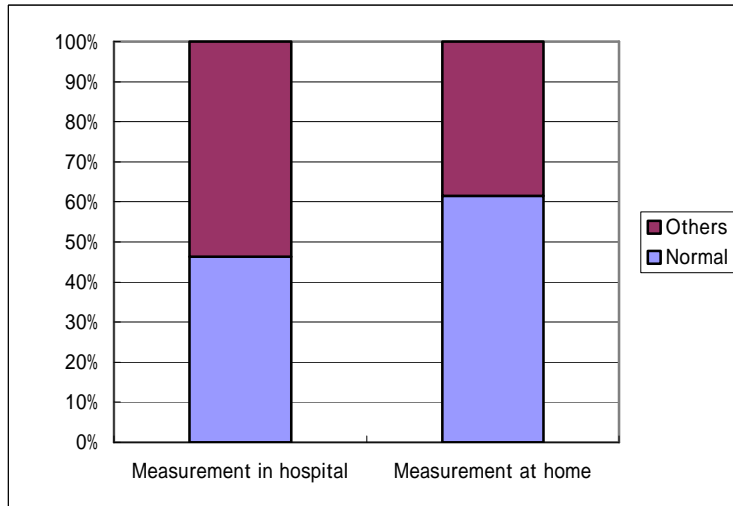


Fig. 3-1 Normal/abnormal data composition in each measurement status

Table 3-1 Data composition (number of measurements)

	Measurement in the hospital	Measurement at home
Normal	76	278
Others	88	174

#### Event results and concordance rates of waveforms

Concordance rates of waveforms from physician 's inspection and algorithm were calculated by each event. The measurement was done both in the hospital and at home. For the setting levels of each event, refer to the attachment 1.

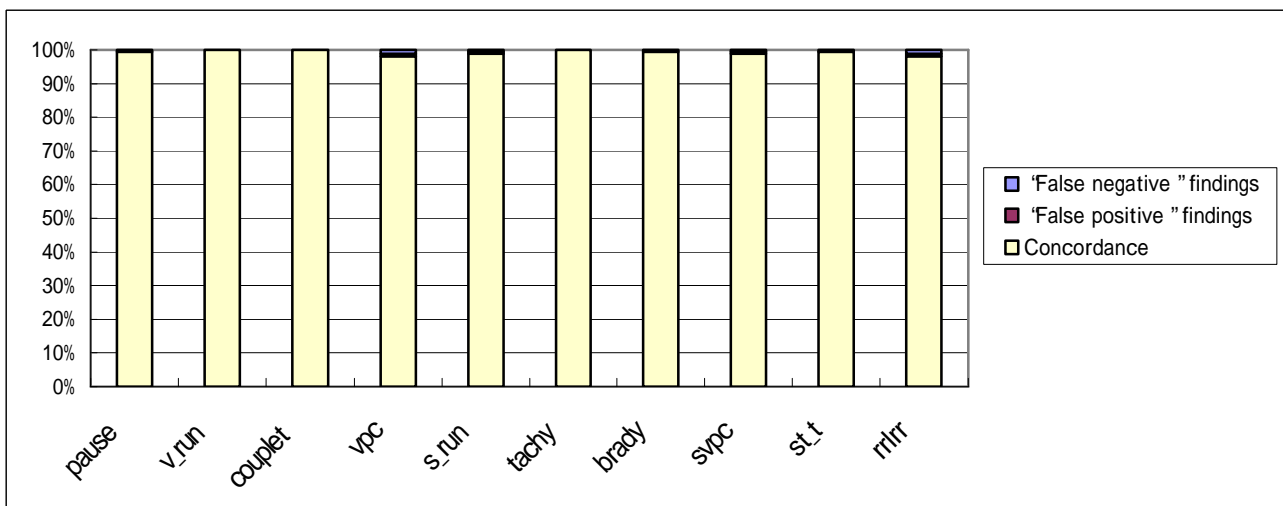


Fig.3-2 Event results and concordance rates of waveforms in measurement in the hospital

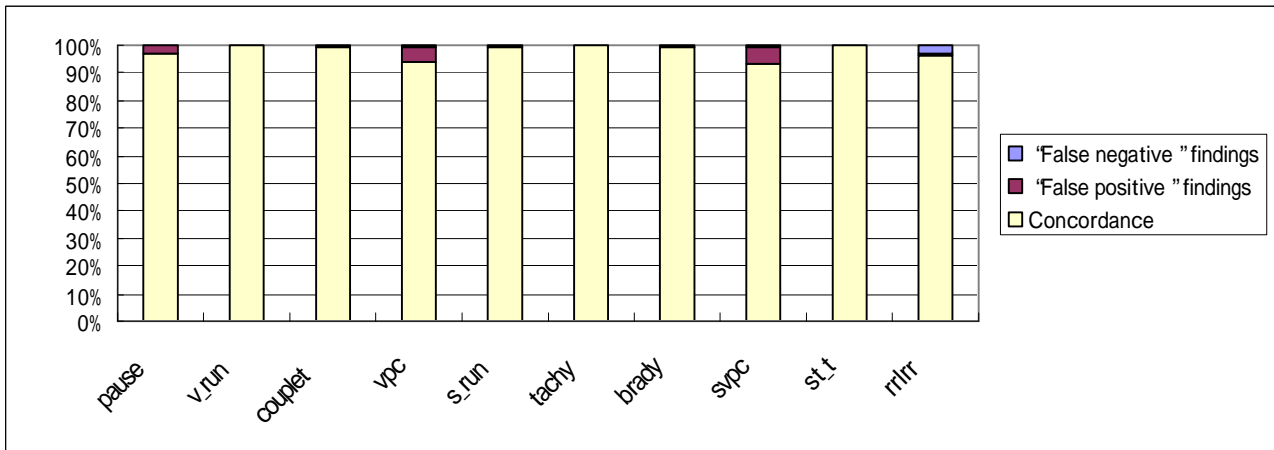


Fig.3-3 Event results and concordance rates of waveforms in measurement at home

Concordance rates are lower when measured at home than in the hospital.

In particular, about 5% 'false positive' findings of VPC, SVPC, and PAUSE were observed.

Message concordance rates (heart rate, heart rhythm, QRS wave)

Message concordance rates in heart rate, heart rhythm, and QRS wave were calculated from event results.

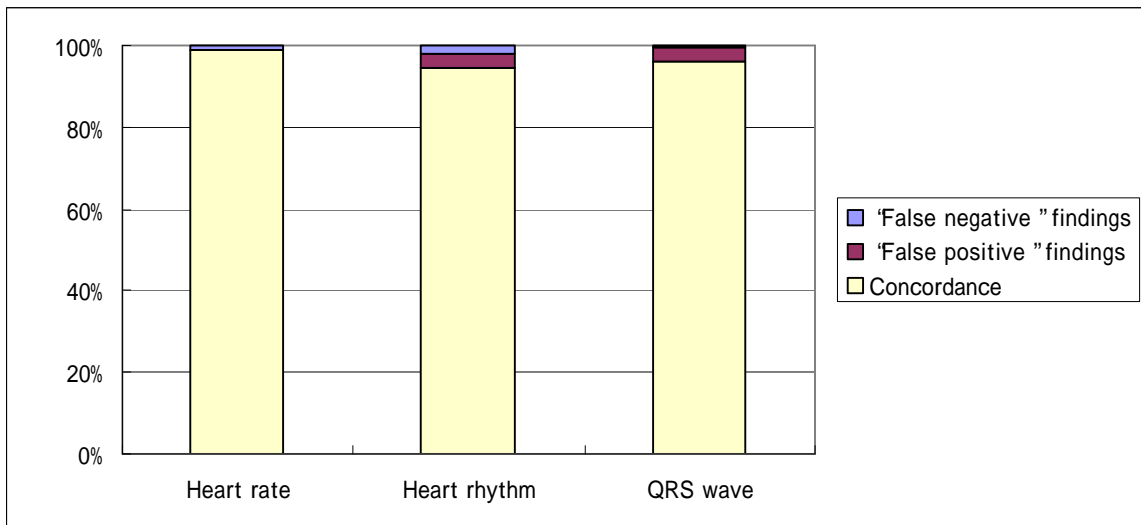


Fig.3-4 Message concordance rates in heart rate, heart rhythm, and QRS wave

Message concordance rates

Concordance rates of messages by physician's inspection and algorithm results are shown below.

Discordance data were classified into three categories: 'false positive' findings, 'false negative' findings, and others. 'Others' refers to data in which abnormalities were observed from both physician's inspections and algorithm results and abnormal messages from both were not identical.

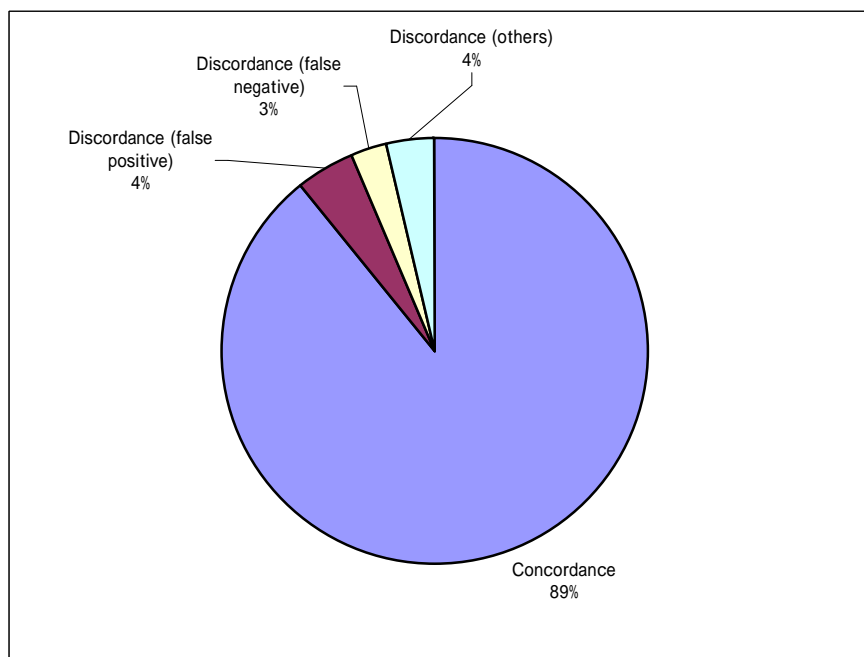


Fig.3-5 Message concordance rate (all data)

Table 3-2 Details of message discordance data (number of measurements)

Breakdown of discordance	Measurement in hospital	Measurement at home	Total
'False positive " findings	1	26	27
'False negative " findings	7	11	18
Others	7	15	22

### Summary of result 3

- The message concordance rate was about 89% (Fig. 3-5).
- 'False positive " findings of messages in heart rhythm resulted from 'false positive " findings of SVPC, and 'false positive " findings of messages in QRS wave is attributed to 'false positive " findings of VPC (Fig. 3-3, 3-4).
- Measurement in the hospital observed more 'false negative " findings than 'false positive " findings. On the contrary, more 'false positive " findings occurred when measured at home. Artifacts had a large influence on the results of events (Table 3-2).

### Result 4 Biocompatibility

No subject showed allergic symptoms to the materials used for electrodes.

And above

## Event conditions

Event name	Conditions
pause	An R-wave was not detected for more than 2.0 seconds
v-run	VPC repeated three times or more in a row
couplet	VPC was detected two times in a row
vpc	VPC was detected
s-run	SVPC repeated three times or more in a row
tachy	Heart rate is above 120 bpm
brady	Heart rate is below 50 bpm
svpc	Premature atrial contraction in which the RR interval is 80% or less of the normal RR interval
st-t	<ul style="list-style-type: none"> <li>·The ST lowered to about -0.4 mV or below</li> <li>·The ST increased to about 0.4 mV or above</li> <li>·Negative T waves below about -0.4 mV could be observed</li> </ul>
rrlrr	The fluctuation rate of the RR interval is 10% or more