

The Clinical Evaluation Report for UA-1010, UA-1020 and UA-1030T

1. General details

Model Name : Digital Blood Pressure Monitor UA-1010, 1020 and 1030T

Manufacturer : A&D Company Limited

2. Description of the device and its intended application

Overview : This is non invasive blood pressure measuring device for measuring SBP(Systolic Blood Pressure), DPB (Diastolic Blood Pressure) and pulse rate.

The method of measuring blood pressure is Oscillometric method.

The device starts measurement when the start button is pressed after wrapping the cuff around the upper arm.

The measurement time is around 1 or 2 minutes.

Component : The Blood Pressure Monitor consists of plastic chassis, main unit which is composed of some general electrical part and cuff.

Sterilization treatment : Not sterilized

Single use or reusable : Reusable instrument

Invasive or non invasive : Non invasive

3. Intended therapeutic and/or diagnostic indications and claims

Intended use : Measure SBP , DBP and pulse rate to manage blood pressure for ordinary peoples.

Security-related item :

There are no notable concerns about safety like the same type of non-invasive blood pressure measuring devices being already released.

4. Context of the evaluation and choice of clinical data types

Generally, clinical tests of non-invasive blood pressure measuring devices are being carried out according to the public protocols such as DIN, BHS, ESH, AAMI SP-10, EN 1060-4.

Each protocol is generally accepted that it is sufficient to assess efficacy and safety. In this time, we chose the AAMI SP-10 Protocol.

The clinical test result of UA-1010/1020/1030T is equated with UA-787 because both design of blood pressure measurement devices are basically same (Attachment: Comparison between UA-1010/1020/1030T and UA-787), so the clinical test report used in this time is for UA-787 (Attachment: Test Report R01006).

5. Summary of the clinical data and appraisal

The clinical test report using this clinical evaluation was carrying out according to AAMI SP-10 protocol, and it's sufficient as UA-1010/1020/1030T clinical evaluation data.

6. Data analysis

6.1 Performance

The accuracy of blood pressure measurement required in AAMI SP-10 and other protocols is within ± 5 mmHg for Mean Difference and within 8mmHg for Standard Deviation .

The result of clinical test is -0.05 mmHg for SBP Mean difference , 4.23 mmHg for SBP Standard Deviation , -2.61 mmHg for DBP Mean Difference , 5.13 mmHg for DBP Standard Deviation.

As a result, the accuracy of blood pressure measurement meet the standard.

6.2 Safety

There is no notable concern about safety because 'Conclusion' in the clinical test report includes about [The unit is an effective device for measuring human blood pressure in clinical field. The patient can be easily measured by oneself for easy of use. Therefore, it is concluded that this unit is useful for clinical check at home.].

6.3 Product Literature and Instructions for Use

The instruction manual includes that it's appropriate to AAMI SP-10.

Additionally, clinical precaution statements to measure accurately are described in the space of 'How To Take Proper Measurement' and 'Notes For Proper Measurement' in the instruction manual. (Refer to Device File UA-1010/1020/1030T Annex B.6.1-A)

7. Conclusions

The clinical test using in this clinical evaluation was confirmed to be carried out according to EN ISO 14155-1:2003 and EN ISO 14155-2:2003 (Attachment: Test Report R09039), and the test is also appropriate to Essential Requirements of MDD and MEDDEV, 2.7.1 rev3 December 2009.

And all the risks in the use of UA-1010/1020/1030T are confirmed that it's acceptable level. (Refer to Risk Management File RISK-NIBP-HHC_ALL)
Additionally, the function, performance and safety of UA-1010/1020/1030T are confirmed that it's sufficient to reach the purpose intended by sixth clause.

Tested by K. Murata Apr.5.2011



Manager of R&D section 24
A&D Company Limited

Qualifications : Refer to Education and Training Ledger 24 section

Comparison between UA-1010/1020/1030T and UA-787

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Comparative result

UA-1010/1020/1030T and UA-787 are equal in intended use, use method, the product structure, the performance, and safety.

Tested by K. Murata Apr.5.2011

K. Murata

1. Intended use

Intended use of UA-1010/1020/1030T is measuring SBP, DBP and pulse rate to manage blood pressure for ordinary peoples.

Intended use of UA-787 is measuring SBP, DBP and pulse rate to manage blood pressure for ordinary peoples.

Intended use of both is the same.

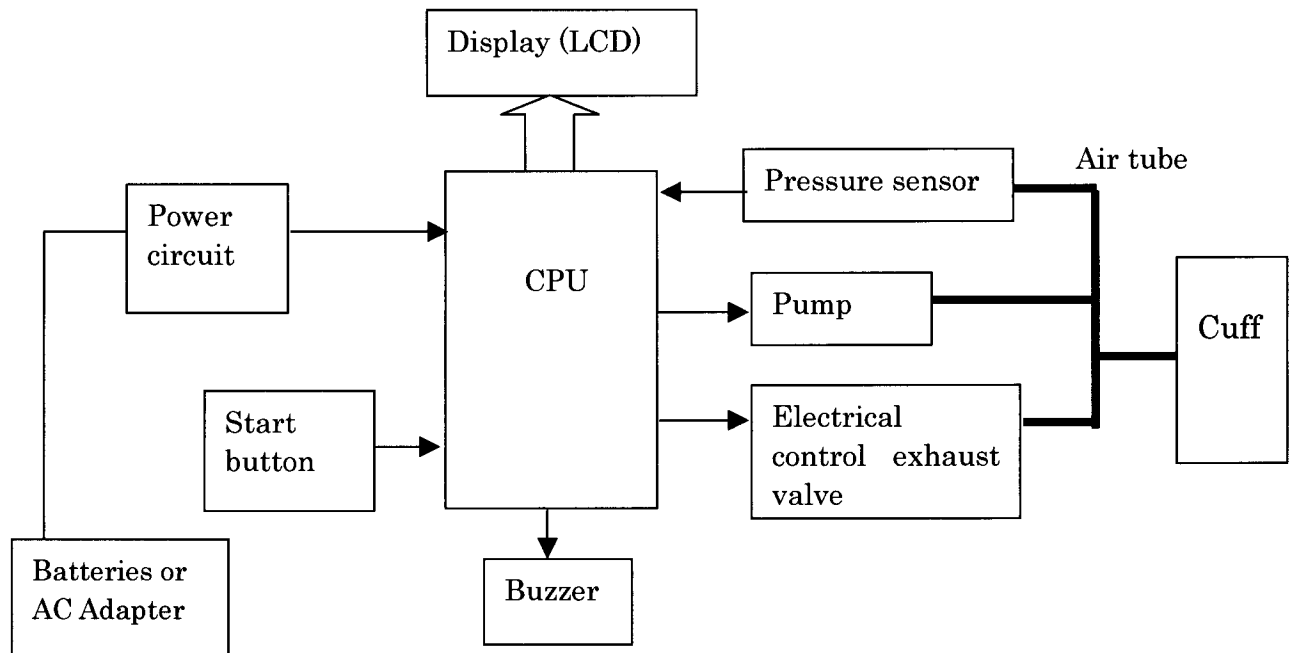
2. Performance Specification

Model	UA-1010/1020/1030T	UA-787	Determination
Measurement type	Oscillometric	Oscillometric	Same
Display	Digital	Digital	
Measurement range	0 ~ 299 mmHg (pressure) 40 ~ 180 beats/min. (pulse)	20 ~ 280 mmHg (pressure) 40 ~ 200 beats/min. (pulse)	UA-1010/1020/1030T has higher performance.
Accuracy	±3mmHg (pressure) ±5% (pulse)	±3mmHg (pressure) ±5% (pulse)	Same
Pressurization	Automatic using a micro pump	Automatic using a micro pump	Same
Power source	R6P or LR6 batteries x 4 or AC adapter	R6P or LR6 batteries x 4 or AC adapter	Same
Depressurization	Electrical control exhaust valve	Electrical control exhaust valve	Same
Deflation	Electrical control exhaust valve	Electrical control exhaust valve	Same

Performance Specification of both is almost the same.

3. Block Diagram

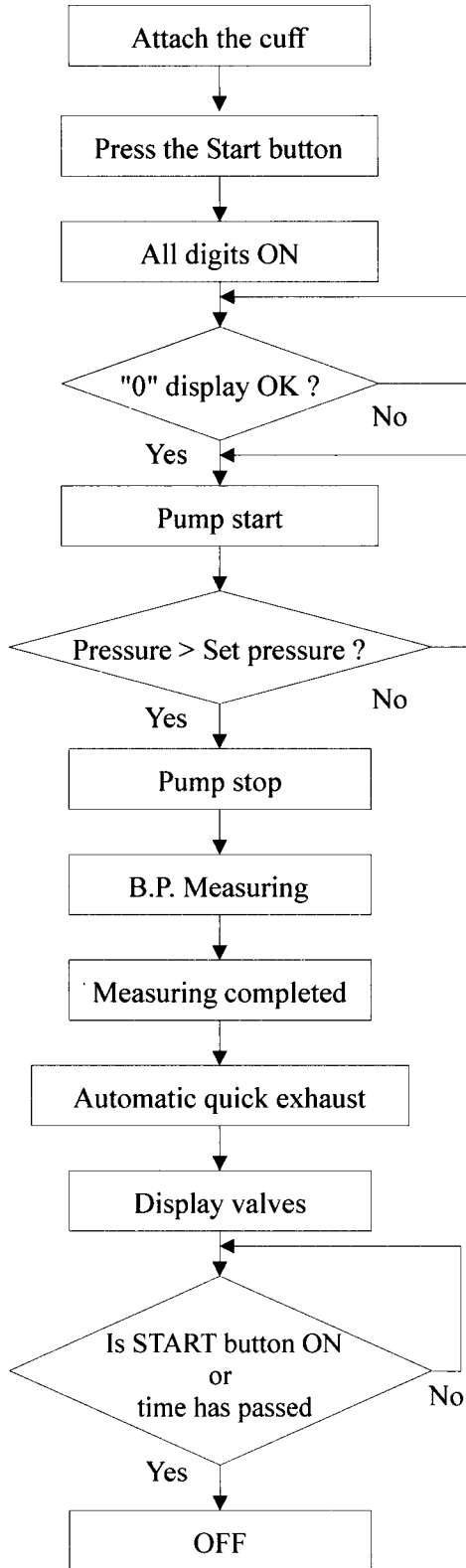
Block diagram of UA-1010/1020/1030T and UA-787 is shown below. And they are same.



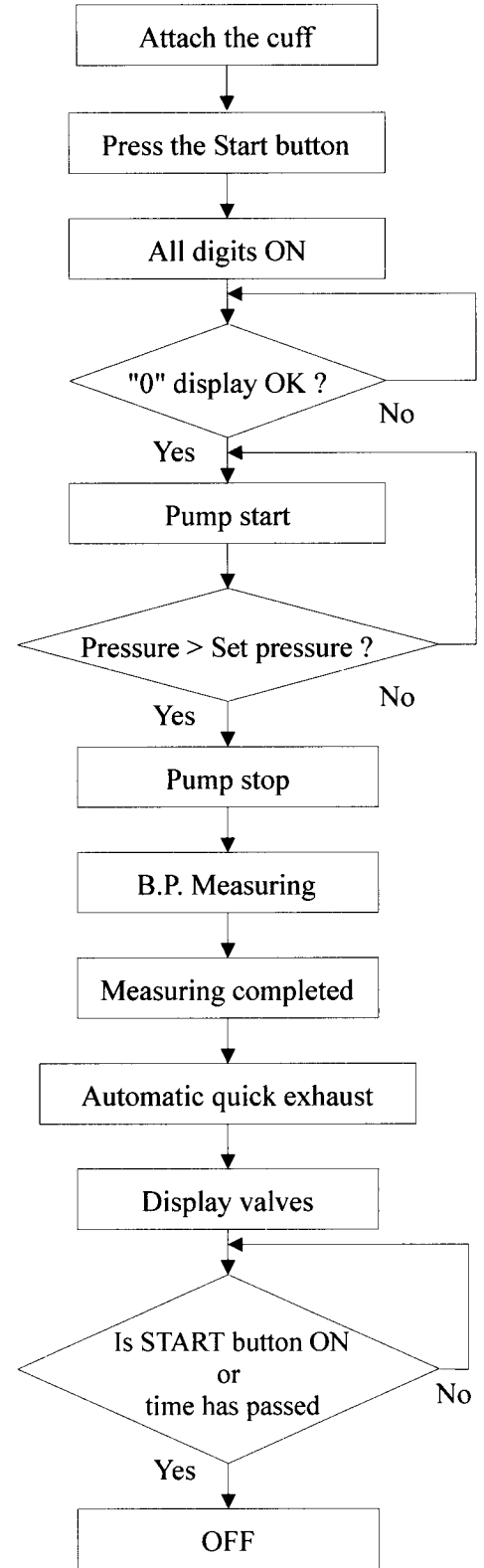
4. Operating Flowchart

Operating method of both is the same.

UA-1010/1020/1030T



UA-787



5. Key-component Comparison

Component	UA-1010/1020/1030T	UA-787	Determination
Pressure detection sensor	Electrostatic capacity type pressure sensor	Electrostatic capacity type pressure sensor	Same
Inflation	Micro pump	Micro pump	Same
Deflation	Electrical control exhaust valve	Electrical control exhaust valve	Same
Quick-deflation	Electrical control exhaust valve	Electrical control exhaust valve	Same
CPU	CPU 8bits (Custom-made)	CPU 8bits (Custom-made)	Same
Display	LCD	LCD	Same

Key-component of both is the same.

6. Safety Comparison

	UA-1010/1020/1030T	UA-787	Determination
Protection for electroshock	Internal power source :BF type AC adapter : class II	Internal power source :BF type AC adapter : class II	Same
Measurement pressure (Maximum)	299mmHg	280 mmHg	UA-1010/1020/1030T has higher performance.
Measurement time (Maximum)	180 sec.	180 sec.	Same
Maximum pressurization value at single failure condition	299 mmHg	320 mmHg	UA-1010/1020/1030T is more safety.

Safety of both is almost the same.

Test Report

Equipment Under Test :

- UA-787

Test Report No.

- R01006

Items

Title : Clinical Test report

Method : We done Clinical test of UA-787/PC/V in accordance with ANSI/AAMI SP-10-1987.

This clinical test report is an examination done in Japan, and the thing to have rewritten this to the form of ANSI/AAMI.

Refer to Design Planning "DB770-00".

Result : • Mean deifference SBP=-0.05mmHg、DBP= -2.61mmHg
• Standard Deviation SBP=4.23mmHg、DBP=5.13mmHg

We got the satisfactory data for standard of ANSI/AAMI SP-10-1987.

Conclusion : This UA-787/PC/V has no problem for Clinical test and has enough accuracy for ANSI/AMMI SP-10-1987.

Tested by : S.Ozaki Date : 07.MAY.2001 sign : *S. Ozaki*

Checked by : H.Yokoi Date : 07.MAY.2001 sign : *H. Yokoi*

Manufacturer 's Name and Address:

- A&D Company, Limited. R&D Technical Center
- 1-243,Asahi, Kitamoto-shi, Saitama, JAPAN

Clinical test of the BP measurement UA-787/PC/V

Summary

The accuracy of the blood pressure monitors (model UA-787/PC/V – hereinafter called D.U.T) has been assessed by the indirect method according to the recommendations of the association for the advancement of medical instrumentation (AAMI).

85 subjects, aged 19-90 with a range of systolic blood pressure (SBP) of 71-202 mmHg and diastolic blood pressure (DBP) of (52-114) mmHg were studied.

The monitor was compared with two observers using the mercury type sphygmomanometer.

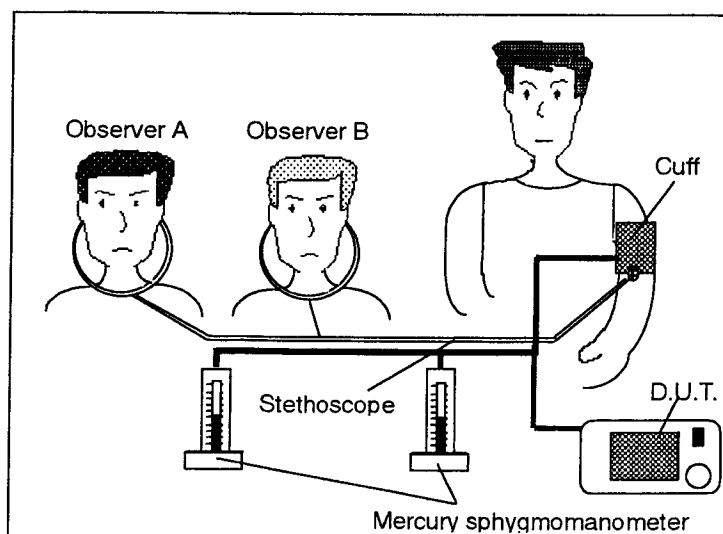
The standard deviation of the difference between observers was 2.12 mmHg for SBP and 2.29 mmHg for DBP. These differences were not significant.

The two observers have done their are three measurements have been done on each subject and comparison measurements. Mean error was calculated -0.50 mmHg (SBP) and -2.61 mmHg (DBP), and standard deviation was figured as 4.23mmHg (SBP) and 5.13(DBP). Both mean error and standard deviation are considered below AAMI standard.

1. Methodology

All the measurement was done in accordance with Electric or Automated Sphygmomanometer (ANSI/AAMI SP-10 1992) 4.4.2.1 auscultatory method as the reference standard by AMMI.

The measurement was done three times on each subject and reference measurement by Mercury sphygmomanometer by two observers was made simultaneously. (See figure Shown below)



Remark:

A measurement was done after calibration of pressure on Mercury sphygmomanometers 1,2 and D.U.T. has been completed.

2. Subjects

The subjects were chosen from hypertension outpatient clinic and normal volunteer to satisfy age, sex and range of blood pressures classified by AAMI standard.

Range of age:

	<=24	25 - 44	45 - 64	>=65	Total
Male	9	7	18	15	49
Female	3	4	11	18	36
Total	12	11	29	33	85
%	14	13	34	39	100

Table 1

Range and distribution of systolic, diastolic pressure and heart rate :

Systolic	<100	100 - 139	140 - 179	>=180	Max: 202
N	18	135	77	25	Min: 71
Diastolic	<60	60 - 79	80 - 99	>=100	Max: 114
N	19	112	99	25	Min: 52
Heart rate	<60	60 - 69	70 - 79	>=80	Max: 109
N	35	96	50	74	Min: 36

Table 2

3. Observer differences

The data by the Mercury sphygmomanometer measurement by two observers were inspected for all the subjects' data for t value.

	Mean	SD	t	γ	Regression Line	
					A	B
Systolic	-0.20	2.12	0.09	1.00	-0.82	1.01
Diastolic	-0.59	2.29	0.48	1.00	1.80	0.97

$$t_{0.975} = 1.990 \quad \text{at } n=255$$

The hypothesis that the two observers measure the same average blood pressure was accepted ($p < 5\%$), as t value is smaller than 1.99. This proves the observations by two observers were valid.

4. Results

Statistical analysis was made as shown below.

Statistical data was calculated by the following approach.

Reference data: Reference data was calculated by the average of 6 data, since three measurements have been done on each subject by two observers.

Device Data: Device data was calculated by the average of three measured data.

		SBP	DBP
Mean Difference		-0.50	-2.61
Standard Deviation		4.23	5.13
Correlation Coefficient		0.99	0.93
Regression Line	A	2.37	5.27
	B	0.98	1.04

Table 3

Fig. 1a and 1b are correlation of observer1 readings with observer2 readings.

Fig. 3a and 3b are correlation of D.U.T. readings with mean of the observer's reading.

Fig. 2a,2b and 4a,4b are standard error of estimate.

Mean difference and standard deviation of D.U.T. was below AAMI standard (mean \pm 5 mmHg, SD 8 mmHg.).

Averaged data for all the subjects and all row data and correlation plots are shown in following pages.

We also analyzed the test data with the format suggested by AAMI SP-10 TableD.1. As follow:

	#of Obs.	Range	Mean of Diff.	S.D. of Diff.	%Exceeding		
					5mmHg	10mmHg	15mmHg
Obs1-Obs2							
Systolic	510	71-202	-0.2	2.12	0.78%	0%	0%
Diastolic	510	52-114	-0.59	2.29	0.59%	0%	0%
DUT-Avg.Obs							
Systolic	255	76-209	-0.5	4.23	13.70%	1.89%	0%
Diastolic	255	42-115	-2.64	5.13	7.05%	1.57%	0%

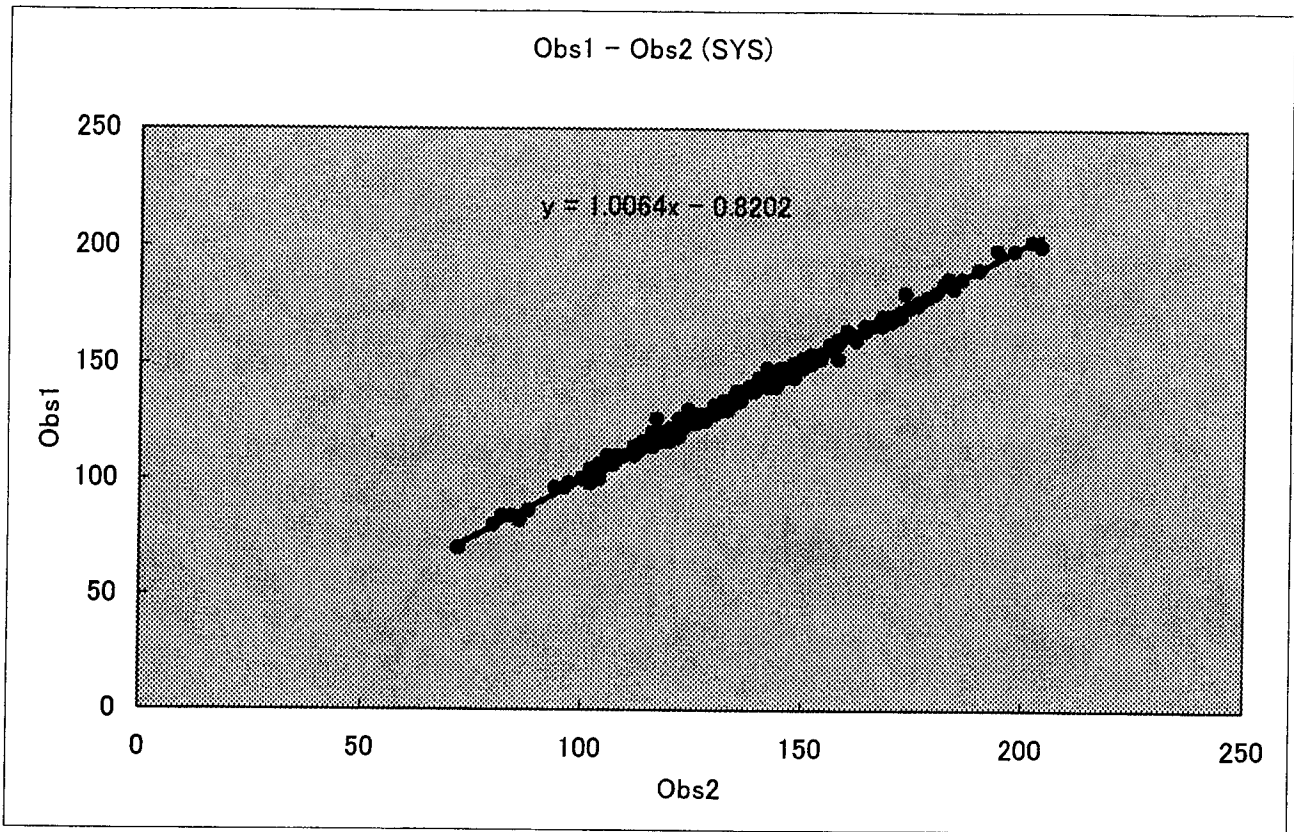


FIG-1a

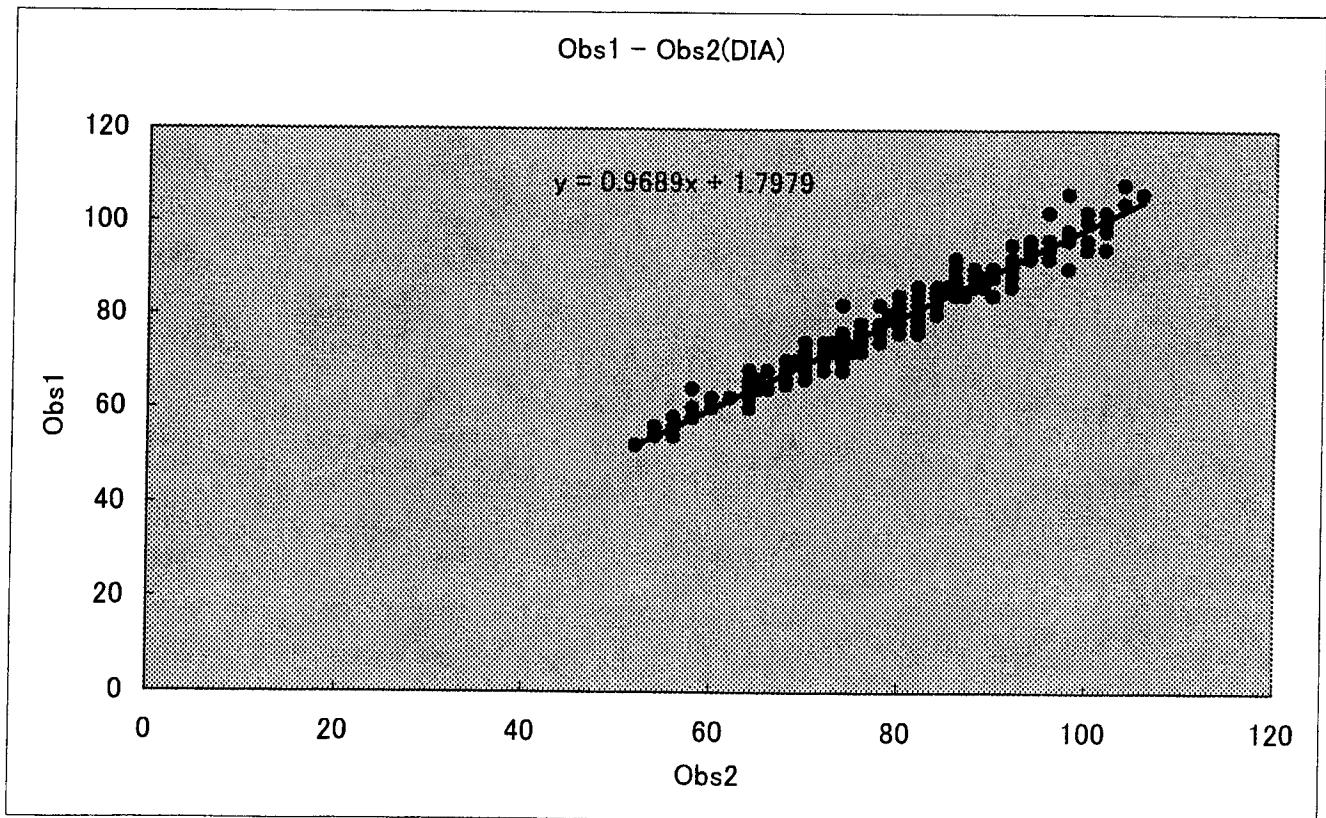


FIG-1b

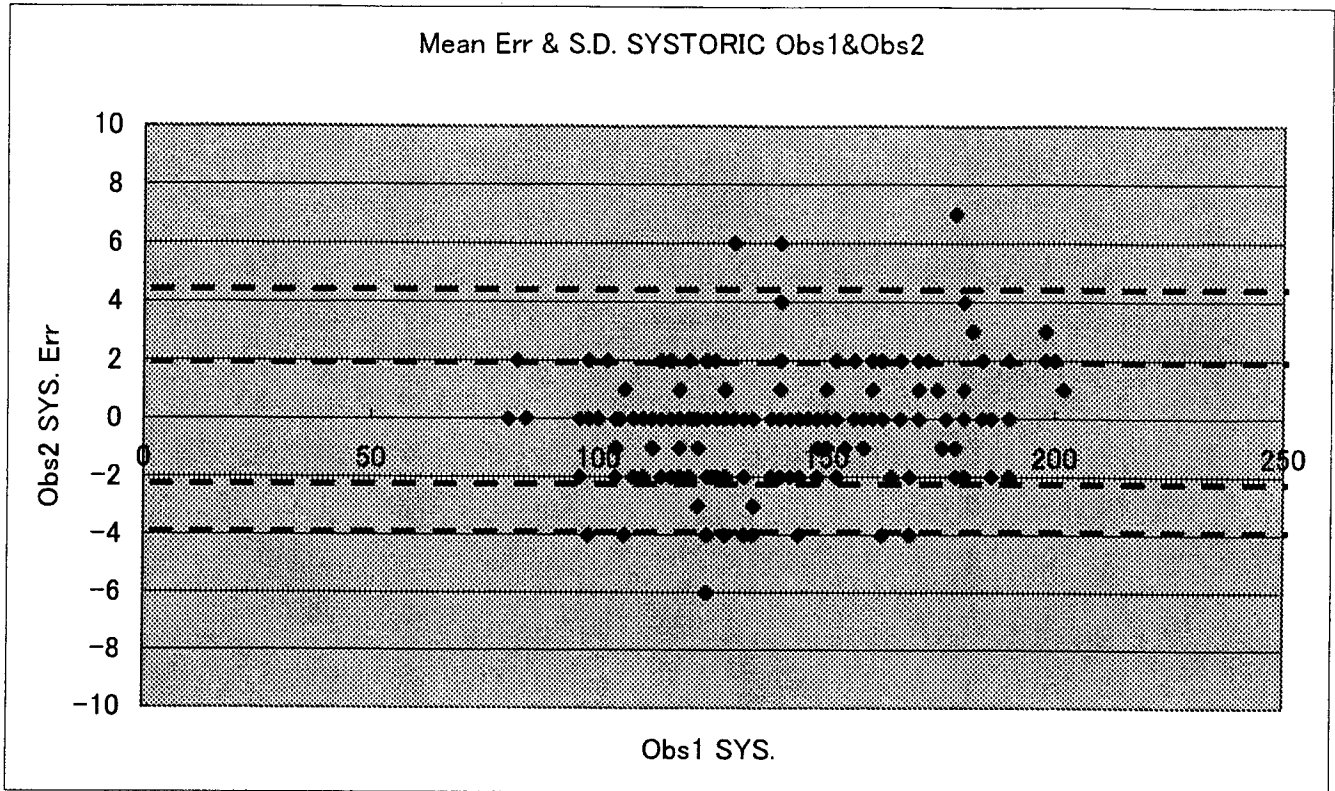


FIG-2a

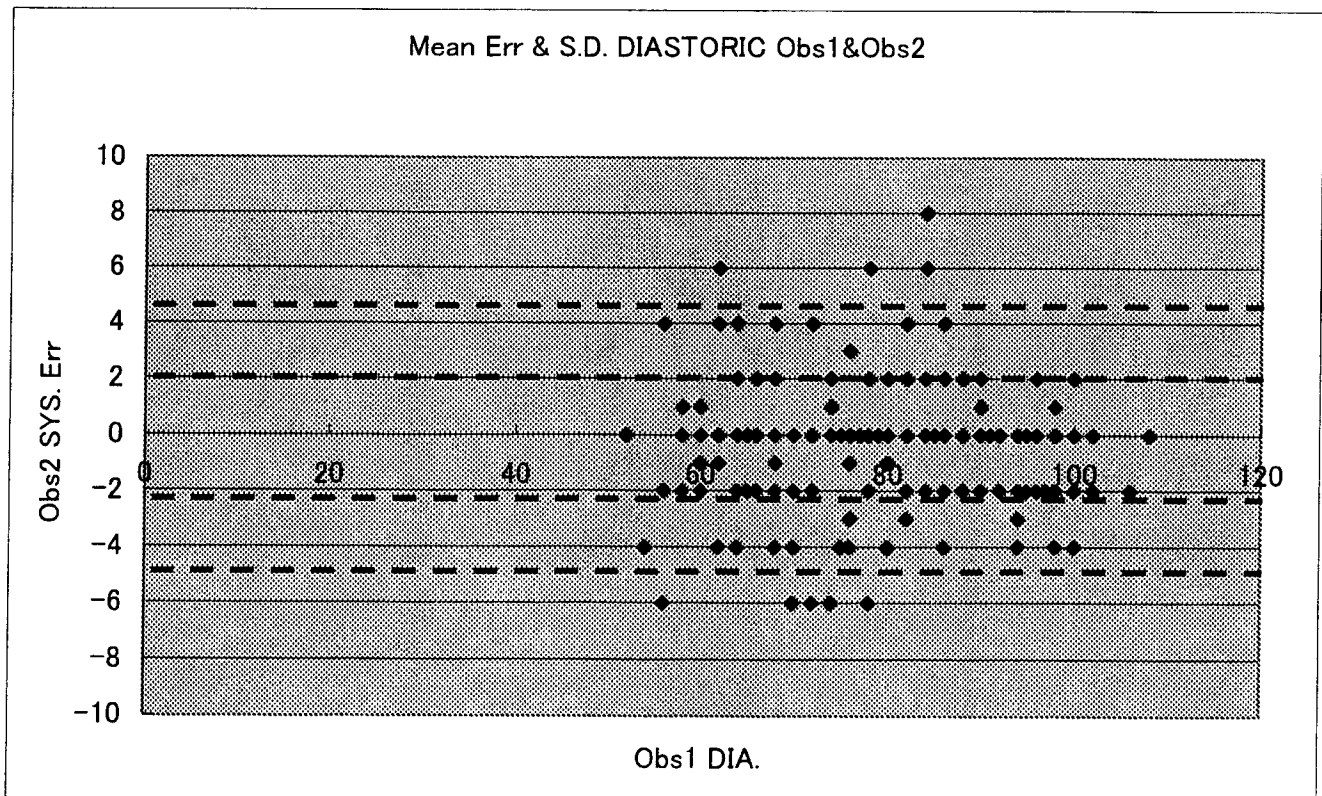


FIG-2b

